Reference 4,7

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date May 14, 1999

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.

INTRODUCTION

The University of Rhode Island is petitioning to amend 21 CFR 179.26 to include the use of ionizing radiation to control salmonella in fresh shell eggs. The University of Rhode Island asserts that ionizing radiation is a safe and effective technology for the control of salmonella in shell eggs. The Division of Product Manufacture and Use has used the data provided by the petitioner, data readily available in the literature, as well as information contained in the Divisions files in its evaluation.

IDENTITY AND USE OF RADIATION SOURCE

The petitioner requests that the maximum absorbed dose for the irradiation pasteurization[1] of shell eggs be set at 1.7 kGy, whereas the minimum absorbed dose of 0.7 kGy is required to effect a two-log reduction of Salmonella enteritidis in shell eggs. The petitioner states that there is no indication that a dose higher than 1.7 kGy would be unsafe; however, a higher dose can result in a greater reduction of vitamin A and an increase in loss of egg quality indicators. A dose range is required to accommodate the requirements of commercial processing facilities. The requested dose maximum was derived from the variation in the density of shell eggs and the dose uniformity ratios that would be expected in different commercial irradiation facilities, given the dose minimum required as well as an assessment of the research. Most shell eggs irradiated will receive an absorbed dose that is lower that the proposed maximum dose. The sources of ionizing

[1]In this review memorandum, the term "pasteurization" is used in the same sense as in the petitioners narrative, that is, to indicate a reduction in the number of pathogenic organisms. The use of this term is not meant to imply that eggs treated at the dose proposed in the petition meet the performance standard for pasteurized shell eggs treated thermally (i.e., a 5-log reduction in the number of pathogenic organisms).

radiation will be those listed under §179.26(a).[2]

The purpose of the proposed irradiation process for shell eggs is pasteurization: specifically the destruction of Salmonella species without causing undesirable changes in the product. The process requested is not a sterilization process. Treated shell eggs would still need to be refrigerated and handled properly.

The fresh shell eggs will be packaged prior to irradiation in commercially available packaging materials. Because the egg shell provides a natural barrier between the edible portion of the egg and the packaging material, the chemical composition of the packaging material for the shell eggs during irradiation is of no concern.

EFFECTS OF IRRADIATION ON FOOD COMPONENTS

The term "radiation chemistry" refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. Like all chemical reactions, these radiation-induced reactions depend on the nature of the reactants and on the energy supplied to the system. In the context of food irradiation, the radiation-induced reactions depend on the chemical constituents of the food and such factors as the ambient atmosphere (which also contains potential reactants), the physical state of the food, the ambient temperature, and the radiation dose. Radiation-induced chemical reactions can affect the chemical composition of the food and the cellular components of the microorganisms in or on the food.

The effects of irradiation processing on the characteristics of the treated foods are a direct result of the chemical reactions induced by the absorbed radiation. Research has established that the types and amounts of products generated by radiation-induced reactions (hereinafter referred to as "radiolytic products") depend on the chemical constituents of the food and on the conditions of irradiation. Scientists have compiled an enormous body of data regarding the effects of ionizing radiation on different foods under various conditions of irradiation.[3]

The amount of radiolytic products generated in a particular food have been shown to be directly

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[2]These sources include γ-rays from sealed sources of ^{60}Co or ^{137}Cs, machine sources of accelerated electrons of energy up to 10 MeV, and machine-generated X-rays of energy up to 5 MeV.

[3] See for example; "Recomendations for Evaluating the safety of Irraidated Foods" (July 1980) Bureau of Foods Irradiated Food Committee Report (BIFIC Report).

Wholesomeness of Irradiated Food, World Health Organization, Geneva, 1981.

Safety and Nutritional Adequacy of Irradiated Food, World Health Organization, Geneva, 1994.

J.F. Diehl, "Safety of Irradiated Foods" 2nd Edition, Marcel Dekker, Inc., New York, NY, 1995.

proportional to the radiation dose. Thus, it is possible to extrapolate from data obtained at higher radiation doses to draw conclusions regarding the amounts of radiolytic products expected to be generated at lower doses.

