125

THE CLEAN OPERATION | October/November 2002

Recent Ozone Applications in Food Processing and Sanitation

By Rip G. Rice, Ph.D., Dee M. Graham And Matt T. Lowe

Ozone, a gas that is a triatomic form of oxygen, has been used for years in applications such as treatment of municipal water and bottled water. In fact, it has been used as a disinfectant in drinking water since 1893, as a food preservative for the cold storage of meats since 1909, and was found to prevent the growth of yeast and mold during the storage of fruits in 1939. Ozone has enjoyed a long history of use and is known as a broad-spectrum biocide against viruses, bacteria, biofilms, fungi and protozoa— none of which can build up a resistive tolerance to ozone, because ozone disinfects by oxidation processes. Ozone does not act as a systemic poison to microorganisms, but rather, destroys them by oxidation. Consequently, it is impossible for a microorganism to build up any resistance to oxidation. Today, ozone technology is beginning to be used effectively as an additional point of intervention in the food and beverage industry.

Ozone gas is generally created on-site by a generator via an electrical charge or from oxygen using the same process. The gas is pumped into water, and the ozonated water is used as a rinse, mist, spray or bath. The ozone survives for only a matter of minutes before decomposing into ordinary oxygen.

As an environmentally friendly disinfectant, ozone now is being studied as an alternative to chlorine sanitizers in many segments of the food industry. Ozone-enriched water kills microbes as effectively as chlorine, and since it is generated on-site its use eliminates the need for personnel to handle, mix and dispose of harsh chemicals for sanitation. Further, since ozone readily reverts to oxygen, an end-product that leaves no residue on contact surfaces. Ozone-enriched water can be sprayed directly on floors, drains, walls, wettable equipment, tanks (externally and internally), and clean rooms via mobile or centralized systems with hand-held or drop-down, low-pressure sprayers. Over time, the use of ozonated water for sanitation in food plants removes and/or prevents biofilm. In addition, resulting runoff water is extremely clean and, over time, will improve overall plant sanitation by reducing overall microbial load.

In response to a Food Additive Petition submitted during August 2000, the U.S. Food and Drug Administration (FDA) formally approved the use of ozone as an *Antimicrobial Agent for the Treatment, Storage and Processing of Foods in Gas and Aqueous Phases*. The approval was published on June 26, 2001.[1] On Dec. 21, 2001, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) approved the use of ozone in contact with meats and poultry, from raw product up to fresh cooked and products just prior to packaging.[2] In addition to direct contact disinfection of foods, ozone also can be applied to food processing equipment and non-food contact surfaces as part of a food company's sanitation efforts.

In this article, we will discuss the FDA approval for ozone and describe the specific conditions under which ozone may be used in the U.S. when it comes into contact with foods, with emphasis on recent evaluations of the use of ozone as a food equipment surface sanitation method.

A Brief History of Regulatory Approval of Ozone Technology

Prior to mid-1997, there were few or no commercial applications of ozone in food processing or treatment in the U.S. The reason was entirely regulatory in nature, and had nothing to do with the technology of ozone. The regulatory control over the use of ozone is the Federal Food, Drug and Cosmetic Act (FDCA), passed in the late 1950s and under which the FDA is required to operate. The act defines any material that comes in contact with food to be a "food additive," which must be approved by the FDA prior to use. The FDA regulates all foods except meats, poultry and egg products. These last three food categories are regulated by USDA. However, the agency will not allow the use of any food additive on its regulated foodstuffs unless that additive has received prior FDA approval.

Attempts to gain FDA approval for the use of ozone in contact with foodstuffs have been long and arduous. In the early 1980s, the International Bottled Water Association (IBWA) petitioned the FDA to affirm that the application of ozone to disinfect bottled water under specified conditions is Generally Recognized As Safe (GRAS). The conditions included a *maximum* dosage of ozone of 0.4 mg/L over four minutes contact time, and that the water to be treated must already meet the potable water requirements of the U.S. Environmental Protection Agency (EPA). The FDA approved IBWA's petition for ozone in bottled water, and in 1982, published in the *Code of Federal Regulations (CFR)* a formal FDA regulation affirming GRAS Status for use of ozone.[3] Later, FDA also approved the use of ozone as a *sanitizing agent* for bottled water treatment lines under a similar GRAS petition.

