Gene Edited Micro-organisms
UK policy context and global developments

Gene edited microorganisms are rapidly moving from research into real-world applications in agriculture, food production, bioremediation and other environmental and biological applications.

Despite this expansion, microbial genetic engineering remains comparatively poorly understood, unevenly regulated and largely invisible in public debate. This stands in contrast to genetically engineered plants and animals, where regulatory frameworks, public scrutiny and political attention are more established.

This matters because microorganisms are fundamentally different from plants and animals in ways that are directly relevant to risk, governance and public oversight. Microbes reproduce rapidly, exchange genetic material horizontally, persist in complex ecosystems and can evolve after release or deployment. Once introduced into soils, water, food systems, or human and animal microbiomes, they cannot be recalled and their long-term behaviour is difficult to predict using existing

assessment tools. These characteristics mean that regulatory approaches developed for crops, fermentation processes, or static products may not be appropriate when applied to living, mobile and adaptive microbial systems.

In the UK, the [Genetic Technology (Precision Breeding) Act 2023](#) removed plants and animals developed using certain gene-editing techniques from GMO regulation, but did not extend this change to microorganisms. As a result, genetically engineered microbes – whether produced using older genetic modification techniques or newer gene-editing methods – remain regulated as GMOs. However, pressure is growing from industry and parts of government to ease regulatory controls in practice, particularly for products developed under contained-use conditions or where no viable organisms are present in the final product.

These changes are not being driven by a single legislative reform, but through incremental and often low-visibility adjustments to existing

regulatory processes, including risk assessment practices, authorisation pathways and innovation programmes. Taken together, they signal a quiet fast-tracking of microbial genetic engineering, particularly in food, feed, fermentation and agricultural inputs, with limited public debate or democratic scrutiny.

The gene edited microbial landscape remains difficult to map. Information is fragmented across regulatory filings, company announcements, research publications and pilot projects and many applications sit at the boundary between research, development and commercial deployment.

This briefing does not claim to provide a comprehensive account of all activity in this space. Instead, it draws together available evidence to illustrate emerging trends, areas of regulatory pressure and key uncertainties, recognising that much remains unclear and that developments are advancing faster than public reporting and oversight mechanisms.

Examples of genetically modified microorganisms are used throughout this briefing as illustrative case studies. This reflects both data availability and development practice: genetically modified products are often easier to identify and document than gene edited equivalents, particularly where regulatory exemptions apply. Experience from GM plant development suggests that developers frequently begin with genetically modified organisms before moving toward gene edited variants as regulatory pathways evolve or become less restrictive.

As such, GM examples provide a practical window into the types of applications, deployment contexts and governance challenges that are likely to arise for gene edited microorganisms.

A central concern explored here is that governance assumptions developed for plant breeding, industrial fermentation, or post-processing products are increasingly being cut and pasted into regulations for microbial systems without adequate consideration of whether these assumptions hold.

Distinctions between 'contained use' and environmental exposure, between viable organisms and final products and between research and deployment are becoming blurred as scale, distribution pathways and novel applications expand. This raises questions about whether existing regulatory frameworks are equipped to manage the specific risks, uncertainties and societal implications associated with the wider deployment of engineered microorganisms.

Right now governance systems are being reshaped indirectly – through pace, categorisation and trade alignment – rather than through explicit democratic choices about risk, responsibility and oversight. Taken together, these dynamics suggest that decisions about microbial genetic engineering are increasingly being made through regulatory practice rather than regulatory debate.

This briefing outlines where the UK and selected other countries currently stand, what changes may be emerging and what kinds of microbial products are now in development or approaching market.

It highlights concerns about environmental persistence, horizontal gene transfer, containment assumptions and oversight, particularly as applications move beyond laboratory and industrial settings toward intentional interaction with soil, water, plants, animals and the human gut. It then provides a structured snapshot of products and platforms under development, grouped by contained use, environmental release and enabling pipeline technologies.

UK Regulation: where it is and where it's going

At present, genetically engineered microbes are not covered by the UK's Precision Breeding legislation. The [Genetic Technology (Precision Breeding) Act 2023](#) applies only to plants and

animals – meaning that all genetically modified or gene edited microorganisms remain subject to the UK's retained EU GMO framework.

The government has so far stated it does not plan to change this. In its [response to the 2021 public consultation on gene editing](#), Defra said:

> *"We also have no plans, at this stage, to change the regulatory requirements for research involving microorganisms produced using genetic technologies. Independent scientific committee, ACRE, has advised that we address microorganisms separately from plants and animals when developing regulatory procedures."*

This reflects longstanding scientific advice that microbial genetics, behaviour and ecological risks are fundamentally different from those of plants or animals.

The Advisory Committee on Releases to the Environment (ACRE), in particular, has cautioned that horizontal gene transfer between microorganisms is common in the environment, making gene flow more likely than in other organisms.

[In its 2021 advice to Defra, ACRE stated:](#)

> *"Given the high levels of horizontal gene transfer that are known to occur between micro-organisms in natural environments, gene flow is more likely to be a realistic possibility. This should be an important consideration in the context of developing any new regulatory procedures for micro-organisms produced using gene editing and/or other genetic technologies."*

As the Precision Breeding Act does not contain delegated powers to add new organism categories, any attempt to extend its scope to microbes would likely require new primary legislation. However, it could be relatively straightforward for the government to keep microbes under GMO law, but change that for 'low risk' cases.

Proportionality and flexibility in existing frameworks

UK regulation of genetically modified organisms already incorporates flexibility and proportionality based on risk. Existing GMO risk assessment frameworks allow for differentiation according to the characteristics of the organism and its intended use, rather than applying uniform scrutiny in all cases.

[ACRE's 2013 guidance](#) explicitly supports this approach, stating that:

> *"A proportionate and tiered approach to environmental risk assessment should be followed, based on the characteristics of the GMO and the intended use."*

This principle reflects long-standing scientific advice that not all genetically engineered organisms pose the same level or type of risk and that regulatory oversight should be calibrated accordingly. In this respect, the UK's retained EU

GMO framework is not inherently rigid and does not require wholesale reform in order to accommodate variation between applications.

Importantly, the existence of proportionality within current frameworks means that regulatory systems already possess tools to adjust scrutiny where risks are demonstrably lower. It also means that changes in regulatory outcomes do not necessarily require new legislation, but can emerge through reinterpretation of existing guidance, assessment practices and thresholds of evidence.

