

-
- 1 WHO, "Wholesomeness of Irradiated Food: Report of a Joint FAO/IAEA/WHO Expert Committee," World Health Organization Technical Report Series, No. 659, World Health Organization, Geneva, 1981.
 - 2 Codex 2003. "Codex General Standard for Irradiated Foods (CODEX STAN 106-1983, Rev.-2003) and "Recommended Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods (CAC/RCP 19-1979, Rev.-2003)." Codex Alimentarius Commission, Food and Agriculture Organization and World Health Organization, Rome (2003)
 - 3 Safety and Nutritional Adequacy of Irradiated Food, World Health Organism, Geneva (1994)
 - *4 Memorandum for FAP 9M4682 from E. Jensen, FDA, to L. Highbarger, FDA, August 2, 2002
 - 5 Diehl, J.F., Safety of Irradiated Foods, Second Edition, Marcel Dekker, Inc., New York, (1995)
 - 6 Seibersdorf Project Report, International Programme on Irradiation of Fruit and Fruit Juices, Chemistry and Isotopes Department, National Centre for Nuclear Energy, Madrid, Spain, Vol 8, 1966
 - *7 Memorandum for FAP 9M4682 from K. Morehouse, FDA, to L. Highbarger, FDA, July 15, 2005,
 - *8 Memorandum for FAP 9M4695 from I. Chen, FDA, to L. Highbarger, FDA, April 7, 2003
 - *9 Uderdal, B., J. Nordal, G. Lunde, and B. Eggum. "The effect of ionizing radiation on the nutritional value of fish (cod) protein," Lebensmittel-Wissenschaft Technologie, 6:90-93 (1973).
 - *10 von Sonntag, C., "Free-radical reactions of carbohydrates as studies by radiation techniques," Adv. Carbohydr. Chem. Biochem. 37:7-77 (1980).
 - 11 WHO, "High-dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy," World Health Organization Technical Report Series, No. 659, World Health Organization, Geneva (1999)
 - *12 Delincée, H., "Recent advances in radiation chemistry of lipids," in Recent Advances in Food Irradiation, P. S. Elias and A. J. Cohen, eds., Elsevier, Amsterdam, pp 89-114 (1983)
 - *13 Kavalam, J.P., and W. W. Nawar, "Effects of ionizing radiation on some vegetable fats," Journal American Oil Chemical Society, 46:387-390 (1969).
 - *14 Nawar, W.W., "Thermal Degradation of Lipids. A Review," Journal of Agricultural Food Chemistry, 17(1): 18-21 (1969).
 - *15 Crone A. V. J., Hamilton, J. T. G., and M. H. Stevenson, "Effect of Storage and Cooking on the Dose Response of 2-Dodecylcyclobutanone, a Potential Marker for Irradiated Chicken," J. Sci. Food Agric., 58:249-252 (1992)
 - *16 Gadgil, P., Hachmeister, K. A., Smith, J. S., and D. H. Kropf, "2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties," J Agric. Food Chem., 50:5746-5750 (2002)
 - *17 Adams, S., G. Paul, D. Ehlerman, "Influence of Ionizing Radiation on the Fatty Acid Composition of Herring Fillets." Radiat. Phys. Chem. 20:289-295 (1982).

