



December 18, 2002

Livestock and Seed Programs
Agricultural Marketing Service
U.S. Department of Agriculture
Stop 0249, Room 2092-S
Washington, DC 20250-0249
Fax: (202) 720-3499

Re: Public Comment on 2002 Farm Bill Food Safety Technologies Provision

Dear Sir or Madam:

On behalf of Public Citizen and the Center for Food Safety, two non-profit consumer organizations, we would like to comment on the United States Department of Agriculture's efforts to implement the provisions of Section 4201 (b) (3) of the Farm Security and Rural Investment Act of 2002 (Farm Bill) – "Use of Approved Food Safety Technologies."

Flawed Process

We would like to state, at the outset, that the comment period on this issue and the notice for it are not sufficient. We make this observation for a number of reasons.

- The November 22, 2002 press release issued by the USDA press office did not specifically mention a deadline for submission of comments. It was only after we contacted the USDA press office that we learned of the thirty-day comment period that is due to expire on December 22, 2002 (that falls on a Sunday). Consequently, we do not believe that the public was properly notified of this comment period;
- The comment period falls during the holiday season when most people's attention is focused elsewhere;
- The Managers' Statement that accompanied this section of the Farm Bill stated: "The Managers expect the Secretary to continue to make commodity purchases, taking into consideration the acceptability by recipients of products purchased and considering the relative costs of products available for purchase."¹ A thirty-day comment period is not sufficient to gauge consumer acceptance or rejection of controversial technologies such as

¹ Joint Explanatory Statement of the Committee of Conference, Farm Security and Rural Investment Act of 2002, p. 119.

irradiation, which your press release specifically cites as one of the technologies you will approve;

- It is our understanding that the contracting specifications for the commodity purchases made for the various nutrition programs USDA administers normally are released during the spring of each year. Consequently, we do not understand why there is a December 22 deadline for comments on this very important issue. Therefore, we strongly urge you to extend the comment period until at least March 31, 2003;
- Even more troubling is the fact that the decision seems to have been already made by the Department even before the comment period has closed. In a December 12, 2002 Reuters story, a USDA official is quoted as saying that the Department intends to permit irradiated products to be served in the National School Lunch Program.²

Farm Security and Rural Investment Act of 2002

Section 4201 (b) (3) of the Farm Bill states the following:

USE OF APPROVED FOOD SAFETY TECHNOLOGY.—

(1) **IN GENERAL.**—In acquiring commodities for distribution through a program specified in paragraph (2), the Secretary shall not prohibit the use of any technology to improve food safety that—

(A) has been approved by the Secretary; or

(B) has been approved or is otherwise allowed by the Secretary of Health and Human Services.

(2) **PROGRAMS.**—A program referred to in paragraph (1) is a program authorized under—

(A) this Act;

(B) the Food Stamp Act of 1977 (7 U.S.C. 2011 et seq.);

(C) the Emergency Food Assistance Act of 1983 (7 U.S.C. 7501 et seq.);

(D) the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.); or

(E) the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.).³

In addition to those programs specifically listed in the legislation, participants in the Food Distribution Program on Indian Reservations and the Commodity Supplemental Food Program will also be affected by this provision. These six programs provide economic and nutritional assistance to the most indigent and vulnerable in our society.

It is obvious from the November 22 press release that it is the intention of the Department to remove the prohibition against commodities that have been treated with irradiation to be purchased for the various nutrition programs that USDA administers. The Department went out of its way to endorse irradiation as a method to implement this section of the Farm Bill. The press release stated:

² Randy Fabi, "Parents Protest U.S. Schools Irradiated Meat Plan," Reuters, http://biz.yahoo.com/rc/021212/food_schools_1.html.

³ Farm Security and Rural Investment Act of 2002.