This flexibility provides an important baseline for understanding subsequent developments. The issue explored in the sections that follow is therefore not whether proportionality is available

within current regulatory frameworks. Instead, it is how it is being interpreted and applied in practice – and whether the ways in which flexibility is now being operationalised for genetically engineered microorganisms remain appropriate given their biological properties, deployment contexts and potential for interaction with complex living systems.

Operationalising flexibility: food, fermentation and 'non-viable' products

In principle, existing flexibility is intended to facilitate scrutiny to specific contexts, rather than to remove oversight altogether.

In practice, however, this flexibility is increasingly being operationalised in ways that narrow the scope of regulatory attention, particularly for microbial products used in food, feed and fermentation.

Recent regulatory developments focus on products derived from genetically engineered microorganisms rather than on the organisms themselves, especially where no viable microorganisms are present in the final product.

This shift reframes risk around end-state characteristics and manufacturing outcomes, rather than around the lifecycle, scale and systemic behaviour of engineered microbes used in production.

Recent and fast moving, initiatives by the Food Standards Agency illustrate this trend:

- **March 2024:** The FSA Board agreed to replace the current product-by-product legislative process with a new public register for novel food products, including precision-fermented and cell-based products.

- **March 2025:** The FSA launched a £1.4m Innovation Hub for precision-fermented foods, funded through the Regulatory Innovation Office (RIO).

- **September 2025:** The FSA launched a dedicated Market Authorisation Innovation Research Programme (IRP) and Business Support Service (BSS) for companies producing precision-fermented food ingredients. See also here.

While these initiatives are formally framed around contained use and post-processing products, they rely on assumptions that engineered microbes used at scale can be effectively contained, rendered non-viable and excluded from broader environmental or governance concerns.

This matters because it sets precedents. By treating microbial genetic engineering primarily as a manufacturing input rather than as a biological intervention, regulatory scrutiny shifts away from questions of persistence, waste streams, cumulative exposure and system-wide effects. Over time, this approach risks normalising reduced oversight for increasingly complex microbial applications, even as engineered organisms move closer to intentional interaction with food systems, agricultural inputs and living environments.

Administrative acceleration & innovation-led governance

Alongside changes in how proportionality is applied, regulatory oversight of genetically engineered microorganisms is increasingly shaped by administrative mechanisms designed to accelerate innovation. These include regulatory sandboxes, innovation hubs and iterative

engagement between regulators and selected developers.

These mechanisms are presented as pragmatic responses to technological change, allowing regulators to 'learn by doing' while supporting emerging sectors.

In the UK, this approach is evident in [FSA's two year cell-cultivated product programme](#) and associated regulatory sandbox, which invites a closed group of developers and companies involved in producing cultivated foods, to help shape future authorisation pathways.

Similar logic underpins the Regulatory Innovation Office [announcement](#), in October 2025 of early achievements and future plans for its programme to remove regulatory barriers and promote growth in four key sectors: space, drones, artificial intelligence in healthcare and engineering biology (including precision fermentation and cell-based products). According to the Regulatory Innovation Office, these reforms are expected to cut approval timelines for certain categories by up to 50%.

While these initiatives do not formally amend legislation, they play a significant role in redefining how regulation operates in practice. By shifting regulatory development into pilot programmes, expert working groups and pre-legislative processes, substantive decisions about risk, evidence thresholds and acceptable uncertainty are increasingly made outside conventional democratic forums. This form of administrative acceleration privileges speed, alignment with industry expectations and regulatory predictability, often before broader questions of public interest, long-term oversight, or societal acceptability are addressed.

For genetically engineered microorganisms, this mode of governance is particularly consequential. Microbial systems are living, adaptive and context-dependent and their behaviour may only become apparent after deployment at scale. Innovation-led governance approaches that prioritise early market access and iterative adjustment risk embedding assumptions about safety, containment and equivalence before robust mechanisms for monitoring, traceability and accountability are in place. In this way, administrative acceleration does not merely speed up regulation; it reshapes what regulation is expected to do.

Industry pressure and expectations of change

Alongside changes in regulatory practice, industry actors have increasingly articulated expectations that regulatory frameworks for genetically engineered microorganisms should evolve to support faster deployment and greater legal certainty.

These expectations are often framed in terms of innovation, competitiveness and the need to modernise regulatory systems to reflect technological advances.

In the UK, the BioIndustry Association (BIA), which represents biotechnology and life sciences companies, has explicitly highlighted microorganisms as a priority area for future [regulatory change](#). Commenting on the scope of the Genetic Technology (Precision Breeding) Act 2023, the BIA noted:

"Microorganisms remain outside the scope of the 2023 Act. Separate primary legislation would be required to bring these technologies within the framework. This is an area where further clarity would be welcomed by industry, particularly given the growing role of engineered microbes in areas such as sustainable agriculture and industrial biotechnology."
– Maddie Cass, Senior Policy and Public Affairs Executive, BIA

Such statements do not simply call for technical clarification. They signal an emerging assumption within the sector that genetically engineered microorganisms should, over time, be governed under bespoke or lighter-touch frameworks,

particularly where applications are framed as low risk, contained, or sustainability-enhancing.

This expectation aligns closely with parallel developments in regulatory practice, including

streamlined authorisation pathways, innovation-led governance mechanisms and a growing emphasis on end-product characteristics rather than organism-level behaviour.

The convergence of industry expectations and administrative reform is significant. As regulatory systems adapt to support emerging markets, industry narratives about safety, equivalence and proportionality increasingly shape the parameters

within which oversight operates. Over time, this dynamic risks narrowing the space for alternative framings – for example, those that emphasise long-term ecological uncertainty, cumulative exposure, or public accountability – particularly in areas where microbial applications remain poorly understood.

In this context, industry pressure does not operate primarily through overt demands for deregulation.

Instead, it functions by reinforcing and legitimising a broader regulatory shift, in which facilitating innovation and reducing friction are central governance objectives. For genetically engineered microorganisms, this raises questions about how competing interests, uncertainties and public values are weighed as regulatory regimes evolve.

Seeking alignment with Europe?

The significance of these domestic regulatory shifts extends beyond the UK context.

In May 2025 the UK and EU announced that they would begin work towards a comprehensive SPS agreement designed to reduce trade friction in agri-food products.

 Under this framework the UK would dynamically align with many EU rules on food safety, animal and plant health, consumer protection, organics, pesticides and marketing standards.

