The impact of regulatory sandboxes for emerging foods

Biosolutions Forum+

> Biosolutions are expected to become a major driver of growth and employment.
>
> Anne Lerche
> Alliance for Biosolutions

Index

Foreword

Biosolutions have the potential to strengthen food security, accelerate the green transition, and create new industrial opportunities. Yet innovation only delivers value when it reaches the market.

If Europe is to lead the green transition, be resilient, obtain food security and secure competitiveness, it must tackle unnecessary regulatory red tape that prevents safe biosolutions from reaching the market.

While the current system provides a globally recognized benchmark for food safety, companies consistently describe challenges related to regulatory uncertainty, lengthy approval procedures, and limited opportunities for early dialogue with authorities.

It is important to acknowledge that either regulation evolves alongside innovation, or innovation will increasingly evolve elsewhere.

Denmark is uniquely positioned to lead this development. Building on more than a century of scientific excellence Denmark has developed one of the world's strongest biosolutions ecosystems.

Translating this scientific leadership into European industrial leadership now requires regulation that evolves alongside technological progress. Ultimately turning Denmark into a **Centre of Excellence** for biosolutions, including emerging foods.

The purpose of this report is to make illustrations and proposals regarding novel and emerging foods to create better conditions for innovators, and to make concrete proposals for influencing practice and regulation. The aim is to:

- Illustrate the regulatory barriers and the need for experimental regulations in emerging foods - based on interviews with pioneering companies.
- Present regulatory sandboxes as a tool to create temporary pilot projects establishing better approval processes to the benefit of companies and to create mutual learning between innovators and regulators.
- Propose EU's Innovation principle as a help making innovation-friendly regulation and changing practice within current regulations - also allowing step-by-step documentation of evidence.
- Allow close collaboration between regulatory sandboxes and Biosolutions Forum+, to represent a journey towards a more adaptive, innovation-friendly regulatory framework built on continuous regulatory learning.
- Argue that EU's Biotech Acts should include regulatory sandboxes for novel foods and establish simple conditions allowing derogations from current regulations, when outdated, and consider temporary national approvals.
- Argue for a Danish Act on regulatory sandboxes - with inspiration from Germany and partly France.

> If we had the courage to fulfill our innovation potential Denmark should become a regulatory sandbox for the world - a place where we dare to test new solutions, learn quickly, and develop regulation alongside innovation rather than after it. If we can create the right framework for innovation here, we can show how smart(er) regulation can accelerate Europe's resilience, food security, competitiveness and green transition at the same time.
>
> Tina Sejersgård Fanø, Novonesis

The ambition is that new regulations - the Biotech Act 1 and 2, the Innovation Act, Omnibus X on Food and Feed etc.- will make the necessary changes. Efforts are made to influence the building of this new legal landscape, but the changes are very time-consuming, as negotiations and implementation take time.

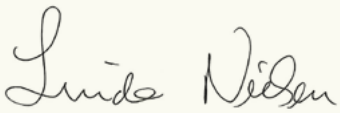
While waiting, it is important to prepare for the changes and propose what can be done, lawfully, while that legal basis is still being built. Innovation-friendly practice is essential - and both the Danish Business Authority, The Danish Veterinary and Food Administration and European Food Safety Authority (EFSA) have shown openness to change.

The Danish *Biosolutions Forum+* is fostering collaboration between the Danish ecosystem of biosolutions – researchers, companies, authorities etc. - and can act as a facilitator, bridgebuilder and knowledge broker.

This report illustrates regulatory barriers and proposes regulatory sandboxes for novel foods, interpretations, collaborations and new regulations that can break down some of these barriers and encourage innovation. The vision is to pave the way to help strengthening Denmark's and Europe's ability to bring safe, sustainable and commercially viable innovations to market faster and more predictably.

Finally, I would like to express my sincere gratitude to the companies and experts who generously shared their time, experience and practical insights to make this report a reality. Their willingness to openly discuss both challenges and opportunities has been invaluable in shaping the findings and recommendations presented:

- Algiecel
- Arla Foods Ingredients
- Bactolife
- BioCulture Nordic
- CariGuard
- Chromologics
- Luvi Bio
- Novonesis
- Spora
- Unibio



Linda Nielsen, Chair of Biosolutions Forum+

Executive Summary

Based on interviews with companies across the Danish biosolutions ecosystem, this report finds broad agreement on the main regulatory challenges caused by the EU Novel Foods Regulation.

European companies experience uncertainty regarding product classification and evidence requirements, limited opportunities for early engagement with regulators, lengthy authorization procedures, and repeated delays during the assessment process (clock-stops).

For many SMEs and start-ups, these obstacles represent a significant commercial risk, despite confidence in the underlying safety assessment system. The EU approval system for novel and emerging foods, built for another era, risks becoming the binding constraint on the competitive advantage Denmark and EU have built.

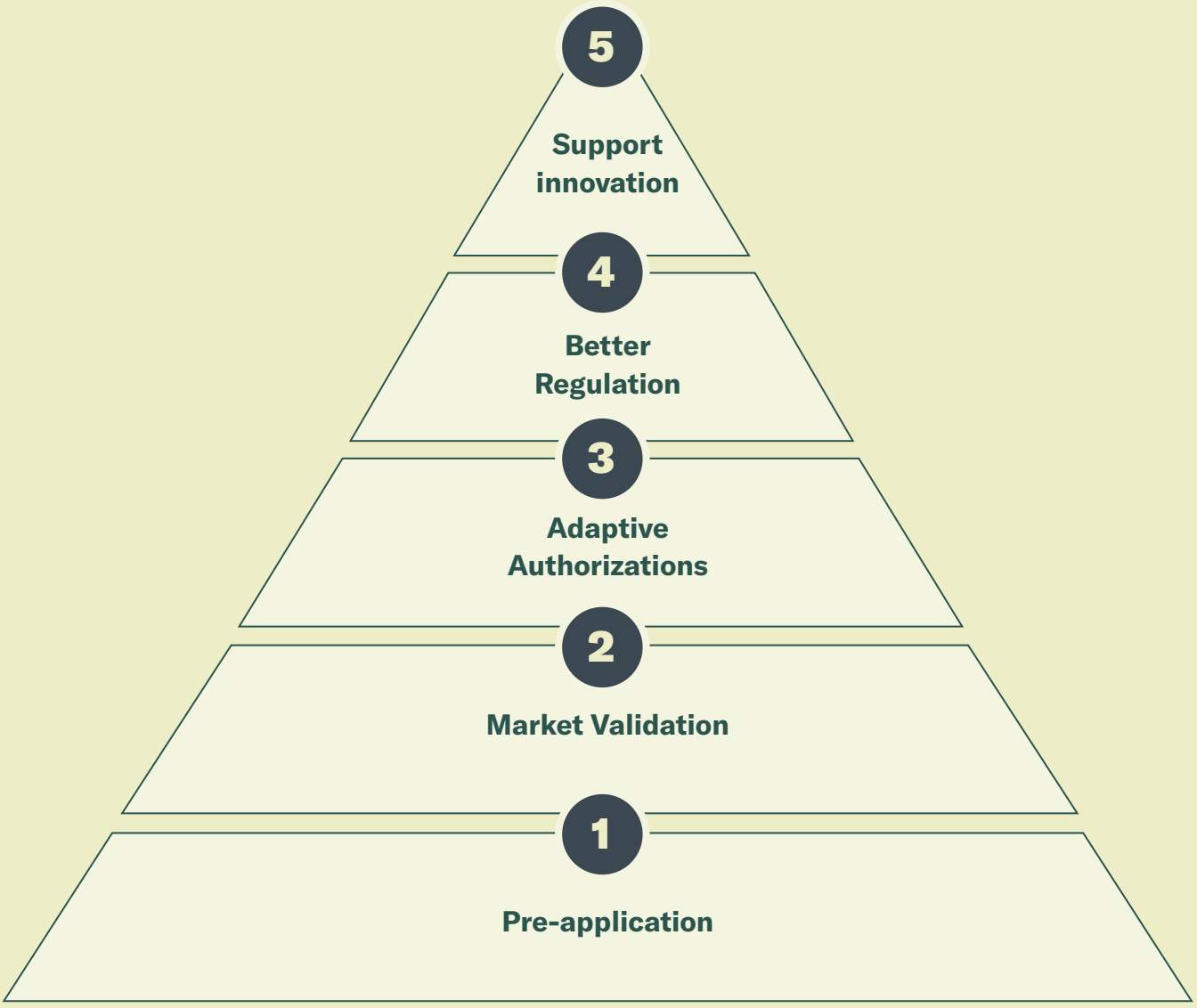
Regulatory sandboxes offer a practical mechanism for improving the authorization process without lowering safety standards.

By facilitating structured dialogue between companies and authorities, supporting evidence generation, and strengthening regulatory learning, regulatory sandboxes can reduce uncertainty and accelerate safe market access.

Biosolutions Forum+

Biosolutions Forum+ is a public-private platform that connects companies, NGO's, academia and authorities with the aim of accelerating the development of sustainable foods and climate solutions in Denmark and the EU through more innovation-friendly regulatory pathways. The forum is chaired by Professor of Law Linda Nielsen. The forum is kindly supported by The Novo NordiskFoundation.

Figure 1: The key elements of a regulatory sandbox for novel foods and emerging foods



A regulatory sandbox on novel and emerging foods and ingredients could consist of 5 key elements, which are interconnected, and can be seen as **building blocks**, representing increased levels of regulatory ambition. They take pending EU proposals of importance into consideration and can in the process benefit from the fact-finding missions facilitated by Biosolutions Forum+ outside of the EU, creating inspiration for the functioning of the emerging foods regulatory sandbox.