“For example, the use of irradiation for raw meat and poultry products was approved in 1999 after the Food and Drug Administration (FDA) determined that it was a safe measure in helping reduce food borne pathogens. Food irradiation is recognized by the World Health Organization as one of the most effective food decontamination methods available for meat and poultry products.”⁴

It has been a longstanding policy of the United States Department of Agriculture to prohibit the purchase of commodities that have been treated with irradiation for the various nutrition programs it administers. For example, the most current “Technical Data Supplement (TDS) for the Procurement of Frozen Ground Beef Items, TDS-136 -- June 2000, Modified – 2002” contains the following statement:

“Irradiation of raw materials or finished products will not be allowed as an intervention step.”⁵

For the National School Lunch Program alone, the USDA purchased 142,050,000 pounds of frozen beef products during the 2001-2002 School Year.⁶ According to FY 2002 data provided by the Food and Nutrition Service (FNS), the decision to remove the irradiation prohibition will affect millions of Americans:

National School Lunch Program: 27,909,346 (participants)⁷

Food Stamp Program: 19,110,045⁸

Other Child Nutrition Act programs

National School Breakfast Program: 8,124,889⁹

Child and Adult Care Food Program: 2,812,691¹⁰

Summer Food Service Program: 1,884,749¹¹

After School Snacks Program
(snacks served): 122,000,000¹²

Emergency Food Assistance Program
(pounds distributed): 611,000,000¹³

⁴ United States Department of Agriculture press release, “USDA REQUESTS INPUT REGARDING FARM BILL REQUIREMENT ON APPROVED FOOD SAFETY TECHNOLOGIES FOR USE IN COMMODITY PURCHASE PROGRAMS,” November 22, 2002.

⁵ United States Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Program, “Technical Data Supplement (TDS) for the Procurement of Frozen Ground Beef Items, TDS-136 – June 2000, Modified – June 2002, p.2.

⁶ United States Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Program, <http://www.ams.usda.gov/lsg/cp/beef/BEEF%20Vendor%20state%20Tables%20SY01-02.pdf>.

⁷ United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/slfypart.htm>.

⁸ United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/fsfypart.htm>.

⁹ United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/sbfypart.htm>.

¹⁰ United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/ccfypart.htm>.

¹¹ United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/sffypart.htm>.

¹² United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/annual.htm>.

Food Distribution Program on Indian Reservations: 110,000 (participants)¹⁴

Commodity Supplemental Food Program: 427,300 (participants)¹⁵

Removing the prohibition will turn these programs into the largest distribution of irradiated food products ever undertaken in the world. It will also turn millions of Americans, particularly children, into unwitting laboratory experiments to determine whether this technology, whose chemical by-products are still being studied for their potential harmful effects, is really safe. What makes this decision even more reprehensible is the fact that the most vulnerable in our society will not have a choice in the matter, nor will they have to be informed that they are consuming foods that have been treated with a controversial and potentially unsafe technology because current regulations do not require meals prepared with irradiated foods to carry identifying labels.

Public Perception of Irradiation/Labeling

There have been a number of studies done on consumer attitudes toward irradiated food and the labeling required for it. While some conducted by industry have been showing increased support for irradiation, there is still significant opposition to consuming foods treated with this technology. One notable group that seems consistently to have serious reservations about food irradiation are women who have children living at home.

At the March 2002 Intertech Annual Conference on Food Irradiation, Dr. Sean Fox, Agricultural Economics Professor at Kansas State University, reported that based on his research, women who have children living at home were the most opposed to food irradiation.¹⁶

Furthermore, this particular demographic group is the most likely to support labeling for irradiated foods. In a national poll conducted for Public Citizen in January 2002, over four-fifths (83%) of women who had children living at home favored labeling for foods that had been irradiated. This compared with 73% of all persons surveyed who favored food irradiation labeling.¹⁷ This supported findings from a 1999 national poll conducted for the Center for Science in the Public Interest and the American Association of Retired Persons in which 92.9% of female respondents favored labeling for irradiated foods as opposed to 84.0% for male respondents.¹⁸

¹³ Ibid.

¹⁴ United States Department of Agriculture, Food and Nutrition Service, <http://www.fns.usda.gov/pd/fdpart.htm>

¹⁵ Ibid.

¹⁶ MeatNews.com, "Marketing Irradiated Meat," March 29, 2002

<http://www.meatnews.com/index.cfm?fuseaction=article&artNum=2968>.

¹⁷ "Public Citizen: Questions on Irradiated Food and Inspection of Meat-Processing Plants – Banners from an Omnibus Survey of 1000 Nationwide Registered Voters." Lake, Snell, Perry & Associates, Inc., January 13 – 15, 2002.

¹⁸ "Food Irradiation." national public opinion survey of 1000 persons over the age of 18 years conducted for Center for Science in the Public Interest and the American Association of Retired Persons by Buskin-Golding Research, April 16-18, 1999.

Since most of the nutrition programs targeted in Section 4201(b)(3) of the Farm Bill benefit children, it is likely that USDA will suffer a significant backlash from parents should the prohibition on irradiation be lifted from the commodities purchased for these programs. The Managers of the Farm Bill recognized this possibility, so the Agricultural Marketing Service should tread carefully and deliberately on this issue. The rushed nature of the public comment period does not indicate that the agency is doing this.

It should also be noted that the U.S. Food and Drug Administration conducted six focus groups during the Summer of 2001 (they were held in Calverton, Maryland; Minneapolis, Minnesota; and Sacramento, California) in which consumers were specifically asked their opinions on labeling for irradiated foods. In its report to Congress on this issue, the FDA stated:

“Everyone agreed that irradiated foods should be labeled honestly.”¹⁹

Even after being given more information about the irradiation process, a typical consumer comment during one of the Minneapolis focus group sessions was:

“I’m very hesitant to buy anything that’s irradiated. I want to make sure that it’s labeled clearly and that I have a choice. And, given that choice, with what I know now, I would choose not to.”²⁰

Research on Harmful Effects of Consuming Irradiated Foods

Another aspect of recipient acceptance that USDA must consider is the safety and wholesomeness of irradiation as a food additive. Serious concerns are outlined in the attached Affidavit, incorporated herein by reference, of William W. Au, Ph.D., an expert toxicologist consulting with Public Citizen and the Center for Food Safety. As shown in his attached C.V., Dr. Au is a Professor in the Department of Preventive Medicine and Community Health, University of Texas Medical Branch, in Galveston. His affidavit details the scientific case against providing irradiated foods to vulnerable school children.

In essence, he indicates that it would be plainly arbitrary and capricious for USDA to approve irradiated food aimed at what he describes as a “physically and economically vulnerable” population. He also states that obtaining informed consent from students and parents to accept the risks of irradiated school food is not practically feasible.

Dr. Au’s affidavit refers to a study of human children eating a freshly-irradiated diet, published in 1975 in the *American Journal of Clinical Nutrition*.²¹ It is the **only** controlled, published irradiation study focused on children, albeit in India. As it specifically examined effects on

¹⁹ U.S. Food and Drug Administration, “Congressional Report on Irradiation Food Labeling: House Rept. 107-116; H.R. 2330 and Conference Action P.L. 107-76,” June 2002, p.5.

²⁰“Consumers’ Understanding of Food Irradiation Labeling: Focus Group Report.” submitted to Food and Drug Administration, Center for Food Safety and Applied Nutrition, ORC Macro, April 2002, p. 8.

²¹ The results of this study were supported, and criticisms against it rebutted, by the researchers in two later detailed defenses, which the USDA also should consider. Vijayalaxmi and S.G. Srikantia, 1989, “A review of the studies on the wholesomeness of irradiated wheat, conducted at the National Institute of Nutrition, India.” *Radiation Phys. Chem.* 34:941-952; and Vijayalaxmi, 1999, “Comparison of studies on the wholesomeness of irradiated wheat: A review.” *Nutrition Research* 19:1113-1120.

malnourished children, who are the high-priority recipients of USDA's commodity program food, USDA should consider the study as persuasive. Dr. Au states:

In one study, malnourished children who were fed freshly irradiated wheat had more chromosome aberrations than those who were fed non-irradiated or stored irradiated wheat (Bhaskaram and Sadasivan, 1975)... There may be subpopulations such as undernourished children who are most susceptible to toxic effects of irradiated food. Strong reasons exist for considering children generally to be especially susceptible to toxic materials (Au 2002). Undernourished schoolchildren in the United States are the population segment most likely to consume a high percentage of their daily food intake from the school meal programs (breakfast, snack, and lunch), as their parents have fewer alternative choices due to economic reasons.

