Strategic brief by Ministry of FUTURE AFFAIRS.

Closing the Food Innovation Gap!

A framework for a pan-European regulatory sandbox for emerging foods and complementary proteins, with a focus on pre-submission advice and the validation phase

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Executive Summary

Europe's position as a leader in biotechnology and food innovation is under threat due to regulatory barriers and inefficiencies that delay the access of complementary proteins to the EU market. This harms European competitiveness, strategic autonomy, and food security.

Europe already depends on the US for the commercialisation of European innovations and on China for the supply of rare earths and other critical materials. Additionally, the EU is also increasingly dependent on feed and food inputs produced by biomanufacturing in China. Food and feed biotechnology is not science fiction – it is already a reality for Europe. Consequently, Europe is exposed to significant supply-chain dependencies which threaten the independence and security of our democracies.

"Just go to the US" – when European investors recommend starting in Europe and scaling elsewhere

Although the EU's novel food pre-market approval is competitive in terms of its regulated timeline and robustness, in practice the timeline is often more than twice the regulated length, making the approval process highly costly by international standards. This, along with the absence of basic favourable regulatory conditions for European startups in general, hinders investment in the EU and the commercialisation of European food innovation in its home market.

Instead, an ever-increasing number of European startups are leaving the EU at an increasingly early stage, after initially finding favourable conditions for setting up in Europe. The European food-and-biotech innovation ecosystem lacks an environment that supports innovation, while international investors and other countries and regions benefit from emerging foods and related manufacturing technologies invented in Europe that are then exported.

As Mario Draghi reminded us a year after his landmark report on the state of European competitiveness:

> **"One year ago, we met here to discuss three challenges set out in the report: Europe's growth model had long been under strain; dependencies threatened its resilience; and without faster growth, Europe would be unable to deliver on its climate, digital and security ambitions – not to mention finance its ageing societies. Over the past year, each of these challenges has grown more acute. […]**
> **The report set out three priorities for Europe: closing the innovation gap in advanced technologies; charting a decarbonisation path that supports growth; and strengthening economic security. As President von der Leyen has underlined, these are also at the heart of the Commission's agenda. I welcome her decision to place competitiveness at the centre, and the programme is ambitious. […]**
> **Europe's citizens and companies value the diagnosis, the clear priorities and the action plans. But they also express growing frustration. They are disappointed by how slowly the EU moves. They see us failing to match the speed of change elsewhere. They are ready to act – but fear governments have not grasped the gravity of the moment.**
> **Too often, excuses are made for this slowness. We say it is simply how the EU is built.**
> **That a complex process with many actors must be respected. Sometimes inertia is even presented as respect for the rule of law.**
> **That is complacency. Competitors in the US and China are far less constrained, even when acting within the law. To carry on as usual is to resign ourselves to falling behind. A different path demands new speed, scale and intensity. It means acting together, not fragmenting our efforts. It means focusing resources where impact is greatest. And it means delivering results within months, not years."[1]**

Despite Draghi's clear diagnosis on a general level and the path set out by the Commission's agenda, we do not see enough decisive and coordinated action taken to support emerging foods derived from food biotechnology as a strategic technology, starting with a competitive regulatory approval process.

Strengthening the competitiveness of the US and China by exporting European food innovation

In order to strengthen European competitiveness, help biotech food companies to scale at home, and avoid further widening the innovation gap between breakthrough food science and regulation, this briefing proposes a framework for a pan-European regulatory sandbox for complementary proteins, such as novel foods. The framework is intended for use by those member states that wish to accelerate safe, science-based regulatory efficiency in order to support food innovators, while maintaining high food-safety standards. Based on an analysis of regulatory key pain points from a user perspective, the authors of this brief propose a framework that responds to Draghi's criticisms and can help to achieve the goals of the national sandbox efforts through pan-European collaboration, rather than continuing with fragmented and inefficient national efforts.

Innovation-friendly regulation as strategic enabler for choosing Europe

The main objective of the proposed framework is to improve efficiency by improving dossier quality, while also creating transparency for applicants in terms of data requirements and timelines. The framework aims to limit approval timelines to the regulated 18-month period, develop best practices, and reduce the fragmentation of sandbox approaches across member states, thereby ensuring that European companies can choose Europe first and scale within the EU. Ultimately, the framework aims to transform regulation from a barrier into a strategic enabler, thus ensuring Europe's food and economic security and its technological leadership. It provides a streamlined regulatory sandbox approach for novel foods for European member states who want to champion and benefit from biotechnology and the biomanufacturing of innovative foods.

1 Draghi, M. (2024). High Level Conference – One year after the Draghi report: what has been achieved, what has changed. p.1-2. https://commission.europa.eu/document/download/0951a4ff-cd1a-4ea3-bc1d-f603decc1ed9_en?filename=Draghi_Speech_High_Level_Conference_One_Year_After.pdf

Introduction

> **“The next question is how we increase speed. In some areas, the EU can do more with the powers it already has. Regulation is where the Union can act fastest and most decisively. Europe has long styled itself as a regulatory power – it must now prove it can adapt to a fast-changing technological landscape. […]**
> **In the meantime, progress may depend on coalitions of the willing, using mechanisms such as enhanced cooperation. Even without treaty change, Europe could already go much further by concentrating projects and pooling resources. […]**
> **Europe’s citizens are asking that their leaders raise their eyes from their daily concerns towards their common European destiny and grasp the scale of the challenge.**
> **Only unity of intent and urgency of response will show that they are ready to meet extraordinary times with extraordinary action.”[2]**
>
> ***Mario Draghi***

The Competitiveness Compass,[3] which guides the work of the European Commission for the period 2024–2029, is based on the landmark report on the Future of European Competitiveness by Mario Draghi.[4] The plan for Europe to regain its economic power and prosperity is built around three strategic pillars:

1. Closing the innovation gap
2. Decarbonising our economy
3. Reducing dependencies

Regulatory efficiency is key to attracting investment and enabling scaling

Despite these ambitious aims, Europe’s regulatory efficiency is falling behind breakthrough science in deep tech, such as in the areas of biotechnology and the biomanufacturing of emerging foods. This is already significantly harming European competitiveness and will do so for generations to come, while also exposing the European Union to new geopolitical risks, particularly with regards to food and feed security. In order to close the innovation gap and reduce external dependencies, Europe’s world-class biotech and food-manufacturing startups, as well as its global food manufacturers and manufacturing-technology companies, need to be able to scale biomanufacturing and commercialise in Europe first, thus allowing them to complement the existing food supply provided by Europe’s rich cultural heritage.

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2 Draghi, M. (2024). High Level Conference – One year after the Draghi report: what has been achieved, what has changed. p.9. https://commission.europa.eu/document/download/0951a4ff-cd1a-4ea3-bc1d-f603decc1ed9_en?filename=Draghi_Speech_High_Level_Conference_One_Year_After.pdf

3 European Commission (2025). A Competitiveness Compass for the EU. https://commission.europa.eu/document/download/10017eb1-4722-4333-add2-e0ed18105a34_en?file-name=Communication_1.pdf

4 Draghi, M. (2024). The future of European Competitiveness. https://commission.europa.eu/docu-ment/download/97e481fd-2dc3-412d-be4c-f152a8232961_en?filename=The%20future%20of%20European%20competitiveness%20_%20A%20competitiveness%20strategy%20for%20Europe.pdf

Extra-EU dependencies in our food and feed supply need to be reduced by bringing the production of critical inputs back to Europe and diversifying supply. As a net-zero technology, food biomanufacturing could generate around $400 billion for food-related biotech markets by 2040.[5] This would enhance the EU's competitiveness, food autonomy, and sovereignty, while strengthening European security and preparedness.

Enabling a coordinated and collaborative approach to a regulatory sandbox for novel food for member states willing to collaborate would contribute to a safe and more efficient pre-market approval process.

Approving emerging foods more efficiently is essential if Europe is to scale up, close the innovation gap, and reduce its external geopolitical dependencies.

However, while the strategic importance of an efficient regulatory pathway is widely recognised in the context of medical biotechnology, this is not yet the case for food biotechnology, including the support of those emerging foods in a defence or dual-use contexts, in the EU.

