

**The Use of Ozone as an Antimicrobial Agent:
Agricultural and Food Processing Technical
Assessment**

November 2001

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Technical Review, November 2001

EPRI Project Manager

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REPORT SUMMARY

Background

In response to the growing concern of the United States scientific community and the general population to ensure ongoing food safety, in the early 1990's, the Food Technology Alliance requested EPRI investigate the use of ozone as an antimicrobial agent to enhance food safety. Discussions began in 1995 and investigation of the use of ozone was started in 1996 with the convening of an expert panel that declared ozone Generally Recognized as Safe (GRAS) in 1997. Although the GRAS Declaration was deemed the proper method to legally allow the use of ozone in food processing during both the investigative period and after the 1997 Declaration, it was never recognized by the USDA. Later its legality became clouded due to a 1982 ruling limiting the use of GRAS Declarations for ozone uses in food processing.

In 1999, recognizing that the 1982 ruling created confusion among the food processors, the FDA encouraged the EPRI AFTA to pursue the development and submission of a Food Additive Petition (FAP) that would allow the use of ozone as a contact Antimicrobial Agent in foods. The FAP was completed and submitted to the FDA in August 2000. After an expedited and rigorous review by the FDA staff, the FDA recognized ozone as an Antimicrobial Agent suitable for use in Food Processing and Agricultural Production. Notice of this recognition appeared in the Federal Register, June 26, 2001.

Objectives

During the development of the GRAS Declaration and the FAP (1995-2001), EPRI Food and Agricultural customers supported twelve major projects to investigate and demonstrate the use of ozone as an Antimicrobial Agent for food and agricultural processes.

Conclusions

Based on the GRAS Declaration, the FAP, and the Research and Demonstration Projects, the following was concluded:

- Ozone is a very strong oxidizer capable of acting as a potent contact Antimicrobial Agent in food and agricultural processes and is an excellent tool in food safety when used either alone or in combination with other Antimicrobial Agents such as chlorine, peroxide, and UV light
- The numbers of applications of ozone in food and agriculture are still evolving and new uses are being found on a regular basis
- When used under Good Manufacturing Practices (GMP), ozonation is a very safe process
- Because ozone rapidly oxidizes to oxygen, very few reaction byproducts are produced. An exception to this generalization are bromide byproducts that can become problems
- Although generally safe, the reactions of ozone as an Antimicrobial Agent are often detailed and complicated. For this reason, all uses should be approached with caution and properly

planned, utilizing the latest technologies to avoid costly mistakes

- Because ozone reactions are often complicated and not well understood, new uses are overlooked. Opportunities for continuing research and implementation of ozone in many new and exciting areas are missed due to lack of knowledge of ozone and its capabilities

This report gives a brief history of ozone use for water and food products and continues with the regulatory background for the use of ozone in the United States. It includes the notice of the acceptance of the Food Additive Petition as published in the Federal Register. The activities and coordination efforts required in the preparation of the Food Additive Petition are discussed. The twelve EPRI sponsored studies and demonstrations conducted on various methods of ozone usage in food processing and agricultural production are outlined. This report concludes with Appendices, which include a complete listing of all references used in preparing the Food Additive Petition and the Food Additive Petition Table of Contents.

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Introduction

Through considerable efforts on the part of EPRI, ozone was recognized and allowed as an Antimicrobial food additive by the US Food and Drug Administration (FDA) in 2001. This recognition by the FDA was the culmination of a great deal of work and preparation by the EPRI Food Technology Alliance (FTA) and Agriculture Technology Alliance (ATA), as well as the combined Agriculture and Food Technology Alliance (AFTA) over the course of several years.

This Technology Assessment covers and summarizes EPRI's efforts to have ozone recognized as an Antimicrobial food additive for both processed foods and agricultural products. This report further summarizes EPRI sponsored research that demonstrates the uses of and needs for ozone as a food additive as well as providing an overview of the Food Additive Petition.

