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Impossible Burger's 'Secret Sauce' Highlights Challenges of Food Tech

By STEPHANIE STROM AUG. 8, 2017

An Impossible Burger, which resembles meat but is made of plant products. Jason Henry for The New York Times

One of the chief selling points of the Impossible Burger, a much ballyhooed plant-based burger patty, is its resemblance to meat, right down to the taste and beeflike “blood.”

Those qualities, from an ingredient produced by a genetically engineered yeast, have made the burger a darling among high-end restaurants like Momofuku Nishi in New York and Jardinière in San Francisco, and have attracted more than $250 million in investment for the company behind it, Impossible Foods.

Now, its secret sauce — soy leghemoglobin, a substance found in nature in the roots of soybean plants that the company makes in its laboratory — has raised regulatory questions.

Impossible Foods wants the Food and Drug Administration to confirm that the ingredient is safe to eat. But the agency has expressed concern that it has never been consumed by humans and may be an allergen, according to documents obtained under a Freedom of Information request by the ETC Group as well as other environmental and consumer organizations and shared with The New York Times.

IMPOSSIBLE FOODS RESPONSE

The heme protein and the Impossible Burger are not made in a laboratory but in food-production facilities that adhere to all regulatory requirements and stringent safety and quality standards. The reporter may be confusing “lab meat” -- which uses animal cells grown in a lab -- with Impossible Foods’ plant-based meat, which is not made from animals at all.

"F.D.A. believes the arguments presented, individually and collectively, do not establish the safety of soy leghemoglobin for consumption," agency officials wrote in a memo they prepared for a phone conversation with the company on Aug. 3, 2015, "nor do they point to a general recognition of safety."

IMPOSSIBLE FOODS RESPONSE

Impossible Foods has complied with all federal food safety regulations since 2014. Its key ingredient, soy leghemoglobin, has been considered "generally recognized as safe," or GRAS, since 2014, when a panel of top food safety experts found it was safe to eat. This finding by the experts constitutes what is referred to as a "self-affirmed GRAS". The effect of a self-affirmed GRAS is that food companies are in compliance with federal regulations and may market the product.

In 2014, the company also voluntarily submitted its safety data to the US Food and Drug Administration via the GRAS Notification process, to seek the FDA's independent review of its self-affirmed GRAS, and to promote transparency about its products, as the FDA publishes these notices on its web site.

As part of the FDA's GRAS Notification process, the FDA asked questions relating to Impossible's food safety testing. Traditionally, food companies conduct safety tests using animals as subjects, and Impossible Foods had not done so. To obtain this type of "industry standard" information, Impossible Foods conducted additional tests and analyses, including a rat feeding study. Analyzing this new data, the same panel of food safety experts concluded the new data further strengthened the safety case and again found that soy leghemoglobin is safe. Impossible Foods will provide the FDA this additional information, as well as the expert panel's analysis, later this month.

Impossible Foods can still sell its burger despite the F.D.A. findings, which did not conclude soy leghemoglobin was unsafe. The company plans to resubmit its petition to the agency.

IMPOSSIBLE FOODS RESPONSE

“findings” - The FDA did not make “findings”; it had questions. In response to the FDA’s questions, Impossible Foods performed additional safety tests (including a rat feeding study, which it previously did not conduct) and gathered additional data, which all have further established the safety of soy leghemoglobin and its low potential for allergenicity. Impossible Foods will submit this information to the FDA later this month.

Impossible Foods has done extensive safety and allergenicity testing on soy leghemoglobin. Soy leghemoglobin -- a protein in the roots of soy plants -- is safe to eat. The molecule carried by soy leghemoglobin -- heme -- is atom-for-atom identical to the heme found in beef, other meats, plants and all living organisms. Humans have been eating heme for hundreds of thousands of years.

“petition” - The FDA’s GRAS process requires a notification, not a petition. Via the GRAS Notification process, Impossible Foods is voluntarily asking the FDA to independently review the extensive safety and allergenicity data it has assembled about soy leghemoglobin. The FDA will respond with an indication of whether it has any more questions regarding Impossible Foods’ methods and data establishing safety.

Impossible Foods is finding out what happens when a fast-moving venture capital business runs headlong into the staid world of government regulation.

Investors like Bill Gates and Khosla Ventures have poured money into a variety of so-called alt meat companies. Silicon Valley has noble goals, applying technological solutions to address major issues like climate change, farm animal welfare and food security.

But food is not an app. It is far more heavily regulated by governments and much more heavily freighted with cultural and emotional baggage.