Regulatory sandboxes are not an objective in themselves but are instruments for creating a more adaptive relationship between innovation and regulation. Their greatest value may be their ability to operationalize *EU's Innovation Principle* and create continuous regulatory learning that benefits companies, consumers and society at large.

Companies can get help navigating regulatory requirements to achieve earlier regulatory certainty, lower development costs, faster access to market, better investment conditions and reduced risk of failed regulatory strategies. The hope is that many companies will participate in regulatory sandboxes and the Biosolutions Forum+.

Consumers can obtain a variety of healthy sustainable food, where food safety is secured and food security is on the agenda. It is important that consumers are involved in the process, including use of tasting to build up market validation.

Society can achieve faster access to safe and sustainable food innovations, increased competitiveness, greater food security and resilience, higher private investment in biosolutions, including emerging foods and more rapid commercialization of green technologies.

Authorities can achieve better understanding of emerging foods technologies, identify regulatory gaps and improve guidance and regulatory practice. They should be encouraged to use EU's Innovation Principle in their practice, to live up to Draghis and EU's wish for more simplicity and innovation-friendly regulation and interpretation.

*Policymakers s*hould support innovation in emerging food technologies, by establishing regulatory sandboxes in the field. It is also important to continue the influence on the EU Biotech Acts, where the Danish Government proposes accepting regulatory sandboxes on novel foods and derogations from outdated national and EU regulations. It seems worth considering creating a legal basis for regulatory sandboxes in Denmark.

What is a regulatory sandbox?

A regulatory sandbox is a *controlled setup* where companies and competent authorities collaborate to test innovative products or technologies under regulatory supervision while maintaining high standards of safety. The innovation can be developed, tested and assessed in relation to applicable, and potentially temporary, regulatory frameworks in collaboration with relevant authorities in a controlled and secure environment. The sandbox must help ensure that innovative products and solutions can be approved and brought to market more quickly. At the same time, they must contribute to regulatory learning[1].

What are emerging and novel foods for Biosolutions?

Within biosolutions, novel and emerging foods are foods or ingredients not consumed significantly in the EU before 15 May 1997. Whether a product is novel depends on its specific ingredients and production process. Thus, not all biosolutions are novel foods, while familiar foods may fall under the Novel Food Regulation if they contain new ingredients or are made using new processes.

Examples include:

- proteins produced through precision ermentation;
- cultivated meat or seafood derived from cell cultures;
- new foods derived from algae, fungi, or microorganisms;
- foods produced using new processes, such as certain forms of UV treatment or nanotechnology.

It is argued that the authorities can use *EU's Innovation Principle* more actively - with due caution, and in dialogue with The Danish Business Authority, The Danish Veterinary and Food Administration, EFSA and the European Commission. This should be backed up at political level.

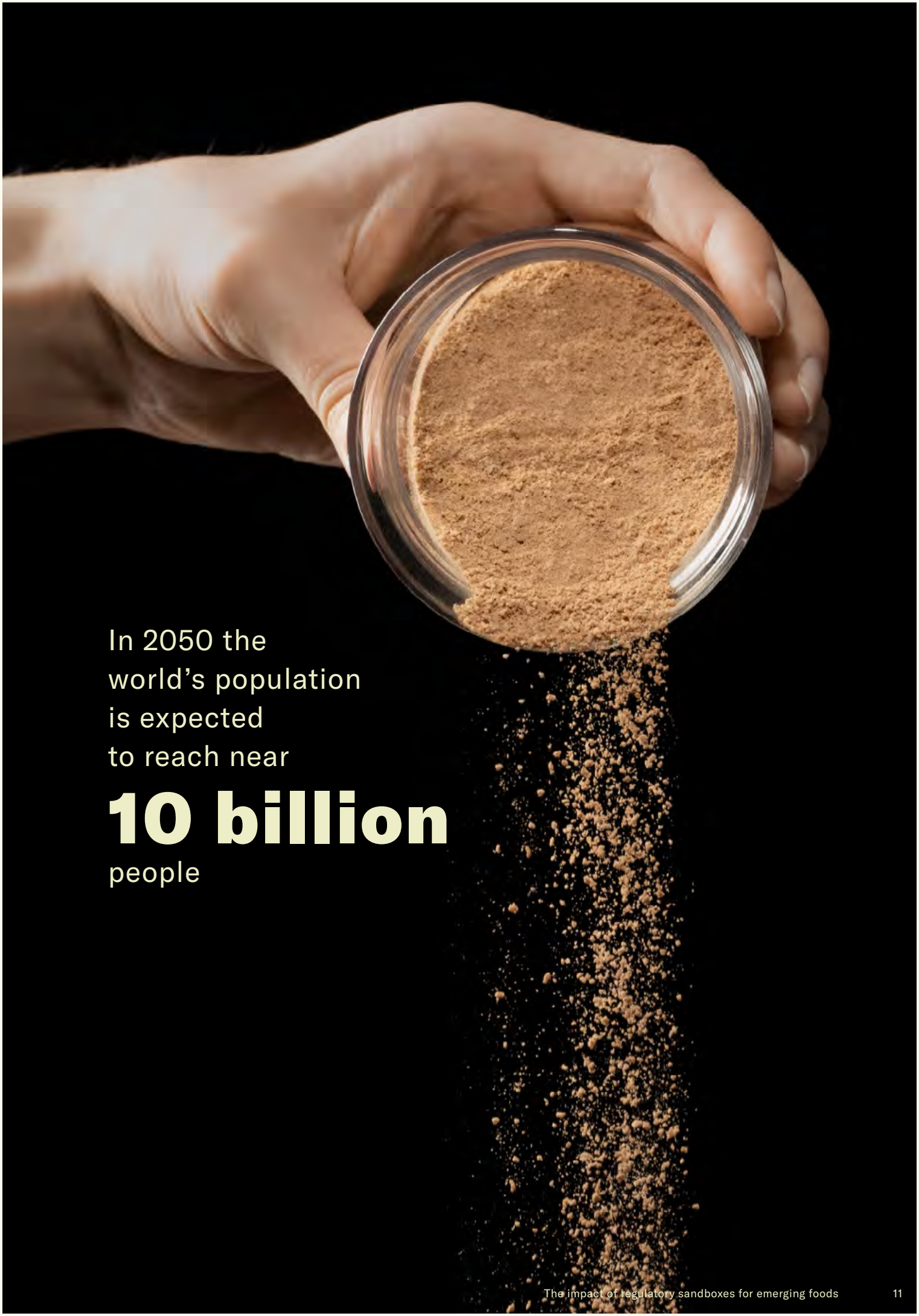
Adaptive authorization is crucial for the companies and this report analyzes the potential for changes of practice while waiting for new legislation. The proposal includes concrete building blocks, including for example risk-proportionate and technology-specific documentation requirements, limiting of clock-stops in EFSA, accept well-documented derogations from outdated national and EU rules, a Danish fast track for emerging and novel foods with low risk and high impact etc.

Finally, this report proposes how Danish regulatory sandboxes and the Biosolutions Forum+ can operate as two halves of the same engine. One generating evidence under authority supervision. The other is converting that evidence into EU-level policy change. Used together, and used now, they offer Denmark a legitimate, cautious, but genuinely offensive route to shaping the practice and influence on the EU Biotech Acts.

Regulatory sandboxes have the potential to function as drivers of innovation in novel and emerging foods. But to unleash this potential it is crucial to accept real flexibility and empower them to change mindset and practice. It has been said that the next competitive advantage is adaptability.

Why novel foods?

This report focuses on novel and emerging foods because they have significant potential to reduce CO_2 emissions and supplement or replace meat-based protein. At the same time, the sector faces substantial regulatory and legal barriers. The interviews illustrate these challenges and provide the basis for proposing a novel foods Sandbox. Such a sandbox could help address regulatory obstacles and create better conditions for bringing novel and emerging food products to market more easily, affordably, and quickly.


In 2050 the
world's population
is expected
to reach near
10 billion
people

The Potential of novel foods

Novel foods offer considerable potential. According to estimations from The Danish Chamber of Commerce (2026) there is currently around 4,500 Danish jobs in the sector of emerging and novel foods and ingredients (biosolutions within foods), and the number is expected to increase significantly towards 2035[2].

By 2050, the world's population is expected to reach near 10 billion - around 20% more people than today[3]. Scenario modelling based on the EAT–Lancet Commission's recommendations indicate that changes in dietary patterns, increased productivity and reduced food waste could make it possible to feed this growing global population with total production only around 8% higher than in 2020 while respecting planetary boundaries.

At the same time, food systems are the largest contributor to the transgression of five planetary boundaries and account for approximately 30% of global greenhouse gas emissions.

The strategic potential is further strengthened by the EU's dependence on imported protein: approximately 94% of the soy protein and 74% of the high-protein plant feed used in the EU is imported[4]. Novel and emerging foods could help meet growing nutritional needs with fewer resources, while supporting supply security, climate objectives and new income streams for agriculture.

