

FDA Food Safety Modernization Act (FSMA) Produce Safety Rule: Opportunities and Impacts on Potential Water Reuse for Agricultural Irrigation

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CONCLUSION:

Recycled water meeting
applicable state regulations
for irrigation of food crops
meets FSMA requirements
for irrigation water quality.

Abstract and Benefits

Abstract:

The Food Safety Modernization Act (FSMA) was a response to recent epidemics traced to the processes and substances that contaminated crops intended for human consumption. One important such substance is irrigation water. The FSMA microbial standard for irrigation water is based on existing recreational water safety criterion of a geometric mean E. Coli concentration in the water under 126 MPN/100 mL. Current microbial standards set by over 25 state regulations and guidelines for irrigation of food crops with recycled water are significantly more stringent, assuring compliance with FSMA by farmers opting to use recycled water. Furthermore, since recycled water is typically supplied from municipal sources, the normally required monitoring of water quality by the providers of recycled water satisfies FSMA requirement for acquisition and maintaining irrigation water quality data.

Benefits:

- Provision of certainty and confidence in the quality of recycled water for food crop irrigation
- Expanded use of recycled water in agriculture
- Greater reliability of the overall water resources for society
- Sustainability of water supply
- Integrated water resources management

Keywords: Recycled Water, Reclaimed Water, Food Crops, Leafy Vegetables, Food Safety

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Acronyms and Abbreviations

E. coli	Escherichia coli
US FDA	United States Food and Drug Administration
FSMA	Food Safety Modernization Act
GM	Geometric Mean
PSR	Produce Safety Rule
STV	Statistical Threshold Value

Executive Summary

Food safety is an important responsibility of all producers and handlers of farm products intended for human (and domestic animals) consumption. Historical disease outbreaks and epidemics have resulted in great suffering and death, some decimating whole communities. These human tragedies are well documented and subject of much cultural and artistic expression. Lessons from these events have gradually been learned and in many cases formalized into standards of practice, norms, and—in most recent times—regulations.

Food Safety Modernization Act (FSMA) is a law, signed by President Obama on January 4, 2011, to protect consumers against exposure to food-borne microorganisms from crops grown on the nation's farms and handled subsequently in the supply chain. The law gives new authority to the US Food and Drug Administration (FDA) to regulate farming practices, harvest, and processing of food crops. The law also requires FDA to publish rules, guidance documents, and other plans, reports, standards, etc. Most importantly, the law empowers FDA to recall food crops suspected of contamination. FSMA has shifted the focus from responding to foodborne disease to preventing it. An important component of FSMA is the Produce Safety Rule (PSR), which "...establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption."

In farms where recycled water is used for irrigation of crops, there is no need for sampling and record keeping. This is because recycled water is generally received from public agencies (city departments, county sanitation districts, special districts, etc.), and these public agencies must comply with their respective state's regulations and guidelines, including frequent sampling for a wider range of parameters and maintaining analytic records, available for public inspection.

CHAPTER 1

Introduction

Prior to enactment of the Food Safety Modernization Act (FSMA), food safety was ensured with recall of culprit foods suspected (or known) to be bearing pathogens. In 2016, FSMA reversed the process by placing the emphasis on **prevention** of foodborne disease outbreaks. The US Food and Drugs Administration (FDA) adopted and updated its food safety regulations to align with the requirements of FSMA. Compliance with FSMA involves a number of activities in the production, handling, packaging, shipping, storage, display, and sale of all types of food items of both animal and plant origin. This white paper is concerned with those aspects of FSMA that impact users of recycled water for irrigation of food crops.

In ancient times, wastewaters were allowed to mingle with water supplies used for growing crops, resulting in widespread epidemics of cholera, typhoid, dysentery, and other gastrointestinal diseases. In more recent time, improved sanitation practices and hygienic habits have resulted in separation of wastewaters, their proper treatment and disposal or reuse. In just the last several decades, wastewaters have been treated to a level considered safe for direct contact with raw-eaten food crops—including leafy greens—and used for unrestricted irrigation of such crops.