In general, the types of products generated by irradiation are similar to those produced by other food processing methods. Radiation-induced chemical changes, if sufficiently large, however, may cause changes in the organoleptic properties of the food. Food processors wishing to avoid undesirable effects on taste, odor, color, or texture, have an incentive to minimize the extent of these chemical changes in the food. Because these types of chemical changes can occur in irradiated eggs, the petitioner has recommended that a maximum dose of 1.7 kGy be used for the irradiation treatment of whole shell eggs. This upper limit is not proposed on the basis of food safety concerns, but rather on acceptability measures (e.g., color, taste, texture, odor and appearance) of shell eggs.

A. Effects on Macronutrients

Fresh, whole eggs are composed mainly of water (75.3%), protein (12.5%), lipid (10.0%) and carbohydrate (1.2%).[4] The majority of the radiation will be absorbed by the water leading to primary water radiolysis products (e.g., aqueous electrons, hydroxyl radicals and hydrogen atoms). These radicals will then react with the other components of the food, leading to secondary radicals and stable products. The radiation will also interact directly with the other major food components leading to free radicals which will undergo reactions leading to stable products. The radiation chemistry associated with water and the other major food constituents is well known.[5] It has been shown that the amount of degradation of a food component by the radiation is directly proportional to the radiation dose. Also, the radiolytic degradation of a particular component in an intact food is much less than that which has been observed when the component is irradiated by itself (mutual protection). Because of the mutual protection exerted when different substances are irradiated together, and because most foodstuffs consist of a great number of components, irradiation of a food will generally not cause much chemical change in any one of the components. The radiation damage will be distributed amongst all of the components, though not evenly. The absorbed dose proposed for the irradiation of shell eggs by the petitioner, will result in only minimal changes in the macronutrients (protein, lipid or

[4]Composition of Foods: Dairy and Egg Products; Raw, Processed, or Prepared. Agriculture Handbook NO. 8-1, USDA, ARS (1976), (as ammended 1989).
USDA Nutrient Data Base for Standard Reference, Release 12 (www.nal.usda.gov/fnic/foodcomp).

[5]See for example; J.F. Diehl, "Safety of Irradiated Foods " 2nd Edition, Chapter 3, pp. 43-88, Marcel Dekker, New York, NY, 1995.
W.M. Urbain, "Food Irradiation" Chapter 3, pp.37-82, Academic Press, Inc., Orlando, FL, 1986.

carbohydrate). Therefore, the nutritional value of the irradiated eggs for these macronutrients will be minimal.

1. Proteins

Protein makes up about 12% of whole eggs (with albumin being a significant component). Since eggs can provide a substantial portion of the protein in the diet of certain individuals, DPMU looked at the potential for degradation of protein in irradiated eggs. While fats and carbohydrates in food serve primarily as sources of energy, proteins provide essential amino acids, which humans need to build up proteins. Evidence exists to show that radiation damage to the amino acids in proteins is limited, with little change in amino acid composition generally being observed at doses below 50 kGy.[6] A large portion of the energy deposited in an irradiated protein goes into protein denaturation, i.e., changes in secondary and tertiary structure, rather than into destruction of constituent amino acids. These changes are similar to those that occur as a result of heating, but are far less pronounced. Degradation of proteins to smaller polypeptides can occur as a result of the splitting of carbon-nitrogen bonds and disulfide bridges. Conversely, globular proteins irradiated in solution may undergo aggregation reactions, producing higher molecular mass proteins and thus solutions of higher viscosity.

The radiolytic products resulting from the reaction of free radicals with amino acids in the polypeptide chain, without the breaking of peptide bonds, are similar or identical to those found in foods that have not been irradiated, and are formed in very small amounts.

Irradiation of shell eggs leads to very small changes in the protein content of the eggs.[7] The pH and solid content were not affected by irradiation in either the egg white or egg yolk. The protein and SH content of egg white were also unchanged by irradiation. The data suggest some breakdown of proteins in egg yolk. The changes in SH content may be attributed to alteration in SS/SH exchange reaction or SH oxidation in the yolk proteins. Both the apparent viscosity and plastic viscosity of liquid egg white progressively decreased while increasing the dose. The apparent viscosity of liquid egg yolk decreased at 0.97 kGy, but increased at 2.37 and 2.98 kGy. Since the changes in viscosity were more pronounced in egg white, which constitutes the major portion of shell eggs, the viscosities of liquid whole eggs were correspondingly decreased by irradiation. The lowering in egg white viscosity and the thinning of albumen may be due to the breakdown of proteins, in particular ovomucin, a glycoprotein. The increase in viscosity in the irradiated egg yolk at higher doses may be attributed to aggregation or partial denaturation of the

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[6]See for example; J.F. Diehl, "Safety of Irradiated Foods " 2nd Edition, pp. 63-72, 242-246, Marcel Dekker, New York, NY, 1995.

[7]C.-Y. Ma, M.R. Sahasrabundhe, L.M. Poste, V.R. Harwalkar, and J.R. Chambers, "Gamma Irradiation of Shell Eggs. Internal and Sensory Quality, Physiochemical Characteristics, and Functional Properties." Can. Inst. Food Sci. Thechnol. J., 23 (4/5), 226-232, 1990.

lipoproteins.

The electrophoretic patterns of egg white proteins showed no significant changes at 0.97 and 2.37 kGy.[6] At 2.98 kGy, the protein bands became much more diffuse. Irradiation, particularly at higher doses, led to the appearance of some minor bands with lower, as well as higher, molecular weights. These minor bands suggest both aggregation and breakdown of the major egg white proteins. Differential scanning calorimetry demonstrated that irradiation did not significantly change the denaturation temperature and total enthalpy (heat of transition) of the two major albumin proteins (ovalbumin and conalbumin), or of lysozyme. The data indicate that gamma irradiation up to 3 kGy did not cause significant changes in thermal stability of the albumen proteins. Gamma irradiation led to significant changes in some physicochemical properties of the egg components, suggesting conformational changes, aggregation and breakdown of proteins.

The petitioner's data support the conclusion that there is little change in the overall structure, digestibility, or biological value of protein when shell eggs are treated with ionizing radiation.

2. Lipids

The radiation chemistry of lipids (fats) is also well established.[8] Numerous studies have been performed with various oils and fats and also on the lipid fraction of irradiated foods. A variety of radiolytic products derived from lipids have been identified, including fatty acids, esters, aldehydes, ketones, alkanes, alkenes, and other hydrocarbons. All of these types of compounds are found in foods that have not been irradiated. These types of compounds are also produced by heating foods, in amounts far greater than the trace amounts that result from irradiating foods.

The petitioner has provided some data (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) on the chemical changes by irradiation on-shell egg lipids. After a post-irradiation storage period of 28 days, little effect on the lipid content in egg yolk was observed. Increasing radiation doses up to 3 kGy resulted in no significant changes in the levels of the individual fatty acids in egg yolk lipids compared to the non-irradiated control.

B. Effects on Micronutrients

Minerals (e.g., iron, phosphorus, and calcium) are unaffected by irradiation. Levels of certain

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[8]See for example, W.W. Nawar, "Reactions Mechanisms in the Radiolysis of Fats: A Review" J. Agric. Food Chem., 26, 21-25, 1978.

W.W. Nawar, "Volatiles from Food Irradiation" Food Revs. Int., 2, 45-78, 1986.

J.F. Diehl, "Safety of Irradiated Foods " 2nd Edition, pp. 72-80, Marcel Dekker, New York, NY 1995.

vitamins on the other hand may be reduced as a result of irradiation.[9] The extent to which this occurs depends on the specific vitamin, the food type, and the conditions of irradiation. Not all vitamin loss is significant, however. The extent to which a reduction in a specific vitamin level is significant depends on the relative contribution from the food in question to the dietary intake of the vitamin.