Figure 2: Approvel processes across USA, Singapore and the EU

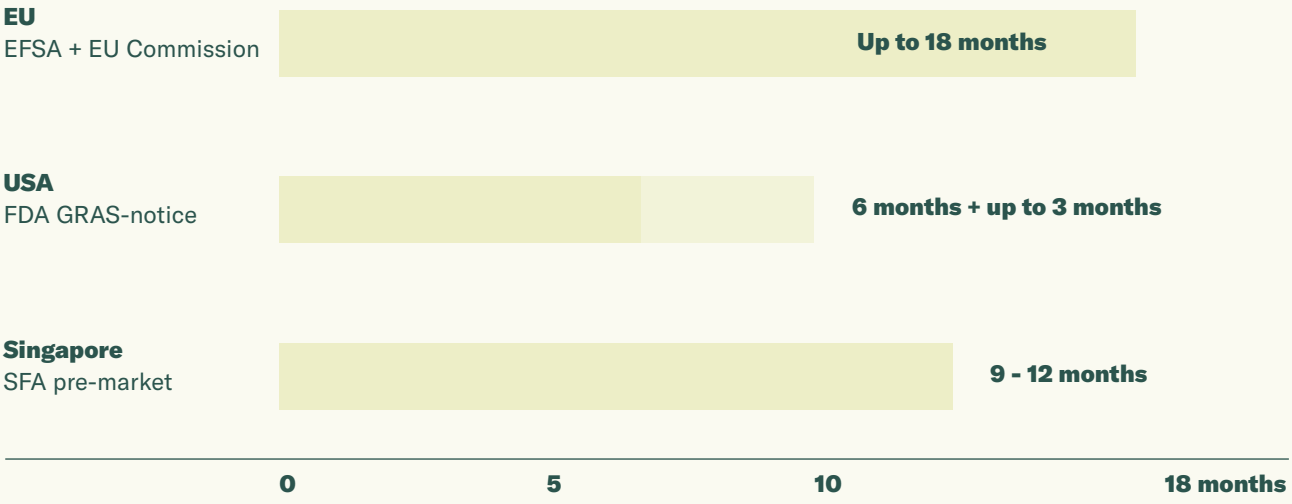


Photo: Spora

Case

Rapeseed oil press cake provides a clear illustration of an untapped potential. Upcycling this side stream could provide enough protein to meet the annual needs of an estimated **8–13 million adults** or enough dietary fibre for approximately 14.5 million people. In Denmark alone, upcycling **533,500 tonnes of rapeseed oil** press cake into food products annually (e.g with fermentation technology) has been estimated to generate an economic impact of approximately **USD 313.4 million**, including market value, savings in waste-management costs, and wider economic contributions[5].

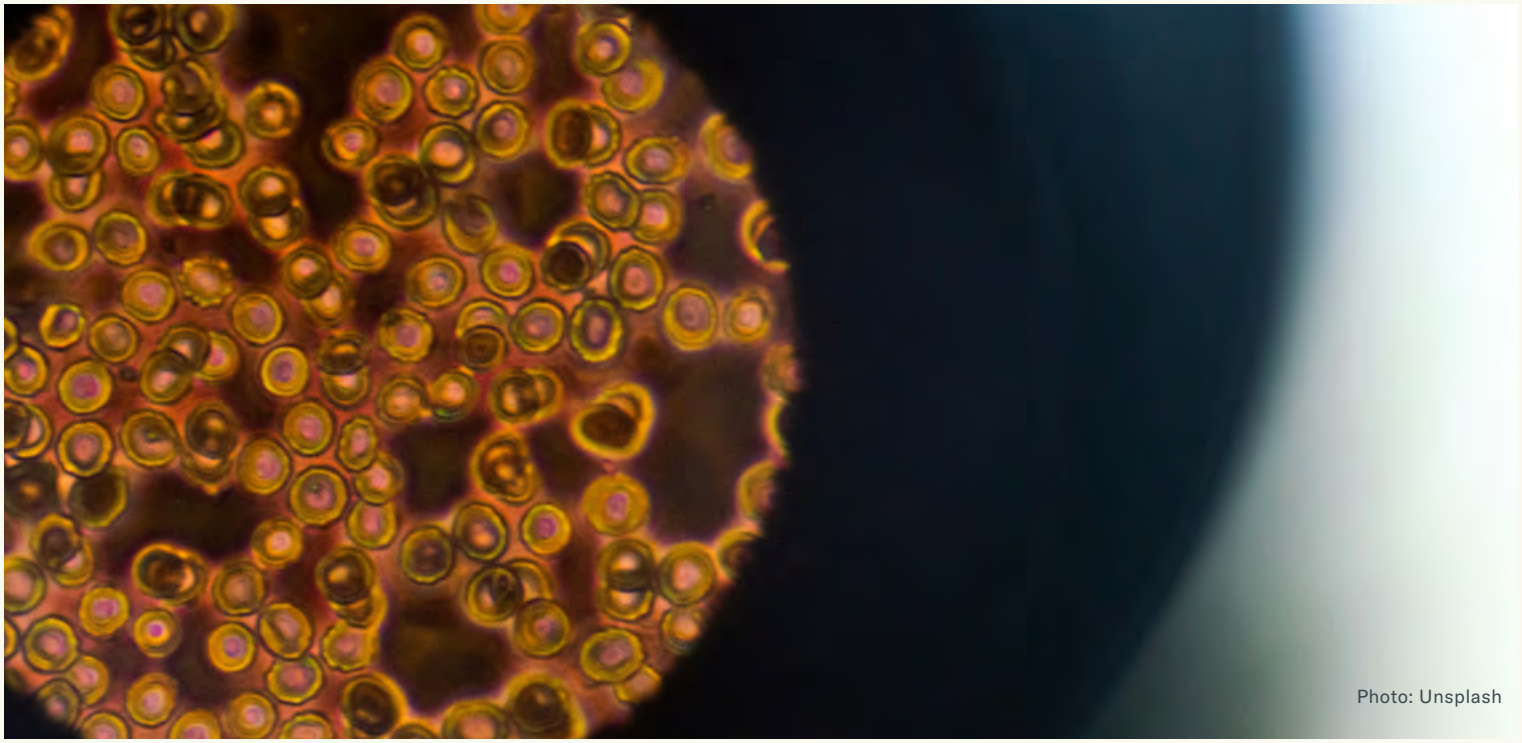


Photo: Unsplash

The need for a more agile EU Novel Foods Regulation

The EU Novel Foods Regulation plays a vital role in ensuring high-level standards of food safety and consumer confidence when new food products and ingredients are introduced to the European market.

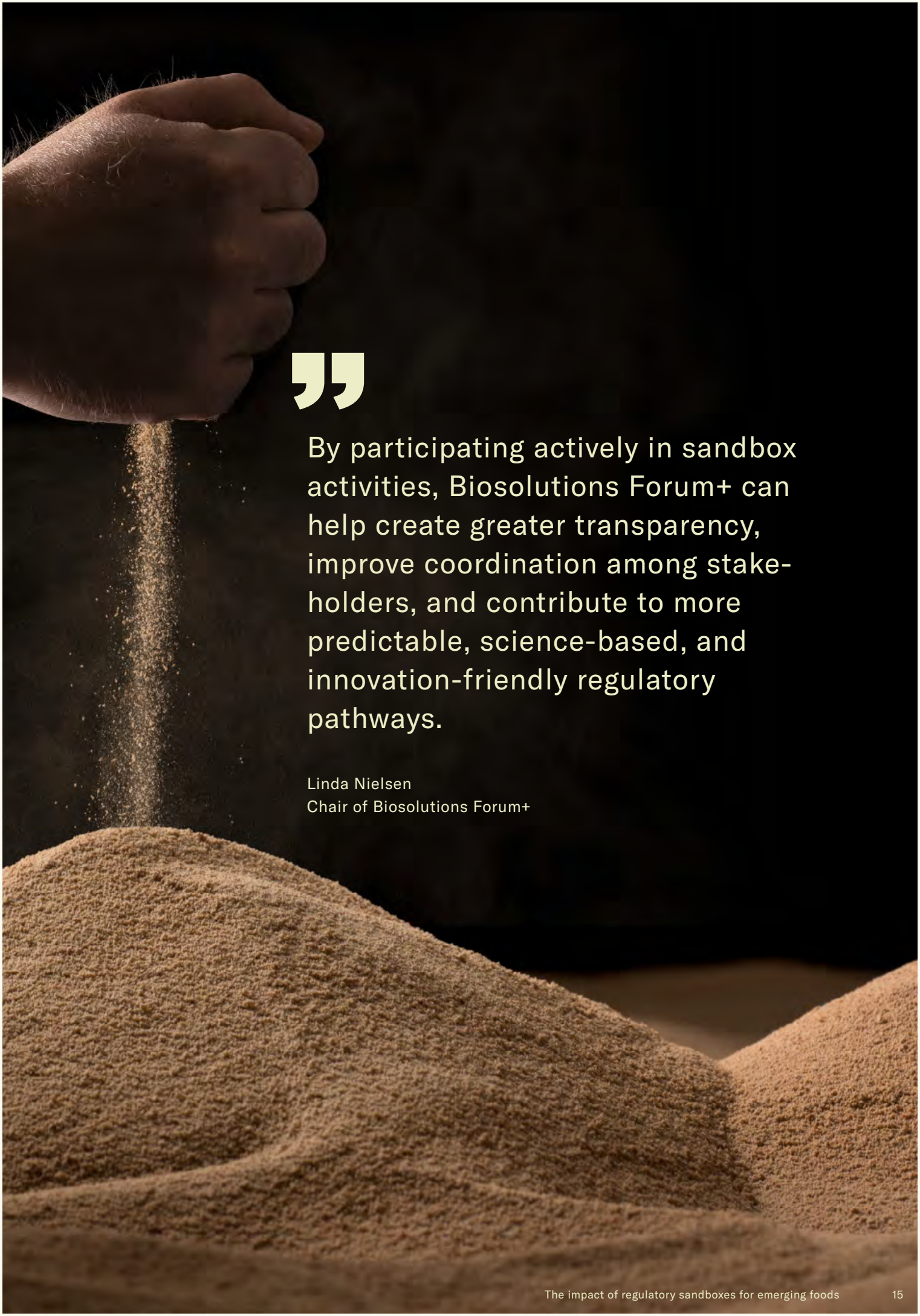
Preserving these standards remains essential. However, experiences from the Danish biosolutions sector indicate that the current regulatory framework can also create uncertainty, lengthy approval timelines, and significant costs that slow the commercialization of safe, more sustainable, less harmful and innovative products.

