THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD OF 2016: PROPOSED FDA APPROVED LABEL

PROBLEM

Public skepticism prevents wide acceptance of GE food and imposes limitations to the benefits of GE production, while required bioengineered label acts as a warning sign[1]

SOLUTION

Include informational package labeling promoting the safety of GE foods for human consumption, increase FDA regulation via already implemented safety inspection program, and offer producers the opportunity to be labeled as FDA approved



Photo Credits: Markus Spiske, Pexels

BENEFITS OF GE PRODUCTION

- Meet growing demand for food and quality nutrition[2]
- Faster crop adaptation to human-driven climate change[3]
- Reduced need for chemical crop protectants[4]

"Mandatory labeling is good for consumers because it will help them be fully informed and less confused when they consider buying GMO products. . . If done right, companies should be proud of the fact that they use genetic engineering."

- Stephen Lamb, Founder at ZBiotics[5]

POLICY RECOMMENDATION -

Addition of a package label indicating FDA pre-approval after genetically engineered (GE) food producer participation in the safety inspection program.

OUTCOMES -

- Increase public acceptance of GE foods
- Increase GE food producers to seek FDA approval
- Greater regulation of GE foods on the market

GOAL - More sustainably grown and stable food supply

1. Pew Research Center. (2016). The New Food Fights: U.S. Public Divides Over Food Science. Pew Charitable Trusts. https://www.pewresearch.org/science/2016/12/01/the-new-food-fights/
2. Igini, M. (2022, October 21). 3 Biggest Threats to Global Food Security. Earth.org. https://earth.org/threats-to-global-food-security/
3. National Academies of Sciences, Engineering, and Medicine. (2016). Genetically Engineered Crops: Experiences and Prospects. The National Academies Press. https://doi.org/10.17226/23395.
4. Ritchie, H., Rosado, P., and Roser, M. (2022). Environmental Impacts of Food Production. Our World in Data. https://ourworldindata.org/environmental-impacts-of-food
5. Lamb, S. (2020, February 19). Why we need mandatory labeling of GMO products. STAT Reporting from the frontiers of health and medicine. https://www.statnews.com/2020/02/19/why-we-need-mandatory-labeling-of-gmo-products/

Supplementary Labeling for Government Approved Bioengineered Foods: Proposed Amendments to The National Bioengineered Food Disclosure Standard of 2016

Jacqueline Warren

November 27, 2023

Abstract

Bioengineered foods have the potential to reduce hunger and malnutrition, support sustainable farming practices to protect the environment, and uphold food production as climate change threatens our traditional crop varieties. However, persistent skepticism around genetically engineered crops is impeding the gains we can receive from the technology. In an unstable world, the acceptance of bioengineered foods is critical to yield the benefits associated with this technology.

Much of the hesitation to consume genetically engineered foods arises from the suspected health risks, despite government regulation. United States government agencies ensure food, environmental, and agricultural safety. Furthermore, The National Bioengineered Food Disclosure Standard of 2016 was enacted, requiring bioengineered foods on the market to be labeled, informing consumers of the transgenic status. Along with this policy, the US Food and Drug Administration (FDA) offers an optional consultation program for bioengineered foods coming to the market to ensure safety, but there is no incentive to participate in this program. To appease advocates of bioengineered labeling, reward producers for getting FDA approval, and better inform consumers, this policy brief proposes an additional label in association with The National Bioengineered Food Disclosure Standard of 2016. The proposed label will be similar to the current label indicating bioengineered ingredients, but will also inform consumers of FDA approval status.

Introduction

Bioengineered agricultural crops for human food consumption have been controversial since the introduction of the technology. However, the global economy is reaching a critical point as the growing human population puts strain on the food system. While the population is projected to reach 10 billion within the next 30 years (United Nations, 2017), the demand for food is growing accordingly. Our food system hosts many of the largest industries because food is a basic necessity. However, agriculture is also one of the most damaging practices to our

planet; land is stolen from important ecosystems, farm soil is misused, and the supply chain produces significant pollution (Ritchie et al. 2022). Additionally, the food supply is threatened by the changing climate and other environmental destruction (Igini, 2022). While we require this degree of food production, bioengineered crops have the potential to keep balance within our planet and ensure food security.

Scientists and advocates of this technology promote the many benefits associated with genetically engineered (GE) crops. The most advertised is the ability to enhance nutrient levels in crops to combat malnutrition. While this process of biofortification is also conducted in conventional farming, GE biofortification is quicker and more accurate. Additionally, plants can be engineered with resistance to disease, pests, and more. Reinforced agricultural crops require fewer toxic chemicals to be applied and yield greater harvests. GE crops also have the potential for quick adaptation to a changing climate. Human driven climate change is impacting the local environments across the entire planet, and this is happening faster than organisms can possibly adapt through evolution (National Academies, 2016). GE crops have even been proposed to support health through human drug and vaccination production, elimination of common food allergens and intolerances, and are equally as nutritious as conventional (non-GE) crops (Animasaun et al. 2023). One further benefit not often discussed is the financial stability offered for farmers. By increasing crop yields and minimizing losses, farmer incomes are more stable. This is the case for American farms, but also especially true for farmers in developing nations. (Brookes 2022).

Current Laws and Regulation

Despite these benefits, the public shares a general fear of the suspected health risks associated with GE food consumption, and fear the labels associated with GE products (Pew Research Center, 2016). Foods containing bioengineered ingredients are subject to the same safety regulation as any other food on the market (Federation of American Scientists, 2011). These are managed through the Coordinated Framework for Regulation of Biotechnology, which consists of a partnership between the U.S. Food and Drug Administration (FDA), U.S. Environmental Protection Agency (EPA), and U.S. Department of Agriculture (USDA). Each organization plays a key role in regulating the safety of GM products; the FDA ensures food safety standards, the EPA ensures the safety of the environment, and the USDA ensures the

safety of the agricultural production and agricultural practices (US FDA, 2022). The National Bioengineered Food Disclosure Standard of 2016 (the Standard) requires foods containing bioengineered crop varieties to be labeled with a specific logo indicating the bioengineered content. However, most foods consisting of bioengineered ingredients do not require approval to be on the market because GM crops are "Generally Recognized as Safe" under the Federal Food, Drug, and Cosmetic Act (FFDCA) (Bickell, 2020). In cases where the FDA expresses concern, for example if the modifications result in foreign proteins expressed, there may be further action and pre-approval required. The FDA also has a voluntary opportunity called the Plant Biotechnology Consultation Program, where GM crop developers provide scientific resources from the project and answer FDA questions to satisfaction. This is an opportunity for companies to demonstrate the safety of the product (US FDA, 2022).

Stakeholders

Consumers -

The primary concern with GE crops is the health risks of consuming these foods. However, "the science has really shown that bioengineered foods are as safe as their conventional counterparts"(Manufacturing News 2021). Eric Edmunds, Director of Food Safety for The Acheson Group (TAG), acknowledges that "When you think about this [Standard], it's not a true food safety law. . . . But it's a consumer information law—people want to know if they're consuming bioengineered food" (Manufacturing News 2021). It is debatable how successful this label has been at informing consumers because reporters suggest that "it's difficult to know if consumers are aware of the disclosure standard" and "the use of 'bioengineered' in place of the more widely known term 'GMO'" was confusing (Peikes, 2023).

Interestingly, a marketing research group at Cornell University "found the mandatory labeling had a negligible effect on which products consumers bought. . . . We don't expect it to have any additional effect on consumer behavior in the short run" (Adalja et al. 2023). This is believed to be because consumers have had over 10 years to decide their stance on GE foods, and individual behavior is likely not going to change now.

Farmers, Industry, and Other Groups -

There have been mixed responses to The Standard from farmers, industry, and other food advocacy groups. Generally, the farmers and industry groups deem the Standard fair, "contending that it provides consumers and regulated entities with needed consistency and transparency" (Croft, 2020). "Agricultural groups praised the Standard," (Clayton, 2018), and "the national Standard was endorsed by some farm industry groups, including the American Farm Bureau Federation" (Peikes, 2023).

Despite objections holding up in court, many stricter advocates of GE labeling still, "argue that it is too permissive because many foods they consider genetically engineered do not require disclosure" (Croft, 2020) because there may be many "options companies can use and how USDA parsed which foods should be labeled" (Clayton, 2018).

Policy Recommendations

The acceptance, usage, and consumption of bioengineered foods are critical to reap the benefits associated with this technology. A major barrier to acceptance is the fear of the bioengineered label because it is often seen as a warning sign. Lack of transparency and education around this technology has led to scared consumers and manipulative media. Increased transparency and regulation are necessary to support the acceptance of GE foods.

While there is an FDA program already available to review novel GM crops for public safety, there is no incentive to do so and it is often not mandatory. However, producers are required to include the bioengineered label, possibly resulting in loss of buyers. This policy brief proposes adding a secondary bioengineered label, similar to the one under the Standard, but including an indicator of FDA approval. To receive this label, companies bringing new GM products to the market may go through the consultation program. The purpose is to incentivize GM food producers to seek FDA pre-approval, result in a more rigorous examination of GM foods on the market, and may increase public acceptance of the products.

Conclusion

Genetically engineered crops have the potential to support human and environmental health, thus should be widely grown and consumed. Lack of trust in the science and regulation of this technology applied to food and human consumption prevents consumers from choosing

these foods at the market. While these foods are generally recognized as safe through government regulation, skepticism remains. Bioengineered foods are required to be labeled, dictated by The National Bioengineered Food Disclosure Standard of 2016, but do not require FDA approval before coming to market. There is an optional safety inspection program the FDA offers to producers, but there is no incentive to participate. This policy proposal suggests the addition of a label indicating FDA approval after participating in the safety inspection program. The desired outcomes are to see an increase in public acceptance of GE foods, incentivize GE food producers to seek FDA pre-approval, and greater regulation of foods on the market. This proposed step makes progress towards GE crop normalization and backs the benefits associated with this technology, eases the health risk concerns among consumers, and encourages greater safety regulation for foods on the market.

