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Regina Hildwine

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Room 1061  
5630 Fishers Lane  
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[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:

The Food Products Association (FPA) submits the following comments on the dockets referenced above.

FPA is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

As the National Food Processors Association, this organization previously commented on the Advance Notices of Proposed Rulemaking issued by FDA and FSIS in 1995 and 1996.

The members of FPA produce food products regulated by both FDA and FSIS, both standardized and non-standardized. FPA members are interested broadly in food standards regulations and policies, and in the specific standards promulgated by each agency. To best advance the views of our members, and to avoid redundancy in our remarks, FPA is submitting a single set of comments to both agencies. We will present general comments on the proposal, and comment on issues unique to FSIS and to FDA.

General Comments:

Summary:

Food Standards and “Modernization.” Many FPA members support a framework of food standards of identity, and generally support the principles proposed by FDA and FSIS. In addition, a number of FPA members have expressed the view that the agencies should undertake an additional rulemaking that would allow for responsible and controlled steps toward modernized food standards and alleviate some need for case-by-case solutions.

Food standards resource issues. The proposed principles governing food standards of identity would maintain the current case-by-case approach to food standards modernization, which poses challenges to the agencies’ resources. The proposed principles, while valuable, may, in fact, place new resource demands on the agencies.

Additional approach to food standards modernization. An outline is presented for government consideration for an additional proposed rule, to supplement the proposed principles, which could allow for some responsible and controlled steps toward modernized food standards, while reducing some of the serious resource demands on the regulatory agencies.

Adjustments to proposed principles. While the proposed principles themselves have value for future work in food standards, they require some adjustment, including an elucidation of how government will respond to any petitions that address the relevant principles.

Food Standards and “Modernization”

Many FPA members support the concept of food standards of identity, and are encouraged that the two agencies envision a framework for food standards maintained into the future. FPA recognizes that food standards of identity are valuable for smooth interstate commerce, in that, through national uniformity provisions, federal standards of identity preempt and displace any competing state standards. National uniformity of U.S.

food standards is important, not only for commerce within the nation, but for trade with other nations. U.S. food standards set the framework for acceptability of foods that are now largely produced abroad and imported, such as canned tuna and canned pineapple. U.S. food standards of identity have helped to shape international food composition standards, such as those of Codex Alimentarius, which have been adopted by many nations. For those foods for which standards of identity exist, the standards have fostered a level of consistency that consumers can trust in their food purchase decisions.

FPA strongly supports the decisions of the agencies not to withdraw food standards of identity in favor of a product naming system that would require declaration of percentage characterizing ingredients. FPA believes that mandatory percentage ingredient labeling would provide the public with no useful information and would create serious burdens for the food industry.

As we noted, the National Food Processors Association, the predecessor of FPA, commented to both FDA and FSIS in the mid-1990s regarding potential future reform of food standards of identity. In those prior comments, we requested that FDA and FSIS work together to develop principles to guide establishment, amendment and removal of any food standards of identity. We are grateful that the agencies jointly developed a proposal that reflects the recommendations in our comments. The proposed principles, with some amendments, should establish a useful framework for the establishment, amendment and removal of any food standards of identity in the future. However, if the principles are to be applied simply to case-by-case reform of food standards of identity, the full potential of the principles could not be realized until many decades in the future. Meanwhile, foods that are not governed by standards of identity would benefit from complete freedom of reformulation. Over time, this difference between standardized and non-standardized foods could place some standardized foods at a competitive disadvantage.

It is important to note that foods without standards of identity are more prevalent in the food marketplace – only about 25% of food products are governed by standards of identity. For foods that are not governed by standards of identity, consumers' interests are addressed through general food labeling techniques – such as truthful and non-misleading product names, descriptive statements of identity that include characteristic features of the food, ingredient declarations and nutrition labeling – rather than through strict product definitions. Non-standardized foods can be reformulated without any delay. In this environment, foods with standards of identity face significant challenges to keep pace with any new consumer interests in food, whether real or perceived. If a standard lags behind consumer demand, the standardized food may become an endangered species in the market. The opportunity to update food standards remains one of the fundamental concepts supporting the proposed principles.