From the above discussion on the macronutrients of foods, it follows that the chemical changes in the other food components, present in lower concentrations, will be even smaller. However, since several vitamins are present in eggs (i.e., thiamin, riboflavin, niacin, pantothenic acid, vitamin B6, vitamin B12 and vitamin A), and the destruction of these vitamins could be nutritionally significant, the potential for vitamin loss during irradiation needs to be discussed. The destruction of vitamins by the radiation was given special consideration by the petitioner and by this reviewer.

Studies of the effects of irradiation on vitamins have centered on the extent of nutrient loss. As with the macronutrients, the radiation-induced loss of a vitamin is much greater in pure solution than in a food irradiated with the same dose. With some exceptions, the irradiation of a food results in minimal vitamin loss and, therefore, little change in the nutritional value of the food. The extent of vitamin loss depends on the food type and storage conditions.[10] The length of storage and the storage conditions are very important with respect to vitamin loss regardless of the food-treatment process. But, it is important to ensure that the analysis of vitamin loss takes these conditions into account. In the interpretation of individual research results, it is also important to keep in mind that natural variation in vitamin content is substantial, depending on many factors, such as plant and animal variety, the season of the year and storage conditions.

1. Water-Soluble Vitamins

Although effects on vitamin levels vary from food to food, the order of sensitivity to irradiation

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[9]Safety and Nutritional Adequacy of Irradiated Food, pp. 135-143, World Health Organization, Geneva, 1994.
J.F. Diehl, "Safety of Irradiated Foods " 2nd Edition, Chapter 8, pp. 241-282, Marcel Dekker, New York, NY 1995.

[10]See for example: P.P. Tobback, "Radiation Chemistry of Vitamins" pp. 187-220, in 'Radiation Chemistry of Major Food Components.' P.S. Elias and A.J. Cohen, Eds. Elsevier, Amsterdam, 1977.
J.B. Fox, Jr., D.W. Thayer, R.K. Jenkins, J.G. Phillips, S.A. Ackerman, G.R. Beecher, J.M. Holden, F.D. Morrows and D.M. Quirbachs, "Effect of Gamma Irradiation on the B Vitamins of Pork Chops and Chicken Breasts" Int. J. Radiat. Biol., 55, 689-703, 1989.
D.W. Thayer, J.B. Fox, Jr. and L. Lakritz, "Effect of Gamma Radiation on Vitamins" pp. 285-325, in 'Food Irradiaiotn.' S. Thorne, ed., Elsevier Appleid Science Publishers, London, 1991.

is generally as follows: thiamine > ascorbic acid > pyridoxine > riboflavin > folic acid > cobalamin > nicotinic acid.[11] Since thiamine is the most radiation-sensitive water-soluble vitamin, the loss of this vitamin during irradiation and subsequent storage is generally studied. However, other than pantothenic acid, none of the water-soluble vitamins are present in eggs in any significant amounts. Therefore, their loss was not investigated by the petitioner. The percent of retention for these water-soluble vitamins in irradiated shell eggs should be similar to that for other foods which have previously been investigated (i.e., poultry and meat).[12] Based on data from irradiated poultry and meat, loss of water soluble vitamins for shell eggs irradiated under the conditions and dose in the petition should be on the order of 10 to 20%.

2. Fat-Soluble Vitamins

As with the water-soluble vitamins, the sensitivity to radiation of the fat-soluble vitamins varies greatly depending on the specific food involved, the radiation dose, and the environmental conditions during irradiation and storage. Nevertheless, in general, the order of sensitivity is as follows: vitamin E > carotene > vitamin A > vitamin K > vitamin D.[13] Of these vitamins, only vitamin A and some carotenoids are present in significant amounts in shell eggs. The petitioner has provided extensive data on the loss of vitamin A and the carotenoids after irradiation and storage of shell eggs under several conditions.

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

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[11] Safety and Nutritional Adequacy of Irradiated Food, pp. 135-143, World Health Organization, Geneva, 1994.

[12] See for Example: J.B. Fox, Jr., D.W. Thayer, R.K. Jenkins, J.G. Phillips, S.A. Ackerman, G.R. Beecher, J.M. Holden, F.D. Morrows and D.M. Quirbachs, "Effect of Gamma Irradiation on the B Vitamins of Pork Chops and Chicken Breasts" Int. J. Radiat. Biol., 55, 689-703, 1989.

