

February 28, 2002

Mr. Joe Levitt, Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5700 Paint Brush Parkway
College Park, MD 20740-3835

Re: GRAS Notice No. GRN 000091; Food Additive Petition FAP 6A3930

Dear Mr. Levitt:

Marlow Foods Ltd.'s Quorn Foods, Inc., of Riverside, Connecticut, recently began marketing a line of meat-free products containing its mycoprotein ingredient, a substance recently self-designated GRAS by Marlow Foods (a division of AstraZeneca) in a notification to the FDA that the FDA did not question.¹ We applaud the company for developing and marketing nutritious products that have little impact on the environment, especially compared to meat and poultry. However, we urge the Food and Drug Administration (FDA) to take enforcement action regarding the deceptive labeling of those products, to reconsider the GRAS designation, and not to approve mycoprotein as a food additive until certain testing is conducted.

I. Labeling

“Quorn meat-free patties” and related products are mislabeled, in violation of section 403(a)(1) of the Food, Drug, and Cosmetic Act. Copies of product labels are attached.

The label states:

“‘Mycoprotein’ comes from a small, unassuming member of the mushroom family, which we ferment like yogurt.”

¹ GRAS Notification for Mycoprotein, Marlow Foods Ltd., Nov. 30, 2001; FDA response letter, Jan. 7, 2002.

In fact, the mycoprotein in this product comes from *Fusarium venenatum* fungus. Though all mushrooms are fungi, not all fungi are mushrooms—and *Fusarium* is not a mushroom. The manufacturer is deceiving consumers by indicating that its product is somehow made from a familiar, natural, rather costly, umbrella-shaped food that people have eaten for a long time. The mycoprotein in this product has nothing to do with mushrooms. Indeed, two articles, written by Marlow Foods employees, in *Food Technology* about the production and marketing of mycoprotein products never use the word “mushroom” even once.² The mycoprotein is produced as a continuous fermentation product and is considered a single-cell protein. It has never been used in the American food supply and has only been used in Europe for the past decade or so. Though it is obvious why the manufacturer does not wish to define mycoprotein as fungal in origin, it should be required to do so and not deceive consumers about the nature of its product.

The manufacturer also compares the production of mycoprotein to the production of yogurt. That, too, is deceptive. Yogurt is basically milk that has been fermented by small amounts of various bacteria (not fungi). Those bacteria moderately alter the characteristics of the basic milk ingredient. In the case of mycoprotein, the fungus *is* the basic ingredient. Fermentation is not modifying other ingredients, but is the means of creating the product itself.

· Common or usual name

The ingredient label identifies Marlow’s new ingredient as “Mycoprotein* ... *Mushroom in origin.” “Mycoprotein” is a word not even included in the dictionary (Merriam Webster’s Collegiate Dictionary, 10th edition; Webster’s New World, second college edition (1982)). Other than a few mycologists, no consumer would understand what the ingredient is (and we suspect that the manufacturer will not be mounting an educational campaign to explain to consumers what the ingredient really is. Furthermore, “*mycoprotein*” suggests that the ingredient is a particular protein, whereas, in fact, the ingredient is only 50 percent protein.³ A common or

² Rodger G. “Production and properties of mycoprotein as a meat alternative.” *Food Technology*, 55, No. 7, 36-41 (July 2001). Wilson D. “Marketing mycoprotein: the Quorn Foods story.” *Food Technology*, 55, No. 7, 48-9 (July 2001).

³ Miller SA, Dwyer JT. “Evaluating the safety and nutritional value of mycoprotein.” *Food Technology*, 55, No. 7, 42-6 (July 2001).

usual name like “fungal extract” would be descriptive. If it allows the unfamiliar technical term “mycoprotein” to be used in the ingredient listing at all, the FDA should stipulate a more explanatory common or usual name, such as “mycoprotein from fungus.”

- “We do not use ingredients that were produced using modern biotechnology.”

Judging from the description of the manufacturing process, it appears that the mycoprotein *is* produced using modern biotechnology. The technology appears to be quite modern or sophisticated, with temperature controls, aeration, and specific nutrients all designed to produce *Fusarium* fungus in a continuous-fermentation process. The fungus is alive (“bio”) and the manufacturing system is certainly a “technology.” Of course, the *Fusarium* fungus is not genetically engineered, but genetic engineering is only one form of biotechnology. It would be accurate for the company to say that its product is not genetically engineered, but that, too, might be misleading, because no mycoprotein is genetically engineered.

- “Made from natural ingredients”

That phrase on the front label suggests that the product is made from familiar ingredients. However, in eight or so products that the company is marketing, mycoprotein is the key ingredient, and it is certainly not a familiar ingredient. We don’t deny that it is natural, but we believe that the average consumer would interpret “natural ingredients” as the kind of ingredients that are used to produce competing meatless patties, cutlets, and the like. Those products are usually made of soy protein, wheat protein, comminuted vegetables (including *real* mushrooms), and other natural, familiar ingredients.

