Illinois Sustainability Awards 2017

OZONE

Non-Thermal, Low Energy, Sustainable Sanitation Technology

BETH HAMIL
O_3 CONSULTING
FOOD SAFETY & INDUSTRIAL OZONE SANITATION

Beth Hamil O_3 Consulting

A Brief History – Ozone Experience

Over 37 years professional experience; 32 years in ozone manufacturing

Ozone system development, ozone applications development, and project management

Food Safety, Wineries, Aquatics, Pharmaceutical and Industrial

Experienced with regulatory compliance responsibilities for the use of ozone

Developed parameters for ozone efficacy and worker/environmental safety protocol for surface sanitation; water and product sanitation with species-specific pathogens, with accredited third-party testing agencies

Authored regulatory code for numerous ozone applications

Beth Hamil O_3 Consulting

Ozone Milestones - Sanitation

Multiple University studies regarding the efficacy of gaseous and aqueous ozone for sanitation applications (1997 to present)

NSF Toxicology Group to test the efficacy and safety of aqueous ozone against US EPA DIS/TSS AOAC methodologies in conjunction with OSHA standards (2000)

NSF International to develop J-00047649; testing and validating the efficacy of low-dose aqueous ozone for a 3 log (99.9%) reduction of *Cryptosporidium parvum* (2007)

MAFMA (USDA) grant as an industry collaborator for the use of ozone in Clean-In-Place technology for Food Safety (2009)

Ozone is an Approved Sanitizer

- Food contact surfaces, non-food contact surfaces & CIP/SIP
- Direct Food Contact and Bottled Water
- Pharmaceutical processes (CIP/SIP/surfaces/product water)
- Personal Care Product and Industrial sanitation processes
- Irrigation water, potable water and waste water

Regulatory Agencies Ozone Approval

FDA – regulates and allows ozone contact with foods (F&V, Seafood, Shell Eggs, Fish and Bottled Water)

USDA/FSIS - regulates and allows ozone contact with Meats, Poultry and Egg products

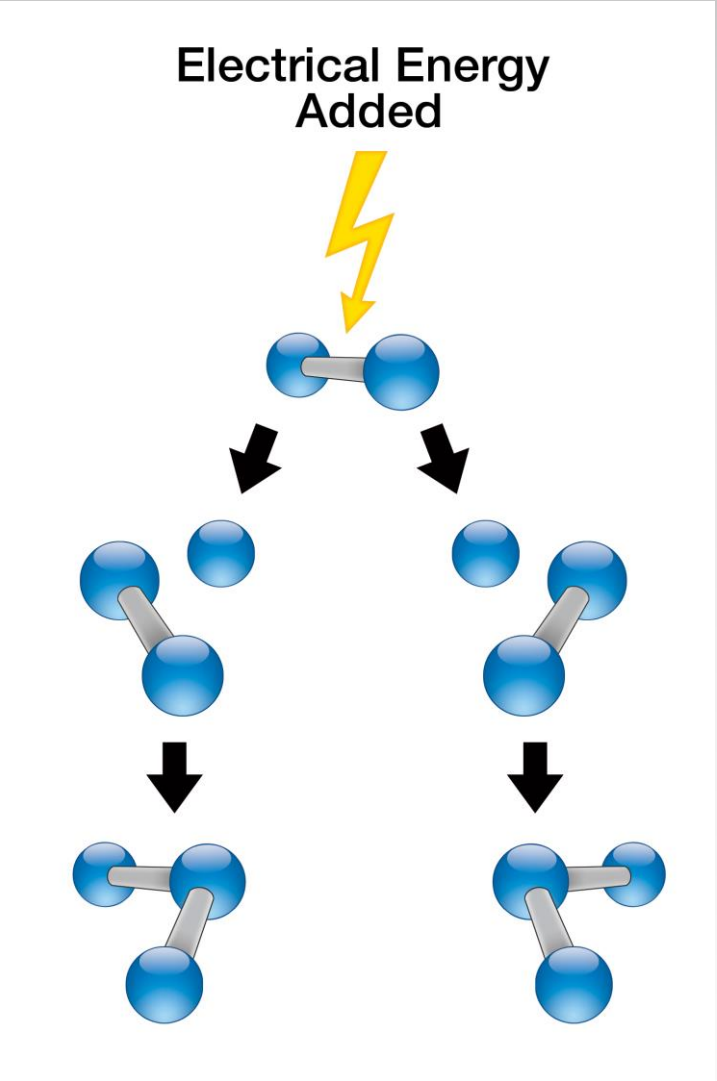
USDA National Organic Program (NOP) – allows ozone for Organic Food contact

EPA - regulates ozone generators under FIFRA for Surface Sanitation and Potable Water

