



Q&A for Produce Washes & Treatments

Dan Dahlman

Regulatory Affairs
Manager

Food, Drugs and
Cosmetics

Ecolab, Inc.

Common questions/concerns related to produce washes & treatments

What are Food Code requirements for the produce wash?

▲ **3-302.15 Washing Fruits and Vegetables.**

(A)...raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants **before being cut, combined with other ingredients, cooked, served,** or offered for human consumption in READY-TO EAT form.

(B) Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.

(C) Devices used for on-site generation of chemicals meeting the requirements specified in 21 CFR 173.315, Chemicals used in the washing or to assist in the peeling of fruits and vegetables, for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer's instructions.

Common questions/concerns related to produce washes & treatments

What does washed “before being cut” mean?

- ▲ Cut= processed or, cored, chopped, sliced, etc. (post-harvest)

Food Code reference system:

- ▲ Question: Does the Food Code definition for “cut leafy greens” apply to leafy greens that have been harvested in the field by cutting into the stem or leaf of the plant but have not otherwise been cut, shredded, sliced, chopped or torn?
- ▲ Response: Harvesting of a leafy green often involves cutting the plant’s root or leaf to remove the leafy green from the ground. At this point the leafy green remains a raw agricultural commodity (RAC) * ...



Common questions/concerns related to produce washes & treatments

- ▲ What kind of products are available?
 - Non-antimicrobial (wash)
 - Antimicrobial (treatment)
- ▲ Does the Food Code have requirements for wash/treatment chemicals, including those generated on-site?
 - Be an approved food additive listed for this intended use in 21 CFR 173, or
 - Be generally recognized as safe (GRAS) for this intended use, or
 - Be the subject of an effective food contact notification (FCN), and
 - Meet the requirements in 40 CFR 156 Labeling Requirement for Pesticide and Devices

Common questions/concerns related to produce washes & treatments

▲ Why do I need them, what do they do?

■ Non-antimicrobial

- Helps remove soils, waxes, residues from the surface of the produce
- Not designed to kill microorganisms in wash water or the surface of the produce

■ Antimicrobials

- Reduce pathogens in wash or process water for RACs
- Reduce pathogens on the surface of processed produce
- Controls spoilage and decay in the wash or process water
Controls spoilage organisms on the surface of the produce surface. Helps extend shelf-life
- Crisping

Common questions/concerns related to produce washes & treatments

- ▲ How do I know if the residues of chemicals are safe to consume?
 - Processing aids (such as produce antimicrobials) are substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.
- ▲ **Products are designed to meet FDA and EPA standards!!**
- ▲ For new chemistries,
 - Data must be submitted to the agency (FDA and if applicable to EPA) to demonstrate the safe and suitable use in food.
 - Safety studies and a comprehensive toxicological profile for each ingredient are required.

Common questions/concerns related to produce washes & treatments

- ▲ How do I know that antimicrobial produce water treatment works?
 - Efficacy data is submitted and reviewed by the agencies and must demonstrate log reductions as determined by the governing federal and state agencies
 - Request performance data from your supplier

Common questions/concerns related to produce washes & treatments

Who regulates antimicrobial treatments?

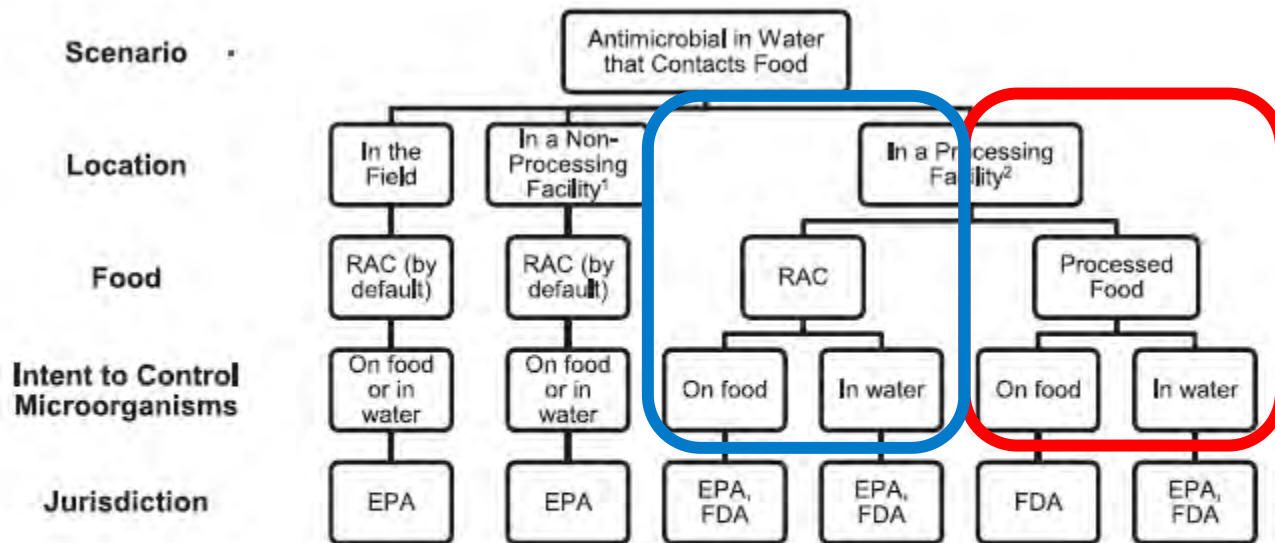


FIGURE 1. U.S. regulatory oversight of antimicrobials for control of microorganisms (46). ¹ A place where RACs (raw agricultural commodities) are the ONLY food treated and the antimicrobial treatment activity does not change the status of the food as a RAC (e.g., washing). ² A place where any of the following are happening: canning, freezing, cooking, pasteurizing, homogenizing, irradiation, milling, grinding, chopping, slicing, cutting, or peeling. Figure created by Ecolab, Inc. Please consult a regulatory representative to ensure product use compliance.

Common questions/concerns related to produce washes & treatments- FDA safety considerations

- ▲ Notifier must submit data to demonstrate:
 - Quantity of residues migrating to food, or in absence of migration data, 100% worst-case transfer
 - Safety of each ingredient/ tox. profile
 - No ongoing effect

- ▲ Residue levels are used to estimate the highest level in food based on consumption data- EDI and CEDI

- ▲ Supporting information

Common questions/concerns related to produce washes & treatments- EPA safety considerations

- ▲ EPA sets tolerances using the following criteria to assess the safety and ensure a reasonable certainty of no harm
 - Toxicity of the pesticide and its break-down products
 - Dosage/Application rate
 - Residues remaining in or on food item by the time it enters the channels of trade
 - All possible routes of exposure (i.e. crop use, drinking water, residential)
- ▲ Dietary risk assessments are performed to ensure that established tolerances are safe
- ▲ Tolerances apply to food grown in the U.S. as well as imports

**Always follow manufacturer label
directions for use!**

Questions?

