

# Public Citizen 30 YEARS

*Protecting Health,  
Safety & Democracy*

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Joan Claybrook, President

July 24, 2001

Dockets Management Branch  
Food and Drug Administration  
HFA-305  
5630 Fishers Lane - Room 1061  
Rockville, MD 20852

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**Re: Docket No. 00F-1482** — “Secondary Direct Food Additives Permitted in Food for Human Consumption.”

**AMENDED TO REPLACE COMMENTS FILED JULY 20, 2001**

To whom it may concern:

Under the provisions of 21 CFR §12.24, Public Citizen is requesting a stay of action and a formal evidentiary public hearing for the purposes of revoking the Food and Drug Administration’s ruling on Docket No. 00F-1482 (66 FR 33829; 6/26/01).

We have identified and seek to present at a public hearing genuine and substantial issues containing evidence that raises material issues of fact, and which questions in a material way the rationale of this ruling. Due to substantial, material shortcomings in the rationale of this ruling, potential risks to public health have not been sufficiently examined.

(1) In its ruling, the FDA did not establish a “safety factor in applying animal experimentation data to man of 100 to 1 ... that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100<sup>th</sup> of the maximum amount demonstrated to be without harm to experimental animals,” as required by 21 CFR §170.22.

*Public Citizen is requesting a formal evidentiary public hearing on this matter.*

(2) In its ruling, the FDA did not certify that it followed the “principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council,” as required by 21 CFR §170.20.

*Public Citizen is requesting a formal evidentiary public hearing on this matter.*

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(3) In its ruling, the FDA stated that based on the "data in the petition" submitted by the Electric Power Research Institute and Food Technology Alliance, "and other relevant material," the use of ozone as food additive is safe. This conclusion is unsound on two counts:

- a) There is insufficient scientific data available to make such a conclusion. Due to its high oxidizing potential, ozone not only reacts with microorganisms, it also:

reacts with other particles and compounds if placed in an environment such as food that is rich in organic matter... It is difficult to predict how ozone reacts in the presence of organic matter. It can oxidize or ionize the compound, or spontaneously decompose to oxygen and free radicals. Mechanisms of decomposition of ozone are complex processes that depend on factors such as the types of radicals formed in solution and various types of organic matter present.<sup>1</sup>

Additionally, the chemical byproducts of ozonization are known for only a very small number of substances, leading researchers to caution: "[O]ur knowledge in this area is quite limited, and from a public health perspective such information [regarding ozonization byproducts] should be obtained before ozone use becomes widespread."<sup>2</sup>

Currently, the National Center for Environmental Research at the Research Triangle Institute is studying the human dietary ingestion exposures to water disinfection byproducts (DBPs) via food. This three-year, EPA-funded study will examine how DBPs — especially those produced by ozonization — are absorbed by food and beverages. The project is particularly designed to examine the risks that DBPs pose to children, and is intended to confirm the significance of this exposure pathway for these byproducts.<sup>3</sup>

- b) The FDA has failed to take account of a substantial body of scientific research that has identified carcinogenic and mutagenic byproducts of ozonization. These include *hydroxyl radicals*, an extremely reactive free radical species that can damage virtually any organic substance;<sup>4</sup> *unsaturated aldehydes*, which are particularly reactive with certain biological molecules and have been shown to block protein and DNA synthesis;<sup>5</sup> and *epoxides*, which are highly mutagenic and variably carcinogenic.<sup>6</sup>

Accordingly, researchers have cautioned:

Ozone is an extremely powerful oxidant which has a remarkable effect on organic matter... One inescapable conclusion from the molecular mechanism for the reactions of ozone is that free radicals will be generated in excess of the normal level present in tissue... Such mechanisms as aging, carcinogenesis, genetic damage, hormonal action and pathological disturbance will all be influenced by the abnormal production of free radicals.<sup>7</sup>

This ruling should not take effect until a comprehensive study into the carcinogenicity and mutagenicity of the chemical byproducts of ozonization is conducted. The FDA should thoroughly evaluate these risks before commercial interests invest heavily in a novel food technology that is potentially hazardous.