Purpose of this strategic brief: understand the barriers to regulatory efficiency and showcase solutions

> "Innovation is always ahead of regulations. Changing or adopting regulations accordingly to innovation might be a lengthy and expensive process in Europe, but there are ways how to make things right. Getting data from experimentation and later implementing results to policy making is key to get levers moving. A Pan European Sandbox for Novel Foods would be a good example that Europe is moving in the right direction."
>
> *Dr Sigrid Rajalo, Director of Department of Innovation and Technology, Ministry of Economic Affairs and Communications, Government of Estonia*

Against this background, the purpose of this strategic brief is to provide a solution-oriented approach to building an innovation-friendly regulatory pathway for emerging foods.

These new foods and their manufacturing technologies are a means to an end, contributing, alongside other food sources, to securing Europe's strategic autonomy, decarbonisation, and food and economic security.

While the authors of this brief fully support the EU's high food-safety standards, we also believe in our capability as Europeans to make our regulatory systems and the regulatory approval process work within the regulated timeline, thereby ensuring that the EU does not further slip into extra-EU dependencies for our feed and food production.

In this sense, this brief should be understood as a contribution to the objectives set out for the mandate based on Mario Draghi's findings. Europe should not see its own food innovation as antagonistic to its traditional food heritage but as essential to strategic autonomy and sovereignty, especially at a time when China is striving to maximise its geopolitical influence and technological dominance and is investing heavily in food and feed biomanufacturing.

As a leader in biotechnology, China will be able to exert the same kind of control over food and feed derived from biomanufacturing that it currently does over rare earths and critical materials, thereby undermining European food and economic security.

From lab to fab? The cost of delaying regulatory efficiency

> "We did choose Europe first - and that choice has come at a significant cost. Our regulatory journey has taken more than twice as long as the EU's own market approval timeline anticipates. In the meantime, we've had to enter other global markets just to remain viable while waiting for approval at home. Ironically, the interpretation of the transparency regulation has brough us less - not more - transparency as applicants. Like many others, we're not asking for lower food-safety standards, but for a regulatory process in our home market that is efficient, predictable, and enables innovation to thrive."
>
> *Dr Juha-Pekka Pitkänen, CSO and co-founder, Solar Foods*

The true cost of regulatory barriers is a further loss of competitiveness and strategic autonomy, as investment in Europe is deterred.

Lost investor confidence has resulted in European capital building abroad

Investor confidence in the European Union's novel foods authorisation process – particularly its time-to-market and predictability – has significantly eroded. As a result, EU-based food-tech investors recommend that companies launch in the United States. However, to safeguard the security and quality of our food supply and uphold Europe's high standards, European companies need to have reliable and effective access to the Single Market.

Regulatory uncertainty, amplified by the absence of a unified market for capital, has led to the EU being deprioritised as an investment destination and undermined the attractiveness of the Single Market. Consequently, European capital that would otherwise have been invested in the EU is ultimately diverted instead to the US and Asian markets, further strengthening the technological leadership and competitiveness of the US and China.

Europe's choice: enable biotech and emerging foods at home or let China take control

The regulation of novel foods is not an end in itself – it is a means to securing Europe's food sovereignty and food security. Europe is facing a choice: enable and control food biomanufacturing at home or get controlled by it from abroad.

Europe's livestock sector already depends on China for critical feed inputs such as essential amino acids and vitamins. Industry data indicates that most of these inputs are imported from China, exposing a key structural vulnerability in our food system and weakening Europe's sovereignty.

5 Advanced Biotech for Sustainability. (2025). Harnessing the economic and environmental benefits of advanced biotechnology. https://framerusercontent.com/assets/mLK942I2HhzAYGubRZGchsFSY.pdf

A recent report from the European Feed Manufacturers Federation highlighted the fact that China produces, by volume, between 65% and 90% of precision-fermentation-derived amino acids and between 50% and 100% of the vitamins currently imported into the EU for animal consumption.[6]

Moreover, China is investing heavily in food biomanufacturing due to its strategic significance. This is evidenced by the number of generally recognized as safe (GRAS) notifications made to the United States Food and Drug Administration (FDA) by Chinese companies. Recently, 49% of the GRAS notices on the first page of the inventory were submitted by Chinese companies, all for innovative ingredients derived from fermentation or precision fermentation.[7] China is clearly aware that gaining a competitive advantage in terms of food security through food biomanufacturing, as part of a broader agricultural-processing and food-manufacturing strategy with biotechnology as a key component, will further consolidate the country's position of leadership at the intersection of geopolitics and technology.[8]

Pan-European regulatory sandboxes: key to European competitiveness and strategic autonomy

Regulatory sandboxes provide an effective solution that can streamline approval processes, reduce costs and workloads, shorten timelines, and alleviate administrative burdens, all while maintaining stringent safety standards. Regulatory sandboxes can facilitate the implementation of evidence-based adjustments to regulation, ensuring that oversight is aligned with technological advancements. They can allow for the use of temporary, flexible frameworks for rapid experimentation and take the principle of adaptive regulation into account, helping to ensure that innovation and oversight evolve in tandem. When applied to deep technologies such as biotechnology and biomanufacturing, regulatory sandboxes can provide a safe, step-by-step testing environment and ensure that the regulatory environment keeps pace with scientific progress. In this way, sandboxes can be powerful and efficient mechanisms for supporting competitiveness and enhancing strategic autonomy.

The enabling of cross-border regulatory sandboxes is vital if Europe wants to benefit from its R&D investments in biotech instead of exporting their economic potential and loosing on another battlefield, this time the 'biotech battlefield' where the Chinese "strategy is to use its growing biotech dominance as economic and geopolitical leverage around the world".[9]

Regulatory sandboxes for novel foods in the United Kingdom and EU member states

> **"The most innovative foods, such as cell-cultivated products, raise questions for regulators about potential safety hazards, how existing regulations apply, and how to ensure innovators know how to produce safe food. The UK's cell-cultivated product sandbox enables UK food regulators to work with industry and academia to generate the information needed to answer outstanding questions and increase the efficiency of the regulatory process, without compromising on existing food standards. Sandboxes like ours facilitate innovation whilst ensuring citizens' safety."**
>
> ***Joshua Ravenhill, Head of Cell-Cultivated Product Sandbox, Food Standards Agency, United Kingdom***

In addition to the United Kingdom, which is well advanced with its cell-cultivated product regulatory sandbox and has just launched a regulatory innovation research programme for precision fermentation, several EU member states, including Denmark, Spain, the Netherlands, and Germany, are exploring or preparing various experimentation spaces for novel foods.[10] The majority of the cell-cultivated regulatory sandbox participants in the UK are novel food companies located in the EU. To date, only two of the participating companies have submitted novel food applications in the EU.

As the example from the UK shows, countries that develop optimised regulatory processes and support experimentation spaces such as regulatory sandboxes can be expected to attract innovators and investors, thereby benefiting in terms of both competitiveness and access to strategic technologies.

In the global biotech race, Europe needs to act more in line with the objectives set out in the Competitiveness Compass and transform the novel food regulation from a barrier into a strategic enabler of biotech leadership, thereby avoiding further loss of competitiveness and autonomy and preventing Europe from slipping into greater dependency on China and the US.

