

Self-reported adverse reactions associated with mycoprotein (Quorn-brand) containing foods



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ABSTRACT

Background: Mycoprotein, which is produced by a mold and is the basis of Quorn-brand meat substitutes, is a novel cause of allergic and gastrointestinal reactions, but little information has been available on its associated symptomatology.

Objective: To describe the nature and frequency of adverse reactions to mycoprotein.

Methods: Self-reports of adverse reactions to mycoprotein were collected via a Web-based questionnaire (www.quorncomplaints.org) and then analyzed.

Results: Analysis of 1,752 adverse reactions found that Quorn products caused allergic and gastrointestinal symptoms, with some people experiencing both. Allergic reactions, including urticaria and anaphylaxis, occurred within 4 hours of consumption in 312 people. Of those reactions, 45.8%, 1 fatal, began within 1 hour of exposure. Of those 312 individuals, 188 (60.3%) reported repeated reactions after repeated consumption of Quorn, and 2 people experienced 8 reactions (13 people did not say whether they experienced more than 1 reaction). Quorn foods caused gastrointestinal symptoms, including emesis and diarrhea, within 8 hours of consumption in 1,692 people. Of the gastrointestinal symptoms, 66.6% occurred 46 to 180 minutes after consumption of the products. Symptoms ranged from mild nausea to emesis severe enough to warrant medical attention.

Conclusion: Mycoprotein may be causing numerous and sometimes life-threatening allergic and gastrointestinal reactions. The acceptance in the food supply of this nonessential ingredient deserves reconsideration.

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Introduction

Mycoprotein was the name given to a processed form of *Fusarium venenatum* fungus that is the basis of Quorn-brand frozen foods, which are marketed as meat and poultry substitutes in grocery stores and in foodservice venues. Quorn and similar plant-based products, if safe, could serve as nutritious substitutes for meat products, which may contribute to heart disease and cancer. The ingredient was developed in the United Kingdom (UK) and originally marketed there in 1985. The maker of Quorn foods, Marlow Foods Ltd., petitioned the U.S. Food and Drug Administration (FDA) in 1986 to approve mycoprotein as a food additive (any substance that is reasonably expected to become a component of food and subject to premarket approval). However, because the FDA never reached a final decision on that petition, in November 2001 Marlow Foods notified the FDA that, consistent with the Food, Drug and Cosmetic Act, it had concluded that mycoprotein was “generally recognized as safe” (GRAS), a legal category of food ingredients for which premarket approval is not required.¹ The FDA accepted

mycoprotein as GRAS in 2002, allowing the product to be marketed, but has not yet approved the product as a food additive.² Quorn products were first sold in the United States in 2002 and are also sold in Europe, Scandinavia, Australia, New Zealand, and several other countries.

Research on Quorn or mycoprotein has used skin-prick testing or other methods to assess allergenicity.^{3,4} Hoff et al⁵ identified a specific ribosomal protein as a likely allergen. This paper includes and expands on previous research by characterizing the respiratory, skin, and other allergic reactions experienced by 312 people and the gastrointestinal (GI) symptoms experienced by 1,692 individuals (some people experienced both symptoms).⁶

Methods

Shortly after Quorn was first marketed in the United States in 2002, the Center for Science in the Public Interest (CSPI), which monitors the safety of food ingredients, learned of possible adverse reactions caused by the product. The CSPI established a website (www.quorncomplaints.org) to collect reports of adverse events, which were assembled into a database. Each report was reviewed, and nonrelevant ones (eg, spam, symptoms other than GI or allergic reactions, reports of no ill effects) were discarded, leaving 2,007

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reports received between March 28, 2002 and March 8, 2014 (since then, CSPI has received more than 900 additional reports). To be included in the analyses described in this paper, adverse event reports generally included personal identifying information; the product eaten; the site where the product had been purchased; date(s), nature, and timing of symptoms experienced; preexisting allergies, if any; and whether medical attention had been sought. (Some people did not know where the product was purchased or the exact variety of Quorn product, and some withheld identifying information, possibly out of privacy concerns.)