OSHA - regulates ozone gas in workplace air

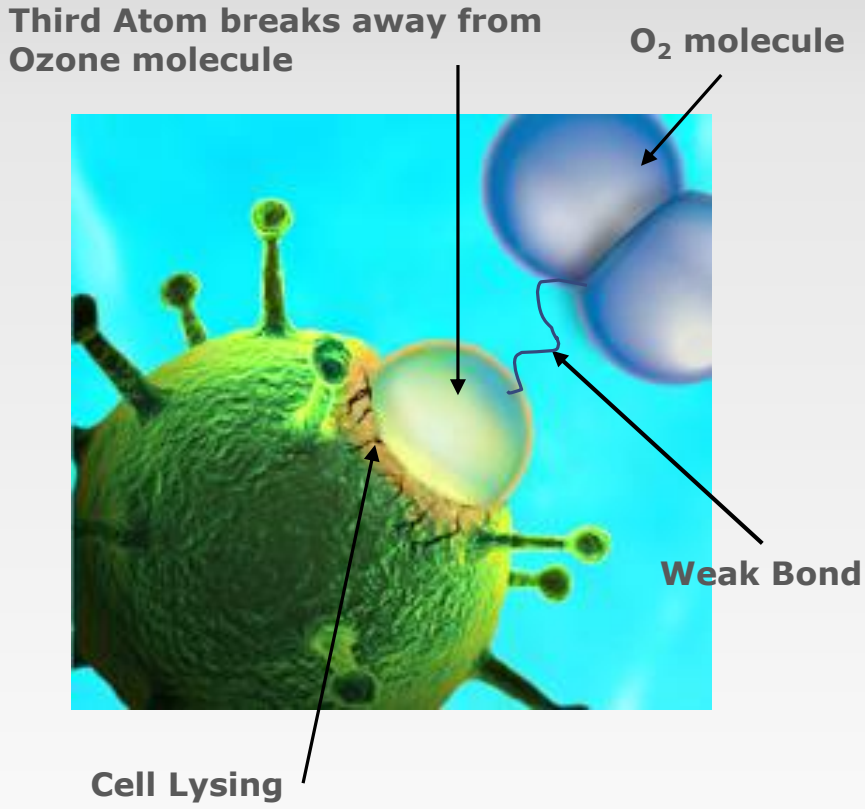
Ozone Properties

- Ozone is a gas produced at the point of use in a device called an ozone generator utilizing oxygen-enriched feed gas and electricity
- Oxygen molecules (O_2) split with the addition of energy, resulting in two individual oxygen atoms (O_1)
- Oxygen atoms (O_1) unite with other oxygen molecules (O_2) to produce Ozone (O_3)
- (O_1) + (O_2) = (O_3) as represented in the diagram



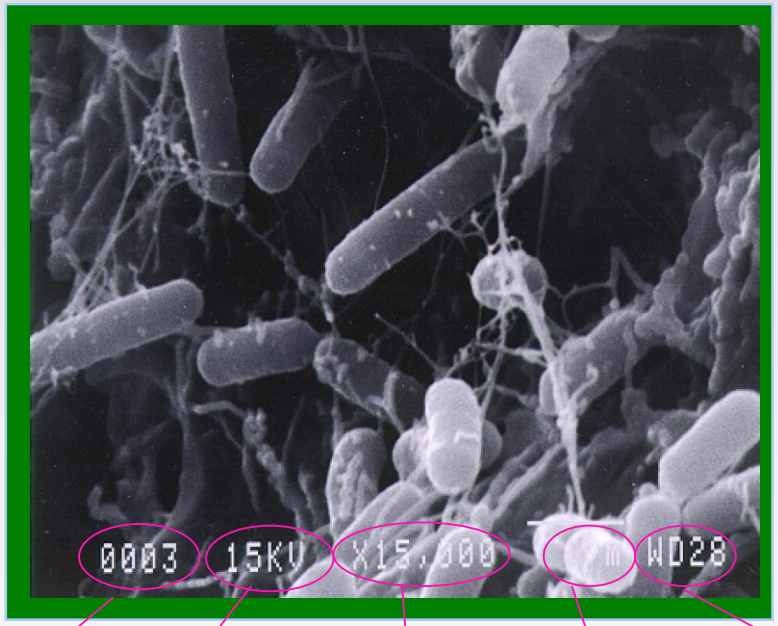
Ozone Oxidizing/Sanitizing Properties (Gaseous or Aqueous)

- The third oxygen atom is held by a weak single bond
- An oxidation reaction occurs upon any collision between an ozone molecule and a molecule of an oxidizable substance
- The weak bond splits off leaving oxygen as a by-product
- The third atom oxidizes the cell membrane, ultimately causing cell bursting (Lysing) and destruction
- This process can attain complete sanitation on surfaces (i.e. 6 log reduction – 99.9999%)



Electron Micrographs of *E. coli* before/after ozone treatment

Before ozone treatment



After ozone treatment

Sequential **Electron Beam Power** **Magnification** **Scale of Measure One Micron** **Working Distance**