Effects that have significant public health implications such as polyploidy, genetic alterations, and tumor promotion are critically important not to ignore when children are involved, especially when those children may be undernourished and have few practical alternatives, therefore are physically and economically vulnerable. The wisdom and fairness of compelled exposure to these effects should be considered seriously and explicitly by USDA with respect to the pending proposal for school food irradiation. Irradiating the food to be eaten by millions of growing children would expose them to toxicity hazards for which it would very difficult, if not impossible, to obtain truly informed consent from them or their parents.

Dr. Au refers to his separate journal-published article that addressed special vulnerabilities of children.²² He comments in that article that profound differences can exist between children and adults as far as exposure to toxic substances. Chemical exposures during childhood could increase health problems such as cancer later in life. This concern is supported by the reported increases in rates of brain cancer in children and of testicular cancer in young adults. He states that regulatory policies generally are still not adequate to protect children.

The reasons for the different vulnerabilities of children and adults are fairly straightforward. Children are more active than adults. As a result, they drink more water, breathe more air and eat more food per pound of body weight compared to adults. Thus, they are proportionally exposed to more toxic chemicals from the environment and from materials they ingest than adults, making them susceptible to toxicants.

Children of course undergo tremendous developmental changes compared to adults. These changes involve complex and integrated activities that lead to differentiation, organogenesis, morphogenesis, rapid and controlled cell division, and developmental stage-specific gene activities. All of these processes can be negatively affected by toxic substances.

Dr. Au's affidavit also highlights the new European information on alkylcyclobutanones. This line of research emerged into view in the English-speaking world only after 1999, when FDA

²² Au, W.W. 2002, "Susceptibility of children to environmental toxic substances." *Int. J. Hygiene and Environ. Health* 205: 501-503.

and USDA approved the sale of irradiated ground beef. Indeed, FDA and USDA have never publicly addressed this new toxicity information. Yet, these European studies, from a well-respected source, establish that substances **unique** to irradiated foods are **cytotoxic, genotoxic, and promote colon tumor formation** in rats.

Two types of alkylcyclobutanones – 2-dodecylcyclobutanone and 2-tetradecylcyclobutanone – have been detected in beef irradiated at 1 kiloGray, far below the maximum allowable dose for beef of 4.5 kiloGray. The concentrations of these chemicals were shown to increase linearly as irradiation doses increased.²³ Additionally, cooking has been shown to reduce the amounts of 2-dodecylcyclobutanone, but "there is no difficulty in detecting it in cooked, irradiated samples."²⁴

The Au affidavit also documents that at least seven peer-reviewed and long published reports found mutagenic effects of irradiated diets fed to mammals. Further, many other experts have called for, at least, more research on food irradiation's safety.²⁵ Notably, 26 medical experts and many other prominent individuals endorsed a detailed warning in a health journal on the dangers of food irradiation generally.²⁶ The list of endorsers is impressive.²⁷

The European alkylcyclobutanone researchers, the most prominent scientists actively working in this area now, "suggest that caution should be exercised before any risk to consumers by exposure to these compounds is denied."²⁸ USDA must likewise exercise caution and must neither deny nor ignore the unresolved questions until the risk issues are settled. If USDA approves the use of irradiated food in school nutrition programs – a decision to intentionally expose students to potentially toxic materials – it would expose the agency to serious scandal, particularly as the new toxicity information from Europe that is now in press is published.

Economically advantaged students would still be able to avoid irradiated food by bringing their own food from home. But, poor students will not be able to avoid it. Anyone who believes "consumer acceptance" for such unequal exposure to a controversial technology will happen without controversy is deluded. Protests and possible litigation will result and will detract from public support for USDA. The health impact and fairness controversies will not go away and they will undercut the faith of students and their parents in long-trusted USDA commodity

²³ Stevenson, M.H. "Identification of irradiated foods." *Food Technology*, 48:141-144, 1994.