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6 FEFAC. (2025). EU vulnerability for the sourcing of essential nutrients. https://fefac.eu/wp-content/uploads/2025/09/COMPRESSED2_FEFAC-Study_EU-vulnerability-for-the-sourcing-of-essential-feed-additives_100925.pdf

7 Analysis performed by Atova Regulatory Consulting on 3rd October 2025. Data retrieved from Gras Notices (n.d.). https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices

8 Ministry of Agriculture and Rural Affairs, People's Republic of China, 科. (n.d.). 农业农村部关于印发《全国农业科技创新重点领域(2024–2028年)》的通知. http://www.moa.gov.cn/govpublic/KJJYS/202502/t20250214_6469956.htm

Zhu, Y., & Begho, T. (2022). Towards responsible production, consumption and food security in China: A review of the role of novel alternatives to meat protein. Future Foods, 6, 100186. https://doi.org/10.1016/j.fufo.2022.100186

Zhang, X., Zhao, C., Shao, M., Chen, Y., Liu, P., & Chen, G. (2022). The roadmap of bioeconomy in China. Engineering Biology, 6(4), 71–81. https://doi.org/10.1049/enb2.12026

9 Young, T. (2025). How America Can Win the biotech Race: To outcompete China, Washington must unleash the private sector. Foreign Affairs. https://www.foreignaffairs.com/united-states/how-america-can-win-biotech-race

10 Food Standards Agency. (2025). FSA champions food innovation in the UK with the launch of a new Innovation Research Programme. https://www.food.gov.uk/news-alerts/news/fsa-champions-food-innovation-in-the-uk-with-the-launch-of-a-new-innovation-research-programme

Ministerie van Algemene Zaken. (2025). Dutch vision on biotechnology 2025-2040. https://www.government.nl/documents/reports/2025/04/11/dutch-vision-on-biotechnology-2025-2040

Deutscher Bundestag. (2025). Entwurf eines Gesetzes zur Verbesserung der Rahmenbedingungen für die Erprobung von Innovationen in Reallaboren und zur Förderung des regulatorischen Lernens. https://dserver.bundestag.de/btd/21/002/2100218.pdf

Beyond novel foods – a new European narrative: emerging foods and new, complementary protein production for strategic autonomy

In recent years, the polarisation around the term 'alternative proteins' has had a negative impact on the novel food sector. According to our research, the term ‘alternative protein’ has its roots in earlier usage in animal-nutrition literature.[11] It is imperative that the EU does not become further embroiled in a proxy war over ‘alternative proteins’ and ‘non-natural foods’, which pits the farming community against new foods. This is counterproductive and undermines Europe’s preparedness, competitiveness, and security.

Food biotechnology as a strategic asset in a new geopolitical landscape

It is hoped that this briefing will contribute to the de-polarisation of emerging foods and return to a discussion in which the geopolitical and technological importance of food biomanufacturing as a provider of complementary proteins is recognised through regulatory efficiency.

Europe cannot afford further polarisation that discredits its own scientific achievments in strategic biotechnologies. Many biomanufacturing technologies for emerging foods have been developed in Europe and received early-stage funding from the EU, only to be scaled up and commercialised outside Europe due to the significant time it takes to bring them to market, compared to other global markets.

It is vital that we close the European innovation gap by establishing optimised regulatory pathways for strategic technologies, including food biomanufacturing and biotechnology.

Objectives of the strategic briefing: an innovation-friendly framework for a pan-European regulatory sandbox

In recent years, regulatory sandboxes have attracted considerable attention as a means of exploring more flexible approaches to governing emerging technologies. However, much of the debate has focused on the limitations of policy and regulatory innovation, rather than on potential solutions. This might also explain why several member states have adopted individual sandbox approaches, with widely varying ambitions and levels of depth.

In order to design a regulatory sandbox that is in line with harmonised EU food law, it’s crucial that member states recognise the importance of regulatory sandboxes and adopt a coordinated approach to unlocking their potential through a joint regulatory learning process. The purpose of this strategic brief is to inspire an efficient and collaborative pan-European approach to a novel foods sandbox.

Rather than presenting another report, this brief offers an action-oriented framework for a Europe-wide novel food sandbox, with the following objectives:

- **Inspire a transparent and innovation-friendly pre-market approval process while maintaining Europe’s high food-safety standards.**
- **Create high-quality dossiers by demystifying the regulatory requirements and helping applicants to build better dossiers.**
- **Simplify and improve the applicant user experience by streamlining regulatory procedures – not by changing the legal process itself but by ensuring that decisions are delivered within the legislative timeline of 18 months, rather than the current average of 30 months.**
- **Foster cross-border collaboration among member states, the European Commission, industry, and innovators in order to achieve regulatory efficiency and enable member states who want to set up regulatory sandboxes for biotech.**
- **Restore investor and industry trust in the EU by meeting legislative timelines.**
- **Support food biomanufacturing as a strategic European asset by ensuring that food-biomanufacturing technologies, which are essential to the Union’s strategic autonomy and security, can be scaled up in the EU. This will reduce our dependency on feed and food supplies, particularly from China.**

11 National Research Council. 1973. Alternative Sources of Protein for Animal Production: Proceedings of a Symposium. Washington, DC: The National Academies Press. https://nap.nationalacademies.org/read/20417

Part 1:

Regulatory sandboxes as spaces for controlled experimentation

1.1. Regulatory sandboxes in an EU innovation policy context

A sandbox is a controlled, time-bound regulatory environment in which innovative products, services, and business models can be tested under supervision, often with temporary exemptions from standard rules.

The OECD report, *The Role of Regulatory Sandboxes in Promoting Flexibility and Innovation in the Digital Age* (2020), views regulatory sandboxes as a key instrument for regulatory innovation:

> **"A regulatory sandbox refers to a limited form of regulatory waiver or flexibility for firms, enabling them to test new business models with reduced regulatory requirements. Sandboxes often include mechanisms intended to ensure overarching regulatory objectives, including consumer protection. Regulatory sandboxes are typically organised and administered on a case-by-case basis by the relevant regulatory authorities. Regulatory sandboxes have emerged in a range of sectors across the OECD and beyond, notably in finance but also in health, transport, legal services, aviation and energy."[12]**

New EU innovation policy on regulatory sandboxes

In 2023, the European Commission referred to regulatory sandboxes as "structured frameworks for cooperation with competent authorities that allow innovators to develop and test new ideas, products, business models and services in a controlled real-world environment under the supervision of a competent authority".[13] Furthermore, regulatory sandboxes can relax or suspend rules under certain conditions and under the supervision of the relevant authorities. These authorities can also provide the necessary legal guidance applicable to products tested in the sandbox. However, it's important to note that regulatory sandboxes are always limited in terms of time and scope. They are structured spaces for experimentation, based on transparent frameworks and operating under strict guidelines.

Regulatory sandboxes based on a pan-European framework can balance stability, integrity, and consumer protection with accelerated innovation, as already demonstrated by the European Blockchain Regulatory Sandbox.[14]

Guidelines for sandboxes in general and for sustainable biotechnology, more specifically, as expected from the Innovation Act and the Biotech Act, would help to provide regulatory clarity, thereby supporting innovation and efficiency.

12 Attrey, A., Lesher, M., & Lomax, C. (2020). The role of sandboxes in promoting flexibility and innovation in the digital age. OECD Going Digital Toolkit Notes. p.7 https://www.oecd.org/content/dam/oecd/en/publications/reports/2020/06/the-role-of-sandboxes-in-promoting-flexibility-and-innovation-in-the-digital-age_ddcd3d40/cdf5ed45-en.pdf

13 European Commission. (2023). Regulatory learning in the EU: Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy. *In EUR-LEX*. p.6 https://research-and-innovation.ec.europa.eu/document/download/fc6f35cd-a8d6-4770-aefe-c09ca85cff8c_en?filename=swd_2023_277_f1.pdf

14 European Commission. (2023a). Launch of the European Blockchain Regulatory Sandbox. Shaping Europe's Digital Future. https://digital-strategy.ec.europa.eu/en/news/launch-european-blockchain-regulatory-sandbox

1.2. Applying sandboxes and regulatory learning formats to the current regulatory framework for emerging foods

Prof. Linda Nielsen describes different types of sandboxes in her 2024 report *Biosolutions, regulatory sandboxes as a tool for breaking down regulatory barriers*, commissioned by the Novo Nordisk Foundation.[15] Since the definition used for "biosolutions" includes novel foods, this categorisation is a useful tool for improving the regulatory efficiency of the food-safety evaluation process in the EU.

According to Nielsen, regulatory sandboxes are typically divided into three generations: **Gen1** being the classic sandbox that can be applied within existing frameworks, **Gen2** offering a sandbox that operates with regulatory exemptions, and **Gen3** being a sandbox based on new regulations.

Gen1: classic sandbox

First-generation sandboxes are regulatory tools that allow businesses to test and experiment with new and innovative products, services, or businesses under the supervision of a regulator for a limited period, while operating within existing regulations. No changes to the law are required in order to establish regulatory sandboxes, since they involve the use of the general supervisory powers available to the competent authorities.