Continuing a strong, meaningful framework for food standards of identity into the future, with opportunity for product modifications when needed, remains important for many FPA members. In order to maintain the importance of food standards, the government agencies should give some thought to additional steps, beyond the proposed principles, that can keep standardized foods vital through broad yet controlled modernization. FPA encourages the agencies to take these steps, and we present some details on this approach later in these comments. Consumers and the food industry both can benefit from more rapid modifications to existing standards, through the application of more efficient technologies, through the use of improved ingredients, and through recipes that better address consumers' nutrition concerns.

#### Food standards resource issues.

While it is important to retain a strong framework for food standards of identity, there is a considerable resource burden on both government and industry to establish, amend, or remove a food standard. This resource burden should be addressed. Government agencies face the burden of persistent interest in food standards yet few resources to devote to that interest. FDA, in particular, maintains a significant inventory of existing petitions on food standards of identity, including a petition on canned salmon submitted by this association. The development of the proposed principles has not escaped resource constraints: this proposed rule has appeared approximately ten years after both FDA's and FSIS's request for comments on food standards reform. Both FDA and FSIS continue to have very limited resources to devote to food standards of identity. The proposed principles, in and of themselves, are unlikely to change this situation.

FPA questions whether the agencies have correctly analyzed the burdens of operating under the proposed principles. The Regulatory Impact Analysis in the proposed rule estimates that three food standards petitions per year would be submitted, based on FDA's recent experience. This estimate could also be applied to FSIS's estimated administrative burden. Even at this rate, the volume of food standards petitions would appear to exceed the agencies' abilities to advance them to rulemaking – there have not been, on average, three proposed or final rules governing food standards per year for the past ten years. Keeping in mind that there are over 280 standards of identity in FDA regulations, and about 80 standards of identity codified in FSIS regulations, along with numerous informal FSIS standards in the Food Standards and Labeling Policy Book, at an estimated three petitions a year to each agency, it is simple to see that a process to modernize food standards case-by-case would take many decades.

The estimated volume of three food standards petitions a year was based on recent regulatory experience and the current standards framework. The agencies have not taken into account the prospect of opportunity brought into focus by the proposed principles:

organizations that wish to reform individual standards or groups of standards may be motivated to develop more petitions to the agencies than recent history has reflected. Increased numbers of food standards petitions would quickly overwhelm the limited resources in FDA and FSIS. The law makes it clear that the agencies engage in rulemaking in order to establish, amend, or remove any food standards of identity.

Even to contemplate amending an existing standard of identity, except for certain nutritional improvements, food companies must now secure prior approval to engage in market testing of a modified standardized food formulation that uses the standardized name. The process of securing such prior approval under FDA's Temporary Marketing Permit rules, or through case-by-case approval through FSIS, is time consuming and, in the case of FSIS, is not transparent. Nevertheless, this process is important for assessing consumer acceptance of any significant modifications of standardized foods that may be contemplated. The regulatory agencies must devote resources to a permitting process, and this detracts from resources that would evaluate proposed modifications to standards.

The proposed principles appear to reflect the process that has transpired, in recent years, to update global food commodity standards in Codex Alimentarius. The Codex process applied key concepts for modernization and simplification of food standards which produced in many standards, for example, the ability to use alternate ingredients that achieve the same technical effect in a standardized food, and which removed standards criteria that were focused strictly on product quality. This reform has been achieved through a range of commodity committees in intergovernmental consultation. Consequently, Codex Alimentarius was able to revise a number of food standards simultaneously. Applying something like the Codex process in the United States would quickly produce food standards reform gridlock.