IMPOSSIBLE FOODS RESPONSE

While it may make for salacious copy, Impossible Foods has not run “headlong into” any regulation; rather, Impossible Foods has diligently complied with all federal regulations, and has constructively and properly engaged in the regulatory process to establish that its food is safe. In fact, the reporter admits “above” that Impossible Foods may sell its burger and is not running afoul of any law or regulation in doing so.

IMPOSSIBLE FOODS RESPONSE

We don’t make apps, and don’t aspire to be treated like one. We make food -- and we fully comply with US food safety regulations.

"This rush to market is the Silicon Valley mind-set," said Michael Hansen, a food safety expert who is the senior staff scientist at Consumers Union, an advocacy group. "They think because they're doing something disruptive, the regulations that apply to other companies don't apply to them."

For now, few food start-ups are selling products to consumers. Only Beyond Meat, which uses a traditional pea protein to make its Beyond Burger; Hampton Creek, which makes plant-based sandwich spreads and salad dressings; and Impossible Foods have any notable presence in the market.

Like Impossible Foods, Hampton Creek faced problems with the F.D.A., which challenged its use of the word "mayo" in the name of its vegan spread, Just Mayo. Federal definitions of foods require mayonnaise to contain eggs.

The agency ultimately allowed Hampton Creek to keep the name but required it to use bigger type on the front of the label to say it was egg-free. The label now defines "just" to mean "guided by reason, justice and fairness," instead of suggesting that it was a replica of mayonnaise.

IMPOSSIBLE FOODS RESPONSE

Impossible Foods doesn't know what the "Silicon Valley mind-set" implies. Impossible Foods certainly does not think that "regulations don't apply" to it or to our foods. Quite the contrary: Impossible Foods has fully complied with federal food safety regulations since 2014, two years before we put the Impossible Burger on the market in 2016. We have extensively tested the burger for food safety and allergens, and an expert panel has repeatedly concluded that the product is safe. We also have proactively engaged with the FDA. In no way do we believe that government regulations "do not apply" to us.

Because of our commitment to quality and safety, we put the burger on the market only after years of extensive testing. We have scrupulously followed all regulations and didn't launch the Impossible Burger until we were certain that it is far safer than any cow-derived burger.

IMPOSSIBLE FOODS RESPONSE

Impossible Foods has never "faced problems" with the FDA; Impossible Foods complies with all regulations, and has had only constructive discussions with the FDA as part of the normal GRAS Notification process.

In the case of Impossible Foods, the debate centers on its use of soy leghemoglobin, which the company's engineeered yeast produces and forms an important ingredient behind the business.

A butcher, a cardiologist, a vegan and a technology reporter try the Impossible Burger, a plant-based hamburger that "bleeds," made by Silicon Valley start-up Impossible Foods. By EMMA COTT and YOUSUR AL-HLOU on January 13, 2017. . Watch in Times Video »

Embed

IMPOSSIBLE FOODS RESPONSE

There is no "debate" with the FDA. Impossible Foods has only had constructive conversations with the FDA, driven by our mutual commitment to food safety and the American consumer.

The company was started in 2011 by Pat Brown, a chemist at Stanford University. His approach, involving genetics, microbiology and cutting-edge chemistry attracted venture capitalists also eager to find plant-and lab-based replacements for hamburgers and chicken wings.

Impossible Foods sought to woo top chefs with a splashy sales pitch about how the burger mimicked the aroma, attributes and taste of real beef. When soy leghemoglobin breaks down, it releases a protein known as heme, giving it that meatlike texture.

Within three years of its founding, Impossible Foods landed big-name investors like Khosla, Mr. Gates and the Hong Kong billionaire Li Ka-Shing. This month, Temasek Holdings, Singapore's sovereign wealth fund, joined an investment round that added $75 million to the company's coffers.

IMPOSSIBLE FOODS RESPONSE

Pat Brown is a biochemist, not a chemist. He's also a member of the National Academy of Sciences and the National Academy of Medicine. Formerly a practicing pediatrician, and a professor of biochemistry at Stanford University for 25 years, Dr. Brown also co-founded Public Library of Science, a nonprofit publisher with a mission to provide open access to science, technology and medical journals.

IMPOSSIBLE FOODS RESPONSE

Heme doesn't give the burger texture -- it gives the burger flavor. More accurately, when soy leghemoglobin is exposed to heat, commonly referred to as cooking, it releases the identical heme molecule that is in meat, which gives the Impossible Burger its meatlike flavor. More specifically, in both meat and the Impossible Burger, this same heme molecule that is released by cooking sparks flavor chemistry that transforms the slightly metallic flavor of raw meat into the rich, cravable flavors and aromas of warm, cooked meat.

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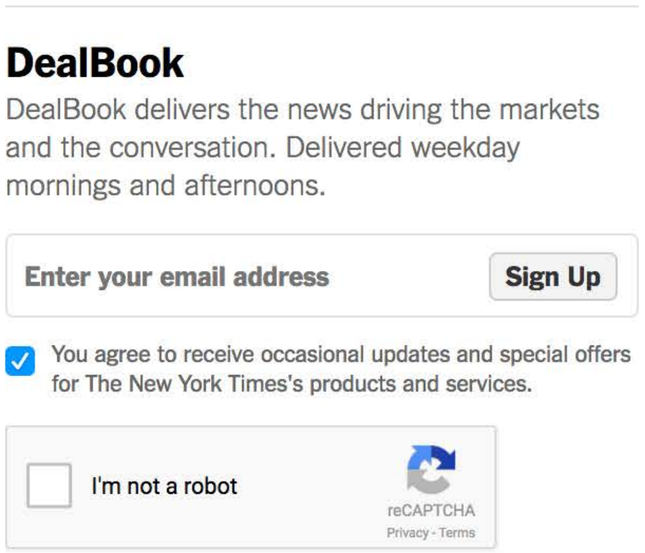

"I love V.C.s and particularly the ones that invested in us," Mr. Brown said at a TechCrunch conference in May, referring to venture capital firms. "But it's truly astonishing how little diligence they do in terms of the actual science that underlies some tech companies."

IMPOSSIBLE FOODS RESPONSE

The reporter did not get this quote in response to any question related to her August 8 article. In fact, the reporter refused to speak to the CEO, General Counsel or any scientist or food safety expert at Impossible Foods, and she repeatedly declined to come to the company's headquarters to learn more about Impossible Foods and its food safety testing. This quote from Dr. Brown (from a speaking engagement at a conference May 2017) is presented completely out of context, and as used in the article seems to imply that Brown is criticizing his own company's investors for not having investigated Impossible Foods. In fact, his comment referred to the apparent lack of diligence by some investors in other start-ups that make lab meat from animal cells—in Dr. Brown's opinion, companies that could not stand up to even very basic scientific scrutiny.

IMPOSSIBLE FOODS RESPONSE

Impossible Foods worked with independent third party food safety organizations to conduct all safety tests and engaged three of the world's leading experts on food safety and allergenicity from universities known for academic excellence in the food sciences to review the results. They unanimously concluded in 2014 that the key ingredient, soy leghemoglobin, is safe. The experts are academics from the University of Nebraska, the University of Wisconsin-Madison, and Virginia Commonwealth University. In addition, Impossible Foods voluntarily took the additional action of submitting its testing data and analyses to the FDA -- and then when the FDA had questions, Impossible Foods properly addressed those questions by gathering more data, including a rat feeding study that the company had previously not conducted. The experts have again concluded, based on the additional test results and information, that soy leghemoglobin is safe. The company will submit all of this additional data to the FDA later this month.

Impossible Foods adhered to that procedure, concluding in 2014 that soy leghemoglobin was safe. But it went further, seeking the regulator's imprimatur.

"We respect the role the F.D.A. plays in ensuring the safety of our food supply, and we believe the public wants and deserves transparency and access to any information they need to decide for themselves whether any food they might eat is safe and wholesome," Rachel Konrad, a spokeswoman for Impossible Foods, wrote in an email.

IMPOSSIBLE FOODS RESPONSE

It's true that Impossible Foods "went further" than is required to comply with US food safety regulations. However, the FDA does not issue an "imprimatur" or "seal of approval" on foods that are, or should be, generally recognized as safe. Rather, the FDA puts the burden on food manufacturers to prove that food is safe. As noted, Impossible Foods is in compliance with federal regulations having obtained food safety experts' opinion that soy leghemoglobin is generally recognized as safe (i.e., its self-affirmed GRAS), and the company is voluntarily submitting its data to the FDA for their independent review pursuant to the voluntary GRAS Notification process. The FDA publishes these submissions on its website.

The F.D.A., however, wanted the company to show the ingredient was safe specifically for humans. It told Impossible Foods to establish the safety of the more than 40 other proteins that make up part of its soy leghemoglobin. F.D.A. officials said the company's assessment of the potential for the ingredient to be an allergen was deficient.

"This product has been touted as the 'secret sauce' in the Impossible Burger," said Jim Thomas, program director at the ETC Group, the Canadian environmental organization that started the Freedom of Information request. "Now we know that the F.D.A. had questions about it, but it was put on the market anyway."

