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Joan Claybrook, President

**Remarks by Mark Worth,
Research Director,
Energy and Environment Program
to the U.S. Food and Drug Administration**

College Park – Jan. 12, 2005

Good morning. I thank you for the opportunity to discuss the increasingly crucial issue of the safety and wholesomeness of irradiated foods.

Allow me to reiterate serious concerns we have raised in two of the many reports we have published over the past five years.

In *Bad Taste*, we examine WHO-IAEA-FAO documents from 1994, 1995 and 1999, which laid the foundation for the ongoing effort to allow any food grown virtually anywhere in the world to be irradiated at any dose – no matter how high.

As hard as it is to believe, research that the agencies initially claimed yielded adverse health effects in lab animals that ate irradiated foods, were later classified as “negative” in these official reports. The United States is just one of many countries that have relied on the WHO-IAEA-FAO endorsement of irradiated foods to shape their public policy.

In the 1994 and 1995 reports, for example, 32 studies initially classified as yielding adverse effects were re-classified as negative in the 1999 report. These health problems include increased mortality, fatal internal bleeding, decreased fertility, tumors, mutations, stunted growth, liver and thyroid malfunction, a blood disorder, prolonged estrous cycles and atrophied testicles.

All told, there are 52 discrepancies in which studies that yielded adverse health effects were reclassified as negative, or in which such studies were completely omitted from later official reports. These discrepancies have never been explained.¹ (Attachment 1)

In *Broken Record*, we examine the adequacy of the FDA’s regulation of irradiated foods.

The agency demonstrated courage and integrity in 1968 when it banned serving irradiated bacon to military personnel during the Vietnam War. Incredibly, the irradiated bacon was deemed too dangerous to feed to soldiers who were *already* risking their lives on the battlefield. The agency banned the food after secret Army documents that finally came to light showed serious health

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problems in lab animals that ate irradiated foods – including cancer in rats, higher mortality rates among very young rats, and low weight gain among rats and dogs.

The scandal forced the Army to withdraw its petition to irradiate ham, and forced the Army and Atomic Energy Commission to withdraw their petitions to irradiate lemons, oranges and strawberries.

For reasons that remain unclear, the FDA has since reversed its position and now believes that irradiated foods are safe for human consumption.

The agency has done this despite the formation of dozens of potentially hazardous chemicals in irradiated foods. Benzene levels in irradiated beef, for example, increase by 650 percent. The FDA contends that because benzene already occurs naturally in eggs, more benzene in the food supply would not pose a health threat. But what if these higher benzene levels are greater than what the human body can tolerate? The FDA's Irradiated Food Committee concluded in 1980 that this is not a danger. In the first of many shortcomings, the Committee provided no scientific evidence to support its claim.

In addition, the Committee prescribed a battery of animal experiments far less extensive than those mandated by the agency's *Toxicological Principles*. Critical experiments such as two-year carcinogenicity tests on rodents, and a multigeneration reproduction and teratology test on rodents, were not prescribed.

The FDA has not complied with the requirements handed down by the Committee, as lenient as they are. The agency has not produced a battery of experiments that meet the Committee's requirements. The agency has legalized irradiation based on research that does not comply with the *Toxicological Principles*. And the agency legalized irradiation for poultry, beef, eggs and sprouting seeds without ensuring that radiolytic products in animal experiments were "maximized."

Finally, the seven key studies the FDA relied upon to approve its "Omnibus Rule" in 1986 are gravely flawed. None of the seven studies complies with the agency's *Toxicological Principles*. Researchers in two of the studies added substantial amounts of vitamin E and other nutrients *specifically* to reverse the harmful effects of consuming irradiated foods, which were well known at the time. Some of the studies actually suggest irradiated foods may *not* be safe to eat. (Allow me to note that three of the seven studies were written in French. Because the FDA could not produce English versions, Public Citizen had the studies translated.)² (Attachment 2)

I have left perhaps the most flagrant example of FDA inadequacy to the last.