Formal negotiations opened in late 2025 and, reports suggest, have an implementation target of mid-2027. Crucially, dynamic alignment means that forthcoming changes with GM microbial regulation in the EU may lead to a similar change in the UK. SPS alignment is particularly significant for genetically engineered microorganisms because microbial products frequently sit at the intersection of food safety, agricultural inputs, environmental protection and trade. Decisions taken within SPS frameworks can therefore shape not only import and export

conditions, but domestic regulatory approaches to authorisation, monitoring and transparency. SPS alignment, therefore, is not neutral harmonisation: it can function as a mechanism for regulatory lock-in, constraining future policy choices and importing assumptions about risk, equivalence and oversight across jurisdictions.

Dynamic alignment creates a pathway through which changes to EU microbial regulation – including proposals to exempt certain genetically engineered microorganisms from full GMO oversight – could be imported into the UK regulatory system without standalone legislative debate.

In this context, SPS alignment risks functioning as a regulatory ratchet: once assumptions about low risk, containment, or equivalence are embedded in trade-facing rules, they become difficult to revisit, even as applications expand or evidence evolves. For microorganisms, where environmental behaviour, gene transfer and long-term impacts remain areas of scientific uncertainty, this raises questions about whether SPS mechanisms are an

appropriate forum for resolving governance choices with significant ecological and societal implications.

Taken together, these developments do not amount to isolated regulatory adjustments. They indicate a shift in governing logic, in which regulatory systems are increasingly oriented toward enabling deployment and reducing friction, rather than interrogating uncertainty or managing long-term exposure. For microbial genetic engineering, this shift is particularly significant, as it alters how containment, risk and responsibility are understood in practice.

EU Developments: towards deregulating microbes?

Genetically modified microorganisms (GMMs) in the EU are currently subject to full GMO legislation, regardless of whether they were produced using older transgenic techniques or newer gene editing tools. However, recent scientific opinions and legislative proposals indicate a potential shift away from this approach, with significant implications for how microbial genetic engineering may be governed in future.

EFSA's Position on Microbial Gene Editing

In 2024, the European Food Safety Authority (EFSA) published a scientific opinion on microorganisms developed using gene editing, or 'new genomic techniques' (NGTs). It argued that risk assessment should focus on the product's characteristics rather than the method used to produce it – a shift from a process-based to a trait-based approach.

EFSA concluded that many gene edited microbes may pose no greater risk than those modified by conventional or long-established genomic techniques. This opinion is significant not because it mandates regulatory change, but because it provides a scientific rationale for reclassifying certain gene edited microorganisms as low risk, thereby enabling legislative and administrative reform.

Draft Directive Released in December 2025

Building on this scientific framing in December 2025, the European Commission published a draft Directive proposing new rules for genetically modified microorganisms. This includes major changes to how environmental and industrial applications are regulated. The proposal includes two key elements:

1. **Environmental release: deregulation by trait**
   - The draft Directive proposes that certain engineered microorganisms could be excluded from GMO regulation if EFSA determines that their traits pose a low environmental risk.

   - This would apply to GMMs used in fertilisers, biocontrol, bioremediation, wastewater treatment and other open-release applications.

2. **Clarification for food and feed**

   - The proposal confirms that products made using genetically modified production organisms (e.g. for fermentation) are not considered to be "produced from GMOs" under EU food and feed law – provided that:

     o No viable GMMs are present in the final product

     o Any residues are "*limited to non-viable cells, are minimized through reasonable attempts to remove them in accordance with good manufacturing practice and have no technological effect on the food or the feed*."

This clarification addresses longstanding industry demands for certainty around GM-derived enzymes, flavourings, vitamins and food additives.

Taken together, these proposals would mark a shift from a precautionary, process-based framework toward a more permissive, trait-based approach for microbial applications, including in open environmental settings.

Reactions

EuropaBio and other industry groups have welcomed the proposals as overdue modernisation. But, civil society organisations and independent watchdogs have warned that exempting gene edited/engineered microorganisms from full oversight – for example by weakening mandatory risk assessment, traceability and monitoring – risks undermining long-standing EU biosafety protections (see also here and here. They note that microbial behaviour in real-world environments remains poorly understood and difficult to predict, especially in cases involving environmental release.
This was echoed in the EFSA public consultation on microorganisms obtained through synthetic biology, which highlighted just how complex these systems are. It noted that engineered microbes can interact with natural ecosystems and existing microbial communities in unpredictable ways, especially once they are outside controlled settings.

The deregulation of GMMs can be viewed as part of a wider deregulatory agenda in the EU and elsewhere. Civil society organisations have explicitly warned that this agenda – including efforts to simplify or weaken GMO/NGT regulations – risks undermining safeguards designed to protect people and the environment.

In an open letter published on 9 September 2025, around 470 civil society groups and public interest organisations urged EU policymakers to resist 'deregulation in disguise', arguing that stripping back regulatory protections could endanger rights, health and environmental safeguards built up over decades.

These proposed changes have prompted debate about whether existing biosafety safeguards would be weakened, particularly for applications involving environmental release and long-term ecological interaction.

The global regulatory landscape

Beyond the UK and EU, genetically modified and gene edited microorganisms are already in commercial use in several countries, particularly in food, feed and industrial applications.

A smaller but growing number of jurisdictions have also approved environmental release of genetically engineered microbes, including soil treatments and open-pond algae trials.

The fragmentation visible across national regulatory approaches to genetically engineered microorganisms is not accidental. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity – the cornerstone international treaty governing the transboundary movement of living modified organisms – places responsibility for implementation and enforcement entirely on individual signatory states.

There is no overarching coordinated international policy. More significantly, several major GMM-producing and exporting countries, including the United States, have not ratified the Protocol at all, creating structural gaps in international governance.
Other bodies, including the World Health Organization and the OECD, offer guidance and propose standards, but without binding authority. The result is a system in which decisions about the

creation, use and environmental release of genetically engineered microorganisms – organisms capable of crossing borders invisibly and rapidly – are made jurisdiction by jurisdiction, with no clear mechanism for coordinating risk assessment, monitoring or response.
The examples below are not intended to provide a comprehensive inventory, but they do illustrate how this has produced a landscape of diverging assumptions about what constitutes acceptable risk, adequate containment and sufficient evidence for market authorisation.

United States

The US has been the most permissive country so far in supporting both contained and environmental uses of genetically engineered microbes:

- **Food and feed**: Products such as GM probiotics (e.g. ZBiotics), GM yeast-derived ingredients (e.g. Impossible Foods' soy leghemoglobin) and enzyme-treated sweeteners (e.g. allulose) are commercially available.

Many food and feed products fall under Generally Recognized as Safe (GRAS) notifications and are not subject to significant pre-market regulatory review if no viable GM material is present in the final product.

