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ARTICLE

Regulatory Sandboxes for Novel Foods

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Abstract

This article conceptualises regulatory sandboxes in the food area, considering them as unique spaces with varying degrees of openness. Through an analysis of closed, semi-open and open spaces, it illustrates the regulatory landscape surrounding regulatory sandboxes of novel foods in the EU, particularly focusing on the concept of "placing on the market." The article contends that the degree of openness of regulatory sandboxes impacts the application of the precautionary principle within these spaces. It explores scenarios where the sandbox tests various aspects of novel foods under EU soft and hard law. The characteristics of the regulatory sandbox (open, semi-open, closed) changes corresponding to what the regulatory sandbox tests in relation to a novel food, eg, a sensory characteristics or safety or other data points, such as effectiveness of labelling. This article contributes to the ongoing discourse on innovation-friendly laws surrounding regulatory frameworks applicable to novel foods in the EU.

Keywords: FoodTec; free movement of goods; novel food; placing on the market; sandbox

I. Introduction

By 2025, calls for innovation-enabling regulation have touched upon every regulatory area, from finance, over AI to food.[1] In these areas, experimental regulation and regulatory sandboxes are considered a potential tool or are already implemented to instrumentalise such regulatory environments. Experimental regulation as well as regulatory sandboxes are testing grounds for innovative products.[2] This article is primarily concerned with investigating regulatory sandboxes for novel foods as emerging regulatory model amidst an uncertain legal interpretation concerning their set-up under the EU Novel Food Regulation.[3] It does so against certain reformist initiatives of a small number of EU Member States and numerous calls of innovators, investors, think tanks as well as the public to reduce time-to-market of novel foods at lower cost, test novel foods with consumers, and provide greater clarity on the

[1] DA Zetzsche, RP Buckley, JN Barberis and DW Arner, "Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation" (2007) 23 Fordham Journal of Corporate & Financial Law 31; M Finck, "Blockchains: Regulating the Unknown" (2018) 19 German Law Journal 665–92; S Ranchordas and V Vinci, "Regulatory Sandboxes and Innovation-Friendly Regulation: Between Collaboration and Capture' (2024) Italian Journal of Public Law 107.

[2] EIT Food Protein Diversification Think Tank, *Accelerating Protein Diversification for Europe* (An EIT Food Protein Diversification Think Tank Policy Brief, 2023) available at <https://www.eitfood.eu/files/EIT-Food-PDTT-Policy-Brief-Accelerating-Protein-Diversification-for-Europe.pdf> (last accessed 22 January 2025).

[3] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, (2015) OJ L327/1 (hereinafter Novel Food Regulation).

authorisation process for novel foods.[4] In the UK/US literature, sandboxes are regularly discussed in connection to administrative frameworks determined by agencies.[5] In the EU, it is not clear who should establish such a novel foods' sandbox, where the regulatory environment does not follow a strong agency model but is rather based on legislative provisions in a multi-level governance framework.[6] For example, the EIT Food Protein Diversification Think Tank recommended that the "[European Food Safety Authority (EFSA)] could enable producers to test products in a controlled environment whilst receiving support in identifying consumer protection measures, ensuring the safe market entry of innovative products."[7] In the literature, it is proposed that such regulatory sandboxes shall be established by implementing acts.[8] Under the existing EU Novel Food Regulation, neither the Commission nor EFSA have a mandate to set up regulatory sandboxes.[9] The initiative is therefore with EU Member States, however, without a guidance from the Court of Justice of the EU about the legal permissibility of an EU Member State's action by which a regulatory sandbox is created. In this grey area of the law, a competitive landscape emerges with varying regulations, each presenting different "innovation-friendly" regulatory pathways towards sustainable food systems. As such, regulatory sandboxes may alter the level-playing field in the market, lead to market fragmentation and regulatory arbitrage.[10]

In the discourse on experimentation with novel foods, the distinction between experimental regulation and regulatory sandboxes does not come always clear.[11] One reason for this lack of clarity is the absence of comprehensive literature on the conceptualisation of regulatory sandboxes in the agri-food sector and specifically as regards novel foods. This article fills this gap. It first grounds the concept of regulatory sandboxes for novel foods in the literature that distinguishes between experimental regulation and regulatory sandboxes. It then discusses why establishing a regulatory sandbox under the EU Novel Foods Regulation is controversial, particularly given the current definition of "placing on the market" in EU law. In light of this definition and various Member States' efforts to establish regulatory sandboxes for novel foods, the article conceptualises open, semi-open, and closed sandboxes, depending on the level of control and risk management exercised by regulators and innovators over participants, location and innovative products within the sandboxes. This article concludes by using this framework to explore possibilities for establishing regulatory sandboxes for novel foods.

[4] M Lesh, "Bangers and Cash: Cutting Red Tape to Put Britain at the Centre of the Cultivated Meat Revolution" in *The Institute of Economic Affairs* (London, 2023) available at <https://iea.org.uk/wp-content/uploads/2023/01/DP118_Bangers-Cash_web-2.pdf> (last accessed 21 January 2025).

[5] J Sherkow, "Regulatory Sandboxes and the Public Health" (2022) University of Illinois Law Review 357.

[6] MG Oyola-Lozada, L Pregelj, A Jenkins, E Siegel, T Munro and D Hine, "Anticipatory Regulation for Pandemic Responses: Are We There Yet?" (2024) Trends in Biotechnology 1067.

[7] EIT Food Protein Diversification Think Tank (n 2).

[8] J Karsten, "Reallabore im Lebensmittelrecht" (2024) Lebensmittel und Recht 385, 386.

[9] The Proposal for the Pharmaceutical Regulation proposes that a regulatory sandbox is established on the basis of a Commission Decision following a recommendation of the European Medicines Agency. As for the regulatory waiver and no action letter, it would require a substantial legislative change in EFSA's powers to be involved in administrative rulemaking legally binding upon individuals, similar to European Commission's decision. Under current regulatory institutional set-up, such change appears unlikely. As for the Commission, discretionary powers, presumably exercised upon the advice of EFSA, would have to be explicitly legislated for in the Novel Food Regulation.

[10] European Commission, *Better Regulation' Toolbox – July 2023 Edition* (Brussels 2023) available at <https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=BR%20toolbox%20-%20Jul%202023%20-%20FINAL.pdf> (last accessed 21 January 2025).

[11] V Sharp and G Blahoudková, "Setting Up the Legislative Framework for the Introduction of a Regulatory Sandbox: The Czech Perspective" (2024) 70 Acta Universitas Carolinae – Iuridica, 35.

II. Regulatory sandboxes for novel foods and experimental regulation

Literature on regulatory sandboxes either views them as a unique subset of experimental legislation or as distinct from experimental regulation.[12] Ronchardas and Vinci (2024) distinguish the two as regards four aspects[13]: (1) Experimental statutes include a derogation from the existing rules, whereas regulatory sandboxes involve temporary loosing of existing regulatory requirements by providing a waiver of certain rules, such as relaxation of liability, individual guidance[14] or the issue of no action letters indicating that an authority will not take legal action against a regulated entity.[15] The purpose of a regulatory sandbox is not deregulation.[16] (2) Experimental statutes lay down requirements for the experiment, such as the duration, geographical area, the scope of derogation, objectives of experiment and the evaluation. Regulatory sandboxes consist of policy decisions on eligibility, objectives, entry and exit requirements and evaluation criteria.[17] (3) Experimental clauses operate generically for a specific group of innovative products or services, such as plant protection products, whereas regulatory sandboxes are set up on a case-by-case basis in a specific sector, such as for cultivated meat.[18] The Commission identified two approaches to regulatory sandboxes as a better regulation tool: either innovators identified a regulatory barrier and ask for establishing a regulatory sandbox, or the regulator prepares new rules to be tested by regulatees in the implementation set-up.[19] (4) Regulatory sandboxes are collaborative tools, whereas experimental clauses are not defined as such. To provide just a few examples of regulatory sandboxes, in telecommunications, 5G testing can take place within a manufacturing facility to verify viable use cases for the regulator.[20] Elsewhere, regulatory sandboxes test new business models, such as in energy transitions.[21] In artificial intelligence or finance regulation, regulatory sandboxes may be also realized in a type of "augmented reality," for example in trials involving autonomous vehicles[22] or digital spaces to test the performance of cryptocurrencies.[23] As such, regulatory sandboxes provide "a structured context for experimentation [to test] innovative technologies ... for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place."[24]

[12] A Flückiger, "Tracing the Evolutionary Path of Experimental Law: From Comparative Law to Regulatory Sandboxes" (2024) 70 Acta Universitas Carolinae – Iuridica 13.