In 1979 the Federation of American Societies for Experimental Biology (FASEB) completed an Army-funded study on radiolytic products in irradiated beef.³

Supplement II of the report raises specific concerns about 2-alkylcyclobutanones, 2-ACBs: "Nothing is known of the fate and toxicity of the [2-ACBs], so no judgment can be rendered on

their possible health effects.” FASEB concluded that “metabolic and toxicological studies of these compounds are desirable.”⁴ (Attachment 3)

The FDA cited the Supplement in its 1984 proposed Omnibus Rule,⁵ which effectively became the basis for every irradiation petition the agency has granted since then – pork, fruit, vegetables, spices, poultry, red meat, eggs and sprouting seeds.

Though the proposed Omnibus Rule cited the Supplement, we frankly are surprised and disturbed that the Rule does *not* discuss FASEB’s concerns and recommendations regarding 2-ACBs – nor has any other food irradiation Rule the FDA has ever handed down.

There are only two possible scenarios: either the agency cited the Supplement without reading it thoroughly, or the agency was aware of FASEB’s concerns and recommendations but ignored them. Either scenario exposes serious flaws in the way the FDA has attempted to assess the safety of irradiated foods.

Whether the oversight has been accidental or intentional, the FDA’s failure to examine the potential hazards of 2-ACBs explains how the agency was able to justify this statement, made in 1987: “There is no evidence, or any reason to believe, that the toxicity or carcinogenicity of any unique radiolytic products is different from that of other food components.”⁶ There is never a problem where no one ever looks.

History has validated FASEB’s warnings – while rendering false the FDA’s long-held position that radiolytic products are no different than natural food components. As you are well aware, a recent series of *in vivo* and *in vitro* experiments conducted in Europe show that 2-ACBs have cytotoxic, genotoxic and tumor-promoting qualities.⁷

In addition, FASEB’s concerns about the unknown “fate” of 2-ACBs in the body were repeated in 2001 by the European scientists, who said studies of “the metabolism of 2-ACBs in the living organism...are deemed necessary to gain insight into the mechanisms of the toxic effects.”⁸

In the face of warnings dating back 25 years, your agency has admitted conducting *no* research into the toxicity of 2-ACBs.

The more we examine the past, the more concerned we become about the future. We would react very negatively if the U.S. Food and Drug Administration approves any further petitions before the many lingering problems and questions regarding the safety and wholesomeness of irradiated foods are thoroughly examined. If unacceptable health risks are identified, the FDA should promptly ban all irradiated foods within the United States.

I thank you very much for your time and attention.

Notes

¹ *Bad Taste: The Disturbing Truth About the World Health Organization's Endorsement of Food Irradiation*. Public Citizen, Washington, D.C., and Global Resource Action Center for the Environment, New York, N.Y., October 2002.

² *A Broken Record: How the FDA Legalized - and Continues to Legalize - Food Irradiation Without Testing it for Safety*. Public Citizen, Washington, D.C.; Cancer Prevention Coalition, Chicago, Ill.; and Global Resource Action Center for the Environment, New York, N.Y., October 2000.

³ *Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef*. Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, Maryland. Prepared for U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, Maryland, Contract No. DAMD-17-76-C-6055. August 1977.

⁴ *Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef. Supplement II: Possible Radiolytic Compounds*. Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, Maryland. Prepared for U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, Maryland, Contract No. DAMD-17-76-C-6055. March 1979.

⁵ Federal Register, Vol. 49, No. 31, p. 5721, Feb. 14, 1984.

⁶ Federal Register, Vol. 52, No. 35, p. 5450, Feb. 23, 1987.

⁷ D. Burnouf, H. Delincée, A. Hartwig, E. Marchioni, M. Miesch, F. Raul, D. Werner. Etude toxicologique transfrontalière destinée à évaluer le risque encouru lors de la consommation d'aliments gras ionisés - Toxikologische Untersuchung zur Risikobewertung beim Verzehr von bestrahlten fetthaltigen Lebensmitteln - Eine französisch-deutsche Studie im Grenzraum Oberrhein, Rapport final / Schlussbericht Interreg II, projet / Projekt No. 3.171. BFE-R-02-02, Federal Research Centre for Nutrition, Karlsruhe, Germany, 2001.

⁸ Ibid.