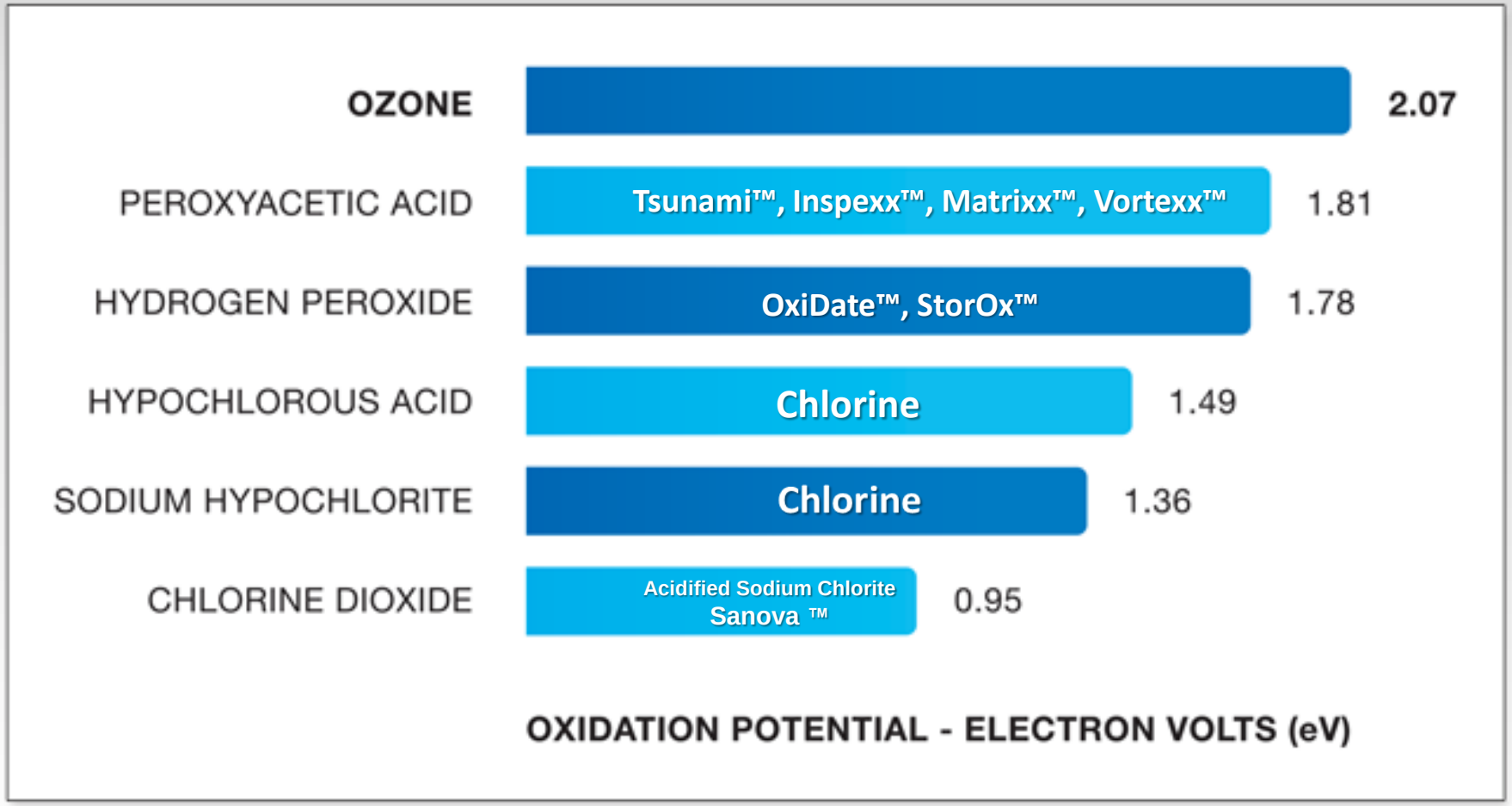
1. **Ozone oxidizes cell membranes, causing osmotic bursting (instantaneously)**
2. **Ozone continues to oxidize enzymes and DNA**

Air Liquide America Corp, Chicago Research Center, James T.C. YUAN, Ph.D., ca 2000

Ozone Functionality

- Ozone is a strong oxidizer, disinfectant and sanitizer
- Ozone has a short half-life (seconds to minutes depending on temperature and pH if aqueous; minutes to hours in air), and reverts to oxygen
- Ozone is generated and applied on-site
- Ozone can be utilized as a gas or a fog (in a confined and controlled-access space) or it can be dissolved in water for targeted application

Oxidation Strength Comparison



Ozone is Sustainable Technology

- Ozone is produced with ambient air and electricity in an apparatus (ozone generator) which utilizes very low energy
- There are no consumables utilized in an ozone generator
- Ozone is not stored, transported or discarded
- Its primary byproduct is simple oxygen
- Microorganisms cannot build up a tolerance to ozone
- Ozone is an approved food and organic food additive
- Its use cannot harm the environment or eco system
- It is more efficacious than traditional sanitizing chemicals; reducing their use and disposal
- Ozone is used in cold water; more energy savings

Common Uses of Ozone

- Drinking water, bottled water, wastewater
- Marine aquaria, aquaculture, pharmaceutical, personal care, ultrapure water preparation (electronics), water reuse
- Pulp & paper bleaching, kaolin bleaching
- Agriculture irrigation water, ground water remediation
- Food processing and food service

Ozone Innovative Applications

Ozone can be applied as an *aqueous* product

- **It can be hard-plumbed into existing sanitation lines as a centralized system**
- **It can be utilized with hand-held or fixed sprayers**
- **It can also be used as a flood or cascade**

Aqueous ozone is sprayed at low pressure (20 psi or less) in cold water (<70°F)

Low pressure use is designed to gently flood surfaces without causing pressurized over-spray that can inadvertently spread microorganisms to other areas of a facility

***Gaseous* ozone and ozone fog can be applied in controlled environments for microorganism control and spoilage reduction which results in increased shelf-life and increased yield**

Ozone Proven Technologies

- Ozone use will reduce levels of fat, oil & grease on surfaces, and it will break down microorganism and biofilm build-up on all surfaces
- Its continuous use will sanitize floor drains with no adverse effect on wastewater treatment systems
- Ozone helps to rid drains and plumbing of biofilm and other microorganisms that can migrate back into the processing area (esp. *Listeria monocytogenes*)
- Ozone is beneficial to sewage treatment systems because it adds dissolved oxygen to the wastewater to be treated
- Ozone sanitation sprays keep conveyor belts clean and free of build-up. "Build-up" may consist of food debris, sugar, fat, grease, etc., while harboring biofilm that may consist of any number of human pathogens, as well as fungi

Ozone Sanitizing in Food Plants

Facilities utilizing ozone for surface sanitation include:

- **Cheese processing plants; Eggs and Diary**
- **Raw and RTE meat and poultry processing plants**
- **Produce packers, produce processors**
- **Seafood processors**
- **Certified organic facilities**

