

§ 101.35 because the regulation is obsolete and does not include many of the protein hydrolysates used in foods.

In addition, consistent with the establishment of new § 102.22, as set forth below, to provide for the declaration of protein hydrolysates by a common or usual name that is specific to the ingredient and that identifies the food source from which the protein was derived, the agency is amending the standard of identity in new § 161.190(a)(6)(iii) to require labeling of the source of protein in the optional ingredient "hydrolyzed protein."

Furthermore, to reflect the agency's decision to revoke § 101.35, the agency is amending the standard of identity for canned tuna in new § 161.190(a)(6) to remove "hydrolyzed protein with reduced monosodium glutamate content" from the list of optional ingredients permitted in canned tuna. As discussed in the June 21, 1991, proposal (56 FR 28592 at 28600 et seq.), all hydrolyzed protein contains MSG, and this MSG is not itself an ingredient that is subject to the ingredient declaration requirements of the act. In that document, FDA stated that after carefully considering the information available concerning the safe use of protein hydrolysates and whether the presence of MSG is a material fact that needs to be disclosed on the label for health reasons, it tentatively concluded that the information does not provide an appropriate basis to require declaration of MSG as a component of protein hydrolysates. However, for the reasons discussed in another document elsewhere in this issue of the Federal Register, the agency has reconsidered this issue and is proposing to require the declaration of glutamate as part of the common or usual name when a component of certain hydrolyzed proteins. Therefore, it will no longer be necessary to distinguish between "hydrolyzed protein" and "hydrolyzed protein with reduced monosodium glutamate content" in the manner currently provided for in this standard.

Accordingly, new § 161.190(a)(6)(i) through (a)(6)(ix) have been renumbered to reflect the elimination of "hydrolyzed protein with reduced monosodium glutamate content" from the list of optional ingredients permitted in canned tuna. "Hydrolyzed protein" will be retained in the list of optional ingredients, as specified in § 161.190(a)(6) below (see section VIII. of this document).

#### 8. Other Related Actions

10. The agency did not receive any comments that objected to its proposal to require that the ingredient declaration

for fruit butter in § 150.110 conform to the regulations in part 101. Thus, the agency is removing § 150.110(e)(2)(ii) (21 CFR 150.110(e)(2)(ii)), which states that if sugar or invert sugar is the sweetener used, the term "sugar" may be used, and if the sweetener used is derived from corn, the term "corn sweetener" may be used. The agency is also requiring that the ingredient declaration for fruit butter conform to the regulations in part 101. In this rule, the agency is terminating the rulemaking to permit the use of the terms "sugar" and "corn syrup" as collective ingredient designations. The agency has determined that declaration of specific names for sweeteners within these collective categories is practicable. Consistent with this action, the agency has concluded that declaration of the specific names of sweeteners is also practicable for standardized foods and is deleting the requirements of § 150.110(e)(2)(ii).

The agency is also deleting the requirements in the standards for mixed nuts and peanut butter in §§ 164.110 and 164.150 (21 CFR 164.110 and 164.150) that provide for the use of the term "hydrogenated vegetable oil" or "vegetable oil" with the optional use of the name of the vegetable source, and the requirement in § 164.110 for label declaration of chemical preservatives. Required label declarations for these types of ingredients are clearly delineated in §§ 101.4(b)(14) and 101.22(j), respectively. Moreover, the "and/or" labeling exemption in § 101.4(b)(14) should effectively eliminate the need for collective names for vegetable oils on these standardized foods.

The agency did not receive any other comments with respect to proposed changes to specific standards of identity. Thus, the agency is finalizing the amendments to the individual standards as proposed.

In the July 21, 1991, proposal on Declaration of Ingredients, FDA withdrew the proposed amendment to § 101.4 (formerly § 1.10) pertaining to the establishment of the terms "sugar" and "corn syrup" as collective ingredient designations that was published in the Federal Register of June 14, 1974 (39 FR 20888); terminated the rulemaking proceeding initiated by that proposal; and denied the petitions commenting on that proposal from the Canada Dry Corp. (June 27, 1975—Docket No. 75P-0144), the Cannery League of California (January 19, 1977—Docket No. 77P-0051), the Independent Bakers Association (September 22, 1977—Docket No. 77P-0357), the California Milling Corp. (June 19,

1978—Docket No. 77P-0051 CP0002), the Orth Co. (July 31, 1978—Docket No. 77P-0357), and L. Karp & Sons, Inc. (August 11, 1978—Docket No. 77P-0357 CP0003).

#### B. Labeling of Sulfites in Standardized Foods

In the Federal Register of December 19, 1988 (53 FR 51062), FDA published a proposed rule to require that any standardized food that contains a sulfiting agent that has a functional effect or that is present at a level of 10 ppm or more is misbranded if the presence of the sulfiting agent is not declared on the label by its common or usual name. The agency proposed to codify this requirement in new § 130.9. The agency also solicited comments regarding sulfite-sensitive consumers' ability to recognize and avoid foods labeled with the six common or usual names for sulfites (sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite). In addition, the agency requested comments on whether any final rule should contain a requirement that the common or usual name of a labeled sulfiting agent should be followed by the term "sulfiting agent." The comments received on these and other aspects of this part of the proposal, and the agency's response, follow.

11. The majority of comments from consumers and industry supported adoption of § 130.9. These comments stated that sulfite labeling of standardized foods would decrease allergic type reactions by increasing consumer awareness, while allowing the vast majority of consumers, who are not sensitive to sulfites, to continue to consume foods containing sulfiting agents. A few consumers' comments, however, requested that all unnecessary uses of sulfites be banned, or, in the alternative, that principal display panel warnings be required. Citing the large number of people adversely affected by sulfites, the comments asserted that there was no established safe threshold for sulfites, and that they are one of the few food ingredients known to cause anaphylactic shock and death.

The agency recognizes that sulfites present a significant health problem for a small segment of the population, particularly some asthmatics. However, sulfiting agents do not appear to present a problem for most people, and the declaration of sulfiting agents in the list of ingredients will provide sufficient information for those people who need or want to avoid unexpected exposure to these ingredients. Thus, FDA does not believe that it is necessary to require