We defined a mycoprotein-associated adverse event as being allergic in nature if the individual reported 1 or more of the following symptoms within 4 hours after ingestion of Quorn: urticaria; pruritus; swelling of the throat, tongue, mouth, or lips; breathing difficulties; or anaphylaxis (defined as a multi-organ reaction characterized by generalized urticaria and pruritus, swelling of the tongue, difficulty with swallowing, hypotension, and tightness in the chest). An additional 59 reports stated that such symptoms occurred more than 4 hours after consumption of the product; they are not included in our calculations. 2 people provided medical records from a physician and a coroner's office.

We considered an adverse event as being GI in nature and of unknown underlying cause if the individual reported 1 or more of the following symptoms within 8 hours of ingestion of Quorn: nausea, emesis, diarrhea, or abdominal cramps. Some people reported experiencing both GI symptoms and allergic reactions. We excluded from this analysis 156 reports from people who reported GI symptoms occurring more than 8 hours after consumption of the product. (Those exclusions, and those described previously, explain why this report analyzes only 1,752 of the 2,007 reports submitted.)

Table 1

Clinical Features of Illness Among 312 Individuals Reporting Mycoprotein-Associated Allergic Reactions, Center for Science in the Public Interest (CSPI), March 28, 2002 to March 8, 2014

Symptom	Number (%)
Pruritus	46 (14.7)
Breathing difficulty	120 (38.5)
Fainted/almost fainted	112 (35.9)
Urticaria, rash	100 (32.1)
Anaphylaxis	39 (12.5)

NOTE. Total number of symptoms exceeds 312 because some people reported multiple symptoms.

Results

Between March 28, 2002 and March 8, 2014, the CSPI received 2,007 reports of Quorn-related adverse events from its Internet site, including 54.6% (n = 1,095) from the United Kingdom, 34.0% (n = 683) from the United States, and 11.4% (n = 229) from elsewhere in Europe, Canada, and Australia. The results are based on symptoms experienced by a total of 1,752 people.

Three hundred twelve reports included symptoms consistent with an allergic reaction (218 also included GI symptoms) (Table 1). No seasonality to the submission of those reports was apparent (month-by-month analysis not shown). Individuals ranged in age from 19 months to 85 years (median, 37 years), and 70.2% were female (similar percentage to all reports received). A reaction consistent with anaphylaxis was reported in 39 (12.5%) of the cases.

Of these individuals, 72.4% (n = 226) experienced allergic reactions after their first exposure to Quorn. Onset of symptoms after ingestion of mycoprotein occurred in less than 15 minutes in 55 cases (17.6%), between 16 and 60 minutes in 88 (28.2%) cases, and between 61 minutes and 4 hours in 169 cases (54.2%) (Fig 1). Seven cases of anaphylaxis occurred within 15 minutes and another 9 in the next 45 minutes; the remaining 23 cases experienced onset of symptoms between 1 and 3 hours after consumption of mycoprotein.

Ninety-two (29.5%) individuals reported seeking medical care for their allergic symptoms. Of those, 44 (26 females) went to the hospital. (Twenty-five others said they wanted to call for help but felt too sick to do so.) Most of those who went to the hospital experienced breathing problems (n = 27), including anaphylaxis (n = 20), 1 fatal. Treatments included antihistamines (n = 11), steroids (n = 9), adrenaline/epinephrine (n = 6), oxygen (n = 3), intravenous fluids (n = 6), and anti-nausea drugs (n = 4); 2 were given an EpiPen. In addition, 17 people indicated an unspecified hospital treatment or testing, and 4 did not state any treatment. Symptoms generally dissipated within 24 hours.