-
- *18 Armstrong, S.G. Wylie, S.G., and D.N. Leach, "Effects of Preservation by Gamma-Irradiation on the Nutritional Quality of Australian Fish," Food Chemistry 50:351-357 (1994)
- *19 Sant'Ana, L.S. and J. Mancini-Filho "Influence of the Addition of Antioxidants in Vivo on the Fatty Acid Composition of Fish Fillets" Food Chemistry 68:175-178 (2000)
- *20 Status Report on Food Irradiation by Member Countries of the International Consultative Group on Food Irradiation, IAEA Headquarters, Vienna, Austria, 20-22 October, 1998
- *21 Morehouse, K.M., Y. Ku, "Gas Chromatographic and Electron Spin Resonance Investigations of Gamma-Irradiated Shrimp," J. Agric. Food Chem., 40(10), 1963-1971 (1992)
- 22 Morehouse, K.M., "Identification of Irradiated Seafood," in Detection Method for Irradiated Foods: Current Status, McMurray, C.H., Stewart, E.M., Gray, R. and Pearce J., eds, The Royal Society of Chemistry, Cambridge, UK, pp249-258 (1996)
- *23 Buck, J.D., "Potentially Pathogenic Vibrio spp. In Market Seafood and Natural Habitats from Southern New England and Florida," J. of Aquatic Food Product Tech., 7(4):53-61 (1998)
- 24 Oliver, J.D. and Kaper, J.B, "Vibrio Species," In M.P. Doyle, L. Beuchat and T.J. Montville (ed.) Food Microbiology, Fundamentals and Frontiers, 2nd Ed., ASM Press, Herndon, VA. (2001)
- *25 Memorandum for FAP 9M4682 from R. Merker, FDA, to L. Highbarger, FDA January 2, 2003
- *26 Tauxe, R.W., Emerg. Infect Dis., 7:516-21 (2001)
- 27 Diehl, J.F., Safety of Irradiated Foods. Marcel Decker, New York, Basel (1990)
- *28 Cotton, P. A., Subar, A. F., Friday, J. E., Cook, A., "Dietary Sources of Nutrients Among US Adults, 1994 to 1996," J. Am. Diet. Assoc., 104:921-930 (2004)
- *29 Anderson D, M.J.L. Clapp, M.C.E. Hodge, and T.M. Weight, "Irradiated laboratory animal diets – Dominant lethal studies in the mouse," Mutation Research: 80:333-345 (1981)
- *30 Buggy L., A.R. Deschreiaer, and J. Moutschen, "Do Irradiated Foodstuffs Have a Radiomimetic Effect: II. Trials with Mice Fed Wheat Meal Irradiated at 5 MRad," Atompraxis, 14, 112 (1968)
- *31 Moutschen-Dahmen M, Moutschen J, and L. Ehrenberg, "Pre-implantation death of mouse eggs caused by irradiated food," Int. J. Radiat. Biol. 18:201-216 (1970)
- *32 Johnston-Arthur T, M. Brena-Valle, K. Twanitz, R. Hrubby, and G. Stehuk, "Mutagenicity of irradiated food in the host-mediated assay system," Studia Biophysica Berlin, 50:137-141 (1975)
- *33 Kesavan, P. C. and Swaminathan, M. S.; Cytotoxic and mutagenic Effects of Irradiated Substances and Food Material; Radiation Botanay; Vol 11; pp 253-281; (1971)
- *34 Verschuurn, H. G., Esch, G. J., and Kooy, J. G.; Ninety Day Rat Feed Study on Irradiated Strawberries; Food Irradiation; 7 (1-2); pp A17-A21 ;(1966)
- *35 Memorandum from Food additives Evaluation Branch, HFF-156 to C. Takaguchi, Ph.D., Petition Control Branch, December 28, 1982
- *36 Bureau of Foods Irradiated Foods Committee, Recommendations for Evaluating the Safety of Irradiated Food, Prepared for the Director, Bureau of Foods, FDA, July 1980
- 37 Toxicological Principles for the Safety Assessment of Direct Food Additives and Color

