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## Milestone Event - *Ozone for Food Processing*

### EPRI Files Food Additive Petition for Ozone as An Antimicrobial Agent

Rip G. Rice 1 and Dee M. Grahain2

1 President, RICE International Consulting Enterprises. Associate Editor, Ozone News 1331 Patuxent Drive, Ashton, MD (USA) 20861 ; RipRice_Ozonet@compuserve.com; rrice@IUVA.org

2 President, R&D Enterprises. 2747 Hutchinson Court, Walnut Creek, CA (USA) 94598 Deeg2 1 3050@aol.com; dgraham@epri.com

On August 2, 2000 a milestone event for ozone occurred when a food additive petition (FAP) was filed by the Electric Power Research Institute (the EPRI) with the U.S. Food and Drug Administration (the FDA) to allow the use of ozone as an antimicrobial agent for direct contact with foods. The FAP was accepted for expedited review by the FDA and action is expected in 60 to 90 days.

### 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 blockage to 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.

### Regulatory Impediments to the Use of Ozone

#### *Food Additive Petitions*

A Food Additive Petition (FAP) is required for approval of a candidate material as a food additive. A major problem with filing a FAP for ozone is that the petitioner must present a range of data showing the minimum amount of exposure to ozone below which ozone is ineffective for its intended purpose, and also data to show the maximum amount of exposure to ozone above which ozone will damage the food item. For a long time, the FDA also required petitioners for ozone approval to present data showing that byproducts formed during ozonation will not be toxic to consumers. Since ozone was not approved by the FDA for food contact, the reciprocal statement became tine - the application of ozone in direct contact with foods is illegal in the USA.

BIOZONE MANUFACTURING (PTY) LTD
**REG NO:** 2020/610707/07
**DIRECTORS:** I. Wright (MD) C. Wright R. Pillay B. Sakuneka
Unit 177, Olympic Duel Avenue
Northlands Business Park
New Market Road, North Riding, 2194
P.O. Box 735, North Riding, 2162
+27 (0)11 791 4403 // office@biozone.co.za

For the small food processor wanting to use ozone to lower microorganism counts on the surfaces of foods to reduce the risks from potential pathogens and to extend the product shelf life, these FDA requirements discouraged the commercialization of ozone for food processing. Approval requires many months, often years, of testing and data gathering for each application - a costly undertaking to say the least. In point of fact, even today, the FDA has not approved any food additive petition involving ozone. On the other hand, the long- anticipated regulatory breakthrough may finally be at hand.

***Gras Affirmations***

Prior to early 1997, the FDA accepted petitions to affirm the GRAS (Generally Recognized As Safe) status of various materials used in food processing. GRAS status could be based on a long history of safe commercial use of such materials prior to passage of the Food, Drug and Cosmetic Act (in the late 1950s). A second procedure to obtain GRAS status was for a panel of recognized (by the FDA) food experts to determine, based on published scientific studies as well as their own direct knowledge and experience in the field of food safety. that the use of a certain material in contact food processing under Good Manufacturing Practices is Generally Recognized as Safe (GRAS). In early 1997. FDA declared that it would no longer accept GRAS petitions; - however, the Expert Panel GRAS affirmation route still is available (FDA, 1997).

***Gras Affirmation of* Ozone *for Bottled Water Treatment***

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. 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 meet the potable water requirements of the U.S. Environmental Protecting Agency. The FDA approved the application for bottled water, and in 1982 published in the *Code of Federal Regulations* a formal FDA regulation affirming GRAS Status for use of ozone (FDA, 1982). Later, the FDA also approved the use of ozone as a **sanitizing agent** for bottled water treatment lines, under a similar GRAS petition.

***At the present time, these** two bottled **water applications are the only FDA - approved food applications for ozone.***

Unfortunately, the GRAS approval for ozone disinfection of bottled water in 1982 contained the statement [21 C.F.R. l84.l(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 the use of ozone in direct contact with foods.