Ten years ago, the federal agenda appeared to press for removing food standards from the Code of Federal Regulations. This association advocated instead for the opportunity to update food standards through the application of principles jointly developed by FDA and FSIS. Only through applying the concepts in the proposed principles can food standards benefit from flexibility and technological innovation. Because of the time needed to address individual food standards petitions, and any supporting market testing, the proposed principles, when applied as the agencies envision, may produce the unintended consequence of retarding, rather than expediting, food standards modernization. The resource constraints in the two agencies dictate that such modernization should not take place case-by-case if it has any hope of progressing in the foreseeable future.

Additional approach to food standards modernization.

Applying some of the concepts in the proposed principles in a controlled and responsible manner can help to maximize limited resources for food standards administration in the government agencies. FPA believes that the agencies can make better progress toward food standards modernization by taking some steps, through an additional proposed rule, to apply concepts in the proposed principles in broad, general strokes. These steps could approach food standards modernization in a horizontal manner, in much the same way that FDA proposed and published a few rules to incorporate requirements for declaring all ingredients of standardized foods (58 FR 2850, 58 FR 2888, January 6, 1993). FDA's ingredient labeling rule was applied in a single action by FSIS to the labeling of meat and poultry products – which often use FDA-regulated foods as ingredients in the formulation of value-added foods.

Both agencies also have adopted provisions for making modifications to standardized foods for improved nutritional profiles. FDA has had such provisions in place since 1993 (21 CFR 130.10), and FSIS recently published final rules applying the same concept (70 FR 33803, June 10, 2005). One of the benefits of such general rules governing standards is that they remove the need to seek permission to modify a standardized food to make nutritional improvements. Under the existing general rules, it is not necessary to seek FSIS advance clearance, and no temporary marketing permit is required from FDA, in order to formulate nutritionally improved standardized foods that would qualify for and express a nutrient content claim (recognizing the FSIS continues to maintain prior label approval).

Thus, there are regulatory precedents for reforming all standards in a single stroke and for authorizing flexibility in food standards formulations. FPA encourages the agencies to develop a proposed rule that follows these precedents to allow for responsible and controlled modernization of food standards. The food industry would insist that such a general rule be developed within the boundaries set by the adulteration and misbranding provisions of the law: standardized foods made with safe and suitable ingredients, and labeled in a truthful, non-misleading manner, would continue to be the norm. Such a general rule could, for example, allow for nutritional improvements, other than to support nutrient content claims, to be made to a standardized food, a situation that would lie outside the scope of existing rules. To illustrate the concept, a 20% decrease in fat, saturated fat, or calorie content would represent a significant improvement to the nutrient profile of a food, yet it is not enough of an improvement to qualify for the nutrient content claims “less” or “reduced.” An increase of 7% Daily Value per serving of dietary fiber – which could be the result of increasing whole grain content in a standardized food to its technical limit – is consistent with the recommendation to eat more whole grains in the

*Dietary Guidelines for Americans*, and would be a significant improvement in the nutrient profile of a food, and is yet it is insufficient to qualify for a “more fiber” claim.

A single rule that could authorize controlled flexibility in the production of standardized foods, without the need to effectuate reforms only through individual permits, petitions and rulemaking, could include such features as:

