Commodity Specific Food Safety Guidelines for the Dry Bulb Onion Supply Chain

2nd Edition • July 2022

All applicable U.S. and/or other regulations must be followed. This document assumes basic food safety practices are in place including good agricultural practices and provides additional guidance specific to dry bulb onions.

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Acknowledgments

Special thanks to the companies, agencies, trade associations, and individuals who helped in developing both the first (2010) and second editions (2022) of these guidelines.

Second Edition Editors (2022):

- Juan Anciso, Ph.D., Texas A & M Agrilife Extension
- Jennifer Dougherty, USDA-AMS
- Audrey Draper, USDA-AMS
- Dante Galeazzi, Texas International Produce Association
- Delbert Gehrke, River Point Farms
- Jared Gutierrez, Columbia Basin Onion
- John Harris, Paradigm Fresh
- Linda Harris, Ph.D., UC Davis
- Mike Hively, Generation Farms
- Arthur Keyes, Glacier Valley Farms
- Jennifer McEntire, Ph.D., International Fresh Produce Association
- Shay Myers, Owyhee Produce
- Anthony Molitor, Industrial Ventilation, Inc.
- Kurt Nolte, Ph.D., U.S. Food and Drug Administration
- Kasarah Pratt, Owyhee Produce
- Bill Rafferty, Wyatt Group
- Logan Skeen, Skeen Farms
- Michelle Smith, U.S. Food and Drug Administration
- Doug Stanley, Harris Fresh, Inc.
- Stuart Reitz, Ph.D., Oregon State University
- Kay Riley, Snake River Produce Company
- Tyler Wagstaff, Central Produce Distributors Inc.
- Joy Waite-Cusic, Ph.D., Oregon State University
- Gretchen Wall, International Fresh Produce Association
- Greg Yielding, National Onion Association

First Edition Editors (2010):

- Marc Asumendi, J.C. Watson Company
- Larry Bauman, L & L Ag Production, LLC
- Greg Bennett, Northwest Onion Co., Inc.
- Candi Fitch, Idaho-E. Oregon Onion Committee
- David Gombas, Ph.D., United Fresh Produce Association
- Scott Jensen, Boardman Foods, Inc.
- Mike Kirby, Bland Farms, Inc.
- Robert Komoto, Ontario Produce Company
- Bob Martin, Rio Farms
- Mike Meyer, Bosgraaf Sales Co.
- Wayne Mininger, National Onion Association
- Kay Riley, Snake River Produce Company
- Doug Stanley, Harris Fresh, Inc.
- Jami Brock, Taylor Farms
- Tim Burnett, Dickinson Frozen Foods
- Emily Camp, River Point Farms
- Bill Dean, River Point Farms
- Lindsay Dixon, Peri & Sons Farms
- Shawn Hartley, Utah Onions
- Shannon Kyle, Torrey Farms
- Ken Patteson, Diamond Onions, Inc.
- R.T. Sakata, Sakata Farms
- Nivia Santiago, Gills Onions, LLC
- Bob Simerly, McCain Foods USA
- John Torrey, Big O Farms, Inc.

Graphic Design: Marissa Bauman, Letter & Line Design

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Users Note

These guidelines provide recommended food safety practices that are intended to minimize the microbiological hazards associated with dry bulb onions. This guide addresses areas identified by an industry working group with diverse stakeholder input from academics, buyers, state and federal governments, and the U.S. Food and Drug Administration (FDA), as the systems-based practices and hazards likely to lead to product contamination. It does not address every known hazard, singular, or cumulative risk factors. It is expected that growers are following the minimum food safety standards as laid out by the FDA's 21 CFR 112 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (i.e., the FSMA Produce Safety Rule) as well as those required by state marketing orders or other local, state, or federal regulations. The information provided herein is offered in good faith and believed to be reliable, but is made without warranty, expressed or implied, as to merchantability, fitness for a particular purpose, or any other matter. These recommended guidelines were not designed to apply to any specific operation. It is the responsibility of the user of this document to verify that these guidelines are appropriate for its operation. The publishing trade associations, their members and contributors do not assume any responsibility for compliance with applicable laws and regulations. It is recommended that users consult with their own legal and technical advisers to be sure that their own procedures meet applicable requirements.

Throughout this document, the word "must" is used to designate practices, policies, and procedures that are required by regulation. The word "should" is used to designate recommendations which operations should consider using and are accepted by the US-based dry bulb onion industry as best practice.

All applicable U.S. and/or other regulations must be followed. This document assumes basic food safety practices are in place including good agricultural practices and provides additional guidance specific to dry bulb onions.

How to Use this Document

The best practices described in this edition represent a current understanding of dry bulb onion production that should be considered by every business within the onion supply chain and implemented for their respective operations. While an attempt has been made to represent a variety of dry bulb onion production practices across the United States, it is not possible to characterize every operation's activity due to the diversity of practices that occur within the industry. In some cases, a company may need to consider the guidelines outlined in more than one section of this document and adapt the recommended best practices to fit their operation's needs. Food safety and postharvest practices may differ among onion types, and this document is not inclusive of all varieties (e.g., green onions are not explicitly discussed in this document, though many of the same practices may apply). Judgment must be made on the applicability and appropriateness of practices for individual operations.

In this second edition, greater attention has been placed on sharing cultivation, harvest, and postharvest practices within the dry bulb onion industry as an effort to educate a wider audience of individuals who may find this information valuable to the responsibilities of their job. This audience includes regulators, auditors, or members of the buying community who are involved in understanding or verifying food safety practices. It also serves as an opportunity to identify practices and conditions which onion producers and handlers may not have previously considered as potential food safety risks. Ultimately, the responsibility for food safety is shared within the onion supply chain and therefore, these best practices have relevancy to many individuals from farm to fork.

Do

...follow Good Agricultural Practices, the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR), and other applicable regulations and guidance.

...actively and continuously evaluate potential food safety hazards, including those introduced by weather or other changing environmental factors, recognizing the diversity of the commodity, harvest, postharvest, storage, and transportation practices.

...keep onions dry by properly managing harvest, curing, and storage practices.

...ensure a properly cured neck as applicable, as this may be an entry point for contamination.*

...expect that onions that show signs of rot or decay are more likely to support the growth of human pathogens and therefore have greater possibility for contamination.

...clean and sanitize (when appropriate) food contact surfaces after handling onions that may have been contaminated or show signs of rot.

...train workers on applicable food safety practices to understand the specifics of onion production and food safety considerations.

...maintain appropriate documentation to meet regulatory and market food safety requirements.

...communicate to customers through the supply chain about the need to properly store and handle onions to keep them dry and minimize the potential for cross-contamination.

Don't

...harvest onions that are visibly contaminated with feces or that are decayed/damaged.

...pack or process onions if the neck is not adequately cured*.

...harvest onions that are wet, if avoidable.

...rely upon the intrinsic antimicrobial compounds in onions as a substitute for food safety best practices because research shows human pathogens may still grow.

Not all onion varieties are harvested after the neck has cured; some are intentionally harvested with green tops (e.g., non-storage type dry bulb onions). Photo credit: National Onion Association

Background

Food safety has long been a priority of the U.S.-based dry bulb onion industry. This industry developed a best practices document over a decade ago, before the passage of the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). This document serves to update the 2010 Commodity Specific Guidelines which provided a solid foundation for the industry to comply with the FSMA Produce Safety Rule (PSR) when it was finalized in 2015 (FDA, 2015). Dry bulb onions are a commodity covered by the FSMA PSR, provided the farm or packinghouse is subject to the rule.

In addition to federal food safety requirements, the dry bulb onion industry is subject to customer requirements which are often verified by 3rd party audits. While these audits generally exceed the minimum food safety requirements established by the FSMA PSR, they may not fully capture the nuances of dry bulb onion production.

This document seeks to promote a common understanding of dry bulb onion production practices and associated food safety risks. In light of two recent *Salmonella* outbreaks implicating dry bulb onions, the dry bulb onion industry has updated these food safety guidelines to highlight key practices in order to reduce risk, and which reflect recent and emerging science (FDA, 2021; FDA, 2022). Though the production practices described in this document are primarily reflective of United States dry bulb onion cultivation and handling, many of the recommendations in this guidance might also be appropriate for operations outside of the United States.

Producing safe onions requires management of several potential hazards; there is no single hazard that dominates, nor is there one single control for dry bulb onions that can overcome poor agricultural practices. Key areas that onion growers and packers should be mindful of include the following:

- Field selection, adjacent land uses, and soil amendments
- Agricultural water quality (e.g., production and postharvest applications)
- Unusual weather events (e.g., flooding, fires, drought)
- Harvesting practices
- Onion curing
- Packing and storage conditions
- Cleaning and sanitation
- Transportation and traceability

It is important to remember dry bulb onions, when removed from the ground, have a non-edible surface that protects the edible portion of the onions and will be removed prior to consumption. The outer papery scales that wrap the onion bulb are relatively impervious to water, and these layers fall off during harvest and packing operations. While the shedding of the papery scales may reduce some risk if contamination were present on the crop, these properties do not negate the need to follow good agricultural practices. Postharvest, the neck is