*Public Citizen is requesting a formal evidentiary public hearing on this matter.*

(4) In its ruling, the FDA stated that, based on the “data in the petition and other relevant material,” the proposed use of ozone “will achieve its intended technical effect.” This conclusion failed to take account substantial scientific evidence showing that ozone’s effectiveness is limited in several ways:

- a) *Limited bactericidal properties:* While ozone is effective against some strains of bacteria, against others it is neutral, and against others it has no reductive effect. Researchers studying beef, for example, recently found that a particular ozonization treatment “was not effective (at the concentrations tested) as a decontamination strategy for the reduction of bacterial contamination.” They stated: “Researchers believe that when treating a sample that is high in organic matter, ozone is decomposed by the organic matter before the ozone has an opportunity to inactivate microorganisms present on the tissue sample.”<sup>8</sup>
- b) *Higher growth rates of bacteria:* After finding recently that ozone-treated water had higher bacteria growth rates than water treated by other forms of sterilization, researchers stated: “This may indicate that the breakdown products of organic water contaminants ... produced during ozone treatment are better nutrients for bacteria than the original organic matter.”<sup>9</sup> Since many food products contain water, this finding could have significant consequences for the use of ozone in food processing — particularly if ozonization can actually *promote* the growth of bacteria.
- c) *Limited application:* there is evidence that ozone has no reductive effect if bacteria colonies are established or if a food sample is heavily contaminated.<sup>10</sup>

These findings call into question the ability of ozone to achieve its intended technical effect. More research is required to determine its proficiency and minimize any risks to human health.

*Public Citizen is requesting a formal evidentiary public hearing on this matter.*

On an even more fundamental level, Public Citizen believes that the ozone treatment of food products is yet another example of the food industry’s flawed approach to food safety, which depends increasingly upon technological quick-fixes. Instead, effort needs to be directed at *preventing* contamination by tackling its root causes, such as unclean production processes and overloaded production lines in the meat industry.

Taken together, these flaws in the FDA’s Final Rule represent genuine and substantial issues containing evidence that raises material issues of fact and questions in a material way the rationale of the ruling. Due to these substantial, material flaws, potential risks to public health have not been sufficiently examined.

We request that a formal evidentiary public hearing on these issues be held at the earliest possible date.

Respectfully submitted,



Wenonah Hauter  
Director,  
Critical Mass Energy and Environment Program

## Notes

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<sup>1</sup> Kim, Jin-Gab et al. "Application of ozone for enhancing the microbiological safety and quality of foods: A review." *Journal of Food Protection*, 62:1071-1087, 1999.

<sup>2</sup> Glaze, William. "Reaction products of ozone: A review." *Environmental Health Perspectives*, 69:151-157, 1986.

<sup>3</sup> "Assessment of Human Dietary Ingestion Exposures to Water Disinfection Byproducts Via Food." National Center for Environmental Research, Office of Research and Development, U.S. Environmental Protection Agency. EPA Grant Number R826836, Oct 1, 1998 - Sept. 30, 2001.

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.

<sup>6</sup> Carmichael, N.G. "The health implications of water treatment with ozone." *Life Sciences*, 30:117-129, 1982.

<sup>7</sup> Ibid.

<sup>8</sup> Smith, C.D. et al. "Effects of activated ozone, as a decontaminant intervention, when applied to hides, carcasses, and to ground beef during blending." 2001 Animal Sciences Research Report, Department of Animal Sciences, Colorado State University.

<sup>9</sup> Kim et al.

<sup>10</sup> Horvath, M.L. et al. "Fields of utilization of ozone," in *Ozone*, R.J.H. Clark (ed.), New York: Elsevier Science Publishing, 1985. Cited in Kim et al.