This report is based on interviews with 10 companies across the Danish biosolutions ecosystem, ranging from start-ups and SMEs to established global companies operating at both the European and global markets, and covering a broad spectrum of emerging foods technologies and ingredients. Although their products and business elements differ, the companies consistently point to challenges related to regulatory predictability, including uncertainty around product classification, evidence requirements, study design, and regulatory timelines in the EU.

These challenges can all together result in unnecessary costs, repeated studies, and delayed market entry, particularly for smaller companies with limited financial resources. If the EU fails to act, Europe will miss out on new food innovations, benefiting consumers, job creation and export opportunities.

The purpose of this report is to identify opportunities to improve how the framework operates in practice. Drawing on industry experiences, it examines where regulatory barriers arise, explores measures that can increase transparency and predictability within the existing legal framework, and assesses how regulatory sandboxes can support earlier dialogue, more efficient evidence generation, and faster pathways from innovation to commercialization.

Ultimately, this report seeks to contribute to the development of an EU regulatory system that continues to safeguard consumers while better supporting Europe's ambitions to lead in sustainable food innovation and biosolutions and ensure European food security and strengthened autonomy.



> By participating actively in sandbox activities, Biosolutions Forum+ can help create greater transparency, improve coordination among stakeholders, and contribute to more predictable, science-based, and innovation-friendly regulatory pathways.

Linda Nielsen
Chair of Biosolutions Forum+

The EU Regulatory Architecture for novel foods

Novel foods sit at the intersection of two regulatory ambitions. The first is food safety, which in the EU is organized around the precautionary principle, centralized scientific risk assessment through the European EFSA, and harmonized authorization before market access in the EU.

The second is innovation policy, which prizes speed, proportionality, legal certainty and the ability of SMEs to reach a market without being priced out by process.

This report maps where innovators face regulatory barriers, where EU's two ambitions collide for novel foods, ingredients etc. and tools currently on offer – and under construction – to reconcile them.

According to the EU, novel foods defined as foods not being consumed before 1997 – almost 30 years ago! The principal legal gate for novel foods in the EU is Regulation (EU) 2015/2283, administered jointly by the European Commission, EFSA and the Member States.

A full safety dossier and an EFSA scientific opinion before the EU Commission can authorize food EU-wide EU-wide is expected to last 18 months. Estimations from The Danish Chamber of Commerce based on OECD's data says about 400 days (or 14 months). The interviews made in this report illustrates – that real-world timelines are closer to 30 months – 2,5 years.

Changes, including improvements in the authorization process, are reflected in recent European policy initiatives. Most notably, the proposed Food & Feed Omnibus Package (2025) introduces pre-application counselling by EFSA, providing companies with earlier scientific guidance. This represents an important step towards reducing regulatory uncertainty and improving the quality of applications.

The EU Commission's proposal for the European Biotech Act I[6] would also amend the General Food Law to enable Member States to establish regulatory sandboxes for innovation across the food and feed chain.

However, the proposed rules explicitly *exclude* novel foods from the scope of these sandboxes. A categorical exclusion may, however, deprive precisely those emerging food innovators facing the greatest regulatory uncertainty of access to a controlled environment for testing technologies, evidence requirements and regulatory approaches.

Not every food-approved technology needs to pass through the EU Novel Foods Regulation. Substances and processes can instead fall under the EU Food Additives Regulation, the Food Enzymes regulation, General Food Hygiene Law – or a combination of these and other frameworks. This regulation can be faster and more proportionate than Novel Food authorization.

National administration of EU Food Law includes day-to-day administration – inspections, national guidance, pre-submission dialogue, and the domestic ecosystem that surrounds applicants.

An applicant's choice of legal basis is not simply an administrative formality, but a strategic and legally consequential decision and getting it wrong – or having a regulator disagrees with it – can cost years.

Conducting a report on novel foods is complicated Policies, Omnibus, EFSA's procedural reforms and the EU Biotech Acts present moving targets as they are still moving through consultation, negotiation or drafting. Therefore, this is not a static description but a snapshot of a fast-moving regulatory landscape.

The interviews made in this report illustrates – that real-world timelines are closer to 30 months –

2,5 years

Photo: Spora

Photo: Spora

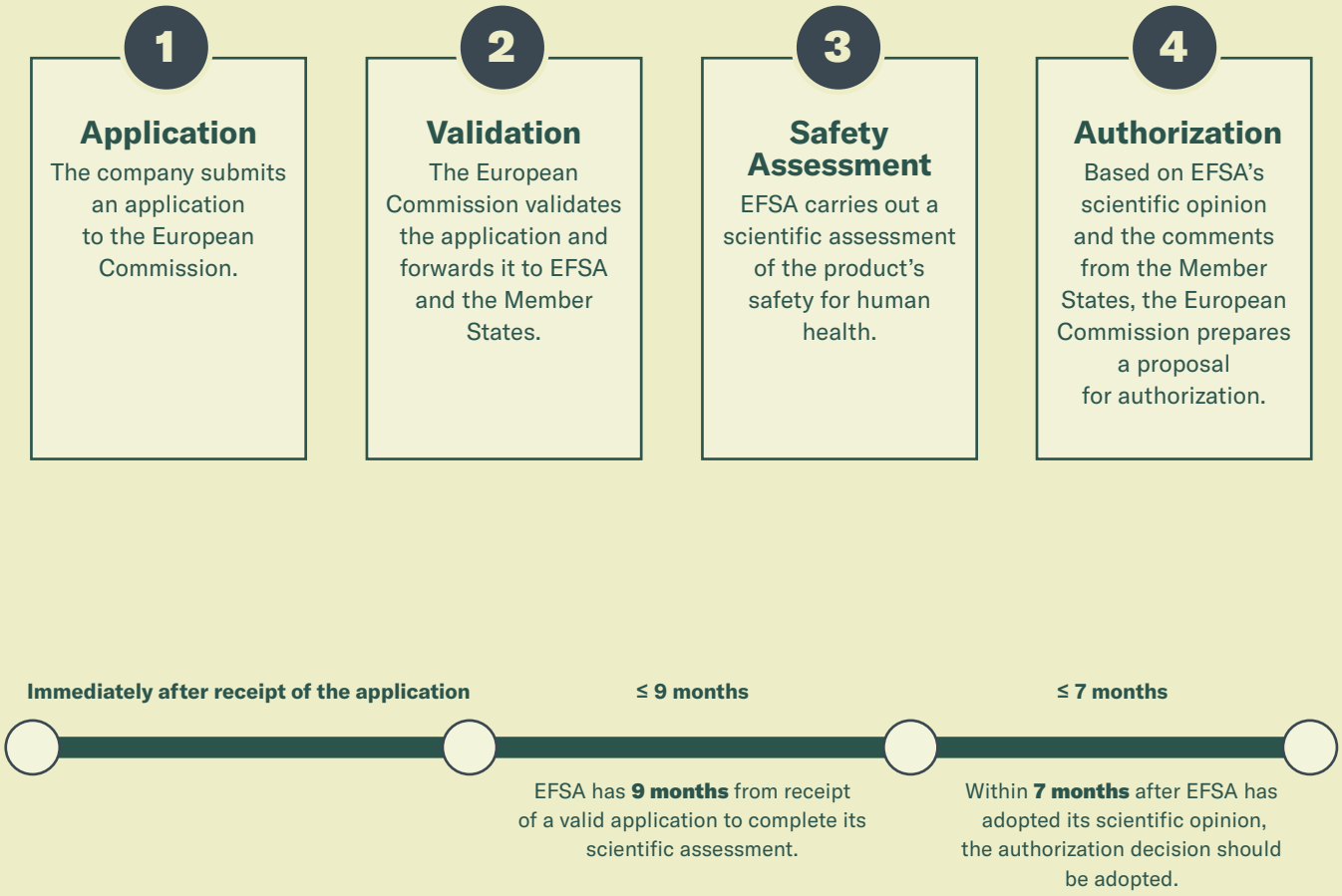
The EU process for novel foods

Valorizing side streams into safe food ingredients represents a significant opportunity to improve resource efficiency and reduce food waste, but such products may also fall within the novel foods framework.

The authorization process begins with an application to the European Commission, followed by EFSA's scientific risk assessment and a final decision by the Commission and Member States. While the legal timeline is approximately 18 months, companies frequently experience approval processes lasting two to three years or longer due to requests for additional information and so-called *clock-stops* by EFSA.

Although the EU novel foods framework provides a high level of consumer protection and confidence, many companies developing biosolutions experience uncertainty regarding product classification, evidence requirements, and the overall approval process. These challenges form the basis of the recommendations presented in this report.

Figure 3: EU's risk assessment process



Source: The Danish Chamber of Commerce

Insights on Barriers in the EU novel foods Authorization Process

The companies interviewed consistently describe the EU regulation on novel foods as a scientifically robust system that delivers a high level of consumer protection. However, they also identify several structural barriers that make the authorization process lengthy, costly and difficult to navigate. Regulatory uncertainty, lengthy approval procedures, high documentation costs and limited predictability all affect companies' ability to develop and commercialize innovative foods and biosolutions in Europe.

The interviews show that barriers arise at different stages of the innovation and authorization process. Some can be addressed within the existing regulatory framework through improvements in guidance, dialogue, transparency and regulatory practice. Others may require regulatory flexibility or derogations from existing rules. A further step is to establish a specific legal basis for regulatory sandboxes for novel and emerging foods.