D.W. Thayer, J.B. Fox, Jr. and L. Lakritz, "Effect of Gamma Radiation on Vitamins" pp. 285-325, in 'Food Irradiaiotn.' S. Thorne, ed., Elsevier Appleid Science Publishers, London, 1991.

J.B. Fox, Jr., L Lakritz, J Hampson, R. Richardson, K. Ward and D.W. Thayer, "Gamma Irradiation Effects on Thiamin and Riboflavin in Beef, Lamb, Pork, and Turkey" J. Food Science, 60, 596-598, 1995.

[13] Safety and Nutritional Adequacy of Irradiated Food, pp. 135-143, World Health Organization, Geneva, 1994.

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), 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.

The effect of cooking (soft boiled) non-irradiated and irradiated (0, 1.0 and 1.5 kGy) shell eggs was also investigated (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). The results indicate a 64% retention in vitamin A in eggs irradiated at 1.0 kGy compared to 51% retention at 1.5 kGy for irradiated shell eggs. Analysis of the cooked samples indicates vitamin A retention for eggs irradiated at 1.0 and 1.5 kGy to be 49.3% and 39.3 % respectively. Further analysis of the data indicates that, irrespective of the irradiation dose, cooking of eggs by soft boiling results in a 76-77% retention of vitamin A in the yolk (based on comparison with uncooked eggs).

b. <u>Effect of irradiation and storage on egg yolk carotenoids</u>

The data in the petition also indicate an inverse effect between the irradiation dose and the concentration of the major carotenoids (lutein and zeaxanthin) in egg yolk (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). The percent retention of lutein and zeaxanthin was similar at each irradiation level. At 28 days post-irradiation storage, retention of lutein at 0.5 and 1.0 kGy was 81.5% and 65.8%, respectively, and zeaxanthin retention was 81.9% and 67.2%, respectively.

c. <u>Effect of irradiation and storage on the retention of egg yolk color</u>

The petitioner also looked at the color loss of the egg yolk. In two experiments, the effect of irradiation on the color of egg yolk, using the Roche Yolk Colour Fan and an AOAC procedure, was examined. Using the Roche Yolk Colour Fan, the panelists noted significant differences in the color of the egg yolk between the non-irradiated control and the irradiated eggs (0, 0.5 and 1.0 kGy) stored for 31 days post-irradiation (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). However, there were no significant differences among the irradiated samples. Panelists were unable to detect significant differences between non-irradiated control and the irradiated eggs (0, 0.5 and 1.0 kGy) stored for up to 56 days post-irradiation (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). Using the AOAC procedure, no significant differences in the egg yolk color among the 0, 0.5 and 1.0 kGy irradiated shell eggs three days post-irradiation storage were noted (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). However, this analytical procedure did detect significant differences in the egg yolk color among the 0, 0.5 and 1.0 kGy irradiated egg yolk after 15 days of storage.

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), shell eggs were irradiated with a maximum dose of 3.1 kGy (0, 1.1 and 3.1 kGy). Using the Roche Yolk Colour Fan, the panelists were unable to detect significant differences between the color of non-irradiated eggs and eggs irradiated at 1.1 kGy and stored for up to 15 days post-irradiation. However, significant differences were detected between these samples and those irradiated at 3.1 kGy. At 28 days post-irradiation storage, significant differences were detected between samples receiving 0, 1.1 and 3.1 kGy irradiation doses. Using the AOAC procedure, significant changes in the color of egg yolk irradiated at 0, 1.1 and 3.1 kGy two days post irradiation storage could be detected.

The color loss in irradiated egg yolk is expected to depend on the loss of carotenoids, which are the primary colorants in the egg yolk. The chemical changes found for the carotenoids in irradiated egg yolk correlate to the chemical results found for the color changes in irradiated egg yolk. Therefore, the acceptability of irradiated shell eggs, based on their color, is one of the factors which will limit the maximum dose practical for the irradiation of shell eggs.

