

**ROUTING SLIP**  
**GENERATED BY: HF-40**  
**DATE: APR 23, 2002**

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**TRACER #:**      **OS #:**

**DATE OF CORRESPONDENCE:** 04/15/02

**DATE INTO FDA:** 04/23/02

**TO:** LESTER M CRAWFORD HF-1  
BERNARD A SCHWETZ HF-1  
JOSEPH A LEVITT HFS-1  
ALAN M RULIS HFS-200  
LAURA M TARANTINO HFS-206

**FROM:** ANDREW KIMBRELL, CENTER FOR FOOD SAFETY  
WENONAH HAUTER, PUBLIC CITIZEN

**SYNOPSIS:** SUBMITS COMMENTS ON FOOD ADDITIVE PETITIONS 9M4697, 1M4727,  
9M4682, 9M4695, 9M4696 REGARDING IRRADIATED FOOD--DOCKET NO.S  
99F-5522, 01F-0047, 99F-4372 99F-5321, 99F-5322 (CC: DOCKETS; A.  
VENEMAN, USDA; M. GLAVIN, USDA).

**LEAD OFFICE:** HFA-305

**HOME OFFICE:** HF-40

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**COPIES:** GENERAL DISTRIBUTION  
HF-1 LESTER M CRAWFORD  
HF-1 BERNARD A SCHWETZ  
HF-2 MURRAY M LUMPKIN  
HF-40 LAJUANA D CALDWELL  
HFS-1

**COORDINATION:**

**SIGNATURE REQUIRED:**

**REFERRALS FROM HF-40**

<b>ASSIGNED TO</b>	<b>ACTION</b>	<b>DUE DATE</b>
----- HFA-305      BUTLERJ	----- NECESSARY ACTION	-----



THE CENTER FOR  
FOOD SAFETY



April 15, 2002

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**Re: Food Additive Petition 9M4697, Use of ionizing radiation for pre-processed meat and poultry; both raw and pre-processed vegetables, fruits and other agricultural products of plant origin; and certain multi-ingredient food products; Food Additive Petition 1M4727, Use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans; Food Additive Petition 9M4682, Ionizing radiation for the control of Vibrio and other foodborne pathogens in fresh or frozen molluscan shellfish; Food Additive Petition 9M4695, Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products; and Food Additive Petition 9M4696, Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products**

Greetings,

The FDA is considering the five above-referenced food additive petitions to irradiate a much greater portion of the food supply, such as ready-to-eat foods, including some meat and poultry items also regulated by the USDA Food Safety and Inspection Service. On May 16 of last year, our organizations filed comments opposing these petitions on grounds of serious safety issues stemming from scientific studies indicating that certain irradiated foods may cause mutagenic

and cytotoxic effects in lab animals as well as in humans.<sup>1</sup> We also have filed several later comments on these petitions.

On behalf of the more than 100,000 consumer members of our two organizations, this is to request you to fully consider the enclosed new evidence. This March, the 34th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) took place in Rotterdam. A particularly contentious agenda item was the proposed draft revision to the Codex General Standard for Irradiated Foods. The present standard sets a maximum average irradiation dose level of 10 kiloGrays (kGy), which applies to all foods. The proposed revision would remove this maximum dose limit. Some delegations expressed their support for the proposal; a full debate ensued.

Spain, speaking on behalf of the European Commission, and supported by Germany, Poland, Sweden and Consumers International, argued that the limit should not be removed. They pointed out that findings of recent studies carried out in Germany indicate that certain chemical by-products formed in food that has been irradiated, known as cyclobutanones, could be toxic enough to cause significant DNA damage, potentially leading to carcinogenic or mutagenic effects. The result of the debate and uncertainty: postponement of a decision on the 10 kGy limit until next year. We have attached copies of the official summary report of the matter from the Codex website; the irradiation standard is the 5<sup>th</sup> major bullet mentioned therein. We also have attached the unofficial draft report of that portion of the CCFAC meeting when this matter was discussed and decided (ALINIMORM 3/12, Agenda Item 10a, particularly paragraphs 77-81).

The Scientific Committee on Food (SCF), which advises the European Commission, also formally considered the cyclobutanones issue, in late February. As indicated in the attached meeting minute from its website, the SCF's national representatives believe that important issues exist requiring expert evaluation as far as the potential risks to humans.