- The flexibility to use additional safe and suitable ingredients, other than the characterizing ingredients of a standardized food, to achieve defined technical objectives that result in no appreciable change to the finished product. Such flexibility could include use of enzyme-modified ingredients that may reduce processing time, the substitution of a liquid form of an ingredient if the standard specifies only a dry ingredient, and vice versa, or the use of new antimycotic or other antimicrobial compounds than the existing standards might accommodate;
- The flexibility to modify a standardized food for the purpose of qualifying for, and expressing, health claims and structure-function claims, thus expanding the nutritional modification concept beyond use of nutrient content claims;
- The flexibility to modify a standardized food to introduce nutritional improvements that may not be sufficient to qualify for a nutrient content claim, or be outside the scope of the nutrient content claim. One such accommodation might be general permission to allow for addition of vegetables, with the objective of gradual increases in vegetable intake by consumers. Vegetable macaroni products (21 CFR 139.125) that use vegetables other than those listed in the standard could be an example of such applied flexibility.
- The flexibility to reduce fat content below the specified minimum fat content in current standards, for the purpose of nutritional improvements;
- The flexibility to use processing and manufacturing techniques beyond those specified in standards of identity, provided that the alternate make achieves the same end result;
- The flexibility to present products in different styles than articulated in the standard, with the use of descriptive style terminology as part of the name of the food. This modification could permit canned diced apricots, or canned petite shaped carrots, to be traded under their respective standards of identity;
- The flexibility to allow for standards of fill of container, when applicable, to follow the FDA general rule at 21 CFR 100.100.

Such a general rule could reduce the burdens on both government and the food industry while modernization of individual food standards proceeds, and allow for controlled and responsible modernization of standards in a broad manner. FPA requests that FSIS and FDA propose new rules that reflect these recommended actions, and simultaneously reopen the comment period on this docket, to permit parallel commentary on standards reform principles.

#### Adjustments to proposed principles

Notwithstanding any additional rulemaking, principles to govern future establishment, amendment, or removal of individual standards can be valuable. Such principles should outline a reliable process for making a modern, flexible standard. FPA generally supports the principles governing food standards of identity that are proposed by FDA and FSIS, as many of them are reasonable for application to future work. However, it must be noted that the proposed principles are chiefly prospective in nature, and do not, in and of themselves, constitute modernization of food standards.

FPA believes that any principles adopted by FSIS and FDA to govern the future of food standards should result in a clear, predictable process for food standards rulemaking. We urge the agencies to incorporate into the principles the elements that would reflect how the agencies will implement future modifications to standards. FPA requests that the agencies affirm, in the final rules, that new, revised, or removed food standards would remain subject to notice and comment rulemaking. We note there are some standards of identity that remain subject to formal rulemaking provisions under the law, and the continuity of this framework also should be affirmed by the agencies in the final rules. Notice and comment rulemaking, and any formal rulemaking provisions, will ensure that all the public has an opportunity to review and express opinions regarding food standards modifications.

FPA supports the assertion of the government agencies that they would hold themselves to the principles with regard to amending or removing any standards of identity. FPA also believes that the agencies should engage in the consultation and consensus building processes that the proposed principles envision, if they work to reform individual food standards or groups of standards under their own initiative. This consensus building process is important, as it would ease the process of subsequent rulemaking on individual standards, and ultimately reduce resource burden on the government. We urge the agencies to consider using advisory committees for this purpose – an approach the law requires for FSIS. The agencies also could solicit comments on Advance Notices of Proposed Rulemaking and/or convene public meetings to gather perspectives on specific



standards or groups of standards that the agencies may consider amending or removing under their own authorities.

FPA recommends that the government agencies incorporate in the proposed principles an affirmation of the process it will follow when petitions to amend, establish, or remove standards of identity meet all the relevant criteria in the principles. As written, the proposed principles constitute criteria for acceptable petitions. They are framed from the perspective of avoiding rejection of petitions. However, there is no statement or suggestion that the government would take prompt or positive action if presented with a petition that addresses all the points in the principles. FPA suggests that the government agencies commit to publishing in the Federal Register a proposed rule to amend, establish, or remove a standard of identity no more than 120 days following receipt of a petition that meets all the relevant criteria, and commit to publishing in the Federal Register a final rule to amend, establish, or remove a standard of identity no longer than 180 days following the close of the comment period on the proposal. Such commitments would reflect the agencies' good faith in operating under the standards principles, and would ensure that the government agencies are equal partners with the other parties that are interested and motivated to modernize standards of identity.

