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Danila B. Oder
Food Irradiation Coordinator
Organic Consumers Association
c/o 6114 Hwy 61
Little Marais, MN 55614
danila@purefood.org

June 27, 2000

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00-014N-5
Danila B. Oder

FSIS-Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service (FSIS)
Room 102, Cotton Annex
300 12th St., S.W.
Washington, DC 20250-3700

Re: Docket No. 00-014N "Announcement of and Request for Comment Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection"

Dear Docket Clerk:

I am the Food Irradiation Coordinator of the nonprofit, public-interest group Organic Consumers Association. We inform and educate the public about food safety, organic farming and sustainable agricultural practices in the U.S. and internationally. Our monthly newsletter has 30,000 subscribers, with 3,000 new subscribers added every month. Our web site <www.purefood.org> receives about 2,000 hits each day, the most active U.S. site dealing with food safety, genetic engineering, and organic agriculture. We are considered a "favorite site" by many journalists and activists worldwide. OCA currently has a staff of 13 people, seven in Minnesota and six in other parts of the country.

We ask FSIS to deny the petition, specifically the following:

- the proposed change to the definition of "hazard"
- the proposed change to the definition of "shipping"
- the replacement of "shipping" with "enters commerce"
- the request to amend 9 CFR 417.6(e) to provide that a HACCP system may be found to be inadequate only when adulterated product has been shipped

If accepted, these changes would allow increased fecal and microbial contamination of the product. In fact, there would be no scientific justification for USDA to impose ANY restrictions on contamination prior to irradiation other than the restrictions that already exist, to wit "food that would be safe in the absence of irradiation," a restriction that the petition seeks to remove. Although the USDA has the power to make the changes requested, we do not believe that Congress, as representative of the people, intended to allow unlimited fecal and microbial contamination in the production of foods, to be 'cleaned up' by irradiation afterwards.

General comments
Regarding the section of the petition "The Definition and Interpretation of a Food Safety Hazard Should Be Amended"

In support of this change, the petition argues that NACMCF Guidelines provide a better definition of 'hazard' than the HACP definition. They argue that "using [the NACMCF] definition [of a hazard] will facilitate development of HACCP plans that focus on food safety, while encouraging firms to utilize prerequisite programs."

Comment: We do not see how the redefinition would give firms any incentive to utilize prerequisite programs, or in fact any limits on fecal contamination prior to irradiation. Irradiation should not be mandated as a knee-jerk alternative to the difficulties industry has found in harmonizing HACCP regulations and prerequisite or GMP programs. We would like FSIS to explain how the consumer will benefit from FSIS abdication of all responsibility for determining the safety *and wholesomeness* of all the meat and poultry produced in this country.

Regarding the section of the petition "The Rule Does Not Adequately Address When a Product Is Within an Establishment's Control"

Comment: The petitioners provide no rationale for changing this section, and appear to ask for changes solely to facilitate the use of irradiation outside the production facility. FSIS should deny this change. We assume that the rationale for the FSIS existing strict definition of "control" is to minimize the possibility that contaminated or dangerous product leaves the processing plant. If the petition is accepted, each year hundreds of millions of pounds of highly contaminated product would leave slaughter facilities. We are quite concerned about the health consequences from consumption of these products, and therefore we believe the FSIS should continue to insist that foods are safe for consumption when they are loaded onto a transport vehicle at the slaughter or processing plant.

In response to the FSIS's specific questions:

2. Would amending 9 CFR 417.2(a) in the manner suggested in the petition result in regulations that provide the level of public health protection required by the Federal Meat Inspection Act and the Poultry Products Inspection Act?
The requested new language is:

> "Every official establishment shall conduct, or have conducted for it, a hazard analysis to develop a list of hazards that are of such severity and significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to cause injury or illness do not require further consideration within a HACCP plan. The hazard analysis shall consider the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer."

Comment:

At present, certain contaminated foods would be considered adulterated under FMIA Sec. 601(m)3 and PPIA Sec. 453(g)3, because FMIA and PPIA do not explicitly include post-production treatments that could reduce the contamination. Irradiated products that exceed current approved levels of contamination *prior to irradiation* would be considered adulterated and not able to be sold under FMIA Sec. 608. However, under FMIA Sec. 624, the USDA Secretary has the power to redefine the regulatory definition of "adulteration", as the petitioners request. The question then is, should the Secretary redefine "adulteration" to allow for unlimited amounts of fecal or bacterial contamination as long as the slaughter/processor includes irradiation in the production process?

This proposal is the next step in the partnership between USDA and the meat and poultry industry to eliminate federal inspection. Acceptance of this proposal will confirm the intent of USDA to conform FSIS to the industry goal of removing federal inspection as an impediment to industry profits.

