Hidden Harm

How the FDA is Ignoring the Potential Dangers of Unique Chemicals in Irradiated Food

A special report by

Public Citizen
and
The Center for Food Safety

Washington, D.C.

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Prepared by Mark Worth and Peter Jenkins

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Public Citizen
215 Pennsylvania Ave., S.E.
Washington, D.C. 20003
tel: 202.546.4996
fax: 202.547.7392
e-mail: cmep@citizen.org
Web: www.citizen.org

Center for Food Safety
660 Pennsylvania Ave., S.E. - Suite 302
Washington, D.C. 20003
tel: 202.547.9359
fax: 202.547.9429
e-mail: office@centerforfoodsafety.org
Web: www.centerforfoodsafety.org

Public Citizen, founded by Ralph Nader in 1971, is a non-profit research, lobbying and litigation organization based in Washington, D.C. Public Citizen advocates for consumer protection, and for government and corporate accountability.

The Center for Food Safety 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 United States food production system on human health, animal welfare, and the environment.

Executive Summary

In 1971, two University of Massachusetts food researchers discovered that when certain fats commonly found in food are irradiated, the resulting by-products include a unique class of chemicals called cyclobutanones. The discovery was significant, because cyclobutanones have never been found to naturally occur in any food.

Thirty years later, the discovery of these chemicals lies at the center of an international debate that could have profound implications for the future of irradiated food.

In recent experiments conducted by German government scientists, one of these chemicals, 2-dodecylcyclobutanone — or 2-DCB — was shown to cause genetic damage when given to rats, and genetic and cellular damage to human and rat cells.

Two other chemicals in the cyclobutanone family — 2-TCB and 2-TDCB — were also shown to cause genetic and cellular damage to human cells.

These revelations about cyclobutanones are both ironic and dangerous. The irony is that cyclobutanones are so easily detected and remain in food for so long that they are used as "chemical markers" to determine whether food has been exposed to ionizing radiation. The danger is that cyclobutanones are found in many foods that can legally be irradiated and sold to the American public — including beef, pork, chicken, lamb, eggs, mangoes and papayas.

Thus, the very chemicals that could help regulators and scientists identify whether certain foods have been irradiated may be hazardous to human health.

Today, people throughout the country could be eating irradiated foods that contain cyclobutanones without realizing it. Though irradiated whole foods sold in stores must be labeled "Treated by Irradiation" or "Treated with Radiation," there is no such requirement for most irradiated ingredients, such as spices used in canned soup, and vegetables used in frozen dinners. Nor is there such a requirement for irradiated food served in restaurants, schools, hospitals, nursing homes, day-care centers and other institutional settings.

Despite a growing body of evidence that cyclobutanones could be harmful to human health, the U.S. Food and Drug Administration has never publicly acknowledged conducting a formal analysis of the potential toxicity of these chemicals in foods that the agency has already legalized for irradiation, including fruit, vegetables, beef, pork, chicken, turkey, eggs and spices.

Neither has the FDA ever publicly acknowledged conducting such an analysis for foods that the agency is currently considering for irradiation — including shellfish and ready-to-eat foods such as frozen dinners, luncheon meat, baby food, pre-cut salads and snack foods, which, according to the National Food Processors Association, comprise 37 percent of the typical American's diet.

Moreover, high-ranking FDA officials admit that they have not compiled a list of foods defined as "ready-to-eat." One agency official said the category could include virtually "anything."

Additionally, FDA officials legalized irradiation for eggs last year shortly after attending an international conference where the toxicity of 2-DCB was discussed.

In the interest of protecting the health of Americans, and in order for the agency to fulfill its federal mandate to protect Americans from dangerous food additives, Public Citizen and the Center for Food Safety are calling on the FDA to:

- Conduct a comprehensive analysis of the fat levels of all foods that the FDA has legalized or has under consideration for irradiation, and the cyclobutanone levels of these foods after they are irradiated;
- Refrain from legalizing the irradiation of any additional foods until comprehensive, published, peer-reviewed research is conducted into the likelihood that cyclobutanones could cause health problems.
- Convene public hearings to thoroughly explore the potential health effects of cyclobutanones.