Safe Washing & Crisping of Produce

Jim Gorny, Ph.D.

Vice President of Food Safety & Technology



What Does RTE mean?

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

(Excerpted from Preventive Controls for Human Foods Rule § 117.3 Definitions)

***Ready-To-Eat (RTE) Food:** The terms RTE food and RAC are not mutually exclusive. Some RACs (such as lettuce, tomatoes, berries, and apples) are ready-to-eat, whereas other RACs (such as artichokes and potatoes) are not. The requirements for product testing as a verification activity are flexible requirements that depend on the facility, the food, and the nature of the preventive control (see § 117.165). See also Response 525.*

(Excerpted from Preventive Controls for Human Foods Rule Response 122 / pg 55955)

Are All RTE Produce Created Equal?

Bunched Spinach



Unwashed

Bagged Spinach



Washed

Frozen Spinach



Washed/Blanched

FDA Consumer Recommendations

- ❖ All produce should be thoroughly washed before eating. This includes produce grown conventionally or organically at home, or produce that is purchased from a grocery store or farmer's market. Wash fruits and vegetables under running water just before eating, cutting or cooking.
- ❖ Many precut, bagged produce items like lettuce are pre-washed. If so, it will be stated on the packaging. This pre-washed, bagged produce can be used without further washing.

Washing Fruits and Vegetables

“Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.”

2013 FDA Model Food Code 3-302.15 Washing Fruits and Vegetables.

Crisping is a method used to improve produce visual quality that involves soaking fresh produce in tepid water followed by refrigeration.

Washing



Washing



Crisping



An Outbreak of *Escherichia coli* O157:H7 Infections Associated with Leaf Lettuce Consumption

M. Ackers et al, 1998 J. of Infectious Diseases 177:1588–93

- ❖ July 1995, 40 Montana residents were identified with laboratory-confirmed *E. coli* O157:H7
- ❖ 4 of 10 retail stores where implicated produce was purchased practiced lettuce crisping.
- ❖ Crisping basin water was changed infrequently, and numerous cartons and types of leaf lettuce were bathed in the same water.
- ❖ Crisping may have facilitated cross-contamination among batches of lettuce as numerous batches of leaf lettuce were processed in the same water.
- ❖ Lack of cases associated with restaurants or other retail markets suggests an amplification event, possibly by “crisping”

Cross-Contamination of Lettuce with *Escherichia coli* O157:H7

MARIAN R. WACHTEL^{1,2*} AND AMY O. CHARKOWSKI^{1†}

- ❖ March 1999, 72 restaurant patrons infected *E. coli* O157:H7
- ❖ Likely food vehicle: shredded iceberg lettuce prepared on-site
 - Lettuce was cored, outer leaves removed then shredded
 - No rinse prior to shredding
 - Stored refrigerated in water
- ❖ Research Conclusions
 - ❖ Water storage of cut lettuce in water is not advisable due to cross contamination.
 - ❖ Washing with chlorinated water may slightly reduce the bacterial load.
 - ❖ All lettuce pieces were contaminated after 24 h of storage in water containing one inoculated lettuce piece.
 - ❖ *E. coli* O157:H7 levels were consistent throughout the tubs, regardless of the distance from the inoculation point.

Hepatitis A Outbreak Associated with Green Onions at a Restaurant --- Monaca, Pennsylvania, 2003 MMWR November 28, 2003 / 52(47);1155-1157

- ❖ 555 Hepatitis A cases / 3 deaths
- ❖ Green onions most likely food vehicle; contaminated by farm workers
- ❖ Food Service workers unlikely Hep A source

- ❖ **Potential Contributing Factors:** restaurant produce handling practices
 - Green onions were shipped in 8.5-lb. boxes containing multiple small bundles (6--8 green onions per bundle).
 - Each box was unpacked, and bundles were stored upright (root side down) and refrigerated in a bucket with ice included in the shipment.
 - Green onions were stored <5 days before processing, which consisted of rinsing intact onion bundles, cutting the roots off, and removing the rubber bands.
 - Green onions from each box were chopped by machine to yield approximately 8 qts.
 - Chopped green onions were refrigerated for approximately 2 days.



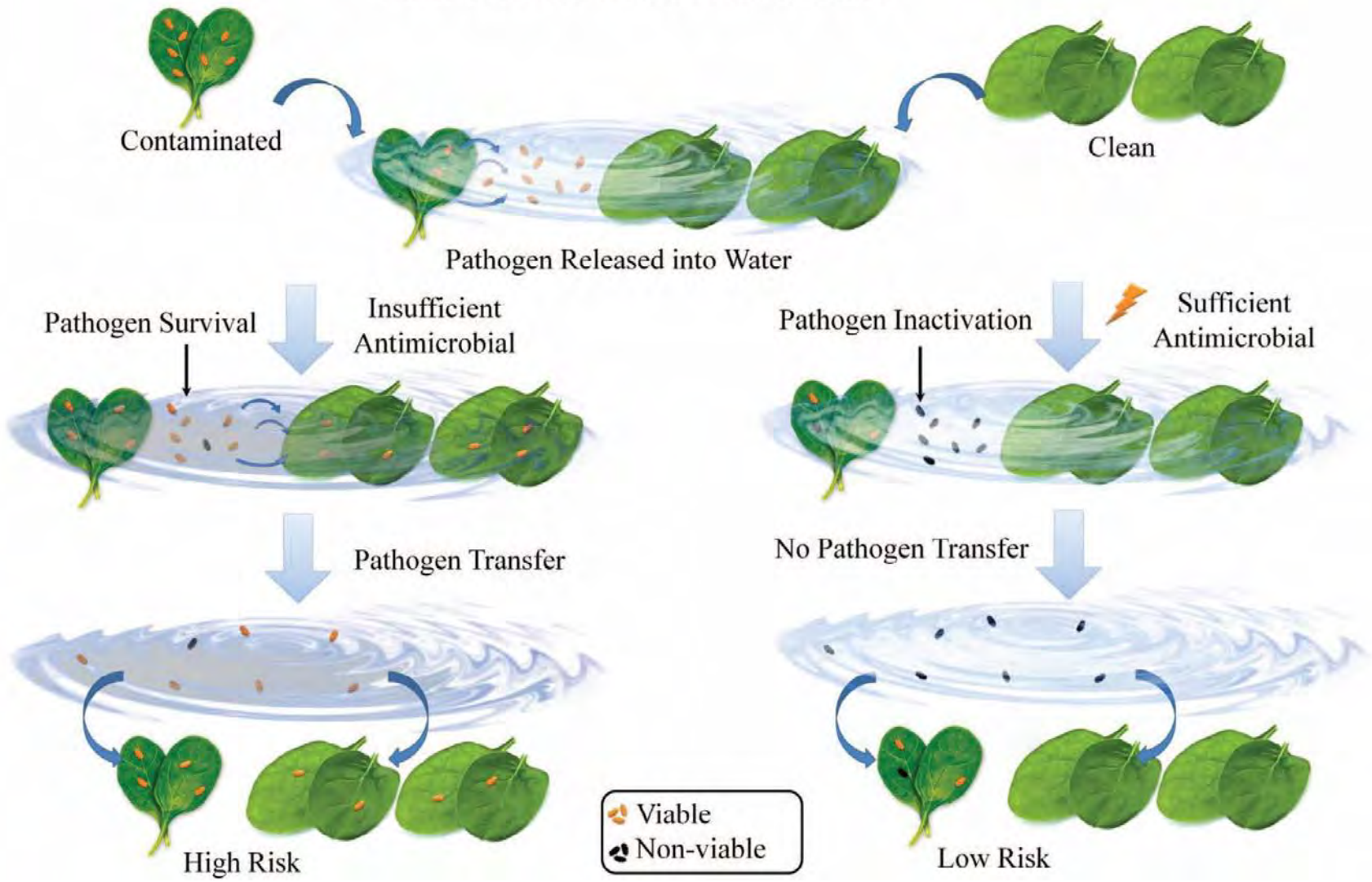
General Interest

Guidelines To Validate Control of Cross-Contamination during Washing of Fresh-Cut Leafy Vegetables

D. GOMBAS,¹ Y. LUO,² J. BRENNAN,³ G. SHERGILL,^{4†} R. PETRAN,⁵ R. WALSH,⁵ H. HAU,⁵ K. KHURANA,^{6‡}
B. ZOMORODI,⁷ J. ROSEN,⁸ R. VARLEY,⁹ AND K. DENG^{10*}



Water-Mediated Cross-Contamination

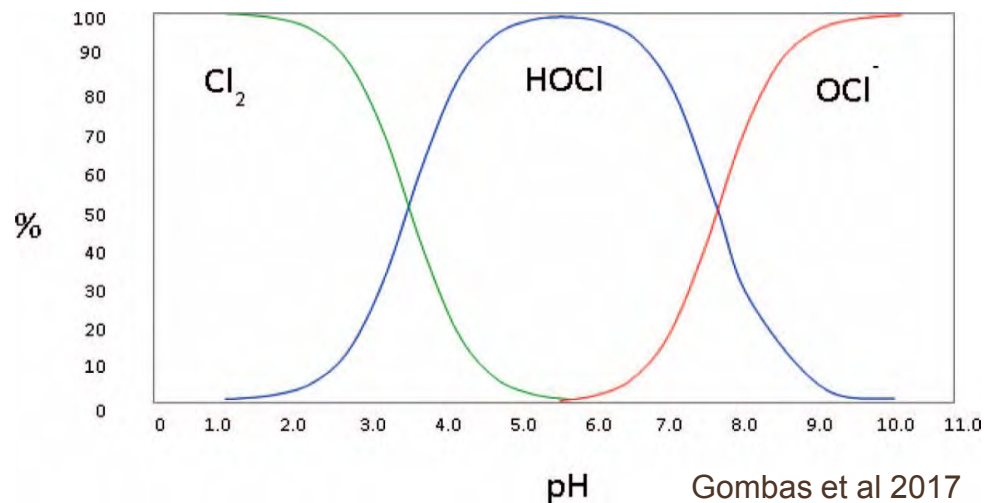


Wash Water Antimicrobials

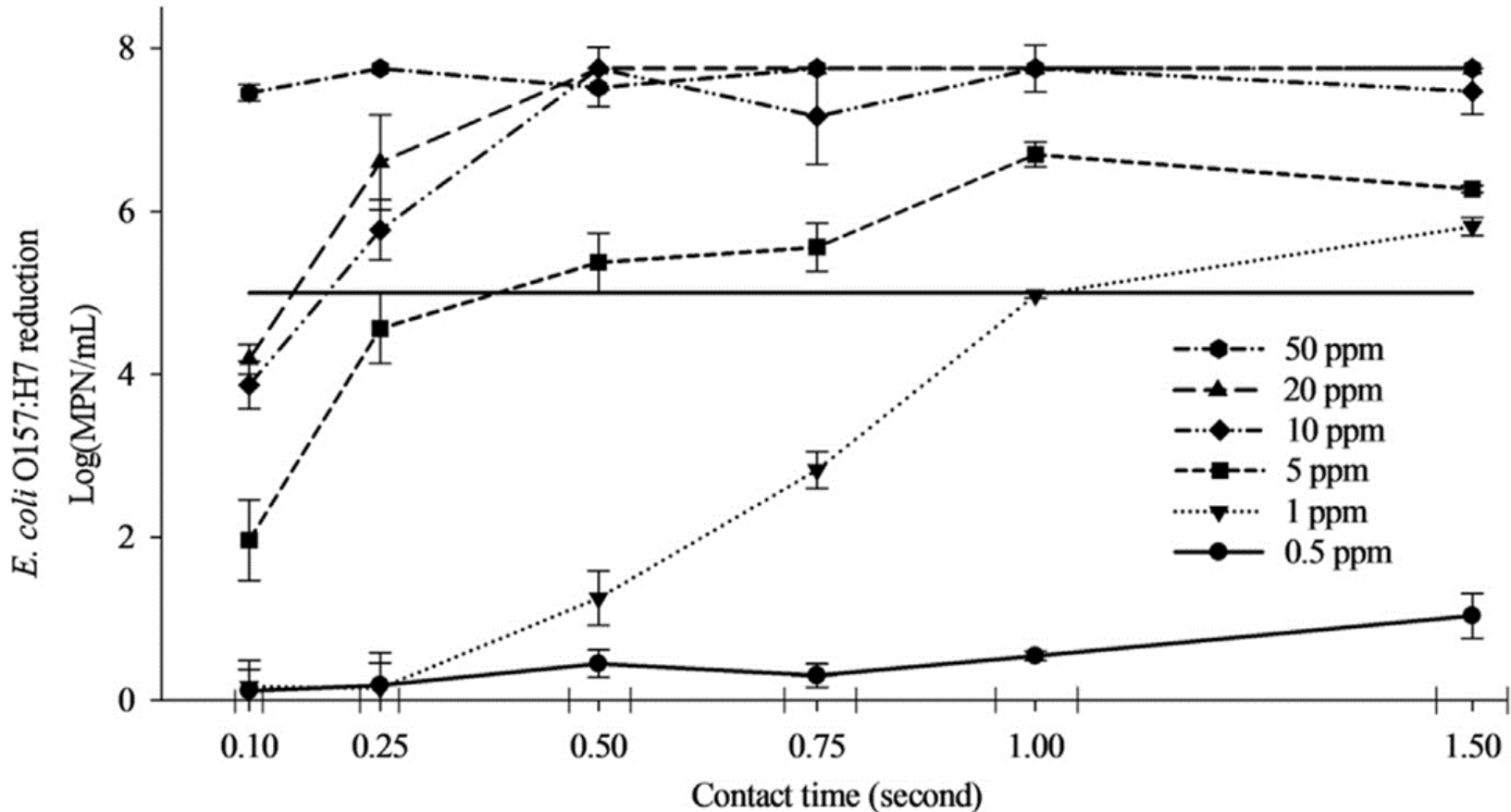
- ❖ Sodium Hypochlorite (NaOCl or Cl_2)
- ❖ Calcium Hypochlorite $\text{Ca}(\text{OCl})_2$
- ❖ Chlorine Dioxide ClO_2
- ❖ Peroxy Acetic Acid (acetic acid + hydrogen peroxide)
- ❖ Ozone

