

Reference 5



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

March 31, 2000

From SCIENTIFIC SUPPORT BRANCH (HFS-207)

Subject Use of Approved Sources of Ionizing Radiation as a Physical Process for the Pasteurization of Fresh Shell Eggs to Kill *Salmonella*

To REGULATORY POLICY BRANCH (HFS-206)

ATTENTION: WILLIAM J. TROTTER

FAP 8M4584
Vol 1-4Food Science and Nutrition Research Center
University of Rhode Island, West Kingston
Rhode Island 02892-1802

Edward S. Josephson, Ph.D. (Professor, University of Rhode Island) has submitted a petition requesting that 21 CFR part 179 of the food additive regulations be amended to allow the use of approved sources of ionizing radiation as a physical process for the pasteurization of fresh shell eggs to kill *Salmonella enteritides*. We reviewed the initial submission, and concluded that fresh shell eggs irradiated at a dose range of 0.7 to 1.7 kGy do not present either a toxicological or a nutritional concern (see Chen memo of 12/11/98). However, in a letter dated 12/22/99, the petitioner requested that the FDA approve an extension of the irradiation dose range to cover up to a maximum of 3.0 kGy.

Based on our previous evaluations of all the available results of chemical analysis and toxicology testing on irradiated food (see Chen memo of 12/11/98), and on the fact that the extension in dose range requested is minor, we conclude that using approved irradiation technology up to a dose level of 3.0 kGy to pasteurize fresh shell eggs poses no toxicological impact to the consumer. We also acknowledge the FAO/IAEA/WHO Joint Expert Committee's conclusion that "the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazards".

We also considered all the available nutritional information in our files and study articles in FAP 8M4584. The reduction in protein and fat levels due to irradiation is insignificant because protein and fat are not significantly altered due to irradiation. However, vitamins are sensitive to irradiation. A study report entitled "Effects of 3.1 kGy Maximum Dose on Some of the Nutrition, Chemical, and Sensory Aspects of Shell Eggs", showed that the vitamin A retention levels in eggs irradiated at 0.5, 1.0, 1.1 and 3.1 kGy, then stored at 4°C up to 33 days, were 90.6%, 75.1%, 73.1% and 20.1%, respectively, compared to unirradiated controls (Volume 3, pp849). In our previously memorandum (see Chen

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memo of 12/11/98), we discussed the loss of vitamins due to irradiation, and concluded that the loss may be compensated by other dietary sources because we consume a variety of foods. In that memorandum, we provided a Table entitled "Vitamin Content in Egg and Some Commonly Consumed Foods", which showed other vitamin rich food sources. Review articles and studies also suggest that the retention values of vitamins are comparable or higher when irradiation was applied to a variety of foods rather than thermal preservation. Extending the maximum dose for irradiation of shell eggs to 3 kGy in no way alters our conclusions regarding nutritional adequacy.

In conclusion, based on all available information fresh shell eggs irradiated at a dose range of 0.7 to 3 kGy does not present either a toxicological or a nutritional concern.

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cc: HFS-200, HFS-207(Hansen, Mattia), HFS-225 (Edwards),
HFS-207:ISChen202-418-3036:Doc:IR8M4584.3kG