Unfortunately, the GRAS approval for ozone disinfection of bottled water in 1982 contained the additional statement: "All other food additive applications for ozone must be the subject of appropriate Food Additive Petitions (FAP)" [21 *CFR* 184.1(b)(2)]. This statement effectively mandates the filing of FAPs in order to gain FDA approval for other uses of ozone that come into direct contact with foods.

During the intervening years, several food additive petitions were submitted to the FDA to approve applications of ozone in contact with specific foods, poultry in particular. However, each of these petitions was withdrawn (without prejudice) for one reason or another.

In June 1997, an expert panel of food scientists convened by the Palo Alto, CA-based Electric Power Research Institute (EPRI) concluded the following: "The available information supports the safety of ozone when used as a food disinfectant or sanitizer, and further that the available information supports a GRAS classification of ozone as a disinfectant or sanitizer for foods *when used at levels and by methods of application consistent with good manufacturing practices"* (authors' emphasis).[4]

EPRI's GRAS affirmation gave a clear green light to food processors to test and use ozone for a variety of food processing applications. Nevertheless, the lack of specific regulatory approval for ozone published by the FDA in the *Federal Register* continued to disturb many food processors and slowed the broader acceptance of ozone in the food industry. FDA recognized this, and also recognized that most applications for ozone in food treatment involve antimicrobial properties of ozone. Consequently, in mid-1999, the FDA suggested to the EPRI that a single FAP that would provide FDA with specific data showing the antimicrobial properties of ozone in a number of food processing applications could be reviewed quickly, and if approved, would overcome the requirement of the 1982 GRAS regulation regarding "other food uses for ozone." EPPJ agreed with this approach and, with considerable support from several interested food processing organizations, developed such an FAP and formally filed it with the FDA in August 2000[5]. FDA approval of this FAP was published June 26, 2001 in the *Federal Register*. Later in the year, USDA/FSIS approved ozone for use on meat and poultry products, including treatment of ready-to-eat meat and poultry products just prior to packaging, with no labeling issues in regard to treated product.

FOOD INDUSTRY APPLICATIONS AND EVALUATIONS OF OZONE

Ozone may be used safely in the treatment, storage and processing of foods, including meat and poultry in accordance with the following prescribed conditions: The additive is *used as an antimicrobial agent* in the gaseous or aqueous phase *in accordance with current industry standards of good manufacturing practice*. By "good manufacturing practice" in relation to ozone treatment, the FDA means the exposure of foods to sufficient ozone (concentrations and times of exposure) sufficient to accomplish its intended purpose(s). In general, but certainly when using ozone, this is *not* a case of "if a lit- tie bit of ozone provides 'X' amount of benefit, then a lot more ozone will provide a lot more benefit." There are two major issues to consider: (1) What minimum exposure to ozone is necessary to provide antimicrobial benefits on specific foodstuffs, and (2) above what (presumably) higher level does ozone damage the food to which it is applied or result in off-gassing of ozone sufficient to violate U.S. Occupational Safety and Health Administration (OSHA) permissible exposure levels and/or EPA environmental limits?

In defining "antimicrobial agents," FDA is showing concern that the agent be added in sufficient amounts/dosages! exposure to accomplish the intended purpose of controlling microorganisms. Clearly, the ozone user should not cavalierly add excessive ozone to the food product. In addition to raising the costs of supplying excess ozone, if there is clear damage to the food product—such as bleaching of carrots and broccoli, or breaking down of coatings on cranberries—the ultimate consumer surely will shy away from purchase of such over-ozonated products. Consequently, it is incumbent upon the potential user of ozone to conduct sufficient testing and evaluation of ozone for controlling microorganisms on specific foods under consideration, so as to clearly define the minimum and maximum ozone exposures required by those foods. (See “Now That It’s Legal: What Next?”, p. 13.)

With respect to the use of ozone in the direct contact disinfection of food, there have been many studies conducted that show benefits ranging from microbial load reduction to increased shelf life of many different types of food products. Although the focus of this article is on the promise of ozone as a sanitizing agent for food equipment surfaces, there are some recent direct contact processing applications of note. For example, Strickland Produce Co. utilizes an ozone and filtration system for processing its fresh- cut salads, and has reported that the system provides the company with a greater assurance of food safety, improves shelf life, and substantially reduces the plant’s water usage. Results from the North Coast Seafood Co. ozone system for fish processing indicate about a 50% increase in the shelf life of white fish. Similarly, two air treatment units that combine ozone and ultraviolet (UV) bulbs installed by Kraft Foods for the control of mold in the vestibule of the packaging room, have yielded better than an 80% reduction in mold.[6-7]