Novonesis explained that the anticipated uncertainty, complexity, cost, and duration of the authorization process shape the company's research priorities from an early stage. Although the company maintains a database comprising 150,000 microbial strains, only a limited number are currently considered commercially attractive because of regulatory uncertainty. Researchers may therefore avoid working with some of the most promising microorganisms because the expected regulatory burden makes it difficult to establish a viable business case. As Novonesis summarized:

> As soon as we know there is a novel foods approval involved, there is no business case.

The current framework can also influence strategic decisions concerning market entry. Luvi Bio and Algiecel are among the companies illustrating this challenge. Algiecel emphasized that companies remain fully committed to ensuring the safety and thorough testing of their ingredients, but questioned whether the regulatory requirements adequately reflect the actual risks associated with biosolutions:

> We are, of course, only interested in commercializing ingredients that are safe and thoroughly tested. But I see the EU Novel Foods Regulation as a series of hurdles that EU has put in place without considering the actual risks associated with biosolutions. Alternatively, you can go to the US and obtain approval within nine to twelve months.

These findings reflect a broader concern among the companies interviewed that the current EU novel foods framework may shift research, investment, innovation, and commercialization activities outside Europe.

The challenge is particularly relevant for biosolutions that valorize agricultural and industrial side streams. Converting these side streams into high-value food ingredients could make an important contribution to a more circular and resource-efficient food system.

However, companies face considerable uncertainty regarding product classification, evidence requirements, and regulatory expectations. Consequently, promising innovations may never reach the market despite their environmental and economic potential.

The interviews point to *five main groups of barriers*, which correspond to the five elements of the proposed setup for a regulatory sandbox on novel foods.

One of the strongest messages emerging from the company interviews is the need for earlier engagement between companies and regulatory authorities.

Biosolutions are often developed using technologies that do not fit neatly within existing regulatory categories. Products may fall at the intersection of several regulatory frameworks, creating uncertainty about the applicable legislation, product classification, evidence requirements and appropriate study design.

This also creates a classification risk: if the applicable regulatory category is clarified too late, companies may invest in studies and documentation that do not meet the relevant requirements, resulting in additional costs and delays. Some needs for clarity and counselling can be established in the national Danish context, while others need involvement from EFSA.

This uncertainty can become particularly costly when companies have already invested substantial resources in analytical testing and documentation. Unibio highlighted the financial consequences of receiving regulatory clarification too late:

> The test had to be repeated because the guidance from EFSA regarding the appropriate test setup was not sufficiently clear.

Unibio, Arla Foods Ingredients and Luvi Bio were among the companies that called for earlier scientific dialogue to clarify study designs, risk-assessment strategies and documentation requirements before significant investments are made. This point was further underlined by Spora:

> Regulatory uncertainty is most costly when it comes too late. Companies need clarity on the appropriate regulatory pathway before investing in extensive studies and documentation.

Across the company cases, these challenges appear to cluster around five recurring regulatory barriers:

1. Procedural, evidentiary and classification barriers

A central challenge for companies is regulatory uncertainty at an early stage of product development. Companies often face uncertainty regarding product classification, the applicable regulatory pathway and the type and extent of evidence required to support an application.

For emerging food technologies within biosolutions, the appropriate regulatory route may not always be clear. Products may fall between or interact with different regulatory frameworks, and uncertainty about classification can have significant consequences for study design, documentation requirements, costs and timelines.

Limited opportunities for early dialogue with authorities further increase this uncertainty. Companies may commit substantial resources to analytical testing and evidence generation before receiving sufficient clarity on whether the planned studies and documentation will meet regulatory expectations.

This is particularly costly for start-ups and SMEs with limited financial resources. Luvi Bio noted:

> A pre-screen before we invest into analytical testing, which is the biggest cost block, would be very valuable.

Greater regulatory clarity before major investments is made would therefore help companies develop more robust applications and reduce unnecessary studies and avoidable costs.

These barriers are addressed primarily through the first proposed element for the sandbox for novel and emerging foods - *Element 1 – Pre-Application.*

2. Lack of opportunities for early market validation

The current regulatory process also creates a commercial challenge. Companies may be required to make substantial investments in product development, safety documentation and regulatory approval before they are able to test basic assumptions about consumer acceptance, product functionality or commercial demand.

For start-ups and scale-ups, this can create a significant “Valley of Death” between product development and commercialization. A technically viable and potentially safe product may still fail commercially, but companies have limited opportunities to generate market evidence before obtaining full authorization.

Controlled forms of market validation, such as tastings (which in some cases are allowed according to the Danish interpretation of the EU General Food Law), consumer studies, product demonstrations or functionality testing under regulatory supervision, could help reduce this uncertainty.

Such activities could enable companies to validate both their product and their business case at an earlier stage while maintaining appropriate food-safety safeguards.

These barriers are addressed primarily through *Element 2 – Market Validation.*

3. Lengthy, unpredictable and insufficiently transparent authorization processes

Companies consistently highlight the length and unpredictability of the EU novel foods authorization process as a major barrier.

Although the legal timeline is approximately 18 months, repeated requests for additional information and so-called clock-stops frequently extend the process to two or three years or more. For companies, the timeline itself creates costs and commercial risk.

AFI has described how losing an additional year of sales as a result of longer approval processes represents a direct commercial cost. Unibio similarly noted that the length of the regulatory process can halt innovation.

Companies also report limited transparency regarding evolving data requirements and regulatory expectations. Fragmented dialogue and repeated requests for supplementary information can make it difficult to prepare robust applications, plan investments and predict when market entry may realistically occur.

A clearer, faster and more proportionate process would therefore require stronger coordination between authorities, greater transparency, more structured communication and a more predictable use of clock-stops.

These barriers are addressed primarily through *Element 3 – Adaptive Authorization.*

4. Regulation and regulatory practice struggle to keep pace with innovation

Several of the challenges identified by companies go beyond the administration of individual applications.

Food technologies such as precision fermentation and other biosolutions enabled food products do not always fit neatly within regulatory frameworks and categories developed for more conventional foods and production methods. This can create uncertainty for both companies and authorities and may result in regulatory requirements that are not always proportionate to the characteristics or risk profile of a specific technology or product.

As mentioned earlier, the definition of novel foods itself is based on whether a food was consumed to a significant degree in the EU before 1997. As technological development and innovation accelerates, this raises a broader question about whether regulatory frameworks and administrative practices are adapting sufficiently quickly to new production methods, technologies and food sources.

Regulatory sandboxes should therefore not only help companies navigate existing regulations. They should also generate practical evidence about where guidance, regulatory practice or legislation may need to evolve.

These barriers are addressed primarily through *Element 4 – Better Regulation.*

5. Regulatory barriers can suppress innovation and commercialization

The interviews indicate that regulatory uncertainty affects companies long before a formal EU novel foods application is submitted.

Lengthy timelines, high documentation costs and uncertainty about regulatory requirements can affect investment decisions, research priorities and decisions about where new products should be developed and commercialized. These effects are particularly significant for start-ups and scale-ups with limited resources and shorter investment horizons.

Bactolife highlights how the costs associated with data generation, lengthy approval timelines, administrative burdens and repeated clock-stops can create significant obstacles for smaller companies. While maintaining the precautionary principle and pre-market safety assessment remains essential and is seen as a stamp of quality, companies also point to the need for greater pragmatism, shorter timelines and additional support mechanisms for SMEs.

The company cases nevertheless suggest that administrative improvements alone may not resolve all the structural challenges facing innovative food and biosolutions companies.

Several respondents also describe a risk that companies may choose to commercialize innovations outside Europe rather than navigate the EU approval process.

Regulatory barriers should therefore be understood not only as a compliance issue but also as an innovation and competitiveness issue. Companies need access to regulatory expertise, appropriate testing infrastructure, financing, stronger regulatory capabilities and an ecosystem that can support the journey from research and development to authorization and commercialization.

These barriers are addressed primarily through the fifth suggested *Element 5 – Support Innovation.*

Opportunities within the existing legal framework

Importantly, not all these barriers require legislative reform. Several improvements can already be achieved within the existing EU novel foods framework, particularly where the challenges relate to regulatory practice rather than the legislation itself.

Several of these improvements are reflected in recent European policy initiatives, including proposals for stronger pre-application counselling by EFSA.

Such measures represent an important first step. They can improve the current authorization process and reduce uncertainty without lowering food-safety standards.

However, the company cases also suggest that process improvements alone may not fully address the structural challenges facing innovative companies. Some barriers may require regulatory flexibility beyond current administrative practice, while others may ultimately require new legal frameworks.

The interviews have shown that many barriers prevent innovators to engage in novel foods and present many regulatory obstacles for those who choose to make submissions for an EU market approval.

The 5 key barriers in the EU novel foods process

- Procedural, evidentiary and classification barriers
- Lack of opportunities for early market validation
- Lengthy, unpredictable and insufficiently transparent authorization process
- Regulation and regulatory practice struggle to keep pace with innovation
- Regulatory barriers can suppress innovation and commercialization

The 5 elements in a regulatory sandbox on novel foods

The interviews indicate that companies encounter different regulatory barriers throughout the innovation journey. Some challenges can be addressed through earlier scientific dialogue and improved guidance, while others require opportunities for controlled market validation, change of administrative practice or, ultimately, new European regulatory pathways.

The elements should therefore not be viewed as competing alternatives, but as *building blocks*. Experience and regulatory learning generated through one element should inform the next, creating a continuous process of improvement for both companies and regulators.

The key building blocks in a regulatory sandbox for novel foods are:

- Element 1 – Pre-Application
- Element 2 – Market Validation
- Element 3 – Adaptive Authorization
- Element 4 – Better Regulation
- Element 5 – Support innovation

Together, the elements illustrate how regulatory sandboxes can support both faster market access for novel foods and continuous regulatory learning, ultimately contributing to a more adaptive and innovation-ready EU novel foods legal framework. Collaboration between companies, national competent authorities, EFSA, the European Commission, and mobilizing actors such as Biosolutions Forum+ are essential.