[13] Ranchordas and Vinci (n 1).

[14] T Buocz, S Pfotenhauer and I Eisenberger, "Regulatory Sandboxes in the AI Act: Reconciling Innovation and Safety?" (2023) Law, Innovation and Technology 359.

[15] Financial Conduct Authority, *Regulatory Sandbox Lessons Learned Report* (Financial Conduct Authority 2017) available at <www.fca.org.uk/publication/research-and-data/regulatory-sandbox-lessons-learned-report.pdf> (last accessed 22 January 2025).

[16] European Commission (n 10).

[17] However, some sources also acknowledge that regulatory sandboxes may be grounded in law such as in experimental statutes, ibid.

[18] AJ Hillary, "Regulatory Sandboxes" (2019) 87 George Washington University Law Review 579.

[19] European Commission (n 10).

[20] Fraunhofer Institute for Integrated Circuits IIS, *Industry 4.0 Test Bed* (2024) available at <https://www.iis.fraunhofer.de/en/ff/kom/mobile-kom/5g-bavaria/5G-testbed-industry.html> (last accessed 22 January 2025).

[21] F Bovera and L Lo Schiavo, "From Energy Communities to Sector Coupling: A Taxonomy for Regulatory Experimentation in the Age of the European Green Deal" (2022) Energy Policy 171, 113299.

[22] OECD, *Regulatory Sandboxes in Artificial Intelligence* (OECD Digital Economy Papers 356, 2023) <https://doi.org/10.1787/8f80a0e6-en> (last accessed 22. January 2025).

[23] L Byunkwon and L Charles, "Regulatory Sandboxes" in J Madir (ed), *FinTech: Law and Regulation* (Cheltenham, UK/Northampton, MT, USA, Edward Elgar 2021) p 579.

[24] Council Conclusions on Regulatory Sandboxes and Experimentation Clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age 2020/C 447/01 [2020] OJ C447/1. Similarly, Recital 133 and definition of Article 2(12) of Proposal for a Regulation of

The need to distinguish experimental regulation from regulatory sandboxes is evident in the recent Commission proposal concerning medicinal products – a regulatory area typically focused on testing innovative products in (pre-)clinical trials prior to marketing authorisation. In this proposal, the Commission introduces specific provisions related to regulatory sandboxes,[25] under which regulatory sandboxes may be established only if "it is not possible to develop the medical product or category of products in compliance with the requirements ... due to scientific or regulatory challenges arising from the characteristics or methods related to the product."[26] A regulatory sandbox for medical products would thus consist of targeted relaxation of the EU pharmaceutical laws following a specific sandbox plan.[27] (Pre-)clinical studies[28] are a type of experimental regulation: such studies do not follow a case-by-case framework, they do not involve a special guidance and do not represent a collaborative tool between innovators and regulators. Rather, (pre-)clinical trials are a form of testing of innovative products that generate data for its authorization following international scientific standards and protocols.[29] In the case of medicinal products, establishing a regulatory sandbox would not preclude the requirement to conduct (pre-)clinical studies in view of acquiring a marketing authorisation.

Clinical trials are not a typical part of a novel food authorisation dossier: unlike authorisation of medical products, authorisation for novel foods[30] does not require human data, although human studies can be considered, for example, to decide whether and which toxicity studies are necessary for the assessment of risk.[31] If a novel food is to be trialed with human subjects to produce relevant data for the risk assessment, there is no specific EU norm similar to the EU Clinical Trials Regulation to govern such trials, which is limited to investigations related to medicinal products. For novel foods, producing human data may involve intervention or observational studies. For example, if a food is granted a generally recognised as safe status in the United States and is consumed, an applicant for authorization of the novel food may gather human data from that use. Furthermore, it can be that a novel food is already authorised in the EU for certain uses, and the applicant

the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM/2023/193 final (hereinafter Proposal for the Pharmaceutical Regulation).

[25] Articles 113–15 Proposal for the Pharmaceutical Regulation.

[26] Article 113(1)(a) Proposal for the Pharmaceutical Regulation.

[27] Article 113(1) and (2) Proposal for the Pharmaceutical Regulation.

[28] Following Article 2(2)(2) and (4) EU Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use [2014] OJ L158/1 (hereinafter EU Clinical Trials Regulation), clinical trials are a subgroup of clinical studies. Clinical trials must assign a subject a particular therapeutic strategy, or it includes an investigation medicinal product prescribed to a subject or it involves diagnostic or monitoring procedures in addition to normal clinical practice. Non-intervention study is a clinical study other than a clinical trial.

[29] European Medicines Agency, ICH E8 General considerations for clinical studies E8(R1) – Final Version (6 October 2021), available at <https://database.ich.org/sites/default/files/E8-R1_Guideline_Step4_2021_1006.pdf> (last accessed 25 January 2025).

[30] Similarly, authorisation of cosmetic products does not require animal or human testing, however, "tests in animals and alternative methods are of predictive value with respect to human exposure", therefore confirmatory compatibility tests in humans concerning cosmetic products may be needed. See European Commission Expert Panel on Effective Ways of Investing in Health, *Opinion Concerning Guidelines on the Use of Human Volunteers in Compatibility Testing of Finished Cosmetic Products – Adopted by the Scientific Committee on Cosmetics and Non-Food Products Intended for Consumers During the Plenary Session of 23 June 1999* (1999) available at <https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out87_en.htm> (last accessed 22 January 2025).

[31] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Products, D Turck J-and Others, "Guidance on the Preparation and Submission of an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283" (2021) 19 EFSA Journal e06555.

wishes to change the conditions of use of that food, for which some human data concerning the consumption of the novel food can be generated and submitted. Also, if novel food's allergenicity testing is conducted under clinical conditions (eg, skin prick testing), one would not designate the testing as regulatory sandbox but a clinical study.[32]

Pre-clinical studies are required for the novel food and other food authorisation, such as food supplements[33]; however, their goal is different compared to the authorisation of pharmaceuticals[34]: pre-clinical studies, such as toxicological tests are not conducted to determine the lowest safe dose of a novel food, but whether novel food is safe as such. Data such as those produced in (pre-)clinical studies may be also generated within regulatory sandboxes. However, such arrangements would be rare if not accidental: a food entering a tasting sandbox would already be assumed to be safe for human consumption. Frequently, tastings (as described below) are highlighted as prime examples of regulatory sandboxes in policy discussions about how to foster innovation in the food industry. Rules may require to assess allergenicity risk prior to the tasting, and companies participating at the sandbox may minimise the risk by requesting the tasters to declare in writing that they do not suffer from known allergies.[35] An emergency response officer and a medical hotline may be required, as well as mandatory reporting of adverse effects.[36] As such, within the food sector, the difference between a regulatory sandbox and experimental regulation, such as a toxicological study, may lie in the fact whether the experimental space is established for the sole purpose of generating data for market authorisation. This article then understands regulatory sandboxes as spaces, either physical or virtual, whose principal purpose is to help develop the product and its features and/or adjust rules applicable to the product when marketized.[37] This does not include generating data for the authorisation process or substitute commissioning of safety studies for an authorisation dossier. As such, a regulatory sandbox may be used to collaterally produce information relevant for the authorisation process in a concrete case only to a limited extent. For

[32] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), "Scientific Opinion on the Evaluation of Allergenic Foods and Food Ingredients for Labelling Purposes' (2014) 12 EFSA Journal 3894.

[33] In the EU in novel food authorisation process, numerous data requirements need to be submitted as a part of the novel food application, currently also subject to notification requirements for any study commissioned or carried out to support an application. The data requirements are specified in Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of the EU Novel Food Regulation [2017] L351/64. Particularly, a dossier submitted in support of an application for the authorisation of a novel food is to enable a comprehensive risk assessment of the novel food. The data requirements then mirror the information that must be included in EFSA's scientific opinion on safety of an assessed novel food. Some of the data requirements for the novel food products also follow Commission Regulation (EU) No 234/2011 establishing a common authorisation procedure for food additives, food enzymes and food flavourings [2011] OJ L64/15; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Products (n 31) 21.