‘Since we would like to know whether,
in the case of cyclobutanones,
DNA [damage] has any significance,
...the results urge caution, and should
provide impetus for further studies.’

– Henry Delincée,
Federal Research Center for Nutrition
Karlsruhe, Germany

Hidden Harm

How the FDA is Ignoring the Potential Dangers of Unique Chemicals in Irradiated Food

Three years ago in Germany, government food researchers made a significant discovery. They found that a unique chemical formed when food is irradiated — a chemical that food chemists had known about for nearly three decades — caused genetic damage to rats, and genetic and cellular damage to human and rat cell cultures. The researchers went on to discover that two other unique irradiation byproducts also had toxic characteristics.

These chemicals are so prevalent and so persistent in certain irradiated foods that they are used as 'markers' to certify that food has been exposed to radiation. More important still, these chemicals are found in foods that can legally be irradiated and sold to the American public — including beef, pork, chicken, lamb, eggs, mangoes and papayas.

In the wake of these discoveries, the U.S. Food and Drug Administration has not responded in a way that one might expect of an agency charged with protecting Americans from hazardous food products. So far, their official response has been to ignore the issue altogether.

In 1971, University of Massachusetts food researchers Paul Letellier and Wassef Nawar discovered that when certain fats commonly found in food are irradiated, the resulting by-products include a unique class of chemicals called cyclobutanones. These chemicals have never been found to naturally occur in any food.

The structure of each cyclobutanone was very easy to predict, Letellier and Nawar wrote, because each particular type of cyclobutanone corresponded to a particular type of fat, based on the molecular structure of each.[1] (See chart, p. 9.)

Thirty years later, the discovery by Letellier and Nawar lies at the center of an international debate that could carry huge implications for the future of irradiated food.

What, on the surface, seems like good news for consumers is that cyclobutanones have been identified as prominent chemical markers that can persist in certain irradiated foods for more than a decade. As a result, tests for these unique radiolytic products

(URPs) have been developed to determine whether food has been irradiated, thus reducing the potential that consumers could unwittingly purchase irradiated food.

Beneath the surface is the bad news that cyclobutanones may be harmful to human health. In 1998 one particular cyclobutanone, 2-dodecylcyclobutanone (2-DCB), an irradiation by-product of palmitic acid, was shown in experiments to cause genetic and cellular damage to human and rat cells,[2] and genetic damage to rats given the substance.[3]

The worry is that palmitic acid is ubiquitous in foods. And, in many foods — including beef, pork, lamb, chicken and turkey — its concentration is the highest or second-highest among all fats. Palmitic acid also occurs in high quantities in dozens of ready-to-eat foods, including sauces, pizzas, baked goods and snack foods.

More recently, two additional cyclobutanones — 2-tetradecylcyclobutanone (2-TCB) and 2-tetradecenylcyclobutanone (2-TDCB), which are irradiation by-products of stearic and oleic acids, respectively — were shown to cause genetic and cellular damage to human cells.[4]

More bad news could be on the horizon: Several other types of cyclobutanones identified as irradiation by-products of other types of fats have never been tested for damage they could inflict on cells or genetic material.

Thus the irony and the danger: The very chemicals that could help regulators and scientists identify whether certain foods have been irradiated may be hazardous to human health.

Amid growing evidence that cyclobutanones could be harmful, to the public's knowledge the FDA has never conducted a formal analysis of the potential toxicity of these chemicals in foods that the agency has already legalized for irradiation, including fruit, vegetables, beef, pork, chicken, turkey, eggs and spices.

Neither has such an analysis been conducted for foods that the FDA is currently considering for irradiation — including shellfish and ready-to-eat foods such as frozen dinners, luncheon meat, baby food, pre-cut salads and snack foods, which comprise more than a third of the typical American's diet.