Until recently, ozonated water was not confirmed as a sanitizing rinse for food contact surfaces such as cutting tables, or for non-food contact surfaces such as floors. In 1999, in one of the very first studies on the use of ozone as a sanitizer for food processing equipment, Hampson showed that microbial load could be reduced by spraying ozonated water on these surfaces.[8]

The location of this early test was the fruit and vegetable pilot plant at the California Polytechnic State University (San Luis Obispo, CA) Food Science and Nutrition Department. The ozone system used in the study was able to deliver an applied ozone dose of 2.0 ppm through a 10 gpm hand-held spray wand, typically delivering a residual (measurable) dose of around 1.5 ppm ozone-in- water solution. Environmental ozone monitoring was performed using an ambient monitor, and concentrations in solution were verified using a dissolved ozone monitor.

Various surfaces in the facility were sprayed with the ozonated water in a back-and-forth fashion for one minute. The test surfaces included a polished, stainless-steel mixing kettle and tabletop, a stainless steel shroud, a central floor drain, a plastic shipping container, and two locations on the non-slip epoxy-coated concrete floor of the facility. Test areas were not cleaned prior to sanitation, so only the effect of the ozone spray wash was measured. Testing was repeated four times, and the microbial load of a 100 cm^2 area was measured before and after ozone application, using both aerobic plate count and bioluminescence (Table 1).

Location	% Reduction (Plate Count)	% Reduction (Bioluminescence)
Stainless Steel (kettle)	89.7 to 98.2	87.6 to 91.8
Stainless Steel (tabletop)	98.9 to 99.7	90.0 to 93.8
Stainless Steel (shroud)	63.1 to 99.9	68.8 to 92.2
Floor Surface (high-traffic area)	67.0 to 95.6	75.2 to 96.1
Floor Surface (low-traffic area)	84.3 to 99.9	32.8 to 48.8
Floor Drain	*	54.7 to 66.5
Floor Drain (2 minutes)	77.5	92.9 to 99.4
Plastic Shipping Container	96.9 to 97.2	68.9 to 97.4

** Due to drainage and sampling problems, results from this location were inconclusive.*

Table 1. Ozone sanitation of a food processing facility (Hampson, 1999).[8]

The results indicate that ozone applied as a spray wash is effective in reducing microbial load in the processing environment. The drain presented problems during the test because the ozonated water applied to the drain washed throughout the long central drain ditch, making results inconclusive. A second test on the drain for two minutes of exposure did provide a reduction in microbial load.

One advantage of ozone is its ability to readily oxidize microbes in solution such that once a surface is spray-washed, the microorganisms physically lifted from the surface will be killed as they find their way to a drain. The Hampson study data represents one series of tests over a two-week period, with evaluations performed approximately every third day. With continued or daily use, this initial focus study of the application of ozone technology to surface sanitation showed that it was reasonable to expect that the microbial load would be significantly eliminated at all locations exposed to the ozone. In 2002, new data resulting from a stringent certification process is showing that the efficacy of ozone technology as it is applied to sanitation purposes has dramatically improved.

An important issue in food plant sanitation, especially in USDA-inspected plants, is regulatory approval of the sanitation system or compound. With the discontinuation of the USDA proprietary substances and nonfood compound approval and listing program in 1998, the status of ozone for sanitation was undefined. The NSF Nonfood Compounds Registration Program, as a continuation of the USDA program, offers technology providers the opportunity to participate in such benchmarking in order to gain registration status with NSF International. Systems that achieve this certification can be considered by food processors as “USDA approved” for sanitation of food contact and nonfood contact surfaces in their plants.

