Aqueous Ozone Regulatory Approvals

With increased interest in adopting more sustainable practices, increasing consumer demand for more organic and healthy food options, as well as much stricter food safety rules (i.e., FSMA, HAACP, and HARPC), the use of ozone has accelerated the move away from multi-chemical-based sanitation treatments. Other events, including water availability and cost, food recalls, foodborne illnesses, wastewater concerns, and the need to reduce operating costs, have advanced the use of ozone-based technology either as a replacement for or in addition to traditional chemical-based and thermal-based sanitation treatments. Ozone is an FDA, USDA, and USDA Organic approved antimicrobial food additive. It is an EPA approved antimicrobial oxidizer for potable water, surface sanitation, and CIP/SIP.

Below is a summary of the current regulatory information on ozone by government agency. Additional documentation further describing the regulations in detail can be found at the end of this document (Regulatory Documentation).

- **FDA (U.S. Food and Drug Administration)** Regulates and allows ozone contact with foods (fruits & vegetables, seafood, shell eggs, bottled water, etc.)
- **USDA/FSIS (U.S. Department of Agriculture/Food Safety and Inspection Service)** Regulates and allows ozone contact with meat, poultry, and egg products
- **USDA National Organic Program (NOP) –** Allows ozone to be listed as a non-organic substance allowed as ingredients in or on processed products labeled as organic
- **EPA/FIFRA (U.S. Environmental Protection Agency/Federal Insecticide, Fungicide, and Rodenticide Act)** Regulates ozone generators and their distribution, sale, and use under their device program (includes sanitation by such devices and the conversion of potable water)
- **OSHA (Occupational Safety and Health Administration)** Regulates ozone (for worker exposure) in workplace environments

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/L)

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 (iodophor)
- (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

USDA/FSIS

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

1. All Meat and Poultry Products
2. In accordance with current industry standards of good manufacturing practice
3. Reference 21 CFR § 173.368

USDA National Organic Program (NOP) Allowed Substances

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

Food Safety and Inspection Service New Technology Information Table Last Updates January 25, 2017

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/new-technologies/new-technology-information-table

Listed technology: Ozone

FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products – January 2014

Post-lethality Treatments and Antimicrobial Agents

Buege, D.R., Ingham, S.C. and J.A. Losinski (University of Wisconsin-Madison), "Evaluation of Del Ozone's Delzone® Sanitation System as a Post-Lethality Treatment to Control Listeria monocytogenes Contamination on Ready-To-Eat Meat Products", Confidential Report to Del Ozone, April 16, 2004.

Use of Antimicrobial Ingredients including Bacteriophages, Lactates, Acetates, Diacetates, and Ozone

Ozone is an antimicrobial gas usually applied in an aqueous solution to products, food contact surfaces as a continuous spray (e.g., belts, moving tables), and nonfood contact environmental surfaces. Currently, the use of ozone is permitted by FDA and FSIS (21 CFR 173.368, FSIS Directive 7120.1) for use with all meat and poultry products, including RTE meat and poultry products.

Buege et al., (2004) showed 1.0 to 2.4 log reductions (average 1.5) of Lm when 0.6 ppm ozone for 30 seconds was applied to ham, salami, meatloaf, natural casing wieners, and skinless wieners.

FSIS USDA Training – Process Category Introduction 3/25/2015 Inspection

Poultry Slaughter – Antimicrobial Interventions

Raw Product – Intact Processing Category

Common Controls – Biological

In addition to the controls that may have already been used during the slaughter process, establishments commonly utilize additional antimicrobial interventions for pathogens of concern.

On August 21, 2014, FSIS published the Modernization of Poultry Slaughter Inspection final rule. FSIS Notice 50-14 addresses how IPP are to verify compliance with approved online and offline reprocessing antimicrobial intervention systems. Establishments that slaughter poultry other than ratites are allowed to use these approved systems to clean carcasses accidentally contaminated with digestive tract contents (9 CFR 381.91). A list of approved systems is included as an attachment to this notice.

Ozone

Ozone may be used in contact with food as a gas or liquid as an antimicrobial in meat and poultry products, including ground meats.

EPA/FIFRA Office of Pesticide Programs (OPP) Disinfectant Technical Science Section (DIS/TSS)

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.

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.

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.