The 1 death linked to consumption of Quorn involved an 11-year-old boy with a history of mold allergy and asthma.⁷ He ate a Quorn Turk'y Burger for dinner, shortly after which he had an asthma attack.⁸ His parents administered an EpiPen, but the boy had no pulse when paramedics arrived. The paramedics brought back his pulse and intubated him, but he died the next morning. The coroner's report states that the cause of death was anoxic encephalopathy secondary to food anaphylaxis.⁹

One hundred eighty-eight of the 299 individuals who provided adequate information (62.8%) experienced multiple reactions after repeated consumption of Quorn, and 2 people experienced

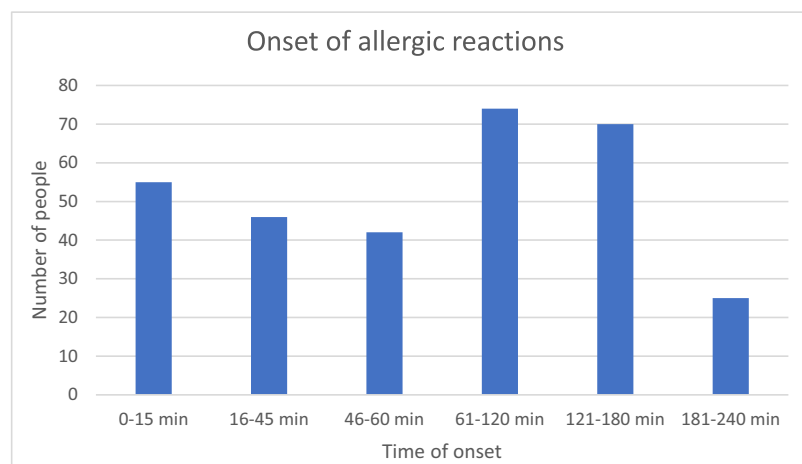


Figure 1. Latency between ingestion of Quorn mycoprotein and initial onset of allergic reactions reported to the Center for Science in the Public Interest, March 28, 2002–March 8, 2014 (n = 312 reports).

Table 2

Adverse GI Reactions Linked to Ingestion of Quorn Mycoprotein Reported by 1,692 Individuals to the Center for Science in the Public Interest, March 28, 2002 to March 8, 2014

Symptom	Number (%)
Emesis	1,255 (74.2)
Diarrhea	702 (41.5)
Nausea	652 (38.5)
Cramps, abdominal pain	587 (34.7)
Blood (in throat, stool; broken vessels in eyes)	48 (2.8)
Total reports	1,692

NOTE. Total number of symptoms exceeds 1,692 because some people reported multiple symptoms.

8 reactions. Among people who had more than 1 reaction and commented on severity, symptoms on each occasion were generally of similar intensity, although sometimes they became increasingly severe. Once people connected Quorn to the symptoms, they typically stopped eating the product. However, 14 allergic individuals who sought to avoid Quorn experienced adverse reactions when they accidentally ate a meal with Quorn at a foodservice facility or friend's home.

In addition to causing apparent allergic reactions, 1,692 people reported that Quorn caused GI symptoms, including nausea, emesis, diarrhea, blood in vomit or stool, and abdominal cramps (Table 2). The individuals affected ranged in age from 19 months to 85 years (median, 39 years), and 68.1% were female. Symptoms appeared within 15 minutes in 7.0% of cases, within 1 hour in 31.8% of the cases, and within 4 hours in 90.4% of the cases (Fig 2). Of people reporting, 67.7% experienced reactions on their first exposure to Quorn. Symptoms usually resolved within 1 day.

Two hundred twelve (12.5%) individuals reported seeking medical care for the GI event. Of those, 66 (3.9%; including 42 females) went to the hospital, with 55 experiencing emesis, 27 nausea, and 29 diarrhea (some people had multiple symptoms). Treatments included intravenous fluid and electrolyte rehydration ($n = 18$), testing and monitoring (electrocardiograms, magnetic resonance imaging, computerized tomography scans) that did not identify a problem ($n = 17$), antiemetics ($n = 11$), antihistamines ($n = 4$), epinephrine ($n = 4$), morphine drips ($n = 2$), glucose ($n = 2$), and an appendectomy ($n = 1$; appendix was normal). In addition, 22 people indicated an unspecified hospital treatment or testing, and 4 were told to rest. In addition, 66 others said they wanted to call for help but felt too sick to do so.