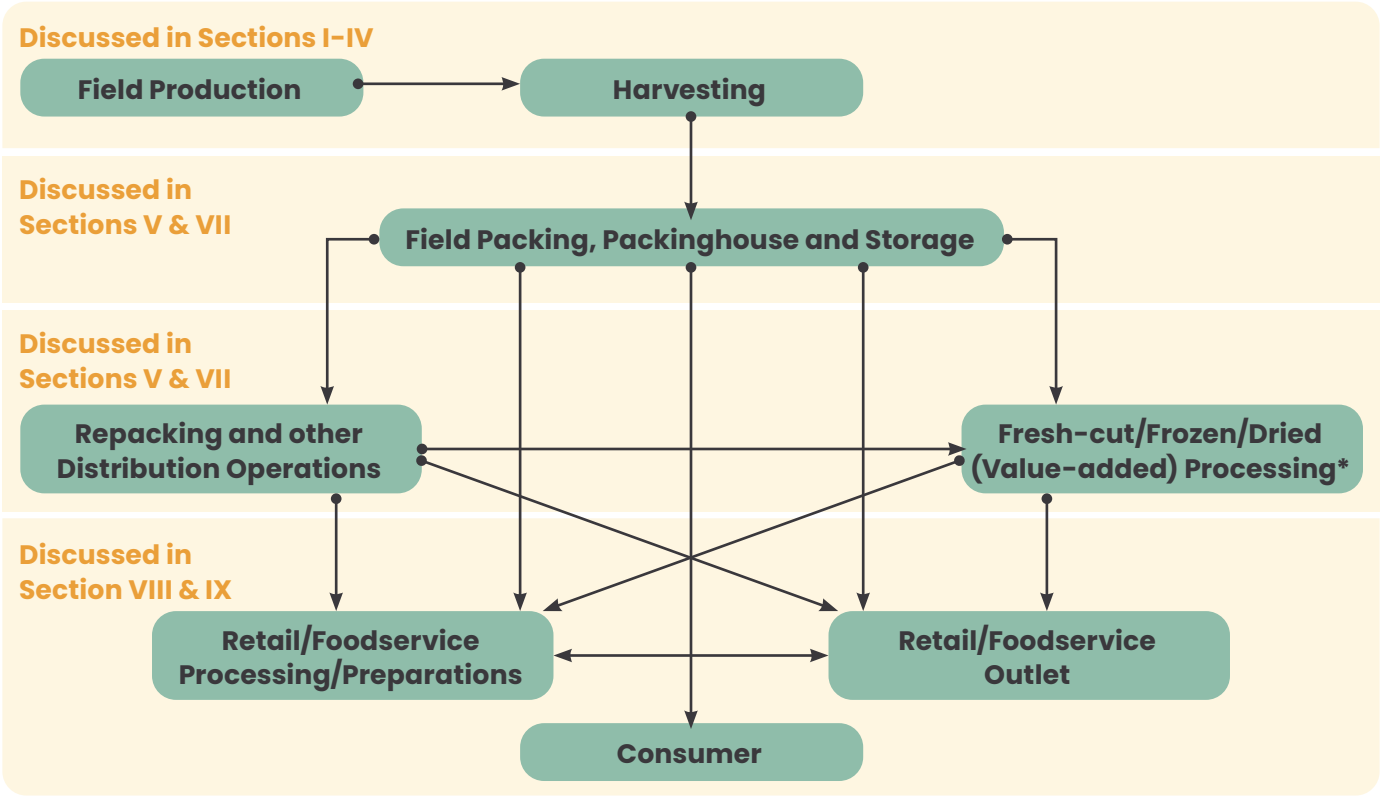
Photo credit: Logan Skeen, Skeen Farms - Oregon

the part of the onion considered most vulnerable to contamination because it is a natural entry point for pathogens. The maturity of the crop in relation to harvest timing and curing can impact the susceptibility of onions to human and plant pathogens. Postharvest, onions should be kept in cool, dry conditions, ideally protected from the elements, and kept where there is adequate air circulation (Matson et al, 1985).

The scope of this document pertains only to whole dry bulb onions, and does not include fresh-cut (sliced, diced, etc.) onions that would be subject to the FSMA Preventive Controls Rule (FDA, 2013), nor does it include onions or onion products that will be frozen (e.g., individually quick frozen), cooked, dried, or otherwise processed. The document does not focus on handling, storage, or use at forward points in the supply chain (e.g., retail or foodservice) although practices at other supply chain points can introduce or exacerbate risks prior to consumption.

The distribution chain for whole dry bulb onions can be complex, and onions may be sold directly or indirectly to the final distributor (**Figure 1**). Often onions are not grown with a specific distribution channel (e.g., retail or foodservice) in mind; growers may supply multiple channels, and these supply chains are not distinguished until long after onions are harvested and packed. Onions are frequently subject to repacking for size and/or quality. Repacking into smaller units (e.g., bag) occurs more commonly for retail than for foodservice. Regardless of destination, the supply chain may be simple or very complex, with onions being handled by several entities prior to being offered for sale to the consumer. In addition, there are multiple varieties of onions with different sensory characteristics (different colors, shapes, flavors, etc.). There are also distinct growing and handling practices that are addressed within this document.

Figure 1. General Supply Chain for Dry Bulb Onions

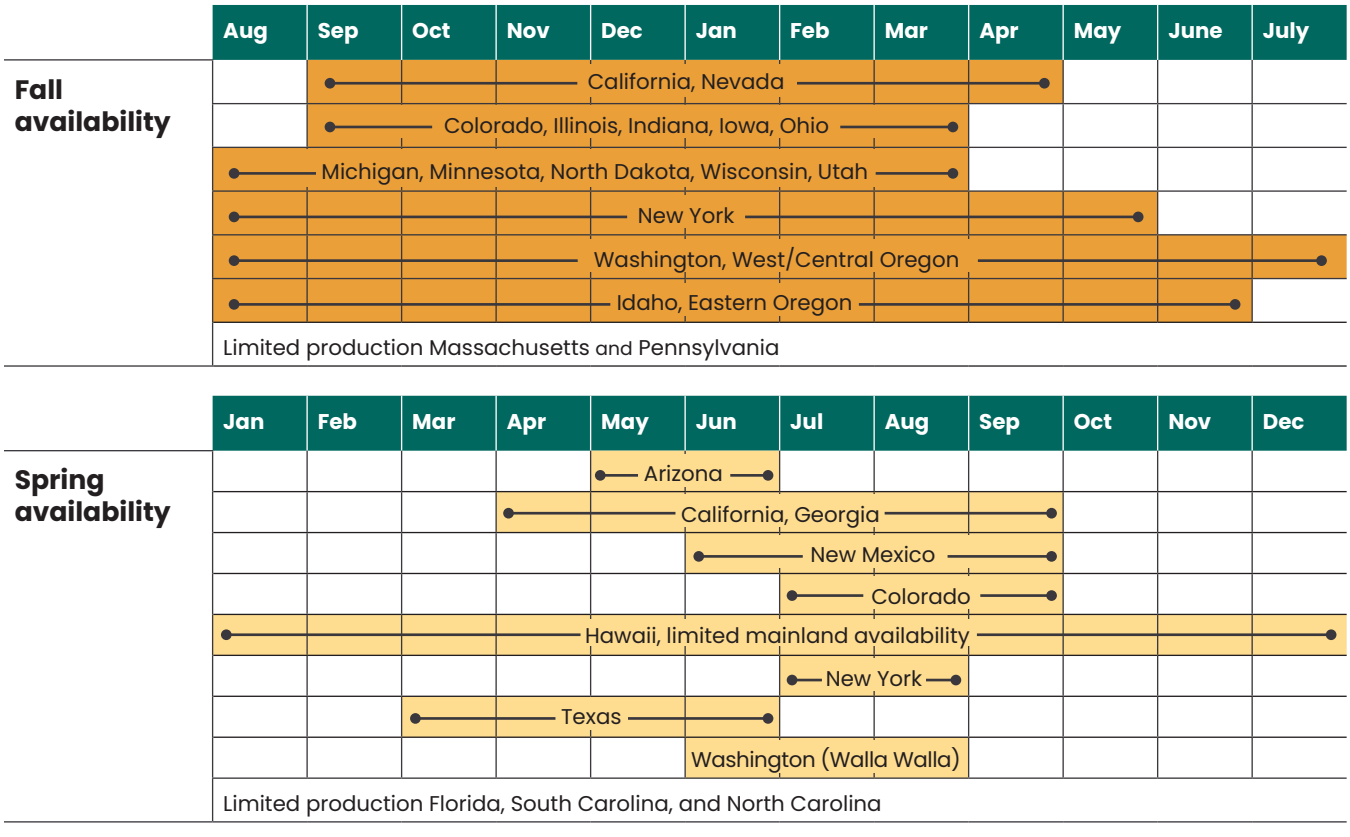


**Processing activities for dry bulb onions such as freezing, slicing/dicing, or drying onions for making spices are not discussed in this best practice document.*

Overview of United States Dry Bulb Onion Production

Dry bulb onions in a variety of shapes, sizes, colors, and flavors are grown throughout the United States. In 2021, onions were in the top three vegetables (by crop size) grown in the U.S. and accounted for $1.04 billion in farm gate value (NASS, 2021). Yellow onions are the most popular type and account for approximately 87% of U.S. production volume, followed by red onions at 8%, and white onions at 5% (NOA, 2022). Different growing regions and onion varieties often call for different growing, harvesting, and handling methods. These differences may impact the food safety risks present in each production area. **Figure 2** shows areas of U.S. production as well as the general availability of each onion type in the marketplace throughout the year. As the figure shows, onions are grown and available throughout the United States in every month of the year. Regardless of the region, type of onion, or production practices, the food safety and quality goals are the same: provide a high quality, safe onion by keeping the bulb dry and ensuring a well-cured neck to minimize postharvest deterioration and potential introduction of human pathogens.

Figure 2. Onion availability and major growing regions in the United States



Production of Short Day, Intermediate Day, and Long Day Onions in the United States

For the purposes of this document, the following terminology and differentiation is used to discuss onion varieties and types (**Table 1**). Note that the United States Department of Agriculture (USDA) grading standards for dry bulb onions may utilize different terminology for onion varieties and types (USDA, 2016).

Short Day Onions – This is a thin skinned, more delicate onion due to higher water content. Short day onions have a very low storability and are usually milder in taste. Short day onions are most commonly available from February through June and are typically not available September through March with the exception of some imported product. Nearly all short day varieties are hand harvested due to the tender nature of the onion. However, labor shortages have led some growers to adopt mechanical harvesting methods. These onions are usually harvested, packed, and shipped within a week due to the low storability of the variety. Measuring soluble solids is one method to determine when onions are ready to harvest. For short day onions, this may be in the 8-10% soluble solids range.

