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Regulating Engineered Nanomaterials in Food: Challenges and Lessons for Australia

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ABSTRACT

The biological and environmental effects of engineered nanomaterials (ENMs) and their environmental impacts remain inadequately understood, posing significant challenges for regulators in an era of rapid advancement in nanotechnology. Currently,

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Australia lacks a comprehensive regulatory framework for ENMs in food products, and existing strategies—whether product-specific or precautionary—fall short of addressing the complexities involved. This Article critically examines the regulatory approaches taken by the United States, EU, and UK, revealing that their strategies often share similarities and complement one another. Building on this insight, this Article suggests that by implementing a meta-regulatory approach, Australia can harmonize risk mitigation, foster innovation, and ensure consistency in regulating foods containing ENMs. This approach is essential for protecting public health while promoting sustainable advancement in nanotechnology in Australia.

INTRODUCTION

Consumers and the environment are increasingly exposed to engineered nanomaterials (ENMs). Exposure can occur from various sources, including the growing use of ENMs in foods and consumer products like cosmetics. However, the biological effects of consuming ENMs and the effects of traces of ENMs in food or human waste on the environment are poorly understood.[1] Studies indicate that ENMs can be more chemically and physically reactive than their bulk counterparts due to chemical properties such as larger surface area and catalytic activity. These properties may lead to interference with organic metabolism, gene replication, or unexpected toxicity levels.[2] Nanomaterials possess the unique ability to infiltrate cells, where they can accumulate within the cytosol, potentially affecting cell viability and overall health.[3] Furthermore, nanomaterials can penetrate the cell's

1 *See generally* Helen Onyeaka et al., *The Safety of Nanomaterials in Food Production and Packaging*, 5 CURRENT RSCH. FOOD SCI. 763 (2022); Mićo Tatalović, *'I Wash All My Food Like Crazy': Scientists Voice Concern About Nanoparticles*, GUARDIAN, (May 29, 2019), https://www.theguardian.com/us-news/2019/may/29/i-wash-all-my-food-like-crazy-researchers-voice-concern-about-nanoparticles [https://perma.cc/6RJZ-3YJM].

2 Vijay Rani Rajpal et al., *The Nano-Paradox: Addressing Nanotoxicity for Sustainable Agriculture, Circular Economy and SDGs*, 23 J. NANOBIOTECHNOLOGY 1, 19–29 (2025); Xiaochuan Huang et al., *Trends, Risks and Opportunities in Environmental Nanotechnology*, 5 NATURE REVS. EARTH & ENV'T 572 (2024); *see generally* Victor Alcolea-Rodriguez et al., *A Refined Dose Metric for Nanotoxicology Based on Surface Site Reactivity for Oxidative Potential of Engineered Nanomaterials*, 10 NANOSCALE ADVANCES 2929 (2025).

3 Xin Wang et al., *Understanding of Endo/Lysosomal Escape of Nanomaterials in Biomedical Application*, 3 SMART MOLECULES, Feb. 2025 at 1, 2–3; Ana Olívia de Souza, *Overview of Nanomaterials and Cellular Interactions*, 13 BIOINTERFACE RSCH. APPLIED CHEMISTRY 367, at 4–6 (2022).

nucleus, leading to issues such as DNA damage, breaks, or mutations.[4] Such alterations in the genetic material can disrupt normal cellular functions and may ultimately contribute to the development of cancer.[5]

With the increase in research on nanotechnology and the impact of engineered nanoparticles in food, regulators are becoming more concerned about the approach they should take to ensure the safe use of nanotechnology and its progress. However, as in any new technology-oriented industry, regulators are in a dilemma in terms of devising regulatory approaches for safe use of nanotechnology. While regulators need effective tools to govern a technology before the risks attached to the technology become too established, they often lack the necessary information to develop suitable regulatory measures early in any novel technology's development.[6] As a result, there is a lack of sufficiently comprehensive oversight of emerging biotechnologies, especially synthetic biology.[7] Countries that produce ENMs use various regulatory approaches including incremental, product-specific, proactive, and precautionary approaches.[8] However, none of these