The primary effects of a classic sandbox are the new knowledge/evidence from supervised testing, the legal clarity obtained, and mutual learning between innovators and regulators. Legal certainty can be obtained in areas where it might be difficult to decide which regulations – if any – are relevant to the products, methods, etc. being tested. However, the restriction of keeping within current regulations limits the scope and tools of the classic sandbox, which has led to the development of Gen2 and Gen3 regulatory sandboxes.

Application in the novel food sector: The Danish Food Administration has facilitated a Forum for Future Ingredients, in which industry representatives, ingredient companies, and research institutions discuss topics relevant to the ingredient industry. The Ministry of Food, Agriculture and Fisheries of Denmark initiated *The Ingredients Strategy* with the aim of creating better framework conditions for the ingredients industry, including identifying regulatory barriers to sustainable innovation in the sector. The ingredients covered by the strategy include additives, enzymes, and flavourings, as well as new raw materials, including protein sources and side streams from feed and food production.[16]

15 Nielsen, L. (2024). Biosolutions: Regulatory sandboxes as a tool to break down regulatory barriers. Novo Nordisk Foundation. https://www.foodbiocluster.dk/Files/Images/FBCD/Biosolutions%20-%20ressourcer/Biosolutions_Regulatory%20sandboxes%20as%20a%20tool%20to%20break%20down%20regulatory%20barriers.pdf

16 Nielsen, L. (2024). Biosolutions: Regulatory sandboxes as a tool to break down regulatory barriers. Novo Nordisk Foundation. p. 59 https://www.foodbiocluster.dk/Files/Images/FBCD/Biosolutions%20-%20ressourcer/Biosolutions_Regulatory%20sandboxes%20as%20a%20tool%20to%20break%20down%20regulatory%20barriers.pdf

Gen2: sandbox with exemptions

Second-generation sandboxes provide the same structure and benefits as Gen1 sandboxes while allowing for exemptions from current regulations, making them potentially far more powerful if used proactively. In practice, however, the primary focus seems to be on exemptions from national regulation rather than from EU-wide regulation, which limits their potential, given the legacy and scope of binding EU regulations. The challenge regarding Gen2 sandboxes is primarily the legal basis, and it is not always clear if exemptions can go beyond national regulations and include EU regulations.

Application in the novel food sector: Gen2 sandboxes have limited application in the food sector due to the predominance of binding EU regulations. Nonetheless, one positive example is the Dutch Code of Practice, which allows for pre-market tastings of cell-cultured foods in a controlled environment. Provided that the tasting protocol is positively evaluated by an expert committee and is adhered to by the company, no food-safety enforcement measures by the Dutch Food Safety Authority will take place.

Gen3: sandboxes based on EU regulation[17]

Gen3 sandboxes are similar to Gen1 and Gen2 sandboxes but operate under a specific legal basis in terms of EU regulation. This version of the sandbox is highly novel, with illustrative examples being the EU AI Act on artificial intelligence, the EU DLT Act on blockchain, the Net-Zero Industry Act, and a proposal on medicinal products.

The Net-Zero Industry Act (Regulation (EU) 2024/1735 or NZIA[18]) and food applications: While the NZIA primarily regulates strategic net-zero technologies, the provisions for regulatory sandboxes also include “other innovative technologies”, including biosolutions. According to Nielsen, “biosolutions” are understood as goods and services derived from combining biology and technology aimed at accelerating the green transition. Regulatory sandboxes for food biotechnologies may be established in these new areas, with the regulation creating a framework for their content. This clearly follows from Articles 2, 33, and 34 of the NZIA.

The NZIA enables the competent authorities in member states to set up a regulatory sandbox and to make derogations from national regulations, but limits their ability to grant derogations from current EU regulations. This may narrow the practical influence of the NZIA, since most biosolution regulations involve binding EU Regulations that cover pesticides, novel foods, additives, genetically modified organisms, and new genomic technologies.

Application in the novel food sector: Precision fermentation could be a relevant candidate for a regulatory sandbox, since there are currently several barriers to gaining the required market approval, including the difficulty of determining which regulations apply (e.g., GM food vs novel food), the difficulty of understanding the data requirements and procedure in practice, and the fact that applications are time-consuming, complex, and costly, and it may take several years to obtain approval.

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17 The paragraphs covering Gen1, Gen2 and Gen3 sandboxes are a summary of paragraphs 4-10 of the Novo Nordisk Biosolutions publication. pp.39-74.

Nielsen, L. (2024). Biosolutions: Regulatory sandboxes as a tool to break down regulatory barriers. Novo Nordisk Foundation. https://www.foodbiocluster.dk/Files/Images/FBCD/Biosolutions%20-%20ressourcer/Biosolutions_Regulatory%20sandboxes%20as%20a%20tool%20to%20break%20down%20regulatory%20barriers.pdf

18 European Parliament & Council of the European Union. (2024b, June 13). Regulation - EU - 2024/1735: Net-Zero Industry act. EUR-LEX. http://data.europa.eu/eli/reg/2024/1735/oj

Part 2

Part 2:

State of play – the novel foods approval process in the EU

2.1. Legal basis: the novel food framework in the EU

Regulation (EU) No. 2015/2283 ("EU Novel Food Regulation"[19]) provides a robust framework for the pre-market safety evaluation and authorisation of novel foods. Together with the other applicable food-safety and hygiene regulations in the EU, this framework ensures a high level of consumer protection. Since 2018, the year in which the current EU novel food regulation became appliable, more than 100 novel foods have been approved for use.

While the EU novel food regulatory framework is often seen as a barrier to market entry, it does offer some unique benefits:

- **Novel-food scope:** The regulation captures a wide range of novel food technologies, including cell-cultured, new production processes, and fermentation.
- **Centralised procedure:** Novel food approval follows a centralised procedure, meaning that, once a novel food is authorised, it can be sold in all 27 EU member states.
- **Five-years data protection:** Applicants can request five-years of data protection for proprietary data that they have generated to support their novel food application, meaning that no other company can market the same novel food unless they submit their own dossier with their own data during the five-year period or receive a license from the data owner.
- **Confidentiality:** Applicants can furthermore request confidential treatment of certain information, except for information that must legally be made public (for instance, data regarding safety). If confidentiality regarding certain data is granted, this shall be for an unlimited period.
- **Unlimited validity:** Novel food approval is for an unlimited period. There is no set provision for the renewal of the authorisation, as is the case for other regulated products (e.g. feed additives and smoke flavourings).

New technologies and innovations in food manufacturing should be encouraged, since they hold great potential to decarbonise the food system, enhance food security, and bring benefits to new consumer groups – so long as the currently high level of consumer protection is ensured.

An overview of the novel food approval process is provided in Figure 1. The approval process can be broken down into four distinct phases:

1 **Pre-submission phase:** Applicants prepare their dossiers and generate the data to support their application. For certain studies, the European Food Safety Authority (EFSA) must be notified before the study start date in order to comply with the EU Transparency Regulation (Regulation (EU) 2019/1381). Applicants can also request general pre-submission advice from EFSA during this period.

2 **Validation phase:** Once the dossier has been submitted to the European Commission (EC) via the e-submission food-chain platform, the EC performs a validity check and then sends a mandate to EFSA, without delay, to perform a suitability check. The suitability check should take 30 days. Once the suitability check is completed, the dossier is validated.

3 **Risk assessment:** EFSA performs a scientific risk assessment of each novel food application. The legal timeline for the risk assessment is nine months, but this can be extended by EFSA if they have additional questions or data requests. Once EFSA has completed their risk assessment, they adopt and publish their scientific opinion.

4 **Risk management:** Based on the EFSA opinion, the EC prepares a draft implementing regulation, which is presented to the Standing Committee on Plants, Animals, Food and Feed (PAFF), where member states vote by a qualified majority to approve novel foods. A qualified majority of 55% of EU member states, representing 65% of the EU population, must be reached. The legal timeline for the risk-management phase is seven months.

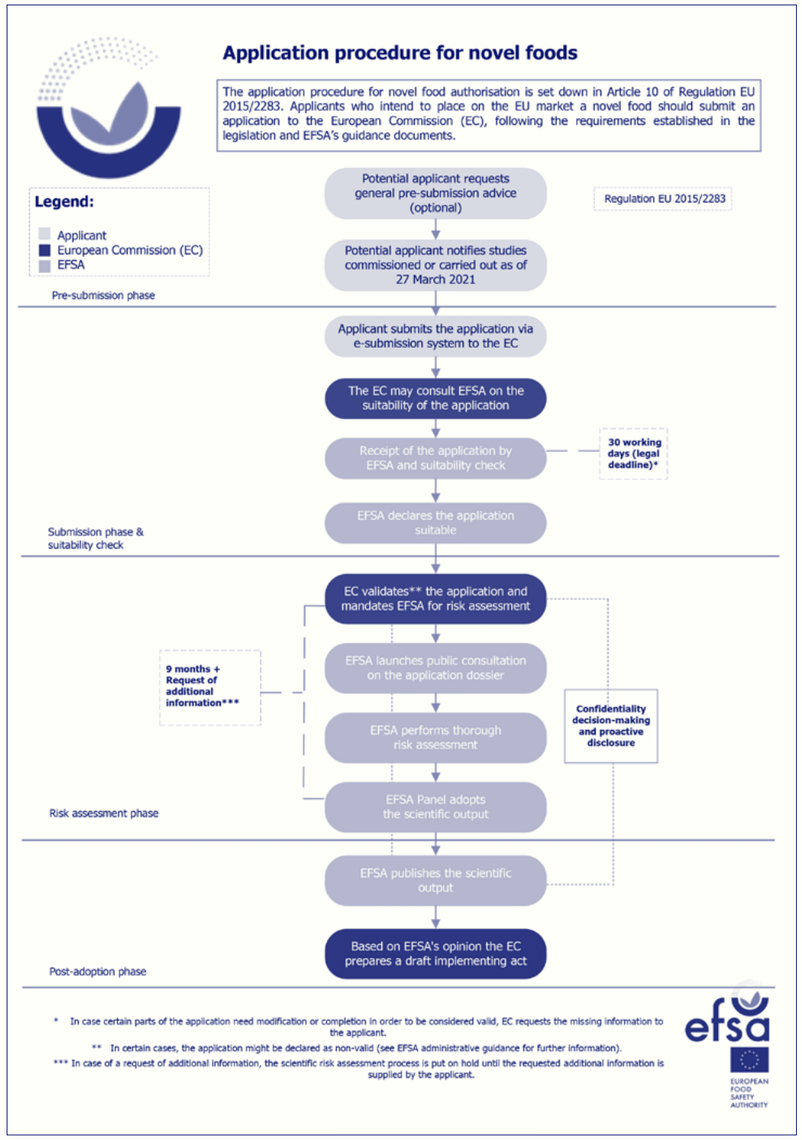

Figure 1. The approval process can be broken down into four distinct phases.

European Food Safety Authority. (2018). Application procedure for novel foods. https://www.efsa.europa.eu/sites/default/files/applications/apdeskap-plworkflownutrinovel2018.pdf

19 European Parliament & Council of the European Union. (2021, March 27). Regulation - 2015/2283: EU Novel Foods Regulation. EUR-LEX. http://data.europa.eu/eli/reg/2015/2283/2021-03-27

2.2. International comparison of market approval processes

> "Clearly, Europe is an attractive location for new companies in the food sector. We have good access to early-stage capital, a highly educated and skilled workforce, and a wealth of expertise. Unfortunately, when it comes to bringing products to market, Europe is rarely the preferred option due to the prolonged and unpredictable nature of its regulatory approval process for novel foods.
> Both the US, and particularly China, are investing heavily in novel foods derived from food biotechnology to ensure food security and maintain a geopolitical position of technological leadership. Although Europe is investing too, companies subsequently leave for the US because the EU's regulatory pathway is so lengthy and opaque.
> The issues are well known. The question is whether there is the political will to tackle these issues or continue exporting European assets to the US and increasing dependency on Chinese biotech."
>
> *Stéphane MacMillan, CEO and co-founder, Verley Food*

When comparing the EU novel food approval process to other regional jurisdictions, the regulated timeline is comparable. However, in practice, when it comes to actual timelines and hidden costs:

- The EU takes an average of two-and-a-half years and is highly unpredictable compared to the other regions. In some cases, it takes more than five years to obtain approval.
- The costs of generating data to support a novel food application in the EU are higher and there is more uncertainty due to the cost of additional data requests that occur during the risk-assessment period. One of the main reasons for the increased costs associated with an EU dossier is that EFSA requires data from at least five independent batches of the novel food ingredient, whereas the other regions require a minimum of three batches. EFSA also requires shelf-life data to be submitted, along with data on the stability of the novel food ingredient in relevant food matrices, adding additional costs and complexity, compared to other regions.

Country/Region	Regulatory framework	Regulated timeline	Actual timeline[20]	Timeline uncertainty[21]	Average study costs at submission (EUR)[22,24]	Cost uncertainty (EUR)[23,24]
EU	Novel food approval – pre-market safety assessment	18 months	Average of 2.5 years, up to more than 5 years in some cases	1-3 years	250,000	150,000->500,000
US	Generally Recognized as Safe (not a pre-market safety assessment or approval)	180 days + 90-day extension	10-12 months	3-6 months	75,000[25]	50,000
Singapore	Novel food approval – pre-market safety assess-ment	9-12 months	12-24 months	6-12 months	100,000	50,000-150,000
Australia/New Zealand	Novel food approval – pre-market safety assessment	12-18 months	12-24 months	6-12 months	250,000	50,000-150,000

20 Average timeline from when dossier is submitted, based on author experience and an analysis of publicly available information.

21 Timeline uncertainty is the minimum and maximum timeline that approval can take in reality, based on author experience and an analysis of publicly available information.

22 Average cost of the studies/data package at the time of submission. This cost does not include the consultant costs or staff costs involved in building the dossier and managing all pre-submission activities, based on author experience.

23 Minimum and maximum additional costs that applicants may face post-submission, based on regulator/risk assessor additional data requests during evaluation. Costs are general estimates, based on author experience.

24 The costs are based on the scenario where the costs for each region are taken in isolation. In reality, the same data can be used for multiple jurisdictions. It is not necessary to perform separate studies for each region.

25 A GRAS dossier is reliant on published safety data, hence the study costs are lower.

2.3. The EU novel foods approval process: regulatory pain points and recommendations for an innovation-friendly user journey

The table below highlights the main challenges faced by applicants, along with specific examples and our recommendations on how to improve efficiency and streamline the approval process. The recommendations are linked to the concrete work packages presented under Section 3.2 of the framework.

We recognise that the loss of efficiency is not only related to the risk-assessment and risk-management phases, but that applicants need to prepare good quality, compliant dossiers to start with. As such, our recommendations are also aimed at improving dossier quality.

Regulatory pain points	What it looks like, according to the EU regulatory framework	What it looks like in reality	Examples	Recommendations and action points
1. Guidance documents	There are two key guidance documents for novel foods (administrative and scientific), along with potentially a further 30 other cross-cutting guidelines that might be applicable, depending on the nature of the novel food. There are also the practical arrangements of the Transparency Regulation that applicants must follow.	EFSA has prepared several guidance documents to assist applicants in preparing their novel food dossiers. While the guidelines provide a good foundation, they can be challenging to interpret and apply. Being able to understand and apply the guidance for a specific novel food is complex and requires extensive experience. Often the guidance is not interpreted correctly, leading to delays in validation and risk assessment. Additionally, the EFSA guidance documents are not updated regularly, leading to EFSA asking applicants for further information/data that is not covered in the guidance documents.	Based on experience, applicants often do not know how to interpret and apply the guidance to their specific novel food and production process. For example, applicants struggle to apply the tiered approach to toxicity studies, and either do not perform studies that are required to support the safety of their novel food, leading to additional costs and timelines during the risk assessment, or they perform toxicological studies that were not necessary in order for EFSA to make their conclusion regarding the safety of the novel food. Moreover, it is a challenge to identify what the test item used in the toxicity studies should be, leading to EFSA requesting that the studies be repeated, or additional studies performed on a different form of the novel food. For example, for novel foods derived from microbial biomasses, EFSA requires applicants to perform *in vitro* genotoxicity tests on the supernatant and lysed cells, meaning that the studies must be performed twice, using two different test items, leading to extra costs and time. For general compositional testing, selecting the right form of the novel food can also be challenging. The data should be generated with relation to the form of the novel food that will be placed on the market, although in some cases, the novel food ingredient is stabilised using another ingredient. However, EFSA typically wants to see the analytical data from the novel food itself, without a stabiliser or carrier, as this is the most concentrated form. Applicants struggle to interpret this and sometimes test the wrong form of the novel food, which can lead to significant increases in time and costs.	**Guidance documents:** Guidance documents are essential for applicants to understand the requirements and build a good-quality dossier. While guidelines should not and cannot be prescriptive due to the heterogenous nature of novel foods, guidance documents should be regularly updated and could be easier to use and interpret. Additionally, EFSA could consider publishing a list of common additional requests for information (clock-stops) in an FAQ document. **Interactive AI-based gap analysis:** We also recommend preparing an interactive gap-analysis template, utilising AI, that can assist in preparing a robust regulatory roadmap for applicants to follow. *See work package 2 in paragraph 3.2 for practical implementation.*