Moreover, high-ranking FDA officials have acknowledged that they have not compiled a list of foods defined as "ready-to-eat." One agency official said the category could include virtually "anything." Additionally, FDA officials legalized irradiation for eggs last year shortly after attending an international conference where the toxicity of 2-DCB was discussed.

The FDA has never formally examined the question of cyclobutanones, despite the fact that numerous studies conducted since 1990 have identified 2-DCB as a unique by-product of irradiated palmitic acid at doses as low as 0.5 kiloGray — far below the levels of radiation to which many types of food may legally be exposed. Beef, for example, may be irradiated with doses 14 times higher.

In the process, the FDA has not lived up to its own legal standards, which require the agency to determine a 100-fold safety factor for food additives proposed for human consumption.[5] (Under the Federal Food Additives Amendment of 1958, food irradiation is officially considered an "additive."[6])

Additionally, the FDA's long-held claim that the URPs formed in irradiated food are chemically and toxicologically similar or identical to natural food ingredients no longer holds water. The FDA made these claims in several Federal Register filings published during the 1980s and 1990s

In a 1987 filing, for example, the FDA wrote: "there is no evidence, or any reason to believe, that the toxicity or carcinogenicity of any unique radiolytic products is different from that of other food components."[7] In light of recent experimental evidence indicating that three URPs have cytotoxic and genotoxic properties, this claim is false.

And, in a 1988 Federal Register filing, the FDA wrote that its rulings to legalize food irradiation could not be legally challenged in a public hearing unless the agency is presented with "some evidence that suggests that there are significant toxicological or chemical differences between radiolytic products and known natural food components."[8]

Accordingly, given the substantial evidence that cyclobutanones have a unique chemical nature, future FDA rulings to legalize irradiation for additional classes of food without taking into account the potential health effects of these chemicals could trigger the necessity of convening public hearings.

The emerging problem of cyclobutanones is far from being resolved — even as food and health officials in the United States, in the European Union and around the world consider legalizing more foods for irradiation, and as the food industry worldwide puts more hope in irradiation as the answer to its food hygiene problems.

The issue is further complicated by the fact that the German government, which co-sponsored the recent cyclobutanone experiments, is officially on record as opposing an international proposal to remove the current 10 kGy dose limit[8a] — which would allow any food to be irradiated at any dose of radiation. (German law allows only herbs, spices and vegetable seasonings to be irradiated.[8b])

German officials have voiced their concerns about the proposal at recent meetings of the Codex Alimentarius Commission, a highly influential, quasi-governmental organization that sets international food safety standards on behalf of more than 160 countries. As of this writing, the proposal is perhaps two or more years from possible adoption.

The Search Begins

In the 20 years following the discoveries of Letellier and Nawar, little scientific interest in cyclobutanones was expressed. Great interest was expressed, however, in irradiation — by the food and nuclear industries, and by U.S. government officials. During that two-decade period, the FDA legalized the irradiation of pork, chicken, turkey, fruit, vegetables and dozens of spices and seasonings.

Eventually, the FDA would also legalize irradiation for beef, lamb, eggs, juice and sprouting seeds. And, at this writing, the FDA is considering proposals to irradiate ready-to-eat foods (which, according to the National Food Processors Association, comprise 37 percent of the typical American's diet); crustacean shellfish (such as crabs, shrimp and lobsters); and molluscan shellfish (such as clams, oysters and mussels).

As the number of food classes being legalized for irradiation increased, interest in finding techniques to detect whether food had undergone the process also increased. As late as 1988, however, the World Health Organization (WHO) reported that there was no "universal method" to make such detections.[9] Accordingly, a search was initiated to identify chemicals that could be used as markers that, if present in food, would prove that food had been irradiated.

In 1990, M. Hilary Stevenson and A. Victoria Crone of the Queen's University of Belfast picked up where Letellier and Nawar left off. In an article published in *Nature*, Stevenson and Crone reported using gas chromatography-mass spectrometry to find 2-DCB in minced chicken irradiated at 5 kGy. (The U.S. legal limit for chicken is 3 kGy.)