- **Environmental applications**: The Environmental Protection Agency (EPA) regulates outdoor R&D of engineered microbes via the TSCA Experimental Release Application (TERA) process. TERA approvals have included:

  - Nitrogen-fixing and enzyme-secreting soil microbes
  - Open-pond trials with engineered algae, such as:

    - *Acutodesmus dimorphus* modified for fatty acid production (2017)

    - *Nannochloropsis oceanica* modified with a carbon uptake gene (2024)

The US framework is product-based, with limited scrutiny if no viable engineered organism remains in the final application.

This approach illustrates the outer boundary of a product-based regulatory model, in which the absence of viable organisms in final products, or classification under GRAS or TSCA processes, substantially limits pre-market scrutiny and post-release oversight.

Canada

Canada requires environmental risk assessments for all novel living organisms – including GM microbes – under the New Substances Notification Regulations (Organisms) (NSNR).

Between March 2024 and February 2025, Environment and Climate Change Canada (ECCC) and Health Canada completed 44 living organism assessments under CEPA, of which 15 were for microorganisms. Most were for industrial or contained-use purposes, but one transgenic *Pseudomonas putida* was assessed for use in field trials for herbicide degradation.

Canada's framework includes microorganisms modified through traditional or newer biotechnologies, but has not yet developed clear guidance for gene edited strains intended for environmental release.
While Canada retains a formal requirement for environmental risk assessment of novel organisms, its case-by-case approach illustrates how regulatory flexibility can accommodate microbial genetic engineering without dedicated gene-editing legislation. Similar dynamics are evident in several Latin American jurisdictions.

Brazil

Gene edited microbes that do not contain foreign DNA and mimic changes achievable via conventional methods are not classified as GMOs under Brazilian law and can avoid full GMO regulatory procedures.

Most gene edited microbes are used in contained industrial settings, including yeast strains for

ethanol production and microbial feed additives. These are registered via standard food or feed pathways, not GMO law.

By November 2024 around [62% of the product candidates](#) evaluated by Brazil's National Biosafety Technical Commission (CTNBio) were for microorganisms or their components/derivatives.

Although Brazil has not yet approved environmental release of gene edited microbial products (e.g. biofertilisers or soil conditioners), several microbial strains – including nitrogen-fixing bacteria and cellulase-expressing *Bacillus* – have been approved as "Innovative Genetic Improvement Technologies," and may move toward market under conventional agricultural input regulations.

Argentina

Argentina operates a case-by-case regulatory system for GMOs and gene edited organisms through its Biotechnology Office (CONABIA), using a Prior Consultation Instance (PCI) process to determine whether a product falls under GMO regulations.

Between April 2024 and March 2025, [28 PCIs were submitted](#), of which 17 were for microbial products. These include fermentation-based products and at least one GM yeast for bioethanol production. Most are intended for contained industrial uses, but a small number involve live environmental [applications](#) (see also below).

From 2022 to present, Argentina has [authorised](#) 19 genetically modified microorganisms (regulated under GMO legislation, not through PCI process) for commercial use across a range of sectors. These include six pharmaceutical applications, five for food and industrial enzymes, three for bioethanol production using engineered yeasts, three animal nutrition/feed additives and one modified yeast for wine fermentation. Details of

microbes not considered GMO are not publicly available.

Australia

In 2020, Australia's Office of the Gene Technology Regulator (OGTR) [approved a field trial](#) of GM *Nannochloropsis oceanica* under strictly contained-use conditions: cultivation was permitted only in closed outdoor vessels with physical and procedural containment.

The OECD Working Party on Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) has begun to address microbial environmental applications. A draft [Consensus Document on Photoautotrophic Microalgae for Biomass Production](#), co-led by the US and Canada, is now nearing finalisation. It sets out data requirements and safety considerations for environmental use of modified microalgae.

Although framed as technical guidance, OECD consensus documents play an important role in shaping regulatory expectations and normalising particular data requirements and risk assumptions across jurisdictions, often ahead of formal legislative change. Taken together, these examples indicate that environmental applications of genetically engineered microorganisms are no longer exceptional.

Even where framed as trials, pilots, or contained outdoor use, they signal a growing willingness among regulators to permit intentional interaction between engineered microbes and open ecosystems, often under regulatory categories not originally designed for such uses.

Concerns and critiques

Although engineered microbes are increasingly proposed for use in agriculture, food and environmental restoration, concerns remain about their behaviour once released into complex ecosystems. Evidence from clinical and environmental trials shows that engineered microbes can mutate, persist, or lose function in ways that escape current risk assessment models.

These systems often rely on outdated assumptions, with limited capacity to model long-term, indirect, or cumulative ecological effects. Researchers warn that engineered persistence, horizontal gene transfer and ecosystem-level interactions are poorly understood – yet critical to understanding potential risks.

At the same time, regulatory systems are struggling to keep pace with technological change. For example, according to [the research](), the market includes approximately 2,920 bacterial-based biopesticides, 1,658 fungal-based biopesticides and 234 viral-based biopesticides. These are often sold with sustainability claims, for example using fewer chemical pesticides. At present, not many of these are genetically engineered, but there is increasing interest in this.

Novel delivery models such as seed coatings and consumer probiotics bypass traditional oversight, while many jurisdictions exempt products from scrutiny if no viable modified organism is present in the final form. Even where oversight exists, monitoring and traceability tools are often inadequate.
The risks associated with genetically engineered microorganisms are not confined to environmental settings. As [Lerner *et al* point out](), human microbiomes – including those of the gut, oral cavity and infant – represent complex, ecologically sensitive systems that are particularly vulnerable to disruption. The effects of GMM exposure on maternal or infant

microbiomes have not been evaluated, yet the routes of potential exposure – including through food ingredients produced by genetically engineered fermentation organisms – are already established.

A concrete illustration of this gap, also raised by Lerner *et al*, is microbial transglutaminase (mTg), a GM-microbe-derived enzyme now widely used as a food additive, with global sales exceeding $200 million annually. mTg acts similarly to a naturally occurring human enzyme but has been implicated in intestinal permeability, gastrointestinal dysbiosis and autoimmune disease, including celiac disease, via a mechanism of molecular mimicry. Crucially, because mTg is a product *derived from* genetically engineered microorganisms rather than a viable organism itself, it falls outside GMO labelling requirements in most jurisdictions.

Meanwhile, dual-use concerns are growing: the same traits that make microbes useful

Bayer & Klebsiella

Bayer, in partnership with Pivot Bio and Ginkgo Bioworks, is developing soil-applied engineered microbes as fertiliser alternatives. In [filings to the U.S. Securities and Exchange Commission,]() Ginkgo has acknowledged that the full ecological impacts of such releases are not yet known.

