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Feb. 4, 2002

FSIS Docket Room
U.S. Department of Agriculture
Food Safety and Inspection Service, Room 102
Cotton Annex, 300 12th Street, SW
Washington, DC 20250-3700.

01-047N
01-047N-1
Peter T. Jenkins

RE: Docket #01-047N ; Comments on the Draft Revised Codex General Standard for Irradiated Foods submitted in response to CL 2001/34-FAC CX/FAC (CCFAC Food additives agenda item 10(a))

Greetings:

The Center for Food Safety (CFS) and Public Citizen are pleased to submit **this** public comment on the above-referenced Draft Revision to the Codex General Standard for Irradiated Foods, which is due to be considered by the Committee on Food Additives and Contaminants (CCFAC) at its meeting of 11-15 March, 2001, in Rotterdam. CFS is a national, non-profit, membership organization established in 1997 to use science and the law to address increasing concerns over the impacts of the global food production system on human health, animal welfare, and the environment. Public Citizen is a national, non-profit, membership organization established in 1971 that advocates for consumer protection and for government and corporate accountability.

CFS and Public Citizen **oppose** the proposed revision of the Codex standards that would remove the existing 10 kiloGray (kGy) irradiation maximum average absorbed dose limit. Important new information indicates that critical concerns remain unresolved **as** to the safety of irradiated food.

The new evidence of unacceptable risk does not originate with **our** groups, it originates with the International Consultative Group on Food Irradiation (ICGFI) itself. Attached hereto is the **summary** document for the unpublished scientific studies by Drs. Delincee, Marchioni, et al. **This summary** is posted on the IAEA/ICGFI (website <http://www.iaea.org/licgfi>) and includes a number of important new observations regarding genotoxicity and cytotoxicity of concentrated cyclobutanones found uniquely in irradiated foods. (Other key documents are also on that website, in particular a new report we prepared called **Hidden Harm** and the affidavit of our consulting expert toxicologist, **Dr.** William Au of the University of Texas Medical Branch; each of these supports the points herein.) Further, it was observed that these unique radiolytic products are capable of potentiating an inducing carcinogen over the long term and that the products are stored in body tissues, not necessarily excreted. **Thus**, their potential effects on cells

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may last for extended periods. The results also confirmed oxidative damage to DNA from radiolytic products.

These new results raised many more questions than they answered. Until the full studies are published, including methods, lowest effective dosages, concentrations, treatment conditions, foods and radiolytic products analyzed, testing techniques, the identity of the tumor-inducing agent used, the possibility of synergistic effects, and so on, one must observe the following statement quoted from the summary on the ICGFI website:

"The experiments demonstrate that pure compounds, known to be exclusively formed upon irradiation of fat-containing food, exhibit some toxic effects including promotion of colon carcinogenesis in rats.... Whether these findings are relevant to the human exposure situation needs to be analyzed. In our opinion further investigations, including confirmation of our results by other laboratories, will help to elucidate a possible risk associated with the consumption of irradiated fat-containing foods."

This statement gives no assurance of safety at all, rather it is a clear call for more studies before safety from now clearly-proven potential risks can be assured.

We also emphasize that the EU in its recent official comments to CCFAC on this draft opposed the change in unambiguous terms based on the same new study results (attached and online at http://europa.eu.int/comm/food/fs/ifsi/eupositions/ccfac/ccfac_ec-comments_cl0134_en.pdf):

"04/12/01
EUROPEAN COMMUNITY COMMENTS
on CL 2001/34-FAC of the Codex Secretariat

Proposed Draft Revision to the Codex General Standard for
Irradiated Foods (ALINORM 01/12A, para **85** and Appendix VII)

1. INTRODUCTION

The proposed revision of the Codex General Standard for Irradiated Foods concerns in particular the replacement of the specific maximum overall average dose value of 10 kGy by a more general wording on minimum and maximum radiation dose. This proposal is based on results of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation of 1997 which concluded that food irradiated to any dose appropriate to achieve the intended purpose was both safe to consume and nutritionally adequate.

During the 33rd CCFAC meeting the WHO representative informed that scientific studies on cyclobutanones are being performed since concerns about their safety had been expressed. Cyclobutanones are created by irradiation of triglycerides and are the only molecules which have been so far exclusively detected in irradiated foods. The ICGFI representative informed that preliminary results of

these studies were negative with regard to genotoxicity and cytotoxicity and that the studies would be completed by November 2001 (ALINORM 01/12A, para 73).

The final report of these studies has been submitted by the authors to the Scientific Committee on Food of the European Commission (SCF) in November 2001. The report indicates tumour promoting and genotoxic potential of purified cyclobutanones. The European Commission has requested the opinion of the SCF on the implications of these results concerning the wholesomeness of irradiated foods. As long as this scientific advice is pending, the European Community considers it as prudent not to proceed with the proposed changes on the maximum dose."