Stevenson and Crone studied 2-DCB because its molecular structure corresponds to that of palmitic acid, which represents 25 percent of the total fatty acid content of chicken. They reported that 2-DCB could be detected 20 days after irradiation. Based on the ease with which this chemical was detected, they concluded: "Our technique shows that 2-DCB is a potential post-irradiation marker for minced chicken meat and possibly for other products."[10]

Over the next decade, Stevenson, Crone and other food chemists broadened their search for 2-DCB in irradiated foods that contain palmitic acid. They also searched for other cyclobutanones in foods that contain other types of fat — mainly oleic acid and stearic acid.

They discovered that the irradiation by-products of each of these three fatty acids include cyclobutanones, which have never been found in any non-irradiated food prepared or stored under any conditions.

Stevenson participated in two key studies published in 1992:

◆ Stevenson and two colleagues discovered that the 2-DCB concentration in irradiated chicken increased in proportion to the radiation dose (ranging from 10-60 kGy). They also found 2-TCB, an irradiation by-product of stearic acid. Additionally, they discovered 2-DCB in chicken irradiated 13 years earlier by another group of scientists, "making it useful as a qualitative marker on long-term storage."[11]

◆ Stevenson reported that 2-DCB levels in irradiated chicken fell only slightly after 18 days of storage. Additionally, the chemical was found in chicken irradiated at 1 kGy — one-third the U.S. legal limit of 3 kGy. Stevenson also found 2-TCB in irradiated chicken. Both 2-DCB and 2-TCB were identified in irradiated eggs and pork. "The compounds," Stevenson wrote, "were not detected in the unirradiated samples."[12]

Three more studies were published in 1993, two of which involved Stevenson:

◆ Stevenson and several colleagues found both 2-DCB and 2-TCB in liquid whole eggs irradiated at 2.5 and 10 kGy. (The U.S. legal limit for eggs is 3 kGy.) Neither chemical was found in unirradiated eggs. The researchers concluded: "The absence of background levels in unirradiated samples should facilitate qualitative identification of irradiated liquid whole egg at very low doses... [And] the method should be applicable to a wide range of products of varying composition."[13]

◆ Researchers at Berlin's Institute for Social Medicine and Epidemiology found 2-DCB in irradiated whole egg and egg yolk. The chemical was not found in any of the unirradiated food.[14]

◆ Stevenson and several colleagues again found that 2-DCB levels in irradiated chicken increased in proportion to radiation dose (ranging from 1-10 kGy). They also reported, for the first time, that cooking either before or after irradiation did not remove the 2-DCB. They also reported that storing irradiated chicken for 21 days in air, in a vacuum or in carbon dioxide did not result in significant reductions of 2-DCB. Additionally, the researchers found both 2-DCB and 2-TCB in liquid whole egg irradiated at 2.5 kGy, below the U.S. legal limit of 3 kGy. "The method has potential for the estimation of irradiation dose," the researchers wrote. "[And] cyclobutanones ... are likely to have potential for the identification of a range of foods of varying fat and fatty acid composition."[15]

From 1994 to 2000, four more published studies expanded the understanding of cyclobutanones:

◆ In 1994, Stevenson found 2-DCB and 2-TCB in pork, lamb and beef irradiated at 1 kGy, far below the U.S. legal limit of 4.5 kGy. Concluded Stevenson: "Since most foods contain at least some fat, [this] method should be applicable to a wide range of foods... 2-DCB has never been detected in any unirradiated or microbiologically spoiled samples, and has always been found in irradiated samples even at doses as low as 0.5 kGy."[16]

◆ In 1995, researchers at Saarland University in Saarbrücken, Germany found a variety of cyclobutanones in irradiated duck (2.5 kGy), peanuts (5 kGy), pistachios (5 kGy) and instant soup mix (2.5 kGy).[17] Of these products, only duck can legally be irradiated in the U.S. (at 3 kGy). The other products could legally be irradiated, under certain circumstances, if the FDA approves a pending petition to irradiate ready-to-eat foods.