The [1999 *Klebsiella planticola* case]() remains a symbolic reference. Engineered to convert plant waste to alcohol, the bacterium killed wheat plants in lab trials, raising concerns about soil toxicity. Although the original findings have been contested, Ingham has continued to defend the scientific basis of the study, which is still cited in biosafety debates as an example of unintended ecosystem consequences from microbial engineering.

adaptability, dispersal, self-replication – also make them attractive for misuse. Advances in AI and synthetic biology are accelerating both innovation and risk, prompting calls for updated, precautionary governance that reflects the distinct challenges posed by live, engineered microbes.

Ecological Persistence and Mutation

Genetically engineered (including gene edited) microbes do not always behave predictably once released into complex ecosystems. A 2025 Stanford University trial of GMO *Phocaeicola vulgatus*, engineered to prevent kidney stones, found that in two human volunteers, the microbe mutated to persist without its engineered dietary input and resisted antibiotic treatment. Some strains also lost the intended function of oxalate degradation.

These findings underscore a broader concern: engineered microbes may adapt, exchange genes, or evolve in ways that are not captured in pre-release assessments, whether in human hosts or environmental settings.

Limits of Current Risk Assessment Models

Many researchers have argued that current biosafety assessments, which are largely developed for static, single-gene GMOs, are poorly suited to living, replicating microbes capable of interaction with complex microbiomes. Key gaps include:

- Insufficient modelling of indirect and cumulative ecological effects
- Over-reliance on containment assumptions
- Lack of methods to assess gene flow or horizontal transfer in dynamic microbial communities

The researchers called for precautionary approaches and updated frameworks that reflect the specific properties of engineered microbes.

In addition, containment itself is often treated as a guarantee of safety – but this assumption is

increasingly contested. Lab leaks and containment breaches happen in both academic and industrial settings, but are poorly documented. As genetically modified microbial products scale up in food and feed production, starter cultures and engineered strains will be used at large volumes – raising questions about waste handling, effluent management and the possibility of escape.

Some proposals have even suggested repurposing precision fermentation byproducts as agricultural fertilisers, as part of a circular bio-economy, which could introduce GM-derived material into the wider environment. These scenarios blur the line between contained and open use and suggest that scale, not just setting, will be a critical determinant of risk.

Regulatory Lag and Oversight Gaps

Brewer *et al* (2026) identify a widening gap between regulatory oversight and the pace of deployment of gene edited microbes. Regulatory systems grounded in product- or process-based assessments are struggling to keep up with:

- Engineered persistence (e.g., microbes intended to survive in soil or the gut)
- Distributed delivery models (e.g., seed coatings, direct-to-consumer probiotics)
- Lack of stewardship and post-release accountability

They emphasise that long-term ecological impacts may be impossible to predict using current tools, especially when regulatory regimes exclude living organisms from scrutiny if the final product contains no viable GMOs.

These concerns are real but 'regulatory lag' in this context is not simply a matter of oversight frameworks being temporarily outpaced by innovation. Rather, it reflects a deeper mismatch between regulatory logics developed for discrete, static products and the realities of living, replicating systems deployed at scale. As genetically engineered microbes move into

distributed use – across farms, food systems, waste streams and biological environments – regulatory approaches that focus narrowly on pre-market assessment or initial use conditions struggle to account for cumulative exposure, ecological interaction and long-term persistence. In practice, this lag creates a structural bias toward permissiveness.

Where regulators lack tools to assess long-term or system-level impacts, products are increasingly channelled into regulatory categories that minimise scrutiny – for example, by treating applications as 'contained', 'intermediate', or 'non-viable', even where real-world deployment challenges these distinctions. The result is not an absence of regulation, but a form of regulatory thinning, in which oversight narrows as scale and complexity increase.

Detection and Traceability

Detecting and monitoring gene edited microbes is difficult, but not impossible. Recent analysis suggests that most are in fact traceable using existing molecular tools. According to a 2023 Inf'OGM review, most genetically modified microorganisms (GMMs) involve:

- Known target organisms (usually well-characterised industrial strains)
- Documented genetic changes, often involving coding sequences
- Traceable molecular signatures, even where no foreign DNA is introduced

The authors argue that assertions of undetectability are politically convenient but not technically grounded. While detection may become more complex over time due to mutation or recombination, it is incorrect to assume that gene edited microbes cannot be distinguished from naturally occurring ones – particularly in the case of commercial products where the genetic construct is well defined.

The question of detectability is therefore not primarily a technical one, but a governance choice. While molecular tools exist to identify and

Consumer choice and transparency

As genetically engineered microorganisms move closer to widespread commercial use, questions of consumer choice and transparency become increasingly salient.

Many current and emerging products are produced using genetically modified or gene edited microorganisms but do not contain viable organisms in their final form, placing them outside existing GMO labelling regimes. In addition, in many countries, some gene edited microorganisms fall outside GMO legislation or are assessed via non-GMO pathways, further reducing formal transparency requirements.

Together, these developments can obscure the role of genetic engineering in food, feed and agricultural inputs, limiting the ability of consumers, farmers and downstream users to make informed choices. From a governance perspective, transparency, traceability and clear communication are particularly important in contexts where public acceptance remains uncertain and where microbial technologies are actively framed as contributing to sustainability and environmental goals.

characterise many genetically engineered microorganisms, detection only becomes meaningful when it is embedded within regulatory

obligations for monitoring, traceability and accountability. In the absence of such obligations, detectability remains theoretical rather than operational.

Assertions that gene edited microbes are 'indistinguishable from natural organisms' have played a strategic role in regulatory debates, supporting arguments against labelling, post-release monitoring, or liability. However, these claims often conflate biological complexity with

regulatory convenience. Where genetic constructs are known and commercialised, the challenge is less about scientific feasibility than about whether governance systems require, resource and enforce detection in practice.

As regulatory frameworks increasingly exempt products from oversight based on end-state characteristics – such as the absence of viable organisms – opportunities for traceability diminish upstream. This has implications not only for biosafety monitoring, but for consumer choice, supply-chain transparency and the ability to respond effectively if unintended effects emerge over time.

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Dual-Use and Security Risks

As genetically engineered microbes become more powerful and accessible, concerns about their potential misuse are intensifying. The same properties that make microbes attractive for sustainable agriculture, biomanufacturing, or environmental restoration – such as self-replication, adaptability and microscopic scale – also raise risks in the context of security and defence.