Recent studies on the safety of irrigation of produce with recycled water have employed quantitative microbial risk assessment (QMRA) to compute the potential risk to public health under different irrigation conditions (Oliveri *et al.*, 2014, Rock *et al.*, 2018). The risks of irrigation with recycled water under current regulatory restrictions is found to be at similar or lower levels than that under conventional irrigation practices. Rock *et al.* (2018) further concluded that “In comparison to metrics in states that currently regulate the use of recycled water for irrigation of food crops eaten fresh, the FDA FSMA water quality metrics are less stringent and therefore the use of recycled water presents a reduced risk to consumers than the FDA regulations.”

As population growth increases demand for water and climate change reduces rainfall in most areas, the existing supply-and-demand balances are increasingly shifted toward water shortage and scarcity. Use of recycled water is thus becoming more commonly adopted, especially for irrigation of food crops. This white paper places recycled water in perspective with respect to FSMA and its Produce Safety Rule—Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

Produce Safety Rule is one of many rules covered by FSMA. Produce that is covered by the rule includes fruits, vegetables, mushrooms, sprouts, herbs and nuts. It excludes grains, produce rarely consumed raw, produce used for personal consumption, and produce that is typically subjected to processing or used in manufacture of non-food products.

Chapter 2 provides background and a summary of the FDA FSMA law followed by Chapter 3, a discussion of the Produce Safety Rule and its relevance to growers using recycled water.

CHAPTER 2

History of Food Safety Regulation

Food-borne diseases have caused huge morbidity and mortality statistics historically and extending to current times. According to the U.S. Food and Drugs Administration (FDA) “About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases” (FDA 2019). This high rate of disease and death imposes a tremendous economic burden on the nation and can be prevented if upstream efforts are undertaken to prevent contamination of food crops with disease agents.

Earliest efforts to safeguard the produce against contamination were initiated by farmers and farm organizations concerned about the reputation of their brand and continued patronage of their customers. The grocery industry, suffering economic losses from sporadic recalls of contaminated produce, engaged in formulation of some of the earliest versions of food safety standards.

The FDA, in its voluntary Good Agricultural Practices (GAPs) food safety guidelines, published in 1998, specified that water should be “adequate” for the needs of the operation but left the meaning of “adequate quality” up to the grower to decide (U.S. FDA, 1998).

“In 2007, following a tragic outbreak of e. coli that sickened over 200 people, California farmers made an unprecedented commitment to protecting public health through the creation of the California Leafy Green Products Handler Marketing Agreement (LGMA). The program’s goal is to assure safe leafy greens and confidence in our food safety programs.” (LGMA, 2019)

The Agreement is effective in California and in Arizona. Approximately 90 percent of the leafy greens consumed in the United States are grown in these two states. Participation in the program is voluntary, but once a grower becomes a signatory to the Agreement, farm practices must follow science-based farming practices, be subject to government audits, and undergo a certification process. Members are required to be in complete compliance at all times and are subject to USDA-certified government inspections. The requirements of LGMA are backed by state law.

The LGMA estimates that 99 percent of the total production of leafy greens in California is covered by the agreement. Leafy greens under the LGMA include arugula, baby leaf lettuce, spring mix, butter lettuce, cabbage (red, green, and savoy), chard, kale, endive, escarole, green leaf lettuce, iceberg lettuce, red leaf lettuce, romaine lettuce, and spinach. (Calvin *et al.* 2017). LGMA requirements apply to practices in the field, while the Food Safety Modernization Act Produce Safety Rule applies to practices in the field and beyond.



Crops covered under Leafy Greens Product Handler Marketing Agreement (LGMA); SOURCE, LGMA, 2019

Food Safety Modernization Act (FSMA)

FSMA is a law, signed by President Obama on January 4, 2011, to protect consumers against exposure to food-borne microorganisms from crops grown on the nation’s farms and handled subsequently in the supply chain. The law gives new authority to the US Food and Drug Administration (FDA) to regulate farming practices, harvest, and processing of food crops. The law also requires FDA to publish rules, guidance documents, and other plans, reports,

standards, etc. Most importantly, the law empowers FDA to recall food crops suspected of contamination. FSMA has shifted the focus from responding to foodborne disease to preventing it.

Between 2011 and 2019, The FDA has issued 18 specific rules, and 56 guidance documents for the food industry. These documents address a large variety of farming, food handling and food processing steps before the consumer purchases the food products. Produce Safety Rule is one of the FSMA rules that includes irrigation water quality requirements at the heart of this white paper.