Seven people (0.4%), ages 25 to 48, said that after eating Quorn they became newly allergic to mushrooms or fungi. Of those, 4 were females. Five people had GI symptoms but no allergic symptoms; 2 had both types of symptoms.

We received numerous reports after the series of cases discussed in this paper, including several that are of interest because they involved medical diagnoses or a death. A medical report concerning a 36-year-old man said that 10 minutes after eating Quorn he experienced urticaria, facial and throat swelling, shortness of breath, and dizziness. He was treated in the emergency room with epinephrine, a steroid, and Benadryl. A week later he underwent a skin-prick test in which a ground-up Quorn nugget caused a 1-cm wheal. His physician stated that “this product should be taken off the market due to the risk of [a] life-threatening allergic reaction that it can cause.”

A 5-year-old Minnesota boy without any known allergies experienced anaphylaxis and full-body urticaria after eating Quorn. After being treated at the emergency room, skin-prick testing found strong reactions to histamine, mold, and Quorn. He did not react to egg whites, an ingredient in Quorn products.

A 16-year-old Swedish girl who had asthma and was allergic to nuts ate a meal that included a Quorn food (which did not contain nuts). She began having difficulty breathing and was taken to a hospital, where she died 2 days later.¹⁰ Subsequent tests were reported to have confirmed the absence of nuts in the meal, and blood tests were said to show “some sensitivity” to Quorn.¹¹

Discussion

We describe a range of symptoms found in the qualified adverse-event reports submitted by 1,752 people who had consumed Quorn-brand foods, which are composed largely of the fungal-derived “mycoprotein.” (The term *mycoprotein* was adopted, according to the British agency that approved that term, even though it was “not, in fact, very informative to the average purchaser,” because a more accurate name such as *fungus* or *mold* would likely produce “considerable consumer resistance.”¹²) This new food has been demonstrated to cause allergic reactions.^{3,5} As of March 2016, the FDA's system for collecting adverse events regarding food, cosmetics, and dietary supplements included 105 reactions said to be related to Quorn (since then, the FDA added numerous reports provided by the CSPI), with symptoms similar to what we found.¹³ The fact that 72.4% of allergic reactions and 67.6% of GI reactions occurred on an individual's first exposure to a Quorn food suggests a

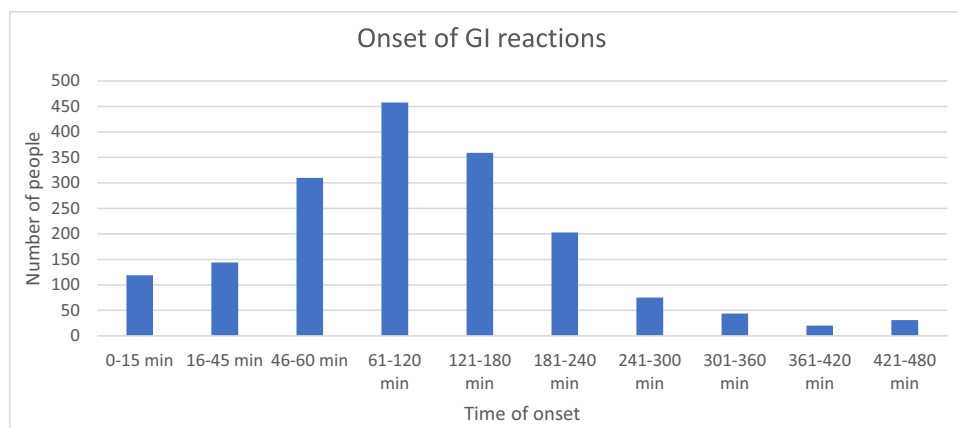


Figure 2. Latency between ingestion of Quorn mycoprotein and initial onset of gastrointestinal reactions reported to the Center for Science in the Public Interest, 2002–2014 ($n = 1,692$ reports).

cross-allergenicity with other foods or antigens or, alternatively, that the reactions were nonallergic in nature.