Key Efficacy Variables: to prevent cross contamination

- ❖ Concentration X Time
- ❖ pH
- ❖ Temperature
- ❖ Insoluble Solids = produce
- ❖ Soluble Solids = produce



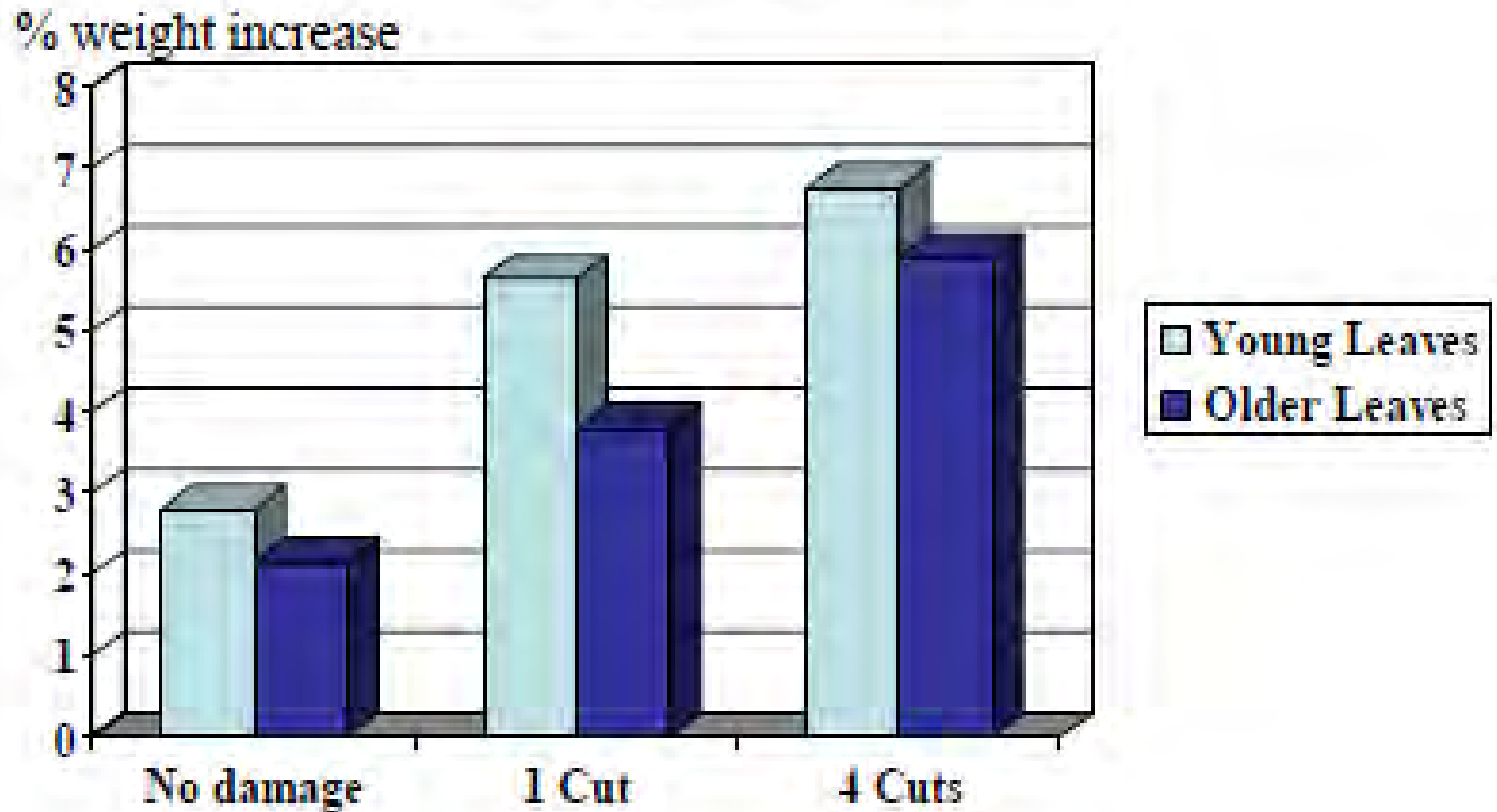
The Chlorine C X T Relationship



A novel microfluidic mixer-based approach for determining inactivation kinetics of *Escherichia coli* O157:H7 in chlorine solutions Zhang et al 2015 Food Microbiology 49 (2015) 152-160.

Spinach Damage Increases Water Absorption in Wash Flume

20°C water 3 min



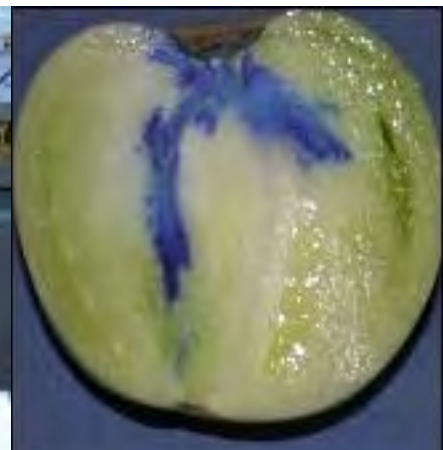
(Cantwell, 2013)

Effects of Tomato Variety, Temperature Differential, and Post-Stem Removal Time on Internalization of *Salmonella enterica* Serovar Thompson in Tomatoes†

XIAODONG XIA,^{1,2} YAGUANG LUO,^{2*} YANG YANG,² BRYAN VINYARD,³ KEITH SCHNEIDER,⁴
AND JIANGHONG MENG⁵

Factors Affecting Water Uptake Into Produce

- ❖ Produce Hydration /Dehydration Status
- ❖ Submersion Depth
- ❖ Temperature Differential (produce vs water)
- ❖ Produce Type & Variety
- ❖ Time After Harvest



Produce Washing or Crisping

- ❖ Produce occasionally harbors human pathogens (low prevalence and low populations)
- ❖ Produce will absorb water during washing or crisping.
- ❖ Surface cross contamination and internalization can occur during produce washing or crisping.
- ❖ Contamination is mediated by wash water-to-produce cross contamination.
- ❖ Food contact surface-to-wash water-to-produce cross contamination can occur.
- ❖ Antimicrobials reduce cross contamination potential; They DO NOT pasteurize produce (1-2 log reduction at best).