Produce Safety Rule

An important component of FSMA is the Produce Safety Rule (PSR), which “...establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.” (FDA, 2018). Compliance dates with the requirements of Product Safety Rule are as follows:

Produce (Except Sprout) Farm Size*	Compliance Date
Very Small Business: >\$25,000 to <\$250,000	January 26, 2024
Small Business: >\$250,000 to <\$500,000	January 26, 2023
All Other Businesses >\$500,000	January 26, 2022
Sprout Farm Size*	Compliance Date
Very Small Business: >\$25,000 to <\$250,000	January 28, 2019
Small Business: >\$250,000 to <\$500,000	January 26, 2018
All Other Businesses >\$500,000	January 26, 2017

* Farm size is defined as the average annual monetary value of produce the farm sold during the previous 3-year period

Source: Federal Register / Vol. 84, No. 52 /Monday, March 18, 2019 /Rules and Regulations, page 9709

The Product Safety Rule includes several subparts, as follows:

Subpart A—General Provisions

Subpart C—Personnel Qualifications and Training

Subpart D—Health and Hygiene

Subpart E—Agricultural Water

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

Subpart K—Growing, Harvesting, Packing, and Holding Activities

Subpart L—Equipment, Tools, Buildings, and Sanitation

Subpart M—Sprouts

Subpart O—Records

Subpart P—Variances

Subpart Q—Compliance and Enforcement

Agricultural Water

FSMA makes a major distinction between farms producing sprouts and farms producing other crops that are normally eaten raw. This is because of the warm, moist environments in which sprouts grow, all the way up to the point of sale for consumption, making them an easy vector for transmission of communicable diseases. The required water quality standard and monitoring requirements for sprouts and other produce are summarized in the Table 1.

Table 1. FSMA Produce Safety Rule Agricultural Water Quality for Irrigation of Produce for Human Consumption.

Water Quality Parameter and Sampling Frequency	Irrigation of Produce (Except Sprout)	Sprout*
<i>E. Coli</i> , Geometric Mean (GM)	≤ 126 in 100 mL of water	Non-Detect
<i>E. Coli</i> , Statistical Threshold Value (STV)	≤ 410 in 100 mL of water	--
Initial Survey, Untreated Surface Water Sources	20 samples	4 samples
Initial Survey, Untreated Ground Water Sources	4 samples	4 samples
Annual Survey, Untreated Surface Water Sources	5 samples per year	1 per year
Annual Survey, Untreated Ground Water Source	1 sample per year	1 per year
Calculation of GM and STV for Surface Water	Running average of last 25 samples	4 samples
Calculation of GM and STV for Ground Water	Running average of last 4 samples	4 samples
Water Received from Public Water Systems	No sampling is required	Ditto
Recycled Water Received from Public System	Not Yet Specified	Not Yet Specified

* In addition to irrigation water for sprout, this criterion also applies to water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest.

FSMA Produce Safety Rule does not specify any special requirements for use of recycled water for irrigation of produce. In farms where recycled water is used for irrigation of crops, it is anticipated that there will be no need for sampling and record keeping. This is because recycled water is generally received from public agencies (city departments, county sanitation districts, special districts, etc.), and these public agencies must comply with their respective state’s regulations and guidelines, including frequent sampling for a wider range of parameters and maintaining analytic records, available for public inspection.



Irrigation Water Quality Requirements

Plants require a continuous supply of water for their growth and development of fruit and other marketable parts. In commercial agriculture water is supplied by way of irrigation, using a variety of application methods. Figure 1 shows a qualitative comparison of the various irrigation methods’ potential to contaminate growing crops—if the irrigation water is contaminated. If the irrigation water is free from contamination—or treated to provide an



acceptable quality—then the irrigation method in use does not affect the safety of produce irrigated with that water source.