Ozone sanitizing is part of many food processors' HACCP programs

Ozone Sanitizing in Industrial Applications

Other facilities utilizing ozone for various sanitation processes include:

- **Pharmaceutical processing facilities**
- **High purity water for biotech processors**
- **High purity water for semiconductor producers**
- **Cosmetic and Personal Care product processors**
- **Process Water Recycling**
- **Municipal drinking water and waste water treatment**
- **Anywhere wettable surfaces need to be sanitized**

Ozone Safety & Control

Ozone SDS (Safety Data Sheet formerly known as Material Safety Data Sheet)

Ozone (Gaseous)

- **OSHA PEL: 0.1 PPM 8 hour**
- **OSHA STEL: 0.3 PPM 15 min**

Ozone (Aqueous)

- **PEL: none established**
- **STEL: none established**
- **Eye Contact:: may cause mild irritation; not expected**
- **Ingestion Hazard: not ingested during application**
- **Inhalation Hazard: not likely; exposure to aerosolized aqueous ozone could become irritating**
- **Skin Contact: not hazardous**

Aqueous ozone systems operated according to GMP, are safe for workers; these systems utilize monitor/control devices to continuously adjust operational parameters to ensure proper efficacy and safety

A secondary air monitor is utilized to instantly cut off electricity flow to ozone generators stopping production of ozone

Ozone Material Compatibility

The following list of materials commonly found in food processing plants have been life-tested or observed under actual use (25 years) in food processing plants to be unaffected by Aqueous Ozone Systems (2.0 – 4.0 PPM dissolved aqueous ozone)

Material List

- **Stainless Steel (304, 316 and foil)**
- **Aluminum (all grades)**
- **Concrete, Painted Surfaces, Wood**
- **Painted Concrete**
- **Plastics: ECTFE, PTFE, PVC, PVDF, HDPE (Polyethylene)**
- **Gaskets: FPM (Viton), EPDM**
- **Rubber Modified Vinyl**
- **Galvanized Steel**
- **Glass**
  - **Mild steel may experience surface rusting similar to exposure to plain water**
  - **Natural latex rubber is not suitable for use with aqueous ozone**

Ozone Facts and *Fallacies*

- ***Fallacy:*** ***Ozone is dangerous, corrosive and off-gasses***
- **Fact:** **Ozone has been safely used in thousands and thousands of applications with no danger to humans or facilities**
- ***Fallacy:*** ***Ozone is cost-prohibitive or expensive***
- **Fact:** **Ozone can provide a return on investment often in 1-2 years; after which, it provides a significant savings (labor, chemicals, energy, sewage); this in addition to product safety**
- ***Fallacy:*** ***Ozone is an oxidizer only***
- **Fact:** **Ozone is a highly efficacious sanitizer, disinfectant and purifier; these provided by its strong oxidation capabilities**
- ***Fallacy:*** ***Ozone is not as strong as traditional sanitizing chemicals***
- **Fact:** **Ozone is exponentially stronger and more efficacious than all standard sanitizers**
- ***Fallacy*** ***Ozone is a new product***
- **Fact:** **Ozone has been in commercial use since 1906**

Ozone System Examples

Footprint 4’X8’

Recirculating Aqueous Ozone System Skid

- Pre-plumbed and Skid-mounted
- Integrated Onboard Oxygen System
- Integrated Ozone Management System
- Automatic Variable Flow Rate
- Automated Proportionally Controlled Ozone Dose
- Fully Automated Control System
- HMI Touch Screen Control Panel