[34] See R Warda, K Purnhagen and M Molitorisová, "Has Mutual Recognition in the EU Failed? – A Legal-Empirical Analysis on the Example of Food Supplements Containing Botanicals and Other Bioactive Substances" (2024) 47 Journal of Consumer Policy 425, 436.

[35] Rijksoverheid, *Rapport Code of Practice Safely Conducting Tastings Cultivated Foods Prior to EU Approval* (2023) available at <https://open.overheid.nl/documenten/39127f7e-b18b-4ddf-95a7-0be5ff660aed/file> (last accessed 21 January 2025).

[36] The Singaporean Food Agency requires to prepare for medical contingencies in the event of unforeseen allergic reactions as well as to inform the agency of any detected or reported adverse events occurring within 2 weeks, Singaporean Food Safety Authority, *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients* (2023) available at <https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-foods-and-novel-food-ingredients.pdf> (last accessed 21 January 2025).

[37] A typified example of a regulatory clause in agri-food sector may be located in Art 13 Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed [1966] OJ 125/2309 of which provides for possibility to organise temporary experiments of maximum 7 years under specified conditions according to which Member States may be released from certain obligations.

example, tasting experiments may be also used to derive limited data on allergenicity and acute toxicity.

This is exemplified by regulatory sandboxes for novel foods as currently established in various jurisdictions, that tend to be relatively modest.[38] They do not serve as long-term testing grounds aimed at generating scientific data required for swift safety assessments under the EU Novel Food Regulation – a process often costly and burdensome for applicants.[39] For instance, the Dutch Code of Conduct, which applies to cultivated foods, only permits tastings. Similarly, in Singapore, sensory evaluations and tastings are the primary activities allowed under administrative exemptions granted by the Singapore Food Authority.[40,41] As regards the accentuation of regulatory learning within the concept of regulatory sandboxes,[42] it may be that both regulatory sandboxes and experimental regulation, ie, traditional scientific studies, increase the regulator's knowledge about innovative foods.[43] In this area, the EU authority– EFSA – is primarily entrusted with conducting risk assessment and could adapt its risk assessment approaches to risk profiles of new foods.[44] This may result in exploring where the current data requirements are no longer necessary or may be relaxed.[45] Evidence from sandboxes may be used to inform the problem definition and baseline scenarios in policy preparation as well as estimating policy impacts.[46] Currently, the Member State where the food business operator intends to place his novel food on the market first is tasked with pre-submission advice regarding the novel food status.[47] EFSA offers pre-submission advice as a part of its services. EFSA, however, cannot provide advice on the design of studies, specific requests on how to develop and manage a study and hypotheses to be tested.[48] Therefore, the service is often criticised by the industry as insufficient.[49] It may be hypothesised that if EFSA officials or regulators attend tastings, they gain firsthand experience with novel ingredients in real-world settings, such as in recipes or through the inventor's explanation

[38] See Karsten (n 8) 385.

[39] A Monaco Alessandro and K Purnhagen, "Risk Triggers as Innovation Triggers? Risk Analysis and Innovation's Promotion under the Novel Food Regulation" (2022) 17 European Food and Feed Law Review 219.

[40] Singaporean Food Safety Authority (n 36).

[41] Singaporean Food Safety Authority, ibid. See also S Hallam and Y Ruperti, "Smart Food: Novel Foods, Food Security, and the Smart Nation in Singapore' (2023) 27 Food, Culture & Society 754.

[42] LA Fahy Lauren, "Fostering Regulator – Innovator Collaboration at the Frontline: A Case Study of the UK's Regulatory Sandbox for Fintech" (2022) 44 Law & Policy 162. See also D Feser, S Winkler-Portmann, TS Bischoff, D Bauknecht, K Bizer, M Führ, DA Heyen, T Proeger, K von der Leyen and M Vogel, "Institutional Rules for the Up-Take of Regulatory Experiments: A Comparative Case Study" (2024) 156 Futures 103318.

[43] K Yordanova and N Bertels, "Regulating AI: Challenges and the Way Forward Through Regulatory Sandboxes" in AH Sousa, PM Freitas, AL Oliviera, C Pereira Martins, E Vaz de Sequeira and XL Barreto (eds), *Multidisciplinary Perspectives on Artificial Intelligence and the Law* (Cham, Switzerland, Springer 2022) 449; K Kubeczko, M Ploder, W Polt and M Weber, "Regulation as an Instrument of Innovation Policy – Two Case Studies" (Vienna/Graz, Austria, Joanneum Research Ltd./Institute for Economic, Social and Innovation Research 2022) 7–8.

[44] C Dall'Asta, "Why 'New' Foods Are Safe and How They Can Be Assessed" in L Scaffardi and G Formici (eds), *Novel Foods and Edible Insects in the European Union* (Cham, Switzerland, Springer 2022) 81.

[45] Y Devos, E Bray, S Bronzwaer, B Gallani and B Url, "Advancing Food Safety: Strategic Recommendations from the 'ONE – Health, Environment & Society – Conference 2022'" (2022) 20 EFSA Journal e201102.

[46] European Commission, (n 10).

[47] Art 4 (2) Novel Food Regulation.

[48] European Food Safety Authority, "Services" (2024) available at <https://www.efsa.europa.eu/en/applications/about/services> (last accessed 22 January 2025).

[49] A De Boer, M Morvillo and S Röttger-Wirtz, "Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation" (2023) 14 European Journal of Risk Regulation 313; H Lester, "Setting the Record Straight on the EU Novel Food Approval Process" (Protein Production Technology International October 26, 2023) available at <https://www.proteinproductiontechnology.com/opinion-posts/setting-the-record-straight-on-the-eu-novel-food-approval-process> (last accessed 21 January 2025).

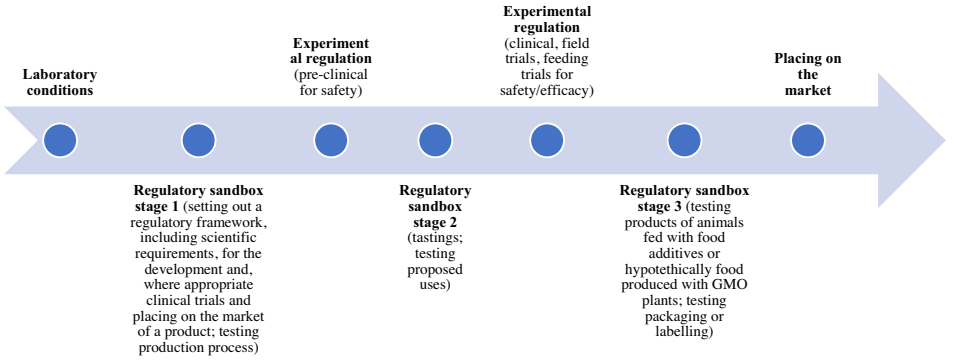

Figure 1. From experimentation to placing on the market of food products and their features.

of their process.[50] However, in the EU, sandbox spaces which would allow for EFSA's regulatory learning need yet to be designed; for now, data needed for such learning are primarily generated elsewhere, for example by EFSA's action during the life-cycle of applications,[51] as well as with the input of relevant stakeholders.[52]

The UK's newly announced regulatory sandbox stands out as an exception. It emphasises the importance of regulatory learning "stemming from a regulatory sandbox [which] should inform future changes to the legal framework to fully integrate the particular innovative aspects into the ... product regulation."[53] This is how the UK's recently announced regulatory sandbox on cultivated meat has been conceived: it will offer pre-application support to innovative companies so that it generates evidence and expertise on cell-cultivated products and the technology to process novel foods application more swiftly.[54] Specific modalities of these sandboxes are yet to be announced. It remains to be seen how the data will be generated, particularly whether (pre)clinical testing will be included as part of the sandbox framework. Although tastings offer a limited learning experience, a sandbox that generates meaningful safety data would require much longer timeframes – more than just a single event. The UK's sandbox anticipates running activities for up to two years.