Recent work in biosecurity and strategic risk highlights several plausible vectors for dual-use exploitation. Engineered microbes could be used to disrupt crop systems, degrade soil fertility, or spread toxins, particularly if designed to persist or spread beyond intended boundaries. Other scenarios include interference with critical infrastructure such as water treatment or energy systems through microbial corrosion or contamination.

Military interest in synthetic biology is also increasing. Defence agencies have explored the potential of engineered organisms for surveillance, cleaning up contaminated soil in conflict zones, or even terrain modification. While many applications remain theoretical, rapid advances in gene synthesis, environmental delivery systems and AI-assisted design lower the technical barriers to weaponisation.

The convergence of synthetic biology with artificial intelligence further compounds the risk. Tools that automate strain design or simulate microbial behaviour could be repurposed for malicious ends, enabling faster development cycles and more targeted applications with less specialist knowledge.

Analysts and policymakers are now calling for governance frameworks that explicitly address dual-use potential – not only for high-consequence bioweapons, but for more diffuse, cumulative threats emerging from poorly regulated deployment. Risk assessment processes will need to incorporate intent, capability and systems-level vulnerability, not just product-level safety.

The Contained Use Fallacy

Regulatory frameworks frequently treat "contained use" as a clear and stable category, implying limited exposure and low risk. In practice, containment is often an assumption rather than an outcome. Laboratory incidents, containment failures and accidental releases are a recognised feature of both academic and industrial bioscience, even in well-regulated settings.

In addition, several applications formally regulated as contained use, including live probiotics and microbiome interventions, involve the deliberate introduction of engineered microorganisms into complex, open biological ecosystems – for example the human gut. Taken together, these examples highlight a broader problem: containment is not binary.

Scale, operational complexity, waste handling and deployment pathways can undermine regulatory distinctions that rely on containment as a proxy for limited exposure, particularly where oversight focuses on initial use conditions rather than whole-system lifecycles.

In response to containment concerns, developers and regulators have increasingly pointed to a range of genetic biocontainment technologies engineered directly into organisms – including kill switches, toxin-antitoxin systems, synthetic auxotrophy, orthogonal ribosomes and CRISPR-based kill switches – as evidence that escape risks can be managed without physical containment alone.

These approaches are designed to restrict survival, reproduction or genetic function outside defined conditions, in effect creating microbes that cannot persist in the environment without a specific synthetic input. However, the reliability of these technologies significantly limited in real-world scenarios due to evolutionary pressure, horizontal gene transfer (HGT), and environmental variability.

What's being developed?

The genetic engineering of microbes is no longer confined to laboratory settings or industrial vats. An increasing number of genetically engineered microbial products are moving toward commercialisation in areas ranging from food processing and animal supplements to biofertilisers, biocontrol agents and other applications involving direct interaction with living systems.

While many current uses are still regulated as contained (for example, food-grade fermentation), the development pipeline increasingly includes products designed for intentional environmental or biological exposure, particularly in agriculture and ecosystem management.

These developments are not merely technical. Genetically engineered microorganisms are now being actively promoted as foundational tools of a "green" or "sustainable" bioeconomy – positioned as solutions to climate change, resource efficiency, food security and reductions in chemical inputs. This framing places living, self-replicating organisms at the centre of sustainability strategies across multiple sectors.

To reflect differing use contexts and their regulatory implications, the examples below are organised into three broad groups: applications generally treated as contained use; applications involving intentional environmental release; and a third category of enabling platforms and pipeline applications that underpin multiple downstream uses. The examples provide a selective snapshot of genetically engineered microbial development globally. They are not comprehensive, but illustrate both the breadth of current innovation and the direction of travel as regulatory frameworks begin to loosen in some jurisdictions.

Food, Feed and Industrial Use

Food, beverage and fermentation cultures

Genetically engineered microbes are now widely used as production organisms in food and beverage fermentation, including for flavour compounds, sweeteners, enzymes and animal-free proteins. Recent reviews describe this as one of the most mature application areas, with gene editing used to optimise metabolic pathways, improve yields and tailor sensory properties in yeast and bacterial strains.

These applications are typically regulated as contained use, on the basis that the microorganisms are removed or inactivated during processing and are not present as viable organisms in the final product. However, the scale at which starter cultures are deployed and the increasing reliance on engineered production strains across multiple food categories, raises questions about containment assumptions, waste handling and traceability.

Table 1 – Food, beverage and fermentation cultures

Company and country	Product	Application	Status
Impossible Foods, USA	Soy leghemoglobin ('heme') – a food-grade hemoprotein originally from soy roots, produced at scale by a genetically engineered yeast (*Pichia pastoris*).	Meat alternative flavour.	2018 – FDA "no questions" approval. 2019- commercialised in the USA. 2024 – EFSA issued a positive opinion on the safety of the ingredient.
Cargill & DSM, USA/ NL	EverSweet® Stevia Sweetener – made with GM yeast strains.	Sweetener.	Approved and sold in USA, Canada 2024 – EFSA and FSA issues positive safety opinions.
Remilk, Israel	Remilk Animal-free dairy protein Komagataella phaffii yeast engineered with cow milk protein genes to produce whey (β-lactoglobulin.	Dairy replacement.	2025 – launched in Israel, US launch expected in 2026.
Perfect Day, USA	ProFerm – Animal-free Whey Protein engineered filamentous fungus (Trichoderma) or yeast that carries the gene for bovine β-lactoglobulin (the main whey protein).	Dairy replacement.	2020 – FDA confirms its GRAS (Generally Recognized as Safe) status. Fully commercial. 2025 – lawsuit filed claiming GM fungal protein levels higher than claimed.
Evola/ Allytix, CH/ USA and Isoibionics, NL	Both companies have developed a 'nookatone' (grapefruit flavour/aroma) product using engineered microbes.	Flavour & biopesticide.	2010s – commercialised by Evola/Allytix. 2015 – US EPA approved nookatone as a biochemical pesticide.
KnipBio, USA	KnipBio Meal is a single-cell protein for aquaculture made from *Methylobacterium extorquens*, including genetically engineered strains designed to enhance nutritional value.	Aquaculture feed.	2020 – reported as "*the first genetically engineered SCP product to obtain GRAS (generally regarded as safe) recognition by the US Food and Drug Administration.*" Unclear if it is now being sold.

Industrial bioproductions

Industrial bioproduction represents the largest and most established category of genetically engineered microbial use, encompassing microbes engineered to produce biofuels, chemicals, industrial enzymes and biomaterials. These microbes are almost universally regulated under contained-use frameworks. While this category is often treated as low risk from a regulatory perspective, there are increasing questions about large-volume fermentation and waste streams, which complicate simple distinctions between containment and environmental exposure.