Ozone System Examples

Footprint 2’X2′

Footprint 4’X6′

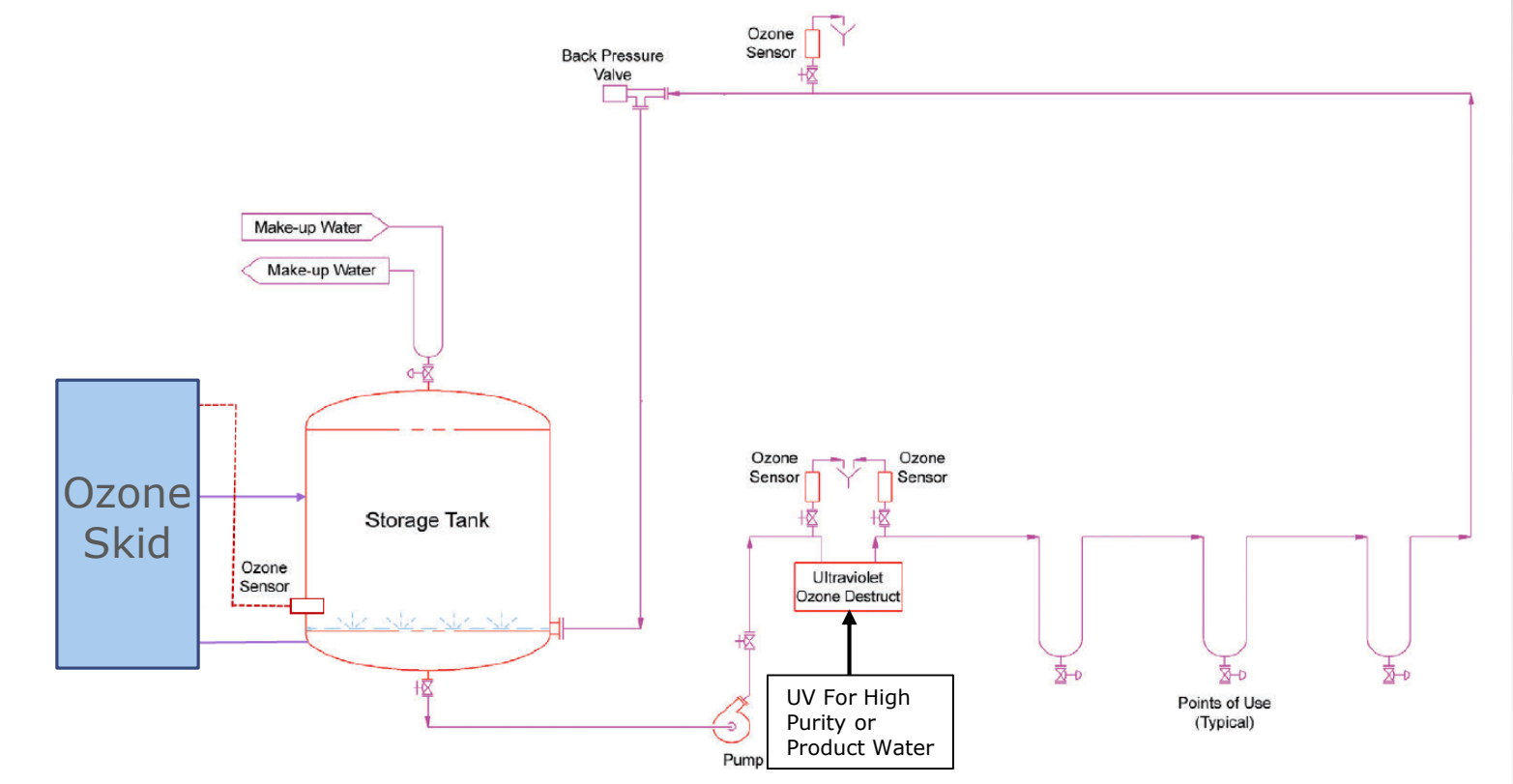
Ozone System Examples

Footprint 2’X3’

Footprint 6’X6’

Footprint 3’X3’

Basic Recirculation Schematic



Tank CIP/SIP

Flume Water Sanitation (Produce)