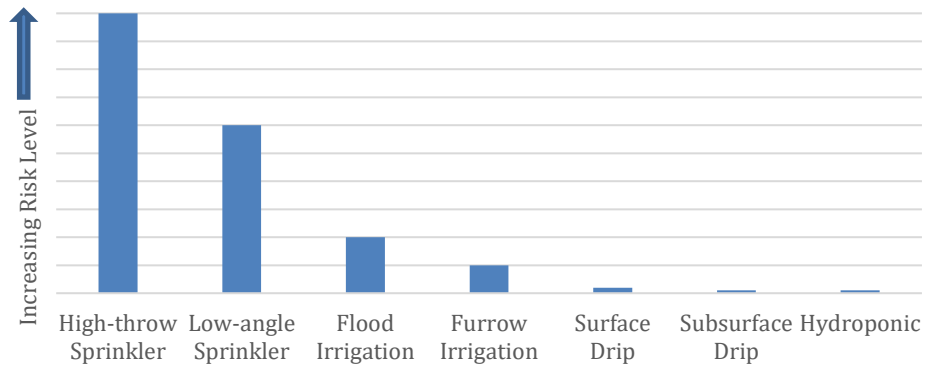


Figure 1. Qualitative (not to scale) Relative Risk of Exposure of Food Crops to Potentially Water-Borne Microorganisms by Irrigation Method.

CHAPTER 3

Regulated Use of Recycled Water in Agriculture

Agricultural water reuse is regulated at the state level in the United States. This has created some variability in the way crops can be produced with recycled water and, in some instances, complete prohibition on the production of food crops with recycled water. In the states where recycled water is allowed to be used for irrigation of food crops, regulations and guidelines have been established to ensure that workers exposed to the water are safe and people consuming the crops are not at a greater risk than they would be if those crops were irrigated with conventional sources of water.

Recycled water has become an option for irrigation of agricultural crops—including all food crops, leafy greens, and organically grown crops—in many semi-arid and arid regions of the world. In the United States, 27 states have established regulations allowing use of reclaimed water for irrigation of food crops. Fifteen other states allow non-food crops to be irrigated with recycled water. The remaining eight states either do not allow irrigation with recycled water or do so on a case-by-case basis (Sheikh *et al.*, 2019), as graphically represented in Figure 1.