IMPOSSIBLE FOODS RESPONSE

All of Impossible Foods' testing has focused on human safety. And while 40 proteins may seem like a lot to those who have not studied food science, it is actually very few. Food is made up of trillions of proteins. The FDA was interested in allergenicity analysis of the proteins present in Impossible Foods's soy leghemoglobin ingredient. Impossible Foods engaged the Food Allergy Resource and Research Program (FARRP) at the University of Nebraska to perform an extensive investigation of the potential allergenicity of these proteins, and has provided the test data to one of the world's leading experts on allergenicity; he agreed multiple times that our key ingredient is safe.

IMPOSSIBLE FOODS RESPONSE

This is specious. Impossible Foods began selling the Impossible Burger two years after it was already in full compliance with federal food safety regulations, having obtained its self-affirmed GRAS. During its voluntary, constructive engagement with the FDA, Impossible Foods performed additional safety testing, including a rat feeding study. Leading food safety experts have reviewed the additional data and have again concluded that soy leghemoglobin is safe to eat. Later this month, Impossible Foods will voluntarily provide this data, as well as the analysis of the expert panel, to the FDA for its review and comments. The FDA will publish Impossible Foods' submission online for public review as well.

Ms. Konrad defended the burger, writing it “is entirely safe to eat” and “fully compliant with all F.D.A. regulations.” She said the company was “taking extra steps to provide additional data to the F.D.A. beyond what’s required.”

Impossible Foods, she said, has tested its ingredient on rats fed “well above” the amount of soy leghemoglobin in its burger. Ms. Konrad said the company’s expert panel had determined those tests also demonstrated the ingredient was safe, and that the company would thus resubmit its petition for F.D.A. confirmation this month.

Companies have “no requirement” to notify the F.D.A. of a food being determined safe, Megan McSeveney, an agency spokeswoman, said in an email. She added, however, that the F.D.A. could question the basis for any such conclusion and “take appropriate action to protect public health.”

Consumer advocates say the experience of Impossible Foods highlights longstanding concerns about the F.D.A.’s oversight of food safety. Congress gave it the responsibility for policing food additives under the Food, Drug and Cosmetic Act of 1938. Twenty years later, it added an exemption to allow a company to sell a product without the agency’s review if the additives were deemed safe.

IMPOSSIBLE FOODS RESPONSE

“well above” -- As we informed the reporter, rats were fed an amount of soy leghemoglobin that would be equivalent to a human consuming more than 200 times the average US daily consumption of ground beef, every day.

“the company’s expert panel” - It is not the company's expert panel; the panel comprises recognized academic experts in food safety and allergenicity, who were engaged by Impossible Foods to provide a critical review of the safety and allergenicity data that Impossible Foods had assembled.

“petition” - There is no "petition for FDA confirmation". This is a misunderstanding of the FDA food-safety process. We are voluntarily submitting the new safety data to the FDA for their independent review and comments via the GRAS Notification process.

In 2010, the Government Accountability Office raised concerns about the agency's interpretation of its responsibilities under the law. A study by the Pew Charitable Trusts found in 2013 that the F.D.A. was unaware of roughly 1,000 of some 10,000 ingredients used in food because companies had used the self-affirmation process. And in May, the Center for Food Safety and other groups sued the F.D.A. over that process.

"The exemption was meant to cover ingredients that had long been used in the food supply, so that companies didn't have to come in every time they made a new product," said Tom Neltner, chemicals policy director at the Environmental Defense Fund, an advocacy group that is one of the plaintiffs in the lawsuit. "It wasn't meant to allow companies to simply bypass the F.D.A."

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IMPOSSIBLE FOODS RESPONSE

As the article states, Impossible Foods has worked voluntarily with the FDA to enable the agency to review all the data demonstrating the safety of its product. Impossible Foods' interaction with the FDA is constructive. The concerns cited in this paragraph are completely inapplicable to Impossible Foods, which has been scrupulous and transparent in its attention to food safety and its compliance with regulations.

IMPOSSIBLE FOODS RESPONSE

This opinion is completely irrelevant to Impossible Foods. Impossible Foods is in no way "bypassing the FDA." Rather, Impossible Foods has proactively engaged with the FDA by choosing to submit its safety data for the FDA's independent review and comment via the GRAS Notification process. Impossible Foods aspires to be a good corporate citizen and a model of transparency by voluntarily submitting its safety data to the FDA, where it also will be made available to the public on the FDA's website.