◆ In 1999, researchers at the University of Alexandria and University of Westminster found 2-DCB in freshwater tilapia and seawater mullet irradiated at a range of 2-8 kGy. The researchers wrote that scanning food for cyclobutanones is among two irradiation-detection methods that "have shown promise."[18]

◆ Last year, researchers at Queen's University of Belfast found 2-DCB in irradiated mangoes, papayas, salmon and Camembert cheese. Additionally, they found 2-TCB in irradiated mangoes, salmon and Camembert cheese.* A third cyclobutanone, 2-TDCB, was also detected in irradiated mangos and papayas, which contain oleic acid. As in several previous experiments, the cyclobutanones were formed in proportion to radiation dose.[19]

As a result of these and other published studies, the scientific community had developed by the end of 2000 a strong indication that cyclobutanones — particularly 2-DCB — could be used as effective chemical markers for certain irradiated foods. Dozens upon dozens of foods for which irradiation is legal or under consideration by the FDA contain palmitic acid, as well as oleic acid and stearic acid.

Further, the scientific community has identified unique cyclobutanone by-products of other types of fat. (See table, this page.)

Cyclobutanone Irradiation By-products of Certain Fatty Acids [20]

Linoleic[1]	> 2-Tetradecadienylcyclobutanone
Myristic[2]	> 2-Decylcyclobutanone
Oleic[3]	> 2-Tetradecenylcyclobutanone (2-TDCB)
Palmitic[4]	> 2-Dodecylcyclobutanone (2-DCB)
Stearic[5]	> 2-Tetradecylcyclobutanone (2-TCB)

[1] Linoleic acid ($C_{18:2}$) is a polyunsaturated fatty acid
[2] Myristic acid ($C_{14:0}$) is a saturated fatty acid
[3] Oleic acid ($C_{18:1}$) is a monounsaturated fatty acid
[4] Palmitic acid ($C_{16:0}$) is a saturated fatty acid
[5] Stearic acid ($C_{18:0}$) is a saturated fatty acid

Problems Emerge

As the scientific community's knowledge of cyclobutanone URPs advanced, so did the FDA's approval of food irradiation petitions. By the end of 2000, the irradiation of most classes of food had been legalized: beef, pork, lamb, chicken, turkey, fruit, vegetables, eggs, juice, sprouting seeds, and spices and seasonings.

At this writing, the FDA is also considering proposals to legalize the irradiation of ready-to-eat foods (such as frozen dinners, luncheon meat, baby food, pre-cut salads and snack foods), and crustacean and molluscan shellfish.[21]

Also at this writing, research into the potential toxicity of URPs is continuing. The initiative began in Karlsruhe, Germany in 1994, when the International Consultative Group on Food Irradiation (ICGFI) recommended that "the literature be searched for identification and quantification of radiolytic products" and that "the presence of such products be evaluated for possible toxicological concern."[22]

ICGFI's recommendation carried a lot of weight. The organization, which has more than 40 member nations, was jointly created and is jointly managed by the United

* In irradiated papayas, 2-DCB was "identified as the principal irradiation marker" and was detected after 21 days of storage at doses at low as 2 kGy. In irradiated mangoes, 2-TCB was "identified as the main marker" and was detected after 14 days of storage at doses as low as 0.1 kGy.

Nations' Food and Agriculture Organization, the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO).

Following this recommendation, ICGFI co-funded research into the potential toxicity of 2-DCB at the Federal Research Center for Nutrition (FRCN) in Karlsruhe, Germany, where approximately 100 food irradiation experiments had been conducted since 1970 with funding assistance by the IAEA. The lead researcher was Henry Delincée of the FRCN's Institute of Nutritional Physiology.

FRCN's first experiment, published in *Radiation Physics and Chemistry*, was an *in vitro* study conducted on human and rat colon cells. The researchers reported that "a cytotoxic effect with increasing dosage [was] clearly demonstrated" with 2-DCB. They also reported that the "results clearly demonstrate a genotoxic effect of 2-DCB. However, concentrations tested are very high compared with actual human intake." Delincée concluded that "more experiments than these preliminary ones are required."[23]

FRCN's second experiment, delivered at the Fifth German Conference on Food Irradiation in Karlsruhe in 1998, was an *in vivo* study conducted on male Sprague-Dawley rats. The administration of 2-DCB caused "no cytotoxic effects" in the colon cells of the rats. However, "slight but significant DNA damage" — specifically, DNA strandbreaks — was detected in the colon cells of rats fed the higher of two concentrations of 2-DCB.

The higher concentration of 2-DCB corresponded to irradiation at 60 kGy, a dose capable of completely sterilizing chicken, and a dose that would be allowable under standards proposed by the Codex Alimentarius Commission. The lower dose corresponded to irradiation at 3 kGy, the U.S. legal limit for chicken.

Delincée concluded that "further clarification is needed to determine whether these results are relevant to the safety of irradiated foods.. The results urge caution, and should provide impetus for further studies."[24]

FRCN's third experiment, an abstract of which was delivered at the 12th International Meeting on Radiation Processing in March 2001 in Avignon, France, tested the toxicity of 2-TCB and 2-TDCB, irradiation by-products of stearic and oleic acids, respectively. In this *in vitro* study conducted on human colon cells, Delincée found that both 2-TCB and 2-TDCB had "a slight cytotoxic effect" that "became obvious by longer incubation times." Regarding "DNA fragmentation," the substances caused "only very slight effects at the highest concentrations applied."

Delincée concluded: "Further studies are progressing to elucidate the relevancy of these experiments for the actual human exposure to cyclobutanones by consuming irradiated fat-containing food."[25]

In further discussing his findings, Delincée said: "Since we would like to know whether in the case of cyclobutanones these DNA strandbreaks have any significance, we concluded that further experiments are required."[26]

The additional studies that Delincée recommended are underway but have not been completed or published.

A Skeptical Response

When Delincée's findings were brought to the attention of international organizations including ICGFI — which co-funded the experiments — they were met with skepticism.

In a 1999 report on the wholesomeness of high-dose irradiated food, the WHO stated that Delincée's *in vitro* experiment yielded "some cytotoxicity and an associated but weak effect in DNA."[27] As stated above, Delincée actually reported finding that "a cytotoxic effect with increasing dosage [was] clearly demonstrated," and that the "results clearly demonstrate a genotoxic effect of 2-DCB." The WHO report also stated that

Delincée used doses of 2-DCB "about three orders of magnitude" (1,000 times) higher than those found in chicken irradiated at 59 kGy. The report does not explain how the WHO arrived at this calculation.[28]

Regarding the *in vivo* study, the WHO report stated that Delincée "found a small positive effect."[29] Delincée actually reported finding "slight but significant DNA damage." And, the WHO report stated that Delincée used an "extremely high level" of 2-DCB.[30] Delincée actually used a level of 2-DCB commensurate with an irradiation dose that would be permitted under a pending Codex proposal. Additionally, when Delincée applied the FDA's standard toxicological safety factor of 100, 2-DCB was shown to have a genotoxic effect, thus failing the safety test required by the U.S. Code of Federal Regulations.[31]

The WHO report also stated that the method Delincée used to test for genotoxicity, the "Comet assay," is an "unvalidated" technique. The technique, however, was endorsed as an additional method for detecting DNA damage at a joint meeting of the Genetic Toxicology Association and the Association of Government Toxicologists in October 1998. Officials from the FDA and U.S. Environmental Protection Agency wrote in a report of the meeting:

> "Most [attendees] said that Comet data generated and submitted to regulatory agencies would be accepted and used along with data from assays in the standard test battery, but would not replace standard tests. Much of the success of this assay is due to its simplicity, versatility, reliability, and speed... [I]t is becoming a well used tool for pre-screening of potential DNA-damaging activity."[32]

The WHO report also stated that an unpublished "Ames" test (which can determine whether a substance causes mutations in bacteria) was negative. The report, however, did not provide any other information on the test, such as who conducted it, or when or where it took place.

Delincée's findings were also met with skepticism at several international meetings attended by food irradiation policymakers, including several policymakers from the United States.

At the 15th meeting of ICGFI held in Vienna in October 1998, Irwin Taub of the U.S. Army's Soldier Systems, the author of numerous articles in support of food irradiation, was one of three attendees who "expressed their skepticism of the outcome" of Delincée's rat study. Other U.S. officials present at the meeting were Peter Grosser, Lloyd Harbert and Ralph Ross, all of the U.S. Department of Agriculture (USDA).[33]

At the 16th meeting of ICGFI held in Antalya, Turkey in October 1999, all ICGFI delegates received a peer-reviewed report on the Delincée studies. Dieter Ehlermann, director of the FRCN in Karlsruhe, stated at the meeting that further studies into the genotoxicity of 2-DCB would be conducted.[34] Again, the Army's Taub raised questions, inquiring into the "purpose" of the studies. Among other U.S. officials present were the USDA's Lloyd Harbert and Fritz Kaferstein.[35]

Delincée's studies were then discussed at the 32nd Session of the Codex Committee on Food Additives and Contaminants (CCFAC) held in Beijing in March 2000. Also discussed at this meeting was CCFAC's proposal to change the Codex General Standard for Irradiated Food by removing the 10 kGy radiation dose cap and allowing any food to be irradiated at any dose.

For the first time, concerns over cyclobutanones led a country's Codex delegation to go on record opposing the proposal to remove the 10 kGy dose cap. The country was Germany, which had been co-sponsoring Delincée's research at the Federal Research

Center for Nutrition. (Among European nations, Germany's food irradiation laws are among the most restrictive, allowing only spices, dried herbs and dried vegetable seasonings to be irradiated.[36])

According to the official report of the meeting: "The delegation of Germany stated that Germany cannot support the [proposal to remove the 10 kGy dose cap] on the basis of safety considerations arising from the formation of cyclobutanones in irradiated fatty foods and referred to a new study being commissioned by the EU [European Union] to examine the toxicological implications of cyclobutanones formed as a consequence of irradiation."[37]

Meanwhile, the U.S. was among the three countries that most strongly supported the proposal to remove the 10 kGy cap. The U.S. delegation included five officials who work within the FDA department in charge of food irradiation policy, including Alan Rulis, head of the FDA's Office of Premarket Approval. Representing the USDA, which works closely with the FDA and has a significant role in regulating irradiated beef, chicken and pork, were David Egelhofer, Ellen Matten and Thomas Whitaker.[38]

On July 21, 2000, Rulis' staff at the Office of Premarket Approval approved a petition to legalize the irradiation of eggs.[39] The petition was filed in 1998, the same year that the first two Delincée studies were made public. The approval came just four months after the Beijing meeting, at which Delincée's toxicity studies were discussed.

Additionally, by the time of the approval, no fewer than five articles had been published in scientific journals indicating that 2-DCB was a unique radiolytic by-product formed in irradiated eggs. Despite Rulis' direct knowledge of Delincée's toxicity studies, no mention of 2-DCB was made in the Federal Register notice that announced the egg ruling.[40]

Moreover, the egg petition included no toxicological data on 2-DCB nor any other potentially toxic chemical formed in irradiated eggs. Instead, FDA staffers relied on three studies — conducted from 1959 to 1974 — that earlier had been criticized by the agency's own scientists.

(Though the studies yielded no evidence of toxicity or carcinogenicity, an FDA staffer wrote that the studies were inadequate for the following reasons: "there were many studies in the report and each study was not clearly stated and, thus, hard to follow;" "only a few parameters [were] studied;" and "it is a summary."[41])

At the next CCFAC meeting, held in The Hague in March 2001, the German delegation once again opposed the Codex proposal to remove the 10 kGy radiation dose cap.

Once again, the Delincée studies were discussed and, once again, the results were dismissed and misstated. WHO's representative at the meeting said "the available scientific evidence did not indicate that 2-DCB posed a public health risk." And, ICGFI's representative falsely stated that Delincée's "preliminary results were negative with regard to genotoxicity and cytotoxicity."[42]

FDA and the Future

The FDA is considering petitions to irradiate ready-to-eat foods,[43] crustacean shellfish[44] and molluscan shellfish.[45] None of these petitions, however, contain any data on 2-DCB or any other cyclobutanone, nor do they contain data on the palmitic acid content of any foods covered by the petitions.

Moreover, the FDA has not compiled a list of foods that are covered by the ready-to-eat foods petition.[46, 47] Accordingly, the agency is not in the position to know the various fatty acid contents of food covered by the petition.

This would be of great concern if the FDA approves the petition, as palmitic acid occurs in pronounced quantities in virtually all types of meat (including fish and shellfish), vegetables, fruit, grains, dairy products and vegetable oils.

Palmitic acid also occurs in significant quantities in dozens of ready-to-eat foods that ostensibly are covered by the petition, including sauces, pizzas, baked goods, snack foods and many other foods.[48]

The high concentrations of palmitic acid in shellfish also give rise to great concern.

Among crustacean shellfish, this fat represents 16 percent of the fatty acids by weight in Alaskan shrimp, 14 percent of the fatty acids in queen crab, and 9 percent of the fatty acids in king crab.[49]

Among molluscan shellfish, this fat represents the largest percentage of fatty acids in American oysters (29 percent), ocean quahog (24 percent) and European oysters (22 percent); and it represents the third-highest percentage of fatty acids in Pacific scallops (19 percent).[50]

Moreover, the FDA has never formally assessed the cyclobutanone content, much less the fatty acid content, of foods that the agency has already legalized for irradiation. This is of great concern, due to the high palmitic content of these foods — some of which are on public sale in grocery stores and meat markets.

Among red meat, palmitic acid is the fatty acid with the second-highest concentration: 26 percent in beef, 24 percent in pork, 24 percent in veal, and 23 percent in lamb.[51]

Among poultry, palmitic acid is also the fatty acid with the second-highest concentration: 22-25 percent in chicken, 21-22 percent in turkey, 26-28 percent in duck, and 23-28 percent in goose.[52]

Recommendations

In the interest of protecting the health of Americans, and in order for the agency to fulfill its mandate to protect Americans from dangerous food additives, Public Citizen and the Center for Food Safety call on the FDA to:

- Conduct a comprehensive analysis of the fatty acid and cyclobutanone levels of all foods covered by irradiation petitions already approved by or pending before the FDA.

- Refrain from legalizing the irradiation of any additional foods until comprehensive, published, peer-reviewed research is conducted into the potential genotoxicity, carcinogenicity, mutagenicity and cytotoxicity of cyclobutanones known or suspected to be present in foods covered by petitions approved by or pending before the FDA. This must include the calculation of a 100-fold safety factor for cyclobutanones, which, in the absence of an alternative safety factor justified by evidence, the U.S. Code of Federal Regulations requires must be calculated before a food additive can be legalized for human consumption.[53]

- Convene public hearings to thoroughly explore the potential health effects of cyclobutanones. The FDA's official legal threshold for convening public hearings on the potential health effects of irradiated food is the presence of "significant toxicological or chemical differences between radiolytic products and known natural food components."[54] In regard to cyclobutanones, this threshold clearly has been met, given the vast body of evidence on the unique chemical composition of these substances, and the growing body of evidence that these substances have cytotoxic and genotoxic properties.

Plainly, to adequately serve the American people, whose health and safety the FDA was created to protect, the FDA should not approve irradiation for any additional foods, and should order a suspension of all ongoing food irradiation, until the agency answers these fundamental questions. Failure to do so could put the health of the American people at serious risk.

Notes

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[6] Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. U.S. Congress, 1958.

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[8] 53 Federal Register 53180, Dec. 30, 1988.

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