

Food & Beverage Ozone Applications: Regulatory Approvals Summary

- **USDA FSIS Directive 7120.1 (12/17/02)**
 - “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
- **21 CFR §173.368 (6/26/01) - 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.
- **AMI (American Meat Institute) Interpretation Request (11/27/01)**
 - November 27, 2001, the American Meat Institute filed a letter with FSIS asking for interpretation on the scope of the FDA rule allowing the use of ozone as an antimicrobial agent.
 - 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 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
- **EPA Registered as a Pesticide-Producing Establishment**
 - As a pesticide, ozone equipment must be registered by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). DEL Ozone is an EPA registered establishment (EPA Estab. No. 071472-CA-001). EPA does not regulate ozone as a chemical.
- **NSF Registered – Hard Surface Sanitation**
 - DEL Ozone systems listed in the *NSF White Book*
 - MPI-300 (132819), AGW-0500 (#123680), AGW-1500G (#124182), AGW-4015 (#129380), AGW-4025 (#129381),
 - 2001: DEL Ozone systems tested by **NSF Toxicology Group** for anti-microbial efficacy and worker safety
 - Antimicrobial Efficacy
 - NSF conducted studies according to EPA established AOAC Official Methodology 961.02 & 960.09, Germicidal Spray Products as Disinfectants, and Germicidal & Detergent Sanitizing Action test procedures.
 - Safety
 - NSF performed safety testing based on Hazard Communications Standard as promulgated through Occupational Safety and Health Act (OSHA) of 1970 and documented in the Code of Federal Regulations Title 29.