Intermediate Day Onions – The skins of intermediate day onions are thin, however there are usually multiple layers offering increased protection during postharvest handling. The bulbs tend to be firmer and have less water content than short day onions. Intermediate day onions are commonly available from May through September. Storability of intermediate day onions can vary depending on the region but is generally much longer than short day onion varieties. Intermediate day onions can be mild or pungent depending on the variety and can be harvested by hand or mechanically. Red and white varieties are harvested by hand more often than yellow varieties, but this also depends on the use and market. Soluble solids typically measure at 9-11% at harvest.

Long Day Onions – Long day onions have many layers of fully developed, hard protective skin and the onion is generally very firm. Storability can be up to a year in some cases under proper storage conditions or sold when market opportunities arise. Long day onions are usually available from September through June and are typically the most pungent onions with the lowest water content of the three onion day-length classifications. Harvest practices of long day onions are primarily mechanical. Soluble solids typically measure at 10-13% at harvest.

Table 1. Differentiation of long day, intermediate day, and short day onion types and characteristics

	Long Day	Intermediate Day	Short Day
Daylight needed	14-16 hours	12-14 hours	10-12 hours
Grow best in these areas*	North, latitudes 27-47°	Latitudes 32-47°	South, latitudes 25-35°
General market availability	September-June	March-September	February-June
Storage	Excellent	Medium to excellent	Low
Color	Red, yellow, white	Red, yellow, white	Red, yellow, white
Harvesting	Mechanical	Mechanical or hand	Hand
Flavor	Pungent	Mild or pungent	Mild

**Long day, intermediate day, and short day onions can be grown in any region of the United States, however some varieties are more common in certain climates and growing areas.*

Onion Characteristics and Their Impact on Potential Food Safety Risk

Prior to 2020 and 2021 outbreaks implicating dry bulb onions, it was thought that human pathogens (such as *Salmonella* and pathogenic *E. coli*) were unlikely to grow or persist in or on dry bulb onions. Given the range in onion characteristics and production practices, additional research is warranted to understand the parameters and factors that influence the growth and survival of human pathogens. As of the publication of this document, research funded by the Center for Produce Safety (CPS) is ongoing, and readers are encouraged to visit the 'funded research projects' portion of the CPS website for more information (https://www.centerforproducesafety.org/).

As the industry awaits further research, this document assumes the following:

- The drier the outer onion skin and layers, the less likely that pathogens can grow, however they may still be able to survive at low levels.
- The heavier the skin of the onion, the less likely it is that any surviving pathogens on the outer surface will be consumed because consumers are unlikely to eat the thick, dried outer layers. Additionally, the outermost dry scales are shed at harvest and the thinner papery layers removed by consumers are not the layers which were most external to the environment prior to harvest. However, cross-contamination can still occur, and human pathogens have been shown to survive and grow in cut onions (Lieberman & Harris, 2019; Liberman et al, 2015).
- Intrinsic antimicrobial compounds vary by variety and maturity of the onion and should not be relied upon as a substitute for food safety practices. Antibacterial activity in onion is primarily attributed to allicin (thiosulfinate) and quercetin (bioflavonoid) (Benkeblia, 2004) and is highly dependent on the onion variety, target organism, and concentration of extract (Kabrah et al, 2016). Research has shown that extracts obtained from all other varieties including the inner edible portion showed low or no bacterial inhibition activities (Sharma, Mahato, Lee, 2018).
- The physical and chemical changes that occur as the result of infection by plant pathogens can create a more favorable environment for human pathogen growth and persistence than onions that are not affected by plant pathogens. This has been demonstrated to occur in other produce commodities (Aruscavage et al, 2010). Though the most recent outbreaks in onions have not asserted decay or rot as a contributing factor, it is prudent for growers to consider the physical integrity of the crop to minimize conditions that may be favorable to human pathogen growth (FDA, 2021; FDA, 2022).

Photo credit: National Onion Association

Worker Health and Hygiene

Dry bulb onion production may require handling by workers during the production, harvest, or postharvest handling stages. Though onions are covered in a layer of papery scales which are not consumed, worker health and hygiene is still important since workers can also contaminate water sources and food contact surfaces which can lead to cross-contamination if they do not understand or follow proper health and hygiene practices. Worker training is the front line of defense in any food safety program – from the resources necessary to accomplish safe food practices (e.g., toilets, handwashing stations) to the practices which workers can implement in the field or packinghouse. Onion growers, packers, and handlers should consider inclusion of other practices relevant to each worker's job responsibilities beyond the basic hygienic practices listed below. All workers should be aware of the practices and standard operating procedures outlined in the food safety plan which can help foster a culture of food safety.

Worker Qualifications & Training

- All workers, whether temporary or permanent employees, who handle onions or food contact surfaces must receive training adequate to their job responsibilities upon hiring, and at least annually. Workers should also receive training when policies change or if a food safety incident occurs which may require retraining workers on a particular topic.
- Training must be provided in a language the workers understand and include 1) principles of food hygiene and food safety and 2) the importance of health and hygiene for all workers and visitors, including recognizing symptoms of a health condition (e.g., vomiting, diarrhea) that could lead to the contamination of onions or food contact surfaces with human pathogens.
- Workers who harvest or conduct other activities in the field (e.g., clipping onion tops or weeding) must be trained to 1) recognize situations when onions must not be harvested due to conditions that could impact the safety of onions, such as the presence of animal feces, excessive animal activity, or flood conditions, 2) inspect harvest containers and equipment to ensure they are functioning properly, are cleaned and maintained, and 3) correct problems with harvest containers or equipment (e.g., fixing/replacing bins in poor condition or visibly dirty).
- At least one supervisor or responsible party for the farm must have successfully completed

food safety training at least equivalent to that received under the standardized curriculum recognized by the FDA (i.e., Produce Safety Alliance training) if they are subject to the FSMA Produce Safety Rule.
- At least one individual must be assigned to supervise or otherwise be responsible for food safety practices.
- A record must be kept documenting the date of training, topics covered, and person(s) trained.
- Visitors must be made aware of the farm or packinghouse's food safety policies and must have access to a toilet and handwashing resources.

Health and Hygiene Practices

Workers must:

- Take measures to prevent contamination of onions and food contact surfaces with human pathogens from any person with an applicable health condition. This includes communicable diseases that present a public health risk in the context of normal work duties including infection, open lesions, vomiting, or diarrhea.
- Maintain adequate personal cleanliness to protect against contamination of onions and food contact surfaces.
- Avoid contact with animals other than working animals and take steps (such as adequate handwashing) to minimize the potential for cross-contamination.
- Wash hands thoroughly by scrubbing with soap and clean water for 20 seconds and dry hands thoroughly with single service towels, electric hand driers, use of a sanitary towel service, or other hand drying device. Handwashing must occur before starting work, before putting on gloves, after using the toilet, upon return to work after breaks, as soon as practicable after touching animals or waste from animals, and any other time hands may be dirty.

- Hand sanitizer cannot be used as a replacement for washing hands with soap and water but can be used in addition to proper handwashing.
- Maintain gloves in a sanitary condition, if used. This can be achieved by either using single use, disposable gloves or by washing and storing reusable gloves so that they are clean prior to contacting onions or food contact surfaces. The use of gloves is not a substitute for handwashing.
- Remove or cover hand jewelry that cannot be adequately cleaned or sanitized during activities in which onions are being contacted by hand.
- Not eat, chew gum, or use tobacco products in onion growing, packing, or storage areas.

Sanitary Facilities and Resources

- Toilet facilities must be provided and readily accessible to the growing and packing areas during harvest and postharvest activities.
- Toilet facilities must be designed, located, and maintained to prevent contamination of onions, be accessible for servicing, and provide for sanitary disposal of waste and toilet paper.
- Handwashing facilities must be provided and readily accessible to the growing and packing areas and include soap, clean water, adequate means for drying hands, and a way to properly dispose of waste and wastewater.

Photo credit: National Onion Association, Hand harvest into burlap

Pre-Harvest Practices

The development of good agricultural practices for dry bulb onion production must consider all the elements of the field production system: field site, adjacent and nearby land use, agricultural inputs (e.g., irrigation water, fertilizers), workers, and production practices.

Land Selection and Assessment

Prior to planting, ensure the land is appropriate for growing dry bulb onions. Many growers establish a multi-year plan for crop rotations that may include onions.

- Conduct an annual environmental assessment that includes topography, land history, risk of flooding, adjacent and nearby land use, and domestic animal and wildlife activity.
- Evaluate nearby and adjacent land uses for potential hazards such as sources of microbial contamination (e.g., domesticated animal activity, run-off), human activities (e.g., landfills, sewage treatment, septic tanks, recreational activity), and chemical or physical contaminants (e.g., pesticides, broken glass).
- Consider the potential for flooding to create conditions that may pose a food safety risk. Flooding is the uncontrolled introduction of flowing or overflowing of a growing area with water outside of the grower's control that is reasonably likely contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of the edible portion of fresh produce in that field (FDA, 2011). Dry bulb onions which have been contacted by flood waters are considered adulterated and must not be harvested for human consumption.
- Appropriate measures must be taken to mitigate any identified food safety hazards. These measures may include installation of berms, fences, ditches, buffer zones, or other strategies to effectively mitigate identified food safety hazards.

Wildlife and Domesticated Animals

Good agricultural practices have long recognized the potential threats posed by fecal contamination from domesticated animals and wildlife. Because the bulk of the onion bulb (the edible portion of the crop) is exposed to the outside environment (i.e., not fully buried), the risk from wildlife and nearby domesticated animals is still present. However, animals may harbor pathogens

Photo credit: Stuart Reitz, Oregon State University

that can directly (e.g., fecal deposit on onion) or indirectly (e.g., contamination via applied agricultural water) affect the safety of onions.

- Measures must be taken to exclude domesticated animals, livestock, and wildlife from onion fields.
- If there is evidence of animal fecal contamination in the field, the affected produce must not be harvested.
- An industry recommendation is to leave a buffer zone around a fecal deposit. Typically, a buffer zone with a 5-foot radius around a fecal deposit is used although this is dependent upon the specific situation. The buffer zone can be increased, depending on additional observations or judgment of the food safety manager. For hand harvested onions, it is common industry practice to flag

off these areas and leave any potentially affected onions in the field. If mechanical harvest is required, assessment of the whole field and ability to maneuver equipment around the affected area(s) to avoid potential cross-contamination should be conducted. Documentation should accompany any actions taken to mitigate the hazard.