-
- Additives Used in Food, "Red Book II", US Food and Drug Administration, Center for Food Safety and Applied Nutrition, (1993, revised 2001)
- *38 Organization for Economic Co-Operation and Development, European Nuclear Energy Agency, Steering Committee for Nuclear Energy Study Group on Food Irradiation, On Genetic Effects Produced by Irradiated Foods and Food Components, Scarascia-Mugnozza, G.T., Natarajan, A. T., and L. Ehrenberg, (1965)
- *39a Miesch, M., Ndiye, B., Hasselmann, C., and E. Marchioni, "2-Alkylcyclobutanones as markers for irradiated food stuffs – I. Synthesis of saturated and unsaturated standards," Rad. Phys. And Chem., 55:337-344 (1999)
- *39b Horvatovich, P., Miesch, M, Hasselmann, C., and E. Marchioni, "Supercritical fluid extractin of hydrocarbons and 2-alkylcyclobutanones for the detection of irradiated foodstuffs," J. of Chromatography, 897:259-268 (2000)
- *40 Delincée H, B.L. Pool-Zobel, and G. Rechkemmer "Genotoxicity of 2-dodecylcyclobutanone," Food Irradiation: Fifth German Conference, Report BFE-R-99-01, Federal Nutrition Research Institute, Karlsruhe, Germany (unpublished, 1998)
- *41 Memorandum for FAP 9M4682 from R. Sotomayer, FDA, to L. Highbarger, FDA, April 28, 2003
- *42 Sommers C. H., and R. H. Schiestl, "2-Dodecylcyclobutanone does not induce mutations in the Salmonella mutagenicity test or intrachromosomal recombination in *Saccharomyces cerevisiae*," J Food Prot. 67(6):1293-8 (2004)
- *43 Sommers, H., "2-Dodecylcyclobutanone Does Not Induce Mutations in the *Escherichia coli* Tryptophan Reverse Mutation Assay," J. Agric. Food Chem., 51:6367-6370 (2003)
- *44 Gadgil, P. and J.S. Smith, "Mutagenicity and Acute Toxicity Evaluation of 2-Dodecylcyclobutanone", Journal Of Food Science, 69(9), 713-716 (2004)
- *45 Delincée H, and BL Pool-Zobel. "Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat," Radiation Physics and Chemistry 52:39-42 (1998)
- *46 Henderson, L., A Wolfreys, J Fedyk, C Bourner and S Windebank "The ability of the Comet assay to discriminate between genotoxins and cytotoxins," Mutagenesis, 13:89-94, (1998)
- *47 Victoria, A., J. Crone, J. T. G. Hamilton, and M. Hilary Stevenson, "Detection of 2-dodecylcyclobutanone in radiation sterilized chicken mean stored for several year," Int. J. J. of Food Sci. and Tech, 27:691-696 (1992).
- *48 Marchioni, E., Raul, F., Burnouf, D., Miesch, M., Delincee, H., Hartwig, A., Werner, D.; "Toxicological study on 2-alkylcyclobutanones – results of a collaborative study;" Radiation Chemistry and Physics, 71:147-150 (2004)
- *49 Raul, F., F. Gosse, H. Delincee, A. Hartwig,, E. Marchioni, M. Miesch, D. Werner, and D. Burnouf, "Food Borne Radiolytic Compounds (2-Alkylcyclobutanones) May Promote Experimental Colon Carcinogenesis," Nutrition and Cancer, 44(2):181-191(2002)
- *50 Rao, C., "Do Irradiated Foods Cause or Promote Colon Cancer?," Division of Nutritional Carcinogenesis, Institute for Cancer Prevention, American Health Foundation—Cancer center, Valhalla, NY (Unpublished, 2003) FDA notes that this article has now been published as a commentary in Nutr. and Cancer, 46(2):107-109 (2003)
- 51 Casserett & Doull's Toxicology, the basic science of poisons (2001)
- *52 Memorandum for FAP 9M4682 from T. Twaroski, FDA, to L. Highbarger, FDA, July 14,

2005

- *53 Mori H., Yamada, Y., Kuno, T., and Y. Hirose, "Aberrant crypt foci and β -catenin accumulated crypts; significance and roles for colorectal carcinogenesis," Mut. Res., 566:191-208 (2004)
- *54 Kesavan, P. C. and P. V. Sukhatame. "Summary of the Technical Report on the Data of NIN," Hyderabad and BARC. Bombay on the Biological Effects of Freshly Irradiated Wheat. Report submitted to the Indian Ministry of Health and Family Planning (1976)
- *55 Memorandum for FAP 4M4428, from D. Hattan, to FAP 4M4428; Further Evaluation of Toxicological Studies, November 20, 1997
- *56 Comment submitted by Henry Delincée to the docket
- 57 Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food, "Red Book I", US Food and Drug Administration, Center for Food Safety and Applied Nutrition, (1982)
- *58 Britto M.S., A.L.C.H. Villavicencio, and J. Mancini-filho, "Effects of irradiation on trans fatty acids in ground beef," Radiation Physics and Chemistry 63:337-340 (2002)
- *59 Memorandum for FAP 9M4682 from K. Morehouse, FDA, to L. Highbarger, FDA, July 15, 2005.
- *60 E-mail from Paul Kuznesof to L. Highbarger to be added to FAP 9M4682, April, 28, 2003
- *61 Jaarma, M., "Studies of Chemical and Enzymatical Changes in Potato Tubers and some Higher Plants caused by Ionizing Radiation, Including Studies on the Wholesomeness of γ -Irradiated Potato Tubers and Effects on Some Carbohydrates in vitro, Biokemiska Institutionen, Kuugl, Univeritetet I Stockholm, Stockholm, Sweden (1967)
- *62 Memorandum 2 for FAP 9M4682 from T. Twaroski, FDA, to L. Highbarger, FDA, July 14, 2005, 2005
- *63 Jaarma, M., G. "Bengtsson On the wholesomeness of γ -irradiated Potatoes II. Feeding experiments with pigs" Nutr. Dieta 8:109-129 (1966).
- *64 Stephansson, O., Dickman, P. W., Johansson, A., and S. Cnattingus, "Maternal Hemoglobin Concentration During Pregnancy and Risk of Stillbirthm," J. Am. Med. Ass., 248(20):2611-2617 (2000)

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and record keeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and re delegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 179 is amended as follows:

PART 179--IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows: