Research & Development

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August 17, 2005

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250-3700

Division of Dockets Management
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: [Docket No. 95-051P, Docket No. 1995N-0294]
Food Standards; General Principles and Food Standards Modernization
70 Federal Register 29214, May 20, 2005

Dear Sir or Madam:

Hormel Foods Corporation (Hormel) appreciates the opportunity to comment on the above-captioned proposal.

Hormel is a major manufacturer of a wide variety of processed food items. Many of the products it markets are presently subject to some type of standard, either formal or informal, as established by the agencies which have developed this proposal. From this perspective, Hormel has a vital interest in insuring that a food standards system is maintained which effectively serves the best interests of the consumer, the government and the private sector alike.

Hormel strongly supports the most basic conclusion of the proposal – that it is important to maintain, at the federal level, a workable food standards system. While such standards have been frequently subjected to various types of theoretical criticism, they have performed, and continue to perform, an important role in protecting the consuming public. In addition, and as the proposal seems to recognize, critics of a system which includes such standards have never carried the burden of positing a better alternative. We commend the agencies for their recognition that food standards will continue to play an important role in the 21st century regulatory environment.

Hormel believes that, on balance, the general principles articulated in the proposal could provide a useful framework for the future establishment, elimination, or modification of various food

standards. In some cases, however, the principles articulated seem vague and difficult to distinguish from one another. It is unclear, for example, how the agencies are to distinguish a standard's ability to "describe the basic nature" of a food versus reflect its "essential characteristics." The fifth and eighth stated principles, which both emphasize clarity appear similarly redundant. Nevertheless, we support the goals of clarity, flexibility and harmonization with international standards which the proposed principles would attempt to advance. Adoption of such principles would appropriately recognize the vast changes in areas such as globalization, technology innovation, and the significance of vast changes in the American diet which have occurred since the bulk of today's food standards were originally codified.

The more critical question, of course, is how these principles will actually be applied in specific situations if and when they are adopted. In this regard, we believe that the agencies need to go further in explaining their current thinking as it would apply in the real world to major categories of standards, particularly compositional standards.

Compositional Standards

Compositional standards are particularly important with regard to the meat and poultry products regulated by FSIS. This reflects the obvious historical and economic fact that, for most of the multi-ingredient products regulated by FSIS, the meat or poultry ingredient is perceived by the consumer to be the critical component of its value. In recognition of this reality, current FSIS regulations contain compositional standards for any number of products such as corned beef hash, meat stew, chili, poultry pies, and poultry a la king. Hormel is a major manufacturer of many products presently covered by such formal compositional standards.

It is our present assumption that the underlying logic of the proposal provides support for continuation of such compositional standards. Given the overarching need to make sure that the consumer is not misled, the consumer's historic familiarity with the compositional characteristics of products labeled with standardized terminology, and the agencies' entirely appropriate rejection of other alternatives, it appears that most of these compositional standards should be preserved. We believe it will be beneficial in any future publications for both agencies, particularly FSIS, to more fully and directly address this significant issue.

Informal Standards

In the publication FSIS also briefly discusses its current practice of developing informal or so-called policy book standards, and expresses, with little in the way of explanation, its expectation that most such standards are to be eliminated if the proposal is adopted.

Given, as noted above, the proposal's underlying support for the continuation of compositional standards, this seems somewhat contradictory. We believe that in this particular context the agency may be blending two issues which require separate consideration – (1) the inherent value of the informal standards themselves, and (2) their procedural validity and enforceability.

FSIS continues to maintain a prior approval system for the labeling of the meat and poultry products it regulates. Such a system has traditionally, and we believe inevitably, included an

informal standards-setting component. Once an approval determination has been reached with regard to the particular terminology on a given label, designed to insure that consumers are not misled, the agency, the public and regulated industry all have an interest in insuring that such a decision is uniformly applied. Documents such as the FSIS Policy Book are simply tools designed to enhance uniformity and provide appropriate transparency in this context.

Given this reality, FSIS's position that, once the principles are adopted, informal standards will be eliminated, is troublesome at best. If, in the agency's view, such informal standards need to be subjected to notice and comment rulemaking, such an approach has the potential to consume significant amounts of agency resources, an outcome which the proposal otherwise strenuously attempts to avoid. If, on the other hand, such informal compositional standards are simply to disappear, this would create a basis for an enormous amount of confusion and lack of consistency within the prior approval system and, ultimately, within the marketplace itself.

Hormel believes that the industry and the public would be better served if this issue of informal standards is more clearly and fully addressed by FSIS, rather than being shoehorned into the existing proposal as something of an afterthought. As long as FSIS maintains a prior approval requirement, we believe that an informal system needs to be maintained in a manner which parallels the more formal system, and applies some of the same general principles articulated in the proposal. Alternatively, if FSIS is committed to eliminating such informal standards, a reasonable period of time (perhaps 60 months) should be established for transition and review. During this period all interested members of the public could participate in the evaluation process. As this suggests, we believe at a minimum that FSIS is obligated to more fully discuss the issue with the public before reaching any decisions for major change in this area.

Administrative Issues

We would encourage the agencies to further clarify questions regarding the future administration of the standards process. We would suggest that petitions for the establishment, revision or elimination of standards which are receiving active consideration by the agencies be published in the Federal Register and thereby be subjected to public comment. This would be consistent with the agencies' goal of privatizing, to a considerable degree, the standard setting process. At the same time, it is also important for the agencies to examine and modify their own procedures to minimize the significant delays which traditionally accompany the rulemaking process. If in a given future situation, a petitioner has developed a position on a standards issue which meets all of the agencies' stated policy goals, is supported by a widespread consensus, and generates no significant issues, such a project should move rapidly through the regulatory system. Absent some additional adjustments in agency procedures, this is unlikely to happen.

The agencies should also clarify their policies regarding the acceptability of petitions which are presently pending as well as those which may be filed during the pendency of this rulemaking process. It would seem, in the interest of fairness, that any parties with pending petitions in this area should be notified and given the opportunity to modify their submissions in accordance with the principles outlined in the proposal. In addition, the agencies should clarify the manner in which petitions filed after the date of this proposal but prior to the establishment of any final rule will be evaluated by the agencies.

Flexibility and Uniformity

Hormel fully supports the efforts of both agencies to actively consult with each other in this process and to, to the fullest extent possible, adopt principles which are to be uniformly applied throughout the entire food industry. Consistent with this effort, we believe that other compatible measures should be taken.

Along these lines, we believe that FSIS should immediately adopt FDA's policy of allowing for temporary marketing permits which would allow controlled experimentation with modified formulations of standardized foods without being burdened with labeling terminology such as "imitation" or "substitute." Such permits allow for increased flexibility in formulation which both agencies advocate, and will also serve to generate the very data the agencies are seeking could ultimately support formal changes to standards themselves.

FSIS should also further evaluate its list of approved substances presently codified at 9 C.F.R. 424.21. In some instances, these so-called restricted ingredients are often interpreted in a manner which has standards implications. For example, several years ago FSIS concluded that it is required to amend some of its standards before it could allow the use of otherwise approved antimicrobials in major product categories. This had the effect of inhibiting, at least for a time, food safety innovation. We therefore believe such ingredient restrictions should undergo further review in order to eliminate such problems. Over time, we believe that the system should evolve in a direction which contemplates a single, unified listing, by FDA, of all restricted ingredients.

Thank you for consideration of our views.

Sincerely,

Forrest D. Dryden, Ph.D.
Vice President Research & Development