In sum, potentially toxic forms of cyclobutanones have been found to be unique to irradiated foods. Two major international food safety groups - CCFAC and SCF - deemed the indications of toxicity strong enough to necessitate considerable additional study. We think each of you will agree that it is inconceivable that U.S. regulators would take a less precautionary approach in weighing the potential risks that the pending petitions pose to Americans from consuming far more irradiated food, especially to our vulnerable children.

Based on this new expert opinion evidence, plus the scientific documentation we submitted in our earlier comments, we strongly urge you at this point to **deny** the above-referenced petitions. Evidence continues to mount that approving them absent thorough, food-specific, published studies of cyclobutanones and other potentially toxic radiolytic products would constitute arbitrary and capricious actions on your part. If you would like further information, please contact Peter Jenkins of the Center for Food Safety (tel: 202.547.9359 x13; email: [peterjenkins@icta.org](mailto:peterjenkins@icta.org)).

Sincerely,



Andrew Kimbrell, Executive Director  
Center for Food Safety

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Wenonah Hauter, Director  
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Enclosures (3)

Cc: FDA Food Additive Petition Docket No.s: 99F-5522; 01F-0047; 99F-4372; 99F-5321;  
99F-5322  
Secretary of Agriculture Ann Veneman  
Margaret Glavin, Administrator, USDA Food Safety Inspection Service

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<sup>1</sup> Copies of these past comments are available on request or they can be accessed on the CFS website at [www.centerforfoodsafety.org](http://www.centerforfoodsafety.org) under Legal Initiatives.

*Codex Committee on Food Additives and Contaminants,  
34th Session, The Hague, Netherlands, 11-15 March 2002*

**The Committee:**

- Agreed to circulate the risk assessment policy statement for the application of risk analysis principles to the standard setting activities of the Codex Committee on Food Additives and Contaminants in conjunction with risk assessments performed by the Joint FAO/WHO Expert Committee on Food Additives for comments and further consideration at its next meeting;
- Agreed to the following action in regard to the further elaboration of the GSFA:
  - Reaffirmed several principles in regard to the relationship between codex commodity standards and the GSFA and as a result, decided to elaborate a proposed draft revision to the Preamble of the GSFA to encompass these basic principles, for circulation, comment and further consideration at its next meeting;
  - Agreed to revisions to the food category system of the GSFA, including provisions related to pastas and noodles, and;
  - Forwarded revisions to Table 1 of the GSFA to the commission for final adoption and circulated revisions to the annex to Table 3 for additional comments.
- Decided to request comments on the discussion paper on processing aids and food additive carriers in the context of the GSFA for consideration at its next meeting;
- Agreed that the discussion paper on active chlorine should be revised for circulation, comment and further consideration at its next meeting;
- Agreed to revise the draft codex general standard for irradiated foods for circulation, comment and further consideration at its next meeting;
- Forwarded the recommended international code of practice for radiation processing of food to the commission for final adoption;
- Forwarded 60 food additive specifications and 276 flavouring agent specifications to the commission for adoption as codex advisory specifications;
- Forwarded amendments to the international numbering system to the commission for final adoption;
- Endorsed food additive and/or contaminant provisions arising from the codex committee on cocoa products and chocolate;

[list discontinued here]

ALINORM 03/12

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION**

*Twenty-fifth Session  
Rome, Italy, 30 June – 5 July 2003*

**DRAFT REPORT OF THE 34th SESSION OF THE CODEX COMMITTEE  
ON FOOD ADDITIVES AND CONTAMINANTS**

*Rotterdam, The Netherlands  
11-15 March 2002*

70. The Committee noted that active chlorine was commonly utilised as a decontaminating/disinfecting agent in water treatment or surface treatment of foodstuffs. In this regard, a number of delegations pointed out that safety problems that might be associated with the use of this compound were mainly related to inappropriate handling or misuse. It was noted that the work of CCFAC in this respect should not prevent countries from using this chemical in the prevention of microbial contamination that might occur in water or food. Other delegations indicated that the CCFAC should take account of the work being done in other Codex Committees and, in this regard, suggested that the Committee could work together with the Codex Committee on Food Hygiene in addressing this issue.

