



November 16, 2011

Mr. Michael Taylor
Deputy Commissioner for Foods
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Taylor,

It has been several years since CSPI provided the FDA with information about adverse reactions to a food ingredient—"mycoprotein"—that has been accepted as "generally recognized as safe" (GRAS) by the FDA. We would like to update the agency on our findings.

Mycoprotein is not a single protein, as the name might suggest, but an RNA-reduced mold, *Fusarium venenatum*, that, mixed with other ingredients, is the basis for products marketed under the brand name Quorn. Quorn foods have been proven to cause serious allergic reactions. Indeed, one particular ribosomal protein has been identified as an allergen; whether other proteins are also allergenic is not known.

Judging from reports of adverse reactions that CSPI has received, reactions to Quorn range from nausea to severe vomiting, diarrhea, hives, and anaphylaxis. (See Attachment for examples.) Some people experience a reaction the first time they consume a Quorn product, while others reported reactions only after consuming the product several times. In many cases, the reactions got more severe with increasing times of consumption. Only a small minority (about 11 percent) reported to CSPI that they had a previous allergy to penicillin or other mold-related substances. CSPI previously provided the FDA with several hundred reports of adverse reactions, and the FDA agreed that Quorn was the cause.

CSPI has now received about 500 reports of adverse reactions from Americans, as well as about 1,200 more from the United Kingdom, other European countries, Scandinavia, and Australia. The reports that we have received undoubtedly are just a tiny fraction of the total number of adverse reactions, because many people don't link Quorn to the adverse reactions, don't consider reporting an adverse reaction, don't use the Internet, don't discover CSPI's website, and don't take the time to send us a report. The following breakdown shows the frequency of various symptoms:

(continued)

<u>Symptom</u>	<u>Number of reactions</u>	<u>Percentage of reactions</u>
Vomiting	1,088	65.4
Diarrhea	636	38.2
Fainting (or feeling faint)	110	6.6
Hives, urticaria	98	5.9
Breathing difficulties	79	4.8
Blood (in stool, vomit, or eyes)	38	2.3
Anaphylactic reaction	32	1.9

(Some people experienced more than one symptom.)

The most serious reactions are hives, breathing difficulties, and anaphylaxis. Many people (about 17 percent) needed medical care, with some going to the hospital. Symptoms typically occur within three hours after consumption of the allergen and dissipate within a day. We have not identified any deaths yet, but suspect that a death (such as might happen if someone fainted and hit his or her head when falling or got into a car crash or had an anaphylactic reaction) would be unlikely to be connected to the eating of a Quorn product.

We believe, and we suspect that any reasonable person would believe, that any novel food ingredient that causes hives, anaphylactic reactions, or vomiting so violent that blood vessels burst cannot, indeed must not, be considered by the FDA to be “generally recognized as safe.” (The “expert committee” of hired consultants that designated mycoprotein as GRAS may never have reviewed an early study conducted by the manufacturer that showed that mycoprotein increased the risk of gastrointestinal symptoms, let alone the subsequent identification of mycoprotein as an allergen or the reports of adverse reactions that CSPI subsequently collected.) FDA officials have told us that the agency’s standard for adverse effects that would disqualify a substance from being considered GRAS is “permanent, severe harm.” That is a ridiculously weak standard for a product that may be consumed by tens of millions of Americans. (In Britain, 40 percent of adults have eaten Quorn foods.)

While our adverse-reaction reports cannot establish the prevalence of allergic reactions to mycoprotein/Quorn, we commissioned a telephone survey in the United Kingdom that did establish the approximate prevalence. A 2003 survey of 1,000 adults found that 40 percent had consumed Quorn, with 5 percent stating that they had experienced an adverse reaction to the product. That same survey asked about allergies to common food allergens and found the following percentages, all lower than reported reactions to Quorn:

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<u>Food</u>	<u>% of sensitive individuals</u>
Quorn	5%
Shellfish	3%
Milk	2%
Peanuts	2%
Gluten	1%
Nuts (not peanuts)	1%
Fish	1%
Eggs	1%
Soy	0.5%
Other	3%

If Quorn sales increase and 30 million (10 percent) Americans consume the product, 1.5 million (5 percent) people might experience an allergic reaction.

Defenders of mycoprotein/Quorn have contended that numerous common foodstuffs cause similarly strong allergic reactions. But there is clearly a difference between traditional components of our food supply, such as peanuts and milk, and an intentionally added, novel, and unnecessary substance. With all the concern about food allergens, it is irresponsible of the agency not to take action to protect consumers from this powerful and unnecessary allergen that affects a sizable percentage of consumers. Consumers shouldn't have to play Russian roulette when they sit down to eat.

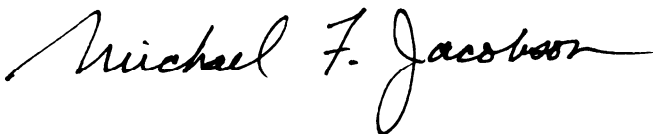
We do not believe that a small-print notice on the back of Quorn packages stating "Contains mycoprotein," as is done for common food allergens like soy and wheat, would adequately protect consumers from an ingredient that few know is an allergen. A prominent and candid front-label disclosure, such as the following, would be more visible and effective:

Warning: This product might cause severe diarrhea or vomiting, or a life-threatening anaphylactic reaction; an allergy might develop only after consuming the product several times.

However, we are skeptical that the FDA would require such a notice.

