IRRADIATION IN MEAT AND POULTRY COMMENTS

April 26, 1999

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102
Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

Re: **FSIS Docket #97-076P**
Irradiation of Meat and Meat Products

S.T.O.P.-Safe Tables Our Priority appreciates the opportunity to comment on the proposed rule to (1) amend the meat inspection regulations to permit the use of ionizing radiation for treating refrigerated or frozen uncooked meat, meat byproducts, and certain other meat food products to reduce the levels of foodborne pathogens and to extend shelf life, and (2) revising existing regulations concerning the use of ionizing radiation in poultry.

S.T.O.P. is a national, not-for-profit organization comprised of victims of foodborne illness, their families and friends, and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness.

FSIS has recognized irradiation as an important technology for helping to ensure the safety of meat and poultry.[1] Recognizing that the larger goal is to increase public health and safety through a safer meat and poultry supply, we urge FSIS to advance rulemaking or changes to existing rules and regulations that will only strengthen, not weaken, standards that are already established.

Consumers Perception of Irradiation

The general public has been "educated" by irradiation advocates, the most vocal being the manufacturers of irradiation equipment, that irradiation produces completely safe, pathogen-free food. This is simply not true, especially for product not irradiated in its final packaging. In fact:

1. Irradiation is not effective against all pathogenic organisms.
2. Food can become re-contaminated before reaching consumers if it is not irradiated in its final packaging.
3. Irradiation is a *reduction* technology, not an elimination technology.

Because of the widespread misunderstanding throughout the public, and the potential health ramifications associated with the misunderstanding, it is critical that if irradiation is used, it utilize effective doses, and that all labeling *truthfully* detail the limitations of irradiation and the need for food preparers to continue to practice safe food handling and to cook foods to safe temperatures.

S.T.O.P. is disappointed that FSIS has proposed a rule that does not require meat and meat products to be irradiated in their final packaging and which also calls to eliminate this current requirement for poultry. Irradiation in the final packaging would make moot the concern of recontamination of intact packages occurring between the time of irradiation and when it gets into the customer's establishment.

Furthermore, S.T.O.P. would like clarification of the benefits cited in the proposed rule. FSIS refers to a 1997 Economic Research Service (ERS) study by Morrison, et al. Morrison, et al.,[2] concluded that the reduction in the incidence of the number of illnesses would be directly proportional to the acceptance of irradiated ground beef; in his estimation, 25% over the next 20 years. We would like to know if this study was conducted with the assumption that ground beef would be irradiated in its final packaging, as was the requirement at the time for poultry. S.T.O.P. suggests that if this is the case, the reduction of foodborne illness statistic is probably inflated because it did not take into consideration re-contamination of product between the time it was irradiated and when it was actually received by the customer.

Minimum/Maximum Doses

In Mario Puzo's book, *Fools Die*, the main character, in an effort to avoid contracting syphilis, winds up dying of it because his self-administered daily dose of penicillin was insufficient in protecting him. He had the right medication but the wrong dosage. Just as insufficient doses of the right medication will be useless in curing or preventing an illness, so will insufficient doses of irradiation in meat and poultry be ineffective in significantly reducing pathogens and protecting the public.

FSIS acknowledges that, "The minimum dosage (of irradiation) for poultry was intended to ensure a certain reduction of pathogens."[3] FSIS further acknowledges that published articles establish *radiation doses necessary to reduce initial bacterial loads* and includes a chart in the proposed rule published by the International Consultative Group on Food Irradiation in August 1996.[4] This chart details dosage ranges for various pathogens. FSIS then states, "Treating the product with the **maximum** (emphasis ours) allowed dose of irradiation, therefore, could result in a significant reduction, or even elimination, of certain pathogens."[5]

FSIS' proposal completely disregards the very issues that it raises, that:

1. There is a range from minimum to maximum for irradiation to be effective.
2. It is the maximum level that is recognized that could result in significant pathogen reduction.

S.T.O.P. strongly opposes FSIS' intention to *not* require minimum doses of irradiation for meat, and furthermore, to propose *eliminating* the minimum irradiation dose for

poultry in order to be consistent with its proposals for meat. Promulgating new policies should be used by FSIS as an *opportunity to strengthen, not weaken, existing policies*. The public looks to FSIS to advance policies that will afford them higher levels of protection, not to weaken existing programs and standards.

We have some serious concerns about FSIS' thinking and goals regarding the drafting of this proposed rule. We question the statement by FSIS that, "It is possible that FSIS will be able to provide for even greater flexibility based upon the comments received in response to this proposal."[6] Is the goal safer food through proper applications of technology or more convenience for companies?

