



INTERNATIONAL HYDROLYZED PROTEIN COUNCIL

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July 21, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0434; Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent; 68 Fed. Reg. 19766 (Apr. 22, 2003)

Dear Sir or Madam:

The International Hydrolyzed Protein Council (IHPC) appreciates this opportunity to offer comments concerning the above-referenced Food and Drug Administration (FDA) proposal to withdraw outdated proposed rules and other proposed actions. IHPC is an international non-profit association, with headquarters in Washington, D.C., and represents manufacturers, users, and sellers of hydrolyzed proteins throughout the world. Hydrolyzed proteins include hydrolyzed vegetable proteins (HVPs), autolyzed yeasts, and yeast extracts. Hydrolyzed proteins and autolyzed yeast extracts have a long history of safe use in food. They function primarily as savory flavors and flavor enhancers in a wide range of products, including snack foods, soups, gravies, and frozen entrees.

IHPC commends the Agency's efforts to eliminate its backlog of pending proposals and agrees that the public interest is well-served by withdrawing rulemakings that are outdated, stale, problematic, or unnecessary. In particular, IHPC supports FDA's intent to withdraw three rulemakings of direct interest to IHPC members: (1) the 1983 proposed rule proposing to affirm protein hydrolysates and enzymatically hydrolyzed animal (milk casein) protein as Generally Recognized as Safe (GRAS), 48 Fed. Reg. 54990 (Dec. 8, 1983); (2) the 1993 proposed amendment to the common or usual name regulation for protein hydrolysates, 58 Fed. Reg. 2950 (Jan. 6, 1993); and (3) the 1996 advance notice of proposed rulemaking (ANPR) concerning declaration of free glutamate in food, 61 Fed. Reg. 60661 (Sept. 12, 1996).

IHPC believes that these rulemakings are unnecessary to ensure that protein hydrolysates are marketed and used in food in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, IHPC believes strongly that special labeling requirements for glutamate-containing foods, including “contains glutamate” labeling of any kind, would be without a sound basis in science or the FFDCA.

GRAS affirmation proposal. The GRAS status of protein hydrolysates is firmly established and is the primary basis upon which protein hydrolysates are marketed for use in food. In the 1983 proposal, FDA recognized that a large margin of safety exists for protein hydrolysates and proposed to affirm protein hydrolysates as GRAS for use in food with no limitation other than current good manufacturing practice (CGMP). Accordingly, although FDA affirmation of GRAS status is certainly acceptable, it is not necessary to enhance public health or clarify the circumstances under which protein hydrolysates may be marketed.

Common or usual name proposal. In the common or usual name proposal, FDA sought to require the term “contains glutamate” as part of the common or usual name of autolyzed yeast extract and certain hydrolyzed proteins. As IHPC commented at the time of its publication, this proposal was not justified by science and would mislead consumers as to the characterizing properties and safety of hydrolyzed protein.

The common or usual name of a food must adequately describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. ^{1/} The flavors of autolyzed yeasts and hydrolyzed proteins are attributed to the synergistic effect between the salt, amino acids (including free glutamate and other free amino acids), nucleotides and other components and not just the free glutamates. In addition, autolyzed yeasts and hydrolyzed proteins are most commonly added to foods which undergo further heating. The heating causes unique chemical reactions that make an additional contribution to the flavor of the finished food. Over 100 aroma compounds have been identified in heated autolyzed yeasts and hydrolyzed proteins. In light of these circumstances and conditions of use, the free glutamate component in hydrolyzed proteins and autolyzed yeasts is not a “characterizing ingredient” that must be disclosed as part of the common or usual name. Although there is no question that autolyzed yeasts and hydrolyzed proteins contain free glutamate, it is

^{1/} 21 C.F.R. § 102.5.

completely incorrect to say that they are used primarily for their flavor enhancing effect due to glutamate.

Indeed, the required use of “contains glutamate” would be false or misleading to the consumer because such nomenclature implies that free glutamate is present at a much higher concentration than, in fact, it is. The required use of “contains glutamate” would thwart one of the purposes behind the common or usual name regulations—to prevent an erroneous impression that a component is present in a greater amount than is actually the case.

For the foregoing reasons, IHPC supports FDA’s determination to withdraw its proposal to require the term “contains glutamate” as part of the common or usual name of autolyzed yeast extract and certain hydrolyzed proteins.

Free glutamate labeling. The 1996 ANPR sought public comment on whether additional labeling requirements were necessary to protect consumers who believe they are sensitive to glutamates in food. The ANPR was prompted, in significant part, by FDA’s interpretation of a 1995 report of the Life Sciences Research Office (LSRO) of the Federation of the Federation of American Societies for Experimental Biology (FASEB) concerning the safety of MSG and other glutamate-containing ingredients. FDA interpreted the FASEB report to support a conclusion that certain sensitive individuals may experience adverse reactions following the administration of a bolus dose of 3 grams of MSG in a fasting state.

In comments submitted to FDA at the time of the ANPR, IHPC strongly opposed any initiative by FDA to require label statements indicating that a food product “contains glutamate.” Available scientific evidence provided, at that time, no support for the conclusion that free glutamate presents the type of health concern that warrants special or unique labeling, even for sensitive population subgroups. This remains the case today.

IHPC was particularly concerned with FDA’s interpretation of the FASEB report as providing a basis for “contains glutamate” labeling. FASEB found no proven causal relationship between ingestion of MSG, a manufactured form of free glutamate, and health effects of any kind, either serious long-term effects or more transitory adverse reactions. Based on available data, the strongest conclusion FASEB could reach was that it had “the overall impression that causality had been demonstrated” among a small subgroup of the population in certain limited circumstances (i.e., ingestion of a 3 gram oral bolus dose of MSG in the absence of food). FASEB cautioned, however, that the data were “not verifiable

without clinical investigations” and were characterized by certain inconsistencies.^{2/} Moreover, the studies reviewed by FASEB and cited in support of its impression involved doses of MSG that are significantly higher than the amount of free glutamate that individuals consume (or could conceivably consume) as part of a normal diet, and these doses were not administered under conditions typical of real-world consumption of glutamates. Accordingly, IHPC commented that any “contains glutamate” labeling requirement would have no sound basis in science or the law.

As the ANPR itself made clear, MSG and free glutamate have been extensively studied, and FDA and other scientific and regulatory bodies have concluded many times that free glutamate is safe for use in foods, without limitation. In light of all of these factors, IHPC continues to believe that a “contains glutamate” labeling requirement would be entirely disproportionate to the level of risk presented. Moreover, such a requirement would confuse and unnecessarily alarm consumers about the nature of free glutamate and, by further cluttering food labels, potentially detract attention from those labeling statements that are provided to notify consumers of legitimate health concerns.

For the foregoing reasons, IHPC fully supports FDA’s proposal to withdraw the 1996 ANPR on free glutamate labeling.

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IHPC looks forward to working with the agency in the future and would be pleased to discuss with CFSAN any of the points made in these comments.

Sincerely,



Martin J. Hahn
Executive Director
International Hydrolyzed Protein Council

^{2/} Life Sciences Research Office, Analysis of Adverse Reactions to MSG (July 1995) (hereinafter FASEB Report), at vii.