Soil Amendments

Prepare land, including the use of chemical fertilizer, manure, compost, biostimulants, and other soil amendments in a way that limits the introduction of human pathogens.

Raw Manure: If raw manure (from any animal source) has been applied to fields, the time between application and harvest of the crop should be at least 120 days prior to harvest to allow for die-off of human pathogens. Die-off of pathogens occurs rapidly, however, research has shown that pathogens can persist in soils beyond 120 days. Growers should note that low levels of contamination may remain in the soil with one study citing low levels of pathogen detection at 240 days (Jiang, Morgan, and Doyle, 2002).

- Most of the onion industry has adopted an application interval for application of raw manure that extends up to several years, well beyond the 120-day minimum. While this is done primarily because of an inability to control the release of nitrogen from soil amendments rather than human pathogen persistence in the soil, the extended interval does allow for additional pathogen die-off. In addition, many onion growers across the country will rotate other crops in between onion production (e.g., sugar beets, wheat) to reduce plant diseases and allow for building of soil fertility.
- When establishing an appropriate application to harvest interval, onion growers should consider several additional factors. The rate of human pathogen die-off in raw manure can be affected by application rate, availability of moisture and nutrients for survival, environmental conditions (such as ultraviolet light exposure and temperature), type of manure (poultry, bovine, etc.), and soil ecology (Sharma et al, 2019).

Compost: In some areas, the use of compost has increased compared to the use of chemical (synthetic) fertilizers. This may be driven by increased organic production, the relative cost, and availability of inputs. Improperly or inadequately treated compost may contain human pathogens.

- Proper composting practices can reduce food safety risks by reducing pathogens through thermal and chemical processes. Parameters of composting must be carefully monitored to ensure appropriate temperatures, times, and turnings are achieved to destroy pathogens.
- Biological soil amendments of animal origin are considered 'treated' by the FSMA PSR if they are processed to completion, have not become contaminated after treatment, have not been

Photo credit: Stuart Reitz, Oregon State University, Killdeer nest in onion field

recombined with any untreated soil amendments of animal origin, do not contain any component of untreated waste, and are not considered to be agricultural tea made with biological materials of animal origin that contain an agricultural tea additive (e.g., molasses).

- For FSMA PSR compliance, the following treatment processes for compost are acceptable:

  A.) Scientifically valid controlled physical, chemical, or biological process (or combination) which has been validated to satisfy the microbial standard for *Listeria monocytogenes*, *Salmonella* species, and *Escherichia coli* O157:H7.

Microorganism	Microbial standard
L. monocytogenes	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
***Salmonella* species**	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
***E. coli* O157:H7**	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

OR

B.) Scientifically valid controlled physical, chemical, or biological process (or combination) which has been validated to satisfy the microbial standard for *Salmonella* species and fecal coliforms.

Microorganism	Microbial standard
***Salmonella* species**	Not detected using a method that can detect three MPN *Salmonella* species per 4 grams (or milliliter, if liquid is being sampled) of total solids; and less than 1,000 MPN fecal coliforms per gram (or milliliter, is liquid is being sampled) of total solids.
Fecal coliforms	Less than 1,000 MPN fecal coliforms per gram (or milliliter, if liquid is being sampled) of total solids.

Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in Option B include:

  - Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing.
  - Turned composting that maintains aerobic conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

- Application of compost: For FSMA PSR compliance, soil amendments of animal origin treated by Option B may be applied in a manner that minimizes contact with the onions during and after application and requires no minimum application interval. Soil amendments of animal origin treated by Option A can be applied in any manner with no minimum application interval.

Recordkeeping:

- Documentation must be kept of compost management practices to ensure proper temperatures and turnings have been achieved. Records should be kept of manure applications including dates and fields where it was applied.
- Onion growers purchasing compost and other treated soil amendments must obtain information (e.g., certificate of analysis or conformance) from the supplier annually to document that a scientifically valid treatment process was carried out with process monitoring and that the compost was handled in a manner and stored in a location to minimize risk of contamination by an untreated or in-process soil amendment of animal origin.

Chemical (synthetic) fertilizers: In general, synthetic fertilizers, which have been treated to reduce human pathogens, present low food safety risks from a microbiological standpoint. Chemical food safety risks associated with synthetic soil amendments can be minimized by following product labels and use of personal protective equipment (PPE) for worker safety.

Biosolids: If biosolids are used for onion production fields, they must be used in accordance with the requirements of 40 CFR part 503, subpart D and any applicable state requirements (EPA, 1999).

Crop rotation

When other crops such as potatoes, wheat, and peanuts are grown in rotation with onions, care should be taken to ensure that these do not serve as attractants for pests or wildlife, including birds.

Seeding and Weeding

- Seeds should be purchased or sourced from reputable providers. Most of the onion industry uses commercial seed sources, though a small number of growers produce their own seeds. If growers choose to produce their own seed, good agricultural practices should be followed to prevent contamination during seed production.
- Seeds are typically mechanically planted in the soil. In some regions, seedlings are transplanted when they have approximately three to five leaves. Attention to personal hygiene, including proper handwashing and toilet use, should be emphasized during transplanting.
- During weeding, workers are unlikely to directly contact the onions with their hands, but they may use tools for this activity that should be kept clean and in good condition. Personal hygiene practices including handwashing, proper toilet use, adherence to illness policies, and use of established break areas must be emphasized.
- Onion producers must provide restroom and handwashing facilities in a location convenient for workers to access during hand weeding and other field work.

Agricultural Water

Agricultural water used in the production of onions can be a route of contamination in the field and may be the carrier of many different microorganisms of public health concern including bacteria *Salmonella*, pathogenic *E. coli*, and *Shigella*, protozoa *Giardia lamblia* and *Cryptosporidium parvum*, and human viruses such as hepatitis A. Several prior produce-related outbreaks have cited water as a suspected vehicle for contamination. Water is subject to often-transient conditions that can introduce human pathogens; for example, wildlife activity upstream, run-off from storms, or dredging of canal systems which may cause pathogen populations to spike temporarily. Conditions which may increase the likelihood of human pathogen presence in agricultural water sources and distribution systems must be assessed. The type of water source (e.g., surface, ground, or municipal), application method, and application timing can influence potential food safety risks during onion production as shown in **Table 2**.

Agricultural water is defined in the FSMA PSR as 'water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing, harvesting, packing, and holding activities'. This means that all water used during the production, harvest, and handling of dry bulb onions will be considered agricultural water for the purposes of FSMA PSR compliance because with all application methods, the water is intended to or likely to contact the crop. Agricultural water must be of safe and adequate sanitary quality for the intended use. Generic *E. coli* has historically been used as an indicator of fecal contamination and more information about agricultural water quality testing is included in this section.

Table 2. Water source, application timing, and application method risk profile for dry bulb onion production.

Higher

Level of Risk

Lower

Source	Timing	Application
Surface (rivers, canals, ponds) *More susceptible to contamination due to open nature of water source*	**Close to harvest** *Less time to allow more pathogen die-off*	**Overhead** *Likely to contact the harvestable portion of the crop, including the neck and surrounding area of the onion; most common method of irrigation in onions. Rain water is not agricultural water.*
Ground (wells, springs) *If properly protected and maintained, ground water sources may limit introduction of contamination to the water source*		**Flood/Furrow** *May contact harvestable portion of the crop, but less likely to contact the neck of the onion; least common method of irrigation in onions*
Municipal (public water system) *Treated to eliminate pathogen presence; however, water distribution system may still introduce contamination*	**Extend the time between application and harvest** *More time to allow for pathogen die-off*	**Sub-surface (drip/trickle)** *May contact harvestable portion of the crop, but unlikely to contact the neck of the onion; second most common irrigation method in onions*

Water Sources

The source of the surface water varies greatly depending on the growing region. In the west, surface water is often sourced from snowpack reservoirs and rivers and delivered to fields through irrigation canals. In the north and southeast, ponds are a predominant source of water for onion production. The different types of water sources may impact how a grower should manage water used to grow onion crops.

- **Surface Water:** In many parts of the United States, surface water is used by onion growers. Environmental factors have a greater influence on surface water sources. Environmental conditions can change rapidly in the event of heavy rain or other severe weather events, migratory wildlife and domestic animal activity, or human activity such as recreational use, canal maintenance, or sewage discharge. Knowledge of nearby and adjacent land use and potential impacts upstream through monitoring can help identify hazards which may cause water quality to change.
- **Reclaimed Water:** The use of reclaimed water (i.e., tailwater) is a common practice in many areas. If growers are using tailwater

to recharge their water system, careful evaluation of the water quality and potential application of water treatment methods should be considered.

- **Ground Water:** If properly constructed and maintained, ground water sources are typically less variable in quality over time. Ground water

Photo credit: National Onion Association, Canal for drip irrigation of onions

from wells can be compromised in situations where wells are not properly sited (e.g., located near septic systems or livestock production areas), improperly constructed (e.g., well casing defects or subject to run-off), or not maintained or inspected (e.g., well head not intact).

- **Municipal Water:** Public water systems provide the lowest likelihood of being contaminated with human pathogens. In the United States, public water systems are required to meet EPA drinking water regulations which provide microbiological standards that the treatment facility must achieve. Not all onion growers have access to public water systems for production purposes and furthermore, the use of municipal water is likely to be cost prohibitive, especially for larger scale operations. Municipal water is sometimes referred to as 'culinary water' or 'potable water' in the onion industry.
- **Treated, Recycled Wastewater:** Recycled wastewater which has been treated by publicly owned treatment works or municipalities is occasionally used for the growing of onion crops. Note that requirements for water reuse on food crops may vary by state (EPA, 2012). Confirm local and state regulations and water treatment class requirements before applying recycled water to onion crops.

Water System Inspection & Assessments

At the beginning of each growing season, but at least once annually, the water system must be inspected to the extent which it is under the grower's control to identify any conditions that may introduce hazards onto the onion crop. This includes consideration of 1) the nature of each water source (e.g., ground surface, municipal), 2) the extent of control over the water source, 3) the degree of protection of each water source, 4) uses of nearby and adjacent land, and 5) the likelihood that another upstream user of the water introduces a hazard to the water source.