Brief History of Ozone Use for Water and Food Products

- 1902 – Ozone used to provide safe drinking water in France
- 1918 – Ozone used to sanitize swimming pools in the United States
- 1936 – Ozone used to treat shellfish in France
- 1942 – Ozone use begun in cheese storage facilities in the United States
- 1972 – Ozone used to purify process water in Germany
- 1977 – Ozone used to reduce *Salmonella* in shell eggs in Russia
- 1995 – Ozone declared GRAS (Generally Recognized as Safe) for bottled water in the United States
- 1997 – Expert Panel convened by EPRI declared ozone GRAS in food processing in the United States
- 2000 – Food Additive Petition filed with the FDA, August 15, 2000
- 2001 – FDA recognizes ozone as a secondary direct food additive. (Federal Register, Vol. 66, no. 123, Tuesday, June 26, 2000. Rules and Regulations)

Regulatory Background for the Use of Ozone in the USA

The chemical ozone has been recognized for more than 100 years and has been used extensively in water purification and other sanitizer and fumigant functions in several countries since the early 1900's.

Though used extensively in water, ozone was not originally included in the GRAS List because it was not viewed as a food chemical. Then in response to a petition filed by the American Bottled Water Association (now the International Bottled Water Association), ozone was classified GRAS for use in bottled water in 1982. The FDA reaffirmed this GRAS classification in 1995. Currently more than 300 water districts in the United States use ozone for treatment of public drinking water supplies.

In order to get ozone cleared for use in food processing, EPRI in 1996 convened an Expert Panel of independent food scientists to evaluate the history and safety of ozone use in food

processing. The panel members were chosen for their expertise in food science, ozone science and engineering, toxicology, human nutrition, medical health, food processing, and food additive regulations. The Expert Panel met over a period of one and one-half years and reviewed worldwide literature related to the uses, effects and safety of ozone as a sanitizer and disinfectant. An Expert Panel Report, “Evaluation of the History and Safety of Ozone in Processing Foods for Human Consumption” (TR-108026, volumes 1-3) was published in 1997 by EPRI.

Based on its critical evaluation of available information, the panel concluded that:

“The available information supports the safety of ozone when used as a food sanitizer or disinfectant, and further that the available information supports a Generally Recognized as Safe (GRAS) classification of ozone as a sanitizer or disinfectant for foods when used at levels and by methods of application consistent with Good Manufacturing Practices”.

After submitting to FDA, and absent any adverse comment for 90 days, a Summary of the Expert Panel findings was published in *Food Technology*, vol. 51(6): 72-75, June 1997. This is as required in the FDA procedures for GRAS Affirmation (Federal Register 1997). At the time, it was felt that the GRAS Declaration would be sufficient for industry to adopt ozone as an Antimicrobial technology. However, two problems arose:

1. With the GRAS Declaration, the FDA was not required to publish in The Federal Register their approval of ozone as a legal food additive and therefore did not inform the USDA of its position on the Declaration. Thus, USDA APHIS did not allow the use of ozone on meat and poultry products. This problem was discussed with the FDA and the USDA at length and a suitable solution was not forthcoming.
2. Overshadowing the problems of the GRAS Declaration not being recognized by USDA APHIS was an even more serious problem. It was found that in the original 1982 GRAS Affirmation for the use of ozone in bottled water, a ruling was issued under 184.1(b) (2) which required ... “any other food uses must have a food additive petition”. This ruling has often been called the “Limiting Rule”.

Due to the Limiting Rule, the status of ozone use in food processing remained unclear and subsequently limited FDA acceptance of the 1997 EPRI Expert Panel GRAS Declaration for food products. With the discovery of the “Limiting Rule”, the FDA and EPRI faced a serious dilemma. The FDA could not accept the GRAS Declaration filed by EPRI, yet the GRAS Declaration had stood for two years and several food processors were using or planning to use ozone as an Antimicrobial agent.

The acceptance of the GRAS Declaration and the problems associated with the Limiting Rule were discussed by EPRI, the FDA and numerous user groups in 1998 and 1999. It was determined that the “best” possible solution was for EPRI and other interested parties to submit a Food Additive Petition to the FDA for formal consideration.

Over nine months, following FDA Guidelines and outline, the literature search and preparation of the Food Additive Petition, *Ozone as an Antimicrobial Agent for the Treatment, Storage, and Processing of Foods in Gaseous and Aqueous Phases*, was orchestrated by Dr. Dee M. Graham. Dr. Rip G. Rice provided expertise and prepared the petition. Dr. Charles D. Sopher provided editorial assistance and worked with Dr. Graham in preparing the final version of the petition at the EPRI Washington, DC Office.

