



AUG 21 2008

• The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter dated April 30, 2008, cosigned by Chairman John D. Dingell, Committee on Energy and Commerce, regarding the safety of our nation's food supply. In particular, you expressed concerns about the review status of certain food additive petitions (FAP) submitted to the Food and Drug Administration (FDA or the Agency) to allow the use of irradiation on foods. You requested specific information and documents concerning these petitions.

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (Title 21, *United States Code* [U.S.C.] section 321(s)), any source of radiation used to treat food is defined as a food additive. Therefore, a FAP must be submitted to the Agency in order to seek approval of any use of irradiation in or on food. Since January 1, 1999, FDA has received 12 petitions requesting amendment of the food additive regulations to permit the use of radiation on food. FDA has issued final regulations permitting the requested uses for four of these petitions, and issued a partial response for a fifth petition, as indicated below; the other petitions are in various stages of review or on hold pending the receipt of additional data or information needed to demonstrate that the proposed uses of irradiation are safe. In those instances where additional information has been requested of the petitioner, the amount of time that it takes the petitioner to provide the requested information will obviously affect the timing of a final decision.

Your letter makes particular reference to a petition submitted in 1999 for the use of radiation on a wide variety of multi-ingredient foods (FAP 9M4697). As FDA was completing its evaluation of this petition, we discovered a reference that suggested that the chemical compound furan was formed when apple juice is irradiated. Apple juice is one of the foods included in the petitioned request. Because furan is known to be a potent rodent hepatocarcinogen, this finding raised a potential concern that needed to be examined and understood before a final decision could be reached. Therefore, FDA and the petitioner, the National Food Processors Association (now the Grocery Manufacturers Association/Food Products Association), began an investigation into the presence of furan in irradiated foods.

FDA and the petitioner confirmed that furan is formed in many foods when irradiated. The Agency also discovered that furan is formed in a variety of unirradiated foods as a result of traditional heat treatment techniques such as retorting foods in cans and jars. In light of these discoveries, we embarked on a program to increase our understanding of the formation of furan in cooked foods and to analyze the potential increase in furan in the diet if food is irradiated and how that may relate to safety. These data analyses have required extensive research, both in developing repeatable, sensitive analytical techniques and in investigating the formation of furan in both cooked and irradiated foods.

FDA's first priorities, upon learning of the potential issue of furan formation in irradiated foods, were to gather data on the occurrence of furan in the food supply, and ensure that furan formation was not a safety concern in those foods where irradiation was then already permitted. Our resources were, for a time, directed to answering these questions. For example, FDA held a public meeting of the Food Advisory Committee in June 2004 to seek input on data needed to evaluate the risk of furan. In September 2005, FDA announced an Action Plan for Furan in Food, and the Agency has posted results of a furan analysis of more than 300 food samples. FDA also confirmed that furan formation as a result of radiation treatment, in foods where irradiation was already permitted, was not a safety concern. The Agency has devoted significant resources to better understanding the potential human health risk of furan, and this effort is ongoing.

More recently, we have been working to resolve the issue of potential furan formation as it may affect pending petitions for irradiation of foods. In particular, at the request of the petitioner for FAP 9M4697, the Agency responded to part of the original request. Specifically, the petitioner requested a response regarding amending the food additive regulations to provide for the safe use of ionizing radiation for control of foodborne pathogens, and extension of shelf-life, in iceberg lettuce and spinach up to a maximum of 4.0 kGy. FDA has just issued a final rule to amend the food additive regulations to provide for such use. This final rule is a partial response to the petition and addresses only the use of ionizing radiation on iceberg lettuce and spinach. The use of ionizing radiation on the remaining foods included in the petition remains under review.

We have repeated your specific requests below, in bold type, followed by FDA's responses.

1. Please list all petitions seeking the approval of irradiation for certain foods submitted to FDA since January 1, 1999.

