Governance Challenges for Direct-to-Consumer Genetically Engineered Organisms

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Executive Summary: In this briefing, we propose that direct-to-consumer (DTC), live genetically engineered (GE) organisms represent a novel and non-obvious category of biotechnology. The context of use for these products raises new governance and regulatory questions. Unlike most GE organisms to date, which have been marketed to large agro-industrial players, DTC GE organisms are marketed directly to individuals. DTC GE organisms are often directed towards at-home lifestyle, ornamental, or wellness applications, as shown through the four case examples explored in this briefing, which include the Glofish, Firefly Petunia, Norfolk Purple Tomato, and ZBiotics probiotic. Challenges for governing these products in society include 1) limited information is available to consumers about broader risks, impacts, and responsible use; 2) deployment and stewardship are under the purview of the individual consumer in society and without explicit containment mechanisms; and 3) accountability or responsibility for addressing any unintended consequences is unclear. We suggest that these challenges could be addressed by considering the context of use as a key part of federal agency product reviews, supporting more comprehensive post-market surveillance of these products, and creating greater transparency mechanisms via a public registry for DTC GE organisms.

I. Introduction

Innovations in genetic engineering are advancing the development of genetically engineered (GE) organisms, including living consumer products that can be applied in and around the home. Unlike most prior commercialized GE organisms (e.g., genetically engineered crops) governed in highly regulated and managed crop production systems, the direct-to-consumer (DTC) product is designed for individual use, and is marketed and distributed directly to consumers. Several different types of organisms—fish, flowers, garden vegetables, and bacteria—have already been developed and distributed in this way. What they share is that they are all deployed in a residential/home environment, a context of use where GE organisms have not been deployed historically.

DTC GE organisms potentially open up new niche markets where GE organisms can be applied. Biotechnology companies have not traditionally targeted the consumer product sector as a space to market and deploy GE organisms. Advances in engineering techniques have also allowed scientists to engineer organisms with greater accuracy and efficiency. Developers can now target gene-trait combinations that they think consumers would find valuable in small or large markets and produce engineered organisms never seen before. Part of the initial hesitancy in entering this sphere might relate to historical social controversy surrounding consumer preferences and perspectives on GE organisms (Motta 2014). However, new companies are marketing their products as "proudly genetically engineered" and appealing to consumers through the lens of improved health and wellness (ZBiotics

2025; Norfolk Healthy Produce 2025). If consumers like the DTC GE organisms they use, this could help ingratiate GE organisms with the broader public over time, helping to open up a new market sector in the bioeconomy.

However, the context of use for DTC GE organisms creates some unique challenges for future governance. Traditional oversight for genetically engineered organisms has been exercised through premarket mechanisms that scrutinize the risk of engineered organisms, such as the United States Department of Agriculture's (USDA) "Petitions for Nonregulated Status" process (Animal and Plant Health Inspection Service, 2024d). As our case studies will demonstrate, the first commercialized DTC GE organisms have followed different pathways through regulation, some of which required far less scrutiny than others. They are also not applied in highly regulated and managed environments like agricultural fields, but rather implemented in more residential settings according to consumer discretion. While evidence suggests that these early products are relatively harmless, they nonetheless open up interesting governance questions and concerns. First, if products are implemented according to consumer discretion, how can we ensure responsible use of these products takes place? Second, if unintended consequences were to occur—such as unintentional spread or propagation of these organisms in unwanted environments—what accountability mechanisms and other safeguards are in place to mitigate negative consequences?

In this paper, we suggest that the DTC GE organism be considered as its own unique category of GE products that deserves some special consideration by regulators and policy makers. First, we will describe some of the common characteristics that can be observed so far with current DTC GE organisms. Second, we will elaborate on case examples of some of the first DTC GE organisms to hit the market, their specific applications, pathways through regulation, and outstanding uncertainties. Case studies include the Tetra-Fish GE "GloFish" (Tetra Fish n.d.), the Light Bio "Firefly" GE petunia (Light Bio 2025), the Norfolk Healthy Produce GE Purple Tomato (Norfolk Healthy Produce 2025), and the ZBiotics Pre-Alcohol probiotic, ZB183 (ZBiotics 2025). To conclude, we draw out some thematic challenges associated with this small collection of cases and provide recommendations for how to respond to these challenges.