Regulatory pain points	What it looks like, according to the EU regulatory framework	What it looks like in reality	Examples	Recommendations and action points
2. Pre-submission advice	Article 32a of Regulation (EC) 178/2002 ("General Food Law Regulation"[26]) outlines the existing scope of pre-submission advice, focusing narrowly on the applicable rules and content required for applications.	General pre-submission advice is limited to discussions around guidance and procedural aspects. There is no scope for discussion on study design or requests for technical clarification regarding the guidance. In the complex process of preparing novel food dossiers, pre-submission advice is a pivotal step for applicants. While the guidelines serve as a crucial foundation, their non-prescriptive nature leaves significant room for interpretation. This ambiguity and lack of transparency for applicants can introduce uncertainties in designing an appropriate safety-data package.	Discussing the need for toxicological studies can save significant time and money. For example, a 90-day subchronic toxicity study in rats costs ca. 300,000 EUR and takes 9-12 months. In EFSA's novel food opinion for apple fruit cell culture biomass,[27] EFSA concluded that the subchronic toxicity study was not needed to establish the safety of this novel food. Moreover, for the same novel food, the applicant had to redo the genotoxicity studies because they did not select the right test item. The battery of *in vitro* genotoxicity tests costs ca. 50,000 EUR and takes three months. This illustrates how critical pre-submission advice would have been to this applicant, saving them considerable time and money.	**Innovation-friendly pre-submission advice:** Recognising the importance of pre-submission advice, it becomes clear that offering non-binding, detailed consultations (while maintaining EFSA's independence) would have dual benefits. For applicants, it presents an opportunity to build better-quality dossiers by clarifying expectations and requirements upfront. For EFSA, it enhances the efficiency of risk assessments by providing a preliminary understanding of the novel food products under consideration. Pre-submission advice should allow companies to present their novel food and ask scientific and technical questions in order to obtain non-binding feedback on studies and study designs. Several regulatory agencies, including the US Food and Drug Administration and Food Standards Australia and New Zealand, offer non-binding pre-submission advice. *See work package 3 in paragraph 3.2 for practical implementation*
3. Transparency regulation and e-submission food chain platform	Transparency Regulation (EU) 2019/1381[28] aims to increase transparency in the risk assessment of regulated products in the food chain. It sets out the requirements for confidentiality and the notification of studies, among others.	Since the Transparency Regulation's entry into force on 27 March 2021, EFSA has rejected 30 applications for non-compliance with Article 32b of the General Food Law Regulation ("failure to notify studies in advance"). Risk of failure to notify studies correctly has a significant impact on the approval timeline. The regulation is difficult and onerous to navigate. It takes significant time and resources to manage the confidentiality requests and to upload a dossier to the e-submission food chain platform (ESFCP).	Since the transparency regulation entered into force, 33 (ca. 30% of dossiers) novel food dossiers have been classified as non-valid because of the failure to notify studies correctly, highlighting the fact that failure to notify studies correctly is a common problem.	**Transparency Regulation review from a regulatory user perspective** Simplify the confidentiality procedure and the ESFCP. Evaluate the scope of the notification of studies (e.g. limit to toxicity studies).

26 European Parliament & Council of the European Union. (2002, January 28). Regulation - 178/2002: General Food Law Regulation. EUR-LEX. http://data.europa.eu/eli/reg/2002/178/oj

27 EFSA (2023). Safety of apple fruit cell culture biomass as a novel food pursuant to Regulation (EU) 2015/2283. https://www.efsa.europa.eu/en/efsajournal/pub/8065

28 European Parliament & Council of the European Union. (2019, June 20). Regulation - 2019/1381: Food Chain Transparency Regulation. EUR-LEX. http://data.europa.eu/eli/reg/2019/1381/oj

Regulatory pain points	What it looks like, according to the EU regulatory framework	What it looks like in reality	Examples	Recommendations and action points
4. Timelines	Regulated timelines to market: EC Validity check: without delay EFSA suitability check: 30 days EFSA risk assessment: 9 months Risk management: 7 months Total = ca. 18 months	The average timelines are: EC validity: 114 ± 181 days (range: 0–1,430 days) EFSA suitability: 185 ± 122 days (range 15–758 days) EFSA risk assessment: 629 ± 338 days (i.e. 20.7 ± 11.1 months). The shortest evaluation lasted 179 days (i.e. 5.9 months), while the longest one lasted 1,714 days (i.e. 56.4 months) EFSA publication of opinion: 48 ± 16 days, with a range of 26 to 107 days EC Risk Management: ca. 7 months	A significant amount of time is lost during the EFSA suitability stage, with EFSA asking for additional scientific data and points for clarification during the suitability check, when this phase should ideally be checking the completeness of the dossier against the guidance. During the risk-assessment itself, the average number of clock-stops/additional data requests issued by EFSA during the risk assessment is 3, adding a significant amount of time and uncertainty to the risk-assessment process. The clock-stops can cover the same sections of the dossiers several times. A dossier section should be fully reviewed and then closed in order to reduce multiple clock-stops for the same section. Also, many questions are highly academic and are not grounded in probable risk in the context of food safety. We also recognise that applicants need to prepare good quality and compliant dossiers. This is intrinsically linked to the interpretation of the guidance documents and the scope of pre-submission advice, as described above. Moreover, applicants often struggle to respond to clock-stop requests adequately, leading to EFSA asking more questions on the same dossier section. This leads to significant and often costly delays and additional work for EFSA.	**Delay analysis in detail** This discrepancy between regulated and actual timelines underscores the critical need to understand why this is happening. Streamlining the evaluation process and exploring measures to align actual timelines with regulated timelines will not only enhance efficiency but is also in line with the innovation principle and supports innovation within the food sector. We propose to further evaluate in depth the main reasons for the delayed timelines to market, looking at what applicants can do better and suggesting procedural changes in order to streamline timelines. **Supporting guidelines for member states** We propose defining guidelines in the respective Act that describe how member state competent authorities can play a role in the pre-submission phase, potentially offering pre-submission reviews of dossiers as an initial quality check in order to ensure that dossiers meet the minimum requirements for passing validation. We also propose that they evaluate the use of AI tools and explore how they can be utilised to improve the quality of dossiers. Guidelines for sandboxes could also allow member states to explore such AI applications for the benefit of all. **Define minimum dossier-quality standards and reject poor-quality dossiers** We recommend that the EC/EFSA reject applications or ask applicants to withdraw poor-quality dossiers that do not meet minimum quality standards. This will reduce the number of poor-quality dossiers in the system, along with the number of clock-stops required. We also recommend that applicants who do not respond to clock-stops by the agreed deadline have their application rejected. This will reduce EFSA's workload as well as the risk-assessment timelines. **Limit clock-stops and streamline communication on additional data requests** There should also be a limit to the number of clock-stops that EFSA can issue (provided that the dossier is of good quality in the first place). We recommend that the number of clock-stops be limited to 3 during the risk-assessment phase, and that all questions or additional data requests for a specific dossier section are requested in one clock-stop. **Provide clear guidelines for communication around clock-stops** Finally, we recommend that there is a section in the novel food administrative guidance document that provides advice to applicants on how to respond to clock-stops. EFSA does offer clarification calls for applicants once a clock-stop is issued, but does not always provide clear feedback on what they want to see, leaving it up the applicant to guess – which often means that the applicant does not address the question specifically, leading to EFSA asking further questions. We recommend that the clarification calls provide applicants with more specific feedback on what the deficiencies are, without compromising EFSA's independence.