Equipment Surface Sanitation

Handheld Low-pressure Aqueous Ozone Spray

Floor Surface Sanitation

Handheld Low-pressure Aqueous Ozone Spray

Drain Surface Sanitation

Handheld Low-pressure Aqueous Ozone Spray

Fish Conveyor w/ Ozone Spray

Fixed Low-pressure Aqueous Ozone Spray

Box Tubing with Ozone Spray Nozzles

Fish Fillet and Skinner

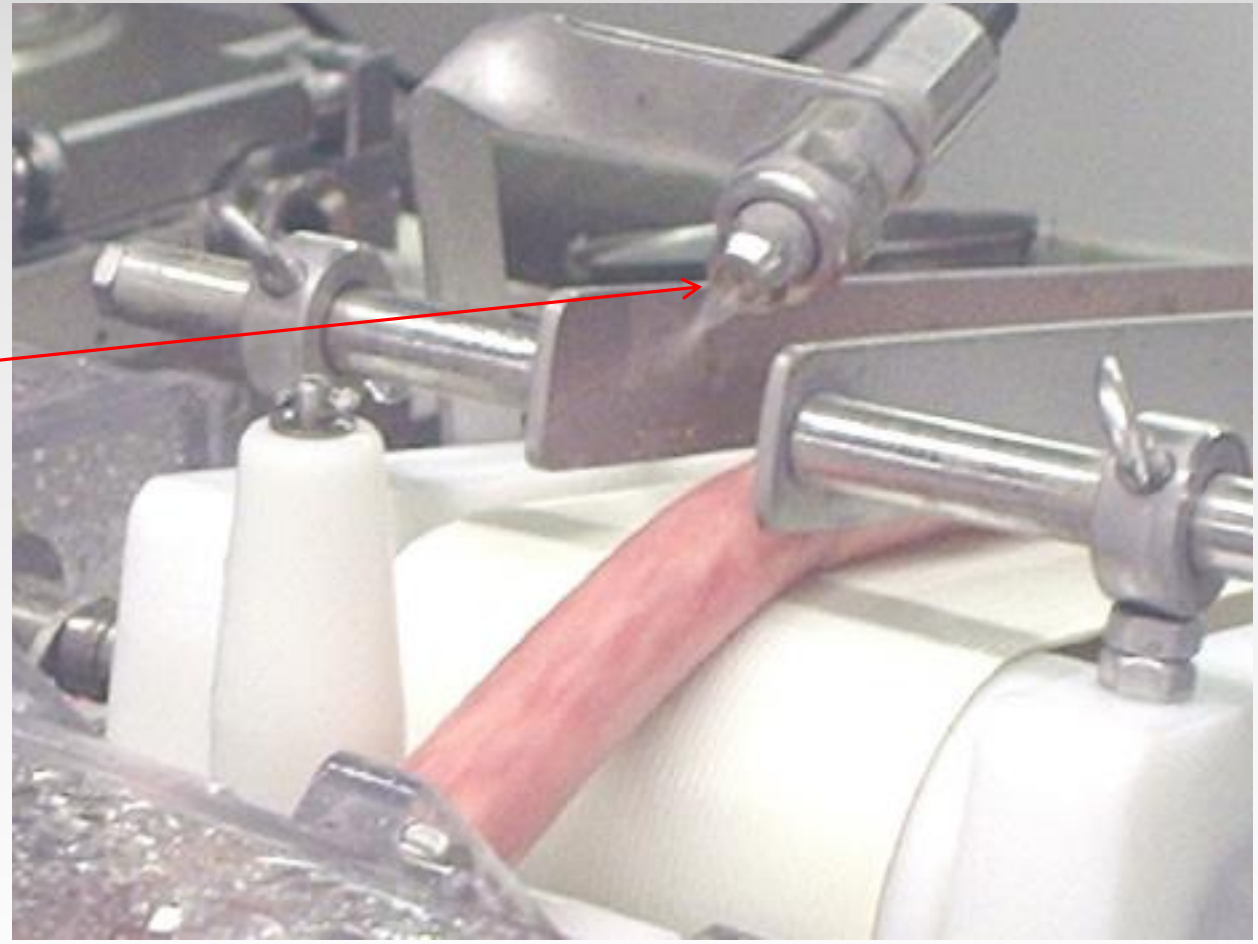
Fixed Low-pressure Aqueous Ozone Spray

PVC Tubing with Ozone Spray Nozzles

Ozone Spray RTE Meat & Conveyor

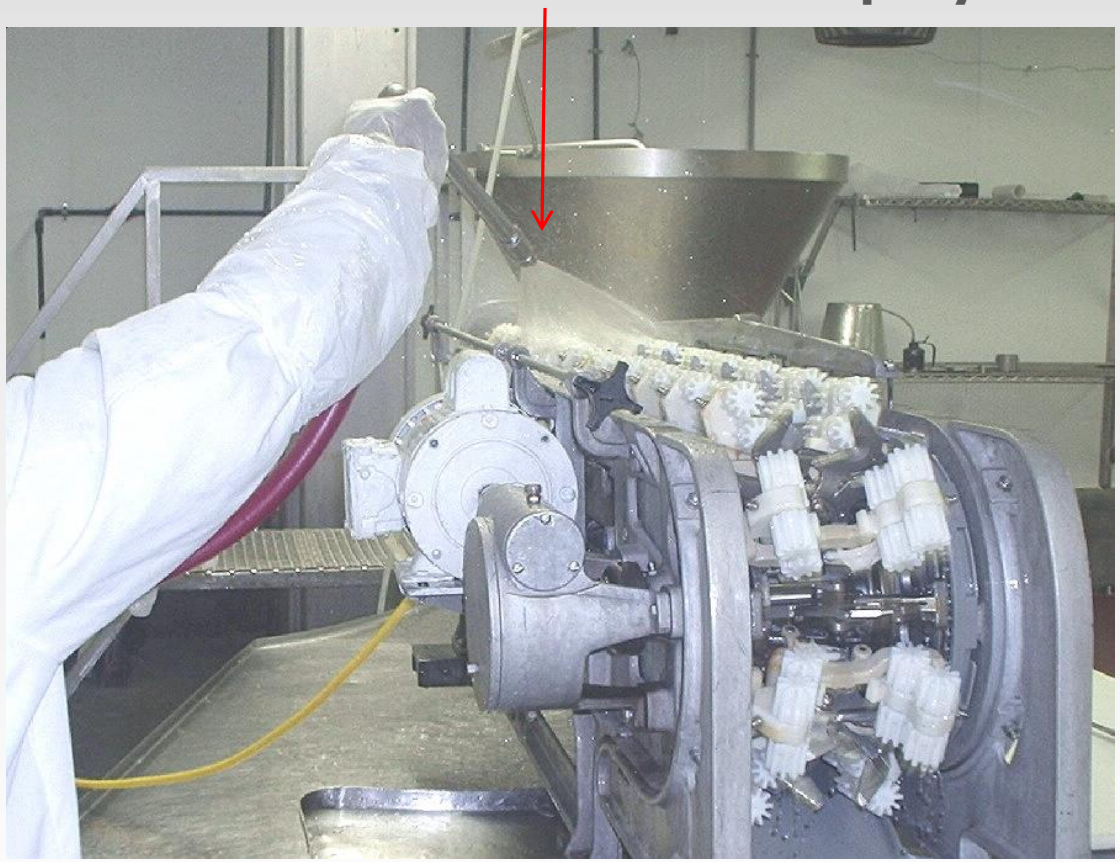
Fixed Low-pressure Aqueous Ozone Spray

Direct Contact and Surface Sanitation on the Conveyor



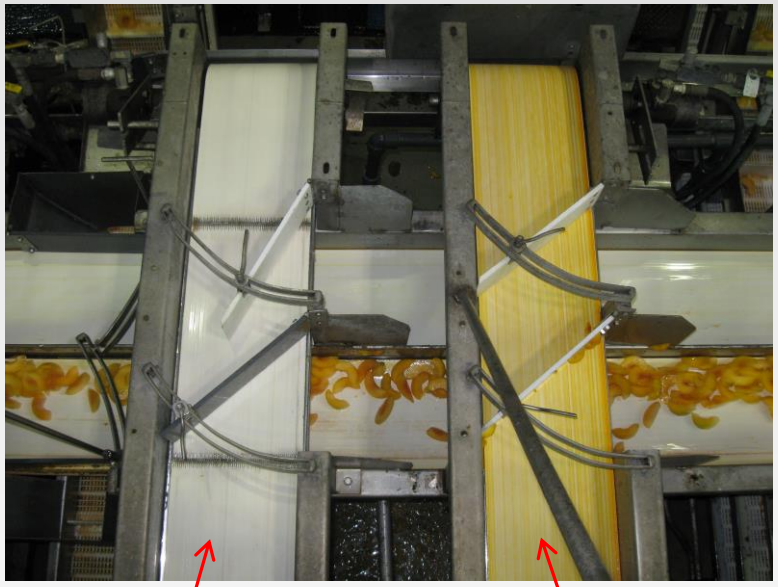
Ozone Spray Sanitation on RTE Meat & Conveyor & Saw Blade