The petition was delivered to the FDA and the USDA on August 2, 2000. The petition, then noted as FAP #0A4721, was quickly placed on a “fast track” by the FDA and received expedited review. Formal recognition of submission of the petition was noted in the Federal Register August 15, 2000.

Notice of the acceptance of the Food Additive Petition was published in the Federal Register, Vol. 66, No. 123, Tuesday, June 26, 2001/Rules and Regulations and is quoted as follows:

**“Part 173-Secondary Direct Food Additives
Permitted in Food for Human Consumption**

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.368 is added to subpart D to read as follows:

§ 173.368 Ozone.

Ozone (CAS Reg. No. 10028-15-6) may be safely used in the treatment, storage, and processing of foods, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319) in accordance with the following prescribed conditions:

- (a) The additive is an unstable, colorless gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.
- (b) The additive is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.
- (c) The additive meets the specifications for ozone in the *Food Chemicals Codex*, 4th ed. (1996), p. 277, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined at the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

- (d) The additive is used in contact with food, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319), in the gaseous or aqueous phase in accordance with current industry standards of good manufacturing practice.
- (e) When used on raw agricultural commodities, the use is consistent with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) and not applied for use under section 201(q)(1)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act.

Dated: June 15, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

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The Food Additive Petition

Once it was decided that a Food Additive Petition was the most feasible method of handling the impasse caused by the conflict between the 1997 GRAS Declaration and the Limiting Rule The Food Additive Petition (FAP) was developed and delivered to the FDA for review. It is the goal of this section to provide an overview of the FAP such that individuals interested in the utilization of ozone as an Antimicrobial Agent can have an understanding of the petition. Individuals interested in additional information can contact the US Government Printing Office and obtain a final copy of the FAP under the Freedom of Information Act.

The FAP consists of seven major sections in three volumes that cover all known aspects of ozone. Included are discussions of ozone chemical and physical properties, manufacture, Antimicrobial properties, safety, and applications. Volume three contains copies of references and pertinent citations found in the development of the FAP. In total, the FAP is contained in three volumes consisting of 373 pages of text and nearly 500 pages of copied references. Many of the references are in Japanese, French or German with summaries translated into English. In addition to printed references, the FAP contains considerable information supplied by ozone equipment manufacturers and companies utilizing ozone. All references utilized are cited.

For the reader of this report to fully comprehend the magnitude of the FAP, the complete Reference List and the Table of Contents as they were submitted to the FDA are attached as Appendices I and II.

EPRI Studies and Demonstrations – 1996-2001

As the GRAS Affirmation was being developed and after the publication of the Declaration, EPRI conducted twelve research studies and demonstrations to ascertain the uses of ozone as an Antimicrobial Agent in both the food processing and agriculture production arenas. These studies were discussed with the FDA and continued after the Limiting Rule was discovered. Information from these studies was made available to the FDA and reviewers of the Food Additive Petition. In all cases, ozone was found to be a useful Antimicrobial Agent.

The following summarizes these EPRI studies and demonstrations conducted as part of the on-going efforts to provide alternative solutions to the increasingly important national focus on food safety in the United States

- 1) ***Ozone Reference Guide: an Overview of Ozone Fundamentals and Municipal and Industrial Ozone Applications.*** EPRI, Community Environmental Center, St. Louis, MO. Report CR-106435 (1996)

Objective:

The *Ozone Reference Guide: an Overview of Ozone Fundamentals and Municipal and Industrial Ozone Applications* as prepared by Rip G. Rice, Ph.D., was compiled to present a comprehensive report on all aspects of ozone from its basic properties to its implementation and usage in water treatments.

Findings:

Process engineers wishing to apply ozone most effectively should know all the chemical characteristics of ozone. Many of the potential applications of ozone are neglected due to lack of knowledge of the specifics of ozone chemistry and their potential to solve and eliminate problems. The main chemical characteristics of an ozonation process should always be reviewed prior to planning and implementation to optimize ozone application.