Consumers want more, not less, regulation of food, and will vigorously oppose any steps to deregulate the food industry, particularly by the very agencies that are chartered to protect them.

Irradiation is not effective on grossly contaminated product. The government and industry have repeatedly told consumers that this technology will not be used "to clean up" food that should be unfit for human consumption. To ensure that irradiation is used as it was intended and that it will be an effective microbial reduction technology, S.T.O.P. strongly recommends that only product meeting stringent microbial standards be eligible for irradiation.

1. **FSIS should establish a maximum initial microbial load performance standard for meat or poultry that is to be irradiated.**
2. **Companies must then irradiate with minimum required dosages that will effectively ensure pathogen reduction to another specific performance standard.**
3. **A dosimetry system to ensure that each lot of treated product has received the specified dose should also be a component of this system.**
4. **Finally, there should be end product testing.**

The International Food Safety Council states, "It is important to remember that irradiation only reduces the number of pathogenic bacteria, so the quality of the product prior to irradiation is still critical." [7] Irradiation must not be allowed to be used as an excuse or as a replacement for good sanitary practices by plants or as an excuse for less regulatory oversight by the government.

S.T.O.P. disagrees with FSIS' assertion that under HACCP, establishments should be free to establish their own irradiation programs, including irradiation doses. There is nothing inconsistent with FSIS establishing minimum and maximum standards and/or requirements for technologies that companies wish to incorporate into their HACCP plans, particularly when the public has been led to believe that a particular technology provides them a high level of assurance and safety. After all, FSIS is not mandating the use of the technology but FSIS should certainly require that technologies that are used do so according to scientific recommendations. **S.T.O.P. considers it essential that FSIS establish both minimum and maximum standards and doses for irradiation for both meat and poultry products.**

We do not have confidence in the meat and poultry industries' ability and expertise to determine these limits for themselves. Perhaps there are a few companies that

have the expertise to make these highly sophisticated, highly technical decisions. But experience has shown that some companies, when left up to their own devices and expertise, fail at delivering the intent of the regulation. There have been inadequacies in companies' HACCP plans during the first two waves of HACCP implementation. Some of these plants are the "biggest and brightest". FSIS has found instances of meat and poultry establishments with HACCP plans that may not address all the food safety hazards that are reasonably likely to occur. If consumers cannot even rely on plants to have even the most basic level of "expertise" in identifying hazards that might occur in their own establishment and product, we certainly cannot depend on these same establishments to develop and implement complex technological strategies.

S.T.O.P. had strongly urged the need for FSIS to validate HACCP plans. Our recommendation did not make it into the final rule. A company's HACCP plan issupposed to be validated, but obviously as cited above, there are instances where plans are either not being validated at all or are being validated by inept and/or unqualified people. We do not wish to see the same mistake repeated. FSIS' proposal of using a "processing authority" does not alleviate our concerns. HACCP plans were to be validated by an "authority", and the results were that some plants failed at identifying hazards that could impact public health and safety.

The public deserves to know and be assured that the technological process used on their food was done according to defined scientific standards to achieve its goal, i.e, the significant reduction of pathogens in their food. We want the impartial eyes of government validating the process.

Labeling Requirements

Just as there are consumers who will only want to purchase irradiated products, there are others who are strongly opposed to irradiation and will only want purchase meat and poultry products that have not been irradiated. S.T.O.P. strongly supports FSIS' proposal for labeling requirements for irradiated products that will allow consumers to make an easily informed choice. We agree that irradiated products should be clearly labeled with the radura and a statement that the product has been treated with irradiation.

Specifically:

1. The symbol and statement must be placed prominently and conspicuously on the topside of the package, near the product name.
2. The statement must be printed in a minimum type size so that those with impaired vision can easily read it.

As earlier stated, dangerous misinformation about the efficacy of irradiation has been publicized by irradiation advocates. The public has been lead to believe that irradiation is a "silver bullet" and food treated with it is basically sterile and can be considered safe. The limitations of irradiation, and the possibility of re-contamination after irradiation, have not been communicated to the public. This could leave food

handlers with the misconception that they can treat food more cavalierly, which could lead to additional foodborne illnesses and deaths.

For these reasons, S.T.O.P. feels that FSIS and the food industry have a responsibility to totally and truthfully communicate the limitations of this technology to the public and that it should be done at point-of-purchase on each product's package or on the bulk container.

