Reference 2,6

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date
April 11, 2000

From
Division of Product Manufacture and Use, HFS-245

Subject FAP 8M4584: 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
Division of Product Policy
Attn.: W. Trotter, Ph.D.

The purpose of this memo is to explicitly address the amended request by the petitioner, dated December 22, 1999,[1] to extend the dose range for this petition to allow for a maximum dose of 3 kGy. In our review of FAP 8M4584, see memo dated May 14, 1999,[2] we based our conclusions on the petitioner's requested maximum dose of 1.7 kGy. However, all of the data presented in the petition, up to a maximum dose of 3.1 kGy, were used for our evaluation. Since the chemical changes induced by the radiation are dose dependent, and any increase should be linear in the dose range of 1.7 to 3.1 kGy, there will be an increase in the degradation of the food components, i.e., protein and vitamins. The proposed increase, from a maximum dose of 1.7 to 3 kGy, is only about a factor of two. Therefore, we would expect a factor of two increase, at most, in the amounts of radiolysis products. As noted in our previous review, using the data from meat and poultry, one would see about a 20-25% loss of water-soluble vitamins at 3 kGy versus 10-20% for 1.7 kGy. As an example, the discussion of the retention of vitamin A from the previous memo is repeated below.

a. Effect of irradiation and storage on retention of vitamin A in egg yolk

The results presented in the petition indicate an inverse relationship between increasing the irradiation dose and vitamin A retention. In one study (Effects of a 1 kGy maximum dose on some of the nutritional, chemical and sensory characteristics of shell eggs. FAP 8M4584, Appendix 3, pp. 772 to 785, Run #1), Vitamin A retention in whole shell eggs irradiated at 0.5 kGy minimum dose and stored for 24 days post irradiation was 90%, and 76% for eggs irradiated at 1.0 kGy and stored for 24 days, compared to non-irradiated control eggs also stored for 24 days. In a similar study (Effects of a 1 kGy maximum dose on some of the nutritional, chemical and sensory characteristics of shell eggs. FAP 8M4584, Appendix 3, pp. 772 to 785, Run #2),

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[1] Letter from E.S. Josephson, University of Rhode Island, to W. Trotter, Regulatory Policy Branch, FDA, dated December 22, 1999.

[2] Memorandum from the Division of Product Manufacture and Use, FDA, to Regulatory Policy Branch, FDA, dated May 14, 1999.

conducted over 56 days post-irradiation storage, vitamin A retention in egg yolk irradiated at 0.5 kGy was 94.7%, and for egg yolk irradiated at 1.0 kGy vitamin A retention was 73%.

In another study (Effects of 3.1 kGy maximum dose on some of the nutritional, chemical and sensory characteristics of shell eggs. FAP 8M4584, Appendix 4, pp. 849 to 860), whole shell eggs were irradiated with a maximum dose of 3.1 kGy (0, 1.1 and 3.1 kGy). For the 3.1 kGy irradiated shell eggs, the retention of vitamin A was 20% after 33 days post-irradiation storage.

Table 1. Effect of irradiation and storage on percent of Vitamin A retained in egg yolk.

	Irradiation Dose (kGy)			
Storage Time (days)	0	0.5	1	3.1
2.	100	93.7	81.0	41.8
15	100	87.4	73.9	35.5
33	100	91.2	73.9	20.1

The significance of the retention of vitamins in radiation treated shell eggs has been addressed in a memo from I. Chen.[3]

CONCLUSION

We have re-reviewed the data and information submitted in the petition, as well as data available in our files, regarding the irradiation chemistry of eggs. The requested amendment to increase the maximum permitted dose for shell eggs to 3 kGy does not change the general conclusions that were presented in our original evaluation.

We have no questions on the chemistry-related issues associated with this petition.

Kim M. Morehouse, Ph.D.

[3]Memorandum from the Division of Product Policy, FDA, to Regulatory Policy Branch, FDA, dated December 11, 1998.