Recently, results from the first study benchmarking ozonated water against EPA standards for sanitation validate ozone’s efficacy as a sanitizer for surfaces, including processing equipment that come into contact with food. Antimicrobial efficacy and safety testing of two mobile ozone surface sanitation systems (DEL Ozone, San Luis Obispo, CA) was conducted by the Toxicology Group, LLC, a division of NSF International, according to EPA-formulated test and performance requirements. The evaluators benchmarked these ozone sanitation systems against test and performance standards for both broad-spectrum and hospital/medical environment efficacy claims, and carried out witness testing on the antimicrobial performance of ozone as measured by the AOAC International Official Method 961.02, Germicidal Spray Products as Disinfectants Test, and by the AOAC International Official Method 960.09,* Germicidal and Detergent Sanitizing Action of Disinfectants.

he following disinfection results indicate percent reduction for specific microorganisms tested, and when compared with the 1999 Hampson study cited earlier indicate the increased level of efficacy improved ozone technology has achieved in the past few years:

• *Escherichia coli**
(ATCG 11229) 99.999%
• *Aspergillusfiavus*
(ATCC 9296) 99.99%
• *Brettanomyces bruxellensis*
(ATCC 10560) 99.99%
• *Campylobacterjejuni*
(ATCC 33250) 99.99%
• *Listeria monoytogenes*
(ATCC 7644) 99.99%
• *Pseudomonas aeruginosa*
(ATCC 15442) 99.9999%
Salmonella choleraesuis
(ATCC 10708) 99.9999%
• *Staphylococcus aureus*
(ATCC 6538) 99.9999%
• *Trichophyton mentagropphytes*
(ATCC 9533) 99.9999%

	Chemical Costs	Wastewater Disposal	Disposal Fee Per Gal/Per Day	Disposal Fee Per Month	Disposal Fee Per Year	Total Per Annum
w/o Ozone	$6,000/year	15,000 gal/day	$1/208 gal	$1,800/month	$21,600/year	$27,600
with Ozone	$0/year	6,000 gal/day	$1/208 gal	$720/month	$8,640/year	$8,640
					Total Annual Savings	$18,960

Table 2. Annual savings in chemical costs and waste water disposal fees at a food processing facility.

Most companies that are changing their sanitation practices to include ozone either utilize the technology as an additional step/final intervention, or as part of food surface sanitation. With regard to the lattes a recent cost analysis of a mobile ozone surface sanitation system performed by a food processing facility showed that the processor reduced the surface sanitation process from four steps to two steps, thereby reducing daily water usage for the sanitation process from 15,000 gallons to 6,000 gallons (Table 2).

The 42,000 square facility contains 20 processing lines operating approximately 300 days per year, 24 hours per day. The return on investment for the facility was calculated based on reduction of chemical costs and wastewater disposal fees (based on a daily water usage reduction). Through the use of the mobile ozone surface sanitation system, the food process so was able to achieve an annual savings of $18,960. The incorporation of the ozone system for the company's sanitation process also allowed for one additional hour of production per 24 hours of operation, equating to 7200 additional production hours per year for the processor.

Conclusion

Formal regulatory approval by the FDA (and by the USDA/FSIS) for the use of ozone as an antimicrobial agent in direct contact with foods clears away the regulatory hurdle that has impeded application of ozone to foods in the U.S., and will reassure food processing firms wishing to improve the qualities of their products by approaches involving ozone.

In addition, because ozone requires no storage or special handling or mixing considerations, it may be viewed as advantageous over other chemical sanitizers used in the food industry for sanitation purposes. Some may consider the fact that ozone leaves no sanitizing residual a disadvantage, but if a residual is desired, there are many other sanitizers available to accomplish that. Ozone can be considered a complimentary sanitizing regime to help maintain the overall cleanliness and sanitation of any food processing facility.

Read Sidebar: 'Now That It's Legal: What Next?'

Rip G. Rice, Ph.D., *is president, RICE International Consulting Enterprises based in Ashton, MD, which specializes in ozone technologies, particularly with respect to water and wastewater treatment. Rice served as an Ozone Resource to the EPRI Expert Panel which declared ozone to be Generally Recognized As Safe in food applications. He also is the senior author of the Food Additive Petition submitted by the EPRI in 2000 to the FDA to request approval of ozone as an antimicrobial agent in the treatment of foods. This petition was approved June 26, 2001. Rice also advises food processors on how to evaluate ozone for various purposes in the food industries. He is a cofounder of the International Ozone Institute (now the International Ozone Association) in 1973, served as its president from 1982-1983. In 1995, Rice received the Morton J. Klein Memorial Award for outstanding service to the association. He can be reached via e-mail at RipRice4Ozone@cs.com.*

Dee M. Graham, Ph.D., *is president, R&D Enterprises located in Walnut Creek, CA and serves as the Electric Power Research Institute's Agriculture and Food Technology Alliance Office manager. EPRI AFTA coordinated efforts for several years to review the use of ozone as a food safety additive and to obtain formal federal regulatory approval. Graham chaired the EPRI Expert Panel that affirmed ozone as GRAS in 1997, and he was instrumental in securing EPRI and other funding for the Food Additive Petition. He also assisted Rip Rice with writing the FAP, which was approved in 2001.*

Matt T. Lowe *is marketing manager for DEL Ozone, San Luis Obispo, CA. Lowe has been involved in the research and development of ozone applications for more than three years. Previously, he worked in the environmental groundwater remediation industry. Lowe holds a bachelors of science degree in biochemistry and cell biology from the University of California-San Diego.*

References

1. U.S. FDA. Secondary direct food additives permitted in food for human consumption. *Federal Register* 66(123):33829-33830. 2001.
2. USDA FSIS. Letter from Robert C. Post (FSIS, Washington, DC) to Mark D. Dopp (American Meat Institute, Arlington, VA). Dec. 21, 2001.
3. U.S. FDA. GRAS status of ozone. *Federal Register* 47(215):50209-50210. 1982.
4. EPRI. Technical Report-i 08026, Vols. 1, 2, 3:
Evaluation of the history and safety of ozone in processing food for human consumption. EPRI. Palo Alto, CA. 1997. www.epri.com.
5. EPRI. "Ozone as an Antimicrobial Agent for the Treatment, Storage and Processing of Foods in Gas and Aqueous Phases." Food Additive Petition filed with FDA. June 2000.
6. Rice, R.G., and D.M. Graham. Recent North American developments in ozone applications in food processing. *Proceedings of the International Ozone Association EA3 Group*. Berlin, Germany. 2000.
7. Rice, R.G., and D.M. Graham, D.M. Recent North American developments in ozone applications in food processing. *Proceedings of the International Ozone Association, Pan American Group*. Orlando, Florida. Oct. 1-4, 2000. www.intl-ozone-assoc.org.
8. Hampson, B.. Use of ozone for winery and environmental sanitation. *Practical Winery & Vineyard,* pp. 27-30. January/February 2000.

Now That It's Legal: What Next?

The primary question asked by those in the agricultural and food industries when confronted with ozone and its approval by the FDA is, "How much ozone do I need to apply to do what I want it to do" Unhappily, the best and most truthful answer is that aside from some guidance from the published literature, the wise approach for the potential ozone user is to determine, by actual testing, the appropriate ozone dosage and exposure times for the specific agricultural and/or food product(s) to be treated.

`The reader must understand, that although there are many studies on ozone in contact with various foods in the literature, specific details on ozone's effects on specific foodstuffs sufficient to design ozonation systems in food/agricultural plants are sparse. Prior to FDA'S approval of ozone in 2001, it was actually *illegal* to use ozone for treating foods in the U.S. Consequently, FDA'S approval of ozone in 2001 was simply a "license to study" ozone in its many potential food and agricultural applications. As such, we offer a recommended ozone evaluation protocol in the form of the following steps that should be taken whenever a food processor becomes seriously interested in testing ozone:

I. *Select food item or process* to be treated with ozone.
2. *Identify specific foliage microorganisms* that will be involved. Not all foods are spoiled by the same microorganisms.
3. *Establish ozone or process* performance *required,* including how many logs of inactivation of the targeted microorganisms are required; how much extension of shelf life is required; how clean must a recycled process water be, and so on.
4. Check published literature. Start with the Food Additive Petition. If insufficient data are available (as expected), then conduct laboratory studies on those microorganisms to determine ozone dosages and conditions for their inactivation. One ozone company

provides pilot systems for conducting such lab testing.
5. *Apply conditions to food/process and confirm results*.
6. *Determine cost-effectiveness*.

In the FAP submitted to the FDA, there is a table that reports ozone dosage/exposure data obtained during specific studies. These data are most useful as guidance to the prospective ozone user, with the caution that the user must determine the minimum ozone dosage/exposure level necessary to accomplish the intended effect. At the same time, the prospective user *should* determine the maximum ozone dosage/exposure level that will cause damage to the agricultural or food product being treated.

If ozone is evaluated in this manner for each potential application, the user will have a comfortable operating range of ozone dosage/exposure. This will allow the user to specify ozone treatment conditions that will always ensure attaining ozone's intended effect(s) while also ensuring that excess ozone sufficient to damage the food product will be avoided.

Categories: Regulatory**:** FDA**,** USDA**;** Sanitation**:** Cleaners/Sanitizers**,** SSOPs

125