S.T.O.P. urges FSIS to require additional information on the statement to educate the public about the limitations of irradiation. Specifically, the label should state:

1. Irradiation is a process that *reduces* some pathogens in food.
2. Irradiation is not effective against all types of harmful organisms.
3. This product could have been re-contaminated prior to reaching the store (for meat and poultry products that have not been irradiated in its final packaging).
4. Safe food handling practices must still be observed.
5. Irradiated food must still be cooked to a minimum internal temperature to ensure safety (160 degrees in the case of hamburger, 180 degrees for poultry, etc.) and a thermometer should be used to verify that safety levels have been achieved.

We urge FSIS to require this information on labels for all irradiated meat and poultry products. Furthermore, regardless if an establishment is irradiating only for shelf-life purposes, it should still be required to carry a label with all the same information. Finally, alternative words such "cold pasteurization" should not be allowed to substitute for the term "irradiation" or "radiation".

Incentive Labeling

Unless food is irradiated in its final packaging, S.T.O.P. does not believe that claims of superior food safety can be legitimately made. After irradiation, unpackaged food is immediately susceptible to re-contamination or growth of surviving organisms.

Meat and poultry irradiated in its final packaging is a different situation, however, and incentive labeling should be allowed. However, there must be specific requirements met in order for companies to be allowed to make claims. Specifically:

1. Claims of meat or poultry being "pathogen free", "*Salmonella* free", "*E. coli* O157:H7 free", etc., must be prohibited.

Consumers and consumer groups have repeatedly been unfairly and unjustifiably accused by industry of being totally unrealistic in expecting a 100% guarantee of safe food; that there is no such thing. "Currently, FSIS does not have the scientific data necessary to propose regulations that specifically address the necessary preconditions for an '*E. coli* O157:H7 free' label or similar labels indicating the elimination of other pathogens."[8] Until there is the necessary science supporting such claims, companies must be prohibited from making them.

On a more technical note, irradiation "kills", not "eliminates", bacteria. Irradiated product is not "free" of the bacteria, it still contains the bacteria, albeit dead.

2. Claims such as "treated by irradiation to reduce *Salmonella* and other pathogens" implies increased safety for the consumer. This type of labeling should be allowed as long as the following conditions are met:

- The product is irradiated in its final packaging.
- The product has met a defined public health-based microbial standard for the pathogens(s) that is to be reduced by irradiation. This standard should be defined as at least one microbe below the infectious dose for the most susceptible consumer populations. Many consumers wishing to purchase irradiated meat and poultry are doing so because of perceived safety benefits, ie, reduced pathogens means "I won't get sick". Labeling offering implied health benefits should be held to standards that will afford a minimum level of protection. And because many of the most at-risk populations will be the most interested in purchasing irradiated product, the level of safety must be one that meets their safety needs.

Trace Back

It is especially critical that product that is not irradiated in its final packaging have trace back mechanisms in place. Irradiated meat and poultry can be re-contaminated anywhere along the distribution system from place of irradiation to the customer. As stated earlier, S.T.O.P. is very concerned that consumers will assume that they can handle food more casually if it's irradiated, not understanding that it may have been re-contaminated since the time of irradiation. This leaves them more vulnerable to contracting foodborne illness. It is important that the route of each lot is documented so that if there is a re-contamination problem the various distributors can be investigated and corrective measures can be taken.

Conclusion

S.T.O.P. has some serious concerns about the potential negative consequences of food irradiation, particularly that there could be an unintended rise of foodborne illness if customers of irradiated product, including food processors, retail establishments, grocery stores and consumers, are relying on a sterile product. For these reason, we find it imperative that FSIS build strong safeguards into this rule including initial load microbial performance standards and testing, minimum/maximum dosages based on these standards, informative labeling and effective trace back systems.

Respectfully submitted,

Nancy Donley
President and mother of Alex (1987-1993)

Endnotes

[1] USDA Docket No. 97-076P, page 9090.

[2] USDA Docket No. 97-076P, page 9098 which cites Morrison, R.M., et al., "Irradiating Ground Beef to Enhance Food Safety,," Food Review, January-April 1997, pages 33-37.

[3] USDA Docket No. 97-076P, page 9091.

[4] USDA Docket No. 97-076P, page 9090.

[5] FSIS Backgrounder, "USDA Issues Meat and Poultry Irradiation Proposal," February, 1999, page 2.

[6] USDA Docket No. 97-076P, page 9097.

[7] International Food Safety Council's Best Practices, page 20.

[8] USDA Docket No. 97-076P, page 9094.