Ozone has many advantages:

- It is the strongest oxidant and disinfectant available commercially for the treatment of aqueous solutions and gaseous mixtures contaminated with oxidizable pollutants and/or microorganisms
- Although only partially soluble in water, it is sufficiently soluble and stable so that its oxidation and/or disinfection properties can be utilized to full advantage
- As ozone does its oxidation/disinfection work, or when it autodecomposes, the stable end-product from ozone itself is oxygen
- Ozone reacts with a large variety of organic compounds, although at varying rates
- Oxidized organic byproducts of ozonation are oxygen-containing. Halogenated organics cannot be produced during ozonation, unless bromide ion is present. The ability of ozone to

produce “free bromine” by oxidation of bromide ion is an advantage of ozone in treatment of swimming pools and cooling towers

- Ozone is safe to handle because it cannot be stored, and thus, must be generated and used on-site. Should an ozone leak be detected, ceasing the flow of electrical power to the ozone generator(s) will cease the production of additional ozone

Ozone has its disadvantages:

- High capital cost compared with other oxidation/disinfection techniques due to the fact that the ozone must be generated on-site, thus eliminating the usual savings from centrally produced chemicals
- The currently most economical generation of ozone in commercially significant quantities (by corona discharge) is an electrically inefficient process due to the fact that more than 75% of the electrical power sent to a corona discharge generator is converted into heat and light. Therefore, the major operation cost of producing ozone is the electrical energy. Even given this fact, ozone can be and is often more cost-effective than alternative treatment techniques
- The equipment required to generate ozone can be complex and intricate to install
- Since ozone is the most powerful oxidizing agent available, it is also potentially the most dangerous of oxidants. This danger was recognized in the early stages of ozone research and techniques have been developed to insure the absence of ozone accidents

2) *Expert Panel Report: Evaluation of the History and Safety of Ozone in Processing Food for Human Consumption.* EPRI, Palo Alto, CA. TR-108026, vol. 1-3 (1997)

Objective:

The objective of this study was to clarify the regulatory status of ozone and seek Generally Recognized as Safe (GRAS) status for ozone use in food processing in the United States.

Results:

The Expert Panel Report provides an unequivocal declaration of GRAS status for ozone use in food processing. As required by FDA guidelines, the result was published in a scientific journal, *Food Technology*, 51(6):72-75, June 1997. The full report was filed with the FDA, thus providing the basis for immediate use of ozone in food processing. The authority for self determination of GRAS based on scientific procedures is stated in the FDC Act at Section 201(s) and 21 CFR 170.30. Volume one of the report includes a Presentation Summary and the Curriculum Vitae of each of the Expert Panel members. Volume two contains abstracts of the literature assembled by the Expert Panel for review. Volume three contains copies of the literature articles cited by the Expert Panel.

3) *Use of Ozone for Food Processing*. Food Technology. 51(6):72-75. June 1997.

Objective:

To meet the criteria outlined by the FDA as part of the procedures for GRAS Affirmation of ozone for use as an effective disinfectant or sanitizer for foods, the results of the Expert Panel findings were published in the scientific journal, *Food Technology*, June 1997.

Results:

With the publication of the article *Use of Ozone for Food Processing* by Dee M. Graham, Ph.D., in the June 1997 issue of *Food Technology*, the FDA requirements were met. The article outlined the history and chemistry of ozone technology, ozone applications in the food industry, and the Expert Opinion: Ozone is GRAS.

4) *Ozone Applications in Apple Processing*. EPRI, Palo Alto, CA. TA-112064. (1998)

Objective:

This study was undertaken to examine the application of ozone treatment for reducing yeast and mold count on apples and to develop and provide Technical Transfer materials outlining the findings.

Results:

Tastee Apple, a privately owned processor in Newcomerstown, Ohio and one of the major packers of caramel apples in the U.S. wanted to improve the quality of the apples shipped to customers while at the same time reducing the use of water and the amount of BOD discharged to the publicly owned treatment works. Prior to the demonstration, the flume water was chlorinated to control microorganisms and dumped daily because it accumulated high levels of soil and organics that washed off the apples. To get away from the chlorine usage and extend the use of water, the company installed an ozone treatment system in the flume water.

Results of the company's decision to utilize ozone in its processing showed that the company has greatly improved its operations. Flume water is no longer replaced daily. The company reuses the same water for an entire week, saving more than 12,000 gallons per week. Since the ozonation system is running 24 hours a day, it is able to reduce the BOD load in the flume water. The ozone treatment also reduces the yeast and mold count in the water, resulting in clean apples and longer shelf life. This TechApplication examines the application of ozone treatment for reducing yeast and mold count on apples, discusses and details test results, and lists the costs of installation, piping, wiring and labor. Other ozone applications are also outlined in the publication.

