

CERTIFICATION OF OZONE IN USA FOOD INDUSTRIES

Rip G. Rice, Ph.D.¹ and Dee M. Graham, Ph.D.²

¹ **RICE International Consulting Enterprises,
1331 Patuxent Drive, Ashton, MD 20861
e-mail: RipRice4Ozone@cs.com**

² **R & D Enterprises,
2747 Hutchinson Court, Walnut Creek, CA 94598-4456
e-mail: DeeG213050@aol.com**

ABSTRACT

In response to a Food Additive Petition submitted during August 2000, the U.S. Food and Drug Administration 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). The purpose of this paper is to discuss the FDA approval for ozone and to describe the specific conditions under which ozone may be used (in the USA) when it comes into contact with foods. An Ozone Evaluation Protocol is suggested for new-to-ozone users.

KEY WORDS

**IOA; OZONE; FOODS; US FDA; OZONE EVALUATION PROTOCOL;
PESTICIDE DEVICES; FOOD ADDITIVE PETITION;**

BACKGROUND

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

Attempts to gain U.S. Food and Drug Administration approval for the use of ozone in contact with foodstuffs have been long and arduous. In the early 1980s, the International Bottled Water Association petitioned the FDA to affirm that the application of ozone to disinfect bottled water under specified conditions is GRAS (Generally Recognized As Safe). The conditions included a maximum dosage of ozone of 0.4 mg/L over 4 minutes contact time, and that the water to be treated must already meet the potable water requirements of the U.S. Environmental Protecting Agency. The FDA approved IBWA’s petition for ozone in bottled water, and in 1982 published in the *Code of Federal Regulations* a formal FDA regulation affirming GRAS Status for use

of ozone (3). Later, the 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 [21 C.F.R. 184.1(b)(2)] “All other food additive applications for ozone must be the subject of appropriate Food Additive Petitions.” This statement effectively mandates the filing of Food Additive Petitions in order to gain FDA approval for other uses of ozone in direct contact with foods.

Over 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.

The 1997 EPRI GRAS Declaration

In June 1997, an Expert Panel of Food Scientists convened by the Electric Power Research Institute (4) 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’ underscoring and italicization for emphasis).”

In April, 1997, FDA published a notice in which the agency proposed that any organization willing to affirm a substance as GRAS when coming into contact with foods is free to utilize that substance, provided the organization is willing to accept responsibility for its actions (5). In other words, since affirming a substance to be GRAS does *not* imply formal regulatory approval by the FDA, it is up to the affirming organization, or any organization intending to apply ozone in contact with foods, to understand what ozone is all about, how it is generated and applied, in what exposure levels, and what the consequences of its use are in terms of providing specific benefits. Included in this caution is knowing what disadvantages might accrue from the over-application of ozone to the particular food(s) being treated.

Post-1997 Regulatory Developments with Ozone in the USA

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 continued to slow 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. However, the statement in the 1982 GRAS approval for ozone in bottled water disinfection which says, "All other food applications for ozone must be the subject of

appropriate food additive petition(s)”, continued to impede the development of ozone for food processing applications in the United States.

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”. EPRI agreed with this FAP approach and, with considerable support from several interested food processing organizations, developed such a FAP and formally filed it with the FDA in August 2000 (6). FDA approval of this FAP was published June 26, 2001 (1) in the Federal Register.

Later in the year (Dec. 21, 2001), the USDA’s FSIS approved ozone for use on meat and poultry products, including treatment of ready-to-eat meat and poultry products just prior to packaging (2).

Details of the Food Additive Petition have been discussed by Rice and Graham (7,8), and Rice, Graham and Sopher (9). The entire FAP as filed is available in the CD-Rom disk containing the Proceedings of the IOA/PAG 2001 Annual Conference held in Newport Beach, California, May 5-9, 2001, and is available for \$75 (U.S.) plus postage by contacting the International Ozone Association, Pan American Group, 31 Strawberry Hill Avenue, Stamford, CT 06902-2608, USA (tel: 203-348-3542; fax: 203-967-4845; mistok@int-ozone-assoc.org).

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 United States, and will reassure food processing firms wishing to improve the qualities of their products by approaches involving ozone.

THE REGULATORY APPROVAL OF OZONE

The specific language contained in FDA 2001 (1) and its explanations have been discussed by Rice and Graham (8). In the present paper, the most significant aspects of the FDA's approval language will be discussed.