II. Background: Examples of direct-to-consumer genetically engineered organisms

i. Case #1: GloFish, the first direct-to-consumer GE organism

The first GloFish were sold in the US in 2003 by Yorktown Technologies (Tetra Fish n.d.). These first products were zebrafish genetically modified to fluoresce green, though they were followed by other species of fish engineered to fluoresce in different colors. The fluorescent zebrafish were initially engineered for research purposes, intended as a preliminary step towards zebrafish that would fluoresce in the presence of pollutants. The fluorescence was accomplished by inserting a gene from jellyfish, which produces green fluorescent protein, using recombinant DNA technology (Pray 2008). None of the United States regulatory agencies claimed jurisdiction over this ornamental, transgenic fish, therefore GloFish proceeded to the market without regulatory oversight. In this vein, the US Food and Drug Administration (FDA) decided after review that it has no jurisdiction over animals kept as pets, rather than those sold as food. Soon after the commercialization of GloFish, US federal regulatory agencies faced criticism (and a lawsuit) from the non-profit organization the Center for Food Safety (Center for Food Safety 2004), as well as from California's own regulatory body, the California Fish and Game Commission (Weiss 2003; Thompson 2004). The concerns raised by these groups were largely related to the fact that the federal regulatory bodies seemed dismissive of the possible impacts that introducing genetically engineered species into the world could have.

Over time, some unintended release of GloFish into natural environments did occur. One of the first instances was reported in 2014 when a singular GloFish was seen in a canal in the Tampa Bay region of Florida. No other GloFish were ever observed in this area, though, indicating that this escape could have been unusual (Moutinho 2022). In 2015, however, GloFish were observed in the wild in greater numbers in Brazil, where GloFish are banned. Transgenic zebrafish (one type of GloFish) were observed in the Paraíba do Sul River Basin in

2015, believed to have escaped from an ornamental fish farm (Moutinho 2022). Researchers began to study the zebrafish and whether it could spread into various regions of Brazil in 2017 by looking at their breeding and feeding habits in Brazilian river systems (Magalhães, Brito, and Silva 2024). Researchers concluded that the GloFish seem to reach sexual maturity faster than the non-transgenic variety and that the GloFish are consuming various native insects and flora, also showing signs of aggression towards native species of fish (Magalhães, Brito, and Silva 2024).

GloFish represents the earliest DTC GE product to be commercialized. It was brought to market with little regulatory oversight and resulted in unintended releases into natural environments. Though these unintended releases have yet to display significant impacts, this case demonstrates the risk of loosely-regulated DTC GE organisms moving into unintended environments.

ii. Case #2: Designer plants Norfolk Purple Tomato & Light Bio Glowing Petunia

Light Bio began selling the Firefly Petunia in 2024. The petunia plant is genetically engineered to express genes from a bioluminescent mushroom which produces the light-emitting molecule luciferin, allowing the plant to exhibit bioluminescence (Light Bio 2025). It was one of the first products to undergo review under the USDA's Regulatory Status Review (RSR), which went into effect as part of the formerly designated "SECURE Rule" in late 2022. RSR considers prior scientific evidence on whether an organism has increased plant pest risk due to its genetic engineering and in some cases requests additional data to be submitted by the developer (Bickell 2023). The petunia was determined not to have increased plant pest risk, therefore regulators determined it to not be a regulated product.

Norfolk Healthy Produce began selling The Purple Tomato to consumers in seed form in February 2024. This is a GE cherry tomato which produces anthocyanins in its flesh and skin, resulting in a purple color throughout the tomato (Norfolk Healthy Produce 2025). Like the Firefly Petunia, the Purple Tomato went through the USDA's RSR and was determined to not exhibit a significant plant pest risk. The company also voluntarily submitted its product to the FDA, which after review decided it was unlikely to be any more toxic than its non-GE counterpart and did not require premarket approval (Zhu 2023; ISAAA 2023).

Since both products are plants, the ways in which they could fail to be contained are similar. Generally, there exist the possibilities of cross-pollination with other plants, including wildtype variants, and of the GE variant spreading to unintended areas. USDA Animal and Plant Health Inspection Service (APHIS) has determined that neither of these specific products poses a serious plant pest risk or hazardous weed risk (Animal and Plant Health Inspection Service 2024b; 2024a), which could relate to the fact that neither of these plants grow in the wild in the United States (Lorenz-Lemke et al. 2006; Moyle 2008), making invasiveness or cross-pollination with wild species unlikely. While ecological or social consequences have yet to be reported with the Firefly Petunia, the Purple Tomato has already faced some controversy. In April 2024, a catalog specializing in heirloom, non-GE tomatoes used the Purple Tomato on its cover, mistakenly believing that it was not genetically engineered. This was purportedly the result of the fact that the seeds were acquired from a hobby gardener in France, where GMOs are banned. Even so, testing indicated that the tomatoes acquired by the catalog were the engineered Purple Tomato, and the distributor destroyed the seeds they had acquired (Woodruff 2024). Another controversy occurred in August 2024, which involved a man selling what he claimed to be Purple Tomato seeds on Facebook Marketplace in Europe, though the Purple Tomato is not authorized for sale or use outside of the US. Norfolk Healthy Produce released a statement clarifying that they had alerted European authorities and felt that he was taking advantage of their consumer model (Norfolk Healthy Produce 2024).

Both the tomato and petunia went through similar regulatory processes and were ultimately left unregulated, following in the footsteps of GloFish. Although these products are unlikely to have ecological consequences in the US due to their lack of persistence, the Purple Tomato has demonstrated that DTC plants can be easily transported to unintended environments, which could prove problematic for particular plants in specific environments. Notably, the framework for Regulatory Status Review was vacated in December

2024, and the former Petitions for Nonregulated Status process has since been re-implemented (Animal and Plant Health Inspection Service 2024c).

iii. Case #3: ZBiotics, a lifestyle probiotic

ZBiotics started selling the Pre-Alcohol probiotic, their first product, in 2019. This probiotic drink includes a genetically modified strain of *Bacillus subtilis*, specifically engineered to produce the enzyme acetaldehyde dehydrogenase (ALDH), which breaks down a toxic byproduct of the human body's decomposition of alcohol. Notably, the *B. subtilis* and ALDH involved in this product are both naturally occurring and can be found in the human body (the bacterium can be found in the gastrointestinal tract; ALDH is produced in the liver) (ZBiotics 2024a). The FDA has no specific, required regulatory pathways for genetically engineered products, and ZBiotics makes no explicit health claims regarding its probiotic, so the FDA considers the bacterium to be a food ingredient. Furthermore, *B. subtilis* is known to have been consumed by humans for centuries and is listed as an ingredient on FDA's Generally Recognized as Safe (GRAS) list. Any product with GRAS "status" is not subject to a premarket approval process under the Food, Drug, and Cosmetic Act (Food and Drug Administration 2016)**.** ZBiotics pursued a notification process with the FDA to affirm that their probiotic fell under the purview of GRAS status, which did not require the submission of robust efficacy or safety studies of its product for premarket review and approval (Gainer and Cianci 2006). Importantly, ZBiotics has published a study regarding the non-toxicity of the probiotic to support its self-certification of GRAS status (Appala Naidu et al. 2019). As such, the ZBiotics Pre-Alcohol probiotic is compliant with the FDA as GRAS, but it has not undergone a pre-market approval process by the agency.

Despite the potential for the engineered bacteria and their genetic elements to end up in the broader environment as part of waste disposal, containment was never framed as a goal by ZBiotics or a primary safety or risk concern by the FDA. ZBiotics is confident that their minimal engineering approach that utilizes a naturally occurring organism will not translate to any human health or environmental safety issues, and no such issues have been reported through the first few years of distribution. However, there are no mechanisms in place to detect nor monitor whether these engineered bacteria end up in the environment and what impacts they have (positive, negative, or neutral). Current scientific evidence suggests that significant environmental impacts or human health hazards are unlikely to occur, but without monitoring strategies in place these outcomes cannot be confirmed.

ZBiotics demonstrates how GRAS status can be an efficient pathway by which to navigate FDA regulation. In spite of the novel trait and application of the modified bacterium, its establishment in a different context in wildtype form qualifies it for GRAS status, which allows it to be commercialized as FDA compliant, circumventing more onerous FDA premarket review and approval procedures. While some policy scholars have supported the GRAS notification process as an efficient, cost effective way to bring products to market (Roberts and Haighton, 2016), others have highly criticized GRAS as not providing sufficient oversight and assurances that all uses of GRAS compounds and organisms are safe (Faustman et al, 2021). The ZBiotics product to date appears to be extremely low-risk, but other DTC GE organisms that utilize GRAS molecules or organisms might not have the same level of transparency and thoroughness in conducting their self-determination process.

Table 1: Summary information of the four direct-to-consumer genetically engineered organisms presented in this briefing. Specifically parsed out is information briefly describing 1) how the technology works, 2) regulatory oversight mechanisms, 3) the ownership model, and 4) whether any containment breaches have been reported.

