

August 9, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm 1061
5630 Fishers Lane
Rockville MD 20852

Dear Sir or Madam,

Re: Docket No. 00N-1351, Use of label term 'fresh' on nonthermally treated foods

IBA Food Safety Division manages several irradiation facilities in the US for the irradiation of food and other new applications. IBA is the leading supplier of irradiation equipment, offering gamma, electron beam accelerators and X-ray technologies to the food, medical and manufacturing industries. IBA owns and operates irradiation facilities in Europe, the United States and Asia. We have a keen interest in all labeling issues pertaining to irradiated foods, and similar competitive treatments.

The recent FDA announcement for comment on this issue asked several questions. We would like to respond to some of them.

Consumer interests are not always known, but we do not believe they are always a prime consideration in the label decisions of FDA. For example, we do not believe consumer interests are served in the requirement for labeling of irradiated foods, especially when other treatments, such as pulsed light, approved for the same purpose, are not labeled. The irradiation label requirement reduces the use of the technology, at a cost of reduced public health benefits. Nevertheless, irradiated foods are labeled. Therefore, it seems reasonable to also allow a 'fresh' label on an irradiated food since consumers will not be misled, only additionally informed.

Irradiation is used for many technical reasons. As noted in current regulation, it is an alternative to disinfestation by pesticides usually at dose of > 1kGy, and in this case, 'fresh' can still be used. Following the same thinking, irradiation when used as a pasteurization technique for meat and poultry, should still be allowed the term 'fresh', since pasteurized milk is allowed to be labeled 'fresh'.

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IBA response to Docket No. 00N-1351

The term 'fresh' is essentially a marketing term, since it is not currently defined by quantifiable measurement, such as by nutrient content. If the term was only allowed to be used by foods that very closely approximated the nutrient content of just-harvested foods, irradiated foods would qualify for 'fresh', and probably for a longer time than other fresh foods.

Irradiation is essentially nonthermal. Irradiation processing is measured in terms of kilograys (kGy). One kilogray is one kilojoule of energy absorbed per kilogram of food. (The maximum irradiation dose allowed for fresh, unfrozen meat is 4.5 kGy).

To summarize our position, we believe the 'fresh' label should not be affected if a food is irradiated. Irradiation does not change a food sufficiently to change its status as a fresh food. The process is essentially nonthermal and is similar in technical benefit to other treatments that are currently allowed to be labeled 'fresh'. In addition, irradiated foods are labeled, so if they are also labeled 'fresh' consumers will not be misled.

Thank you.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'P. Adams', written in a cursive style.

Patterson Adams
President
Food Safety Division

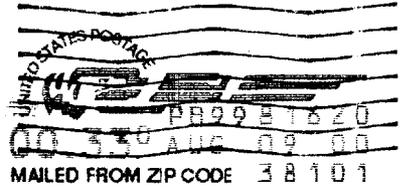


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