FDA Consumer Recommendations

- ❖ All produce should be thoroughly washed before eating. This includes produce grown conventionally or organically at home, or produce that is purchased from a grocery store or farmer's market. Wash fruits and vegetables under running water just before eating, cutting or cooking.
- ❖ Many precut, bagged produce items like lettuce are pre-washed. If so, it will be stated on the packaging. This pre-washed, bagged produce can be used without further washing.

Recommendations for Handling Fresh-cut Leafy Green Salads by Consumers and Retail Foodservice Operators

- ❖ Leafy green salad in sealed bags labeled “washed” or “ready-to-eat” that are produced in a facility inspected by a regulatory authority and operated under cGMPs, does not need additional washing at the time of use unless specifically directed on the label.
- ❖ Additional washing of ready-to-eat green salads is not likely to enhance safety.
- ❖ The risk of cross contamination from food handlers and food contact surfaces used during washing may outweigh any safety benefit that further washing may confer.

Issue: Lettuce Re-Crisping

Lettuce may be re-cripsed by placing fresh-cut lettuce/leafy greens in containers with tap water. The small amounts of chlorine present in the re-cripsing tap water may be quickly inactivated by the organic load presented by lettuce/leafy greens. This may increase the potential for lettuce/leafy greens cross contamination particularly if additional lettuce/leafy greens are added to the re-cripsing container (Wachtel and Charkowski, 2002).

Things to Consider (Retail and Foodservice):

- When re-cripsing whole lettuce, reduce the potential for water and utensils to contaminate lettuce/leafy greens. Clean and sanitize the sink or container first and use water supplies that meet drinking water standards for re-cripsing. The water should be changed at a frequency sufficient to ensure that it is of appropriate microbial quality for its intended use.
- Evaluate use of running water to re-crips lettuce as needed, in lieu of re-cripsing by water soaking, to reduce the potential for cross contamination.

Commodity Specific Food Safety
Guidelines for the Lettuce and
Leafy Greens Supply Chain

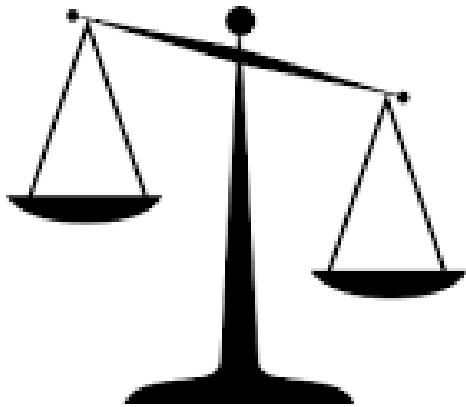


Crisping & Washing POS Considerations

Risk of Cross Contamination Exists

Vs

Risk of Improper Antimicrobial Use Exists



Crisping & Washing POS Considerations

Wash Water Antimicrobials are not a panacea

Wash Water Antimicrobials Need to be Managed

- ❖ Concentration
- ❖ Time
- ❖ Total Solids (Soluble & Insoluble)
- ❖ Water re-fresh

If Wash Water Antimicrobials are NOT used

- ❖ Use running water
- ❖ Keep batches small
- ❖ Change water often

Always clean & sanitize food contact surfaces

Crisping & Washing POS Considerations

Limit the need for crisping, if possible

- ❖ Inventory control
- ❖ Supply chain management (Temp, RH, Packaging)

Washing

- ❖ Don't re-wash fresh-cut produce that has been washed and is ready-to-eat.
- ❖ Always wash whole produce before preparation.





let's grow



CONNECTED SOLUTIONS
FOR A NEW ECONOMY

Thank You

Dr. Jim Gorny

**VP, Food Safety &
Technology**

Tel: 302.607.2197

JGorny@pma.com

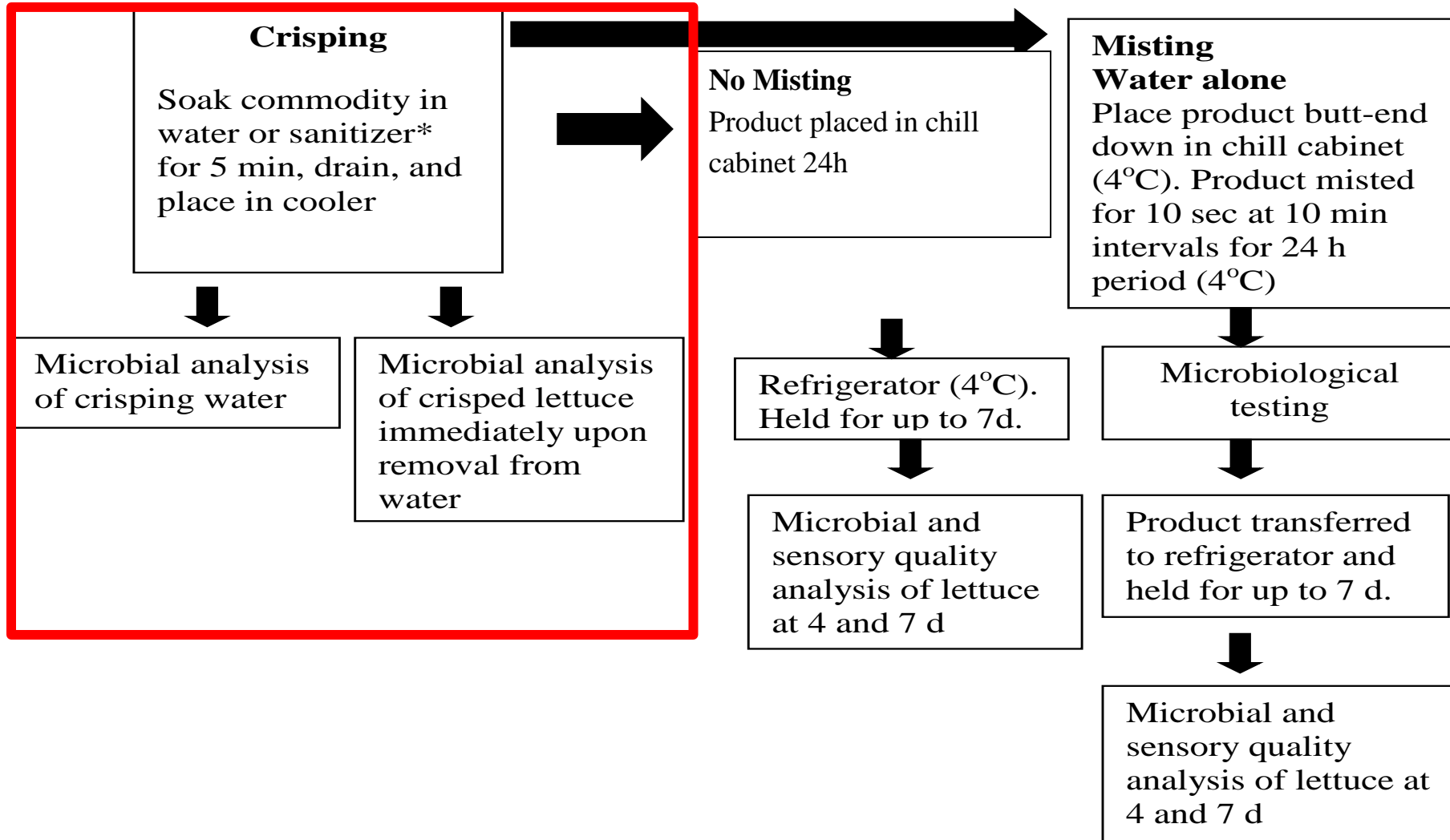
Sanitizer efficacy in preventing cross-contamination of heads of lettuce during retail crisping