- Nutrition claims

“**Quorn meat-free Fettuccine Alfredo**” emphasizes the nutritional value of Quorn, stating that it has “About half the calories and a third less fat than skinless chicken breast.” That statement may be true about mycoprotein itself, but not about the products in which it is used. In this case, the Quorn version of Fettuccine Alfredo provides 16 grams of fat (25% of the Daily Value), 9 grams of saturated fat (45% of the DV), and 920 milligrams of sodium, which is far more than is present in a skinless chicken breast. The back of the package claims that the mycoprotein is “very healthy.” While that may be true of the mycoprotein itself, the product contains too much fat, saturated fat, and sodium to permit such a claim. (see 21 C.F.R. 101.6) We have similar concerns about “**Quorn meat-free lasagna**.” Also, it is worth noting that the mycoprotein being bragged about comprises only 11% and 7%, respectively, of those products.

II. Safety and GRAS status

We question the Food and Drug Administration’s (FDA) acceptance (“...the agency has no questions at this time...”) of a recent GRAS notification by Marlow Foods Ltd. for its

mycoprotein product.⁴ The mycoprotein in this product comes from *Fusarium venenatum* fungus, a novel food with virtually no history of use. Indeed, the company states that this fungus was obtained only a couple of decades ago in a soil sample obtained from Buckinghamshire, United Kingdom. Commercial-scale production in the United Kingdom only began in 1994.

It is possible that this fungus can cause allergic reactions. Marlow Foods states that in 1999 and 2000 it received only about 90 reports per year of adverse reactions, including several IgE food-allergy reactions, from consumers of its products. That observation provides some assurance that the fungal proteins do not cause many severe reactions, but it is still weak evidence that those proteins do not cause numerous milder reactions or occasional severe reactions. Assuming that all the reported reactions were actually due to the mycoprotein and not other ingredients of the foods, one should presume that, because no systematic effort was made to encourage reporting, only a small percentage, perhaps one percent, of people who suffered reactions (a) actually figured out that the reaction might have been due to the mycoprotein product and (b) contacted the company. Thus, the true rate of reaction might not be on the order of 1/140,000, as asserted in the GRAS petition, but closer to 1/1,400. Also, the limited consumption, mostly by adults, of mycoprotein in Europe sheds little light on whether the product may sensitize young children and result in allergic reactions at subsequent eating occasions.

The FDA and Environmental Protection Agency (EPA) are gaining greater experience, and evolving policies for, evaluating the potential allergenicity of novel food ingredients introduced into the human food supply through genetically engineered (GE) crops. Typically, the FDA and EPA consider a protein's molecular weight, heat stability, acid stability, and amino acid sequence to determine whether it is likely to pose a risk of allergenicity. In the case of the Bt protein in StarLink corn, the EPA and its Scientific Advisory Panel recognized that that protein's moderate stability in a simulated gastric environment suggests the possibility that the protein could cause allergic reactions. The EPA has ruled that StarLink protein may be allergenic and that even minute amounts should not be allowed in food. That ruling followed from allergists'

⁴ Agency Response Letter, GRAS Notice No. GRN 000091, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Jan. 7, 2002.

acknowledgment that thresholds are not known for either sensitizing a person to an allergen or eliciting a reaction.

In contrast to the minute amounts of the individual novel (to the human diet) proteins in current GE foods, (a) mycoprotein is consumed in *multi-gram* quantities in the form of imitation meat products, (b) mycoprotein contains hundreds or even thousands of proteins not normally consumed by humans, and (c) Marlow Foods apparently has not assessed whether *any* of the novel proteins share the characteristics of known allergens.

We recommend that the FDA rescind its acknowledgment of Marlow Foods' GRAS notification and not approve the food additive petition for mycoprotein/*Fusarium venenatum*. Instead, the FDA should require the company to determine whether any of the proteins in the fungus have the characteristics of known allergens (heat stability, simulated gastric stability, and amino acid sequencing of any stable proteins to identify homologies to known allergens) and pose a risk to consumers.

The company's Expert Panel did not express any concerns about possible allergenicity. That may reflect the fact that none of its members was an allergy expert. The absence of such a key expert disqualifies that panel from being considered "expert," and on that ground alone the FDA should have denied GRAS status.

We also note that *Fusarium venenatum* is a member of a group of fungi known to produce toxins. The company says that it ferments the fungus under conditions that preclude the formation of toxins, but the GRAS notification did not specify in any detail the nature and frequency of the company's assays for toxins of concern. The FDA, at the very least, should specify both manufacturing practices and how often batches must be assayed for mycotoxin content, as well as accepted levels of known mycotoxins. The company should routinely and frequently assay its product, and the FDA should do its own spot-checks.

Thank you for your attention to this matter.

Sincerely,

Michael F. Jacobson, Ph.D.
Executive Director

Doug Gurian-Sherman, Ph.D.
Co-Director, Biotechnology Project

cc: Christine Lewis, Bradford Williams, Alan Rulis

Attached: product labels