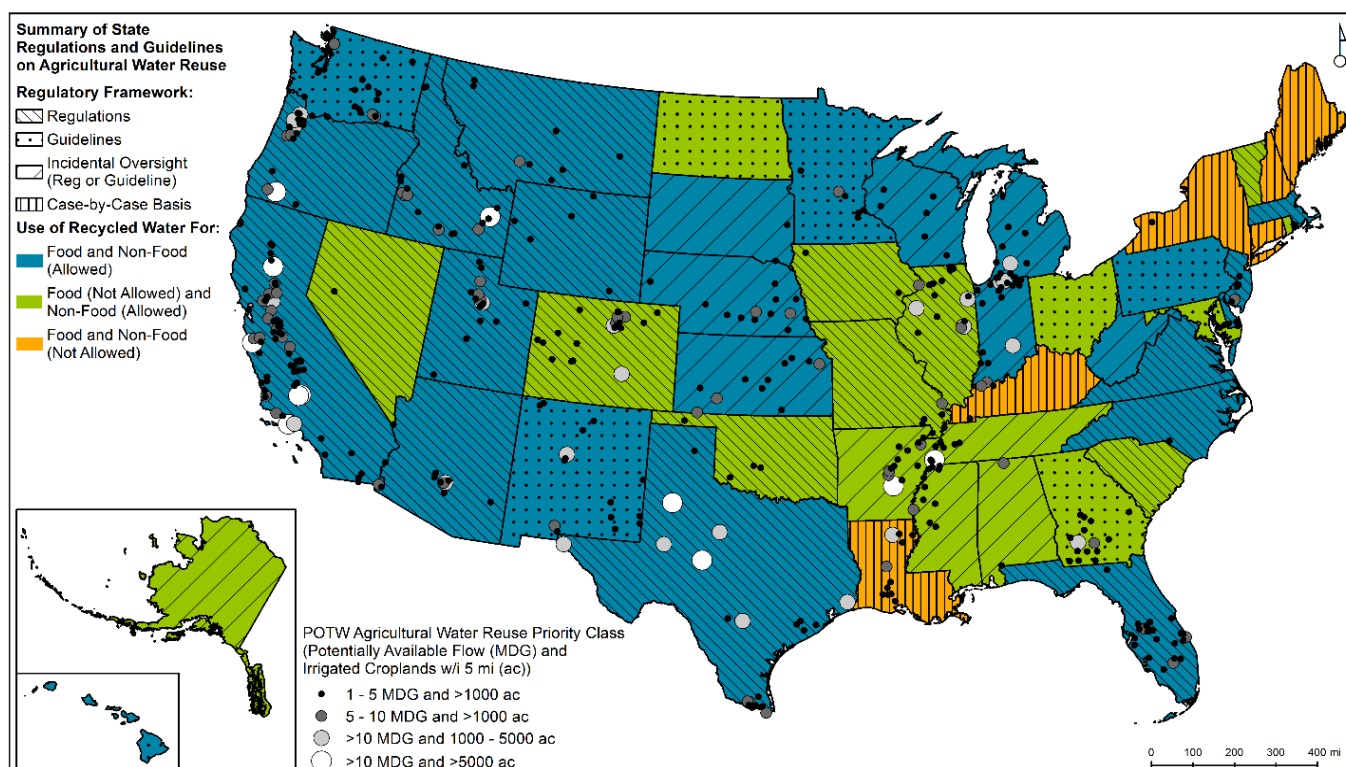


Figure 1 Regulation of Irrigation with Recycled Water in the United States

Source: Sheikh *et al.*, 2019, data from 2012 USEPA Guidelines for Water Reuse, updated to January 2019

Food safety is an important responsibility of all producers and handlers of farm products intended for human (and domestic animals) consumption. Historical disease outbreaks and epidemics have resulted in great suffering and death, some decimating whole communities.

These human tragedies are well documented and subject of much cultural and artistic expression. Lessons from these events have gradually been learned and in many cases formalized into standards of practice, norms, and—in most recent times—regulations.

Recycled Water under FSMA

Recycled water that is allowed to be used for irrigation of food crops must meet state regulations and guidelines established to protect the public health. A summary of the microbial standards for irrigation with recycled water for states that have established such criteria is presented in Table 2.

“We will consider providing guidance on the use of various types of water, including recycled, reclaimed, and gray water, in the future.”

Response to Comment 182 in Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations, page 74431

Table 2. State Criteria for Microbial Safety for Irrigation of Food Crops.

State*	Criterion for Microbial Indicator of recycled water quality	Limit for irrigation of food Crops, Average colonies / 100 mL	Highest allowed, colonies / 100 mL	Comparison with FSMA for Sprouts	Comparison with FSMA for Crops Other than Sprouts
Arizona	Fecal coliform	ND	<23	equal	superior
California	Total coliform	<2.2	<23	equal	superior
Colorado**	E. coli	ND	<126	equal	superior
Florida	Fecal coliform	ND	<25	equal	superior
Hawaii	Fecal coliform	<2.2	<23	equal	superior
Idaho	Total coliform	<2.2	<23	equal	superior
Maryland***	Fecal coliform	<2.2	<200	equal	superior
Massachusetts	Fecal coliform	0	<14	equal	superior
Minnesota^	Total coliform	<2.2	<23	equal	superior
Nebraska^^	Fecal coliform	<200	<400	Unfit	equal
Nevada	Total coliform	<2.2	<23	equal	superior
New Jersey	Fecal coliform	<2.2	<14	equal	superior
New Mexico^^^	Fecal coliform	<5	<23	equal	superior
North Carolina	E. coli	<3	<25	equal	superior
Ohio	E. coli	ND	<2	equal	superior
Oregon~	Total coliform	<2.2	<23	equal	superior
Pennsylvania	Fecal coliform	<2.2	<23	equal	superior
Rhode Island	Fecal coliform	<2.2	<23	equal	superior
Texas~~	Fecal coliform	20	75	equal	superior
Utah	Fecal coliform	ND	NS	equal	superior
Virginia~~~	Fecal coliform	<14	<49	Unfit	superior
Washington	Total coliform	2.2	23	equal	superior