It is conceivable that a regulatory sandbox may be established at any point prior to the placing on the market (see Fig. 1). It may be set up prior conducting (pre-)clinical trials to enable a more extensive regulatory learning for risk assessment. It may be open for companies which determined a minimum level of safety for the products to be consumed. It may be established after a product was tested in trials according to a respective experimental regulation. This may be the case of consuming the secondary products of the regulated product, such as meat of an animal fed with a tested

[50] See also L Graeme Laurie, "Regulation as Play: Establishing a Normative Basis for the Regulatory Sandbox in Human Health Research" in R Brownsword, D Beyleveld and M Duwell (eds), *Law, Governance and Bioethics: Concepts, Challenges and Future Directions* (Edward Elgar Publishing in press).

[51] European Food Safety Authority, "EFSA's Catalogue of Support Initiatives during the Life-Cycle of Applications for Regulated Products" (2021) 18 EFSA Journal 6472E available at <https://www.efsa.europa.eu/en/supporting/pub/en-6472> (last accessed 22 January 2025).

[52] European Food Safety Authority, "Innovative Food/Feed" (22 October 2021) available at <https://www.efsa.europa.eu/en/call/innovative-foodfeed> (last accessed 22 January 2025).

[53] Recital 135 Proposal for the Pharmaceutical Regulation.

[54] Food Standards Agency, "Groundbreaking Sandbox Programme for Cell-Cultivated Products Announced' (8 October 2024) available at <https://www.food.gov.uk/news-alerts/news/groundbreaking-sandbox-programme-for-cell-cultivated-products-announced> (last accessed 22 January 2025).

feed additive.[55] A food business operator may also theoretically obtain a temporary marketing authorisation that may be considered a borderline case between experimental regulation and a regulatory sandbox at the latest stage of a product's development.

To avoid potential liability for the products in development, companies typically take risk mitigation measures, such as conducting safety assessments. When presenting novel foods to the public – such as at fairs – or involving third parties – such as testing potential applications of a novel food ingredient – companies may face the challenge of determining when these activities could be considered as placing the food on the market. To provide legal clarity in such situations, a regulatory sandbox may be exploited *de lege ferenda*.[56] A regulatory sandbox would change the context in which liability may be incurred and facilitate experimentation.[57] Certain flexibilities were already explored by Union legislature in the context of animal health and EXPO Milan 2015.[58] However, the EU Novel Food Regulation, which governs novel foods, does not provide for any waivers that national competent authorities may provide. The regulation also cannot be overridden by Member States' legislation establishing regulatory sandboxes. Therefore, regulatory sandboxes can only be established in scenarios where the EU Novel Food Regulation does not apply – that is, in the theoretical example when an implementing act would provide for a derogation or when a novel food is not yet considered to be placed on the market. The challenge lies in defining when that moment takes place, making it ready for sale.[59] Clarifying the boundaries of such a regulatory sandbox would help shape its modalities, which will be further explored in the next two sections.

III. Regulatory sandboxes for novel foods and placing on the market

It is often the case that regulatory regimes based on pre-market authorisation, such as in case of novel foods, would not permit establishing regulatory sandboxes that amounts to placing on the market of the product, meaning the first making available of a product on the market of an EU Member State. According to Article 3(8) GFL,[60] placing on the market is defined as "the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and

[55] J Byrne, "Tesco Trials Methane-Cutting Feed as UK Retailers Race for Greener Dairy" (*Feednavigator* 12 July 2024) available at <https://www.feednavigator.com/Article/2024/07/12/Tesco-tests-methane-cutting-feed-on-UK-dairy-farm/> (last accessed 22 January 2025).

[56] E Marden, D Kulkarni, EM McMahon, MS Rowand and K Verzijden, "Chapter 11 – Regulatory Frameworks Applicable to Food Products of Genome Editing and Synthetic Biology in the United States, Canada, and the European Union' in C Lopez-Correa and A Suarez-Gonzalez (eds), *Genomics and the Global Bioeconomy (Translational and Applied Genomics)* (London, UK/San Diego, CA, USA/Cambridge, MA, USA/Oxford, UK, Academic Press 2022) 255.

[57] C Wendehorst, "Strict Liability for AI and other Emerging Technologies" (2020) 11 Journal of European Tort Law 150; J Truby, R Dean Brown, IA Ibrahim and O Caudevilla Parellada, "A Sandbox Approach to Regulating High-Risk Artificial Intelligence Application" (2022) 13 European Journal of Risk Regulation 270.

[58] Commission Implementing Regulation (EU) 2015/329 of 2 March 2015 derogating from Union provisions on animal and public health as regards the introduction into the European Union of food of animal origin destined for EXPO Milano 2015 in Milan (Italy), [2015] OJ L 58/52 and Commission Implementing Regulation (EU) 2015/448 of 17 March 2015 establishing specific animal health rules for the introduction into the Union of certain products of animal origin from Japan destined for EXPO Milano 2015 [2015] OJ L 74/24. See also Karsten (n 8) 385.

[59] C Simpson, "Issues Concerning the Definition of 'Placing on the Market' Under Regulation (EC) No 178/2002" (2020) 15 European Food and Feed Law Review 540.

[60] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1 (hereinafter GFL).

other forms of transfer themselves."[61] According to the Blue Guide on the Implementation of EU Product Rules, a product is placed on the market when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.[62] Such supply includes any offer for distribution, consumption or use on the Union market which could result in actual supply (eg, an invitation to purchase, advertising campaigns).[63] According to the Blue Guide, placing a product on the market presupposes a possible transfer of ownership, possession or any other property right concerning the product following its manufacture.[64] Placing on the market can be also said to be equated to "putting into circulation" – a term which was used in earlier EU legislation and corresponding case law.[65] In that respect it was clarified that a product is put into circulation when it leaves the production process operated by the producer and enters a marketing process in the form in which it is offered to the public.[66] According to the Commission's interpretation, which has been, however, never endorsed by an authoritative interpretation of EU law, "placing on the market is considered not to take place where a product is transferred for testing or validating pre-production units considered still in the stage of manufacture, displayed or operated under controlled conditions at trade fairs, exhibitions or demonstrations or in the stocks of the manufacturer."[67] Here note 53 states that: "The prototype must be safe and under complete control and supervision. Controlled conditions would mean expert operators, restrictions to public contact with the product, avoiding inappropriate interaction with other neighboring products, etc."[68] Restrictions to public contact with the product does not necessarily imply that the public must have no contact with the product; rather it implies specific limitations or control, such as limiting access to certain individuals or locations. For example, "organizing tastings during regular opening hours of restaurants ... would fall within the scope of placing on the market" per Article 3(8) GFL.[69] However, it is possible to argue that under the Commission's interpretation, a food may be merely displayed at a fair or operated, which does not involve a food's consumption. After a food is consumed, arguably, it ceased to be "under complete control and supervision."

In the literature, differences in the definition of "placing on the market" under the GFL relating to food and the interpretation provided by the Commission that relates to any product, not only food, have been noted. The GFL's definition "contains no spatial limit" regarding where the placing on the market takes place or where the food is ultimately consumed.[70] Therefore, certain provisions of the GFL specify that the placing on the market takes place in the Community (now Union) or in a third country.[71] The Blue Guide

[61] Case C-13/23 *cdVet Naturprodukte GmbH v Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LA-VES)*, ECLI:EU:C:2024:175.

[62] Commission notice, "The 'Blue Guide' on the Implementation of EU Product Rules" [2022] OJ C247/01.

[63] Ibid.

[64] Ibid.

[65] For example, Art 1 Council Directive 96/51/EC of 23 July 1996 amending Directive 70/524/EEC concerning additives in feedingstuffs, OJ L235/39.

[66] Case C-127/04 *Declan O'Byrne v Sanofi Pasteur MSD Ltd and Sanofi Pasteur SA.*, ECLI:EU:C:2006:93, para 32.

[67] As for the fairs, exhibitions and demonstrations, n 54 states that "a visible sign must clearly indicate that the product in question may not be placed on the market or put into service until it has been made to comply." If reports from such fairs are publicly accessible, such as on the Internet, and lack similar warnings, it raises doubts about whether the product display at these events could be construed as advertising. Furthermore, per the authors' interpretation, attending fairs, exhibitions and demonstrations with the product as activities that do not amount to placing on the market cannot involve testing or trialling the product, only its display.

[68] Commission notice (n 62).

[69] K Verzijden, "Tasting of Cultivated Foods Now and Tomorrow" (*Food Health Legal*, 14 December 2023) available at <http://foodhealthlegal.eu/?p=1271> (last accessed 21 January 2025).

