



Saputo Cheese USA Inc.
P.O. Box 198
317 Hwy. 141 North
Lena, WI. 54139
920-829-5251

August 16, 2005

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

RE: Docket No. 2005N-0231. Draft Report of the Threshold Working Group, Center for Food Safety and Applied Nutrition: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food; Availability; Request for Comments and for Scientific Data and Information.

Dear Sir or Madam:

Saputo Cheese USA Inc. appreciates the opportunity to comment on the draft report, "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." We manufacture a wide variety of cheeses including Blue Cheese. An ingredient in the cheese, the cheese culture, utilizes wheat protein hydrosylates in the microbial fermentation process at a level of <1% of the fermentation medium. After filtering and separating, the ingredient is used in our process at a level of 80 milliliters per 1000 kilograms of cheese. (This estimate is 10 fold higher than expected as 90% of the culture would be expected to be lost along with 90% of the whey.) Therefore, assuming that no culture was lost in the whey, and that all of the starter is wheat, the overstated level of wheat would be 0.00008 gram per gram of cheese.

As documented in the European Union correspondence SANCO/D4/JH/eo/D440332 (2004), the EU has determined that any potential allergens from these ingredients are not required to be labeled.

In obtaining GRAS status for enzymes, it has been noted that many proteins in bioengineered foods are derived from microbial sources and the developers have demonstrated that those proteins do not have the same characteristics associated with food allergens such as a difference in structures, and they are not resistant to digestive enzymes and acid.

Finally, both the ingredient and our finished product have been submitted wheat protein analysis and the test results were negative.

Due to the absence of published available data, the history of safe use at minute levels should be considered. The level of wheat in Blue Cheese has not changed for decades and there are no known reports of allergic reactions. There is no reason to halt the use of this ingredient at this level and further limit the choices of nutritious products from consumers.

Based upon this information and analysis, we would request that any fermentation ingredient that are minor components of the fermentation media (>10%) are exempt from labeling in the finished ingredient. These are not the major food allergens that the law was intended to address.

Sincerely,

Sarah Alger-Feser

Sarah Alger-Feser
Quality Assurance Director
Saputo Cheese USA Inc.