References

Adalja, A., Liaukonytė, J., Wang, E., and Zhu, X. (2023). GMO and Non-GMO Labeling Effects: Evidence from a Quasi-Natural Experiment. *Marketing Science* 42(2):233-250. https://doi.org/10.1287/mksc.2022.1375

Animasaun, D. A., Adedibu, P. A., Shkryl, Y., Emmanuel, F., O., Tekutyeva, L., and Balabanova, L. (2023). Modern Plant Biotechnology: An Antidote against Global Food Insecurity. *Agronomy* 13(8):2038. https://doi.org/10.3390/agronomy13082038

Bawa, A. S., Anilakumar, K. R. (2013). Genetically modified foods: safety, risks and public concerns—a review. *Journal of Food Science and Technology*, 50(6):1035–1046. DOI 10.1007/s13197-012-0899-1

Bickell, E. G. (2020). The National Bioengineered Food Disclosure Standard: Overview and Selected Considerations. *Congressional Research Service Report Prepared for Members and Committees of Congress*. https://crsreports.congress.gov/R46183

Brookes, G. (2022). Farm income and production impacts from the use of genetically modified (GM) crop technology 1996-2020. *GM Crops Food: Biotechnology in Agriculture and the Food Chain* 13(1):171-195. doi:10.1080/21645698.2022.2105626

Clayton, C. (2018, December 21). USDA Releases National Bioengineered Food Disclosure Standard. *Northern Ag Network*. https://northernag.net/usda-releases-national-bioengineered-food-disclosure-standard/

Croft, G. K. (2020, February 7). The National Bioengineered Food Disclosure Standard: Overview and Select Considerations R46183. *Every CRS Report*. https://www.everycrsreport.com/reports/R46183.html

Executive Office of the President, Office of Science and Technology Policy. (1986). Coordinated Framework for Regulation of Biotechnology 51 FR 23302. *US Department of Agriculture, Animal & Plant Health Inspection Service*. https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

Federation of American Scientists. (2011). U.S. Regulation of Genetically Modified Crops. *Case Studies in Agricultural Biosecurity*. https://biosecurity.fas.org/education/dualuse-agriculture/2.-agricultural-biotechnology/us-regulation-of-genetically-engineered-crops.html

Igini, M. (2022, October 21). 3 Biggest Threats to Global Food Security. *Earth.org*.

https://earth.org/threats-to-global-food-security/

Manufacturing News. (2021, December 6). Are you ready for USDA's "Bioengineered Food" labeling rule?. *Food Engineering Magazine: Manufacturing News*. https://www.foodengineeringmag.com/articles/99838-are-you-ready-for-usdas-bioengineered-food-labeling-rule#:~:text=With%20a%20mandatory%20compliance%20date,BE)%20food%20and%20BE%20food

National Academies of Sciences, Engineering, and Medicine. (2016). Genetically Engineered Crops: Experiences and Prospects. *The National Academies Press*. https://doi.org/10.17226/23395.

Pew Initiative on Food and Biotechnology. (2001). Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products. *Pew Charitable Trusts*. https://www.pewtrusts.org//media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_and_biotechnology/hhsbiotech0901pdf.pdf

Pew Research Center. (2016). The New Food Fights: U.S. Public Divides Over Food Science. *Pew Charitable Trusts*. https://www.pewresearch.org/science/2016/12/01/the-new-food-fights/

Peikes, K. (2023, February 10). GMO food labeling has been required in the U.S. for a year. Have consumers noticed?. *Illinois Public Media*. https://ipmnewsroom.org/gmo-food-labeling-has-been-required-in-the-u-s-for-a-year-have-consumers-noticed/#:~:text=It's%20difficult%20to%20know%20if,foods%20should%20be%20labeled%20accordingly.

Ritchie, H., Rosado, P., and Roser, M. (2022). Environmental Impacts of Food Production. *Our World in Data*. https://ourworldindata.org/environmental-impacts-of-food

United Nations. (2017). *World population projected to reach 9.8 billion in 2050, and 11.2 billion in 2100*. https://www.un.org/en/desa/world-population-projected-reach-98-billion-2050-and-112-billion-2100#:~:text=COVID%2D19,World%20population%20projected%20to%20reach%209.8%20billion%20in%202050%2C%20and,Nations%20report%20being%20launched%20today

US Food and Drug Administration. (2022, July). *How GMOS Are Regulated in the United States*.

https://www.fda.gov/media/135278/download#:~:text=FDA%20regulates%20most%20human%20and,standards%20as%20all%20other%20foods.