Thus, it is not just consumer groups and scientists who have raised concerns, but also the EU itself. **It is inconceivable that the United States delegation would seek a less careful approach to this critical safety question than the EU seeks.**

We also read with interest the "Conference Room Document" distributed by the World Health Organization (WHO) at the 33rd CCFAC meeting in 2001, entitled "Comment from WHO on the 2-Dodecylcyclobutanone," prepared prior to the study results summarized on the ICGFI website and prior to the above EU comment. That document contains the following statements (copy attached):

"A new study is underway which includes an initial screening phase, using the comet assay and other tests, and then if necessary a confirmatory phase, using test procedures that have wide acceptance for reliability in determining actual genotoxicity. Phase I will also test other alkylcyclobutanones derived from other fatty acids, and is expected to be completed sometime late in 2001. Phase 2 may not be necessary if the screening results are negative. **On** the other hand, if screening results are positive, WHO will take immediate action to inform the Codex CCFAC of any possible hazard to human health and to consider additional precautionary steps as appropriate. We can assure you that WHO is committed to a full and complete assessment of 2-DCB if there is any question of a potential hazard to public health."

The attached scientific **summary** of the studies undeniably states a "question of a potential hazard to public health." In view of the new evidence, and as confirmed by the EU's comment, it is plain that initial toxicity has been shown and that Phase 2 testing is unambiguously needed, yet not complete. It is now the obligation of the WHO to advise the Codex CCFAC and other international bodies that the 2001 Conference **Room** Document was incorrect in its numerous assertions that no plausible **risks** existed. Is it now further incumbent on WHO to "take immediate action" - as it promised - to immediately advise the CCFAC delegates that "precautionary steps" are needed due to the need for the Phase 2 studies to be completed and published. **It would be irresponsible for the United States to act on this in the absence of such further WHO review.**

We have received a communication directly from the WHO liaison to the ICGFI Secretariat, Dr. Gerald Moy, who has stated (2/1/02 email attached):

“We are in the process of requesting copies of the full report of the studies from the EU and if these are received, WHO will organize an international peer review of these studies by experts in the field.”

We hope that Dr. Moy is able to follow through with this commitment. Plainly, the U.S. delegation must await the results of the international peer review before taking a further position supporting the proposed change.

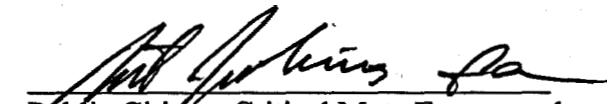
Public Citizen and CFS made an earlier joint comment to the Codex CCFAC dated May **14, 2001** (at <http://www.centerforfoodsafety.org/commcodx.htm>) that raised mutagenicity concerns that go far beyond this recent cyclobutanone debate, based on careful review of decades of scientific articles. That comment demonstrated mistakes in the **1999** FAO/WHO/IAEA Technical Report #890. High-Dose Irradiation: Wholesomeness of Foods Irradiated Above **10** kGy, WHO, Geneva. At least ten positive in vivo published studies that found mutagenic effects in mammals - including one in humans - were misclassified or ignored in that **1999** report, upon which the Codex CCFAC explicitly relied in its preliminary approval of removing the **10** kGy limit. These ten positive studies compare to only **17** published in vivo studies that were reportedly negative for mutagenicity. Similarly, for published in vitro studies, five mutagenicity studies were positive and 8 were negative. Overall, more than one-third of published studies indicate mutagenicity of irradiated food substances. This is hardly a record upon which the United States can assert safety.

In sum, both new and old evidence indicates a lack of proof of safety for food irradiation. The demonstrated health risks would magnify at higher irradiation levels. Raising the allowable absorbed dose above the existing **10** kGy limit would be imprudent and potentially unsafe at **this** time. The Center for Food Safety and Public Citizen strongly urge the U.S. delegation to reject it.

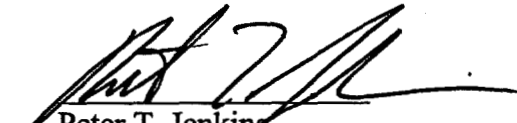
The U.S. Codex delegation must be mindful of the international scandal that will result if Codex approves removing the **10** kGy limit, and then the demonstrated potential risks to humans from eating foods irradiated at these newly-approved higher doses become manifest in the subsequent studies recommended by numerous scientists, and supported by the WHO and EU representatives. Indeed, the opinion of many is that the risks already established are beyond what is prudently acceptable.

Thank you for your attention to this comment. For further discussion about the issues herein please contact Peter Jenkins of CFS at peterjenkins@icta.org.

Sincerely,



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