Yangjin Jung, Hyein Jang, Mengqi Guo, Jingwen Gao, Karl R. Matthews*

Department of Food Science, Rutgers University, New Brunswick, NJ 08901, United States

Food Microbiology (2017) 64:179-185

Cross-contamination is a concern
when processing products at retail
establishments?



Inoculation of lettuce

- *Salmonella* Newport H1275 (sprout outbreak), *S. Stanley* H0558 (sprout outbreak), *S. Montevideo* G4639 (raw tomato outbreak).
- *E. coli* O157:H7 isolated from lettuce and clinical samples.
- *L. monocytogenes* L008 (serotype 4b, Canadian coleslaw/cabbage outbreak), L2624 (serotype 1/2b, cantaloupe outbreak), and L2625 (serotype 1/2a, cantaloupe outbreak).
- Dip-inoculated in 6 L of sterile tap water containing a cocktail for 5 min to achieve approximately 5 log CFU/g



Experimental Approach

Three consecutive soaking processes were performed as follows. For the first batch, one head of inoculated lettuce and seven heads of non-inoculated lettuce were soaked together in 76 L of TW, EW, LPA, or CA. After 5 min of soaking, the seven heads of non-inoculated lettuce were removed from each treatment sink and placed in a perforated crisping tray. The inoculated lettuce was handled separately. The inoculated and non-inoculated heads of lettuce were subjected to microbiological analysis. For the second and third batch, eight heads of non-inoculated lettuce per batch were soaked for 5 min in the same TW, EW, LPA, or CA crisping solutions that had been used to soak the first batch.

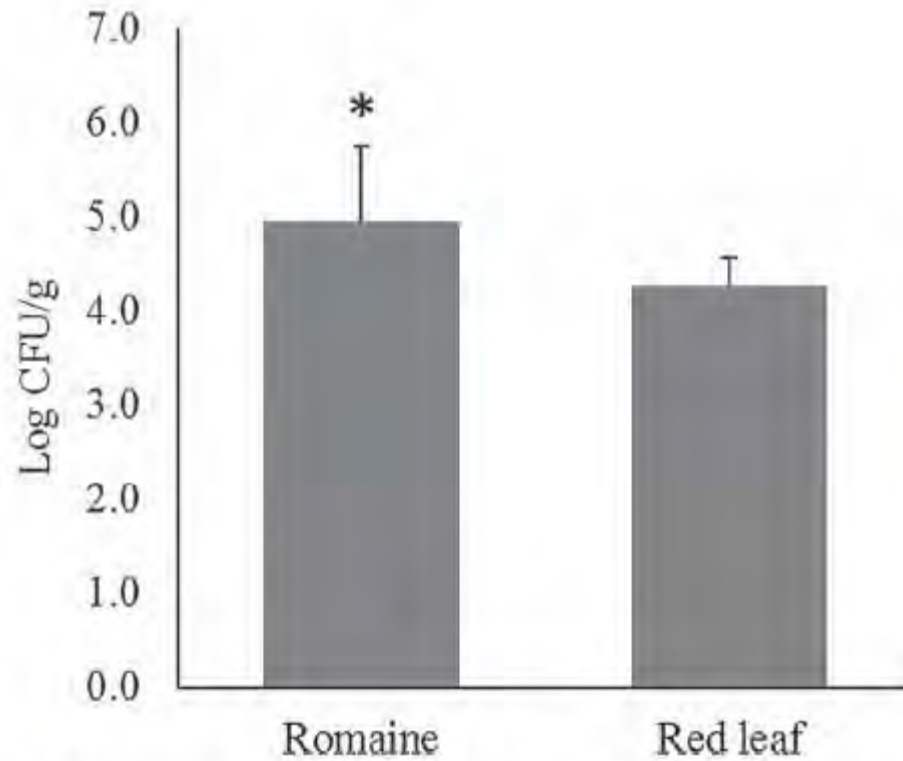


Fig. 1. Natural flora of whole heads of Romaine and Red leaf lettuce. Asterisk indicates a significantly different mean value between Romaine and Red leaf lettuce (PROC TTEST, $p < 0.001$).