Hand-held Sanitation Ozone Spray



Direct Ozone Contact & Saw Blade Sanitation

Chlorine vs. Ozone 11 Days Without Sanitation - Fruit



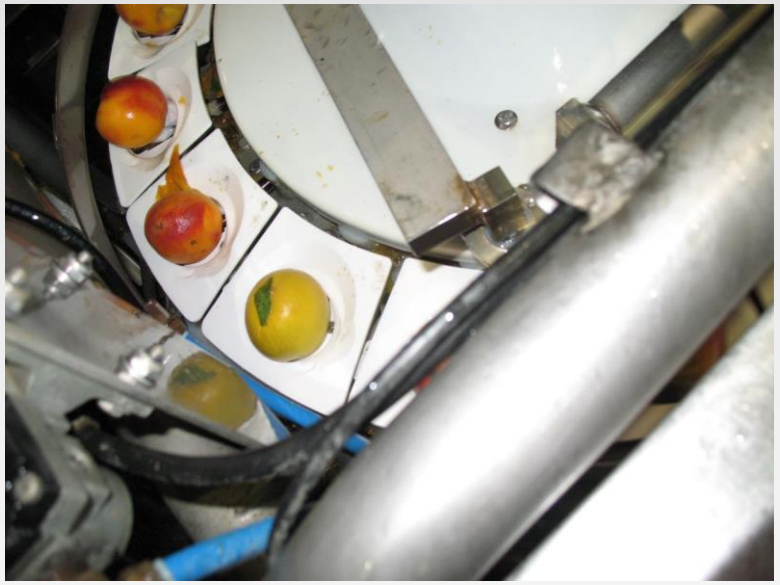
With Ozone Without Ozone

With Ozone Without Ozone

Courtesy Atlas Pacific

Chlorine vs. Ozone 11 Days Without Sanitation - Fruit

Without Ozone



With Ozone

Courtesy Atlas Pacific

Regulatory Summary - FDA

21 § CFR 129.80 (3/15/1977; amended 4/4/2012)

Bottled water plant sanitizing of contact surfaces and any other critical area

0.1 PPM ozone-enriched water solution for at least five minutes (Ct value of 0.5 mg-min)

21 CFR §173.368 (6/26/2001)

FDA Secondary Direct Food Additives Permitted in Food for Human Consumption

Ozone may be safely used in the treatment, storage, and processing of foods, including meat and poultry

Ozone is used as an antimicrobial agent in accordance with current industry standards of good manufacturing practice

21 § CFR 178.1010 (b) (1, 3, 9, 30, 38) (3/16/1977) "Category Three Certification": <15 cfu per cm for Yeast, Mold, Bacteria; No rinse

§178.1010 (b): "The solutions consist of one of the following, *to which may be added components generally recognized as safe (GRAS) and components which are permitted by prior sanction or approval*."

- **(1) 200 PPM chlorine**
- **(3) 25 PPM iodine (iodophore)**
- **(9) 200 PPM quaternary ammonia compound**
- **(30) 400-600 PPM peroxide**
- **(38) 128-156 PPM peroxyacetic acid**

Ozone is (GRAS) and listed under prior sanction (USEPA/FIFRA) Standard Dose 1-3 PPM Ozone

Regulatory Summary - USDA

November 27, 2001, the American Meat Institute filed a letter with USDA/FSIS requesting interpretation of the scope of the FDA rule allowing the use of ozone as an antimicrobial agent

USDA/FSIS determined that, "The use of ozone on raw and ready-to-eat meat and poultry products just prior to packaging is acceptable," and that there are "no labeling issues in regard to treated product"

USDA/FSIS Directive 7120.1 (12/17/02) (Revised 3/3/16)

"The attachment below identifies the substances that have been accepted since January 2000 by FSIS as safe and suitable for use in the production of meat and poultry products"

(Attachment 1) Antimicrobial - Ozone

- **All Meat and Poultry Products**
- **In accordance with current industry standards of good manufacturing practice**
- **Reference 21 CFR § 173.368**

USDA National Organic Program (NOP) Allowed

Ozone is listed in the NOP Final Rule (§ 205.605 (b) (20) pg. 437 - Nonagricultural (non organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"

- **(b) Synthetics allowed: (20) ozone**

Regulatory – USDA - 2

Prior to 1998, the USDA "White Book" listed authorized non-food surface contact compounds (including those for which sanitation claims were made) for meat or poultry

1998: NSF took responsibility for USDA "White Book", updated listing, and

NSF encourages 3rd party testing to add candidates to the list and for approval by EPA OPP Disinfectant Tech Service Science Section (DIS/TSS) for no-rinse surface sanitation compliance

(Although recommended, this is not mandatory)

Regulatory Summary – EPA

EPA regulates ozone as a pesticide- producing device

Ozone generators must be registered by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Each Ozone Generator Manufacturer has a unique EPA registered establishment number as a pesticide-producing device

Regulatory – EPA - 2

For no-rinse surface sanitation compliance the USEPA/FIFRA Office of Pesticide Programs (OPP) Disinfectant Technical Science Section (DIS/TSS) requires:

1. **Antimicrobial efficacy data determined by AOAC International methods**
2. **Toxicological profiles**
3. **Environmental impact information**
4. **Specific label information and directions for use**

Ozone Generators are recognized by the EPA as antimicrobial producing devices per EPA documentation published in 1976, with an EPA Establishment Number necessary for compliance.