Product	Technology	Regulatory oversight & process	Ownership & propagation model	Containment challenges and breaches
GloFish	Zebrafish (and other species) modified with glowing	No US regulatory agency has claimed oversight	Live fish sold to consumers	Single GloFish found in Florida waters; many GloFish found in Brazil waters (Moutinho 2022)

	fluorescence protein from jellyfish			
Firefly Petunia	Petunia modified with genes from mushroom to exhibit bioluminescence	USDA (RSR review)	Propagation and sharing not permitted by the company	None reported to date
Purple Tomato	Tomato plant modified (with snapdragon genes) to express anthocyanins in flesh and skin	USDA (RSR review), voluntary FDA submission	Seed packets sold to consumers; individuals can save and share seeds within the US but not sell them	Purple Tomatoes mistakenly marketed as non-GE by a tomato catalog (Woodruff 2024); Purple Tomato seeds sold by a man in Europe (Norfolk Healthy Produce 2024)
ZBiotics	*Bacillus subtilis* modified to express acetaldehyde dehydrogenase in the human gut	Self-notification of FDA Generally Recognized as Safe status	Bottles of probiotic sold to individuals; culturing of more probiotic at home not easy (or permitted by the company)	None reported to date

III. Discussion: Key challenges for deployment of DTC GE organisms

Based on the case studies (Table 1), we have found that robust regulatory oversight for DTC GE organisms is limited, and this opens up three potential challenges for governing these organisms in the future. First, the lack of regulatory scrutiny reinforces a transparency problem between companies and consumers, the possible consequences of which are exacerbated by the DTC model. Historically, plant gene-traits underwent a rigorous regulatory review process to determine whether GE crops posed significant plant pest risk and hazardous weed risk (Animal and Plant Health Inspection Service, 2024a). This required developers to submit technical descriptions of their products and field trial data for agencies to assess to determine whether a product could be nonregulated. After assessment, this information was stored in a publicly available "Petitions for Nonregulated Status" archive at APHIS. Anyone in the public sphere could access this information to learn more about the technical dimensions and field trial testing of these products (Animal and Plant Health Inspection Service, 2024d). DTC GE organisms are a different case. Information on the technical dimensions and safety testing is not available for these products to the same degree as those that have gone through more rigorous regulatory review, such as the USDA APHIS petitions process (Kuzma 2023). Developers (e.g. ZBiotics, Norfolk Health Produce, LightBio) may self-select to publish some safety studies and open access web articles explaining details about how their products were created and how to properly use them (Appala Naidu et al. 2019; Hassan-Casarez et al. 2024). However, sharing this information is completely voluntary. Customers that are not completely informed on what they are buying and bringing into their homes could lose trust in companies producing DTC GE products.

Second, under current circumstances for DTC GE organisms, their deployment and stewardship is under the purview of individual consumer discretion, and they can be deployed in spaces without requirements for built-in guidelines for best practices or containment mechanisms. In the historical example of GE crops, if granted nonregulated status, GE crop plants are then deployed into the agricultural field under the stewardship of growers. Deployment of GE crops happens at the site of the agricultural field—a semi-controlled environment that is intensely managed. Best practices for planting GE crops usually require the implementation of a “buffer zone” to prevent any possibility of cross-pollination with native species or other, non-GE crop fields (Urechean and Bonea 2018; Colbach, Devaux, and Angevin 2009). DTC GE organisms, on the other hand, might not have analogous best-use practices or standards of containment attached to their deployment which could result in some unintended spread of these organisms. For example, petunias are a species that cross-pollinates quite frequently, so it’s possible that GE varieties could cross-pollinate with other garden petunias or be transported and propagated to other areas of the world as invasive organisms, similar to GloFish.

Lastly, under existing regulatory guidelines, these organisms do not have accountability or responsibility mechanisms attached to their application in the home. If negative impacts were to occur—such as an unintended ecological consequence because of a spreading GloFish, or Firefly Petunia, or microbiome impacts because of ZBiotics product usage—it’s not clear what entity would be responsible if products are not used as intended. Would companies be absolved of responsibility if individuals misused their products? And, perhaps more importantly, how would consequences be addressed? Individual consumers don’t necessarily have the capacity to organize full-scale recalls nor cleanups, and federal regulatory agencies may not have the purview nor the power depending on the product type. In addition, it's not clear if any agency would be responsible for collecting any post-market data on potential adverse effects of DTC GE organisms as they do not neatly fall into established categories of reporting requirements for the FDA, EPA, or Consumer Product Safety Commission's post-market surveillance of consumer products (Kingston et al. 2021). This could also create challenges for preventing the illegal export and distribution to other countries, as demonstrated in the Norfolk Purple Tomato case.

