



ENZYME TECHNICAL ASSOCIATION

1900 K Street, NW
Washington, DC 20006

Telephone (202) 496-7380
Fax (202) 496-7756

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August 23, 2000

VIA FEDERAL EXPRESS

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

**Re: Docket No. 98N-0359 – Program Priorities in the Center
for Food Safety and Applied Nutrition; Request for
Comments**

To Whom It May Concern:

The Enzyme Technical Association ("ETA") respectfully submits these comments, in duplicate, in response to the Food and Drug Administration's ("FDA's") Notice entitled "Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments." 65 Fed. Reg. 39415 (June 26, 2000) (the "Notice"). ETA is a trade association composed of the majority of enzyme manufacturers and distributors in the United States. As such, ETA members are directly affected by the program priority decisions that currently face the FDA's Center for Food Safety and Applied Nutrition ("CFSAN").

ETA submitted comments to this docket following similar requests for comments on CFSAN's program priorities in 1998 and 1999. See 63 Fed. Reg. 30242 (June 3, 1998) and 64 Fed. Reg. 47845 (September 1, 1999). ETA also took advantage of an opportunity to orally present its suggestions at a public meeting that was held in July, 1998, and we appreciate CFSAN's willingness to seek and give serious consideration to comments submitted to this docket suggesting specific program priorities. In the time since ETA submitted its comments in 1998, CFSAN has taken action with respect to a number of ETA's suggestions. For example, the agency has renewed funding for the Food Chemicals Codex ("FCC") and has taken partial action with respect to our request that the Generally Recognized as Safe ("GRAS") Affirmation Petition 3G0016 ("GRASP 16") be completed. Furthermore, the agency has responded to ETA's and numerous other parties' suggestions by listing the completion of the GRAS Notification rule on CFSAN's "A" List. We

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applaud the agency for these program priority decisions. However, many important issues remain unresolved. We are therefore submitting these comments concerning the following issues that we believe warrant a high priority: (1) the GRAS Notification rule should remain on the "A" list of priorities and be completed as soon as possible; and (2) the GRASP 16 should be completed. Our detailed comments are provided below.

I. GRAS NOTIFICATION REGULATION

ETA renews its request that the GRAS Notification regulation be completed before the end of the fiscal year 2000. Simply put, the importance of this regulation cannot be overstated. CFSAN needs to move forward on this important initiative. However, if it is not possible to complete the final rule in FY2000, it should be placed at the top of the "A" list for FY2001.

The current GRAS affirmation petition process is a dismal failure. The system discourages the development of new products and hinders FDA's ability to monitor the nation's food supply. The time and resource intensive GRAS petition process provides little or no benefit to the public or the industry when the resources required to prepare a petition are weighed against the average time required to receive a GRAS affirmation regulation. The GRAS affirmation petition process discourages submissions to the agency. FDA is well aware of the shortcomings of the current GRAS affirmation process and proposed GRAS Notification as a remedy. The agency has taken this a step further, encouraging the use of GRAS notification while still a proposal. A simpler, more effective, GRAS notification system based on the existing Federal Register proposed rule would provide an incentive for manufacturers to inform FDA of their GRAS determinations. This would improve FDA's ability to ensure safer foods by increasing the agency's awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances. FDA's publication of the GRAS notification proposal represents a critical first step in streamlining the GRAS process, freeing vital agency resources to address food issues that are a public health priority.

Furthermore, the lack of a functional GRAS system places U.S. products at a significant disadvantage in the global marketplace. Foreign companies want some governmental confirmation that U.S. food ingredients are safe. Marketing pressures make it very difficult for manufacturers to globally market products that have been self affirmed as GRAS and, as noted above, waiting for FDA affirmation of GRAS status is not an acceptable alternative.

If finalized, the GRAS notification system would also assist other federal agencies that review the safety of food substances. Other agencies typically look to FDA when addressing issues related to food safety. For example, the Bureau of Alcohol, Tobacco and Firearms ("BATF") and the United States Department of Agriculture ("USDA") routinely rely on prior FDA determinations when reviewing the safety of food substances subject to these agencies' jurisdictions. Both the USDA and BATF normally require a specific FDA regulation (GRAS or food additive) or an FDA advisory opinion before they will accept a substance for a regulated use. Thus, the GRAS petition process presents a bottleneck when attempting to deal with other regulatory agencies. Even if FDA is unable to complete the GRAS Notification rule this year, the agency should streamline the process of dealing with other agencies by consulting with BATF and USDA to ensure that those agencies understand and are in agreement with the GRAS notification procedure and by confirming that the procedure provides a means by which those agencies may accept substances which are the subject of GRAS notifications.

In sum, CFSAN needs to move ahead promptly to remove the uncertainty created by this unfinished rulemaking process. By finalizing the GRAS Notification, agencies within the US government and foreign governments alike would no longer be confused by the ad hoc situation that presently exists. A final regulation would provide a much needed public statement of FDA's acceptance of a GRAS notification. Furthermore, a cost-benefit analysis demonstrates that finalizing the GRAS Notification rule is a "win-win" situation for CFSAN. Finalizing the rule is not only feasible in a relatively short period of time, it is clearly desired by a majority of the food industry, and would provide an opportunity for CFSAN to eliminate an obviously inefficient regulatory scheme.

II. GRAS AFFIRMATION PETITION 3G0016

CFSAN should conclude its review of GRASP 16. See 38 Fed. Reg. 9,256 (Apr. 12, 1973); 38 Fed. Reg. 15,471 (June 12, 1973); 49 Fed. Reg. 34,305 (Aug. 29, 1984); 52 Fed. Reg. 23,607 (June 23, 1987); 58 Fed. Reg. 48,889 (Sept. 20, 1993); 61 Fed. Reg. 40,648 (Aug. 5, 1996). The petition seeks GRAS affirmation for a significant number of enzymes that are used in food products. Although the petition was accepted for filing by FDA over 27 years ago, the FDA has yet to complete the review of the petition. 38 Fed. Reg. 9,256.

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While the GRASP 16 enzymes from animal, plant and *Bacillus* sources have been affirmed as GRAS (See 60 Fed. Reg. 32904 (June 6, 1995), and 64 Fed. Reg. 19887 (April 23, 1999)), the fate of the remaining enzymes remains uncertain despite the relative ease with which the matter could be resolved. As required by 21 C.F.R. § 170.35, GRASP 16 provided substantial data to support the historical use and therefore the safety of the GRASP 16 enzymes. Furthermore, because FDA has had 27 years to review this information, any safety concerns relating to these enzymes have been resolved long ago. Therefore, FDA has merely to publish the GRAS affirmation final order and regulation for the remaining enzymes in order to complete this 27 year project. GRASP 16 presents an excellent opportunity to make an immediate positive impact with a minimal expenditure of resources.

In closing, ETA appreciates the opportunity to comment on the Notice and supports the Center's decision to involve the public in its priority making decisions. If you have any questions concerning these comments please contact me at (919) 929-6057.

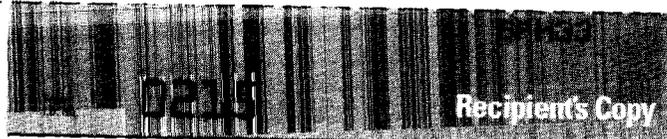
Sincerely,

A handwritten signature in black ink that reads "Nancy Zeman" with a stylized flourish at the end.

Nancy Zeman
Chair, Enzyme Technical Association

NZ/mhh

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