Element 1 – Pre-Application

A regulatory sandbox could provide a structured mechanism for early dialogue between companies and national authorities during the pre-authorisation phase and, where permitted under the applicable legal framework and within EFSA's mandate, involve EFSA.

Under the current framework, the sandbox could draw on existing procedural guidance and regulatory engagement opportunities without replacing or prejudging the formal authorisation process. Separately, the pre-application counselling envisaged in the European Commission's 2025 Food and Feed Safety Omnibus proposal - if adopted - could complement the sandbox by providing a broader legal basis for early regulatory guidance.

This guidance could reduce regulatory uncertainty, avoid unnecessary studies and improve the quality of submissions.

Where a sufficient legal basis already exists, the sandbox could also facilitate the controlled testing of innovative biosolutions under regulatory oversight and help identify areas in which clarification or legislative change may be required.

Within the sandbox, companies and authorities could jointly clarify the relevant regulatory pathway and product classification, identify documentation and data requirements, review planned studies and risk-assessment strategies, and detect potential data gaps before major investments are made.

This would require dedicated expertise within the relevant national public authorities, including a strong understanding of technologies, business models and other characteristics specific to food technologies within biosolutions.

The improved pre-application guidance has the potential to help companies navigate in the regulatory jungle. This way the *complexicity* question is addressed, and some help is provided regarding the wish for more legal certainty and faster approval. It is relevant to emerging foods in general, both novel foods and other forms of emerging foods. But more is needed regarding market validation, adaptive authorizations and better regulations.

Element 2 – Market Validation

Once the regulatory pathway and product classification have been clarified, participating companies may proceed to controlled testing and evidence-generation activities within the regulatory sandbox.

The Dutch 2023 *Code of Practice for Safely Conducting Tastings of Cultivated Foods Prior to EU Approval* is a useful example. By treating tastings as controlled demonstrations rather than market placement, it enables engagement with consumers, regulators and value-chain partners without compromising the novel foods framework's core safety principles. This could address the difficulty of obtaining basic consumer feedback before authorization.

Element 2 combines early regulatory guidance, practical testing, controlled market validation, and structured regulatory dialogue. The objective is to accelerate responsible market access for novel and emerging foods, improve the evidence base for regulatory decision-making, and test innovation-friendly interpretations of existing legislation.

In the longer term, the knowledge generated at national level through the sandbox could contribute to more consistent and future-proof regulatory practices without compromising food safety or consumer protection. This element adds the following components upon element 1:

- **Controlled testing and validation pathways:** Participating companies undertake structured testing and evidence-generation activities within the applicable legal framework to strengthen their novel foods applications before submission to EFSA. Activities may include controlled tasting panels, consumer studies, product functionality testing, market acceptance assessments, and demonstrations involving value-chain partners.
- **Regulatory dialogue:** The sandbox facilitates early and continuous dialogue among companies, national authorities, and, where possible, EFSA. This includes clarification of product classification, data requirements, and scientific expectations, as well as exploration of innovation-friendly regulatory interpretations within the existing legal framework.

Element 3 – Adaptive Authorization

Adaptive authorizations from Danish and EU authorities are crucial to help break down some of the barriers illustrated by the companies. This should involve encouragement to take present societal needs and new promising products into account when assessing applications for emerging foods. A crucial point is how to achieve faster approvals.

Another is how to deal with the novelty of emerging foods, when it does not fit into well-known categories. Independent EU risk assessment is crucial, but relevant tools seem applicable for the authorities in the administrative process – and can be very helpful for the companies and for innovation as such.

EU's Innovation Principle

A central proposal is the systematic application of the EU *Innovation Principle*. Authorities should consider how regulatory objectives - above all food safety - can be achieved proportionately, predictably and in ways that support innovation. The principle should guide documentation requirements, guidance, application assessments and risk-management measures. Where several approaches provide the same level of safety, the least burdensome approach to innovation and market access should be preferred.

This would neither lower safety standards nor override the precautionary principle. It would instead ensure that requirements reflect technological development, product and production characteristics, and the circumstances of startups and SMEs. Authorities should transparently document how innovation impacts have been considered.

Risk-proportionate requirements

Documentation requirements should be proportionate to the risks of the individual product. Companies such as Luvi Bio have noted that extensive analytical testing may be required irrespective of a product's actual risk profile. Requirements should therefore be risk-based and technology-specific, rather than one-size-fits-all. Sandboxes can test this through early dialogue, tailored evidence requirements and alternative ways of demonstrating safety.

This would neither lower safety standards nor override the precautionary principle. It would instead ensure that requirements reflect technological development, product and production characteristics, and the circumstances of startups and SMEs. Authorities should transparently document how innovation impacts have been considered.

Fewer "clock-stops" and more predictable procedures

Repeated or lengthy clock stops can make authorization timelines far less predictable than formal timetables suggest, creating difficulties for startups and SMEs. Clock-stops should therefore be limited, transparent and used only where additional information is necessary to resolve a material safety issue.

Information requests should be consolidated, clearly justified and proportionate to the product's risk profile, with reasonable deadlines for applicants and authorities and prompt restarting of the assessment once information has been supplied.

A request concerning one part of an application should not unnecessarily suspend assessment of unaffected parts, and published timelines should distinguish applicant-caused delays from the authority's review of supplementary information.

A holistic approach, in which EFSA considers both risks and *wider benefits* when assessing applications, would also be valuable. Benefits related to resilience, competitiveness, sustainability, and public welfare should form part of the broader EU vision, particularly where emerging foods may deliver significant societal benefits.

Risk assessment and approval procedures should therefore allow fast-track pathways for emerging foods characterized by low risk and high impact, like the approach proposed for biopesticides in the EU Food and Feed Omnibus (2025). Preliminary or conditional authorizations, combined with enhanced monitoring and continued evidence generation, could enable uncertainties to be addressed progressively under close regulatory oversight.

Regulatory sandboxes can help test these measures, including structured pre-submission dialogue, early identification of evidence gaps, staged submissions, dedicated case managers, and rapid clarification meetings.

Step-by-step evidence generation could accelerate authorisations where regulatory sandboxes across the EU provide evidence that other Member States can build upon. Partnerships between Member States may be particularly useful in generating relevant evidence for emerging foods.

Finally, regulatory sandboxes should allow consideration of *temporary derogations* from Danish and EU rules where existing requirements are demonstrably outdated. Innovative emerging food products should not necessarily be assessed solely against rules that no longer reflect current bioscience, risk knowledge or sustainability challenges.

Danish regulation already provides for temporary regulatory frameworks in regulatory sandboxes, and this could be used to explore whether clearly outdated requirements may be set aside temporarily where it can be documented that the underlying conditions have changed significantly.

Adaptive authorization is needed to break down many of the barriers, the interviews have demonstrated. Crucial proposals to deal with need for simplicity and speed are:

Innovation-friendly interpretation in all phases of the submission and risk assessment, could include:

- √ Proportionate documentation requirements, risk-based and technology-specific
- √ Clock-stops should only be used when subject to clearer limitations and greater transparency
- √ Accept a holistic approach, including benefits for resilience, competitiveness and sustainability
- √ Fast track, when the innovative product is low-risk and high impact
- √ Accept evidence-generation step-by-step, building on other regulatory sandboxes
- √ Use preliminary or conditional authorization with enhanced monitoring
- √ Accept derogations both from national and EU regulations, when they are clearly outdated.

Element 4 – Better Regulation

The regulatory sandbox should not only support individual companies and products but also function as a structured mechanism for improving the regulatory framework itself. Experience generated through elements 1–3 can provide valuable evidence on where existing rules, guidance, procedures, and regulatory practices create unnecessary barriers to innovation or are not sufficiently adapted to emerging technologies and biosolutions.

Element 4 therefore focuses on translating regulatory learning from the sandbox into "Better Regulation" for innovative food technologies. The objective is to establish a systematic feedback loop between companies, national competent authorities, EFSA, the European Commission, and relevant stakeholders, ensuring that practical experience from innovative products contributes to the continuous improvement of the EU novel foods framework.

The sandbox can help identify recurring regulatory challenges across companies and technologies. These may include unclear product classifications, disproportionate or unclear data requirements, overlapping regulatory frameworks, differences in interpretation between authorities, lengthy procedures, or requirements that were designed for more conventional food products and production methods.

Rather than addressing these challenges on a case-by-case basis only, experiences from the sandbox should be collected, evaluated, and translated into recommendations for regulatory improvement. This could include changes to administrative practices and guidance as well as proposals for future legislative amendments where existing legislation does not provide sufficient flexibility.

The expected outcome is a more adaptive, proportionate, predictable, and innovation-ready regulatory framework. Regulatory learning generated through individual sandbox cases should benefit not only participating companies but the wider biosolutions ecosystem. The fourth element could include:

- **Regulatory Feedback Loop:** Establish a structured process for collecting and evaluating regulatory challenges identified through sandbox activities and translating them into recommendations for EFSA, the European Commission, national competent authorities, and policymakers.

- **Guidance and Regulatory Practice:** Use sandbox experience to identify opportunities for clearer, more proportionate, risk-based, and innovation-friendly guidance and administrative procedures within the existing legal framework.

- **Identification of Regulatory Gaps:** Identify areas where existing legislation or regulatory categories are no longer sufficiently adapted to technological developments, including challenges arising at the interface between different regulatory frameworks.

- **Evidence for Future Regulation:** Generate practical evidence that can inform future revisions of the EU novel foods framework and other relevant EU initiatives, including the EU Biotech Acts and the EU Innovation Act.