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P.O. Box 735, North Riding, 2162
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**The *1997* EPRI** GRAS **Declaration**

In June 1997, an Expert Panel of Food Scientists convened by the EPRI (EPRI, 1997) 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 for emphasis)."**

Naturally, the FDA had been advised of the creation of the EPRI-sponsored panel of for experts, their technical qualifications, and the intent of this group. Additionally, a copy of the FPRJ-sponsored Expert Panel Report was provided to the FDA for their information. By FDA's own internal policies, the agency has 90-days after receipt of such a document to disagree or to otherwise indicate that it has problems with the GRAS declaration

No such disagreement with the EPRI GRAS declaration has been received since it was published in June 199 (Graham, 1997)

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 (FDA, 1997). 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 gives a clear green light to food processors to test and use ozone for a variety of food processing applications. Also, the lack of a negative response from FDA to the EPRI GRAS declaration supports the EPRI Expert Panel conclusions. And although FDA's published proposal not to contest food applications for substances that have been affirmed to be GRAS by a duly constituted panel of experts, nevertheless the lack of specific regulatory approval for ozone published in the Federal Register continues to disturb many food processors and still slows the broader acceptance of ozone in the food industry.

FDA recognizes this, and also recognizes 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)', continues to impede the development of ozone for food processing applications.

Consequently, in mid-1999, the FDA suggested to the EPRI that a single FAP which provides FDA with

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New Market Road, North Riding, 2194
P.O. Box 735, North Riding, 2162
+27 (0)11 791 4403 // office@biozone.co.za

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 has agreed with this FAP approach and, with considerable support from several interested food processing organizations, has developed such a FAP and formally filed it with the FDA in August 2000 (EPRI, 2000). Responsive action on this FAP from the FDA is expected beginning in 2001.

Formal regulatory approval by the FDA for the use of ozone as an Antimicrobial Agent in direct contact with foods will clear 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 EPRI Ozone Antimicrobial Food Additive Petition**

This FAP is rather large (> 400 pages plus cited references) and involves a review of as much published information on the subject of antimicrobial effects of ozone on as many specific types of foods as these authors could assemble within the time frame involved. Many organizations in the food industry have assisted in this effort, and their help is acknowledged with gratitude.

The basic outline of the FAP is as follows:

> ***Title: Ozone as an Antimicrobial Agent for the Treatment, Storage and Processing of Foods in Gaseous and Aqueous Phases***
>
> ***Outline:***
>
> Identity/Technical Properties of Ozone
> Amounts of Ozone, Purpose(s),
> Directions and Labeling
> Supportive Data for Specific Ozone
> Applications
> Specific Applications for Ozone
> Analytical Methods for Ozone
> Safety of Ozone
> Tolerance Conditions and Proposed
> Regulation
> Modification of Existing Regulation
> Environmental Assessment
> Each of these sections is required by the FDA for any FAP.

Copies of the FAP are only available through the FDA's Freedom of Information Office in Washington, DC. Once the FAP has been approved by the FDA, then EPRL is expected to make copies of the FAP itself available for a fee, but not copies of the literature references. This is because FDA might request some additional information to be submitted or for some modifications to be made prior to final approval.

In a paper presented at the IOA's PAG Orlando meeting and again at the IOA's EA3G Berlin meeting (both in October 2000), the authors of the FAP presented a detailed discussion of the subject matter and

included the **following Summary And Recommendations:**

"It is abundantly clear that ozone is a remarkably effective microbiocidal agent. However, it is also a very powerful and effective oxidizing agent as well. The trick to the propitious use of ozone in treating food products is to apply sufficient ozone to accomplish its intended purpose(s), but to ensure that not enough ozone is applied to damage the food by oxidation. For example, ozone treatment of carrots resulted in somewhat lighter colors (Liew; and Prange, 1994).

Therefore, anyone wishing to apply ozone to control microorganisms on a particular food, whether the ozone is employed in the aqueous or gas phases, is advised to conduct sufficient testing to determine the following:

1. The minimum ozone exposure to accomplish the intended purpose(s)

2. The maximum ozone exposure above which the food is damaged oxidant

3. The conditions of ozone application so as to protect plant workers from being exposed to ozone

4. The costs of ozone application under these "good manufacturing practices".

**References**

EPRI, 1997, Technical Report-108026, Vols. 1, 2, 3 Expert Panel Report: "Evaluation of the History and Safety of Ozone in Processing Food for Human Consumption" (EPRI, 3412 Hillview Ave., Palo Alto, CA 94304)

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