* Only states with water reuse standards (in mid-2019) are included

** Regulation 84 is undergoing reform to allow use for food crops

*** Groundwater protection--not food crops

^ Using the California standards for uses of recycled water

^^ Land disposal--not food crops

^^^ Food crop irrigation allowed with no contact and no spray irrigation

~ These standards are for graywater reuse

~~ Also Enterococci 4 and 9 CFU/100 mL

~~~ Also E coli 11/35 colonies/100 mL and Enterococci 11 and 24 colonies/100 mL

Source: Websites of the various states' regulatory agencies—updated from USEPA (2012)

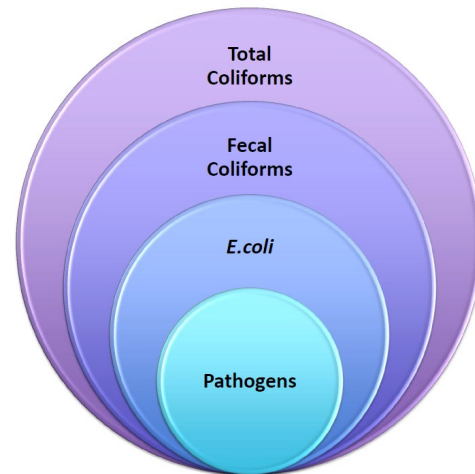
As noted in Table 2, the microbial water quality criteria used by various states are based on three different microbial indicators of the potential for presence of pathogens:

- total coliform
- fecal coliform
- Escherichia coli (E. coli)



The FSMA Produce Safety Rule criterion for acceptable water quality is based on the concentration of E. coli in the water sample as an indicator of fecal contamination. Most of the states' water recycling regulations are based on

either total or fecal coliform concentrations, although a few have adopted E. Coli for this purpose. This difference in microbial indicators is significant, but not necessarily problematic. E. coli is a subset of fecal coliform, which is a subset of total coliform, as illustrated graphically (though not to scale) in Figure 2.



**Figure 2. Illustration of the relative situation of pathogens within three different indicator colony forming organisms.**

Source: Channah Rock, University of Arizona

Fecal coliform and E. coli indicators were compared for their relative usefulness in protecting the public exposed to recreational water bodies in a USGS study in 1993 (Francy, D.S. et al.) The authors examined extensive data sets from recreational waters in the state of Ohio, using statistical test. They concluded that the geometric mean standard for E. coli provides a similar level of protection to that for fecal coliform. Arguably, total coliform limits, set at a corresponding level, would be the most protective, followed by fecal coliform and followed by E. coli. Comparing the limits set for recycled water by various states, shown above, with those in FSMA Produce Safety Rule, shown in Table 1, it is clear that the recycled water quality in almost every state shown above exceeds the requirement of FSMA Produce Safety Rule. The only exceptions (in the case of irrigation of sprouts) are the states of Nebraska and Virginia. In those states, the water quality limits are intended not for food crop irrigation, but for "land disposal".

The regression equation used by the USEPA to develop recreational water-quality criteria for E. coli in freshwater is

$$y = -11.74 + 9.40 (\log x)$$

where y is the swimming-associated gastrointestinal illness rate per 1,000 swimmers, and x is the concentration of E. coli colonies per 100 mL (Dufour, 1984)

NASDA

<https://www.nasda.org/policy/issues/food-safety>



## APPENDIX A (Calibri 20-point, PMS360C, R:108, G:194, B:74)

**Title** (Calibri Bold, 20-point, PMS3025C, R:0, G:79, B:113)



## APPENDIX D

### Glossary of Terms)

**FSMA:** Food Safety Modernization Act; a federal law passed by congress and signed by President Obama in 2011.

**Produce Safety Rule:** Food and Drugs Administration's mechanism for implementation of FSMA, effective January 26, 2017.

**Compliance Schedule:** Dates by which growers must come into compliance with the Produce Safety Rule

**Covered Activities:** Farming practices subject to Product Safety Rule

**Covered Farms:** Farms with average annual monetary value of produce within three specifically defined dollar-value ranges

**Produce:** Fruits, vegetables, mushrooms, sprouts, herbs, tree nuts

## References (Calibri Bold, 20-point, PMS360C, R:108, G:194, B:74)

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### Personal Communication

Personal communications, including email and text messages and direct messages sent through social media, are usually cited in the text only. They are rarely included in a reference list.

#### ***Personal Communication in-text citation***

(Sam Gomez, Facebook message to author, August 1, 2017)