Ozone (CAS Reg. No. 10028-15-6) may be safely used 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 little 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:

- (a) what minimum exposure to ozone is necessary to provide Antimicrobial benefits on specific foodstuffs? and**
- (b) 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 OSHA (Occupational Safety and Health Administration) PEL¹ or STEL² and/or EPA (Environmental Protection Agency) environmental limits?**

In defining “Antimicrobial agents”, the FDA is showing concern that the agent be added in sufficient amounts/dosages/exposure to accomplish the intended purpose of controlling microorganisms.

Clearly, the user of ozone clearly should not want to cavalierly add excessive ozone to the food product. In addition to costing more money for supplying excess ozone, if there is clear damage to the food product (e.g., bleaching of carrots and broccoli, breaking down of coatings on cranberries, etc.), the ultimate consumer surely will shy away from purchase of such over-ozonated products.

¹ PEL = Permissible Exposure Limit = 0.1 ppm time-weighted average over 8 hrs

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.

EPA REQUIREMENTS FOR OZONE UNDER THE FIFRA

When the FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) was enacted years ago, EPA was required to regulate any chemical for which a pesticidal claim is made. An example of a claim made by purveyors of ozone equipment that can be considered to be a pesticidal claim is “ozone kills/inactivates microorganisms, fungi, molds, algae, etc.). Pesticides historically are chemicals of commerce that are supplied in bulk in cylinders or containers that are shipped throughout a geographic region and are labelled (with approval of the EPA) as such. Ozone does not fall into that category of “chemicals”, in that it is generated and used on-site, is not transported or stored, and quickly dissipates or is self-destroyed during use.

Consequently, in interpreting the requirement of the FIFRA, EPA concluded that ozone is not a “pesticide chemical”, and therefore the gas itself is not to be regulated under the FIFRA. However, ozone generators, while not

² STEL = Short Term Exposure Limit = 0.3 ppm, not to exceed 15 min exposure time no more than three times per day

chemicals, are regulated under the FIFRA as “pesticide devices”, as is equipment that produces ultraviolet radiation.

Under the FIFRA, EPA requires that all pesticide devices (which includes ozone generators) that are made or distributed in the USA, for which a pesticidal claim is made must carry an Establishment Number. This is a number granted by the EPA upon receipt of a properly completed EPA Form 3540-8 (rev. 5/99), “APPLICATION: ESTABLISHMENT REGISTRATION FOR PESTICIDE AND DEVICE PRODUCERS”. The application form can be obtained currently by contacting Ms. Carol L. Buckingham (Room 6118), U.S. Environmental Protection Agency, Agriculture and Ecosystem Division (2225A), 401 M Street, SW, Washington, DC 20460 USA, tel: 202-564-5008; e-mail: buckingham.carol@epa.gov. The requirement applies for any producer of ozone (or UV) generating equipment to be sold in the USA.

Once an Establishment Number has been assigned to a manufacturing facility, that number is required to be placed on devices (ozone generators) produced at that facility.

An establishment number does not constitute EPA regulatory approval for the use of ozone on foods (such as that granted by the FDA on June 26, 2001). It merely confirms that the facility that manufactures ozone generating devices has complied with the registration requirements of the FIFRA.

The complete regulations applicable to Pesticide Producing Establishments (including those producing pesticide devices == ozone generators) are available on the Internet at <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Establishment regulations are in title 40, Part 167 of the Code of Federal Regulations.

NOW THAT OZONE IS LEGAL FOR USE ON FOODS IN THE USA, 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, “Aside from some guidance from the published literature, the wise approach is for the want-to-be-ozone-user 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 even though 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 United States. Consequently, FDA’s approval of ozone in 2001 was simply a “license to study” ozone in its many potential food/ag applications.

A RECOMMENDED OZONE EVALUATION PROTOCOL

The current authors recommend that the following steps be taken whenever a food processor becomes seriously interested in testing ozone:

1. *Select food item or process to be treated with ozone.*
2. *Identify specific spoilage microorganisms that will be involved. Not all foods are spoiled by the same microorganisms.*
3. *Establish ozone or process performance required (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, etc.).*
4. *Check published literature – start with the Food Additive Petition (6) -- if insufficient data are available (as expected), then conduct laboratory studies on those microorganisms to determine ozone dosages and conditions for their inactivation.*
5. *Apply conditions to food/process and confirm results.*
6. *Determine cost-effectiveness.*

In the Food Additive Petition submitted to the FDA, there is a table which 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 (Good Manufacturing Practice). 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.

SUMMARY

Ozone is now approved as an Antimicrobial Agent in direct contact with foods in the gas and/or liquid phases by both the U.S. FDA and the USDA's FSIS. However, it is important for new ozone user to conduct testing with ozone to determine minimum and maximum ozone application/exposure levels prior to designing specific ozonation systems for specific food or agricultural products. An Ozone Evaluation Protocol is presented to accomplish these objectives.

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