- **Temporary and limited market access:** Subject to legal feasibility, a controlled pathway could be explored under which companies may undertake temporary and strictly limited marketing in Denmark following a favourable sandbox risk assessment, while awaiting the completion of the EU authorization process and EFSA's risk assessment.

It could present an opportunity for especially SME's to survive the "Valley of Death" to accept temporary marketing in Denmark based on the results of risk assessment in a regulatory sandbox, while waiting for the EU market approval based on the EFSA risk assessment.

Further, regulatory sandboxes can become an important instrument for better regulation in the future. Instead of regulation developing separately from technological innovation, regulators can use practical sandbox experience to understand how rules operate when applied to emerging technologies and adjust regulatory practices accordingly.

Element 5 – Support innovation

Several respondents stressed that the EU Novel Foods Regulation affects innovation long before an application is submitted. Regulatory complexity and uncertainty influence not only whether products reach the market, but also which research projects companies pursue, where they invest, and in which markets they choose to commercialize their solutions.

Element 5 focuses on embedding the regulatory sandbox in a broader innovation-support ecosystem. The sandbox should provide early regulatory clarification while also serving as a gateway to the practical support companies need to develop robust evidence, test and scale their solutions, attract investment, prepare for regulatory approval, and enter the market successfully.

This requires stronger connections among regulatory authorities, research institutions, testing facilities, investors, innovation programmes, and the wider biosolutions ecosystem.

Support provided through this element could include:

- **Access to Expertise:** Connecting companies with relevant scientific, technical, legal, and regulatory expertise to strengthen their regulatory strategies and evidence generation.
- **Testing and Research Infrastructure:** Facilitating access to laboratories, pilot facilities, demonstration environments, research institutions, and other infrastructure required to validate innovative products and processes and generate high-quality evidence.
- **Funding and Investment Readiness:** Strengthening links between sandbox activities and relevant national and European funding instruments. Greater regulatory clarity could reduce investment uncertainty and improve companies' ability to attract private capital.
- **Regulatory Capacity Building:** Developing regulatory capabilities within companies, particularly start-ups and SMEs, while strengthening authorities' understanding of emerging technologies, ingredients, and production methods.
- **Innovation Ecosystem and Partnerships:** Facilitating collaboration among companies, universities, research organizations, investors, national competent authorities, EFSA, the European Commission, and organizations such as Biosolutions Forum+.
- **International Competitiveness:** Identifying regulatory and structural barriers that may encourage companies to develop or commercialize products outside Europe and exploring how the European regulatory and innovation ecosystem can become more internationally competitive.

Photo: Unsplash

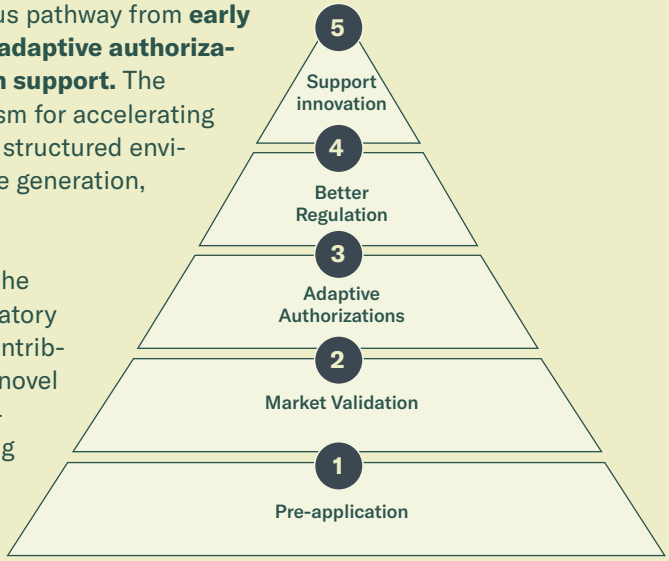
Case

Singapore has established one of the world's most innovation-friendly frameworks for alternative proteins and emerging foods. The Singapore Food Agency combines intensive pre-submission dialogue, risk-based assessment, international cooperation and adaptive regulatory development. Singapore became the first country in the world to approve cultivated meat[8]. Lessons learned are that regulatory certainty is often as important as regulatory speed.

Over time, recurring findings from sandbox activities can provide an evidence base for updated guidance, more consistent regulatory practices, simplified procedures, and, where necessary, legislative change at EU level. This creates a continuous feedback mechanism in which regulation evolves alongside scientific and technological development while maintaining the EU's high standards of food safety and consumer protection.

The 5 element-model

Together, the five elements establish a continuous pathway from **early regulatory guidance and market validation to adaptive authorization, better regulation, and broader innovation support.** The sandbox thereby becomes more than a mechanism for accelerating individual novel foods applications. It provides a structured environment for regulatory experimentation, evidence generation, regulatory learning, and innovation support.



Experience from each element should feed into the next and, importantly, back into the overall regulatory system. In this way, regulatory sandboxes can contribute to a more adaptive and innovation-ready EU novel foods framework that enables European biosolutions to reach the market faster while maintaining high standards of food safety and consumer protection.

The Role of Biosolutions Forum+

Across all five elements, the core of a regulatory sandbox for novel foods is close collaboration between companies and the relevant competent authorities to address a concrete regulatory challenge.

Facilitating ecosystem organizations such as Biosolutions Forum+ can support this process by enabling dialogue, bringing stakeholders together, sharing knowledge and international experience, and contributing deep scientific and regulatory expertise through a science- and research-based approach.

As a public-private platform, Biosolutions Forum+ may contribute by coordinating company cases, facilitating knowledge exchange, documenting lessons learned, and helping translate practical experience into recommendations for future regulatory improvements. In this way, Biosolutions Forum+ can support both individual sandbox projects and the broader development of more innovation-friendly regulatory practices.

Importantly, Biosolutions Forum+ can act as a facilitator, bridge-builder, and knowledge broker, helping to bridge the gap between regulatory requirements and innovation needs - and between companies and competent authorities - while ensuring that dialogue and recommendations are grounded in scientific evidence and research.

By participating actively in sandbox activities, Biosolutions Forum+ can help create greater transparency, improve coordination among stakeholders, and contribute to more predictable, science-based, and innovation-friendly regulatory pathways.

The role of Biosolutions Forum+ include:

- **Adding scientific** support and a science-based approach to implementing new regulatory frameworks
- **Identifying suitable company cases** and coordinating participation across companies, authorities, and other relevant stakeholders (such as The Consumer Council and universities).
- **Facilitating dialogue** and knowledge exchange between innovators, regulators, and other relevant actors throughout the sandbox process.
- **Bringing international experience** and best practices into the design and implementation of sandbox activities.
- **Collecting and disseminating lessons learned**, including documenting regulatory barriers and opportunities identified through sandbox cases.
- **Identifying opportunities for regulatory flexibility** within existing legislation and translating sandbox findings into recommendations for future regulatory practice and policy development.
- **Supporting mutual learning** between companies and authorities to inform the continued development of innovation-friendly regulatory frameworks.

Conclusion

Europe has a unique opportunity to consolidate its global leadership in biosolutions including emerging food technologies. Scientific excellence alone will not be enough. Safe and sustainable innovations must also reach the market within timelines that support investment, competitiveness, and industrial scale-up.

Regulatory sandboxes offer a practical, structured, and dialogue-based way forward. Through earlier regulatory engagement, stronger evidence generation, controlled market validation, and mutual learning, they can help bridge the gap between innovation and commercialization - without compromising Europe's high food-safety standards.

Sandboxes can also support the implementation of emerging EU legislation by allowing authorities and innovators to test approaches, build regulatory experience, and prepare for future requirements before they become mandatory.

This report sets out five complementary elements with varying degrees of immediate applicability, providing a stepwise block approach to regulatory reform.

In the short term, administrative improvements - including stronger pre-submission guidance, greater transparency, a more proportionate use of clock-stops and use of the EU *Innovation Principle* - can make the existing framework more predictable and efficient.

In parallel, national regulatory sandboxes can generate the practical experience and regulatory learning needed to inform future European initiatives, including the Biotech Acts, the Innovation Act and the continued development of the novel foods framework.

The Danish government's regulatory sandboxes, established through the broadly based 2024 Entrepreneurship Agreement, should therefore be viewed not as isolated pilot projects ending in 2027, but as the first step towards a wider European framework.

By testing new regulatory approaches in practice, Denmark and other Member States can help shape a permanent European model for regulatory learning, building up evidence and more efficient market access for biosolutions.

The ultimate objective is an innovation-friendly regulatory system that enables safe new foods, ingredients, and biosolutions to reach the market faster and more efficiently - strengthening Europe's competitiveness and food security while accelerating the transition to a more resilient and sustainable food system. Based on interviews with companies, experiences from other parts of the world, and academia, Biosolutions Forum+ has the following recommendations:

Companies: The regulatory sandbox model is designed to deliver earlier regulatory certainty, lower development costs, faster market access, and better investment conditions. Real flexibility is needed to replace the current pattern of investing blindly and finding out too late whether a study design or classification will hold up. Involvement in relevant regulatory sandboxes and Biosolutions Forum+ is crucial to help keeping biosolutions companies, including novel foods, in Denmark.

Authorities and civil servants: Regulatory sandboxes offer a structured way to build practical understanding of fast-moving technologies (like precision-fermentation), spot regulatory gaps or inconsistencies earlier, and generate a stronger evidence base for future guiding and rulemaking – turning individual company cases into system-wide learning. This necessitates using the EU's own Innovation Principle to make a real difference for the companies and this way help placing Denmark as a frontrunner.

Politicians: Denmark strongly supports regulatory sandboxes regarding novel and emerging foods, and has made recommendations regarding the EU Biotech Acts, including the possibility to make regulatory sandboxes on novel foods and derogations from current outdated national and EU regulations. Moreover, politicians can support the authorities' use of the EU's Innovation Principle and can make a specific Danish Act on regulatory sandboxes, inspired by Germany and partly France.