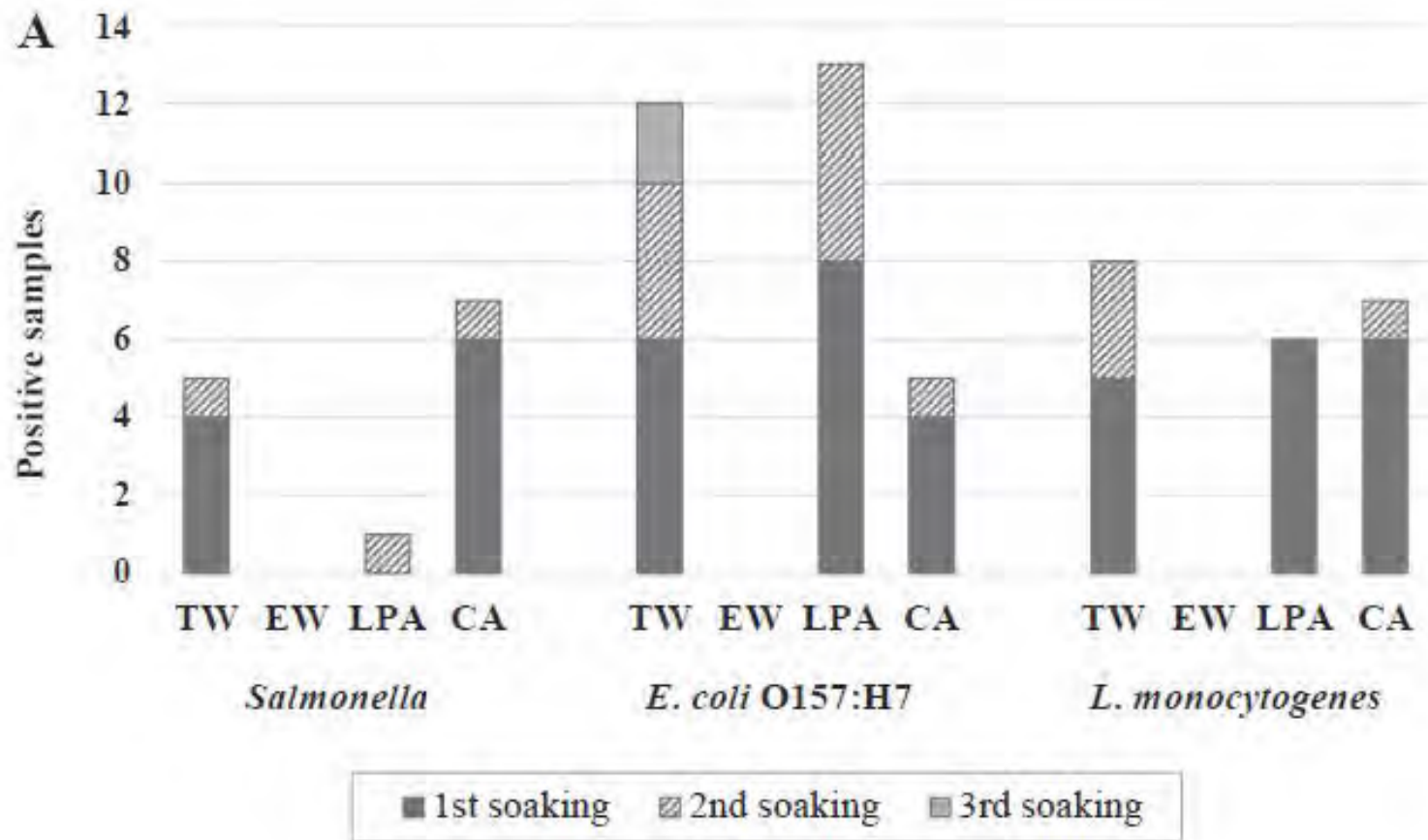


Fig. 2. Cross-contamination of non-inoculated Romaine (A) and Red leaf (B) lettuce associated three consecutive uses of soaking water. Colonies were not detected following direct plating of samples, so all samples were subjected to enrichment and processed for presence of *S. enterica*, *E. coli* O157:H7 and *L. monocytogenes*. Positive samples from all experiments are reported.

Table 3
Microbiological quality of soaking water.

		Soaking event ^B	Treatment ^A			
			TW	EW	LPA	CA
Romaine lettuce	Aerobic filter counts ^C	1st	>250	0	>250	>250
		2nd	>250	0.1 ± 0.3 ^D	>250	>250
		3rd	>250	0.1 ± 0.3	>250	>250
Red leaf lettuce	Aerobic filter counts	1st	>250	0.1 ± 0.3	>250	>250
		2nd	>250	0.5 ± 0.8	>250	>250
		3rd	>250	0.5 ± 0.8	>250	>250

^ATap water alone (TW), electrolyzed water (EW), citric acid-based sanitizer (CA), and lactic acid and phosphoric acid-based sanitizer (LPA).

^BThree consecutive soakings were processed without changing crisping water.

^CAerobic filter count: Total colony count associate with 100 mL soaking water.

^DValues are the mean colony count from samples for all experiments (n = 12).

Table 2

Log reduction of *S. enterica*, *E. coli* O157:H7 and *L. monocytogenes* on Romaine lettuce following a 5-min soak.

Treatment ¹	<i>S. enterica</i> ²	<i>E. coli</i> O157:H7	<i>L. monocytogenes</i>
TW	1.8 ± 0.3 ^{ab} _B	2.2 ± 0.6 ^a _B	1.5 ± 0.5 ^b _A
EW	3.0 ± 1.2 ^a _A	3.7 ± 1.5 ^a _A	3.4 ± 1.3 ^a _A
LPA	1.2 ± 0.1 ^b _B	1.7 ± 0.3 ^a _B	0.9 ± 0.1 ^c _A
CA	1.8 ± 0.2 ^a _B	1.9 ± 0.2 ^a _B	1.9 ± 0.3 ^a _A

¹Tap water alone (TW), electrolyzed water (EW), citric acid-based sanitizer (CA), and lactic acid and phosphoric acid-based sanitizer (LPA).

²Population on inoculated lettuce of *S. enterica*, *E. coli* O157:H7, and *L. monocytogenes* were 5.1 ± 0.3, 5.3 ± 0.2, and 5.4 ± 0.2 log CFU/g, respectively, prior to treatment.

^AAverages compared between soaking treatments on each foodborne pathogen with the same capital letter are not significantly different ($P > 0.05$).

^aAverages followed by the same lower case letter indicate no significant difference between foodborne pathogens on the same soaking treatment ($P > 0.05$).

While the project is interesting, it is hard to assign priority when there is no solid data to show how much of the contamination is attributed to the handlings of produce at retail levels.

While retail operations are not required to incorporate sanitizers in wash, crisp or misting waters to prevent cross-contamination, there is extensive amounts of peer-reviewed research available to demonstrate their effectiveness in systems of various sizes. In reality, a small-scale farmer will very closely mimic the handling described in this proposal. The lack of novelty to this approach is a major drawback to the proposal.

Washing steps have been very well studied for cross-contamination in produce. Although the food code does not require retailers to incorporate sanitizers, their efficacy has been validated. Additionally, how well the data mirror parameters experienced at retail is not discussed. As it stands, it appears that research parameters were not obtained based upon retail observations.