A viable ozone system is compliant with items 1-4

Some Ozone Systems are listed in the "NSF White Book"

Regulatory Summary - OSHA

OSHA has two ozone standards to protect plant workers from exposure to harmful levels of ozone in facility air:

Permissible Exposure Level (PEL):

- **0.1 PPM ozone (by volume). Time-weighted average over an 8-hour work day, 5-days per week**

Short Term Exposure Level (STEL):

- **0.3 PPM ozone (by volume) for no longer than 15-minutes, not to be exceeded more than four times per day.**

These OSHA standards have been adopted worldwide wherever ozone is used commercially

Adherence to these allowable ozone exposures ensures that workers will never be exposed to toxic levels of gaseous ozone during working hours.

3rd Party Aqueous Ozone Testing

Ozone systems with an aqueous ozone output of 1.5-2.0 PPM dissolved ozone were 3rd Party tested by NSF Toxicology Group for antimicrobial efficacy and worker safety

Antimicrobial Efficacy Protocols

DIS/TSS-1 (AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants, for both broad-spectrum and hospital/medical environment efficacy claims) was chosen by the Microbiology and Toxicology Groups at NSF as the best testing protocol efficacy testing of aqueous ozone sanitizing on hard surfaces

NSF also chose DIS/TSS-4 (AOAC Method 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants) for additional efficacy testing

NSF conducted studies according to EPA-established AOAC Official Methods 961.02 & 960.09, Germicidal Spray Products as Disinfectants, and Germicidal & Detergent Sanitizing Action of Disinfectants test procedures

3rd Party Aqueous Ozone Testing Antimicrobial Efficacy Results

1.5-2.0 PPM Dissolved Ozone Dose

AOAC 961.02 Results

◦ ***Salmonella choleraesuis***	**6 log reduction (99.9999%)**	**180 seconds**
◦ ***Staphylococcus aureus***	**6 log reduction (99.9999%)**	**600 seconds**
◦ ***Pseudomonas aeruginosa***	**6 log reduction (99.9999%)**	**300 seconds**
◦ ***Trichophyton mentagrophytes***	**6 log reduction (99.9999%)**	**30 seconds**

◦ **Additional evaluations as per AOAC 961.02 Results**

◦ ***Campylobacter jejuni***	**4 log reduction (99.99%)**	**180 seconds**
◦ ***Aspergillus flavus***	**4 log reduction (99.99%)**	**300 seconds**
◦ ***Brettanomyces bruxellenis***	**4 log reduction (99.99%)**	**180 seconds**
◦ ***Listeria monocytogenes***	**4 log reduction (99.99%)**	**180 seconds**

AOAC Method 960.09 Results

◦ ***Escherichia coli***	**5 log reduction (99.999%)**	**30 seconds**

3rd Party Aqueous Ozone Testing

Ozone Safety

Protocol

- **NSF performed safety testing based on Hazard Communications Standard as promulgated through the Occupational Safety and Health Act (OSHA) of 1970 and documented in the Code of Federal Regulations, Title 29.**

Results

- **"It is the professional opinion of the Toxicology Group, LLC that Specific Ozone devices deliver a consistent applied ozone dose which meets both the critical level required to ensure the antimicrobial efficacy claims while still maintaining exposures below the OSHA Permissible Exposure Limit (PEL).**

  Their product literature has provided sufficient information characterizing the physical and chemical hazards associated with use of their devices thereby allowing the employer adequate guidance to put in place a hazard communication program around the use of this device as required by the Hazard Communication Standard."

Antimicrobial Studies

Antimicrobial Validation for *Cryptosporidium parvum* Reduction, by NSF International – Low Dose Ozone (~0.8 PPM Dissolved Ozone)

Pass compliance requires a 3 log (99.9%) reduction of *Cryptosporidium parvum*

Actual Microbial Reductions in 30 Seconds

Cryptosporidium parvum	**3.0 log (>99.9%)**

Antimicrobial Studies

Bacillus subtilis

- **"It is evident that ozone is superior to hydrogen peroxide in killing bacterial spores. Hydrogen peroxide at ~10,000-fold higher concentration was less effective than ozone against Bacillus spores. The comparatively low concentration needed to eliminate large populations of spores at ambient temperature in short time periods makes ozone best suited for industrial settings."**
  - **M.A. Khadre, A.E. Yousef, International Journal of Food Microbiology 71 (2001) 131–138**

Antimicrobial Studies

B. cereus

- **0.12 mg/l @ 5 minutes (CT 0.6) @ 28°C = > 2 log**
  - **M.A. Khadre, A.E. Yousef, International Journal of Food Microbiology 66 (2001) 1247**

B. cereus

- **11.0 mg/l @ 1 minutes (CT 11.0) @ 22°C = > 6 log**
  - **M.A. Khadre, A.E. Yousef, International Journal of Food Microbiology 71 (2001) 131**

Both studies provide statistical comparison only; therefore the ozone was not optimized, it is very likely more efficient and should be re-evaluated for optimum CT value and efficacy for Bacillus

- **Per Dr. Ahmed Yousef, February 2009**

Conclusion

An effective ozone system design balances microbial efficacy with worker and environmental safety.

Thank You! For Further Information

Beth Hamil
1955 Carpenter Canyon Rd.
San Luis Obispo, CA 93401
(805) 544-8624 (805) 441-4444
bethhamil30@gmail.com
www.bethhamilo3consulting.com

BETH HAMIL
O_3 CONSULTING
FOOD SAFETY & INDUSTRIAL OZONE SANITATION