Regulatory pain points	What it looks like, according to the EU regulatory framework	What it looks like in reality	Examples	Recommendations and action points
5. Clock-stops	During the EC validity check and the EFSA suitability check and risk assessment, applicants can be asked to provide additional information. During the EFSA suitability check, the requests should be limited to ensuring compliance with the guidance. During the risk assessment, EFSA may ask for further information/data. During a clock-stop, the 9-month risk-assessment timeline is paused.	During the scientific evaluation phase, EFSA frequently issues clock-stops, which contributes to extended timelines and represents nearly half of the total evaluation time. While these clock-stops often arise from missing or incomplete information required to assess novel food safety, they may also reflect EFSA's cautionary approach and high workload, with EFSA using the clock-stop mechanism to buy time. According to Le Bloch et al., on average, applicants receive 2.7 ± 1.9 clock-stops, ranging from 0 to 8 requests. Applicants need 130 days, on average, to answer one EFSA clock-stop (range 0–733 days). The overall accumulated time needed to answer all EFSA clock-stops is 353 ± 299 days (range 0–1213 days). The time taken by applicants to answer EFSA requests represents 47 ± 25% of the total evaluation time, while EFSA evaluation represents only 53 ± 25% of the total time needed for evaluation.	Clock-stops have been discussed in the section above, but additionally, due to the length of time that the risk-assessment phase extends to, changes to panel members can lead to new questions on sections of the dossier that have already been addressed. While it is understandable that new panel members bring new knowledge and insights, new questions and clock-stops should be kept to a minimum and changes in panel members should not automatically lead to new questions. [29]	**Clock-stop analysis** Understand the mechanisms behind clock-stops and analyse the main reasons for clock-stops by analysing publicly available data. For example, if most clock-stops are related to toxicology or absorption, distribution, metabolism, and excretion, then this indicates a need for further clarity in the guidance. Additionally, we propose that the timelines for applicants' responses be evaluated. As described above, we recommend a maximum number of 3 clock-stops, with rigid timelines for the applicant to reply (e.g. the applicant can only request one extension with a good justification). If the applicant does not respond, then EFSA moves to issue their opinion swiftly. *See work package 4 in paragraph 3.2 for practical implementation*
6. Pre-market testing/tasting	Neither the EU Novel Food Regulation, nor any implementing legislation, provide for the option to set up formal testing or tastings of novel foods prior to obtaining EU novel food authorisation. This may be justified for food-safety reasons but clearly misses an opportunity to address an urgent need for companies involved in EU food innovation. Telling the story about alternatives to conventional meat or dairy is clearly not sufficient to create an appetite for these products. The proof of the pudding is in the eating!	Whereas EU food companies do test their novel foods *sub rosa* in their labs, they would love to offer their foods for tastings in a closed-loop setting to a broader public, also prior to market authorisation. However, they are not legally allowed to do so. Currently, this challenge is being addressed on a very fragmented level, i.e. tasting of cell-ag products prior to obtaining market authorisation has only been possible in the Netherlands since 2023. A similar regime is currently being put in place for fermentation-based products, expected to be live in Q4 2025. Both initiatives are, however, only open to companies with operations in the Netherlands.	Many EU based cell-ag companies are eager to set up pre-market tastings and have made inquiries whether they could do so in the Netherlands. For several reasons, these tastings can only be performed by companies with business operations in the Netherlands. From this example, it follows there is a clear need for the establishment of an EU-wide tasting framework.	**Offer guidelines on novel food tastings across member states** The possibility to legally set up public tastings of EU novel foods under supervised conditions should be extended to a pan-EU level. This could be done, for example, by creating an option in the Biotech Act to extend Dutch practices to other EU member states, for instance, on the basis of an opt-in mechanism. *See work package 5 in paragraph 3.2 for practical implementation*

29 Bloch, J., Rouault, M., Langhi, C. et al. The novel food evaluation process delays access to food innovation in the European Union. npj Sci Food 9, 117 (2025). https://doi.org/10.1038/s41538-025-00492-x

Regulatory pain points	What it looks like, according to the EU regulatory framework	What it looks like in reality	Examples	Recommendations and action points
7. Scale-up and process changes	Companies can submit a modification-of-use dossier to change the proposed uses or specifications of the original authorisation.	In the EU, once a novel food dossier is submitted, process optimisation is not easy to navigate, especially when the production process is optimised during the risk-assessment phase prior to authorisation.	Many companies are not operating at full commercial scale when they produce their regulatory batches. This is usually because they cannot invest in large-scale manufacturing until they obtain authorisation. Moreover, for precision-fermentation-derived ingredients, strain optimisation is required to maximise efficiency and improve yields. For cell-cultured meat production, the culture media may need to be optimised or updated downstream processes may need to be implemented.	**Provide innovation-friendly mechanisms for process optimisation** Provide clear guidance and mechanisms for process optimisation. For example, building in flexibility during the risk assessment, so that applicants can provide data to support process optimisations without leading to extensive delays in risk-assessment timelines. Additionally, provide a fast-track mechanism for modifications-of-use requests, with clear guidance on what data applicants should provide.
8. Data requirements	Commission Implementing Regulation (EU) 2017/2469 on the administrative and scientific requirements.[30]	The data requirements for novel food ingredients are outlined in EFSA guidance.	EFSA requires five independent batches of the novel food, which means that each batch should be produced with new batches of raw materials. This is often complex and cost prohibitive. Raw-material quality and specifications should be managed in accordance with HACCP and the novel food should meet the defined/authorised specifications. Moreover, EFSA requires applicants to provide shelf-life stability studies on five independent batches and stability of the novel food ingredient in relevant food-matrices. Under HACCP, food businesses are already obliged to produce data on shelf-life. Stability in food matrix studies is complex and can be costly if a novel food ingredient is proposed for use in many different types of food matrices. Moreover, these stability studies can require a large amount of the novel food ingredient.	**Offer flexibility during risk assessment** Review the need for “independent” batches and for five batches for stability studies, and permit dossiers to be submitted with ongoing shelf-life studies. Permit applicants to provide data regarding stability in food-matrix studies during the risk-assessment period. Consider providing data on certain regulated contaminants (e.g. dioxins and PCBs) for three batches of the novel food, as these contaminants should be controlled within the principles of HACCP and supplier-verification programmes.

30 European Commission. (2017). Commission implementing regulation: Administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods. In EUR-LEX (No. 2017/2469). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2469

Part 3

Part 3:

Proposal for a pan-European regulatory sandbox for novel foods

> “Innovation-friendly regulation lies at the heart of European competitiveness. It has the power to make or break an industry. If we want biotechnology to be a central pillar of decarbonisation and our future industrial infrastructure, we need to regulate for this future. Biotechnology and biomanufacturing are already a reality. A coordinated European approach to regulatory sandboxes for the sector would enable member states to collaborate and build on each other’s expertise. For us as an investor, this would help our portfolio companies to stay and scale up in Europe.”
>
> *Rinke Zonneveld, CEO Invest-NL*

3.1. Key features of a pan-European regulatory sandbox

The following framework for an innovation-friendly pan-European regulatory sandbox for novel foods sets out recommendations for an experimental space that combines different features. Some of these features incorporate elements of Gen1 and Gen2 sandboxes. Others require exemptions from current regulations in a Gen2 sandbox context, or a new regulatory basis in a Gen3 sandbox context.

The proposed framework aligns with the typology of experimentation spaces and their features, as outlined in the Commission’s guidance documents from 2022 and 2023.[31] It also supports the call for enhanced dialogue on food innovation, as set out in the Vision for Agriculture and Food.[32] Acknowledging that food cultures vary across the EU, such a pan-European regulatory innovation format should consider a variety of aspects, including social, ethical, and economic impacts.