[70] Simpson (n 59) 540.

[71] Ibid.

does not consider the supply of products for export outside the EU market as making available.[72] As a result, novel foods intended only to be exported to third countries may be subject to authorization procedure under the EU Novel Foods Regulation.[73] Following this proposition, if certain arrangements of experimentation with a novel food is to be considered "placing on the market," then shipping the food for such experimentation to a third country would require authorization under the EU Novel Food Regulation "unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country."[74]

Apart from examining what constitutes placing on the market subject to market authorisation, no regulations exist in EU law concerned with experimentation with food for human consumption.[75] Nonetheless, legislative, and administrative initiatives of various kinds exist at national level that explore this silence of EU law and create frameworks under which certain type of experimental activities with relation to unauthorised novel foods become possible. There have been four known examples of tastings of novel foods conducted in the EEA (the Netherlands, Iceland, Estonia and an expected tasting in Czechia[76]) and an established framework for experimentation with novel foods in Singapore. In the Netherlands, the 2023 Code of Practice for Safely Conducting Tastings of Cultivated Foods Prior to EU Approval is the first legal guidance of its kind to enable a certain type of novel food regulatory sandbox.[77] The code could draw on the legal interpretation of the placing on the market as put forward by the Commission, supposedly linking the testing environment for a novel food to the notion of "demonstrations." The code requires that participants to a tasting session must be invited so that public access is excluded. The number of persons who may attend a tasting session is 30, with maximum of 10 tasting sessions approved.[78] Furthermore, per the Dutch rules, participants cannot be renumerated. Also, tasting is permitted only to designated and pre-selected tasters, but the tasting session may be attended by investors, journalists, regulators and "political stakeholders" whereas the latter may post information on social media.[79] It is, however, not clear from the rules whether investors, journalists and others cannot be simultaneously pre-selected as tasters. Within such demonstrations, opportunities may arise to present certain commercial activities related to the product or the company developing the product, despite the exclusion of the public. Therefore, it is questionable whether certain standards should not be followed for such demonstrations, such as to the selection of participants in sensory panels.[80] While certain participants, owing to their professional backgrounds, may not fall under the umbrella of the general public, their presence at the trial may imply commercial activity of the experimenting company, since they could be potentially addressed with offers for product development and other investments, aside from direct product sale. Other participants may stir a lot of

[72] Commission notice (n 62).

[73] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, OJ L 327/1. Simpson (n 59) 540.

[74] Art 12(1) GFL. Simpson (n 59) 540.

[75] One of the earliest examples of exemptions made for investigational use of food additives may be found in the US 1958 Food Additives Amendment, 52 Stat. 1041, 21 USC 321.

[76] Expats.cz Staff, Czech Startup Debuts Ground-Breaking Burger Made from Lab-Grown Meat, (*Expats cz*, 1 July 2023) available at <https://www.expats.cz/czech-news/article/pork-burger> (last accessed 22 January 2025).

[77] T Kamer, "Motie van de leden Tjeerd de Groot en Valstar over onder gecontroleerde omstandigheden proeverijen van kweekvlees mogelijk maken" (2023) available at <https://www.tweedekamer.nl/kamerstukken/moties/detail?id=2022Z04324&did=2022D08835>.

[78] Rijksoverheid (n 35).

[79] Ibid.

[80] GD Fernandes, CA Ellis, A Gámboro and D Barrera-Arellano, "Sensory Evaluation of High-Quality Virgin Olive Oil: Panel Analysis versus Consumer Perception' (2018) 21 Current Opinion in Food Science 66.

media attention. For example, if a Prime Minister and a Minister of Agriculture attend publicly such tastings, it may amount to advertisement,[81] and therefore be considered to involve a commercial activity. To contrast, under Singapore rules, it is not possible to offer unassessed novel foods for consumption "for the purpose of advertisement or in furtherance of any trade or business."[82]

Not placing on the market includes some extent of limiting public access to the product under development. However, limiting public access would not necessarily mean that a product under development escapes the EU food law's scrutiny. The GFL sheds additional light on the permissibility of such tastings or similar novel foods experimentation considering the notion of placing on the market. The GFL differentiates between "private use" and "placing on the market" of food, whereas "private use" can be seen as a reverse space of "market use." The GFL does not explicitly acknowledge the existence of any other "uses," eg, experimental uses of food. Article 1 GFL stipulates that the GFL does not apply "to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption," thereby excluding the application of the EU Novel Food Regulation also from these forms of use. Some authors suggest that the exclusion is of functional case and relates to the satisfaction of private domestic needs.[83] According to a German commentary on the German food law (*Lebensmittel- und Futtermittelgesetzbuch*) on the term "private domestic area" that largely copies its scope of application from the GFL, private domestic consumption includes the private sphere of the household, ie, people who are fed from a single kitchen or at a table, and private socializing with guests, eg, private celebrations, even where they take place in rented rooms.[84,85] If a food is distributed from the kitchen to the street, as street food, or to guests at guesthouses, this activity is beyond the private domestic area.[86] If a food is provided as a part of a service even if this service is performed at home, this too falls outside the private domestic area.[87] It could be then that if food innovators test their products with their family members and friends only, it is considered private use, thereby excluded from the EU Novel Food Regulation authorisation regime. Also, in some language versions of the GFL, such as the German, the definition of placing on the market in EU food law is broader than the one proposed by the Commission's Blue Guide. It focuses on handovers in the broadest sense, not only transfers of property rights, excluding only handovers for private use. Therefore, in order to escape the application of the EU Novel Food Regulation on tastings or other similar experimentation with a novel food, "private use" must be positively established. In doing so, "private," as an exemption, needs to be interpreted narrowly. In EU food law, it is exactly this notion of "privateness" which allows the disapplication of the GFL and other food law acts; designating an activity as non-public, without positively establishing "private use", is not a sufficient ground to escape EU food law's scrutiny.

The Commission may, however, consider those tastings that would merely limit public access complaint with the EU Novel Food Regulation. While there is some guidance in EU law as to what is considered private (see *infra*), there is little guidance on what is considered "public", particularly in food law. Other areas of law could perhaps provide

[81] PR Newswire, "Milestone Tasting of Cultured Meat in Europe" 13 February 2024, (2024) available at https://www.prnewswire.com/news-releases/milestone-tasting-of-cultured-meat-in-europe-302060944.html.

[82] Singaporean Food Safety Authority (n 36).

[83] P Wojciechowski, "Administrative Liability of a Farmer Acting as Food Business Operator" (2016) 18 Przegląd Prawa Rolnego 33.

[84] T Boch, "§ 1" in *Lebensmittel- und Futtermittelgesetzbuch* (10th ed, Baden-Baden, Nomos 2024) para 8.

[85] The first group includes naturally family members, domestic servants or even craftsmen, according to the commentary Boch (n 84) para 8.

[86] Boch (n 84) para 8.

[87] KD Rathke, "§ 1 LFGB" in O Sosnitza and A Meisterernst (eds), *Lebensmittelrecht* (187. ed., München, CH Beck 2023) para 36c.

guidance by analogy. In copyright law, following the case *SBS Belgium NV/SABAM*,[88] the public encompasses an indeterminate number of potential recipients and "a fairly larger number of persons" which continues causing interpretative difficulties.[89] The criterion of "a fairly large number of persons" designates that the public consists of a certain minimum number and does not include an overly small or even insignificant number of relevant persons.[90] If one were to take this interpretation analogically to food law, one could assume that there should be a supervised selection of a small number people who have access to a tested novel food so that general public is excluded from the regulatory sandbox. It would not matter which discrimination criteria are used for the selection. One could however question how consecutive tastings conducted by the same company satisfy the quantitative limitation of the "public". To hypothesise further, if a publicly accessible website features a reservation system through which anyone can book a participation at a tasting event of a novel food, the tasting would be considered accessible to the public. If, however, an invitation is sent to the thirty best and most loyal customers of a restaurant to attend a tasting, such an event would not be considered as being accessible to the public, provided that it would not be a repeated invitation. If a street stall offers tastings of unlabelled and unadvertised novel food, this would still fall under the notion of the public. If a start-up opens a tasting booth at another company's premises to which only a company's employees have access, this would not be considered as an event open to the public. For example, the Singaporean guidelines on tastings and sensory evaluation is strict in that sense that it only allows the testing to be conducted in a non-food facility designated for sensory evaluation R&D, such as test kitchens, research institutes or institutes of higher learning or in a licensed restaurant.[91] Other countries may be less restrictive, potentially contradicting not only the GFL but also the Commission's understanding of placing on the market: for example, a recent tasting event in Estonia was explicitly designated as "public." It was set up at a start-up conference venue involving a select number of "novel food enthusiasts."[92] To explore these differences further, consider two scenarios: In the first scenario, a food product undergoes a testing akin to a new car on a German motorway. Only the product's shape is observable, with no branding or marketing evident.[93] Similarly, a testing of a novel food which appears as an unbranded and unlabelled product may take place at a location accessible to any person, contingent upon providing personal data, including contact information. Immediate feedback on taste, texture, and other sensory aspects are collected. In the second scenario, a tasting event takes place in a researcher's house with exclusively invited guests, who may subsequently disseminate information about the event through traditional and social media channels. Marketing materials are prominently displayed in the tasting room, arguably imbuing the event with a more commercial aspect than the former scenario. Consequently, there appears to be some incongruity in categorising the first scenario as placing the product on the market while not applying the same classification to the second. This incongruity arises partly due to the pivotal consideration in the GFL, which

[88] Case C-325/14 *SBS Belgium NV v Belgische Vereniging van Auteurs, Componisten en Uitgevers (SABAM)* ECLI:EU:C:2015:764.

[89] Cases C 682/18 and C 683/18 *Frank Peterson v Google LLC, YouTube Inc., YouTube LLC, Google Germany GmbH and Elsevier Inc. v Cyando AG*, ECLI:EU:C:2021:503 para 69 and the case-law cited.

[90] R Xalabarder, "The Role of the CJEU in Harmonizing EU Copyright Law" (2016) 47 IIC – International Review of Intellectual Property and Competition Law 635.

[91] Singaporean Food Safety Authority (n 36).

[92] S Sillasoo, "Estonia's First Public Novel Food Tasting Accelerates Sustainable Food Production' (*Trade with Estonia*, May 2024) available at <https://tradewithestonia.com/estonias-first-public-novel-food-tasting-accelerates-sustainable-food-production/> (last accessed 22 January 2025).

[93] These cars are conventionally referred to as "Erlkönig," a reference to a poem from JW von Goethe, as they hide their real guise behind a camouflaged foil.

centres on the positive establishment of whether the activity occurs within a domestic setting.

Conversely, if neither "placing on the market" nor "private use" can be established with certainty. This may lead to a regulatory gap, which may then create leeway for national administrations to establish national laws on tastings. If an activity (non-public or non-market use of a food) does not involve placing a product on the market, it raises questions as to whether Member States regulated that activity at all, ie, whether "placing on the market" is not fully harmonised at the EU level precluding the respective Member State freedom to regulate. Consequently, if a food is not placed on the market it becomes necessary to consider "private use" or "non-public" use for Member States to assert jurisdiction over it. However, if food's use does not amount to"placing a product on the market," it may fall outside the regulatory ambit of Member States.[94] It is for this reason that some EU Member States may consider the tasting of non-authorised novel foods as non-compliant with the EU Novel Food Regulation. With such a view, the lack of a clear harmonisation measure may contribute to some national administrations hesitating to engage in the currently observed race to make law more innovation-friendly or future-proof.[95,96] Hence, they may await Union action as a means of deviating from existing novel food regulations. They can be doing so in consideration that EU food law, applied horizontally throughout different food regulations, aims at high level of human health protection.[97] In that regard, the Court of Justice of the EU recently ruled that authorisation systems encompassing pre-market authorization procedures, such as that in the EU Novel Food Regulation "constitutes an appropriate means of ensuring compliance with the precautionary principle" which is a general principle of EU food law.[98,99] Also, centralised authorisation procedures, such as the one provided for by the EU Novel Food Regulation is designed to maintain the high level of scientific evaluation.[100] Creating regulatory sandboxes for novel foods at national level and potentially eliminating the requirement of uniform "high level of protection" across the EU internal market is a matter of constitutional kind, potentially infringing upon Article 114 TFEU and the related norms in the TFEU and the Charter, which are applicable horizontally to all policies.[101]

Taking the opposite stance, that is that tastings are allowed under the EU Novel Food Regulation, the regulation presupposes that an applicant tests the food because the regulation requires submission of scientific evidence demonstrating that the novel food

[94] For instance, Germany has broadened the scope of its food law to encompass personal use or activities within the private domestic area, see A Meisterernst and T Boch, "§ 1 LFGB" in R Streinz and A Meisterernst (eds), *BasisVO/LFGB* (2nd ed, München, CH Beck 2024) para 12.

[95] F Peter and S Madeleine, "How UK Regulators Are Missing a Chance to Make the Best of Brexit' (*Financial Times*, 27 February 2024) available at <https://www.ft.com/content/07c98087-3914-4107-a6ee-56cc4086459e> (last accessed 22 January 2025).

[96] A Lähteenmäki-Uutela, M Rahikainen, A Lonkila and B Yang, "Alternative Proteins and EU Food Law" (2024) 130 Food Control 108336.

[97] Art 4(2) and Art 5(1) GFL.

[98] Case C-13/23 (n 61) para 50.

[99] The principle maintains a possibility to adopt risk management measures to achieve high level of health protection, pending further scientific information to enable more comprehensive risk assessment (Article 7 GFL); A Szajkowska, "The Impact of the Definition of the Precautionary Principle in EU Food Law" (2010) 47 Common Market Law Review 173.

[100] Analogically Recital 7 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1.

[101] SA De Vries Sybe, "Chapter 3: The Charter of Fundamental Rights and the EU's 'creeping' Competences: Does the Charter Have a Centrifugal Effect for Fundamental Rights in the EU?" in S Douglas and N Hatzis (eds), *Research Handbook on EU Law and Human Rights* (Cheltenham, UK/Northampton, MT, USA, Edward Elgar Publishing 2017) p 58.

does not pose a safety risk to human health.[102] How else to generate such evidence than by scientific experiments? One way to arrive at a certain interpretative reconciliation would be to propose that "food" in experiments designed to prove its safety is not food at all within the meaning of Article 2 GFL.[103] This is supported by the fact that scientific data concerning novel food safety is primarily derived from in-vitro, animal studies, theoretical considerations, and only then human studies. Therefore, if tastings do not constitute placing a product on the market but is a type of testing of the novel food, the requirement to restrict access to the tested food, and the corresponding level of control over the product, prompts a number of questions. For example, if consuming a product at home with friends is deemed private use, and consuming it in a designated area with selected individuals is not considered market use, could testing on a larger scale with control and supervision, such as within entire municipalities, also be exempt from the EU Novel Food Regulation? Or does the distinction hinge on the scale at which the testing occurs which brings back the question of the relevant size of the "public" at which an experiment is directed? Does the permissibility of a regulatory sandbox for novel foods repose in its personal or spatial aspects or both? Or does it repose in the control exercised over the experimental food? One may hypothesise that compliance with the requirement not to place unauthorised novel foods on the market in a regulatory sandbox depends on three key modalities: (1) the participants involved, (2) the sandbox's location, and (3) the control and traceability of the tested products as they move beyond the sandbox location; these may be subject to modification given the limitations of the GFL and EU internal market law. Additionally, depending on the stage of product development during which the novel food or its features are tested, the sandbox may impose varying entry requirements concerning safety. These modalities are further elaborated in the following section.

IV. Regulatory sandboxes for novel foods as open, semi-open and closed spaces

In a novel food regulatory sandbox, both regulators and innovators have an interest to exercise control over the object of the sandbox, ie, the innovative food product, as well as its participants. The reason for this control is to mitigate risks associated with the product's consumption. In that regard, a regulatory sandbox enables a safe innovation.[104] We propose to categorise these regulatory spaces, according to the degree of control and risk mitigation strategies, into open, semi-open, or closed (see Fig. 2):

A closed regulatory sandbox is highly restricted, where no external third parties can access the sandbox. The innovative product itself is confined within the sandbox, meaning it cannot leave the regulated environment during the testing phase or be reached from the outside. An analogy may be found in some pieces of experimental regulation: For example, under the EU GMO Directive, borders and buffer zones are important features of GMO experiments.[105] There is no public access to the field, and the GMO produce must be discarded after the experiment has ended. A closed regulatory sandbox could be used to test a product at the earliest stages of development and enable the most extensive regulatory learning via collaboration.