Table 2 – Industrial bioproduction

Company and country	Product	Application	Status
Novenesis, DK	Innova® family of yeasts.	Bioethanol production and animal feed.	Widespread use in USA, Brazil, Canada. 2024 – approved in Argentina for bioethanol production.
Mascoma and Lallemand Biofuels & Distilled Spirits, USA	Transferm™ – genetically engineered industrial yeast .	Bioethanol production.	Used in USA and potentially elsewhere.
Novenesis	Cellerity® 1.0 designed for 2G (cellulosic) ethanol production, capable of fermenting both glucose and xylose released from biomass such as corn stover, sugarcane bagasse, wheat straw, etc.	Second-gen (cellulosic) ethanol fermentation (glucose + xylose).	Commercially available worldwide, with real deployment in US and Brazil, plus pilots/demos in Europe and Asia.
Lesaffre (LEAF – Lesaffre Advanced Fermentations)	CelluX™ engineered for tolerance to inhibitors, variable pH and harsh industrial 2G processing conditions.	Cellulosic ethanol from lignocellulosic feedstocks.	Commercially offered globally, with the strongest real-world use in Brazil and emerging use in US, Europe and India,
Developed originally by Toyota Central R&D, now commercialised by Lallemand LBDS.	XyloAce™ – Genetically engineered yeast capable of fermenting glucose, xylose and arabinose, making it one of the few commercial strains that utilise multiple pentose sugars simultaneously.	Converts glucose, xylose, arabinose for advanced ethanol.	Commercially available worldwide, with verified roots in Japan and marketing presence in US and Canada.
Lallemand/ Mascoma, USA	Sourvisiae® Yeast.	Bioengineered brewing yeast allowing brewers to ferment and sour the beer in one step.	Commercial in USA, other markets unclear.

Health Applications

Pharmaceutical and therapeutic applications of genetically engineered microorganisms are a significant area of CRISPR microbial engineering, particularly for the production of enzymes, vaccines, antibodies and other biologically active compounds. These applications are not covered in detail in this briefing, as they generally follow distinct regulatory pathways with containment, quality control and post-market surveillance requirements. They are included here for completeness and contrast with other contained-use categories that operate under less specialised oversight.

Probiotics and microbiome applications

A growing body of CRISPR microbial engineering research focuses on probiotics and other microbes intended to function within human or animal microbiomes, including strains engineered to deliver enzymes, modulate metabolism, or suppress pathogens.

Although such applications are typically regulated as contained use or as food, feed, or supplement products, they involve the deliberate introduction of live genetically engineered microorganisms into complex, dynamic biological ecosystems.

This places them in a regulatory grey zone: formally treated as contained, yet biologically deployed in open systems with potential for persistence, gene transfer and downstream environmental exposure via shedding and waste pathways

Table 3 – Probiotic applications

Company and country	Product	Application	Status
Zbiotics, USA	ZBiotics® Pre-Alcohol Probiotic Drink breaks down an unwanted alcohol byproduct called acetaldehyde – apparently linked to hangovers. (FOR HUMANS).	Hangover-targeted probiotic.	2019 – launched in the US, described as "*likely the world's first genetically engineered probiotic.*"
Zbiotics, USA	ZBiotics® Sugar-to-Fiber is an engineered *Bacillus subtilis* probiotic (strain ZB423) that expresses the enzyme levansucrase, which converts dietary sucrose into levan – a prebiotic soluble fibre.	Probiotic supplement.	2024 – launched in the USA as a daily supplement (powder form).
BiomEdit, USA	BE-101 (Optavant™) is the first probiotic-based product engineered to deliver antibodies that neutralize Clostridium perfringens toxins, targeting the main cause of necrotic enteritis in poultry.	Probiotic animal feed additive for disease resistance.	2025 – company reported that the product has entered the final phase of the U.S. Department of Agriculture's (USDA) conditional licensure process and is advancing toward commercialization, expected in 2026.
Folium Science, UK	BiomElix® One – GM *E. coli* to suppress *Salmonella* in chickens.	Live genetically engineered probiotic for pathogen suppression in poultry (regulated as feed additive).	2024 – approved by Brazil's Ministry of Agriculture for use as an animal feed additive and included in their Positive List of Feed Ingredients. Reportedly close to commercialisation in Brazil.
Folium Science, UK	Guided Biotics® CRISPR-based system for reducing Campylobacter in poultry production.	Pathogen control in poultry.	2024 – awarded a Defra grant through Innovate UK to further develop the product.

Environmental Applications

Environmental applications represent the most challenging and least reversible uses of genetically engineered microorganisms. Unlike contained industrial or food-production systems, these applications are explicitly designed to function in open environments – including soil, water, crops and other ecological systems – where containment, recall and long-term control are inherently limited.

Once released, engineered microbes may persist, spread, exchange genetic material with existing microbial communities, or evolve in ways that are difficult to predict or monitor using current risk assessment tools.
As a result, environmental applications place the greatest strain on regulatory assumptions

developed for contained use, non-viable end products, or static organisms and raise distinct questions about ecological uncertainty, stewardship and accountability.

The examples below illustrate that such uses are no longer purely experimental, but are moving steadily from research and pilot stages toward wider deployment, often under regulatory categories not originally designed for living, adaptive systems interacting with complex ecosystems.

Agricultural inputs & plant-associated microbes

Genetically engineered microbes are increasingly being developed for direct use in agriculture, including as biofertilisers, seed coatings, soil inoculants and biological pest or disease control

Table 4 – Agricultural inputs and plant-associated microbes

Company and country	Product	Application	Status
Pivot Bio, USA	PROVEN 40 and PROVEN G3 – gene edited nitrogen-fixing bacteria.	Biofertiliser (seed coating / inoculant).	Commercially available in the US. Their 2024 impact report states that their products have been used on nearly 15 million acres, across 6,147 fields in 34 states.
BioConsortia	Fixi 33 / Always-N – gene edited nitrogen-fixing seed treatment.	Nitrogen-fixing seed treatment.	2024 – launched in New Zealand in collaboration with seed company H&T, under the produce name 'Fixi 33'. August 2025 – announced that they are preparing to launch across North and South America.
Elemental Enzymes / BASF, USA	Bacillus thuringiensis EX297512 (TWO.O).	Engineered Bt spores delivering growth-enhancing enzymes as seed or soil treatment.	Commercialized by BASF in 2019 as part of Poncho/VOTiVO 2.0 seed treatment.
Switch Bioworks	Microbial fertiliser.	Powder to deliver microbes directly to roots.	R&D.
Ginkgo and Bayer	Microbial fertiliser .	Seed-coating.	R&D.
Novonesis	Soil/plant 'biosolutions' (e.g. plant health and yield enzymes).	Soil/plant health improvement.	R&D.