C. Analysis of data variability

The data for vitamin A retention, as well as that for the carotenoids and lipids, show a variability of the retention within a particular group (0, 0.5 or 1.0 kGy for experiment set one, or 0, 1.1 or 3.1 kGy for experiment set two). This variability is not unexpected considering that the composition of nutrients for shell eggs will vary from egg to egg depending on various variables which are beyond the control of the experiments.[14] It should be noted that whole fresh shell eggs were used for these experiments (up to eight eggs per analysis).

Egg composition is dependent on the nutrients present in the rations given to laying hens. Even for eggs obtained from the same supplier utilizing one strain of hens, the proportion of the various nutrients found in each egg will vary. Moreover, biological differences in a hen's ability to deposit nutrients into the eggs (e.g., age of the hen) will affect egg composition.[15]

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[14] See egg composition data from the Egg Nutrition Center (see attached) for an example of the variability of nutreints found in eggs.

[15] Bandemer, S.L., Evans, R.J., Davidson, J.A. "The Vitamin A content of Fresh and Stored Shell Eggs." Poultry Science 37, 538-543, 1958.

In order to correct for the variability of the nutrients in shell eggs, a large number of eggs would have had to be analyzed for each set (up to eight shell eggs were used in these experiments), or a large number of eggs (without intact shells) would have had to be mixed together, forming a composite batch, and a different aliquot of this large batch used for the 0, 0.5 and 1.0 kGy batches for experiment set one, or 0, 1.1 and 3.1 kGy for experiment set two. The larger the number of shell eggs used for the analysis, the better the statistical significance of the data, and the closer the analysis would approach that for a composite analysis. By using a large volume of well-mixed liquid eggs, the quantitation for the determination of vitamin A and the carotenoids present in the test mixture would have initially been the same for each analysis set. By utilizing a larger number of shell eggs the quantitation for the determination of vitamin A and the carotenoids present in the test mixture would have shown less variability. However, since these experiments were carried out using up to eight shell eggs per analysis, it was not possible to analyze the same mixture for each of the analytes, at each irradiation level, at each test interval that the analysis was performed which a throughly mixed composite would have given. The variability of the data presented in Appendix 3, Tables 4 to 10, and Appendix 4, Tables 5 to 7 of the petition are most likely due to the variability of the content of the analytes present in the shell eggs prior to treatment.[16]

CONCLUSION

We have reviewed the data and information submitted in the petition, as well as data available in our files, regarding the irradiation chemistry of eggs. In summary, the results obtained from the chemical analysis of irradiated foods in general, and eggs in specific, establish that there would be very small amounts of individual radiolytic products generated by the radiation dose proposed in the petition (i.e., no detectable changes in the fatty acid composition of eggs after irradiation). Although the petitioner did not analyze for the generation of radiolytic products, only the depletion of nutrients, the amount and types of radiolysis products formed by the irradiation of eggs will be similar to that for other foods. Because of the relatively low irradiation dose which will be used for shell eggs (1.7 kGy maximum), the extent of chemical changes that are expected to occur in irradiated shell eggs will be small. That is, the composition of the irradiated eggs will remain comparable to that of non-irradiated eggs. The effects of irradiation on eggs will be distributed over all of the components of the eggs, although not evenly, and no one component will be greatly affected. In addition, most of these radiolytic products are either the same as, or structurally similar to, compounds found in foods that have not been irradiated.

Forsythe, R.H. "Chemical and Physical Properties of Eggs and Egg Products." Cereal Science Today, 8, 309-312, 1963.

[16]As an example; USDA Nutrient Data Base for Standard Reference, Release 12 (www.nal.usda.gov/fnic/foodcomp).

Egg composition data from the Egg Nutrition Center (see attached) for an example of the variability of nutreints found in eggs.

Although htere is some variability among the data presented in the petition for some of the nutrients, this variability can be accounted for and ascribed to the use of shell eggs for the analysis instead of a composite of eggs used for all of the analyses.

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

Kim M. Morehouse, Ph.D.

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