[102] Art 10(2)(e) Novel Food Regulation.

[103] "'Food' means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans."

[104] GFI Europe, "UK Creates Cultivated Meat Regulatory Sandbox to Boost Innovation' (8 October 2024) available at <https://gfieurope.org/blog/uk-creates-cultivated-meat-regulatory-sandbox-to-boost-innovation/> (last accessed 22 January 2025).

[105] K Purnhagen and J Wesseler, "The Principle(s) of Co-Existence in the Market for GMOs in Europe: Social, Economic and Legal Avenues" in N Kalaitzandonakes, PWB Phillips, J Wesseler and SJ Smyth (eds), *The Coexistence of Genetically Modified, Organic and Conventional Foods* (Cham, Switzerland, Springer 2016) p 71.

Stage of regulatory sandbox	Participants	Location	Product	Degree of openness	Safety entry requirements	Risk to human health after consumption
Stage 1	Excluded	Confined	Limited access	Closed	No special requirement	Lower
Stage 2	Selected	Permeable	Traced	Semi-open	Minimally safe	Medium
Stage 3	Public	Local market or zone-based	Traced or unmonitored	Open	Minimally safe	Higher

Figure 2. Modalities of food-related regulatory sandboxes at different stages where a regulatory sandbox may be established.

An open regulatory sandbox allows for broader participation, with public access permitted in a limited area, such as a designated market or testing location. Theoretically, if an experimental space is open, anyone can enter the testing ground, facilities in which testing takes place are not separated from other facilities of ordinary commercial activity, and the product in testing is not labelled in any particular way, documented or traced. In an open area, certain commercial operations may be taking place,[106] but such a regulatory sandbox must be carefully established as not to contradict with the EU's law prohibition to place on a market product prior to its authorization. Certain propositions could be explored as potential sandboxing venues with the caveat that they would require changing the law and provide for special exemptions from the placing on the market; for example, if a company wishes to host a cooking event where chefs aim to incorporate novel ingredient into food products, offering a novel food at a fair or in a supermarket, or a European city thriving to become a food innovation hub open to trial novel foods within its municipal borders. With the latter option, a newly conceived exemption from the "placing of the market" concept could accommodate situations where a regulatory sandbox is established by lower administrative entities within "innovation zones." Open regulatory sandboxes would allow food business operators to engage in activities with a potentially higher level of risk emanating from their operations, compared to closed or semi-open regulatory sandboxes, provided risk mitigation measures, such as traceability are put in place to ensure "high level of protection human health and consumers' interest."[107] It is conceivable, for instance, that certain food business operators might consistently introduce unauthorised novel foods in their restaurant offerings. In case of adverse events, food business operators would only be liable under civil liability rules[108] and may have to offer compensation.[109] As for the current understanding of the placing on the market, an open regulatory sandbox could be established only for certain product features, such as labelling or packaging, ie, not for testing the product itself.

In semi-open regulatory sandboxes, only selected participants are permitted to engage with the innovative product. While the product remains controlled and is not freely available to the general public, it can leave the sandbox environment, provided that it remains under regulatory oversight via traceability, for example, by registering the test

[106] L Bromberg, A Godwin and I Ramsay, "Fintech Sandboxes: Achieving a Balance between Regulation and Innovation' (2017) 28 Journal of Banking and Finance Law and Practice 314.

[107] Art 1 GFL and Art 114 TFEU.

[108] LM Sokołowski, "Liability for Damage Caused by Unsafe Innovative Food – A Legal Perspective' (2020) 26 Przeglad Prawa Rolnego 47.

[109] ESMA, EBA, EIOPA 'FinTech: Regulatory sandboxes and innovation hubs' (Report JC 2018 74, 2018) p 28 available at <https://www.esma.europa.eu/sites/default/files/library/jc_2018_74_joint_report_on_regulatory_sandboxes_and_innovation_hubs.pdf> (last accessed 22 January 2025).

users. Tasting and testing other food sensory characteristics would likely fall within a semi-open space. Here, again, analogies with experimental regulation may be found: although food is served, and medical products are administered at one place, consumers and trial "subjects" continue to live in other places. A clinical trial continues with the subjects until the last visit of the last subject of the clinical trial at a clinical trial site, and for that reason numerous monitoring and reporting requirements need to be followed.[110] Similarly, when a medical device undergoes a clinical investigation at an investigational site, the investigation ends with the last visit of the last subject and follow-up measures are implemented.[111] For the duration of the trial, the tested device leaves the site of investigation. In feed additives trials,[112] an emphasis is placed on the exercise of the control over the experimental feed additive by means of traceability ensured via documentation, spatial separation of animals fed with experimental feed and other animals or labelling of the experimental feed additive featuring the name of the test farm. A new feed additive is administered to animals kept and housed in one place, and during the experiment, animals are controlled at unannounced controls and may not be moved. However, once the experiment is terminated, animals concerned may be used for food production only if the authorities establish that this will have no adverse effect on animal health, human health, or the environment.[113] Therefore, the subjects of the experiment may ultimately leave the experimental space and even be traded following the EU food law traceability requirements.[114]

Tasting a novel food would typically take place in a semi-open space, in which, however, the degree of control and risk mitigation measures may vary depending on the specific way a novel food product is consumed in "real-world" experimental scenarios. Such measures would depend on how closely the designers of controlled environments stick to the proposition of mimicking or simulating the real-world environment,[115] from lab to field to table, as the more real the conditions are, the less scientifically measurable they are. For example, in the real world, a bag of newly approved crickets and new energy drinks can be easily consumed by a group of friends in a single road trip, whereas a new infant formula would be carefully dosed in a home environment. In a regulatory sandbox, it is conceivable that a bag of five locusta or a small bag of novel algae powder to bake one cupcake, ensuring personal use only, can be distributed to the sandbox's participants to take home or a precisely fermented cheese can be served exclusively in a controlled room. As a risk mitigation measure, some regulatory authorities already limit the tasting to one-time consumption only.[116]

If a novel food is tested with businesses to explore potential proposed use, it may even be conceived that a novel food is exported to another country: for example, if a novel food ingredient is to be sent to a respected chef located in another EU jurisdiction for experimentation. Different legal interpretations over the permissibility to set up regulatory sandboxes under the EU Novel Food Regulation make it unlikely to establish

[110] Chapter VII Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use [2014] OJ L158/1.

[111] Article 77 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2016] OJ L117/1.

[112] Our written survey was sent to competent authorities of Bavaria, Baden-Württemberg, Hessen, Rheinland-Pfalz, Nordrhein-Westfalen, Niedersachsen, Sachsen, Sachsen-Anhalt, Hamburg, Bremen, Berlin, Brandenburg, Schleswig-Holstein, Thüringen, Saarland and Mecklenburg-Vorpommern.

[113] Art 3(2) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [2003], OJ L268/29.

[114] Art 18 GFL.

[115] F Engels, A Wentland and SM Pfotenhauer, "Testing Future Societies? Developing a Framework for Test Beds and Living Labs as Instruments of Innovation Governance" (2019) 48 Research Policy 103826.

[116] Singaporean Food Safety Authority (n 36).

any multi-jurisdictional sandbox for novel foods. However, one may theoretically consider a particular testing session as one of a series of cooking explorations taking place at different locations and even jurisdictions. Let us envision a German-based company seeking to benefit from more innovation-friendly regulatory conditions. In this scenario, the company would arrange consecutive testing sessions across various EU Member States, such as the Netherlands and Denmark. During these sessions, a novel food would traverse borders, and the testing processes would encounter diverse regulatory frameworks. In the future, the potential for such activities may be curtailed by harmonisation rules, akin to consultations for novel food status.[117] Under such regulations, a company might only participate in a regulatory sandbox in a country where it plans to initially introduce the product to the market. These harmonisation rules would effectively eliminate disparities between EU countries regarded as innovation-friendly and those perceived as less so.