Comments Regarding FSIS Proposed Principles and Food Standards:

FPA recommends that FSIS clarify its first proposed principle, that the food standard should protect the public. Protection of the public is embraced by FSIS rules in addition to food standards, including food safety regulations and nutrition labeling rules. Food standards should not duplicate other general measures that FSIS has in place for public protection. In the preamble to the proposed rule, FSIS discusses consumer protection from an economic standpoint as the objective of food standards of identity, and this is the meaning that should be emphasized.

In the preamble to the proposed rule, FSIS notes that it intends to remove any informal "policy" standards from the Food Standards and Labeling Policy Book that are not converted by petition to formal standards of identity. Given the environment of prior label approval under which FSIS operates, the informal standards provide guidance that is equally valuable to food companies and to FSIS label reviewers, with respect to the expectation of minimum meat or poultry content for a given product. Absent a formal or informal standard, food companies may have little guidance as to FSIS's expectations of product formulation. FPA also notes that for products with formulations in both meat and poultry, the meat product may be governed by a standard of identity while the composition of the poultry product is addressed in the Food Standards and Labeling Policy Book, and vice versa. In this situation, it is unclear whether one standard would govern both meat and poultry product composition, whether the codified standard of

identity would be the only relevant requirement, or how FSIS would communicate its expectations for meat and poultry composition. FPA requests that FSIS clarify its views on this subject. We believe, however, that it is not necessary for FSIS to consider any provisions that would require percentage characterizing ingredient labeling. If items in the Food Standards and Labeling Policy Book are converted to petitions for standards of identity, we estimate that it would take FSIS decades to process such petitions, possibly to the exclusion of all other work in labeling and standards.

FPA believes that FSIS must provide opportunities for collecting market data, particularly for projects to establish any new standards of identity. To provide some assurances to food companies in an environment of in-plant inspection, FSIS should articulate a clear policy for such market experiments.

In order to allow for appropriate use of safe and suitable ingredients for modified standardized foods in the future, FSIS should delete its existing list of approved substances, and should follow the food additive and GRAS provisions of FDA. This approach would help to expedite food standards reform.

#### Comments Regarding FDA Proposed Principles and Food Standards:

In past years, FDA has received a number of petitions for new or revised standards of identity that have not advanced to proposed rules. FDA did not discuss this petition inventory in the proposed rule for food standards principles. FDA should offer some clear perspectives on the status of this petition inventory. FPA believes that petitioners should not be required to revise their petitions to reflect the proposed principles. FDA also should commit to rulemaking to resolve this pending petition inventory as it moves forward with food standards reform.

FPA notes that FDA has not discussed the regulatory construct for common or usual name rules (21 CFR Part 102) in the discussions around the proposed principles governing food standards of identity. Food standards reform presents the potential to remove a standard of identity and replace it with a simpler common or usual name rule. Applying some of the principles that FDA has proposed for food standards could result in future standards of identity that may fit best within FDA's common or usual name rules. FPA believes that establishing a common or usual name by regulation also benefits from the protection of national uniformity through federal preemption. Thus, FPA urges the agency to articulate the potential value of common or usual name rules for food standards modernization, to affirm that the federal preemption principle relates to common or usual name rules, and to discuss the applicability of food standards principles to the establishment of common or usual name rules, in future rulemaking or related guidance.

Conclusion

FPA is committed to supporting food standards of identity that are meaningful for the food industry and reflect consumers' interests. Our comments support the value of food standards, and explore the possibility for responsible and controlled steps toward modernization that would remove some resource demands by alleviating some need for case-by-case solutions. Additionally, our comments suggest some improvements to the proposed principles, which are best suited for future work in food standards. We respectfully urge both FDA and FSIS to implement our recommendations expeditiously.

Thank you for the opportunity to comment on this important issue.

Sincerely,

A handwritten signature in cursive script that reads "Regina Hildwine". The signature is written in black ink and is positioned above the typed name and title.

Regina Hildwine  
Senior Director,  
Food Labeling and Standards  
Food Products Association