Unknown developers, Brazil	Gene edited nitrogen-fixing bacteria.	Biofertiliser.	Approved as an "Innovative Genetic Improvement Technology" (equivalent to PBO. [Reportedly in market development]().
Unknown developers, Brazil	A modified strain of *Bacillus thuringiensis israelensis* (*Bti*), a naturally occurring soil bacterium. Insertion of a β-1,4-endoglucanase gene (a cellulase enzyme) from another bacterium so microbe breaks down cellulose improving soil conditioning.	Soil conditioner (breaks down organic matter).	Approved as an "Innovative Genetic Improvement Technology" (equivalent to PBO. [Reportedly in market development]().

agents. Unlike fermentation-based applications, these products are designed for intentional release into soils, plant roots, seeds, or livestock environments, where they interact with complex and dynamic microbial communities.

Although often promoted as sustainable alternatives to chemical inputs, such applications raise distinct biosafety and governance challenges due to their potential persistence, spread and horizontal gene transfer in open ecosystems.

Beyond products currently approaching market, the research pipeline for genetically engineered microbial applications is extensive. In 2024, Miklau *et al*, as quoted in GeneWatch (2025), identified dozens of projects at both application-oriented and basic research stages, particularly in agricultural biocontrol, plant-associated microbes and aquaculture systems.

At the application-oriented stage, 17 genetically engineered microbial biocontrol products are under development, with a further 17 projects at the basic research stage. These systems commonly involve bacteria and micro-fungi that naturally occur in soil or agricultural environments and are engineered to infect or suppress pest species, including insects and locusts. Their use would involve deliberate interaction with open ecosystems and existing microbial communities.

Miklau *et al* also describe six advanced research applications involving freshwater and marine

algae, including *Chlamydomonas reinhardtii* and and *Nannochloropsis* species, developed for disease control in aquaculture through the production of vaccines, antivirals, antimicrobials, or antibiotics. Such applications blur conventional distinctions between contained production and environmental release, particularly where live organisms are deployed in aquatic systems.

A further area of activity is paratransgenesis, in which genetically engineered microbes that naturally inhabit plant tissues or insect guts are used as delivery systems for pest control. One application-oriented project targets the glassy-winged sharpshooter using engineered *Pantoea agglomerans*, while three additional studies at the basic research stage explore similar approaches for aphids, nematodes and other pests.

From a governance perspective, this body of research is significant not because individual projects are near commercialisation, but because it demonstrates the breadth and maturity of development pathways aimed at environmental deployment. As regulatory frameworks evolve, such pipelines increase the likelihood that these agricultural applications will move rapidly from research into practice, often ahead of tailored oversight mechanisms.

Environmental & bioremediation applications

Beyond agriculture, genetically engineered microbes are also being developed for environmental sensing, remediation and ecosystem-level

Table 5 – Environmental & bioremediation applications

Company and country	Product	Application	Status
University of Tennessee, USA	Pseudomonas fluorescens HK44.	Help scientists detect and monitor the toxic chemical naphthalene. The bacterium glows if it senses naphthalene and helps metabolise it.	2003 – approved for field trials in the US.
Unknown developer	Engineered *Nannochloropsis oceanica* with bicarbonate transporter	Carbon capture and fluorescence biosensor.	2024 – approved for open pond trials in the US (p112-3).

interventions, including pollutant degradation, wastewater treatment and carbon capture. CRISPR-based engineering is used to enhance metabolic capacity, environmental responsiveness, or survivability in non-controlled settings.

These applications represent some of the most uncertain and difficult-to-govern uses of engineered microorganisms, as they are explicitly designed to function in open environments where containment, recall and long-term monitoring are inherently limited.

Table 5 includes both an historical and an emerging example of genetically engineered microorganisms developed for environmental sensing, remediation and ecosystem-level applications, illustrating that intentional environmental release is not new, but is evolving in scale, scope and technical sophistication.

Enabling Platforms and Pipeline Applications

Alongside products developed for specific end uses, a growing share of genetic engineering activity in microbes is focused on enabling platforms and pipeline applications.

These include advanced strain-engineering systems and research organisms used to develop, test and scale genetic tools, rather than to function as final products in their own right.

Although typically developed under contained-use conditions, these platforms shape downstream deployment across food, agriculture, environmental and health applications. Their regulatory significance lies less in immediate release than in how they lower barriers to scale, standardise genetic modification and accelerate the movement of engineered microbes into multiple use contexts.

Advanced strain engineering and platform development

A significant share of current activity in microbial genetic engineering is focused not on single end-products, but on the development of advanced strain-engineering platforms designed to support multiple downstream applications.

This includes the growing use of multiplex genome editing, reusable microbial chassis and automated design–build–test–learn systems to accelerate strain optimisation and scale-up across food, industrial, agricultural and environmental contexts.

These platform approaches are typically developed under contained-use conditions, but are explicitly intended to reduce technical barriers, standardise genetic modification and enable rapid redeployment of engineered traits across diverse use cases. As such, their regulatory relevance lies in their cumulative and enabling effects, rather than in any single product outcome.

Research, model systems and tool development

Alongside commercial and near-market activity, CRISPR-based microbial engineering continues to rely heavily on research organisms, model systems and tool-development platforms used to test, refine and extend genetic technologies. [This includes](#) microbes and microbial systems engineered to improve editing efficiency, develop and apply new CRISPR variants, explore delivery mechanisms and study stability and interaction in biological systems.

Although typically framed as research-stage or proof-of-concept work, these systems frequently form the foundation for later commercial applications, with tools and organisms transitioning from laboratory studies into agricultural, food, or environmental deployment. Their significance for governance lies in the way they shape the pace, direction and feasibility of future applications, often well before regulatory frameworks engage with end uses.

For example, research groups at UCLA/ Innovative Genomics Institute, USA [have developed](#) virus-mediated CRISPR delivery platforms, such as systems based on Tobacco rattle virus, that enable gene editing in plants via seed coatings or foliar sprays without stable insertion of foreign DNA.

These systems are used as research and tool-development platforms to test delivery efficiency, editing outcomes and heritability and illustrate how microbial and viral tools developed at the research stage can rapidly feed into agricultural deployment pathways.