5) *Ozone Use in Agriculture and the Food Industry*. EPRI, Palo Alto, CA. CR-110735. (1998)

Objective:

To respond to the needs of industries to find safe, effective, and economical alternatives to conventional disinfection technologies, this report was prepared by Tom Chester and is based on the EPRI *Ozone Reference Guide* (CR-106435).

Results:

Ozone shows much promise in the agriculture industry, but more research and development is required before it can be widely used in this area. Prior to ozone being declared GRAS (Generally Recognized as Safe) in 1997, ozone was not approved for food sanitation, so the food industry was limited to using it mainly for the treatment of wash water and wastewater. Food processors are now beginning to use ozone for sanitation. Ozone eliminates a significant problem associated with chlorine disinfection: the potential build-up of toxic chlorine residues in water that has been treated more than once.

6) *Ozone in the Food and Agriculture Industries*. EPRI, Palo Alto, CA. TC-113814. (1999).

Objectives:

The objective of this TechCommentary was to explore ways in which the food processing and agriculture industries could apply ozone's special characteristics to their needs for safe, economical alternatives to traditional disinfection and pest control techniques.

Results:

Ozone is now being used as a safe, powerful disinfectant to control biological growth of unwanted organisms in products and equipment used in the food and beverage industries. In liquid solution, ozone can be used to disinfect equipment, process water, and some food products. In gaseous form, ozone helps sanitize and assist in the preservation of certain food products, and is also used to sanitize food packaging materials. Some products currently being preserved with ozone include eggs during cold storage, fresh fruits and vegetables, and fresh fish.

In the agriculture industry ozone is being used for disinfection. Another important application is the use of ozone as an alternative to methyl bromide as a fumigant to control insect infestations in stored food, grains and other agricultural products. It is also being used as a general soil fumigant/sterilant in drip irrigation systems.

Emerging applications include:

- Washing fresh garlic cloves with ozonated water resulting in 2 to 3 log reduction of bacterial counts, suppression of molding and extension of shelf life of finished product
- Sanitizing whole shell eggs to eliminate potentially pathogenic bacteria
- Storing potatoes and other agriculture products in an atmosphere containing gaseous ozone, resulting in dramatic reduction of rot and mold, as well as shelf life extension
- Controlling indoor air quality in confined animal facilities and in egg storage houses
- Treating pre-process wash water for fruits and vegetables harvested in Mexico and transported into the United States
- Sanitizing sausage processing equipment for microbial control and to reduce use of hazardous chemical sanitizers
- Sanitizing chopped celery to remove and inactivate soil bacteria from fresh salad materials
- Sanitizing poultry chiller water to reduce potential pathogenic bacteria, and recondition overflow water for recycling and reuse (within USDA guidelines) with major energy savings
- Sanitizing alfalfa sprouts during growth to block potential pathogen contamination in fresh sprouts
- Controlling potential microbiological contamination in the barley malting process
- Preliminary data indicate that ozone treatment of water in aquaculture tanks greatly reduces foaming even without purifying the water

7) *Ozone Gas as a Soil Fumigant: 1998 Research Program*. EPRI, Palo Alto, CA. TR-113751. (1999).

Objectives:

To meet the challenge to develop environmentally safe alternatives to the scheduled phase out of methyl bromide (to be banned starting in 2001) for soil fumigation, SoilZone, Inc. in 1998 conducted ten field trials utilizing the injection of on-site generated ozone gas into the soil. With initial success in carrot and tomato trials in California, SoilZone, Inc. received assistance contracts from EPRI and Edison Technology Solutions to more widely test this technology to control soilborne pathogens and increase the yields in a range of crops in different geographical locations.

Results:

The results of these field trials generally demonstrated the broad effectiveness of ozone treatment in soils to increase plant yield and reduce the detrimental effects of soil pathogens on a variety of crops and soils under a range of climatic conditions.

When the ozone preplant application was compared to untreated controls, improvements in crop yield and plant vigor were seen in all except those trials conducted on peaches. The results indicate that soil treatment with ozone show a decrease in soil pathogen pressures (due to biocidal effects) and increased nutrient availability due to oxidation of organic compounds.

