§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

(a) The food industry is encouraged to experiment voluntarily, under controlled conditions and in collaboration with the Food and Drug Administration, with and other formats for presenting nutrition and other related food labeling information that is consistent with the current quantitative system in §§101.9 and 105.66 of this chapter.

(b) Any firm that intends to undertake a labeling experiment that requires exemptions from certain requirements of §§101.9 and 105.66 of this chapter should submit a written proposal containing a thorough discussion of each of the following information items that apply to the particular experiment:

(1) A description of the labeling format to be tested;
(2) A statement of the criteria to be used in the experiment for assigning foods to categories, e.g., nutrient or other values defining “low” and “reduced”;
(3) A draft of the material to be used in the store, e.g., shelf tags, booklets, posters, etc.;
(4) The dates on which the experiment will begin and end and on which
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a written report of analysis of the experimental data will be submitted to FDA, together with a commitment not to continue the experiment beyond the proposed ending date without FDA approval;

(5) The geographic area or areas in which the experiment is to be conducted;

(6) The mechanism to measure the effectiveness of the experiment;

(7) The method for conveying to consumers the required nutrition and other labeling information that is exempted from the label during the experiment;

(8) The method that will be or has been used to determine the actual nutritional characteristics of foods for which a claim is made; and

(9) A statement of the sections of the regulations for which an exemption is sought.

c) The written proposal should be sent to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The proposal should be clearly identified as a request for a temporary exemption for purposes of conducting authorized food labeling experiments and submitted as a citizen petition under §10.30 of this chapter.

d) Approval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product.

e) Reporting requirements contained in §101.108(b) have been approved by this Office of Management and Budget and assigned number 0910–0151.


APPENDIX A TO PART 101—MONEY-WILLIAMS PROCEDURE (WITH MODIFICATIONS) FOR SULFITES IN FOOD, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION (NOVEMBER 1985)

The AOAC official method for sulfites (Official Methods of Analysis, 14th Edition, 20.123–20.125, AOAC INTERNATIONAL) has been modified, in FDA laboratories, to facilitate the determination of sulfites at or near 10 ppm in food. Method instructions, including modifications, are described below.

Apparatus—The apparatus shown diagrammatically (Figure 1) is designed to accomplish the selective transfer of sulfur dioxide from the sample in boiling aqueous hydrochloric acid to a solution of 3% hydrogen peroxide. This apparatus is easier to assemble than the official apparatus and the back pressure inside the apparatus is limited to the unavoidable pressure due to the height of the 3% H2O2 solution above the tip of the bubbler (F). Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

The apparatus should be assembled as shown in Fig. 1 with a thin film of stopcock grease on the sealing surfaces of all the joints except the joint between the separatory funnel and the flask. Each joint should be clamped together to ensure a complete seal throughout the analysis. The separatory funnel, B, should have a capacity of 100 ml or greater. An inlet adapter, A, with a hose connector (Kontes K–183000 or equivalent) is required to provide a means of applying a head of pressure above the solution. A pressure equalizing dropping funnel is not recommended because condensate, perhaps with sulfur dioxide, is deposited in the funnel and the side arm.) The round bottom flask, C, is a 1000 ml flask with three 24/40 tapered joints. The gas inlet tube, D, (Kontes K–431000–179000 or equivalent) should be of sufficient length to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, E, (Kontes K–430000–2430 or equivalent) has a jacket length of 300 mm. The bubbler, F, was fabricated from glass according to the dimensions given in Fig. 2. The 3% hydrogen peroxide solution can be contained in a vessel, G, with an i.d. of ca. 2.5 cm and a depth of 18 cm.

Buret—A 10 ml buret (Fisher Cat. No. 03–848–2A or equivalent) with overflow tube and hose connections for an Ascarite tube or equivalent air scrubbing apparatus. This will permit the maintenance of a carbon dioxide-free atmosphere over the standardized 0.01N sodium hydroxide.

Chilled Water Circulator—The condenser must be chilled with a coolant, such as 20% methanol-water, maintained at 5°C. A circulating pump equivalent to the Neslab Coolflow 3 is suitable.

Reagents

(a) Aqueous hydrochloric acid, 4N.—For each analysis prepare 90 ml of hydrochloric acid by adding 30 ml of concentrated hydrochloric acid (12N) to 60 ml of distilled water.

(b) Methyl red indicator—Dissolve 250 mg of methyl red in 100 ml ethanol.

(c) Hydrogen peroxide solution, 3%—Dilute ACS reagent grade 30% hydrogen peroxide to