The framework combines a variety of characteristics and features of experimentation spaces:

- **Testbed and regulatory sandbox:** Focused on assessing the needs of applicants as users of the regulatory process, helping them to prepare their dossiers, and guiding them through the process.
- **Living Lab:** Tastings of novel foods offered under a shared framework provide an opportunity to enhance dialogue with citizens and other stakeholders about the social, ethical, economic, environmental, and cultural aspects of food biotechnology, as set out in the Commission’s communication on the Vision of Agriculture and Food from 2025.[32]
- **Cross-border, shared experimental regulatory learning space** across participating member states to reduce fragmentation, foster real-time regulatory learning, and accelerate efficiency throughout the process, from dossier preparation to support during the process.
- **Shared learning resources** such as shared templates, for example, for a novel food gap analysis, as well as a tasting framework applied across collaborating member states.
- **Shared development of AI and digital tools** in order to streamline processes. These tools should improve efficiency without creating additional regulatory burdens.
- **Scope:** Recruit 10 companies that are planning to submit novel food dossiers in the next 12 months, across participating member states.
- **Key result:** At least two novel food dossiers submitted and validated according to the regulated timelines, and under risk assessment
- **Duration:** 2.5 years

3.2. Framework for a pan-European regulatory sandbox programme

The sandbox set-up presented below contains a number of recommendations that will contribute to innovative food products entering the EU market with greater efficiency. All activities described in the ‘work packages’ column can be applied as soon the stakeholders involved agree to move forward. The subsequent deliverables can be implemented in a Gen1 sandbox context, while others will require exemptions from current regulations in a Gen2 sandbox context, or a new regulatory basis in a Gen3 sandbox context. Learnings taken at member state level in one country can relatively easily be applied in other countries, such as the Dutch sandbox example for tastings (See Gen2 sandbox example). For recommendations requiring a legal basis in the EU regulatory framework, the EU Biotech Act could and would need to fill this gap.

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31 Kert, K., Vebrova, M. and Schade, S., Regulatory learning in experimentation spaces, European Commission, 2022 https://publications.jrc.ec.europa.eu/repository/handle/JRC130458

European Commission. (2023). Regulatory learning in the EU: Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy. In EUR-LEX. https://research-and-innovation.ec.europa.eu/document/download/fc6f35cd-a8d6-4770-aefe-c09ca85cff8c_en?filename=swd_2023_277_f1.pdf

32 European Commission. (2025). A Vision for Agriculture and Food: Shaping together an attractive farming and agri-food sector for future generations. In EUR-LEX. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0075

Work packages	Scope	Deliverables	Timeline (1 - 130 weeks)
WP1 – Joint call from participating member states for companies to join the sandbox	• Define and finalise the scope and criteria for participating companies. • Ideally, companies should be planning to generate the regulatory batches and analytical data to support their novel food application within the next 12 months.	• Define the joint framework. • Select 10 companies across participating member states.	**Weeks 1-8**
WP2 – Review of guidance documents, catalogue of services, and gap-analysis framework **Deliverables to be implemented in a Gen1 sandbox:** • Update EFSA guidance documents. • Publication of gap-analysis template. • Checklists on EFSA website.	• Review of novel food guidance documents and cross-cutting guidelines, along with the EFSA catalogue of services and tools. • Identify the main grey areas or parts that are unclear/confusing. Work with applicants to identify the sections of the guidance that are unclear to them.	• Series of workshops with sandbox participants. • Report on the main parts of the guidance, support services, and tools that lack clarity. • Provide recommendations for improvement. • Build an interactive gap-analysis template to help applicants understand the requirements and improve the quality of their novel food dossiers. • Assess the use of AI tools. • Use the gap-analysis template for each sandbox member.	**Weeks 8-22**
WP3 – Pre-submission advice **Deliverables to be implemented in a Gen3 sandbox context:** • Changes to EU Novel Food Regulation, enabling the extension of the scope of pre-submission advice. • Deliverables to be implemented in a Gen1 context. • Changes to EFSA Practical Arrangements, extending the scope of pre-submission meetings (provided that they stay in line with EU Novel Food Regulation).	• Analysis of pre-submission advice in other jurisdictions. • Interviews with applicants to determine what would help them in pre-submission advice meetings. • Explore the role of member state competent authorities in providing pre-submission advice and as partners throughout the process.	• Workshop with sandbox participants. • Report on recommendations for pre-submission advice.	**Weeks 12-22**
WP4 – Novel food approval process deep dives **Deliverables to be implemented in a Gen1 sandbox context:** • EFSA to publish a non-confidential summary of insight interviews on its website.	• Analysis of novel food timelines, identifying the main reasons for delays. • Analysis of transparency regulation, clock-stops, and the main questions asked by EFSA. • Establish dialogue platform: Engage with the EC and EFSA to get their feedback on what applicants can do better to build more robust dossiers. • Interview companies that have been through the novel food process in order to identity the main reasons for delays.	• Series of confidential interviews with novel food applicants, as well as with the EC and EFSA. • Prepare a report identifying the main reasons for delays and offer recommendations for improvement.	**Weeks 12-30**
WP5 – Pre-market tasting protocol and consumer panel **Deliverables to be implemented in a Gen2 sandbox context:** • EU member states to allow pre-market novel food tastings and agree not to apply enforcement with respect thereto.	• Analysis of the existing frameworks for tasting novel foods prior to market authorisation (i.e. Singapore and the NL). Interview companies that have set up tastings, recording both their positive and negative experiences. • Develop a best-practice guidance for enhanced tastings with consumer panels across member states.	• Prepare a pre-market tasting protocol, distilling best practices from existing tasting protocols. Consider whether any specifics should apply in the case of tastings that are set up at a pan-EU level, taking into account cultural and culinary traditions/preferences. • Share protocol with participating member states. • Host combined tastings and consumer panels across the EU. • Report back to the Commission and share consumer-panel insights.	**Weeks 30-85**
WP6 – Build novel food dossier **Deliverables to be implemented in a Gen1 sandbox:** • Better-quality novel food dossiers.	• Review of successful public-facing novel food applications. • Build a dossier template and prepare an application, thereby exploring how the use of generative AI could yield efficiency improvements. • Request non-binding feedback from the EC and EFSA regarding the quality of the submitted dossier. • Explore the role of member state competent authorities in providing a pre-submission dossier review.	• Build a novel food dossier template and prepare a high-quality, compliant novel food dossier for submission.	**Weeks 30-100**
WP 7 – Novel food dossier	• Submit a compliant dossier to the EC. • Pass validation and continue to the risk-assessment phase.	• Submit at least two novel food dossiers and pass validation within the regulated timeline.	**Weeks 100-130**
WP 8 – Publication of summary of sandbox findings and policy recommendations	• Review together with applicants as regulatory users, materialise learnings, and transform the sandbox into a permanent testbed	• Review defined framework. • Return to applicants for feedback on the process. • Formulate key learning and refine framework. • Establish a permanent testbed to ensure continuous regulatory learning.	**Weeks 120-130**

Conclusion and next steps

> “Effective regulation has a trickle-down effect. For example, in the case of the lengthy EU approval process for novel foods, this means that, once they have been established here, all our European assets leave the continent, because the time it takes to bring products to market is simply uncompetitive on an international comparison. The introduction of pan-European regulatory sandboxes would be a key mechanism for regulatory innovation, helping to close the European innovation gap - such as in novel foods.”
>
> *Lars O. Lüke, Innovation Manager AgTech and (Novel) Food, SPRIND, German Federal Agency for Disruptive Innovation*

The proposed framework provides a foundation for a coordinated approach among member states towards a pan-European regulatory sandbox.

As the authors of this report, we are aware of the significant interest in a pan-European regulatory sandbox for emerging foods, such as novel foods, from industry players of all sizes.

If regulatory sandboxes can be established for other critical technologies, they can also be established for innovative food-manufacturing technologies, such as food biotechnology and food biomanufacturing. We are calling on the European Commission to enable Gen3 regulatory sandboxes in this context.

We invite member states that wish to stimulate economic growth and job creation through biotechnology and emerging foods to align with the proposed framework, agreeing on a common process towards a pan-European novel foods sandbox. This will contribute to a more efficient and competitive EU novel foods approval process.

At think-and-do tank The Ministry of Future Affairs, we are committed to inspiring and supporting this process in collaboration with the authors of this report.

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