When ozone is applied as a preplant treatment, these two benefits promote increased plant growth and yield without detrimental environmental effects. Additional work is necessary to be able to accurately predict the specific growth response achieved by ozonation in different crops, soils and climatic conditions.

8) *Ozone Conference II: Abstract Proceedings*. EPRI, Palo Alto, CA. GC-113975. (1999).

Objectives:

The Ozone Conference II: Pre- and Post-Harvest Applications Two Years after GRAS, was held September 27-28, 1999, in Tulare, California to present recent developments in ozone usage in food processing and agricultural applications after GRAS.

Results:

Twenty-two presentations were given during the one and one-half day Conference attended by over 170 participants. Presentations included:

- Ozone fumigation
- Ozone generation techniques
- Ozone system and design applications
- Prewater treatment requirements
- Poultry water reuse
- Soil treatments with ozone gas
- Post-harvest aqueous and gaseous ozone research results.

A live videoconference between Tulare and Washington, DC, was held to discuss the regulators' views on ozone usage. This report is comprised of the Abstracts of each presentation, biographical sketches for each speaker and a registration/attendees list.

9) *Ozone Sanitizing for Meat Processing Equipment: TechApplication*. EPRI, Palo Alto, CA. TA-114172. (1999).

Objectives:

Plumrose USA, Inc. in Booneville, Mississippi wanted to assure the highest possible level of sanitation and protection from potential pathogens and spoilage microbes while minimizing the need to store and handle hazardous chemical cleaners and sanitizers. This plant slices and packages ham, turkey, chicken and deli meats as well as smoking some meat prior to slicing. They maintained an outstanding food safety record using chlorinated detergent cleanser and chlorine-based sanitizers. The company realized that in order to follow the stringent regulations and expense of meeting strict environmental standards, and at the same time contain operating costs and personal safety standards, it would be necessary to change their system.

Plumrose decided to install a state-of-the-art ozone system to provide ozonated water on demand for several sanitizing operations in the processing plant.

Results:

The new ozone system began operation in October 1999. With its installation, the system is providing the highest level of sanitation and has allowed the company to avoid the use and handling of hazardous chemicals. Because of the design of the system, water from the final rinse is recovered, reozonated, and used for the first rinse thereby reducing water usage, effluent burden, and treatment and disposal costs. Additionally, ozone effectively kills *E. Coli*, *Giardia*, *Cryptosporidium*, and other pathogens that resist chlorine. The decision to install the new ozone sanitizing system has resulted in a safer work environment, excellent sanitation and reduced operating costs.

10) *Membrane Filtration and Ozonation of Poultry Chiller Overflow Water: Study of Membrane Treatment to Reduce Water Use and Ozonation for Sanitation at a Poultry Processing Plant in California.* EPRI, Palo Alto, CA. TP-114435. (1999).

Objectives:

Poultry processing plants use large volumes of water and the cost of obtaining and disposal of this water is increasing rapidly. Chlorine is widely used in poultry sanitation operations; however, chlorine generates several byproducts that are harmful to the environment. The objectives of this study were to address these two issues:

- Evaluation of the feasibility of reduction of water use in poultry chiller operation by membrane filtration
- Evaluation of the efficacy of ozonation as an alternative to chlorination in chiller operation

Results:

Trials were conducted with ozone in combination with hydrogen peroxide, Tween 80, and trisodium phosphate. A 30-second rinse of the cavity with ozonated water was done prior to soaking the carcasses for 30 minutes to improve the contact between ozone and the carcass. These trials produced significant reduction of microbial counts.

Results showed that membrane treatment could be used effectively to reduce water use in the chiller operation. Ozonation can be used with proper additives and application methods as a replacement for chlorine in chiller operations.

11) *Ozone and UV for Grain Milling Systems*. EPRI, Palo Alto, CA. Report No. 1000591. (2000).

Objectives:

Harvest States Amber Milling in Huron, Ohio, recognizing the current concerns with food safety, collaborated with First Energy Services and EPRI, on a project to investigate the feasibility of using ozone as a substitute for chlorinated water to control bacteria and mold in grain processing.

