

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

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

[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:

We in the The Solae Company<sup>1</sup> appreciate the opportunity to comment on the proposed Rule to modernize food standards by establishing a set of general principles for food standards proposed by the Food Safety and Inspection Service (FSIS), USDA, and the Food and Drug Administration (FDA), HHS [Proposed Rule, Food Standards; General Principles and Food Standards Modernization, 70 FR 29214, May 20, 2005].

With several suggested additions and changes that are outlined below, The Solae Company fully supports the process detailed in regulatory option two in the proposed Rule. This option would establish a set of principles that FDA and FSIS would use when assessing food standards, and a statement describing the system that FDA and FSIS would use to revise, eliminate, or establish standards in response to petitions that will be submitted by external parties or that are initiated from within FDA or FSIS.

The Solae Company also supports the objectives of the rulemaking effort by the Agencies to establish food standards that promote honesty and fair dealing in the interest of consumers, protect the public, allow for technological advances in food production, and that are consistent with international food standards to the extent feasible.

To this end, we believe that the changes in the regulation need to go further in allowing flexibility that will enable the full use of past and future advances in nutrition science, and processing innovation in order to satisfy consumer desires and needs. For this reason we offer the following suggestions:

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<sup>1</sup> The Solae Company refers to Solae, LLC, a Delaware limited liability company, and its global affiliates. The Solae Company is a leading research, manufacturer, and marketer of high quality soy ingredients, including soy protein isolates and concentrates, textured vegetable proteins, and specialty lecithin ingredients.

- Improved Flexibility: Since 1993 the FDA and FSIS have made important efforts to allow for the development, production and labeling of substitute standardized foods. The best examples of these efforts are found in an amended 21 CFR 130.10 approved by the FDA and the recent Final Rule issued by FSIS in 70 FR 33811. We believe that the FDA and FSIS should build on this effort and allow further flexibility to food processors across all food standards in a broad based Rule. In general, we urge the Agencies to finalize a Rule that would allow for the use of safe and suitable alternative, optional ingredients, the use of mandatory ingredients at different levels, the addition of safe and suitable nutrients not listed in a food standards, and appropriate variations in standardized macronutrient content to achieve the desired consumer need. We believe that by so doing the Agencies will enable food processors to more effectively and efficiently respond to consumers evolving needs as advances in nutrition science, and ingredient and processing technology becomes available.

Many improvements have been made in the areas of science and technology that are currently unavailable to consumers in current standards due to the lack of flexibility in the current regulatory process. For example, in the area of nutrition science, the Protein Digestibility/Corrected Amino Acid Score (PDCAAS) method for determining the quality of protein was unknown when the current standards were developed. This analytical method is now the official method recognized by the FAO/WHO as well as FDA and USDA when judging the quality of protein in the human diet<sup>2</sup>. Using this analytical methodology we now have the capability to accurately measure the correct relative nutritional value of animal and vegetable sources of protein in our diet. Current Standards restrict the use of vegetable protein ingredients in standardized products partly based on the earlier belief that they were inferior in nutritional quality to animal protein sources. The FDA has since established a regulatory precedent allowing for the adjustment of the nutrition profile in the nutrition facts panel that recognizes the relative value of alternative protein sources. By extending this nutrition science based precedent to allow future flexibility in developing and approving reasonable changes in current standards and the development of new standards the Agencies will enable processors to respond to consumers evolving needs as advances in nutrition science, and ingredient and processing technology becomes available. This can be done while at the same time adhering to the other required principles as outlined in the proposed rule. This is but one example of how the FDA and FSIS can benefit consumers by amending the rulemaking processes to facilitate well reasoned, justifiable flexibility in the future rule.

- In a related comment, we note that in the fourth principle (*Proposed 7 CFR 410 (a) (4) / 21 CFR 130.5 (b) (4)*), the term “vehicle” suggests the food will carry some additional benefit, i.e. that within a Standard a food may have its nutrients restored, enriched, or fortified. We request that this principle enable Standards to have an increased level of flexibility for the purpose of encouraging industry innovation in the development of food products so long as the food adheres to the principles and guidelines set forth in the proposed Rule. Specifically, that the Rule would be sufficiently flexible to expressly allow the development of food products within the Standard that would have improved nutritional profiles. This should allow modifications in micronutrients and macronutrients that would enable foods to be labeled with a nutrient content claim under

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<sup>2</sup> 21 CFR 101.9

21 CFR 130.10 and 70 FR 33803, June 10, 2005, or with a Structure Function claims or Health Claim that has been granted if the food meets the requirements of such claims and adhered to the principles and guidelines set forth in the proposed Rule.

- As has been noted by others who have commented on the proposed principles, we assume that the intent of the text in principle three (*Proposed 7 CFR 410 (a) (3) / 21 CFR 130.5 (b) (3)*) “. . . foods may be defined or distinguished by . . . the manner in which they are produced” includes among others, mechanical and thermal processing methods that affect characteristics of the food. We believe both FDA and FSIS should confirm that this criterion does not require, and would not support a petition seeking to require, defining or distinguishing a standardized food or an ingredient used in a standardized food if it was produced or derived from plants or animals resulting from biotechnology if the characteristics of the food were essentially the same as the traditional standardized food. This is consistent with the current Policy that also requires such foods or ingredients that are significantly different from their traditional counterparts to be labeled<sup>3</sup>.
- We request that the final Rule establish time limits for the various stages of the regulatory process including the acknowledgement of receipt of a petition, the publication for public notice and comment, and the finalization of a new or revised standard or elimination of an existing standard. If a petitioner makes the substantial commitment to prepare and submit a petition using this process, it is reasonable for FDA or FSIS to commit to act on the petition in a defined and reasonable period of time. Making a commitment to a defined time period in which the Agencies will evaluate and approve or disapprove Standards gives consumers and industry reassurance that this modernization effort will result in the intended consumer benefits, namely food products that are enabled by new developments in food ingredients, nutrition, safety and processing.

### **Final General Comment**

In addition, we recognize that the effort to finalize this Rule may require significant time to complete. We suggest that, during the intervening period, the FSIS and the FDA allow petitioners for new Standards of Identity to prepare and submit petitions in accordance with the proposed principles and process contemplated in this Rule and that the Agencies issue temporary guidelines for use during this period.

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

Sincerely,

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<sup>3</sup> See “Guidance for Industry. Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.” Available at <http://www.cfsan.fda.gov/~dms/biolabgu.html>