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Felicia Satchell
Division Director
FDA Office of Nutritional Products, Labelling and Dietary Supplements
5100 Paint Branch Parkway
College Park, Maryland

Dear Ms Satchell,

GUARDiON, the Food Safety Division of IBA, designs, builds and operates gamma, X-ray and electron beam irradiation facilities. Our company operates 17 irradiation facilities in the United States; several of these used to process food. Our company currently irradiates approximately 90 million pounds of food and food ingredients each year in the US. We have been working with USDA to achieve Grant of Inspection for the irradiation of meat and poultry products in several of these facilities.

GUARDiON has been investigating and grappling with the use of the terms 'pasteurized' and 'electronic pasteurized' for irradiated foods. To this end, we have written and held conversations with Robert Post and colleagues, Lynvel Johnson and Loretta Carey. We acknowledge there are several aspects to the responsible use of these terms in food labeling and so Robert Post suggested we note our comments and reveal some of our opinions on the subject to assist USDA and FDA in their deliberations.

Our comments cover three aspects: the need to be responsive to legislative direction; the need to use the terms in an honest and not misleading way; and the need to inform the public about the positive food safety attributes of irradiated foods. Most of our comments pertain to the use of 'pasteurized' but since the radiation processing industry usually discusses this term in the context of electronic modes of treatment, we have addressed that issue as well.

Legislative direction -

First, concerning responsiveness to legislative direction, FDA has taken too much time to resolve food irradiation labeling issues. In 1997, FDAMA directed FDA to ensure the label on irradiated foods is informative and not negative. The current label requirements of the symbol and words 'irradiated' and 'treated with irradiation' were judged to give people negative opinions about irradiated foods, harming the adoption of this safe food process. FDA, while conducting focus groups and other tasks, has not responded to this legislative direction, five years later. The irradiation

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label remains the same, while competitive techniques such as the use of ethylene oxide for spices, chemical treatments for meat and poultry and methyl bromide for disinfestation do not have to be labeled. As a result, GUARDiON notes that many food processors continue to reject or delay adoption of irradiation because of their concerns about the consumer impact of the irradiation label.

Now, the Farm Bill of 2002 has indicated that 'pasteurized' can be attributed to any safe food technology that achieves the same level of protection to public health as is already allowed for other pasteurized foods. USDA has indicated to GUARDiON that FDA is the lead agency to settle policy issues on the use of the term 'pasteurized' for irradiated foods, but that USDA also has labeling mandate for meats and poultry, subject areas where FDA has less experience.

GUARDiON is quite concerned that FDA will continue to allow unacceptable delays in responding to the legislative direction that clearly expresses a need to improve the labeling for irradiated foods, to allow greater adoption by food processors and consumers. GUARDiON requests that FDA provide clear regulatory direction allowing the use of 'pasteurized' on irradiated foods by summer 2003. We are willing to work with FDA in a consultative role to allow FDA to know the experiences and viewpoints of our company as a major radiation processing company.

Using the terms in a positive and not-misleading way—

GUARDiON recognizes that using the term 'pasteurized' has to be clearly and usefully defined microbiologically. Its use on irradiated food labels has to be validated in HACCP plans (or in GMP plans for non-HACCP products).

Part of the problem is that the direction provided to date by USDA on the use of the term 'pasteurized' does not work for irradiation and is unrealistic. USDA has variously defined that 'pasteurized' means that foods such as raw poultry have to be safe enough to be eaten raw; or sometimes pasteurized has been defined at a 5 or 7 log reduction of key pathogens such as *Salmonella* or *E. coli*. With the exception of pasteurized eggs (which are not in common use by consumers), USDA has not applied the term pasteurized to raw foods where cooking before consumption is the norm. (USDA allows 'pasteurized' labeling on milk, fruit juices, eggs and honey). Consequently, when considering the use of the term for raw poultry and meat, USDA has been applying what we think are inappropriately high hurdles.

We note, for example, that the dose required to fulfill a 5 or 7 log reduction in *Salmonella* or *E. coli* would in many cases, require a higher maximum dose than allowed by FDA (based on a D₁₀ for *Salmonella* in poultry of 0.4-0.7 kGy). We do not believe it follows the spirit of the Farm Bill to define the use of 'pasteurized' in a way that is prevented by the Food, Drugs and Cosmetics Act.

If the processor was allowed to validate that their entire process, including the irradiation step, resulted in a 5-7 log reduction, then it might be possible. We note, however, this results in a difficulty in saying the product was 'electronically pasteurized' or 'pasteurized by irradiation' or

similar wording because, in fact, the pasteurization was accomplished by a system approach and not the result of one treatment. We also note the difficulty in validating that a 5-7 log reduction has occurred in an entire process when, in fact, it should never happen that commercially produced chicken or meat has a 5-7 log bioburden of pathogens.!

Historically, 'pasteurized' has not been used for meats and poultry. With the exception of the niche consumption of untreated raw meat (as carpaccio), meat and poultry are cooked before consumption. They are supposed to be cooked before consumption. Given that the definition of 'pasteurized' will probably be defined in terms of one or two pathogens, and since meat and poultry can be contaminated by other pathogens, it is our opinion that even 'pasteurized' meats and poultry should be stored and cooked as is commonly done.

Acknowledging that cooking is still required, means that it is unrealistic to require that a pasteurization process for raw meat and poultry result in a ready-to-eat product. The term 'pasteurized' when used for raw meat and poultry has to be re-defined to a system approach that includes a cooking step. We acknowledge that consumer and food-service cooking mistakes are made, and that is why raw meats and poultry should be pasteurized by irradiation as a step in HACCP processing.

GUARDiON recommends that USDA and FDA consider that 'pasteurized', when used for raw meat and poultry, be defined as a system approach, that irradiation is not the only step required in achieving the kill requirements, and that it be assumed and still recommended that cooking will be part of the pathogen control system. The required kill step for irradiation cannot be defined so that the dose required is higher than the maximum allowed by regulation, or even high enough to cause quality changes in the food.

Informing the public about the positive food safety attributes of irradiated foods –

Both USDA and FDA acknowledge that irradiation can make foods safer, and that certain foods need to be safer, given the continuing problems caused by pathogens in foods. Surely the economy, and the meat and poultry industry in particular, cannot continue to withstand the waste of huge recalls when the situation is preventable.

The label requirements for irradiated foods are a clear detriment to the adoption of irradiation by the food industry. Look at it their way: the need to label irradiated foods costs more, and the label is perceived by the consumer (and promoted by the anti-irradiation activists) as a warning. Government has not required irradiation, and has not been sufficiently pro-active to allow the public to clearly see irradiated foods as more likely to be safe.

We acknowledge the efforts made in the communications efforts of USDA and FDA, and we certainly are appreciative of the statements made by government officials in conferences and other venues. GUARDiON, however, does not believe the adoption logjam will be cracked unless the label situation is improved. GUARDiON and other companies marketing food irradiation as a processing technology need much improved labels. In fact we also need required labeling for competitive treatments such as chemical treatments (which in spite of known residues seem to avoid labeling by being considered processing aids). Government needs to

clearly and repeatedly say that irradiation makes food safer, and why. It is a tough balance when government's most repeated statement is, "We have the safest food supply in the world." Safest, maybe. Could be and should be safer, definitely.

The use of the term 'electronic' –

IBA owns, operates and manufacturers the widest range of electronic radiation processing equipment. Therefore we understand the interest in moving away from terms such as 'irradiation' and using terms such as 'electronic'. We are, however, also the largest owner of contract gamma irradiation equipment in the US. Some members of the radiation processing industry prefer the term 'electronic' because it distances them from gamma, and the negative viewpoint they helped to create for competitive reasons. So, we see the issue from both sides. However, the fact remains that whatever the mode of irradiation, the food is still irradiated and the effect that different modes have on the food is so negligible as to be non-existent.

We believe that government should allow the use of 'electronically pasteurized' when the food has been treated by electron beam or X-ray, and assuming the microbiological conditions and validations as outlined above are met. But we also believe the term 'gamma pasteurized' could be used under the same micro and validation conditions for foods treated by gamma equipment. The radiation processing industry should work to find a suitable word to explain 'gamma', that does not have negative connotations, and companies should not be allowed to inappropriately cast aspersions on gamma, because it misleads the public.

In summary –

As a supplier of electron beam, X-ray and gamma equipment, and as the company that produces the most irradiated food in the US, GUARDiON is uniquely situated to work with USDA and FDA to resolve the label situation to the benefit of American consumers, the food industry and the radiation processing industries. With this letter, we open communication channels and encourage government to involve us and other members of the radiation processing industry in consultations to make label policy changes that work.

Yours sincerely,



Chip Colonna
President