Produce Crisping Risks and Mitigations

Jennifer McEntire, Ph.D.
VP Food Safety & Technology
jmcentire@unitedfresh.org



Overview

- Why crisp produce?
- Risks
- Antimicrobials in water
- Alternative considerations
- Resources

RACs vs RTE

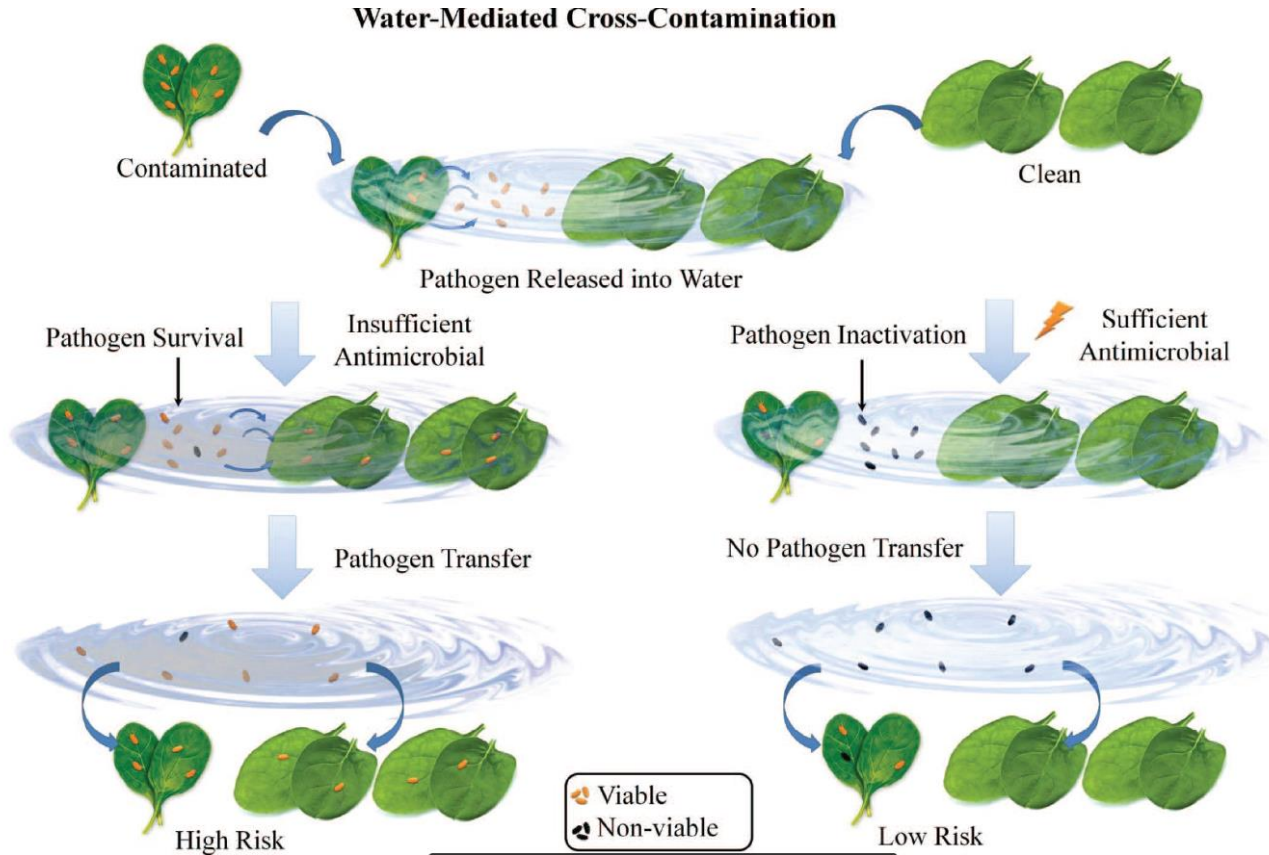
- Most fresh produce is considered RTE
 - “Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards” (117.3; Preventive Controls for Human Food Rule)
 - FDA guidance on RTE forthcoming
 - RTE and RAC are not mutually exclusive
 - Includes apples, tomatoes, lettuce, cherries etc.



Process

- Trim
- Soak 3-20 minutes
 - Tepid/ lukewarm water
- Refrigerate

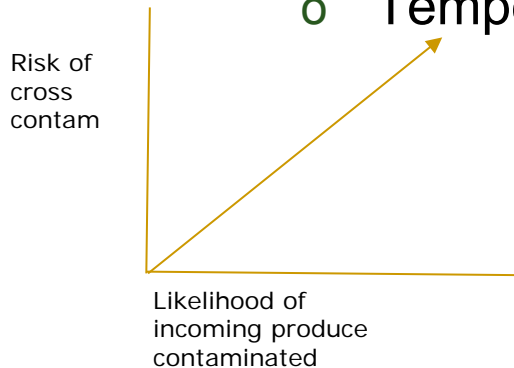
Risks



Journal of Food Protection, Vol. 80, No. 2, 2017, Pages 312–330

Risks

- What is risk of contamination of individual piece?
 - Supply chain control & previous handling
 - Produce Safety Rule
 - Washing (not a kill step!)
 - Post wash contamination (Lm)
 - Temperature control



Commercial Washing

- Antimicrobials
 - Chlorine (hypochlorite)
 - PAA (peracetic acid/ peroxyacetic acid)
 - Ozone and aqueous chlorine dioxide
- Temperature
 - 10 degrees warmer than product
 - Prevent infiltration
 - (For crisping, you want infiltration)

Purpose

- Prevent cross contamination
- NOT a kill step

Effectiveness

- Concentration
- Product: water
- Contact time
- pH
- Temperature
- Water hardness
- Insoluble solids
- Soluble solids
- Product type and quality

TABLE 1. *Comparison of commonly used antimicrobial agents^a*

Key attributes	Hypochlorite	Peracetic acid	Ozone	Chlorine dioxide
Final rinse with potable water required	Yes	No ^b	No	Yes
pH must be controlled	Yes	No	No	No
Organic load tolerance	Very sensitive	Less sensitive	Very sensitive	Less sensitive
Off-gassing hazard potential	Yes at low pH	No	Yes	Yes
Approved for use in wash water for organic produce	See NOP ^c	Yes	Yes	See NOP
Mechanism of action	Oxidizer, metabolic poison	Oxidizer	Oxidizer	Oxidizer

^a Always follow label instructions. Similar chemistries may have different claims or use requirements, depending on the product.

^b A final rinse is not required when usage does not exceed 80 ppm in wash water.

^c National Organic Program (44).

Retail Considerations

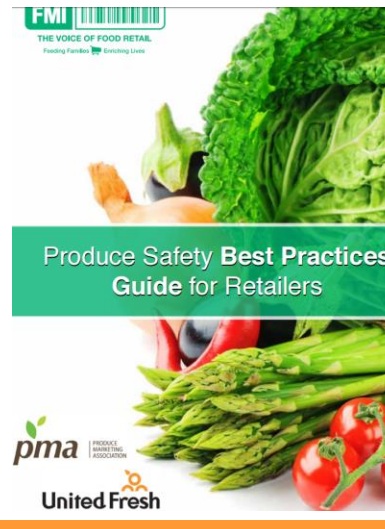
- Risk of cross contamination vs risk of improper antimicrobial use
- Need to maintain effective levels
- Need for potable water rinse

Alternatives

- Limit need for crisping
 - Manage supply chains and inventory
 - Control environment (temperature, humidity, packaging)
- Limit scope of cross contamination
 - Small batches
 - Change water

Resources

- <https://www.fmi.org/docs/default-source/food-safety/produce-safety-best-practices-guide-for-retailers.pdf?sfvrsn=15>
- <http://ucce.ucdavis.edu/files/datastore/234-2083.pdf>



Questions?