The objectives of the project were:

- To utilize ozone in steeping water for the hydration of wheat to 15 percent moisture, prior to milling to flour
- Reduce microbiological activities in steeped and hydrated wheat
- Reduce micro-organisms in the milling facilities and in the wheat or flour products treated with ozone and UV

Results:

The EPRI Tailored Collaboration project began with a plant survey. This survey was followed with a process design, equipment specification and installation performed by RGF Environmental Group. The treatment system used consists of ozone treatment supplemented by photo-ionization (UV), which delivers both ultra-violet light and ozone to create hydroxyl radicals for the control of microorganisms on grain and the processing equipment.

Results of the data gathered during the project indicate a potential 75 to 80 percent reduction in total plate count when ozone is used in place of the traditional chlorinated water treatment. Although the project did not include mold counts to quantify the effectiveness of ozone versus chlorine in mold abatement, visual inspection of equipment and processing lines indicates a similar reduction of mold growth in equipment. RGF, the equipment supplier, estimates cost savings of about \$40,000 per year, using ozonation and UV in place of chlorination. (According to RGF, electrical costs to operate the ozone system are 18 cents per hour or approximately \$1,600 per year; thus, this rate of savings would pay out the capital investment in the ozonation and UV equipment within thirty months).

(It should be noted that this analysis does not include the potential of additional savings from reduction in equipment maintenance and plant downtime previously required to remove mold from processing lines and equipment, and the costs for reprocessing grain which fails to meet microbial standards).

Strickland Produce

12) In addition to the previous eleven studies, a detailed study and demonstration was conducted by EPRI and TVA at Strickland Produce in Nashville, Tennessee. This study was undertaken to find methods of reducing chlorine levels in a cut produce

operation. The study was needed because chlorine levels of 100 ppm were becoming necessary to control microbial levels in packaged salads and slaws.

Although the project findings are in the summary process and the study results have not yet been published, Strickland's project is rapidly becoming a benchmark demonstration showing that utilizing ozone greatly reduces chlorine levels and improves product quality.

Summary

In the early 1990's, the Food Technology Alliance requested EPRI investigate the use of ozone as an Antimicrobial Agent to enhance food safety. This investigation began in 1996 with the convening of an expert panel that declared ozone Generally Recognized as Safe (GRAS) in 1997. Although the GRAS Declaration was deemed the proper method to legally allow the use of ozone in food processing, it was never recognized by the USDA. Later its legality became clouded due to a 1982 ruling limiting the use of ozone in food processing.

To overcome these problems, the FDA encouraged the EPRI AFTA to pursue the development and submission of a Food Additive Petition (FAP) that would allow the use of ozone as a contact Antimicrobial Agent in food processing. The FAP was completed and submitted to the FDA in August 2000. After a rigorous review by the FDA staff, in June 2001, the FDA recognized ozone as an Antimicrobial Agent suitable for use in Food Processing and Agricultural Production.

During the development of the GRAS Declaration and the FAP (1995-2001) EPRI Food and Agricultural customers supported twelve major projects to investigate and demonstrate the use of ozone as an Antimicrobial Agent for food and agricultural processes.

Conclusions

Based on the GRAS Declaration, the FAP and the Research and Demonstration Projects the following was concluded:

- Ozone is a very strong oxidizer capable of acting as a potent contact Antimicrobial Agent in food and agricultural processes
- The numbers of applications of ozone in food and agriculture are still evolving and new uses are being found on a very regular basis
- When used under Good Manufacturing Practices (GMP), ozonation is a very safe process
- Because ozone rapidly oxidizes to oxygen, no residue remains and very few reaction products are produced. An exception to this generalization are bromide byproducts that can become problems
- Although generally safe, the reactions of ozone as an Antimicrobial Agent are often detailed and complicated. For this reason, all uses should be approached with caution and properly planned to avoid costly mistakes.

Both past studies and recent demonstrations have shown ozone to be a very effective Antimicrobial Agent and an excellent tool in food safety when used either alone or in combination with other Antimicrobial Agents such as chlorine and UV light. Because ozone reactions are often complicated and not well understood, new uses are often overlooked or opportunities are missed due to lack of knowledge of ozone and its properties. When utilizing ozone, never underestimate the need for proper planning, the most current technology detailed operating procedures, and maintenance of ozone systems.

Appendix I: References

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SPECIFIC OZONE APPLICATIONS

Poultry and Poultry Chiller Water Processing

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