Additionally, the proposed agricultural water rule (also called Subpart E) requires that an agricultural water assessment be conducted annually and include information about the water system, agricultural water practices, crop characteristics, environmental conditions, and additional relevant factors such as water testing results (FDA, 2021). At the release date of this document, a final version of Subpart E has yet to be published. This means growers, educators, regulators, and industry members must seek out the most up-to-date information regarding the status of Subpart E until the final provisions are released and able to be incorporated into this document.

Application Methods & Timing

Effective management of water applications can help optimize onion bulb yield and size. Irrigation is used to establish the crop following direct seeding or transplanting with typical peak water usage during the bulb formation stage and towards the middle of the season. Water use declines as growth of the bulb slows and the crop nears maturity. A common practice is to avoid application of water within one week of harvest and many long and intermediate day onion growers utilize a 30-day irrigation-to-harvest interval. In some growing regions, irrigation ceases and curing begins when 50% or more of the field have 'tops down' (i.e., about half of the onion plants have naturally fallen over and the onion goes into dormancy). Water application may be used closer to the time of harvest for short day onion types. Onion growers may utilize a single method or multiple methods of water application depending on the growing region, availability of irrigation equipment, and stage of dry onion bulb growth. When considering the variation nationwide, overhead irrigation is the most common method of water application during the production of onions followed by sub-surface (drip/trickle) and flood/furrow irrigation.

Photo credit: Stuart Reitz, Oregon State University

- **Overhead Irrigation:** Overhead irrigation provides the greatest relative opportunity for contaminated water to enter the onion plant. The ability of *Salmonella* or other human pathogens to enter onions via overhead irrigation has not been fully evaluated, but overhead irrigation is generally considered to present greater food safety risks compared to other application methods because water can trickle down the neck and potentially get inside the bulb.

- **Flood/Furrow Irrigation:** Flood or furrow irrigation should be managed so that water does not flood at the field bottoms and to avoid unintended leaks in drip irrigation systems.

- **Sub-surface Irrigation (drip/trickle):** In some regions, sub-surface application (such as use of drip tape) is ideal to reduce evaporation. Sub-surface irrigation should be maintained so that there are no cracks or punctures that cause water to spray upward onto the plant unintentionally. Care should be taken by workers and equipment so that drip tape does not become damaged. Although animals are not ordinarily attracted to onions, they may be attracted to drip tape, especially in dry regions. Observation of drip tape is one way to gauge potential animal activity in the onion industry.

Human Pathogen Die-off

Research suggests that conventional curing is a possible mitigation strategy for dry bulb onions produced with drip irrigation but not necessarily overhead application of poor quality water (Emch & Waite-Cusic, 2016; Moyne et al., 2022; Wright et al., 2018). Dry bulb onion harvest proceeds best under dry conditions, however, given the diversity of growing locations across the United States, this is not always possible. Dry conditions combined with curing time after irrigation shows that die-off of pathogens occurs, however, research also shows that while pathogen levels may be reduced to very low levels they may not be eliminated entirely. Therefore, growers should consider the quality of the water applied prior to use of a die-off interval since environmental conditions that affect pathogen die-off (such as ultraviolet light exposure, desiccation, or humidity) will vary depending on growing location and caution should be exercised to ensure the safety of the crop. Applying a combination of approaches or technologies, also known as a hurdle concept, can minimize food safety risks.

Figure 3. Example application of a 'hurdle concept' to minimize food safety risks with agricultural water.

1. Assess agricultural water quality
2. Allow exposure to UV rays from the sun
3. Extend time between application of water and harvest

Photo credit: 1. National Onion Association, overhead irrigation of onions, 2. National Onion Association, Furrow irrigation of onions in Georgia, 3. Linda Harris, UC Davis, drip irrigation of onions

- **Other Applications Using Water (Pesticides, Herbicides, Sprout Inhibitors, Sunshade):** Any water that contacts the onion will be considered agricultural water under the FSMA PSR. Occasionally, water may be utilized in ways on the farm which could impact the microbial safety of the crop, especially if water is applied close to harvest. For example, irrigation systems may be run with the intent to loosen hard soil for removal of the drip lines in the field and for lifting/harvesting onions. Though not a traditional irrigation activity, water is still likely to contact the onion and therefore must be of safe and adequate sanitary quality.
  - Well or municipal water is the recommended water source for chemical applications such as pesticides, herbicides, sprout inhibitors, and sunshade because the water will directly contact the onion. Additionally, there are fewer particulates so these water sources are less likely to cause clogs or other issues with the application equipment and/or distribution system.
  - Sunshade (typical ingredient is clay or kaolin) is commonly applied to white, red, and intermediate onion types which may be harvested before they are fully cured. These compounds are usually applied after bulb initiation, within the last 6 weeks of the production cycle, or after lifting to prevent sun scald which causes onions to not qualify for U.S. #1 grade.
  - If chemical applications are contracted by a third party (such as a commercial pesticide applicator), growers should verify through documentation that the contractor utilizes water sources that are not likely to introduce contamination to the onion crop.
  - If dust abatement is used, care should be taken to ensure that water applications do not contact the onions, especially close to harvest. If the water is likely to contact the onions, then the water used must be of safe and adequate sanitary quality.

Water Testing

Testing water used to grow onions is part of a responsible food safety program. Testing water sources is the only way to establish a history from which to evaluate trends in water quality. Many onion growers have been testing their water to quantify generic *E. coli* as required by their third-party audits or buyer requirements. Regardless of whether testing is required, growers should consider testing water used to grow dry bulb onions to establish an understanding of their water quality over time and to help in making water use and management decisions.

- **Frequency**: At a minimum, onion growers should test their water three times per season; at the beginning of water use, during the middle of production, and close to harvest. Frequency of testing will be determined by several factors including the onion growing region, onion type, water source, identified hazards that may impact water sources, or by audit requirements. Testing throughout the season can help identify trends in water quality and enable growers to better understand any risks that might impact the onion crop. **Table 2** outlines the risk profile for the water source type, application method, and timing to best determine the frequency of testing appropriate to the growing operation.
- **Analyte**: Water testing has historically relied upon generic *E. coli* as an indicator of fecal contamination in agricultural water. Though this is an imperfect analyte for testing, the science is still evolving to determine a more effective analyte that would help a grower assess risk. Growers should stay abreast of advancements in research to inform best practices for water testing by maintaining contact with industry or grower associations or their local extension office.

Photo credit: 1. Stuart Reitz, Oregon State University, removal of drip tape, 2. Logan Skeen, Skeen Farms, application of sunshade to red onions

- **Sampling**: Samples for testing should be collected at the point of use (e.g., spigot or irrigation emitter) to capture any contamination introduced within the distribution system. Sampling directly from the water source or intake pipe may also provide beneficial information to help understand the quality of the water before it entered the distribution system and the origin of potential contaminants. Growers or those responsible for collecting water samples should follow the instructions provided by the lab for sample collection, preparation, and shipment to ensure they are not inadvertently contaminating the water sample.
- **Results**: All water testing results should be reviewed to determine if action is necessary to continue use of the water (e.g., treatment of the water), identify any trends over time, or determine if any risks exist to the onions if water of questionable quality was applied. Establishing a baseline of water quality over time can help onion producers understand their agricultural water quality and identify circumstances where high test results may indicate a food safety hazard.

Water Treatment

The treatment of water sources during onion production has historically been conducted for irrigation system maintenance and equipment protection rather than for food safety purposes, though secondary food safety benefits may exist. A few common industry practices are described below.

- **Chemical Water Treatment**: Irrigation water is commonly treated with bactericides/algaecides to minimize algae growth and biofilm build-up, reduce the risk of foliar plant disease, and to keep irrigation lines clear. Secondary benefits to food safety may exist, though onion growers should not rely upon products that are not labeled for efficacy against pathogens of human concern. Few chemical water treatments targeting human pathogens have been EPA approved for use in the field, so care must be taken to always use products according to the labeled use(s). FDA and EPA have been working to align with the needs of the industry by developing a testing protocol which is intended to help companies develop data on the effectiveness of their products for inactivating human pathogens in agricultural water (EPA & FDA, 2020), thereby making more products labeled for in-field use accessible to onion producers. It is recommended that onion growers check with their chemical supply company regarding these updates and identify products which are approved and labeled for this specific purpose.
- **Other Water Treatment**: Physical water treatment, such as sand filtration, ultraviolet (UV) treatment, and ozone, may also present opportunities for reducing plant and human pathogens. In addition, filtration is commonly used to reduce particulates in the water prior to irrigation or spray applications. Water treatment used for human pathogen reduction should be validated, monitored, and verified.

Documentation

Documentation must be kept of water test results, water treatment methods and monitoring, annual water system inspections, and supporting literature for determining appropriate testing frequency, analyte, or die-off application interval.

Lifting, Topping, and Curing

The timing of lifting, topping, and curing activities are often determined by the stage of onion maturity. In some locations, growers will wait until 50% of the crop naturally have tops down (i.e., about half of the onion tops have fallen over) before starting the lifting and curing process. In other growing regions, the onion tops will be mowed or shredded to begin the process of curing. The removal of onions from the ground (lifting) and subsequent curing of onions are critical points for food safety. This is because during this stage the neck begins to dry and shrink, providing physical protection from pathogen entry (both plant and human).

The order of operations and types of activities conducted prior to and during harvesting will vary depending on the onion type and whether the harvest is conducted by hand or mechanically. A broad overview of each of the steps for hand and mechanical harvest is provided later in this document, but practices may vary.