The severity of many allergic reactions is indicated by descriptions individuals provided, such as “Tingling of lips when eaten. Increasing difficulty in breathing followed by full systemic anaphylaxis (blood pressure 50/30, facial swelling, hives, abdominal cramps) requiring adrenaline and hospitalization”; “My hands itched, my body was bright red, my lips and throat swelled, and by the time I got to the emergency room (only 10 minutes later) I was blacking out because I couldn’t breathe”; “This caused extreme vomiting for hours, heavy sickness, to the point that I thought my wife was going to die on 3 separate occasions” (typos corrected).

That some of the reactions to Quorn were immediate type 1 immunoglobulin E (IgE)-mediated reactions is supported by the nature of the symptoms (generalized pruritus, difficulty breathing, and lip and tongue swelling³ and urticaria and an asthma attack⁵ shortly after consuming Quorn), skin-prick testing of people who had experienced anaphylaxis,¹⁴ and the occurrence of almost half of the reactions involving breathing and skin reactions within 1 hour of exposure. In the case of a patient who experienced an asthma attack, allergy to mycoprotein was confirmed by a double-blind placebo-controlled food challenge.⁵ Those researchers concluded that the symptoms were likely caused by a cross-reactivity between the mycoprotein derived from *Fusarium venenatum* and the 60S ribosomal protein P2, identified as allergen Fus c 1 from *Fusarium culmorum* and also described as an allergen for several molds.

We also describe the GI symptoms reported by people who had consumed Quorn foods. The severity of many such reactions is indicated by descriptions individuals provided, such as: “Severe vomiting culminating in blood”; “[Vomiting] so severe that she [2 years old] lost consciousness and an ambulance had to be called”; “Severe vomiting/diarrhea/hot and cold/nearly passing out for a total of about 3 to 4 hours. I wanted to die!”; “projectile vomiting, diarrhea, shaking, sweating, and severe cramps to the extent that the host almost called an ambulance.” Although those reactions did not permanently impair health, they may be severe enough to warrant preventive action.

A double-blind study conducted by the developer of mycoprotein found that 9 of 200 people fed mycoprotein experienced GI symptoms. Five symptoms were rated as “minor” and 4 as “more severe” (violent vomiting, difficulty breathing, severe abdominal pains), whereas only 1 of 100 people fed a control food reported significant symptoms (exceedingly loose stools).¹⁵ Two of the 4 subjects who experienced severe reactions agreed to be retested, and 2 declined. One person ate 1 meal without a problem and was not further tested. Another person experienced nausea, stomach pain, and slight retching after a first meal and violent vomiting, stomach pains, and red patches on her face, arms, and legs after a second meal.

The maker of Quorn claims that its products cause adverse reactions in fewer than 1 in 100,000 people, although the basis of that estimate has not been described.¹⁶ The CSPI has received adverse-reaction reports from approximately 1 of 30,000 Britons who have eaten Quorn (calculation based on CSPI’s 2003 survey that found that 40% of Britons had eaten Quorn, a percentage that presumably has increased since 2003). The 157 reports to the CSPI of allergic reactions from UK residents who had eaten Quorn indicates a prevalence of 1 in 165,000. However, certainly only a small percentage of people who suffered allergic reactions filed reports with CSPI, indicating that the fraction of people who have allergic reactions is far greater than 1 in 100,000. Adding in people who suffered GI reactions would increase the prevalence by approximately 5-fold. In addition, a 2003 random-digit-dialing telephone survey commissioned by CSPI found that 4.5% of 409 Quorn consumers in the United Kingdom reported having an adverse reaction to Quorn (all GI, except for 1 report of urticaria).⁶

Consumers sometimes have difficulty identifying Quorn as the cause of adverse reactions and suffer multiple reactions before determining their sensitivity to Quorn. Avoiding the product after recognizing a sensitivity to it may be difficult, because a Quorn-containing meal might be described only as a “vegetarian stew” or similar term on a train, at a restaurant, or at a friend’s home. One small restaurant chain (Flat Top Grill in Chicago) identified Quorn in its buffet line as “mushroom meat” (author’s observation).