All: Monitor the development of the EU Biotech Act and the Food and Feed Safety Omnibus. Engage directly with Biosolutions Forum+ at an early stage. TRY IT – eat emerging foods!

Regulatory sandboxes have the potential to function as drivers of innovation in emerging foods. But to unleash this potential it is crucial to accept flexibility and empower them to change mindset and practise. It has been said that the next competitive advantage is adaptability – not AI. Why not use both?

> If reforming EU novel foods legislation is the regulatory canopy, removing unnecessary barriers to already food-approved solutions should be the low-hanging fruit.

Linda Nielsen
Chair of Biosolutions Forum+

Further Perspectives

One striking example of regulatory inertia in the EU's food regulation is the concept of "novel foods". Whether a food is considered novel still depends on whether it was consumed to a significant degree in the EU before 15 May 1997. Almost three decades later, European food innovation is therefore still being measured against what Europeans happened to eat in the 1990s.

The irony is obvious: The calendar has moved on, but the regulatory definition of novelty has not. Safe and innovative ingredients may consequently face substantial barriers, not necessarily because they pose a particular risk, but because they cannot demonstrate a sufficient history of consumption before an increasingly arbitrary-looking date in 1997.

This calls for an update. Novel foods today should not be based on outdated regulations made 30 years ago.

The novel foods issue is admittedly difficult to solve, as it raises fundamental questions about safety assessments and market access for genuinely new foods. However, there should be more obvious opportunities for regulatory simplification elsewhere. Safety is the crucial policy consideration behind the regulation, and when products have been approved as foods, the approval process should be easy and fast.

Food-approved products and technologies designed to address well-known food safety challenges – such as Listeria and other pathogens – should be an easier place to start.

This can be illustrated by relevant examples, showing regulatory barriers. These cases could form the basis of a dedicated sandbox to develop clearer, science-based criteria for classification, documentation, health claims, labelling, and market access:

CASE

BioCulture Nordic

BioCulture Nordic is a Danish company that has invented a solution that extends the shelf life of food, such as fish products by using beneficial lactic acid bacteria to produce naturally fermented lactic acid.

Though the innovation has been assessed as safe for their intended food use yet still face regulatory barriers that prevent or severely restrict their commercial application. After having its first innovation rejected by the The Danish Veterinary and Food Administration (DVFA) the company innovated a new one.

After developing a new product (lactic acid) aligning entirely with the food regulatory acts and following two years of case processing. The DVFA has yet to allow the company any commercial activity, placing the company in a multiple year regulatory deadlock.

This creates an unfortunate paradox: Europe calls for greater innovation, competitiveness, and food safety, while potentially preventing already assessed solutions – and substantially delaying promising new ones – from reaching the market because of overlapping, complex or outdated rules. Robust safety requirements are essential, but once safety has been demonstrated, additional barriers should have a clear and proportionate justification.

If reforming EU novel foods legislation is the regulatory canopy, removing unnecessary barriers to already food-approved solutions should be the low-hanging fruit.

CASE

CariGuard

CariGuard, a Danish research-based oral-health product containing well-characterised lactic acid bacteria. Despite its scientific foundation, the product is effectively blocked by current labelling rules from communicating its documented health purpose, thereby limiting its commercial application.

CASE

Chromologics

Chromologics has developed Natu.Red®, a natural red food colour produced through precision fermentation. The product is designed to offer a stable, scalable and more sustainable alternative to both synthetic colourants and conventionally extracted natural colours. Although food colourants follow a regulatory pathway distinct from the novel foods regime, the case illustrates the same broader challenge: European biotechnology companies may spend many years and substantial amounts of capital moving from demonstrated technical performance to regulatory submission and, ultimately, market access.

Regulation must ensure that new colourants are safe, but the process should also be predictable, proportionate and sufficiently responsive to scientific evidence and technological development.

Notes

1. Executive Order No. 108/23, Section 2 from The Danish Business Authority: Bekendtgørelse om nationalt kontaktpunkt for oprettelse af regulatoriske sandkasser og sandkasseforløb

2. The Danish Chamber of Commerce, 2026, Danmark fører i innovation af bio-solutions til fødevarer men EU-regler bremser potentialet

3. The Good Food Institute (n.d.). Environmental benefits of alternative proteins. Good Food Institute on environmental benefits of alternative proteins

4. Rockström, 2025

5. Think Tank OneThird, 2024

6. EU's proposal for Biotech Act I

7. Under current Danish regulatory guidance, companies may carry out non-commercial tests with food products before they are authorised in the EU. This can include tastings, consumer studies, functionality tests and demonstrations with value-chain partners. The activity must be a genuine experiment, not marketing. Participants should be informed that the product is part of a test and is not authorized for sale in the EU. Companies should keep simple documentation showing the purpose and design of the test. If the activity cannot be documented as an experiment, normal food legislation applies. This follows from the Danish Authorization of Food Businesses.

8. Cell-cultured meat industry set for another leap forward with new Changi plant | Singapore EDB

Appendix

The following companies that work with biosolutions have contributed to the findings in this catalogue:

Camilla Juhl Pørksen, Founder, CariGuard

Christel Jørgensen, SVP of IP & Regulatory, Bactolife

Christian Bülow, CEO, BioCulture Nordic

David Benjamin Selesko, Senior Regulatory Affairs Specialist, Arla Foods Ingredients

Eleni Ntokou, New Product Development, Sustainability & Regulatory Affairs Director

Lisbet Khan, VP of Business Development, Chromologics

Mads Bjørnvad, CSO, Spora

Susanne Palsten Buchardt, CEO, Algiecel

Therese Scherer, CEO and founder, Luvi Bio

Wieke Edinger, Senior Public Affairs Manager, Novonesis

Anders Kroman Liin, Project Manager, Biosolutions Forum+,
Linda Nielsen, Professor of Law, University of Copenhagen, Chair of Biosolutions Forum+
Anne Lerche, Managing Director, Alliance for Biosolutions at The Danish Chamber of Commerce

First edition: September 2026

Photos: Chromologics & Unibio

Sources

Code of Federal Regulations. (n.d.). 21 CFR § 570.265: *What FDA will do with a GRAS notice*. Retrieved September 4, 2026, from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-570/subpart-E/section-570.265

European Food Safety Authority (EFSA). (2025). *novel foods*. Available at: https://www.efsa.europa.eu/en/topics/topic/novel-food

European Commission. (2025). *Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening the Union's biotechnology and biomanufacturing sectors, particularly in the area of health, and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)* (COM(2025) 1022 final/2). EUR-Lex

European Commission. (n.d.). *Authorisations: Novel foods.* Retrieved September 4, 2026, from https://food.ec.europa.eu/food-safety/novel-food/authorisations_en

The Danish Chamber of Commerce (2026). *"Danmark fører i innovation af biosolutions til fødevarer men EU-regler bremser potentialet".* https://www.danskerhverv.dk/politik-og-analyser/analyser/2026/september/danmark-fører-i-innovation-af-biosolutions-til-fødevarer-men-EU-regler-bremser-potentialet/

Nielsen, Linda (2024). *Biosolutions: Regulatory Sandboxes as a Tool to Break Down Regulatory Barriers.* Copenhagen: Novo Nordisk Foundation.

Nielsen, Linda (2025). "*Supporting Innovation on Novel Foods. Using regulatory sandboxes as a tool.*"

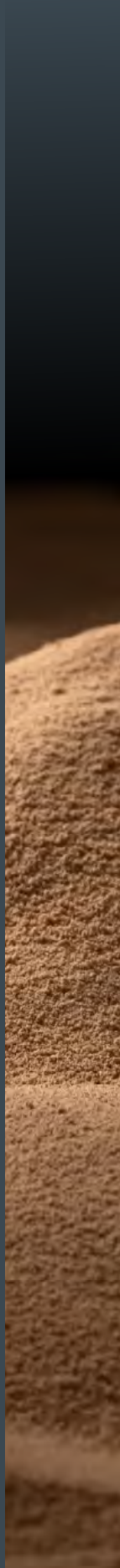
ONE\THIRD (2024). *Upcycling af sidestrømme i dansk fødevareindustri: Inspirationskatalog.* https://onethird.dk/wp-content/uploads/2025/05/Upcycling-af-sidestromme-i-dansk-fodevareindustri-inspirationskatalog.pdf

Rockström, J., Thilsted, S. H., Willett, W. C., Gordon, L. J., Herrero, M., Hicks, C. C., Mason-D'Croz, D., Rao, N., Springmann, M., Wright, E. C., Agustina, R., Bajaj, S., Bunge, A. C., Carducci, B., Conti, C., Covic, N., Fanzo, J., Forouhi, N. G., Gibson, M. F., ... DeClerck, F. (2025). The EAT–Lancet Commission on healthy, sustainable, and just food systems. *The Lancet*, 406, 1625–1700. https://doi.org/10.1016/S0140-6736(25)01201-2

Singapore Food Agency. (n.d.). *Guidelines on applying for pre-market approval for a Novel Foods*. Retrieved September 4, 2026, from https://www.sfa.gov.sg/regulatory-standards-frameworks-guidelines/novel-food-framework/guidelines-on-applying-for-pre-market-approval-for-a-novel-food

Yue, S. R., Verhoeckx, K. C. M., Houben, G. F., & Bøgh, K. L. (2025). Analysis of trends and allergenicity risk assessments in Novel Foods approvals within the European Union between 2018 and 2023. *Food and Chemical Toxicology,* 197, Article 115249. https://doi.org/10.1016/j.fct.2025.115249

Read more
Biosolutions Forum+



Biosolutions Forum+