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Division of Documents Management (HFA-305)
Food and Drug Administration
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Food Ingredients

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Subject : Docket No. 2005N-0231

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To Whom It May Concern:

Degussa Bioactives US, LLC are involved in the manufacturing and marketing of enzyme ingredients used in the manufacturing of dairy products such as cheese. These enzyme products include a variety of animal extract and microbial fermentation products. In 2003, the U.S. average cheese consumption per person was 31lbs.

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Enzymes produced by microbial fermentation play essential roles in the food industry. The microbial fermentation process utilizes either wheat and or soy protein hydrolysates at a level of $\leq 1\%$ as ingredients in the fermentation medium. During the fermentation process, the protein hydrolysates are broken down further for utilization by the microorganism. At the end of fermentation, the resulting enzyme will be separated and filtered several times.

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Dairy manufacturing use of these enzymes is typically at a rate of 63 grams per 1,000 liters of milk or approximately 0.0063 grams of enzyme per gram of cheese. (Normally this rate is 50% of this but we elected to demonstrate the levels based upon a worst-case scenario.) At the highest usage for the microbial fermentation and cheese manufacture, the largest volume of wheat and/or soy would be 0.000063 per gram of cheese. This number is overstated, because the level would be lower because some or all of the proteins are broken down/utilized during the fermentation process, and the end enzyme is purified and filtered multiple times as previously stated.

We know that in the European Union they have determined that any potential allergens from these ingredients are not required to be labeled. This is from their correspondence SANCO/D4/JH/eo/D440332 (2004).

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, we have submitted our finished products (which are food ingredients) for wheat and soy protein analysis. The test results were negative.

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.

If there are any questions on these statements please feel free to contact us at your convenience.

Kind regards,

Nancy Eggink
Quality Assurance and Regulatory Lead

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