IV. Key questions and recommendations for governing DTC GE organisms

To conclude, we propose that the four disparate product cases we have presented—GloFish, Firefly Petunia, Purple Tomato, and ZBiotics probiotic—together illustrate important challenges for governing an emerging direct-to-consumer product category of GE organisms. Therefore, we offer what we think are three key questions for regulators, policy makers, and developers to consider regarding the governance of future DTC GE organisms. First, should different contexts of use be an important consideration for regulating DTC GE organisms? The cases explored in this paper show lower bars of regulatory scrutiny applied to DTC GE organisms, particularly when it comes to concerns over containment. Environmental consequences from a lack of containment for these products may not be immediate (or occur at all), but the scope of regulation presumes minimal impacts despite a lack of data and testing for these organisms. Further, DTC GE organisms raise the question of context of use as it relates to regulation. For example, does the USDA RSR procedure presume a large scale, industrial consumer when enacting its review procedure? Deploying a product with actors who are already embedded in a system that includes industry surveillance mechanisms, as well as checks and balances (e.g. crop production), is much different than deployment within a consumer’s household. This could be a useful variable in future risk assessments of DTC GE organisms.

Second, by what mechanisms will consumers be educated on responsible use of these products, especially ones that contain novel genetic elements? Companies that produce DTC GE organisms are not required to educate their customers on responsible use of their products, nor label them as genetically engineered unless it is specifically a food product (Food and Drug Administration 2024). Under the current system, a company has to take the initiative to label their non-food product as GE and provide extensive information on their engineering methods, additional ingredients, and responsible use recommendations, which companies such as ZBiotics have done (see ZBiotics 2024b).

To address this issue, the United States should extend the National Bioengineered Food Disclosure Standard (Bickell 2020; Agricultural Marketing Service 2018) to also apply to consumer products. So far, compliance with the mandatory labelling law has been a success and not resulted in significant negative impacts on the food industry (Caputo et al 2025). However, some experts have questioned whether consumers comprehend the meaning behind these labels and whether they really promote awareness of bioengineered foods (Adalja et al 2022). Consumers failing to grasp the meaning behind the labels might defeat the purpose of having them at all. Therefore, we propose a two-pronged approach that connects mandatory GE labels with the use of a national product registry database. This registry could help developers make information about the engineering mechanisms, contents, function, and risks of DTC GE organisms available to consumers. Potential benefits of this labelling and registry strategy include building transparency and trust between consumers, developers, and the government, as well as supporting an "opt in" model of distribution where consumers know exactly what they are purchasing and deploying in their homes. The product registry could also include information on how to properly use products within the home, as well as warnings and cautionary statements on how to avoid misuse. Other biotech product categories have made use of registries to this effect, such as cell and gene therapies (Food and Drug Administration 2025). A DTC GE product registry could be modeled off these examples and be made available for use through an interagency office in the federal government, which we elaborate on below.

Third, if something went wrong with these products, who is responsible? It is not clear what entity would be held accountable for damages, authorize a recall, or monitor for any potential negative impacts of DTC GE organisms post-commercialization. Once a DTC organism is in the ground, in the air, or in someone's body, removing it and its genetic and biochemical elements could prove difficult. Given this challenge, we suggest that DTC GE organisms present an opportunity to re-think monitoring responsibility in post-market release of consumer products. One solution is to dedicate federal resources to an interagency office that is focused on gathering and curating consumer data and responsible use information on DTC GE organisms. Similar to how the economic research service gathers data and runs analyses on agricultural economics for the USDA (Economic Research Service 2025), an interagency office dedicated to collecting data on the distribution, use, and outcomes of deploying DTC and other GE organisms could provide agencies with timely, important information on the impacts of these products. This could be used to inform proactive enforcement mechanisms, should negative outcomes or patterns of misuse occur. This data-gathering mission could be dovetailed with the construction and maintenance of the aforementioned product registry database, making this interagency office the one-stop-shop for comprehensive information on DTC GE organisms.

An interagency office would be ideal to carry out this work, as DTC product categories span different jurisdictions of federal regulatory agencies. Importantly, funds to support the creation of an interagency coordination office have been set aside as part of the National Engineering Biology Research and Development Initiative (117th Federal Congress 2022). Specific duties related to DTC GE organisms have not been established as part of this office's mandate, which is to coordinate federal interagency research, strategic plans, and programs as part of the Development Initiative. We suggest that one of these research programs implements the construction of a product registry that includes DTC GE organisms.

Applications of DTC GE products are likely to keep expanding as efficient engineering mechanisms continue to allow developers to pursue novel gene-traits for product categories across different sectors. However, disparate regulatory mechanisms, issues with ensuring responsible use, and lack of accountability mechanisms in the face of unintended consequences could hinder the full potential of genetic engineering in consumer products. Our recommendations represent some initial steps that developers and policymakers could agree upon as sensible, practical mechanisms for ensuring safety, assigning responsibility, and building public confidence in the next generation bioeconomy.

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