²⁴ Crone, A.V.J. et al. "Effect of storage and cooking on the dose response of 2-dodecylcyclobutanone, a potential marker for irradiated chicken." *Journal of the Science of Food and Agriculture*, 58:249-252, 1992. Cited in Stevenson, M.H. "Identification of irradiated foods." *Food Technology*, 48:141-144, 1994.

²⁵ See, Louria, D.B. 1993. Food irradiation: Perceptions of a qualified opponent. *Infectious Diseases in Clinical Practice* 2:313-316; Tritsch, G.L. 2000. Food irradiation. *Nutrition* 16:698-701; Steinberg, J., quoted in R. Papazian 1992. Food irradiation - A hot issue, *Harvard Health Letter*, vol. 17, no. 10, p. 3.

²⁶ Epstein, S.S., and W. Hauter. 2001. Preventing pathogenic food poisoning: Sanitation not irradiation, *Intl. J. of Health Services* 31:187-192.

²⁷ Some examples of prominent MD and Ph.D. endorsers of the warning: Neal Barnard, President, Physicians Committee for Responsible Medicine; Donald Dahlsten, Professor and Associate Dean, Univ. of California, Berkeley; Robert Elder, Senior Microbiologist, Neogen Co.; Samuel Epstein, Emeritus Professor of Environmental Medicine, Univ. of Illinois School of Public Health, and Chairman of the Cancer Prevention Coalition; Jay M. Gould, Director, Radiation and Public Health Project; William Lijinsky, past Director of Chemical Carcinogenesis, Frederick Cancer Research Center; Donald Louria, Chairman, Department of Preventive Medicine, New Jersey Medical School; Vincente Navarro, Professor, The Johns Hopkins Univ. and Univ. of Pompeu Fabra, Spain; and Dr. Quentin Young, past President, American Public Health Association.

²⁸ D. Burnouf, H. Delincée, A. Hartwig, E. Marchioni, M. Miesch, F. Raul, D. Werner. "Comment on a statement of the SCF [EU Scientific Committee on Food] on a report on 2-alkylcyclobutanones." Unpublished report, Sept. 19, 2002.

programs. These amount to additional consumer acceptance and indirect cost factors that USDA must take into account in its decision-making.

Increased Costs of Commodities

Irradiation will add costs to the commodities purchased under the programs enumerated in Section 4201 (b) (3) of the Farm Bill. As the Managers of the legislation anticipated, the treatment of commodities with most, if not all, of the “approved food safety technologies” will engender additional costs to the programs for which they will be procured. For products treated with irradiation, consumers currently pay between \$.02 cents per pound²⁹ to as much as \$.20 per pound³⁰ more than non-irradiated food. If these additional costs were applied to the frozen beef purchases made during the 2001-2002 school year, they would have raised the program costs for the National School Lunch Program between \$4,065,800 and \$40,658,000. Unless there are additional appropriations from the Congress to cover these additional costs, commodity purchases may have to be curtailed to implement this provision of the Farm Bill.

Administrative Concerns

Some irradiation proponents have proposed that irradiated meat purchased for the National School Lunch Program be segregated from non-irradiated meat to allow school districts to opt-out from using irradiated meat should they wish to do so.³¹ How will USDA be able to ensure that such segregation takes place? The controversy surrounding the failure to segregate genetically modified StarLink corn from the human food supply makes such a suggestion seem impractical.

In addition, parents have already expressed an interest in being informed when irradiated food products are being served in the National School Lunch Program.³² We agree that parents should be notified. Should a notification requirement be adopted, whose responsibility will that be? Will it be USDA’s? Will it be the school district’s? Will there be additional costs incurred for such notification? Who will be responsible for those costs?