If accepted, the petition's new language would allow an *unlimited* amount of contamination prior to irradiation. The petition does not use the word "irradiation," but the meaning is clear. Hazards would be *defined in respect to the entire process.* If irradiation is used, USDA will not be able to justify any pre-irradiation controls on microbial adulteration. There is only one possible rationale for intermediate controls if the USDA chooses to permit irradiation at the end of the slaughter/production process: if the USDA *also* requires that *throughout the production process* all food is tested to be safe for human consumption using current HACCP control points, combined with government inspection. But *even these* specified contamination levels could be successfully challenged by industry as "arbitrary" impediments to efficiency. Result: unlimited fecal contamination prior to irradiation.

Unlimited fecal contamination prior to irradiation is within the letter of the law but in our opinion is not the *intent* of the law. The law's intent is to minimize adulteration and contamination. If accepted, the petition would have the effect of *maximizing* adulteration and contamination, then relying on a "magic bullet" to clean it up.

A second point: irradiation at approved doses is not effective against all microbial pathogens, and among targeted bacteria like *Salmonella* some survive. With no incentive to limit contamination prior to irradiation, meat/poultry slaughterhouses and packers will provide a product with substantially higher microbial levels than at present. This will maximize the numbers of remaining radiation-resistant bacteria, which pose a long-term human health threat (by transferring genes to other food bacteria) as well as shortening the time during which currently approved doses of irradiation will be potentially useful.

A third point: if the USDA has no defensible justification for limiting contamination, government inspectors will not be necessary for sanitation controls except to examine paperwork. We believe that company-supplied inspectors will not be as diligent as government inspectors. If there is no government inspection and unlimited contamination, the irradiation facility has to function properly 100% of the time. The public health consequences of even one error in dosing energy could be immense.

Redundant safeguards for food processing are essential. We do not believe irradiation is an appropriate technology to use on *any* food for the public. However, if irradiation is employed, FSIS should permit it only be a *voluntary* supplement to government inspection and pre-HACCP levels of allowable contamination. The petition language cited should not be accepted.

6. Should the changes suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and by other countries?

Comment:
This question asks for a projected reaction by Codex and other countries. We would like to broaden the definition of "other countries" from "other government regulatory agencies" to "the consumers in other countries."

Consumers in other countries. It would be foolish for FSIS to ignore European and other consumers' concerns about the safety and wholesomeness of U.S. meat/poultry products. USDA inspectors have told us that they have personally seen hormone-treated beef being slaughtered, but can no longer intervene because this is not considered a problem under HACCP. Despite USDA denials, this beef is still going to Europe, and European consumers are furious.

The USDA has dragged its feet on regulations to stop ruminant-to-ruminant feeding to prevent BSE in the U.S., and still has not done the necessary testing to determine if a variant form of BSE is present in U.S. downer cows. Consumers in other countries are right to consider U.S. beef a possible carrier of BSE. Antibiotics for growth promotion are still routinely given to animals, especially poultry, reducing these drugs' usefulness in human medicine. Consumers abroad are becoming aware of the risks posed by U.S. use of rBST. All of these dangers to human health are due to USDA collusion with the meat/poultry industry and its drug suppliers. Mandatory irradiation to cover up unlimited fecal contamination will further tarnish the image of U.S. meat/poultry exports, and will provoke intense consumer reaction abroad.

Codex: The section dealing with HACCP is the Annex to CAC/RCP 1-1969, Rev. 3 (1997), found in the Basic Text on Food Hygiene.

The USDA could allow redefinition of their HACCP plan and continue to meet the letter of Codex, because Codex leaves the definition of critical control points to individual regulatory bodies. However, we believe that this would be an unwise decision for the same reasons given in our response to question #2.

Conclusion:

The petition states: "HACCP requires acceptance by industry that it is responsible for ensuring the safety of products it produces. That concept, and the challenges it presents, has been accepted by industry." Hypocritical is too generous a word to describe that statement. If the petition is accepted—even excluding the human health effects of irradiation--food will not be safer than at present, as we have stated: irradiation must work properly 100% of the time, the level of bacterial contamination after irradiation will be higher than at present (and thus contaminated

food will be potentially more toxic if handled improperly), and radiation-resistant bacteria will multiply and transfer resistance to other bacteria.

Again, we would like FSIS to explain how the consumer will benefit from FSIS abdication of all responsibility for determining the safety *and wholesomeness* of all the meat and poultry produced in this country. FSIS would be very unwise to accept the petition.

Sincerely,

Dana B. Ofer
for Organic Consumers Association