Key Food Safety Practices for Lifting, Topping, and Curing

- Prior to beginning lifting, topping, or curing activities, evaluate growing areas for signs of potential contamination such as observation of wildlife and domesticated animals, fecal contamination (human or animal), flooding, or crop destruction. Determine whether lifting, topping, and curing activities can proceed or whether contamination could be spread through movement of equipment and workers in the field.
- Agricultural water must be of safe and adequate quality. This includes water used for irrigation and for other purposes such as the removal of drip tape, application of sunshade or chemicals, or for dust abatement.
- All tools and equipment used in the bulb onion production process must be cleaned, and when appropriate, sanitized. This includes knives, clippers, and other equipment which will directly contact the crop.
- Visually inspect food contact surfaces such as harvest totes/bins, bags, or transportation equipment prior to loading onions to ensure they are visibly clean, free from debris, and in good repair.
- All workers must follow proper health and hygiene policies including hand washing, toilet use, avoiding contact with onions and food contact surfaces if they are ill, and using separate break areas for eating/smoking regardless of whether activities are conducted mechanically or by hand.
- Curing, drying, and other onion storage facilities must be kept clean, dry, and properly maintained. This includes preventing and managing pest activity.

Lifting, Topping, and Trimming

- **Tops Down/Laying Over and Mowing/ Topping/Shredding**: Depending on the onion type, producers may wait until the onion neck naturally falls over (also referred to as 'laying over' or 'tops down') or mow the necks down (also referred to as 'topping', 'flailing', or 'shredding') before lifting the onions and curing. Laying over is a common practice for green topped onions whereas mowing is more common for long term storage onions.
- **Undercutting/Lifting**: Some onions are undercut and put in bins or bags while they are still green topped and before they are fully dry while others are lifted and may remain in the field to cure for varying amounts of time depending on environmental conditions (e.g., sunlight and temperature).
- **Trimming/Hand clipping**: Short day onions tend to be hand clipped and field cured for a brief period of time (hours – days depending on conditions). Hand hygiene and sanitation of hand clippers and other tools which contact the onions must be prioritized.

Curing

- **In field**: The effects of weather conditions, in particular rain, temperature, and UV exposure from the sun may determine the length of curing in the field. Onions should not be harvested when they are wet, since this can encourage microbial growth which is detrimental to quality, safety, and storability.
- **In an indoor facility/storage area**: Some onions, particularly short day onions, may be cured in a drying room. If onions might be subject to heavy dew or rain near harvest time, growers may continue the drying/curing process in a drying room. Inspection of indoor storage and curing areas should include evaluation of any conditions which might pose a risk of contamination such as from pest activity, presence of water (e.g., water from a leaking roof or run-off from outside), or other gross debris (e.g., trash, onion skins, culls). Additional considerations for cleaning and sanitation of onion curing and storage areas are included later in this document.

Photo credit: 1. Stuart Reitz - Oregon State University, topping onions, 2. National Onion Association, trimming onions by hand, 3. National Onion Association, onions curing in Michigan, 4. Stuart Reitz, Oregon State University, onions hand topped and bagged

How does weather impact onion harvest, curing, and storage?

Onions are grown in every region of the United States and therefore, a wide range of environmental conditions can impact the production, harvest, and handling of the crop. Onion growers rely on experience to balance the maturity of the onion with weather events and forecasts. Each growing operation will likely encounter differing environmental conditions and options for managing their crop.

Heat: Excessively hot temperatures can dry out the onion, causing layers to collapse which may ultimately lead to decay. This type of deterioration would only occur if onions were left exposed to the elements for too long. Generally, moderate warm and dry conditions can aid in the curing process.

Cold: Onions can be impacted by frost but not necessarily have quality issues (i.e., resulting in translucent layers). If onions freeze, they can rebound depending on the point in the growing cycle that frost occurs and the number of translucent layers which develop. Onions affected by frost should be stored separately to allow for close monitoring and assessment of postharvest deterioration.

Moisture/Drought: Excessive rain toward the end of the production process can be associated with greater plant disease and postharvest deterioration. The use of drying rooms and general movement of onions during postharvest handling increases air flow and can help mitigate excess moisture. Storage and curing areas designed to have better circulation will reduce postharvest losses. Drought and flood conditions can impact the quality of agricultural water sources used during the production of onions. Growers should carefully assess if any risks exist before using agricultural water impacted by weather events like heavy rain or drought. If the edible portion of a crop is exposed to flood waters, it is considered adulterated under section 402(a)(4) (21 U.S.C. 342(a)(4)) of the Federal Food, Drug, and Cosmetic Act and should not be harvested for human consumption (FDA, 2011). Dry conditions may require the use of dust abatement. As described earlier in this document, the quality of water used for activities such as dust abatement or removal of drip tape is important, especially if water is used close to harvest and likely to contact the onion crop.

Unusual weather or environmental events: Hurricanes, hail, dust storms, wildfire, and earthquakes are just a few climactic and environmental events that growers may encounter during the production season which could impact produce safety. After a significant event that could negatively impact growing areas or water sources, growers should assess if any risks exist (UC Cooperative Extension; Produce Safety Alliance, 2018). For example, smoke from wildfires which could impede UV penetration through the atmosphere, in turn affecting proper curing of onions or severe weather could impact septic systems, resulting in water quality concerns if sewage enters agricultural water sources. If wildfires have occurred nearby onion growing or packing areas, there may be concern for chemical contamination from firefighting compounds applied and onion producers should reach out to their local emergency management agency to help determine if their crop may have been affected.

Photo credit: Stuart Reitz, Oregon State University, frost damage to onions in the Treasure Valley

Harvesting

Dry bulb onion harvest may be mechanized or completed by hand. The type of onion, grower's access to equipment and workers, and cost largely determine what harvest methods might be utilized. Each type of harvest method comes with unique considerations for produce safety as described below.

Key Food Safety Practices for Harvesting

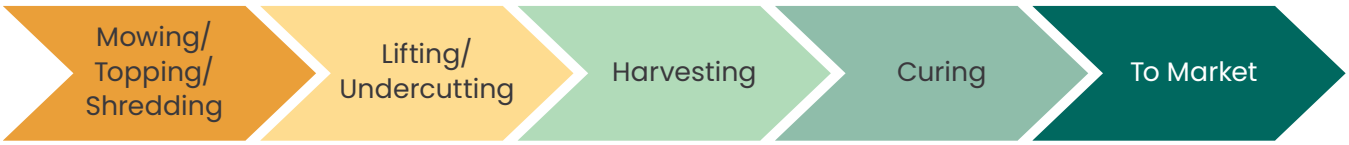
- Evaluate growing areas for signs of potential contamination such as observation of wildlife and domesticated animals, fecal contamination (human or animal), or crop destruction prior to harvest to determine whether harvest can proceed.
- Visually inspect food contact surfaces such harvest totes/bins, bags, or transportation equipment prior to loading onions to ensure they are visibly clean, free from debris, and in good repair.
- All workers must follow proper health and hygiene policies including hand washing, toilet use, avoiding contact with onions and food contact surfaces if they are ill, and using separate break areas for eating/smoking regardless of whether activities are conducted mechanically or by hand.
- When practical, onions harvested from different fields should not be mixed in a truck or in storage but rather they should remain segregated and traceable. Lots are generally identified by the combination of variety, field location, and date of harvest. The potential impacts of a recall can be minimized with delineation of smaller lot sizes and accurate recordkeeping.

Mechanized Harvest

- Harvest equipment should be cleaned, and when appropriate, sanitized, prior to each season's harvest.
- Many growers also conduct cleaning protocols at the end of the harvest season or any time a potential contaminant could be introduced onto equipment, such as during excessively wet or muddy conditions.
- Assuming dry harvesting conditions are maintained, harvest equipment should be dry cleaned to remove debris before harvest begins in a new field.
- Harvesting equipment is generally owned by the grower and dedicated to onion harvesting. If equipment is shared among farms or used on different commodities, cleaning practices should be conducted and documented between uses.
- Long day onions are generally mechanically harvested due to their firmer qualities and more protective skin, however other varieties can also be harvested mechanically.

- Mechanically harvested onions are transferred to trucks which may be owned by growers or contracted to outside companies. Onion growers using contracted transportation should inquire about other materials carried or stored in trucks and verify (e.g., through review of documentation as well as visual inspection) that appropriate cleaning and sanitation of trucks has occurred prior to loading onions.

Mechanical Harvest Overview
For short day (green top) onions



Overview: Mowing/topping/shredding is done to remove green tops to begin the process of maturation. This usually occurs a few days before the desired harvest date. Temperature and sun exposure plays a role in the timing of these activities. For example, if it is cool enough, onions may be left in the field longer to dry down naturally. Temperature and sunlight also play a role in the timing of the next step, which is lifting/ undercutting. Lifting/undercutting may occur at the time of harvest or up to 5 days ahead of harvest depending on temperature and sun exposure. Because these onions are not yet fully cured, they are often transported into a bulk storage building with forced air to continue drying or placed into bins which can also be moved either into storage buildings with air flow or left outside to continue the drying and curing process. Once onions are adequately cured, they are ready to be marketed. This process can range from a few days to weeks. Onions harvested in this fashion typically are kept in storage for less than a month.

Mechanical Harvest Overview
For long day storage onions

Overview: Onion maturity is critical to ensure an onion will keep long term in storage. The desired process is that onion tops reach maturity and fall over or kink naturally (often referred to as 'tops down'). In some instances, this does not occur naturally, and a grower may use a roller to help kink the necks (also referred to as 'laying over') of the onions so they start to mature. Lifting/undercutting is often done while the onion tops are still green, though they are maturing and likely senescing at this stage. This triggers the beginning of the field curing process as the roots are loosened and detached from the soil. The curing stage can range from 5 days to multiple weeks and growers determine readiness to harvest mechanically based on dryness of the neck and development of the papery skin. During mechanical harvesting for long term storage onions, the dried tops are

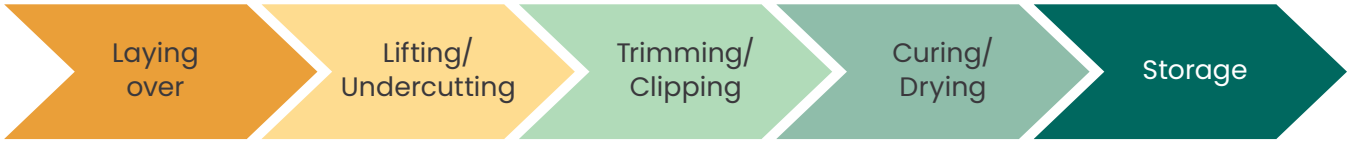
Photo credit: Stuart Reitz, Oregon State University

trimmed by the machine and often at least one outer skin layer of the onion is lost. Once harvested, onions are put into bins or in bulk storage. Storage facilities are temperature and air flow controlled to create optimal storing conditions. Storage may be up to 9 months or longer if optimal storage conditions are achieved.