Quorn’s manufacturer has been inconsistent in characterizing whether the product causes allergic reactions. Labels (U.S., August 2017) do not list mycoprotein as an allergen but acknowledge that Quorn causes “rare cases of adverse reaction.” The manufacturer’s GRAS notification to the FDA acknowledged that approximately 5% of adverse reactions to Quorn represent true IgE-mediated hypersensitivity.¹ Elsewhere, however, the company states that “The main ingredient in Quorn products Mycoprotein is not an allergen, as defined by the FDA”¹⁷ and that the product is as “benign as a potato.”¹⁸ (The FDA does not define allergens, but requires special labeling of the 8 most common food allergens.)

Quorn labels and website have stated that, “being high in protein and fiber, [Quorn] may cause intolerance in some people.”¹⁷ However, it is unlikely that protein and fiber cause intolerances, because the average 81-g serving (range, 60–166 g) of Quorn products (n = 21; <https://www.quorn.us/products/all>; November 9, 2017) contains only 10.9 g (range, 5–20 g) of protein and 3.9 g (range, 1–9 g) of dietary fiber. That amount of protein is less than the 22 g in an 85-g serving of broiled 90% lean ground beef, and that amount of fiber is similar to the 3.8 g in 2 slices of whole-wheat bread.¹⁹ Ground beef and whole-wheat bread rarely, if ever, cause GI symptoms.

Quorn labels and website have associated the source of mycoprotein as being similar to culinarily and economically valuable mushrooms, truffles, and morels, as opposed to mold or fungus. However, as the result of a lawsuit, in 2017 the maker of Quorn agreed to remove from U.S. labels those references to protein, fiber, mushrooms, truffles, and morels, as well as to require a more noticeable acknowledgement that Quorn causes “rare cases of allergic reactions.”²⁰ Still, that notice downplays the likelihood and possible severity of a reaction. Because mycoprotein is an obscure scientific or marketing term (and not even included in the Merriam-Webster online dictionary), governments should require that word always to be accompanied by “fungus/fungal protein” or “mold protein” to be completely transparent. In addition, governments should require that label warnings indicate that adverse allergic and GI reactions may be severe. In any case, even a prominent label notice stating the potential for allergic reactions would not protect first-time consumers who would not know whether they were sensitive to the ingredient and would not protect people eating mycoprotein at restaurants, cafeterias, or other foodservice venues where ingredients are not disclosed.

One unknown about Quorn is whether the GI symptoms it causes are IgE-²¹ or non-IgE-mediated allergic reactions or are mediated by a non-immunological mechanism. Also, the degree of cross-reactivity between mycoprotein (from *Fusarium venenatum*) and other fungi, such as *Aspergillus*, is not known. Further research is needed.

Practicing allergists should consider asking patients suffering from chronic allergy symptoms (urticaria, angioedema, and others) of unknown origin whether they are consuming Quorn foods and would like to be tested for possible mycoprotein allergy.

A limitation of this study is its reliance on self-reports not confirmed by oral food challenges. The symptoms attributed to Quorn could have been caused by other foods, drugs, or other agents. However, the nature of the symptoms reported are consistent with what has been described in previous reports.^{3,5,14} In addition, some consumers could have filed fictitious negative reviews on Quorncomplaints.org because of factors other than medical reasons,

such as possible lack of refund, customer-service dissatisfaction, and others.

In summary, consumption of Quorn foods, likely because of its mold-based mycoprotein ingredient, is associated with allergic and GI symptoms. Although traditional foods, such as peanuts and shellfish, may cause allergic reactions, mycoprotein may represent the first time that governments have knowingly authorized the use of a novel food ingredient that causes severe and even fatal adverse reactions. Physicians, health departments, and lay allergy organizations should be aware of this possibly underrecognized mycoprotein-associated cause of adverse reactions. Health officials should consider whether this unnecessary cause of severe adverse reactions should be permitted in the food supply, which new protein-containing ingredients should be permitted in foods, and whether to require in-depth allergenicity testing of future novel ingredients.

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