71. The Committee recognised the need for active chlorine to be assessed on a global basis by JECFA. In this regard, it was indicated that any risk assessment should take into account different uses of this compound including by-products of reactions between active chlorine and organic materials in food and/or water. The JECFA secretariat indicated that any question put to JECFA on the issue must be clear as to just exactly what aspect(s) are to be assessed.

72. The Representative of WHO indicated that the *WHO Guidelines for Drinking Water Quality* recommended a maximum level of 5 ppm of active chlorine and indicated that this level was both safe and protective of consumer's health. He drew the attention of the Committee to the fact that the use of active chlorine in water treatment in food processing might compromise the balance between benefits of reducing microbial contamination and public health. He strongly suggested that the CCFAC continue to study this issue so that all public health risk/benefits be considered in order that the health of consumers not be put at risk.

#### **Status of the Discussion Paper on Active Chlorine**

73. In view of the above discussion, the Committee agreed that the Discussion Paper should be revised by Denmark, in cooperation with Finland, Israel, Norway and WHO, in light of the above discussion and comments to be submitted in response to a Circular Letter appended to this report, for circulation, comment and further consideration at its next meeting.

#### **DRAFT REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS (Agenda Item 10a)<sup>33</sup>**

74. The 33<sup>rd</sup> CCFAC forwarded<sup>34</sup> the proposed draft revised Codex General Standard for Irradiated Foods to the 24<sup>th</sup> Session of the Commission for adoption at Step 5. The 49<sup>th</sup> Session of the Executive Committee

<sup>33</sup> Comments submitted in response to CL 2001/34-FAC from Argentina, Poland, USA, CI, EC, IAEA (CX/FAC 02/11), India (CRD 7) and Philippines (CRD 20).

<sup>34</sup> ALINORM 01/12A, para. 85 and Appendix VII

adopted<sup>35</sup> the proposed draft revised Standard at Step 5. The Committee considered Appendix VII of ALINORM 01/12A as the basis for its discussions.

75. The Committee agreed to revise the first sentence of Section 1 - Scope to read "This standard applies to food processed by ionizing radiation that is used in conjunction with applicable hygienic codes, food standards and transportation codes". After some discussion, the Committee decided to retain the second sentence in its current form.

76. Despite the opposition of the delegation of Spain, speaking on behalf of the EC, several countries (Argentina, India and the Philippines) had indicated that they were using or were planning to use Cesium-137 as a radiation source. The Committee therefore agreed to amend Section 2.1 - Radiation Sources, Subsection (a) to include Cesium-137 (<sup>137</sup>Cs), so that Section (a) reads as "Gamma rays from the radionuclides <sup>60</sup>Co and <sup>137</sup>Cs".

77. The delegate of the Philippines proposed to delete the reference to an upper limit of 10 kGy, which appeared in square brackets in Section 2.2 - Absorbed Dose. She stated that such a limit was not necessary in the light of the report of the FAO/IAEA/WHO Study Group on high dose irradiation.<sup>36</sup> The delegate of Spain, on behalf of the EC, proposed to retain the reference without square brackets because of toxicity concerns for 2-alkylcyclobutanones. An assessment being undertaken by the Scientific Committee for Food is not yet complete and while the representative of the EC was unable to give a date when the final report would be available, it will be published, made available to all concerned, and the data can be used by JECFA for further assessment.

78. It was noted that there were no known applications of irradiation above 10 kGy. However, the delegate of Australia noted that they had recently approved irradiation of herbs and spices up to a dose of 20 kGy. Consumers International suggested that it would be useful if countries could provide more information on their use of high dose food irradiation.

79. The WHO Representative noted that the FAO/IAEA/WHO Study Group conclusion that food irradiated to any dose appropriate to achieve the intended technical objective was both safe to consume and nutritionally adequate was still valid as no credible scientific evidence has been provided to the contrary. He noted that concerns about the safety of alkylcyclobutanones reported in a recent EC-supported study could not be substantiated because the three organizations could not obtain a copy of the report for review. However, he emphasized that WHO was willing to re-open any risk assessment if new evidence indicated a public health risk. He informed the Committee that JECFA would be able to consider the study at its meeting in June 2001 if it could be made available in the near future.