Within the EU, applicants typically wait up to 36 months for a novel food to be authorised.[118] Thus, regulatory sandboxes for novel foods can facilitate innovation both before and after the submission of a novel food application. During this period, regulatory sandboxes could allow applicants to test product features like labelling, health claims, and packaging, as well as explore potential business cases or the production process, some of which could be used in the authorisation process:

1. Production process – in South Korea, a regulatory sandbox is conceived as a multiple phase support framework for innovative companies working on cultivated meat. In the first phase, they establish storage, handling and manufacturing standards. In the second phase, they demonstrate mass production and commercialization.[119] A regulatory sandbox could help establishing production standards in a closed set up.
2. Sensory characteristics, such as taste or texture – a regulatory sandbox may be set up to gauge acceptance, preferences, and perceptions of new food products. It would involve human consumption, and thus be considered of medium risk if set up as a semi-open tasting.
3. Proposed use – is an important part for authorisation of a novel food.[120] The applicant should specify, for example, the form of uses (eg, as whole food, ingredient), the food categories in which the novel food (if an ingredient) is proposed to be used, the proposed maximum amounts in products as consumed and the proposed average and maximum daily intakes for different age/gender groups as appropriate.[121] Categorisation follows a food classification and description system developed by EFSA (Foodex2), and includes broad categories, such as baked goods, dairy products, etc., as well as more specific categories of Foodex2, such as "Caesar salat," "meat loaf," "omelets with bacon."[122] Here, a regulatory sandbox, developing new food products with an innovative food ingredient may be helpful. In that case, under a regulatory supervision and

[117] K Niewalda, "Systematics of the Novel Food Regulation – An Analysis of the Consultation Results to Date" (2023) 18 European Food and Feed Law Review 10.

[118] N Baldwin, "Revised EU Novel Foods Regulations Set for Adoption" (*Intertek*, 3 November 2015) available at <https://www.intertek.com/blog/2015/11-03-novel-food/> (last accessed 22 January 2025).

[119] South Korea Designates Regulation-Free Zone for Cultivated Meat to Boost Production & Safety (cultivated X by vegconomist, 1 May 2024) available at <https://cultivated-x.com/politics-law/south-korea-regulation-free-zone-cultivated-meat-production-safety/#:~:text=The%20zone%2C%20officially%20named%20the,for%20the%20cultivated%20meat%20industry> (last assessed 22 January 2025).

[120] Art 10(2)(g) Novel Food Regulation.

[121] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Products et al (n 31).

[122] European Food Safety Authority, "Food Classification Standardisation – The FoodEx2 system" available at <https://www.efsa.europa.eu/en/data/data-standardisation> (last assessed 22 January 2025).

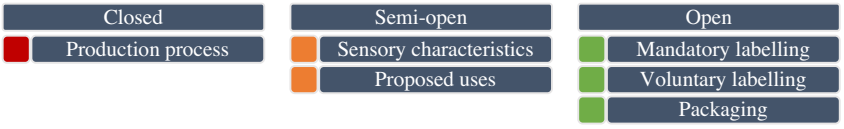

Figure 3. Regulatory sandboxes for novel foods from closed to semi-open to open spaces.

guidance, participants of such regulatory sandbox may involve other food business operators on the B2B basis.

4. Labelling – labelling requirements inform the consumer, where appropriate, of any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population.[123,124] In that regard, an application for authorisation of a novel food must make a proposal for specific labelling requirements, which do not mislead the consumer or a justification as to why labelling is not necessary.[125] It may be desirable for future applicants to test appropriate labelling in consumer behavioral studies.[126] Such testing would not necessarily involve any consumption of unassessed novel foods.
5. Other labelling such as sustainability or health claims – as many novel foods involve food supplements and food for speical groups, a regulatory sandbox may serve assessing consumers' willingness to pay for regulatory properties. Consumers act differently in willingness to pay studies compared to a real-world shopping scenario, ie, a competitive choice environment.[127] In this potential set-up of a regulatory sandbox, an unassessed novel food would be present in a supermarket among regularly marketed foodstuff. A consumer entering a supermarket where a novel food is placed would need to sign a consent form acknowledging that s/he may be part of a consumer behavioural experiment. If a consumer is willing to purchase a novel food, s/he would be stopped at the cash register and would not be allowed proceed further with the purchase, thus avoiding the food's consumption.
6. Packaging – a regulatory sandbox may be used to assess the consumer-friendliness of packaging, also, for example, in light of the reduction of waste objective.[128] In a regulatory sandbox involving a novel food, consumers may be provided with the packaged food and be instructed to use the food as they are normally. The food tested may be potentially consumed, and depending on that may be considered a semi-open space. Also, *de novo*, EFSA's Guidance on the scientific requirements for an application for authorisation of a novel food requires for every material in

[123] Art 6(2) Novel Food Regulation; see A Molitorisová and A Monaco, "Innovating Food with Mycelium: EU Regulations" in M Möstl and K Purnhagen (eds), *Die Regulierung von Innovationen im Lebensmittelsektor: Produkte – Probleme – Perspektiven* (Frankfurt am Main, Germany, dfv Mediengruppe 2023) 69.

[124] Art 9(3)(b) Novel Food Regulation.

[125] Art 10(2)(g) Novel Food Regulation.

[126] H Schebesta and K Purnhagen, "The Behaviour of the Average Consumer: A Little Less Normativity and a Little More Reality in the Court's Case Law? Reflections on Teekanne' (2016) 41 European Law Review 590.

[127] MH Bazerman, GF Loewenstein and SB White, "Reversals of Preference in Allocation Decisions: Judging an Alternative versus Choosing among Alternatives" (1992) 37 Administrative Science Quarterly 220. See also CK Hsee, 'The Evaluability Hypothesis: An Explanation for Preference Reversals between Joint and Separate Evaluations of Alternatives' (1996) 67 Organizational Behavior and Human Decision Processes 247.

[128] In the EU, packaging is governed by the Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food [2004] OJ L338/4, which requires that food contact materials do not release their constituents into food at levels harmful to human health or change food composition, taste, and odour in an unacceptable way.

contact with the novel food during the production process a declaration of compliance with respective EU legislation, and from that perspective, setting up a regulatory sandbox, albeit closed, may prove useful.

These examples of regulatory sandboxes for novel foods would not have the same degree of openness (see Fig. 3). The regulators and inventors would likely seek to have a different level of control over participants and the innovative products in the sandboxes depending on the risk exerted in the experimentation.

V. Conclusion

Scholarship pertaining to regulatory sandboxes has evolved within distinct domains, contingent on the specific technology under consideration. This has led to challenges in their scholarly evaluation for regulatory purposes, detached from the relevant technological context. While regulatory sandboxes have been extensively discussed in fintech and Artificial Intelligence research, only some academic exploration exists for the life sciences sector. However, no comprehensive scholarly analysis of sandboxes in the realm of food technology has been identified. To address this gap, we applied a conceptualisation of regulatory sandboxes to the context of food technology, focusing on novel foods within the EU.

We categorised sandboxes into open, semi-open, and closed sandboxes, each offering distinct regulatory environments by scaling the required control over participants and the innovative product within the sandboxes. Open sandboxes often require minimal regulatory intervention. In contrast, closed sandboxes afford more flexibility to relax regulatory requirements via regulator's learning while restricting the access to that space. In that regard, regulatory sandboxes are adjusted to different risk profiles of different technologies tested within them.[129] The European Commission could, where possible, establish regulatory sandboxes by making use of existing possibilities to issue implementing acts, such as for example in Regulation (EU) 2016/429.[130] Such a solution, however, has limited application and would only allow for selected features to be regulated in a sandbox. The realisation of an all-encompassing regulatory sandbox would be difficult, if not impossible to achieve applying existing possibilities for implementing acts scattered over various EU acts.

From a regulatory standpoint a significant obstacle to establishing sandboxes in the EU lies in the uncertainty regarding whether sandbox activities qualify as "placing on the market," triggering the applicability of EU food laws. This applies more so "when a sandbox is created in a domain that is heavily regulated by EU law ... as the national regulator cannot provide any exemptions from the rules established by the European Union."[131] In this regulatory ambiguity, EU Member States are hesitant to address this gap through national laws or regulations. Those that do engage in such efforts risk entering a competitive race for the most innovative legal space, with potential implication for the cohesion of the internal market. Harmonising efforts at the Union level to facilitate and frame such regulatory sandboxes in the area of food technology, especially for novel foods, are warranted.

[129] Yordanova and Bertels (n 44) 447.

[130] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ("Animal Health Law"), OJ L84/1.

[131] Yordanova and Bertels (n 44) 448.

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