Potential Conflict of Interest

The Food and Nutrition Service of the USDA administers all of the nutrition programs enumerated in Section 4201 (b) (3) of the Farm Bill. Most of these fall under the jurisdiction of the Special Nutrition Program of the Food and Nutrition Service. The current deputy FNS Administrator for this program is Dr. Peter S. Murano. Dr. Murano is currently on-leave from

²⁹ United States Food and Drug Administration, “Food Irradiation: A Safe Measure,” <http://www.fda.gov/opacom/catalog/irradbro.html>.

³⁰ Patricia Callahan, “Supermarkets Test Appetite for Irradiated Meat,” reprinted from *Wall Street Journal* in *Minnesota Star-Tribune*, November 28, 2002, <http://www.startribune.com/stories/1556/3450026.html>.

³¹ Randy Fabi, “Parents Protest U.S. Schools Irradiated Meat Plan,” Reuters, http://biz.yahoo.com/rc/021212/food_schools_1.html.

³² Ibid.

his teaching position at Texas A & M University and is a well-known food irradiation advocate.³³

Not too long prior to his appointment to his current position at FNS, the SureBeam Corporation, a leading food irradiation company in the United States, entered into a strategic alliance with Texas A & M University.³⁴ Texas A & M signed a 10-year research and development deal with SureBeam. SureBeam provided the school with millions of dollars worth of irradiation equipment – which Texas A&M employees operate at low costs or for free – and SureBeam enjoys the economic benefits. The company has stated that this arrangement is worth more than \$10 million. In March 2002, a research facility was dedicated at Texas A & M in which SureBeam’s electron-beam irradiation technology will be used.³⁵

SureBeam has been actively signing contracts with food processing firms across the country, and it is very likely that one or more of these firms will be bidding on contracts to supply the programs that Dr. Murano is now administering with commodities treated with irradiation.

Incidentally, Dr. Peter Murano is the spouse of the USDA Under Secretary for Food Safety, Dr. Elsa Murano, another well-known advocate for food irradiation.³⁶ Prior to her current position, she served as the Director for the Center for Food Safety at Texas A & M University. We strongly urge that a firewall be established to prevent her involvement in this process.

Conclusion

While we welcome this opportunity to comment on this very important issue, we do not believe that there was proper notice given to the millions of Americans who will be affected by a potential policy change by the USDA. The request for comments needs to be better publicized and more time needs to be allotted to solicit input from the public. In addition, for this process to be meaningful, the Department needs to evaluate all of the comments before moving forward.

Irradiation is not a cure-all for food safety problems in schools. In the last year, several prominent media outlets have exposed a range of problems that can make school food unsafe, ranging from appalling conditions in crumbling school cafeterias, to budget cuts that force administrators to cook food across town from where it is served. There is much that should be done to improve the safety of food served to our nation’s schoolchildren, but irradiation will not get us any closer to that goal.

Finally, and most important, for the health reasons cited above, we believe that the ban on the use of irradiation to treat commodities purchased for the various nutrition programs USDA administers ought to be continued. USDA should increase its inspection resources to ensure that the food processed in meat and poultry facilities is safe and wholesome. Irradiation is not the

³³ see <http://www.tamu.edu/foodscience/fresearch.htm>

³⁴ Titan Corporation, “Titan Corporation and Texas A & M University System Enter into Strategic Alliance,” press release, June 15, 2000 (the Titan Corporation was the former parent of SureBeam).

³⁵ SureBeam Corporation, “Texas A & M Dedicates Nation’s First SureBeam Research Facility,” press release, March 4, 2002.

³⁶ “Food Irradiation Considered Safe,” press release, Texas A & M University, May 16, 2000, <http://agnews.tamu.edu/stories/NUTR/May1600a.htm>.

answer to poor sanitation or improper slaughtering and processing practices in meat and poultry plants. As a consumer during one of the FDA focus groups on food irradiation labeling stated:

“I’d rather see the food-butchered process and packing cleaned up, rather than to kind of keep that dirty and then zap it afterwards.”³⁷

Should you have any questions, please feel free to contact us.

Sincerely,

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³⁷ ORC Macro, op. cit., p. 9.