<sup>35</sup> ALINORM 03/3, para. 19 and Appendix II

**Status of the Draft Revised Codex General Standard for Irradiated Foods**

80. Because of the volume of comments received, the Committee agreed to suspend further discussion and to request a drafting group led by the Philippines and assisted by Argentina, Australia, China, France, Germany, India, Japan, Korea, Poland, Sweden, Thailand, United Kingdom, United States, EC, IACFO, ICGFI, FAO and WHO to revise the current Standard on the basis of the written comments submitted and the committee's discussions for circulation, additional comment and further consideration at its next meeting.

81. To facilitate the revision of the Standard, the delegate of the Philippines requested that the question of the need for a limit of 10 kGy be linked to the results of the EC-supported study on the toxicity of 2-alkylcyclobutanones and that the EC provide the report of the study to JECFA for evaluation (see Agenda Item 17). She also noted that issues related to labelling of irradiated food were within the mandate of the Codex Committee on Food Labelling.

**PROPOSED DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR RADIATION PROCESSING OF FOOD (Agenda Item 10b)<sup>37</sup>**

82. The 33<sup>rd</sup> CCFAC decided<sup>38</sup> that the Recommended International Code of Practice for Radiation Processing of Food would be revised by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture based on the Committee's discussions and written comments submitted for circulation, comment and further consideration at its next Session. The 49<sup>th</sup> Session of the Executive Committee approved<sup>39</sup> the elaboration of the proposed draft revised Code of Practice as new work. The Committee considered CX/FAC 01/12 as a basis for its discussions.

83. The representative of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture introduced the comments submitted by the EC and the USA. She noted that the comments improved the text and were mainly editorial in nature except for proposed changes in Sections 5.3.5 and 6.3 as discussed below. In addition, she noted that a proposal by the EC to amend Section 8 Labelling could only be made after agreement was reached on labelling requirements in the General Standard for Irradiated Food and in consultation with the Codex Committee on Food Labelling.

84. The Committee agreed to include the following new first paragraph to Section 5.3.5:

<sup>36</sup> *Report of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation, WHO Technical Report Series 890, WHO, Geneva (1999)*

<sup>37</sup> CX/FAC 01/12 and comments submitted by the United States (CX/FAC 01/12 - Add. 1) and the EC (CX/FAC 01/12 - Add. 2).

<sup>38</sup> ALINORM 01/12A, para. 89

<sup>39</sup> ALINORM 03/3, Appendix III

[http://europa.eu.int/comm/food/fs/sc/scf/out119\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out119_en.pdf)

**Minutes' statement adopted by the Scientific Committee on Food  
at its 131<sup>st</sup> plenary meeting (25/26/27 February 2002)  
corresponding to item 14 of the agenda**

**14. Food Irradiation**

**14.1. Consideration on 2-alkylcyclobutanones**

The Commission's legislative service explained the background of the request for an evaluation by the Committee of a report on 2-alkylcyclobutanones (2-ACB)<sup>1</sup>. The Secretariat also distributed a copy of a letter received from "Center for Food Safety" and "Public Citizen".

The Committee identified a number of issues in the report<sup>2</sup> that need further clarification and evaluation as to the interpretation of the studies and their relevance for the risk assessment of food irradiation. The Committee noted that the studies in the report were not of the type usually required for the safety assessment of toxicological effects from exposure to chemicals.

In the context of the on-going update of the SCF opinion on food irradiation expressed in 1986, the Committee requested some members of the SCF, assisted by additional experts in the field of irradiation, to further evaluate these and other studies on 2-ACB.

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<sup>1</sup> Burnouf D, Delincée H, Hartwig A, Marchioni E, Miesch M, Raul F, Werner D (2001). "Etude toxicologique transfrontalière destinée à évaluer le risque encouru lors de la consommation d'aliments gras ionisés / Toxikologische Untersuchung zur Risikobewertung beim Verzehr von bestrahlten fetthaltigen Lebensmitteln – Eine französisch-deutsche Studie im Grenzraum Oberrhein." Rapport final / Schlussbericht Interreg II. Project / Projekt N° 3171 (submitted to the Commission by the authors in confidence).

<sup>2</sup> A summary of the report is available on Internet at:  
<http://www.iaea.org/programmes/rifa/icgfi/documents/summary-press.pdf>