Since January 1, 1999, FDA has received 12 petitions seeking amendment of our food additive regulations for the use of radiation on food:

- FAP 9M4676 – Use of UV radiation to reduce human pathogens in juice products
- FAP 9M4673 – Use of ionizing radiation to control microbial pathogens in seeds for sprouting
- FAP 9M4682 – Use of ionizing radiation to control foodborne pathogens in fresh or frozen molluscan shellfish
- FAP 9M4695 – Use of ionizing radiation as an additive in unrefrigerated, uncooked meat food products

- FAP 9M4696 – Use of ionizing radiation as an additive in unrefrigerated, refrigerated and frozen poultry products
- FAP 9M4697 – Use of ionizing radiation as an antimicrobial agent in certain refrigerated, frozen or dried meat, poultry, fruit or vegetable products
- FAP 1M4727 – Use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans
- FAP 2M4741 – Approved sources of gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137 to reduce microorganisms on dietary supplements and nutritional function foods
- FAP 3M4745 – Increase maximum permitted x-ray energy level for treating food
- FAP 3M4744 – Request approval for shelf stable foods processed with irradiation in combination with other methods
- FAP 7M4768 – Carbon dioxide laser for etching information on food
- FAP 7M4770 – Ultraviolet irradiation of aqueous sugar solutions and potable water

2. Please describe what actions FDA has taken on each petition seeking the approval of irradiation for certain foods submitted to the Agency since January 1, 1999.

- FAP 9M4676 – Final rule issued 11/29/2000
- FAP 9M4673 – Final rule issued 10/30/2000
- FAP 9M4682 – Final rule issued 8/16/2005
- FAP 9M4695 – Petition remains under review pending resolution of furan concern.
- FAP 9M4696 – Petition remains under review pending resolution of furan concern.
- FAP 9M4697 – On December 4, 2007, the petitioner submitted a request that we issue a partial response to the petition with regard to leafy green products, i.e., iceberg lettuce and spinach. We issued this partial response on August 21, 2008. For other uses, the petition remains under review pending resolution of furan concern.
- FAP 1M4727 – Petition remains under review pending resolution of furan concern.
- FAP 2M4741 – Petition remains under review pending resolution of furan concern.
- FAP 3M4745 – Final rule issued 12/23/2004
- FAP 3M4744 – Petition remains under review pending resolution of furan concern.
- FAP 7M4768 – Additional information requested from petitioner; awaiting response.
- FAP 7M4770 – Additional information requested from petitioner; awaiting response.

3. Please provide all records relating to petitions seeking the approval of irradiation of certain foods submitted to the agency since January 1, 1999.

In a meeting on July 1, 2008, at which the status of the 12 FAPs were discussed, Mr. Kevin Barstow of your staff asked that FDA proceed with the production of documents on the following petitions: FAP 9M4695; FAP 9M4696; FAP 9M4697; and FAP 3M4744. Enclosed are documents responsive to this request.

Please be advised that some of these documents contain trade secret, commercial confidential or other information protected from public disclosure under the Freedom of Information Act (5 U.S.C., section 552), the Trade Secrets Act (18 U.S.C., section 1905) and/or FDA regulations.

This information should not be published or otherwise made public. We would be glad to discuss the protected status of any specific information with you or your staff.

We are continuing to examine our files for additional documents relating to these food additive petitions and will provide them in a subsequent submission.

4. Describe when FDA plans to issue a final decision on each petition seeking the approval of irradiation for certain foods submitted to the agency since January 1, 1999.

FDA continues to work on completing its evaluation of those petitions in which furan formation may be a potential safety issue. FDA is acting as rapidly as possible to reach final decisions in light of the questions regarding the presence of furan in food. We cannot predict when a final decision will be issued on those petitions for which additional data/information has been requested, as this will depend on when the petitioner submits the requested data.

Thank you again for your interest in this matter. If you have any further questions or concerns, please let us know. The same letter has been sent to Chairman Dingell.

Sincerely,



for Stephen R. Mason
Acting Assistant Commissioner
for Legislation

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce