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Regulatory and Legislative Framework for Novel Foods

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REGULATORY AND LEGISLATIVE FRAMEWORK FOR NOVEL FOODS

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16 September 2020

ABSTRACT

The paper discusses how novel foods are regulated in the EU, US, and elsewhere. It reviews some of the reasons novel foods might be regulated and how such regulatory goals can be accomplished. Regulation of novel foods is the policy maker's reaction to the unknown, although what is novel today may not be novel tomorrow. Indeed, the novel food industry has grown immensely over the past decade due to the need to feed a growing world population while using less land, water, and other limited natural resources. Ultimately, policy makers have the difficult task of balancing adequate government oversight over novel foods without stifling innovation and creativity.

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I INTRODUCTION

Scientific advances have made it possible to produce foods from unconventional sources or through new techniques. At the same time, globalization and integrated value chains have facilitated the movement of foods and food ingredients from regions where they have been in use for decades or longer to other regions where they are unknown – and therefore perceived as “novel.” Earlier chapters of this book provided an overview of novel food ingredients and processing techniques. They also explored the use of novel food ingredients in the formulation of novel and health-promoting food products. With more and more of these foods and food ingredients circulating in the market, interest in regulation is increasing.

The purpose of this paper is to review how novel foods are currently regulated in the European Union (EU), United States (US), and elsewhere. We briefly review what novel foods are – and in later sections we look at special categories of foods such as foods derived from insects, 3D printed food, and food formulated for special population segments – and why they are regulated. We then discuss the various types of regulation of novel foods – primarily official review and approval (or rejection) of the introduction of these types of foods on the market, but also intellectual property law, marketing law, tort law, and criminal law.

This paper provides an overall picture of what public and private entities should take into account when regulating or trading in novel foods.

II WHAT IS A NOVEL FOOD?

In most jurisdictions, new foods and ingredients introduced into the stream of commerce are generally referred to as “novel foods.” In some ways it is a

circular effort to define a novel food because the definition varies depending on what the applicable legislation says it is. In turn, whether a food is “novel” according to legislation may depend on geographic, temporal, or cultural variables, i.e., whether it is unfamiliar to a specific region, time period, or culture. The definition of a novel food may also differ depending on the purpose for which the food is being regulated. For example, one piece of legislation might define a novel food for purposes of protecting public health, while another piece of legislation may propose a different definition for another purpose, such as securing intellectual property rights.

Some examples of what might be considered novel foods are newly developed and innovative foods, foods produced using new technologies and production processes, or foods traditionally eaten outside of a geographical region.¹ More than 30 years ago, the International Programme on Chemical Safety (IPCS), a joint UN body with representation from the World Health Organization, the International Labour Organization, and the United Nations Environment Programme, defined a novel food as “a food or food ingredient produced from raw materials not normally used for human consumption or food that is severely modified by the introduction of new processes not previously used in the production of food.”² In the EU, the Novel Food Regulation (NFR),³ which in its current form came into force on January 1, 2018, defines novel foods as foods that have not been used for human consumption to a significant degree within the EU before May 15, 1997 and that fall within one of ten enumerated categories.⁴ The European Commission provides the following specific examples:

Examples of Novel Food include new sources of vitamin K (menaquinone) or extracts from existing food (Antarctic Krill oil rich in phospholipids from *Euphausia superba*), agricultural products from third countries (chia seeds, noni fruit juice), or food derived from new production processes (UV-treated food (milk, bread, mushrooms and yeast)).⁵

¹ European Commission, What is Novel Food? https://ec.europa.eu/food/safety/novel_food_en (accessed 28 March 2020).

² World Health Organization (1987). International Programme on Chemical Safety [hereinafter IPCS], Environmental Health Criteria 70, Principles for the Safety Assessment of Food Additives and Contaminants in Food. <http://www.inchem.org/documents/ehc/ehc/ehc70.htm#SubSectionNumber:6.2.4> (accessed 28 March 2020).

³ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods [hereinafter NFR] Article 3(2)(a), amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (text with EEA relevance), OJ L 327, 11.12.2015, p. 1-22.

⁴ See *infra* text at n. 32.

⁵ See *infra* text at n. 32.

In the US, the Food and Drug Administration (FDA), which serves as the primary food regulatory agency, has no formal definition and in fact does not recognize “novel foods” as a category of food. Instead, any new food (no matter its technological, temporal, or geographical origin) is regulated like any other food. Instead, a new substance or new food ingredient is regulated through the food additive process, unless it meets an exception under the Federal Food, Drug, and Cosmetic Act⁶ or is considered Generally Recognized as Safe.⁷

We examine the regulatory frameworks for new or novel foods in greater detail in the next section.

III OVERVIEW OF REGULATORY FRAMEWORKS FOR NOVEL FOODS

A Why Regulate Novel Foods?

There are many reasons to regulate novel foods. At the most fundamental level, regulation of novel foods represents how society has chosen to deal with the unknown consequences of new technologies and materials. This decision-making process is implicated not only with respect to novel foods but also to all novel techniques and materials on the market. Scholars call this “regulating the unknown.”⁸ Policy makers weighing and choosing regulatory approaches must find a balance between, for example, protection and innovation, between financing of research and reaping of societal benefits, and between societal acceptance and necessary government interference. Depending on the culture and legal system, the balances may shift, and one factor may be privileged over others. In Ulrich Beck’s work, which has guided EU regulation,⁹ technologies create risks that trigger regulation.¹⁰ Commentators in the economic

⁶ Food, Drug, and Cosmetic Act 1938, 21 U.S.C. s 301 et seq.

⁷ Magnuson, B., Munro, I., Abbot, P. et al. (2013). Review of the Regulation and Safety Assessment of Food Substances in Various Countries and Jurisdictions. *Food Additives & Contaminants. Part A, Chemistry, Analysis, Control, Exposure & Risk Assessment* 30 (7): 1189. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3725665/> (accessed 28 March 2020).

⁸ See, e.g., Finck, M. (2018). Blockchains: Regulating the Unknown, *German Law Journal* 19: 665. (blockchain technology); Åm, H. (2011). Regulating the Unknown: Governing Nanotechnologies by a Logic of Pre-emption, p.11 (“nanotechnology brings to the fore the difficulties of regulatory policymaking under conditions of uncertainty”). Dissertation. University of Vienna. https://www.researchgate.net/profile/Heidrun_Am/publication/265276233_Regulating_the_Unknown_Governing_Nanotechnologies_by_a_Logic_of_Pre-emption/links/544f230cf24e8f7374a53a/Regulating-the-Unknown-Governing-Nanotechnologies-by-a-Logic-of-Pre-emption.pdf (accessed 28 March 2020).

⁹ Opinion of AG Bobek delivered on 30 March 2017, Case C-111/16, Criminal proceedings against Giorgio Fidenato and Others, ECLI identifier: ECLI:EU:C:2017:248, para. 31 (stipulating that Ulrich Beck’s work guided EU regulation).

¹⁰ Beck, U. (1992). *Risk Society: Towards a New Modernity*. London: Sage. But see Bergkamp, L. (2016) *The concept of risk society as a model for risk regulation – its hidden and not so*

arena have noted that this approach focuses on maintaining the status quo,¹¹ and critics charge that it therefore limits flexibility and stifles innovation. But at the least, regulation of technologies should preserve society's ability to understand potential future uses of the technology to evaluate whether risks are worth taking to reap potential future benefits.¹² Whatever the locale or justification, regulation in this context generally consists of testing, data, and scientific evaluation of potential adverse effects on health, safety, and the environment.

The problem arises when data on potential hazards is non-existent or inconclusive. Whereas the United States' regulatory approach requires scientific proof of harm, Europe requires regulators to take action when, after assessment of available information, a possibility of harmful effects on health is identified but scientific uncertainty persists:¹³ this is known as the precautionary principle, which applies under the General Food Law (GFL) (the pre-eminent EU Regulation on food)¹⁴ and hence to novel foods.¹⁵ Although this definition is widely shared, it is important to note that that the exact wording and application of the precautionary principle in EU law depend on the legal sector and/or type of good it applies to.

The European Commission describes the principle's justification as follows: "decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health."¹⁶ Equally, policy makers are divided over how to weigh and evaluate the relative importance of types of adverse effects: should one prioritize conservation, innovation, or consumer health? These are political decisions which regulations cannot solve, but rather are left to the political realm. At least within the EU, the precautionary principle is the only tool available to regulate decisions under circumstances of uncertainty, and policy makers have determined that the precautionary principle applies to novel foods.¹⁷

hidden ambitions, side effects, and risks. *Journal of Risk Research* 20 (10) (criticizing the risk society approach, *inter alia* because it politicizes science and taints risk management decision-making).

¹¹ In economic terms this is called the existence value. See Dana, D. (2004). Existence Value and Federal Preservation Regulation. *Harvard Environmental Law Review* 28: 345.

¹² Cicchetti, C., Wilde, L. (1992). Uniqueness, Irreversibility, and the Theory of Nonuse Values, *American Journal of Agricultural Economics*. 1121-1122.

¹³ General Food Law [hereinafter GFL], 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, 1.2.2002, Art. 7(1).

¹⁴ GFL Arts. 1(3) and 4(1).

¹⁵ *Id.*

¹⁶ Commission of the European Communities (2000). Communication from the Commission on the precautionary principle, Document 52000DC0001, COM/2000/0001 final. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52000DC0001> (accessed 28 March 2020).

¹⁷ NFR Recital 20.

B How Are Novel Foods Regulated?

Novel food regulation can be categorized in a variety of ways to facilitate understanding. The first division is between content-related vs. information-related measures. Content-related measures, in this context, consist of measures such as approval procedures, where responsible authorities examine the type of food before approving or rejecting an application to commercialize it or before banning certain types of foods. Information-related measures, by contrast, are measures where regulators control information about the food through labelling or through information released to consumers to affect consumer choice.

Regulation of novel foods can also be categorized based on the phase of market introduction of the product. Here, measures can be conceptually divided into those regulating market access (e.g., pre-market measures such as approvals) and those regulating products already on the market (e.g., post-market measures such as liability).

Regulation can also be grouped into measures that are process-related (i.e., regulating the technique used to produce the food) and those that are product-related (i.e., regulating different features of the product). Which of these might be given more or less attention or weight in the regulation of novel foods at a particular time depends on the jurisdiction. It is worth noting, however, that most novel food regulations apply a product-related approach, which experts consider the favoured strategy in the face of uncertainty.¹⁸ With this type of regulatory framework, whether a food is subject to special regulation as a “novel food” mainly depends on evaluation of the “nutritional composition, presence of known toxins or anti-nutrients, and allergenicity of proteins as well as . . . the potential nutritional impact of introducing the novel food into the human diet.”¹⁹

It is important to underline here that although some technology-related regulation exists, in some respects this is just another type of product-related measure. For instance, the EU applies the novel food regulatory regime to foods containing engineered nanomaterials, but in fact it is not the technique that is being regulated, but rather the risks stemming from the use of the technique.

Regardless of how one conceives of the regulation of novel foods, in all jurisdictions that regulate them we find most of these categories in use.

¹⁸ See, e.g., Finck, *supra* note 8, at 682-90. As one researcher pointed out, “Uncertainty poses particular problems for governments, as decision-making is highly politicised when no recourse to ‘facts’ is possible when faced with new technologies.” Åm, *supra* note 8, at 15. *But see* Cicchetti & Wilde, *supra* note 12 (an early example of the increasing literature in law and economics on the valuation of uncertainty, which can be used in assisting such decisions).

¹⁹ Magnuson, et al., *supra* note 7, at 1202.

C *How Novel Foods Came To Be Regulated Internationally*

More than 30 years ago, the IPCS developed guidelines for the safety assessment of novel foods. The IPCS defined a novel food as “a food or food ingredient produced from raw materials not normally used for human consumption or food that is severely modified by the introduction of new processes not previously used in the production of food.”²⁰ The definition applied to foods intended for direct consumption or for consumption after some alterations to make the product more acceptable.

The IPCS was particularly concerned about circumstances where novel foods are intended to replace a significant portion of traditional food in the diet, because of the likely nutritional impact. For this reason, in addition to recommending animal and human tests, the IPCS proposed examining the effect of the introduction of the new substance on the nutrient composition of the diet as a whole. It recommended particular care where the food is intended for groups such as “children, the elderly, and ‘captive populations,’ e.g., hospital patients and school children.”²¹

As we saw in earlier chapters of this text, complete chemical identification of novel foods may not be feasible, but it is important that the regulatory system ensure microbiological purity and that levels of potentially hazardous contaminants are kept to a minimum. The IPCS pointed out that if the novel food is intended to be an alternative significant supply of protein, tests on its protein quality will be necessary.²² Other studies should analyse: (a) the availability of vitamins and minerals in the novel food in comparison with the food it would replace; and (b) any interaction the novel food might have with other items of the diet that would reduce the whole diet’s nutritional value. IPCS also recommended testing for allergenicity.²³

Currently, the Joint FAO/WHO Committee on Food Additives (JECFA), a scientific advisory body, evaluates the safety of food additives for purposes of advising the Codex Alimentarius Commission, which is the reference body for international food standards under the World Trade Organization (WTO)²⁴ that produces standards to guide national legislators. Although JECFA’s safety determinations are not binding at national level (i.e., at the moment a particular jurisdiction is deciding whether to approve a particular new food additive), its recommendations are broadly accepted and so are likely to be taken into consideration.²⁵

²⁰ IPCS, *supra* note 2.

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ FAO, *About Codex Alimentarius*, <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/#c453333> (accessed 28 March 2020). On the relationship between Codex standards and WTO law, see Dominique, S., Purnhagen, K. (2016). Reversed Harmonization or Horizontalization of EU Standards? *Wisconsin International Law Journal*. 34: 102-104.

²⁵ Magnuson, et al., *supra* note 7, at 1148.

D *How Novel Foods Are Regulated in the European Union*

Before looking specifically at the regulation of novel foods in the EU, it may be useful to review the complex institutional and legislative framework underpinning the regulation of food within the Union.²⁶ Legislation issued at EU level in the form of a Regulation, such as the NFR, is paramount and directly applicable in member states, without any need for national adoption or enactment. Member state legislation that conflicts with an EU-level Regulation is invalidated in case of conflict, much as federal law pre-empts state law in the US. Since most food laws in the EU are in the form of Regulations, they are directly applicable to EU institutions, all member state authorities, and all persons within the EU. Enforcement responsibility rests with food business operators, although member states are also obligated to establish appropriate enforcement mechanisms.²⁷ The European Commission in turn carries out regular audits to identify and minimize variations among these member state controls.

The European Commission's integrated approach to food safety is set out in the White Paper on Food Safety,²⁸ now almost 20 years old, which has become binding law through the GFL. The regulatory system covers all stages "from farm to fork," starting with feed production and primary production and continuing through food processing, storage, transport, and sale. The GFL sets out an overarching framework for the development of food legislation and regulation at EU and member state levels. It establishes the "general principles, requirements, and procedures that underpin decision making in matters of food and feed safety."²⁹ As noted, since the GFL is a Regulation, it is directly applicable and does not need to be transposed into member state legislation.

In the EU, pre-emption occurs only where EU law regulates the precise topic at issue. To take a simple example, if member state law says that strawberries must be green but EU law states that they must be red, then EU law pre-empts all national laws with regard to strawberries (but not to apples). What distinguishes the GFL from most EU law is that it applies a horizontal (systemic) approach, meaning that it covers not only legislation but all types of action by member states, businesses, and other private parties active on the internal EU market. If the GFL said that all fruits must have their natural colour, this would cover all laws, regulations, rules, and practices in a member state regarding strawberries, apples, and all other fruits – no matter the form of

²⁶ For more background, see Vos, E., Wendler, F. (2007). Food safety regulation in Europe. A comparative institutional analysis. In: *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (ed. E. Vos and F. Wendler), 74. Antwerp: Intersentia; Faure, M. (2018). The Economics of Harmonization of Food Law in the EU. In: *Regulating and Managing Food Safety in the EU* (ed. Bremmers and K. Purnhagen), 283. New York: Springer.

²⁷ GFL Art. 17.

²⁸ Commission of the European Communities (1999). White Paper on Food Safety.

²⁹ European Commission. General Food Law. https://ec.europa.eu/food/safety/general_food_law_en (accessed 28 March 2020).

the rule or business practice in the member state. The GFL also introduces a science-based approach, meaning that no decision on foods can be made without scientific evidence being available.³⁰

Within the EU, the enactment of the NFR has provided the region with a comprehensive novel food definition and regulatory framework, which was substantially revised as of January 1, 2018. Under the NFR, novel foods are foods that have not been used for human consumption to a significant degree within the EU before May 15, 1997 and that fall within one of ten enumerated categories:

1. food with a new or intentionally modified molecular structure;
2. food consisting of, isolated from, or produced from microorganisms, fungi, or algae;
3. food consisting of, isolated from, or produced from material of mineral origin;
4. food consisting of, isolated from, or produced from plants or their parts obtained by non-traditional propagating practices if significant changes in the composition or structure of the food affect its nutritional value, metabolism, or level of undesirable substances;
5. food consisting of, isolated from, or produced from animals or their parts obtained by non-traditional breeding techniques;
6. food consisting of, isolated from, or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi, or algae;
7. food resulting from a new production process if significant changes in the composition or structure of the food affect its nutritional value, metabolism, or level of undesirable substances;
8. food consisting of engineered nanomaterials;
9. vitamins and minerals and other substances used in accordance with Food Supplements Directive 2002/46/EC obtained by a new food production process or containing engineered nanomaterials;
10. food used exclusively in food supplements within the EU before May 15, 1997, intended to be used in foods other than food supplements.³¹

³⁰ There are exceptions when the precautionary principle applies. See GFL Art. 7.

³¹ NFR Art. 3 II (a).

The NFR's regulation of novel foods attempts a maximum harmonization approach,³² so that EU law provides both floor and ceiling for member state regulation. What this means in practice is that member states, in general, cannot introduce higher protection measures in their national legislation than the EU standards. If, for example, EU member states would like to add additional labelling requirements for novel foods which are not foreseen in the NFR or accompanying EU texts, this would be against EU law. However, EU law provides some options to deviate from this strict regime if new scientific evidence comes to light.³³ In such circumstances, the member state has to notify the Commission, which decides whether the proposed member state measure is justified.³⁴ This accords with WTO rules, in that international standards are a floor, and member states may enact more rigorous standards so long as they are based on science and do not violate other WTO principles.³⁵

The NFR applies to novel foods placed on the market within the EU.³⁶ Some foods, however, including those made with genetically modified organisms (GMOs), food enzymes, food additives, food flavourings, and extraction solvents, are covered by other legislative measures and hence fall outside the scope of the NFR.³⁷ For example, if a food has been in continual use in a non-EU country, it is not considered "novel" if its safety has been confirmed with compositional data: continual use is defined here as use for at least 25 years in the customary diet of a significant number of people residing within in at least one non-EU country.³⁸ If these criteria are not met, non-EU or "third-country foods" are considered "novel."³⁹ Third-country foods are also considered novel if the food belongs to one of the categories that are excepted from the NFR, set out above.⁴⁰ The burden of establishing whether a foodstuff is "novel" lies with the food business operator that intends to place the food on the EU market,⁴¹ although member states and the Commission have a duty to assist food business operators in making that assessment.⁴²

Novel foods may only be placed on the market within the EU if they are authorized via inclusion on a publicly available list established by the Commis-

³² *Id.* Recital 42.

³³ Treaty on Functioning of the European Union Art. 114 (5).

³⁴ *Id.* Art. 114 (5, 6).

³⁵ World Trade Organization. Understanding the WTO: The Agreements, Standards and Safety. https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm (accessed 28 March 2020).

³⁶ NFR Art. 2 I.

³⁷ *Id.* Art. 2 II.

³⁸ *Id.* Art. 3 II (b).

³⁹ *Id.* Art. 3 II (c).

⁴⁰ *See supra* text at n. 31.

⁴¹ *Id.* Art. 4 (1).

⁴² *Id.* Art. 4 (2, 3).

sion.⁴³ Article 10 of the NFR lists some generic requirements that must appear in all authorization applications, including:

1. the name and address of the applicant;
2. the name and description of the novel food;
3. the description of the production process(es);
4. the detailed composition of the novel food;
5. scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
6. the analysis method(s) applied, where applicable;
7. a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer, or a verifiable justification why those elements are not necessary.⁴⁴

In assessing the safety of a novel food under the NFR, the EU Commission may grant authorization only where:

1. the food does not pose any risk to human health on the basis of scientific evidence;⁴⁵
2. the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;⁴⁶
3. where the food is intended to replace another food, it does not differ from that food such that its normal consumption would be nutritionally disadvantageous for the consumer.⁴⁷

E How Novel Foods Are Regulated in the United States

As we did for the EU, in this section we briefly review the legislative framework for food in the US. The US system consists of federal law, which applies throughout the country and exists concurrently with the individual regulatory frameworks of the 50 states. Local legislatures (such as counties and cities) may also regulate aspects of food within their jurisdictions. Both state and local legislatures are free to regulate food so long as their regulation does not contradict federal law. However, certain topics are relegated to the federal government's purview exclusively, such as import, export, and interstate commerce.⁴⁸

⁴³ *Id.* Art. 6 (2).

⁴⁴ *Id.* Art. 10.

⁴⁵ *Id.* Art. 7 (a).

⁴⁶ *Id.* Art. 7 (b).

⁴⁷ *Id.* Art. 7 (c).

⁴⁸ FDA Center for Food Safety and Applied Nutrition (2018). Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food: Guidance for Industry. <https://www.fda.gov/media/101042/download> (accessed 28 March 2020).

In the US, federal law is often, but not always, considered supreme to state law. Federal law operates within the federal government's constitutionally established bounds. In contrast, state law often concerns intrastate matters that fall outside of these boundaries or are not covered by federal law. State law can fill in the gaps that federal law, sometimes purposely, leaves behind for states to legislate. All US states have passed laws regulating foods and other products.

The Pure Food and Drug Act (PFDA), enacted in 1906, was the first federal law to regulate food in the United States; the Meat Inspection Act was passed the same year.⁴⁹ Both laws were adopted to respond to burgeoning public attention to food hygiene and safety issues. The PFDA hewed closely to the model of the state-level laws that had proliferated in the latter half of the 19th century, in that it mandated accurate product labelling, outlawed interstate trade in “adulterated” and “misbranded” foods, and required producers to indicate on food labels the presence of mixtures or impurities.⁵⁰ Congress later passed the 1938 Food, Drug, and Cosmetics Act (FDCA) to expand federal regulatory authority over drugs while also more generally strengthening the powers of the FDA.⁵¹ Another piece of federal legislation, the Nutrition Labeling and Education Act enacted by Congress in 1990, required all packaged foods to contain standardized information on nutrition and on serving sizes.⁵² Four years later, the Dietary Supplement Health and Education Act classified dietary supplements as foods rather than drugs.⁵³ In more recent years, Congress reformed major food safety laws via the 2011 Food Safety Modernization Act; this overhaul shifted the FDA's focus from reacting to food safety issues to preventing foodborne illnesses through expanded regulatory authority.⁵⁴

The US does not specifically define or regulate novel foods; instead, they are regulated as food, regardless of their technological, temporal, or geographical origin. If not a food, a new substance would be regulated as a direct food additive or food contact substance, depending on its intended use. The FDA considers any new food ingredient either a food additive (requiring a pre-market approval by the FDA) or Generally Recognized as Safe (GRAS) for specific uses (as classified by a panel of experts and determined independently from the FDA).⁵⁵

The FDCA defines “food additive” as any substance that is intentionally added to food as a consumable component or will affect the characteristic of

⁴⁹ Mark T. Law. History of Food and Drug Regulation in the United States. <http://eh.net/encyclopedia/history-of-food-and-drug-regulation-in-the-united-states/> (accessed 28 March 2020).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ See Strauss, D. (2011). An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business. *Food & Drug Law Journal* 66: 354-355.

⁵⁵ Intertek. Novel Food & Food Additive Services. <http://www.intertek.com/food/consulting/novel-foods> (accessed 28 March 2020).

the final end product, unless it falls under a listed exception (such as a colour additive, new animal drug, pesticide chemical, or dietary supplement) or is considered a GRAS substance.⁵⁶ Food additives are considered unsafe until the manufacturer can prove in a Food Additive Petition (FAP) that the ingredient is food-grade pure and meets food safety regulations.⁵⁷ The FDA will review the scientific data and information submitted in the FAP to ensure it is “safe,” which is defined as a reasonable certainty of no harm to consumers.⁵⁸ After the FDA approves the FAP, the substance may enter interstate commerce.⁵⁹

Most companies opt to list new food ingredients as GRAS where possible, to avoid the tedious FAP pre-market approval process.⁶⁰ The key difference between the GRAS and food additive classification process is who reviews the scientific data and information to make the final decision. As indicated above, the FDA approves food additive safety based on privately held data and information about the substance that the producer compiled in the FAP.⁶¹ By contrast, a company relies on the opinion of “experts qualified by scientific training and experience to evaluate . . . safety” in making its own (not the FDA’s) determination that a substance’s use is GRAS.⁶² This self-determination still requires both technical evidence of safety and a basis to conclude that this evidence is generally known and accepted.

There is no requirement for the FDA to corroborate the company’s findings before the self-determined GRAS substance is released on the market; instead, the company may voluntarily submit a notification of its determination to the FDA for review before putting it on the market.⁶³ The notification in-

⁵⁶ 21 U.S.C. s 321(s); *see also* International Food Information Council and U.S. Food and Drug Administration (2010). Overview of Food Ingredients, Additives & Colors. <https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094211.htm> (accessed 28 March 2020).

⁵⁷ Merrill, R., Francer, J. (2000). Organizing Federal Food Safety Regulation. *Seton Hall Law Review* 31: 96.; FDA. Determining the Regulatory Status of a Food Ingredient. <https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm228269.htm> (accessed 28 March 2020).

⁵⁸ FDA (2016). FAQs About GRAS for Substances Intended for Use in Human or Animal Food: Guidance for Industry. <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM525233.pdf> (accessed 28 March 2020); 21 C.F.R. § 170.3(i).

⁵⁹ *See* 21 U.S.C. s 170.20(a) (establishing general principles for Food Additive Petition pre-market approvals); 21 U.S.C. s 171.1.

⁶⁰ *See* Kelly Damewood, Food Safety News (2014). The GRAS Process: How Companies Legally Add Ingredients to Food. <https://www.foodsafetynews.com/2014/01/the-gras-process-how-companies-legally-add-ingredients-to-food/> (accessed 28 March 2020).

⁶¹ FDA, *supra* note 58.

⁶² 21 U.S.C. s 321(s); FDA (2005-2006). How US FDA’s GRAS Notification Program Works. <https://www.fda.gov/food/ingredientspackaginglabeling/gras/ucm083022.htm> (accessed 28 March 2020).

⁶³ Substances Generally Recognized as Safe, 81 Fed. Reg. 54960 (Aug. 17, 2016). *See also* 21 C.F.R. s 170 subpart E; FDA (2016). About the GRAS Notification Program

cludes a detailed description of the substance, the conditions of use, and the basis of the determination.⁶⁴ A “no questions” response from FDA does not mean that the FDA has approved the substance; as noted, in the GRAS process the FDA relies on the determination made by the company submitting the substance for approval.

In the US, companies have already taken advantage of the GRAS pathway to get their vegetarian food products, which contain new food ingredients, to market quickly. For example, the FDA examined extensive test data about the Impossible Burger’s key ingredient, a protein called “soy leghaemoglobin,” before affirming its GRAS status.⁶⁵ Approval for this protein was key to its success because it carries heme and makes the vegetarian patty “bleed” like real meat.⁶⁶

Alternatively, a substance can be classified as GRAS if it has been used in food before 1958 and has been commonly ingested by a significant number of consumers; however, this route is rarely utilized today.⁶⁷

F How Novel Foods Are Regulated in Other Jurisdictions

Governments make different choices on how to design, enact, and enforce novel food regulation within their borders. In Australia and New Zealand, the establishment of a new, joint regulatory body has led to the creation of a new set of food standards that apply in both countries. In Brazil, the country’s own regulation exists alongside concurrent regulation across almost all of South America, through Mercosur, the South American Common Market. Novel foods are specifically defined and regulated in several countries including Australia/New Zealand, Brazil, Canada, and China; we look at each of these in turn.

Australia/New Zealand

By agreement in July 1996, Australia and New Zealand authorized the bilateral agency “Food Standards Australia New Zealand” (FSANZ) to establish and maintain food standards that apply in both countries.⁶⁸ The two countries have also harmonized labelling and compositional standards under the Australia New Zealand Food Standard Code (the Code).⁶⁹ Within Australia, enforcing compliance with the Code with respect to all foods is the responsibil-

<https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm2006851.htm> (accessed 28 March 2020).

⁶⁴ Damewood, *supra* note 60.

⁶⁵ Business Wire (2018). Impossible Foods Receives No-Questions Letter From US Food and Drug Administration. <https://www.businesswire.com/news/home/20180723005786/en/Impossible-Foods-Receives-No-Questions-Letter-Food-Drug> (accessed 28 March 2020).

⁶⁶ *Id.*

⁶⁷ Damewood, *supra* note 60. *See also* 21 C.F.R. s 170.30(c), 170.3(f).

⁶⁸ Magnuson, et al., *supra* note 7, at 1150.

⁶⁹ *Id.*

ity of State/Territory Health Departments,⁷⁰ while for imported foods, enforcement is the responsibility of the Australian Quarantine Inspection Service.⁷¹

The Code regulates all aspects of food including labelling, food additives, processing aids, nutritive substances, contaminants, approval of new foods (novel foods, genetically modified foods, and irradiated foods), and composition of standardized and special purpose foods, among others.⁷² Other standards that are not part of the joint food standards setting system cover food safety, agricultural compounds, veterinary medicines, and primary food production and processing.⁷³

Food ingredients are not defined under the Australia New Zealand food regulations;⁷⁴ ingredients are generally considered to be either foods or substances added to food.⁷⁵ FSANZ defines a novel food as a non-traditional food with no history of safe use where the food requires an assessment of the public health and safety considerations with regard to:

1. the potential for adverse effects on humans;
2. the composition or structure of the food;
3. the process by which the food has been prepared;
4. the source from which it is derived;
5. patterns and levels of consumption of the food; or
6. any other relevant matters.⁷⁶

Non-traditional food is defined as:

1. a food that does not have a history of human consumption in Australia/New Zealand;
2. a substance derived from a food where that substance does not have a history of human consumption in Australia/New Zealand other than as a component of that food;
3. any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia/New Zealand.⁷⁷

⁷⁰ *Id.* at 1155.

⁷¹ *Id.*

⁷² *Id.* See also FSANZ 2011, <http://www.foodstandards.gov.au> (accessed 28 March 2020).

⁷³ Magnuson, et al., *supra* note 7, at 1150.

⁷⁴ *Id.* at 1156.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

An application to vary the Code is required to approve the use of a nutritive substance or to change the permissions for a currently used nutritive substance.⁷⁸

Brazil

The main authority within Brazil for food regulation and safety assessment is the Ministry of Health (Ministério da Saude) through its autonomous regulatory agency, Agencia Nacional de Vigilancia Sanitária (ANVISA – National Agency of Sanitary Surveillance).⁷⁹ ANVISA's function is to evaluate the safety of use of food additives and ingredients in foods. Specific working groups within ANVISA work on the approval of novel foods and novel food ingredients with functional health claims.⁸⁰ Novel foods and ingredients require a pre-market approval by ANVISA:⁸¹ pre-market approvals are valid for five years from the date of their publication in the Brazilian Official Gazette and may be renewed.⁸²

The following foods must be registered in the category of novel food, even if they do not bear functional and/or health claims:⁸³

1. foods with no history of use in the country;
2. foods containing novel ingredients;
3. foods containing substances already consumed that may be added or used at levels much higher than those currently observed in the foods that constitute part of a regular diet; and
4. food offered in the form of capsules, pills, tablets, and the like.

Brazil is a member of the Southern Common Market, Mercosur, whose other members are Argentina, Paraguay, Uruguay, and Venezuela. Like the other member countries,⁸⁴ Brazil is gradually replacing many of its food standards with official Mercosur standards as they are developed. Mercosur standards are influenced by the EU, the Codex Alimentarius, and the FDA.⁸⁵ Mercosur does not have a definition of novel foods, although such foods are recognized in practice.⁸⁶

Canada

⁷⁸ *Id.* at 1157.

⁷⁹ For more information, see Ministry of Health, www.saude.gov.br (accessed 28 March 2020); see also National Agency of Sanitary Surveillance website, portal.anvisa.gov.br (accessed 28 March 2020).

⁸⁰ Magnuson, et al., *supra* note 7, at 1161.

⁸¹ See Annex II of Resolution RDC 240/2018. See also <http://portal.anvisa.gov.br/en/food> (accessed 28 March 2020).

⁸² *Id.*

⁸³ Magnuson, et al., *supra* note 7, at 1161.

⁸⁴ *Id.* at 1192.

⁸⁵ *Id.* at 1161.

⁸⁶ *Id.* at 1152.

In Canada, the Health Canada Food Directorate is responsible for establishing policies, setting standards, and providing advice and information on the safety and nutritional value of food.⁸⁷ It is also responsible for promoting the nutritional health and well-being of Canadians by defining, promoting, and implementing evidence-based nutrition policies and standards.⁸⁸ In addition, it administers the provisions of the Food and Drugs Act (1920) that relate to public health, safety, and nutrition.⁸⁹ The Canadian Food Inspection Agency is responsible for enforcing the food safety and nutritional quality standards established by Health Canada.⁹⁰

Health Canada defines a novel food as:

1. a substance, including a microorganism, that does not have a history of safe use as a food;
2. a food that has been manufactured, prepared, preserved, or packaged by a process that has not been previously applied to that food and causes the food to undergo a major change; and
3. a food that is derived from a plant, animal, or microorganism that has been genetically modified.⁹¹

Pre-market application is required for a new substance, for an extension of the use of a permitted food additive, for permission to change the maximum level of a permitted food additive, or for authorization to add a new organism to the list of permitted sources of enzymes used as a food additive.⁹²

China

In China, the Ministry of Health (MOH) is responsible for drafting health laws, regulations, policies, and standards.⁹³ It also supervises enforcement of these standards, unlike many other countries that assign enforcement authority to a different entity.⁹⁴

Novel foods are referred to as new resource foods, which are defined as raw food materials or food ingredients that do not have a significant history of consumption in the country.⁹⁵ Chinese legislation under the MOH defines a

⁸⁷ *Id.* at 1164; *see also* Government of Canada (2019). Food and Nutrition <https://www.canada.ca/en/health-canada/services/food-nutrition.html> (accessed 28 March 2020).

⁸⁸ Magnuson, et al., *supra* note 7, at 1164.

⁸⁹ *Id.*

⁹⁰ *Id.*; *see also* Government of Canada, Canadian Food Inspection Agency (2018). About the CFIA. <http://www.inspection.gc.ca/about-the-cfia/eng/1299008020759/1299008778654> (accessed 28 March 2020).

⁹¹ Magnuson, et al., *supra* note 7, at 1199.

⁹² *Id.* at 1198.

⁹³ *Id.* at 1170.

⁹⁴ *Id.*

⁹⁵ *Id.* at 1199.

new food additive as an additive that is not included in the national food safety standards, not included in the public announcement of permitted use issued by the MOH, and whose scope of use or dosage is increased.⁹⁶ Pre-market application is required for new food additives.⁹⁷

IV SPECIFIC REGULATORY ISSUES

A *Regulatory Issues Connected to Food Formulation*

A food that results from a process not used for food production in the EU before May 15, 1997 but that gives rise to significant changes in the composition or structure of a food (affecting its nutritional value, metabolism, or level of undesirable substances) is considered a “novel food” under the NFR. The same applies if vitamins, minerals, and other substances are used in the production process and the process was not used for food production within the EU before May 15, 1997.

As discussed in the next section, more specific regulations apply if the novel food is being prepared for specifically defined vulnerable groups such as infants. In such circumstances, the rules of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control apply in addition to the rules of the NFR.⁹⁸

In the US, federal agencies regulate food produced through unconventional methods within existing legal frameworks. Accordingly, the FDA focuses on the characteristics of the food product rather than the method by which the food is produced or developed.⁹⁹ It justifies this approach by reference to the agency’s dual purpose: protecting the public’s health by assuring the safety of food that enters the US market, while also fostering innovation and technological advances in the food sector.¹⁰⁰

⁹⁶ *Id.* at 1198.

⁹⁷ *Id.* at 1199.

⁹⁸ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 Text with EEA relevance, OJ L 181, 29.6.2013, pp. 35-56.

⁹⁹ FDA (1992). Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm> (accessed 28 March 2020).

¹⁰⁰ FDA (2018). What Does FDA Do? <https://www.fda.gov/about-fda/fda-basics/what-does-fda-do> (accessed 28 March 2020); FDA (2018). Press Release, Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner Anna Abram on emerging food innovation, “cultured” food products. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610869.htm> (accessed 28 March 2020).

Anticipating a boom in the application of the genomic editing technology called clustered regularly interspaced short palindromic repeats, also known as CRISPR-cas9 (CRISPR), the FDA released a draft guidance document in 2017. In it, the FDA proposes to expand the definition of “new animal drug” to include animals altered or developed through genome editing and genetic engineering (GE) technologies.¹⁰¹ The agency justifies the expansion on the basis that altering an animal’s genome to affect its bodily structure or function or to cure, treat, or prevent disease in the animal falls within the FDCA’s definition of drug.¹⁰² In addition to CRISPR, the guidance document also identifies rDNA as a new animal drug, even though rDNA has been widely used in plants to create GMOs. The Guidance Document clarifies that the genetically modified animal is not a drug, but rather the genome editing technology is a new animal drug (NAD).¹⁰³ Similar to food additives, NADs are subject to an expensive and time-consuming pre-market review process.¹⁰⁴ The FDA anticipates releasing a final guidance document by the end of 2020.¹⁰⁵

B Regulatory Issues Connected to Food Formulation for Special Populations

In the EU, Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (Food for Specific Groups (FSG))¹⁰⁶ stipulates a special regime for formulation of food for specific populations. According to FSG Recital 23, the rules in the FSG complement the rules of the NFR in the sense that no novel food shall be added to food covered by the FSG unless such substances fulfil the FSG’s conditions for being placed on the market.

¹⁰¹ Regulation of Intentionally Altered Genomic DNA in Animals: Notice of Availability of Draft Guidance for Industry #187 (“Notice of Availability: GFI #187”), 82 Fed. Reg. 6561, 6563 (Jan. 19, 2017).

¹⁰² *Id.*; 21 U.S.C. s 321(g).

¹⁰³ FDA (2017). Q&A on FDA Regulation of Intentionally Altered Genomic DNA in Animals. <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/qa-fda-regulation-intentionally-altered-genomic-dna-animals> (accessed 28 March 2020).

¹⁰⁴ FDA (2019). New Animal Drug Applications. <https://www.fda.gov/animal-veterinary/development-approval-process/new-animal-drug-applications> (accessed 28 March 2020).

¹⁰⁵ FDA (2019). Guidances Under Development for 2019. <https://wayback.archive-it.org/7993/20190422162610/https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucmo42451.htm> (accessed 28 March 2020).

¹⁰⁶ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 Text with EEA relevance, OJ L 181, 29.6.2013, pp. 35–56.

Where a food promises health benefits or nutritional benefits and the food business operator makes use of these benefits in its marketing communication, the EU's special regime of health claims applies. In this regard, Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (NHCR)¹⁰⁷ introduces EU-wide quality requirements, which apply in addition to the novel foods regime. According to the NHCR, health and nutrition claims concerning foods need to be based on scientific evidence¹⁰⁸ and not be "false, ambiguous or misleading."¹⁰⁹ In addition, the NHCR introduces an authorization procedure for health claims.¹¹⁰ Certain uses of health claims are also prohibited without exception, such as those that "make reference to the rate or amount of weight loss."¹¹¹ The EU Register of Nutrition and Health Claims lists all permitted nutrition claims and all authorized and non-authorized health claims.

C Regulatory Issues Connected to Genetically Modified Food

In the EU, genetically modified foods are not subject to the novel foods regime.¹¹² Rather, a special regulatory regime requires authorization and traceability of GMOs before they are released into the environment, introduced into the market, or used in food for human beings or animal feed.¹¹³ Furthermore, EU law foresees certain liability requirements for damage caused by GMOs.¹¹⁴

In addition, specific labelling requirements exist for (authorized) GMOs. Regulation (EC) No 1829/2003 (GMO Labelling Regulation) concerns labelling of foods which contain or consist of GMOs or are produced from or contain ingredients produced from GMOs.¹¹⁵ Article 13(1)(a) of this Regulation introduces an EU-wide labelling requirement, according to which each food containing or produced from GMOs must bear a label with mandatory information attached to it, indicating that the food or the respective ingredient contains GMOs. Article 12(2), however, exempts all "foods containing material which

¹⁰⁷ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9), last amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012 L 31036 9.11.2012 [hereinafter NHCR].

¹⁰⁸ *Id.* Art. 6 I.

¹⁰⁹ *Id.* Art. 3(a).

¹¹⁰ *Id.* Art. 10.

¹¹¹ *Id.* Art. 12(b).

¹¹² NFR Art. 2(2)(a).

¹¹³ See Purnhagen, K. (2019). How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in Confederation paysanne and Others, *Common Mkt. L. Rev.* 56 (5): 1379-1396.

¹¹⁴ Article 18(3)(b) Directive 2004/35/EC on Environmental liability with regard to the prevention and remedying of environmental damage, OJ 2004, L 143/56.

¹¹⁵ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance), OJ L 268, 18.10.2003, pp. 1-23.

contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.”¹¹⁶ It is also important to note that GMOs obtained by mutagenesis are not considered to be part of the special GMO regulation in the EU, with the exception of techniques developed after 2001 such as CRISPR.¹¹⁷

In the US during the 1970s and 80s, there was increased application of innovative biotechnology in formulation of food products, specifically GMOs. The White House investigated how to regulate biotechnology products and who should be responsible for the review of their safety and for enforcement.¹¹⁸ After 18 months of public comments, the White House finalized a federal policy entitled the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) in 1986.¹¹⁹ The Coordinated Framework outlines three basic regulatory principles.¹²⁰ First, agencies should focus on the end products, not the process used to create GE¹²¹ food.¹²² Second, GMOs are low risk and no more dangerous or risky than traditionally produced food.¹²³ Third, existing federal statutes are sufficient to ensure that GMOs and their by-products meet the same safety standards as their conventional counterparts; thus, GMOs do not require pre-market approval.¹²⁴ The Coordinated Framework tasks the Environmental Protection Agency, United States Department of Agriculture, and the FDA with enforcing biotechnology regulations according to the three principles just listed.¹²⁵ Under the Coordinated Framework, human and animal

¹¹⁶ NFR Art. 12(2).

¹¹⁷ See Purnhagen, K., Kok, E., Kleter, G. et al. (2018). EU Court casts new plant breeding techniques into regulatory limbo. *Nature Biotechnology* 36 (9): 799-800.

¹¹⁸ The National Academies of Science, Engineering, and Medicine et al. (2017). *Preparing for Future Products of Biotechnology*. National Academies Press. <https://www.ncbi.nlm.nih.gov/books/NBK442204/> (accessed 28 March 2020).

¹¹⁹ *Id.*

¹²⁰ Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986) [hereinafter Coordinated Framework].

¹²¹ Organisms modified through recombinant DNA (rDNA) technology are known as genetically modified (GM), genetically modified organism (GMO), or GE, but the FDA prefers referencing the rDNA technology as “genetic engineering.” FDA (2018). Questions & Answers on Food from Genetically Engineered Plants. <https://wayback.archive-it.org/7993/20180908125544/https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/cm346030.htm> (accessed 28 March 2020).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ Marden, E. (2003). Risk and Regulation: US Regulatory Policy on Genetically Modified Food and Agriculture. *Boston College Law Review* 44: 734, 747; Coordinated Framework, *supra* note 120.

¹²⁵ Marden, *supra* note 124, at 739.

food derived from GE plants is held to the same food safety and labelling standards as all FDA-regulated food.¹²⁶

The White House issued two updates to the Coordinated Framework, in 1992 and 2017. Both continued to emphasize a “product-focused, not process-focused” regulatory approach to GMOs.¹²⁷ Accordingly, the Coordinated Framework continues to provide that GMOs should not be subject to excessive oversight compared to their non-modified counterparts, unless the risk posed by the GE product is unreasonable: this occurs when the amount of risk reduced by regulatory oversight exceeds the cost of regulation.¹²⁸

As set out in the Coordinated Framework, GE plants are regulated under the relevant agency’s existing framework, but additional regulatory programs have been enacted to ensure GE food safety.¹²⁹ For example, while the FDA operates under the assumption that GE plants are not materially different from their conventional counterparts, the agency established a voluntary pre-market Plant Biotechnology Consultation Program. To date, all GE plant developers have voluntarily participated in the Consultation Program and waited for final FDA approval before selling their products.¹³⁰ The FDA evaluates factors such as whether the GE plant is as nutritious as its conventional counterpart and whether the genetic alteration may contain a new toxin or allergen.¹³¹ After reviewing the sponsor’s data, the agency issues a letter of its findings to the developer and publishes the consultation package online for the public.¹³² As noted earlier, the FDA does not impose special GE labelling requirements.¹³³ The FDA treats GE products as GRAS, but GE developers must demonstrate

¹²⁶ FDA (2018). How FDA Regulates Food from Genetically Engineered Plants. <https://www.fda.gov/food/food-new-plant-varieties/how-fda-regulates-food-genetically-engineered-plants> (accessed 28 March 2020).

¹²⁷ Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992) [hereinafter 1992 Coordinated Framework Update]; Executive Office of the President (2017). Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf [hereinafter 2017 Coordinated Framework Update] (accessed 28 March 2020).

¹²⁸ 1992 Coordinated Framework Update, *supra* note 127.

¹²⁹ Coordinated Framework, *supra* note 120.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ FDA (2018). Labeling of Foods Derived From Genetically Engineered Plants. <https://wayback.archive-it.org/7993/20190917033156/https://www.fda.gov/food/food-new-plant-varieties/labeling-foods-derived-genetically-engineered-plants> (accessed 28 March 2020).

that the modified crops are substantially equivalent to their non-modified version and are safe before placing them in interstate commerce.¹³⁴

D Regulatory Issues Connected to Food Containing Nanomaterials

In the EU, foods containing engineered nanomaterials are considered “novel foods.”¹³⁵ “[E]ngineered nanomaterial” means any intentionally produced material that has one or more dimensions of the order of 100 [nanometers] (nm) or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

(i) those related to the large specific surface area of the materials considered; and/or

(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.”¹³⁶

If a food contains such nanomaterials, the entire legal regime of the NFR applies.

Nanomaterials, or “nanoparticles” are already present in many foods, both natural and processed. Some nanoparticles are specifically designed for incorporation into foods as a delivery system.¹³⁷ In the US, engineered nanomaterials are considered food additives and must go through the FAP pre-market approval process before entering the market. The FDA declared as policy in its guidance document that food ingredients created through nanotechnology and foods containing engineered nanomaterials are not eligible for GRAS status, although this guidance is not binding.¹³⁸

E Regulatory Issues Connected to 3D Printed Food Products

3D printing in the area of foods is still at an early stage. Potential applications include the production of food with special nutritional and dietary needs (for example for people suffering from illnesses) or substitution of food materials. In the EU there is no specific legal framework for the application of 3D printing

¹³⁴ Consumer Reports (2001). Comment Letter from Consumers Union to FDA Regarding Docket No 00N-1396, Premarket Notice Concerning Bioengineered Foods. https://advocacy.consumerreports.org/press_release/cus-comments-on-premarket-notice-concerning-bioengineered-foods/ (accessed 28 March 2020).

¹³⁵ NFR Art. 3(2)(a)(viii).

¹³⁶ *Id.* Art. 3(2)(f).

¹³⁷ Takhistova, K. (2009). Note, Food Nanotechnology – In Search of a Regulatory Framework. *Rutgers Computer & Technology Law Journal* 35: 261.

¹³⁸ Use of Nanomaterials in Food for Animals: Guidance for Industry #220, 80 Fed. Reg. 46587 (August 5, 2015).

techniques for foods. Therefore, in the absence of specific legislation, the applicable regulatory framework will depend on the product. It is unlikely that 3D foods will mimic foods which have been in circulation in the EU before May 15, 1997 and alter some of their structure, and so they are likely to fall under the regulatory scrutiny of the NFR. And if the additional prerequisites of the NFR are met, i.e. the 3D printing is conducted such that it falls within the NFR's initial list,¹³⁹ most of these 3D foods would qualify as "novel" and hence require authorization in the EU. If, as expected, they are designed for specific groups, the rules of the FSG would also apply, as described above. Here, a regulatory obstacle with 3D printing is very likely to arise under FSG Article 4(2), which only allows such personalized foods to be sold prepacked in retail markets.

Although the US FDA has released a final guidance document for industry on 3D-printed medical devices, there is no similar policy in place for 3D printed food.¹⁴⁰ The two main outstanding questions regarding 3D-printed food are whether it should be considered "imitation" food and be labelled as such, and whether 3D-printed foods will lead to economic adulteration or "food fraud."¹⁴¹ An example would be the sale of 3D-printed food without proper labelling.¹⁴²

F Regulatory Issues Connected to Food Made from Insects

In the EU, foods made from insects are generally defined as novel foods. According to NFR Recital 8, if insects or their parts are used as food, they are also considered novel: this was subject to debate before the NFR came into force. Since the term "insects" has not been defined in the NFR, it is unclear how it might apply. Some possible questions are whether it would cover only the insects themselves, or also processed insects or their products. Since insect food is a business of particular interest for start-ups, the compliance risks with the NFR can serve as a barrier to innovation for these companies.

In the US, there is no official FDA regulation or guidance document that prohibits or approves using insects as human food,¹⁴³ and novelty foods such as chocolate-covered ants have been on the market for years. The FDCA forbids the adulteration of food in interstate commerce, with adulteration defined as containing "*filthy* . . . substances, or if it is otherwise unfit for food."¹⁴⁴ Courts have affirmed the FDA's interpretation of "filthy" to include the *unintentional* addition of insects and insect parts,¹⁴⁵ but this would not apply to

¹³⁹ See *supra* text at n. 31.

¹⁴⁰ See Technical Considerations for Additive Manufactured Medical Devices, Final Guidance for Industry, 82 Fed. Reg. 57462 (Dec. 5, 2017).

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ Boyd, M. (2017). Cricket Soup: A Critical Examination of the Regulation of Insects as Food. *Yale Law & Policy Review* 36: 66.

¹⁴⁴ 21 U.S.C. s 342 (emphasis added).

¹⁴⁵ Boyd, *supra* note 143, at 40-41.

insects *intentionally* added to food. Recognizing the unavoidable presence of insects in certain food products, the FDA permits a certain amount of negligible insects in a food before it is deemed adulterated.¹⁴⁶ Again, where insects are the main feature of the food and are in more than negligible quantities, it is unlikely that the FDCA's prohibitions would apply.

To date, the FDA has given little attention to insects as an intentional component of food.¹⁴⁷ Many American consumers have a generally negative view of consuming insects, but there are a growing number of companies seeking to promote insects as an alternative form of protein.¹⁴⁸ Until specific guidelines appear regarding the use of insects, companies may find it risky to invest in this type of food.¹⁴⁹ It is also worth noting that companies that seek to sell insect-based human food in the interstate market will likely need to go through the pre-market food additive approval process.¹⁵⁰

G Other Legal Issues

To this point, this chapter has addressed and discussed regulation of novel foods – but only regulation in the sense of regulatory approval. Other regulatory (in the sense of legal and legislative) issues are implicated with respect to novel foods. For this reason, the remainder of this chapter turns more broadly to the constellation of other legal issues implicated by novel foods. In particular, we examine how producers of novel foods may run afoul of legal requirements in different regulatory areas.

1 Intellectual Property Law

We saw in earlier chapters that scientists have become ever more creative in devising new food ingredients and processes. The question is at what point an inventor would seek intellectual property protection for a novel food.

Note first that “novelty” for the purposes of patent law generally concerns prior art (e.g., whether the claimed invention has already been patented, described, in public use, on sale, or otherwise available to the public) rather than a history of consumption, which is key to the definition of novel foods.¹⁵¹ Another feature of intellectual property law is that novelty alone does not make a product patentable. There is also a requirement of non-obviousness of the purported invention.¹⁵² This means that a claimed invention is only patentable

¹⁴⁶ *Id.* at 43; 21 C.F.R. s 110.110(a).

¹⁴⁷ Boyd, *supra* note 143, at 20.

¹⁴⁸ *Id.* at 21.

¹⁴⁹ *Id.* at 37.

¹⁵⁰ *Id.* at 44-45 (discussing a federal case in which the FDA sought to enforce its regulation of intentionally added insects to animal-feed grain as a food additive).

¹⁵¹ *See, e.g.*, 35 U.S.C. s 102 (US statute setting out rules for patentability).

¹⁵² Legal Information Institute. 35 U.S.C. §103; Conditions for patentability; non-obvious subject matter. <https://www.law.cornell.edu/uscode/text/35/103> (accessed 28 March 2020).

if, prior to the effective filing date, it would not have been obvious to a person having ordinary skill in the art to which the claimed invention pertains.¹⁵³ In terms of novel foods, this could mean that a food that merely substitutes one ingredient for another might not be considered patentable due to obviousness.

Alternatively, companies may seek to protect their investment by applying for patents on the technology that makes the novel food product possible. For example, as mentioned earlier, the US Patent Office has granted patents to the company Impossible Foods, Inc. for its technology which uses the key ingredient, soy leghaemoglobin, to make its plant-based Impossible Burger bleed like real meat.¹⁵⁴

In the US and in the EU, the issues of intellectual property rights and GMOs are deeply intertwined. As members of the WTO, countries must comply with Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 27, “Patentable Subject Matter.” TRIPS provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology,” although member countries may exempt plants and animals from patentability.¹⁵⁵ Both the US and the EU have afforded patent protection for genetically modified plants and animals.¹⁵⁶ For example, in *Diamond v. Chakrabarty*, the US Supreme Court held that “anything under the sun made by man,” such as genetically engineered microorganisms, are patentable subject matters.¹⁵⁷

2 Tort Law

Legal issues can also arise in the tort area. The seller of an unregulated food found harmful to consumers could be subject to a wide variety of potential litigation. In the EU, liability under tort law varies widely, as national tort law systems are generally not harmonized. One exception is the area of product liability, which according to Article 21 of the GFL also applies to foodstuffs. A comparable liability regime applies in the US, where a claim can be made under tortious product liability if the seller of a substance is found to have sold a product that caused the plaintiff injury due to its defective or unsafe nature.¹⁵⁸ In such a case, the seller could be liable for damages.

In addition, where a harm results from a substance which misleads the consumer, a cause of action might potentially be filed under the contract and consumer law-based principle of an implied warranty of fitness for a partic-

¹⁵³ See, e.g., 35 U.S.C. s 103 (US statute setting out the rules for non-obviousness).

¹⁵⁴ US Patent # 9,700,067, Justia <https://patents.justia.com/patent/9700067> (accessed 28 March 2020).

¹⁵⁵ Torrance, A. (2007). Intellectual Property as the Third Dimension of GMO Regulation, *Genetically Modified Organisms: Philosophy, Science, and Policy Symposium, Kansas Journal of Law & Public Policy* (16): 279.

¹⁵⁶ *Id.* at 280.

¹⁵⁷ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

¹⁵⁸ Legal Information Institute. Products Liability. https://www.law.cornell.edu/wex/products_liability (accessed 28 March 2020).

ular purpose, which is outlined in § 2-315 of the Uniform Commercial Code (UCC).¹⁵⁹ Under this claim, where a seller has reason to know any particular purpose for which the goods being furnished are required, and the buyer justifiably relies upon the seller's knowledge, skill, or judgment to furnish goods suitable for a particular purpose, the seller may be held liable if the goods do not fulfil that purpose.

3 Marketing Law

In the EU, the Food Information Regulation (FIR)¹⁶⁰ covers most food marketing and outlines a number of fair information practices.¹⁶¹ The basic principles are that food information must be accurate, clear, and easy for consumers to understand. Specifically, food information must not be misleading:

- as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;
- by attributing to the food effects or properties which it does not possess;
- by suggesting that the food possesses special characteristics (when in fact all similar foods possess such characteristics), in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients;
- by suggesting, via the appearance, the description, or pictorial representations, the presence of a particular food or an ingredient when in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or ingredient.

Food information may not attribute to any food the property of preventing, treating, or curing a human disease, or refer to such properties. The prohibitions extend to advertising and the general presentation of foods, regarding their shape, appearance, or packaging; the packaging materials used;

¹⁵⁹ The Uniform Commercial Code (UCC) is not a federal law but rather a model commercial code for the states, governing commercial transactions to facilitate interstate commerce.

¹⁶⁰ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 Text with EEA relevance, OJ L 304, 22.11.2011, p. 18–63.

¹⁶¹ FIR Art. 7.

the way in which they are arranged; and the setting in which they are displayed. The FIR does not distinguish between foods and “novel foods,” and so all foods are treated the same, with no special requirements for marketing novel foods to consumers.

4 Criminal Law

Gene-editing technology, such as rDNA and CRISPR, holds great potential to revolutionize the food supply. Many laboratories are exploring the use of these technologies for the benefit of humankind, such as by formulating transgenic goat’s milk to combat juvenile diarrhoea in developing countries.¹⁶² However, just as food can be bioengineered to enhance or insert desirable characteristics, it could potentially be bioengineered for nefarious purposes. A bad actor could potentially target a nation’s food supply chain to inflict serious damage on thousands of people.

In the EU, comparable to tort law, criminal law is generally a matter for individual member states. Hence, it would depend on the specific national legal system whether an act or an omission relating to novel food would be subject to criminal charges.

In the US, FDCA Chapter III explicitly prohibits certain actions and outlines potential civil and criminal liability.¹⁶³ For example, it prohibits introducing adulterated or misbranded food into the market,¹⁶⁴ and corporate officers have been found guilty of knowingly introducing adulterated food into interstate commerce.¹⁶⁵ Since criminal liability attached even where those corporate officers did not intentionally set out to create contaminated products, it is clear that criminal liability would also apply in the case of an intentional act.

V CONCLUSION

This chapter discussed how novel foods are regulated within the EU, US, and elsewhere. We reviewed some of the reasons novel foods might be regulated and how such regulatory goals can be accomplished. Regulation of novel foods is the policy maker’s reaction to the unknown, although what is novel today

¹⁶² Cooper, C., Klobas, L., Maga, E. et al. (2013). Consuming Transgenic Goats’ Milk Containing the Antimicrobial Protein Lysozyme Helps Resolve Diarrhea in Young Pigs. 8 *PLoS ONE*. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0058409> (accessed 28 March 2020).

¹⁶³ 21 U.S.C. s 331 et seq.

¹⁶⁴ *Id.* s 331(a).

¹⁶⁵ Department of Justice (2015). Department of Justice, Former Peanut Company President Receives Largest Criminal Sentence in Food Safety Case; Two Others also Sentenced for Their Roles in Salmonella-Tainted Peanut Product Outbreak. <https://www.justice.gov/opa/pr/former-peanut-company-president-receives-largest-criminal-sentence-food-safety-case-two> (28 March 2020).

may not be novel tomorrow. Indeed, the novel food industry has grown immensely over the past decade due to the need to feed a growing world population while using less land, water, and other limited natural resources. Ultimately, policy makers have the difficult task of balancing adequate government oversight over novel foods without stifling innovation and creativity.