



Could Impossible Burger's Key GMO Ingredient Cause Weight Gain, Kidney Disease in Humans?

Description

A rat-feeding study commissioned by Impossible Foods suggested the Impossible Burger's key ingredient — genetically engineered soy leghemoglobin — caused the rats to develop unexplained changes in weight gain, changes in the blood that can indicate the onset of inflammation or kidney disease, and possible signs of anemia.

By Claire Robinson and Dr. Michael Antoniou

The Impossible Burger is a plant-based burger, the key ingredient of which is a protein called soy leghemoglobin (SLH for short), derived from genetically modified (GM) yeast. It's already being sold in restaurants and supermarkets in the U.S.

In 2019 the manufacturing company, Impossible Foods, applied for permission to market the burger in the EU and the U.K.

However, the results of a rat feeding study commissioned by Impossible Foods and carried out with SLH suggest that the burger may not be safe to eat.

SLH is the substance that gives the burger its meaty taste and makes it appear to bleed like meat when cut. The U.S. Food and Drug Administration (FDA) initially refused to sign off on the safety of SLH when first approached by the company.

The rat-feeding study results suggest that the agency's concerns were justified. Rats fed the GM yeast-derived SLH developed unexplained changes in weight gain, changes in the blood that can indicate the onset of inflammation or kidney disease, and possible signs of anemia.

2015: FDA says SLH safety not proven

The company maintains that SLH is safe to eat. It wanted the FDA to agree with its self-declared conclusion that SLH is “GRAS” (Generally Recognized As Safe), providing reassurance for consumers.

But in 2015, in response to Impossible Foods’ first application, the FDA refused to agree that the substance was safe. It responded with tough questions for the company, as revealed in documents obtained under a Freedom of Information request.

The FDA was concerned that SLH has never been consumed by humans and may be an allergen.

The agency pointed out that the safety information submitted by Impossible Foods was not specific enough:

“Although proteins are a part of the human food supply, not all proteins are safe. Information addressing the safe use of modified soy protein does not adequately address safe use of soybean leghemoglobin protein from the roots of the soybean plant in food.”

The FDA concluded:

“FDA believes that the arguments presented, individually and collectively, do not establish the safety of SLH for consumption, nor do they point to a general recognition of safety.”

2017: Impossible Foods tries again

In 2017 Impossible Foods tried again with a new application for GRAS status. It submitted data from a study that the company had commissioned in which rats were fed SLH.

Although Impossible Foods had in its 2015 submission told the FDA it intended to conduct a 90-day feeding study (the standard length for subchronic toxicity in rats), the company said that following “feedback” from the agency, it had decided on a shorter study of 28 days.

While this change would cut costs for Impossible Foods, it is not in the public health interest. That’s because the shorter the duration of a study, the less likely it is to find health effects such as organ damage, which take time to show up.

The number of animals and duration of a feeding study are two key design elements in an investigation of the safety of a GM food substance.

It was always unlikely that SLH would have strong and obvious toxic effects in the short term; any adverse effects from a novel food substance would likely be subtle. Long-term studies with relatively large numbers of animals are required in order to reveal the significance of such effects.

Given these requirements, it seems clear that Impossible Foods’ study was statistically weak. There were too few animals in each test group (10 per sex per group) and again, the study was too short in duration (28 days in a rat is equivalent to just 2-3 years in a human) to clarify any health concerns from long-term consumption of this product.

Potentially adverse effects in SLH-fed rats

In light of these limitations, it is remarkable that the SLH-fed rats did show a large number of statistically significant potentially adverse effects, compared with the control group — for example:

- unexplained transient decrease in body weight gain.
- increase in food consumption without weight gain.
- changes in blood chemistry.
- decreased reticulocyte (immature red blood cell) count (this can be a sign of anemia and/or damage to the bone marrow where red blood cells are produced).
- decreased blood clotting ability.
- decreased blood levels of alkaline phosphatase (can indicate malnutrition and/or celiac disease).
- increased blood albumin (can indicate acute infection or damage to tissues) and potassium values (can indicate kidney disease).
- decreased blood glucose (low blood sugar) and chloride (can indicate kidney problems).
- increased blood globulin values (common in inflammatory disease and cancer).

The fact that these changes were seen in spite of the statistical weaknesses of the study (stemming from the short duration and low number of animals in each group) gives particular reason for concern.

Reproductive changes in SLH-fed females?

In the study, apparent disruptions in the reproductive cycle were found in some groups of females fed SLH. In normal healthy rats, the uterus fills up with fluid during the proestrus phase of the cycle, in the run-up to the fertile and sexually receptive phase (estrus).

In the SLH-fed rats, significantly fewer “fluid filled” uteri were seen. This correlated with decreased uterus weight, as might be expected.

In response to this finding, Impossible Foods commissioned a second rat feeding study, which found no effect on the SLH on the rats’ estrus cycle. The company concluded that the findings of the first study had been a mere artifact of the experimental method used.

For the sake of the women who may eat the Impossible Burger on a regular basis, we hope that the company is correct.

All effects dismissed

Impossible Foods dismissed all these effects as “non-adverse”, as having “no toxicological relevance”, as “transient” on the grounds that they appeared to reverse themselves after some days, and as not dependent on the dose (i.e. the effect did not increase with increasing dose).

It is true that the adverse outcomes may appear somewhat haphazard. However, the fact that there were so many statistically significant changes in multiple organs and systems suggests that closer scrutiny of the safety of SLH is urgently required.

The apparent randomness of the effects may be due to the fact that the study design was statistically weak. And it is well known that toxic effects do not always follow a linear dose-response pattern. Dismissing the findings as irrelevant appears irresponsible.

The only way of ascertaining if potentially adverse effects seen in short studies are truly adverse or have lasting consequences is to extend the study length to the rats' full lifetimes (2-3 years) and to do multigenerational testing. In this case, neither was done.

FDA capitulates

Impossible Foods' second attempt to obtain GRAS status for SLH succeeded and the FDA issued a "no questions" letter, indicating that it had no further questions.

Contrary to what many people believe, such letters are not an assertion by the FDA that the food in question is safe. They state that the company asserts that the food is safe and remind the company that it, and not the FDA, is responsible for ensuring that it only puts safe foods on the market.

"No questions" letters may protect the FDA from liability in case something goes wrong. But they do not protect the consumer from unsafe novel foods.

Another GMO ingredient

In 2019 Impossible Foods introduced a new recipe for its Impossible Burger. In addition to GMO-derived SLH, the burger now contains another GMO ingredient: protein from herbicide-tolerant soy.

The company introduced soy protein to replace wheat protein in order to improve the texture and to avoid gluten, the protein in wheat that some people cannot tolerate.

As a result, Impossible Burger Version 2.0 can contain residues of the "probable carcinogen" glyphosate, the main ingredient of the herbicide used on GM soy.

Testing by Health Research Institute Laboratories, commissioned by the advocacy group Moms Across America, found glyphosate at a level of 11.3 ppb.

The level was 11 times higher than the Beyond Meat burger, another plant-based burger that is made from non-GMO ingredients. (However, Beyond Meat's crashing stock suggests that the hype over any fake meat product is misplaced.)

Knowing the concerns that the use of GMO soy protein and glyphosate residues may raise, Impossible Foods CEO Pat Brown has gone to some lengths to reassure the buying public.

But based on what the rat feeding studies tell us about the potential health effects of the Impossible Burger, the company would be well advised to shelve SLH and then reformulate their product with natural — and if possible organic and minimally processed — ingredients.

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