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Tab 4

Summary of Supporting Documents for Wholesomeness Studies of Precooked (Enzyme Inactivated) Chicken Products in Vacuum Sealed Containers Exposed to Doses of Ionizing Radiation Sufficient to Achieve "Commercial" Sterility

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FINAL REPORT: A Chronic Toxicity, Oncogenicity, and Multigeneration Reproductive Study Using CD-1 Mice to Evaluate Frozen, Thermally Sterilized, Colbalt-60 Irradiated, and 10 MeV Electron Irradiated Chicken Meat.

Submitted by Ralston Purina Company to:

U.S. Department of Agriculture
Agricultural Research Service
Eastern Regional Research Center
600 East Mermaid Lane
Philadelphia, Pennsylvania 19118

In partial fulfillment of:

Contract 53-3K06-1-29, "Animal Feeding Study for Irradiation Sterilized Chicken"

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SUMMARY

Chicken meat sterilized by high doses (ca. 2.5 Mrad) of either gamma radiation from a ^{60}Co source (G) or electrons of up to 10 MeV from a linear accelerator (E) was tested against control chicken meat (F) for chronic toxicity, oncogenicity, and effects on multigeneration reproduction in the CD-1 mouse. A group of mice fed thermally processed chicken meat (T) and a husbandry control group which was fed a commercial mouse diet (N) were also included. On a dry weight basis, diets F, T, G, and E were composed of 65% N diet and 35% chicken and typically contained 35-38% protein and 18-20% fat. A comprehensive schedule of chemical analyses found diets F, T, G, and E to be indistinguishable in nutrient content and essentially free of common toxic contaminants.

Exposure of the F_0 and subsequent generations to test and control diets began in utero and continued until death or scheduled termination. The chronic feeding study which continued for 24 months postweaning was comprised of F_0 generation mice from which subgroups were also assembled for the reproduction phase.

In reproductive performance through three generations, the only important difference seen in mice fed diets F, T, G, and E was comparatively decreased fertility in Group T. There were no differences in fecundity, stillbirth incidence, or birth to weaning survival in Groups G and E as compared to the F group controls.

Through the F_0, F_{1b}, F_{2b}, and F_{3b} generations, the four chicken diets supported growth to adult body weight comparably. Male F_0 mice in Group G experienced a significant decline in mean body weight relative to the other groups in the second year of the chronic study. This was due to significantly higher mortality among Group G male mice in the upper weight quartile as compared to males from the same quartile in other groups; though mortality rates overall did not differ among Groups F, G, and E males. No specific pathology could be associated with the heavy G males.

Chronic study mice in Groups G and E presented in-life health problems indistinguishable from the control F group. The major health problem observed among F_0 mice was a urinary system condition which affected breeder animals at a much higher frequency than non-breeders.

nonneoplastic lesions were few and most emerged only upon comparison using time-adjusted analyses; the limitations of which were noted earlier. The significantly lower incidence of neoplasms in E group females compared to Group G indicates that to two irradiated test articles elicited different responses. In contrast however, the high incidence of testicular interstitial cell tumor in G and E groups as compared to the controls was a similar response to both irradiation-sterilized test articles.

While no single finding from the study is highly illuminating, a collective assessment of study results argues against a definative conclusion that the gamma-irradiated test material was free of toxic properties. Any one of the detrimental findings discussed above, when considered alone, would not provide sufficient cause for concern regarding Group G. Three factors however, when considered together, cannot be discounted:

1. Survival of both sexes in Group G was significantly reduced, at least in certain subgroups, compared to the controls.

2. Group G had the highest incidence of several tumors among those discussed. In particular, the results on alveologenic tumor incidence cannot be summarily dismissed as an artifact resulting from differential survival rates.

3. Also, many of the lesions which occured infrequently and for which statistical analyses could not be performed, were often found most frequently in the G group.

Thus, while there is no evidence of a highly toxic effect from diet G, the preponderance of evidence suggests some degree of toxicity was present.

FINAL REPORT

Evaluation of the Mutagenicity of Irradiated Sterilized Chicken by the Sex-linked Recessive Lethal Test in *Drosophila melanogaster*

Contract DAMD 17-76-C-6047

Submitted to

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ABSTRACT

Four samples of chicken meat, identified as FC, TP, GAM, and ELE, along with negative and positive controls, were evaluated for mutagenic activity employing Drosophila melanogaster in the sex-linked recessive lethal test. The four samples of chicken meat were determined to be non-mutagenic in the test. The positive control containing 100 ppm tris (2,3-dibromopropyl)phosphate gave a significant positive response in the test.

Reduced production of offspring in cultures reared on irradiated chicken was observed. A dose response effect was produced with gamma irradiated and frozen control chicken meat. Normal production of offspring could not be effected by changing the basal medium, adding vitamins, or using a different lot of gamma irradiated chicken meat.

The results are shown in Table 10a (page 40) and summarized in Table 10b (page 41). The addition of the vitamin supplement from Bio-Serv, Inc. at 1.3% concentration did not increase the number of offspring produced in cultures containing gamma irradiated or frozen control chicken meat. However, the addition of the vitamin supplement reduced mortality of the parent Drosophila in the negative control and in both the frozen and gamma irradiated chicken diet groups.

Summary

Based on the data that were gathered in Part II of this study the following conclusions are warranted.

1. The production of Drosophila offspring in cultures containing gamma irradiated chicken meat was much lower than cultures containing frozen control chicken meat or in those without chicken. The above findings were consistent in the two production lots of gamma irradiated chicken that were tested.

2. The production of Drosophila offspring in cultures containing gamma irradiated chicken meat was not increased by changing the basal medium or by adding a vitamin supplement to the basal medium.

3. A dose response pattern was found in Drosophila cultures containing gamma irradiated and frozen control chicken meats. The higher the concentration of chicken meat in the media, the fewer offspring that were produced. The greatest effect occurred in the media containing gamma irradiated chicken.