Hand harvest

Because short day onions are more easily bruised, they are more likely to be hand harvested. Personal health and hygiene practices must be followed by workers involved in hand harvesting. This includes providing proper handwashing and toilet facilities, designating break areas, not working while sick, and emphasizing proper sanitation and storage of harvest tools (such as clippers) and gloves.

Hand Harvest Overview
For all onion types, but predominantly short day onions



Overview: Five to seven days after the last application of water to the crop, onion tops are laid over and furrows are cultivated which helps prepare the onion for harvest. The following day, onions are undercut/lifted. Undercutting is normally completed during the late afternoon or early evening in some regions to avoid sunburn. The tops of the onions are immediately clipped/trimmed and placed into bins or burlap sacks. Yellow and red onions are commonly left in the field in bins for 2-3 days after which they are transported to the dryer. White onions are moved immediately to indoor drying due to their increased susceptibility to sunburn. Some growers who hand harvest into burlap sacks may leave bags in the field for 5-7 days before sending them to the dryer. Hand harvested onions are left in the drying room until the necks are well cured before packing them for sale. Most hand clipped onions go directly to market and very few end up in storage for any length of time.

Photo credit: National Onion Association

Storage

Key Food Safety Practices for Storage

- Curing, drying, and other onion storage facilities must be kept clean, dry, and properly maintained.
- Domesticated animals and pests must be excluded from fully enclosed buildings; for partially enclosed buildings, measures must be taken to prevent pests from becoming established.
- Buildings (including storage) must be suitable in size, construction, and design to facilitate proper cleaning and maintenance activities.
- The flow of traffic, including foot and equipment, should be evaluated to minimize introduction of contamination into storage areas.
- Adjacent land use and areas immediately outside of storage must be assessed for food safety hazards, as previous outbreaks in packinghouses have identified factors outside of the storage and packing areas which may have contributed to contamination of equipment and produce.
- Storage areas must have adequate drainage and minimize potential for contamination from drip or condensate from equipment such as air exchanges, heaters, or humidity management.
- Trash, waste, and culls must be managed so they do not serve as an attractant or harbor pests.
- Packaging, including onion bags or bins, must be stored in clean, dry area in a way that minimizes the potential for contamination to occur.

Storage time

After harvesting and packing, almost all onions are capable of being stored for future use. However, the duration of storage varies dramatically among regions, varieties, and seasons. Long day onions are often referred to as storage onions. Under optimal conditions, long day onions can theoretically be stored for over a year, although market movement generally makes this unlikely. Intermediate and short day onions have shorter storage compared to long day onions. As an example, a short day onion may last 6-8 weeks in storage, where a long day onion may last 6 or more months.

Photo credit: National Onion Association

Ventilation, Humidity, and Temperature

- Proper ventilation is critical to managing the drying and curing process of onions. Drying may be needed if rain or dew occurs before or during harvest and/or if immature onions are brought to storage. For example, short day onions may be harvested prior to the neck being fully shrunk and the skin being set. Short day onions will typically spend 3-5 days in a drying room with 90-104°F air flow prior to being graded, sized, packaged, and shipped.
- Ideal storage temperatures usually range from 34-40°F.
- Avoid cooling onions too quickly. This can help prevent condensation from forming and therefore limits the growth of black mold in the storage environment. Most growers and storage facilities will have a process to gradually reduce temperatures for proper storing.
- Mechanical heat can be applied as a tool to aid in the drying process and to maintain proper temperatures if ambient temperatures are below the ideal temperature range for storage.
- Relative humidity should be maintained at 65-70% to preserve onion quality.

Thermal Fogging and Postharvest Treatments

- Once in storage, the ventilation system can be used to apply thermal fogging treatments such as peracetic acid (PAA). Thermal fogging applications are commonly used to control microorganisms that cause decay and rot and maintain the postharvest integrity of the onion crop, especially in the Pacific Northwest, for long term storage onions. Treatments can also be applied to the crop directly in the field or applied in storage to sanitize storage rooms, bins, and equipment. These products are typically labeled for non-public health microorganisms and should not be relied upon to manage human pathogens of concern.
- In some regions, gaseous ozone is introduced into the air stream during storage. This controlled atmosphere environment is used to maintain onion quality but may also offer a food safety benefit. Validation of ozone application for human pathogens should be conducted if this treatment is applied to manage food safety concerns.

Onion Containers, Bins, and Contact Surfaces

- Both wood and plastic are standard materials for storage containers and bins within the onion industry. The FSMA PSR does not prohibit the use of wood, however all food contact surfaces must be kept clean, in good condition, and stored properly to prevent contamination.
- Storage containers and bins should be visually inspected prior to loading onions for potential sources of contamination such as bird droppings, trash, or excessive dirt and organic matter. Unclean containers and bins should be set aside for re-cleaning or replacement.
- Allowing containers and bins to dry out between uses can also minimize postharvest and food safety concerns. There is a low likelihood of transfer of human pathogens from containers and bins to onions, especially if dry environments are maintained throughout the postharvest production process.
- Bins and containers should be cleaned, and when appropriate, sanitized, between use on different commodities.
- All materials used for onion packing equipment and binning stations must be made of materials that can be cleaned, and when appropriate, sanitized. Carpet, vinyl covered foam padding, and other porous materials should not be used on surfaces which will directly contact onions.

Photo credits: National Onion Association

Cleaning & Sanitation

Equipment, Storage, and Packing Area Cleanliness

- Equipment used in the field should be kept clean and free of debris, including removal of decaying onions, onion skins, or culls. Compressed air is often used for this purpose. Steam cleaning equipment may also help minimize movement of weeds and plant pathogens among fields. Steam cleaning may have secondary benefits to reducing human pathogens as well.
- Any area or building used to collect or store onions must be maintained in a clean and sanitary manner. Trash and onion waste must be handled and disposed of in a manner that minimizes the potential for attracting and harboring pests and minimizes the risk of contamination to stored onions.
- A pest management program must be implemented in onion storage areas. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the chemical contamination of onions, food contact surfaces, and packaging materials.
- SOPs should be developed for each operation and may include basic cleaning, sanitation, and pest management protocols.
- Cleaning and sanitation should occur between storing different commodities to maintain lot segregation, when practical.

Wet sanitation

In general, sanitation procedures which require the use of water should be avoided in onion postharvest handling environments. Limiting the introduction and use of water is a primary means of controlling human pathogens in onion packing and storage areas.

- If wet sanitation procedures are conducted, water that contacts food contact surfaces must have no detectable generic *E. coli*.
- All surfaces must have ample time to dry prior to unloading or packing onions. Tools such as floor squeegees can help move water to drains or fans can be used to aid in the drying process. Color-coding of sanitation tools can help identify the areas each tool can be used. For example, brushes used to clean drains should never be used on a food contact surface and should be colored-coded differently from tools approved for use on food contact surfaces.
- Equipment such as onion conveyances which are typically used outside should be cleaned outside to avoid introducing pathogens into the storage and packing areas. Other equipment and tools including totes should be cleaned and sanitized in a designated location away from onion packing and storage areas.

Dry sanitation

Keeping onion packing and storage areas dry is critical to the postharvest quality and safety of the onion crop.

- Soil, onion skins, and other debris should be removed from onion packing and storage areas by sweeping and/or vacuuming.
- If dry cleaning is done during the production season, onions should be covered or otherwise protected to prevent cross-contamination during cleaning and sanitation activities.
- Food contact surfaces can be scrubbed with an alcohol-based detergent to collect and remove any remaining soils.
- If a sanitizing step is required for food contact surfaces, select alcohol-based sanitizers with a high percentage of isopropyl alcohol or those that are available in powder form (e.g., alkaline peroxide powder).
- Dry packing and storage buildings may consider doing a deep cleaning at the end of the season, and this may include water as part of the cleaning process. Packing and storage areas should be thoroughly dried before handling or storing onions again.

Sanitation verification

Food contact surfaces should be visually assessed after cleaning and sanitation procedures to ensure no visible soil, food residue, or other material remains.

Product Testing

Testing onions (or any other commodity) for levels of indicator organisms or presence of human pathogens can provide a false sense of security. Testing is a tool but is not a control. Although some buyers require testing of finished product, onion growers and their customers should discuss the following questions before beginning a testing program:

- What is the purpose of testing? Is testing being used to ascertain trends, or for lot acceptance?
- What is the desired balance between resources aimed at proactive prevention measures compared to resources dedicated to reactive measures like testing, recognizing that better preventive measures result in lower contamination rates, which are less likely to be detected?
- Has a statistician calculated the percent contamination likely to be detected in the proposed sampling plan?
- How will testing data be evaluated on an ongoing basis to reveal trends (geographic, seasonal, etc.) to inform risk assessments?

Please visit the IFPA website for more resources on sampling and testing of fresh produce: https://www.freshproduce.com/resources/food-safety/sampling-and-testing/.

Packing & Repacking

Packing operations may be owned and operated by the grower or may be independent entities. Packing operations may be located on or very close to the production farm, or many miles away. Regardless of the business structure, the food safety controls are similar.

Key Food Safety Practices for Packing and Repacking

- Packing areas must be kept clean, properly maintained, and designed in such a way that packing areas and equipment can be cleaned, and when appropriate, sanitized.
- Domesticated animals, rodents, birds, and other pests must be excluded from fully enclosed buildings; for partially enclosed buildings, measures must be taken to prevent pests from becoming established.
- Buildings (including packing areas) must be suitable in size, construction, and design to facilitate proper cleaning and maintenance activities.
- Packing areas must have adequate drainage, if water is being utilized, and minimize potential for cross-contamination to occur.
- Trash, waste, and culls must be managed so they do not serve as an attractant or harbor pests.
- Areas immediately outside and adjacent to the packinghouse should be assessed to ensure that no cross-contamination is likely to occur from nearby animal activities, soil amendment storage, or other sources of contamination which could impact the safety of the onions being packed or stored.
- Packaging, including onion bags or bins, must be stored in a clean, dry area in a way that minimizes the potential for contamination to occur. If this storage area is outside, bins should be covered or protected from contamination (when possible) and at minimum, visually inspected before each use. Any bins that are not clean or are in poor condition should be set aside for cleaning and/or repair.

Packing and Repacking

- Packing may occur directly in the field (such as with the practice of packing onions in burlap sacks) or after indoor curing and storage. Packing onions in the field generally occurs with mature onions so extra care to cull and remove any damaged onions should happen at that time.

Photo credits: National Onion Association

- Packing areas may be open sheds or closed buildings. For open packing sheds, pest and wildlife access must be addressed to limit their impact to the safety of the onions. Closed packing areas afford better control over food safety by minimizing potential influences from environmental hazards such as pests, wildlife, or wind-blown dirt.
- Any onion conveyance (e.g., conveyor belts) and sorting equipment (e.g., sorting tables) must be maintained and stored in a manner that protects food contact surfaces from potential contamination. Growers and packers should consider storing this equipment inside or covered, when possible, and must implement cleaning procedures before onions are packed and between use on other commodities.
- Onions that fall off packing/repacking equipment and contact the floor should be discarded. Onions that drop to the ground may become bruised and therefore are more susceptible to postharvest decay and potential cross-contamination from non-food contact surfaces.

Electronic & Manual Grading & Sorting

- There are varying levels of sophistication and technology when it comes to grading and sorting onions. Electronic systems can be used, or grading may be done manually. Cameras can help identify internal decay and defects and sort onions by size.
- Proper handwashing and toilet use must be emphasized for packinghouse workers who are responsible for grading, sorting, and culling onions.
- Grading and sorting equipment must be kept dry and free of debris. Each packing operation must establish a cleaning schedule appropriate to the volume of product and activities being conducted throughout the year. This may include basic cleaning practices conducted on a regular basis (e.g., once a week) or more thorough sanitation protocols conducted on a less frequent basis (e.g., full tear down and clean at end of season).

Onion Packaging

- Onions may be packed in mesh bags, boxes, or cartons. Regardless of packing material, onion packaging must be stored in a clean, dry environment, protected from contamination and free of pest activity.
- Packed onions should be staged in a clean, dry area and not in direct contact with the floor.
- Onions may be repacked into smaller units (e.g., 2, 3 or 5 lb. bags) for retail sale to consumers. See recommendations for repacking below for maintaining traceability.

Shipping

- Because of their shorter shelf life, short day onions are generally shipped within 48 hours after packing. Most short day and sweet onion varieties have retail outlets pre-arranged.
- Regardless of storage length prior to shipping, sanitary conditions must be maintained throughout storage and distribution to protect the onions from contamination.

Repacking & Traceability

- At the point of initial packing, traceability is at bin level. To maintain traceability, onions from different growers should not be mixed during packing.
- Ideally, lot segregation should be maintained. If onion lots are commingled, then containers should be accurately labeled with the repacker's information and lot identification that maintains the integrity of traceability information to the included sources.
- Cleaning and sanitation of packing/repacking equipment (such as netted bagging equipment) should be prioritized in each packing operation's food safety program.

Photo credits: National Onion Association

Transportation

Transportation considerations

- Inspect transportation vehicles for cleanliness, odors, and visible dirt, and debris before loading. If needed, the vehicle should be cleaned, or cleaned and sanitized, prior to loading.
- If vehicles are used for multiple purposes besides transportation of onions, they should be checked for cleanliness between uses. Should there be any potential food safety risks, such as garbage, debris, off-odors, or other indicators of contamination, then the vehicle must be cleaned and a corrective action documented prior to transporting onions.
- Vehicle traffic patterns on the farm or near packing areas should be evaluated to ensure that cross-contamination is not likely to occur from vehicle tires into onion storage or packing areas.

Photo credit: National Onion Association

Markets & Best Practices for Buyers

Although the target audience of this best practices document are onion growers and packers, all points in the supply chain should work to maintain the food safety integrity of onions. Considerations for alternative (non-fresh market) and onion buyers are outlined below.

Alternative/Processing Markets

Onion growers may decide to sell their crop to an alternate market if fresh market sale is not an option. This could occur due to not meeting U.S. #1 grading requirements or because of postharvest limitations of the harvested crop, such as frost-damaged onions. For example, onion growers may divert their crop to processors who dice, blanch, and freeze the onions. Determination for alternate markets will vary and is highly subjective to the crop quality and farm's protocols. Onion growers should be aware that onion processors may have their own food safety protocols established by the FSMA Preventive Controls Rule for Human Food which requires supplier verification that growers are implementing produce safety practices.

Best Practices for Buyers

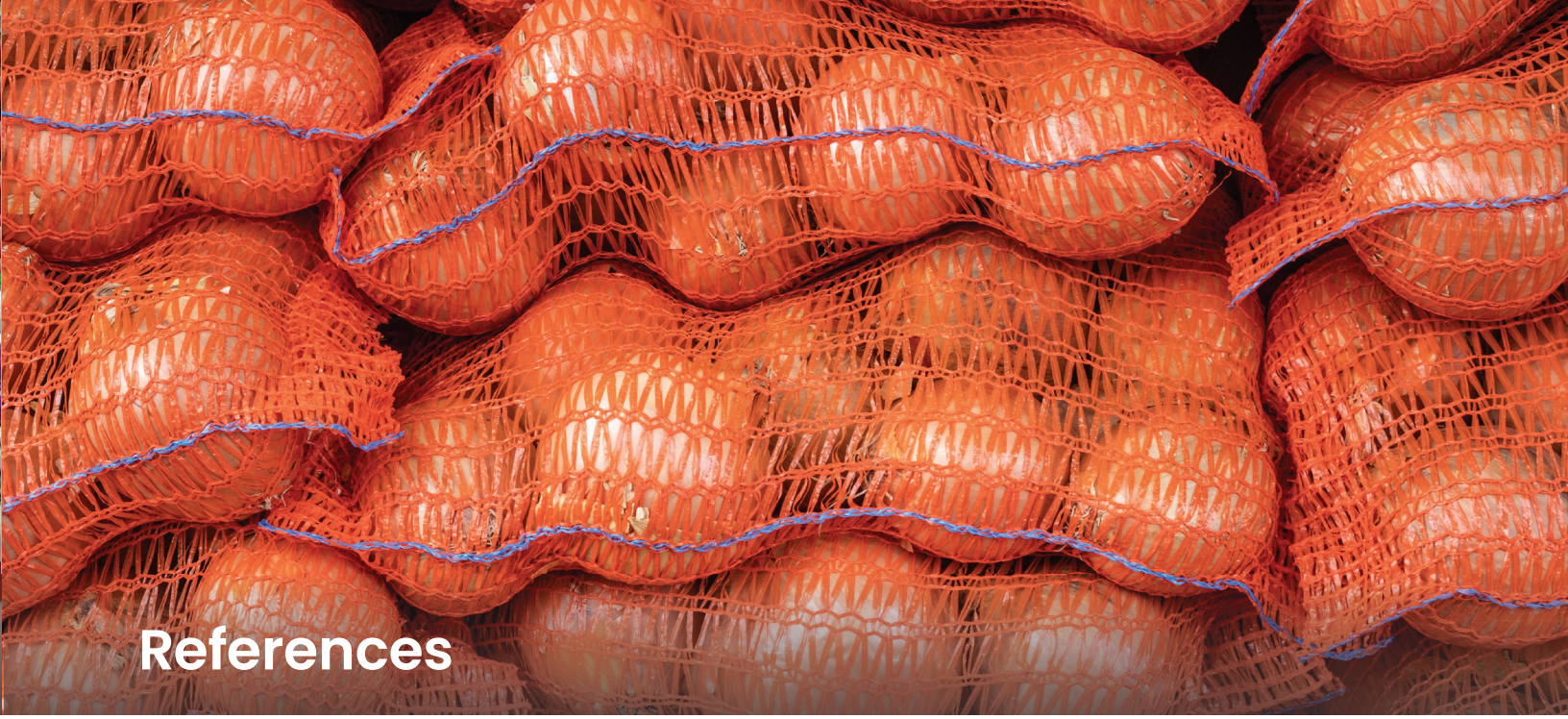
- Purchase onions from growers/packers who adhere to the best practices outlined in this document.
- Buyers must implement practices to minimize the potential for cross-contamination to occur by properly storing onions in a clean, dry, cool location off the floor.
- For onion importers, foreign supplier verification programs must be implemented.
- If purchasing onions that have been rejected by another buyer, affirm that the reasons for rejection do not have potential food safety implications.
- Remove and do not use or sell onions that show signs of spoilage or rot.
- Resist the urge to let market forces influence buying decisions that could have food safety implications.

Photo credit: National Onion Association

Further Research

Through the initial scoping of this best practices document, and as discussions with industry members progressed, several key research questions were identified. While several projects are currently underway or in the proposal stage, specific research focused on human pathogen prevalence, persistence, and contamination mechanisms is currently limited for dry bulb onions.

- Can internalization of human pathogens occur through the neck of the onion? Are there other points where pathogens are likely to enter and proliferate?
- Postharvest handling of onions is a dry process. How can dry sanitation protocols be implemented effectively within the bulb onion industry?
- Do onions that are subject to different quality conditions (for example conditions which result in bruising, damage, rot, excessive moisture) have an increased potential for human pathogen persistence and growth?
- Do postharvest treatments during curing or storage result in food safety benefits? For example, how does the application of ozone or thermal fogging treatments for plant pathogens impact human pathogen survival?
- What unique production practices may need further evaluation as potential higher risk activities that may contribute to the contamination of dry bulb onions? For example, application of clay for sun protection or use of burlap sacks for in-field curing.



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