

Public Citizen

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Joan Claybrook, President

April 28, 2003

Mr. Joseph Levitt
U.S. Food and Drug Administration
CFSAN - HFS-001
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Mr. Levitt:

We are writing to present new information of which the agency should be made aware before issuing any additional rulings regarding food irradiation.

A series of recent studies has detected carcinogenic-related, genotoxic and cytotoxic properties of food irradiation byproducts called 2-alkylcyclobutanones, or 2-ACBs. These chemicals were discovered in irradiated fat-containing foods in 1971.

Research into the utilization of 2-ACBs as food irradiation markers began in 1990. This research determined that 2-ACBs have never been found to naturally occur in any food. The governments of the European Union and England have established the detection of 2-ACBs as an official method to determine whether fat-containing foods have been irradiated.

Research into the toxicity of 2-ACBs began in 1998. This research has found that 2-ACBs:

- Promoted the carcinogenesis process in the colons of rats.
- Can be genotoxic and cytotoxic to human cells.
- Can be genotoxic to rats.
- Were stored in small quantities in the adipose tissues of rats, and were found in small quantities in the feces of rats, but that the 2-ACBs could not be entirely accounted for. The metabolism of these chemicals is still unknown.¹

The scientists who released the most recent studies stated:

“Further studies are absolutely necessary in order to elucidate the metabolism of 2-ACBs... To characterize the potential risk, hazards need to be identified, the exposure, the exact dose-response and particularly the kinetics and metabolism of 2-ACB in the living organism should be elucidated. All these studies are deemed necessary to gain insight into the mechanisms of the toxic effects.”

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In light of these findings, several statements made by the FDA regarding the safety of irradiated foods are now inaccurate and/or obsolete, and must be readdressed. These statements have been made in Federal Register filings dating to 1986.

- Approval of the “Omnibus Rule,” at 51 FR 13377-13379, April 18, 1986:

“BFIFC (Bureau of Foods Irradiated Food Committee) recognized that scientists do not know the extent to which these substances, although characterized as URP’s, may actually be present as common constituents of the human diet... [B]ecause any URP’s are likely to be toxicologically similar to other food components, it would be virtually impossible to detect potential toxicological properties of these substances. The current state-of-the-art toxicity tests are not sensitive enough to detect the potential toxicity of URP’s at these low levels unless the URP’s are far more potent than experience in the radiation chemistry of foods and in toxicology would suggest... The important issue the agency must consider with regard to radiolytic products is the probability that a toxic radiolytic end product may be formed and whether such a product would be present in sufficient amounts to make the food unsafe.”

- Denial of a stay related to “Omnibus Rule” and the rule approving irradiation for pork, at 52 FR 5451, Feb. 23, 1987:

[T]here is no evidence, or any reason to believe, that the toxicity or carcinogenicity of any unique radiolytic products is different from that of any other food components.

- Denial of a public hearing related to “Omnibus Rule” and the rule approving irradiation for pork, at 53 FR 53179, Dec. 30, 1988:

[R]adiolytic products unique to irradiated foods are “chemically similar to known natural food components (and) are likely to be toxicologically similar also.”

- Denial of a public hearing related to rule approving irradiation for poultry, at 62 FR 64104, Dec. 3, 1997:

Extracts of irradiated foods have not been relied on primarily for testing because radiolytic products of food do not differ in any particular chemical or physical properties from other components of food that would allow them to be specifically extracted from food. Additionally, radiolytic products are typically identical to substances that occur naturally in foods.

Because these statements are now inaccurate and/or obsolete, we strongly urge the agency to comprehensively examine the presence of 2-ACBs in fat-containing foods covered by pending


petitions, and the potential health threats of these chemicals, before issuing any additional rulings regarding food irradiation. In particular, the petition to legalize irradiation for ready-to-eat foods – which represent 37 percent of the typical American’s diet – should be held in abeyance until this examination is completed.

For that matter, because research into the toxicity of 2-ACBs is continuing, no examination can legitimately be considered complete without additional information on the toxic properties of these chemicals. We trust that the agency will not proceed without thoroughly reviewing the results of ongoing research.

As 2-ACBs have been shown to have carcinogenic-related, genotoxic and cytotoxic properties, failure to thoroughly assess the toxicity of these chemicals would represent a serious regulatory oversight that could endanger the American public health.

If we can provide any additional information to the agency, please feel free to contact me.

Sincerely,



Wenonah Hauter
Director, Critical Mass Energy and Environment Program

Enclosures

cc: Secretary Tommy G. Thompson
Commissioner Mark McCellan
Deputy Commissioner Lester Crawford
Dr. Bernard Schwetz
Dr. Alan Rulis
Dr. Laura Tarantino
Dr. George Pauli
Docket No 99F-4372, Food Additive Petition 9M4682
Docket No 99F-5321, Food Additive Petition 9M4695
Docket No. 99F-5322, Food Additive Petition 9M4696
Docket No. 99F-5522, Food Additive Petition 9M4697
Docket No. 01F-0047, Food Additive Petition 1M4727

¹ Delincée, H. and Pool-Zobel, B. “Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat.” *Radiation Physics and Chemistry*, 52:39-42, 1998.
Delincée, H. et al. “Genotoxicity of 2-dodecylcyclobutanone.” Food Irradiation: Fifth German Conference, Report BFE-R-99-01, Federal Nutrition Research Institute, Karlsruhe, Germany, 1998.
Delincée, H. et al. “Genotoxicity of 2-alkylcyclobutanones, markers for an irradiation treatment in fat-containing food – Part I: Cyto- and genotoxic potential of 2- tetradecylcyclobutanone.” *Radiation Physics and Chemistry*, 63:431-435, 2002.
D. Burnouf, H. Delincée, A. Hartwig, E. Marchioni, M. Miesch, F. Raul, D. Werner. “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 d’étude Interreg II, projet N° 3.171. BFE-R-02-02, Federal Research Centre for Nutrition, Karlsruhe, Germany, 2002.

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