In view of the harm that consumers are suffering, and that many more will suffer in the future, we urge the FDA to revoke the GRAS status of mycoprotein and get this dangerous product off of grocery store shelves. There are plenty of other imitation meat products.

Sincerely,



Michael F. Jacobson, Ph.D.
Executive Director

Attachment

Examples of Reactions to Quorn

30-year-old female, USA: Friend made vegan lasagna with Quorn. I ate a slice during lunch. Came home and had some more. It was my first time having this stuff. I went to the bathroom a few times with the runs. About 36 hours later, I got blurry vision, headache, migraine, chest pain, a tingling sensation down my entire right arm and into my fingers, and developed stomach pain and fever.

72-year-old male, Marshall, VA: On two occasions in a two week span, I ate a Quorn product. Within two hour of eating the product I became nauseous and vomited violently at least six times, with the last two containing what looked like bile. After the vomiting stopped, I had to evacuate my bowels several time, ended up with diarrhea and finally passing a yellowish substance which I assumed to be bile. For years I have had pain in my right side said to be by the doctors as an irritated gall bladder. I became a vegan nine months ago and that pain went away. After both of these events the pain came back with a vengeance and lasted over a week. I didn't recognize the problem the first time but finally got in the second time.

62-year-old female, Crittenden, KY: One hour after eating Quorn beef flavor in spaghetti, I became very hot then my face and neck began burning and turned dark red. Benadryl did not help so I had to go to the emergency room about two hours after eating the product. My blood pressure jumped to 185/98. They treated me at the hospital but my face, neck, eyes and arms were red for about four days until it was out of my system. I continued to take Benadryl at night and Claritin in the AM. It took blood pressure medicine and a week to get my blood pressure to level out.

65-year-old female, Allentown, PA: About 3 hours after eating Quorn the first time I started to feel nauseous. Then I began throwing up. I threw up for 2 to 3 hours. I also had diarrhea. I didn't think it was the Quorn because my husband had no reaction to it. I ate some again (less) six days later and the same thing happened again but started two hours after I ate the Quorn. I will not eat this product again.

25-year-old female, Troy, MI: On three separate occasions I have become violently ill from eating Quorn products. The first time was so severe that I checked myself in to the hospital. The other two times I was up all night vomiting and having stabbing stomach pains along with diarrhea.

20-year-old male, Waco, TX: About two hours after eating Quorn Chik'n Nuggets, I felt tingling in my upper abdomen, and fluid would slowly work up my throat. Suddenly, I felt very nauseous. I tried to open the window to vomit (the closest bathroom was too far away) but I blacked out, and hit my head on a trash can. My girlfriend scrambled to turn on a light (supposedly, but I wouldn't KNOW because I was blacked out on the floor) and tried to talk to me. I drifted in and out of consciousness for a moment as she tried to pull me onto the bed. Luckily, I did not vomit though. Throughout the night, I was either cold, or

hot, and I had an unusual tense feeling in my stomach. It is now morning and the only remaining problems I'm having is a bruise on my head, and a lingering unusual feeling in my stomach.

24-year-old female, Brooksville, FL: A little over a year ago I tried the Gruyere Chick'n cutlet and got really sick for about 8 hours. I thought it was because I had gallbladder problems so I haven't eaten it. My gallbladder was taken out about a year ago. I decided to eat them again. Big mistake. I had one about 4 days ago and was sick all night. I had the turk'y roast tonight which I have had before and got sick shortly after eating it. I realized that when I eat some of the products I get extremely sick. Horrible stomach cramps, chills, aches and can barely move.

75-year-old female (filed by her daughter), Towson, MD: On Friday, March 4, 2011, my 75 year old mother had 2 severe allergic reactions to eating Quorn Chickn Patty - once in December 2010 and most recently on Friday, March 4, 2011. On Friday, March 4, 2011, during the Les Mis production at the Hippodrome in Baltimore, MD, my mother vomited within 4 hours of eating half a Quorn Chickn Patty and immediately passed out cold in the theater. She was rushed to Maryland General, spent the night in the ER, and was subjected to a battery of tests which yielded nothing wrong with her. She had 2 bouts of antinausea medicine to stop her vomiting.

42-year-old female, O'Fallon, MO: My 11 year old son had some for supper at 5pm and around 11pm was saying that his stomach felt like he'd been punched. The pain worsened until he was in agony. He finally vomited violently several times throughout the night and had severe diarrhea as well. He was almost delirious through the night with pain, dizziness, hot and cold flashes, feeling 'weird' all over, weakness, and the next morning still can't walk without dry heaving. The Quorn was the only unusual thing he's eaten and after looking up these reactions people have, I am appalled that this is marketed as 'similar to mushrooms'. I have never seen anything except food poisoning make a person so ill. The fact that it is a mycotoxin explains the severity of his illness. I am extremely angry to have put my son through this to say the least!

46-year-old female, Los Angeles, CA: I woke up at 1am, 2.5 hours after eating the Quorn products and was immediately, what I can only describe as violently ill. I threw up horribly, non-stop until 7 am. I slept on the bathroom floor because I couldn't leave. I was sweating profusely, and was unlucky enough to have diarrhea on top of that... not good. I had to miss work, continued throwing up until 4 pm, just not as much. Today, day 2, I still feel the effects but I'm able to go to work. My body is very sore from the severity of it trying to get Quorn out of my system. It was traumatic. This product should have a huge warning on it. I had had it once years before and got sick. I thought it was a fluke so I tried it again. Had there been a warning, I would never have eaten that. I am NOT allergic to eggs, wheat or milk. I eat those daily. This product could kill someone that couldn't handle what I went through.