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4 Miguel Encinas-Gimenez, Pilar Martin-Duque & Ana Martín-Pardillos, *Cellular Alterations Due to Direct and Indirect Interaction of Nanomaterials with Nucleic Acids*, 25 INT'L J. MOLECULAR SCI., Feb. 2024, at 1; James C.L. Chow, *Biophysical Insights into Nanomaterial-Induced DNA Damage: Mechanisms, Challenges, and Future Directions*, 11 AIMS BIOPHYSICS 340, 340–69 (2024); Ritesh K. Shukla et al., *Genotoxic Potential of Nanoparticles: Structural and Functional Modifications in DNA*, 12 FRONTIERS GENETICS, Sep. 2021, at 1, 7.

5 Elijah J. Petersen & Bryant C. Nelson, *Mechanisms and Measurements of Nanomaterial-Induced Oxidative Damage to DNA*, 398 ANALYTICAL & BIOANALYTICAL CHEMISTRY 613, 616–18 (2010); Encinas-Gimenez, Martin-Duque & Martín-Pardillos, *supra* note 4, at 4–6.

6 *Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009*, at 8–10, COM final (June 7, 2005).

7 James W. Wagner, Vice Chair, Presidential Comm'n for the Study of Bioethical Issues, Presentation to the President's Council of Advisors on Sci. & Tech. (January 7, 2010), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-wagner-1-7-2011.pdf [https://perma.cc/E33J-USA6]. *See Regulatory Frameworks for Nanotechnology in Foods and Medical Products*, OECD, 3–6 (Apr. 24, 2013) (presenting an idea of a comprehensive regulatory framework for managing the negative effects of nano technology-based products); Rakesh Kumar Gupta, Proshanta Guha & Prem Prakash Srivastav, *Investigating the Toxicological Effects of Nanomaterials in Food Packaging Associated with Human Health and the Environment*, 5 J. HAZARDOUS MATERIALS LETTERS 1, 2–4 (2024).

8 David B. Resnik, *How Should Engineered Nanomaterials Be Regulated for Public and Environmental Health?*, 21 AMA J. ETHICS 363, 363–69 (2019); *Global Regulations - Nanotechnology*, NANOTECHNOLOGY, https://nanotechnology.blog/about/index/global-regulations (last visited Mar. 25, 2026) [https://perma.cc/6U7D-JQTY]; *Regulation of*

approaches have been proven to be entirely effective. Each approach has drawbacks that prevent it from being a sustainable method for regulating ENMs in foods.

An incremental approach to regulation means that a country uses an existing regulatory framework and adjusts only as necessary to regulate new technology.[9] The European Union has adopted this approach to regulate the nanotechnology-based industry. The success of this approach depends on the alignment between the nature of the technology and the existing regulatory framework. However, the main drawback is that existing regulations often cannot keep pace with new technology due to a lack of necessary data, suitable measurement tools, and sufficient information on toxicological effects.[10] This approach to regulation also does not encourage stakeholders to address unforeseen negative effects proactively. It allows regulated entities to focus more on their returns and ignore the long-term societal impacts of their products since they do not face effective pressure from regulators or society. Nonlegal factors are essential in such regulation.[11] However, due to the lack of information on the exposure and risks of ENMs, nonlegal factors, such as the media and civil society groups, lack the expertise to respond effectively to regulations and industry performance.[12]

The concept of a product-specific regulatory approach involves creating regulatory tools that can effectively address the specific nature

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Nanotechnology Materials and Products, UNDERSTANDINGNANO, https://www.understandingnano.com/nanotechnology-regulation.html (last visited Mar. 25, 2026) [https://perma.cc/RLS8-LT8C].

9 Elisabeth Vogelezang-Stoute, *Regulating Uncertain Risks of New Technologies: Nanomaterials as a Challenge for the Regulator*, *in* EU ENVIRONMENTAL LEGISLATION: LEGAL PERSPECTIVES ON REGULATORY STRATEGIES 211, 216 (Marjan Peeters & Rosa Uylenburg eds., 2014). For details of this approach, see Health & Consumer Protection Directorate General Eur. Comm'n, *Nanotechnologies: A Preliminary Risk Analysis on the Basis of a Workshop Organized in Brussels on 1–2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission*, at 22 (May 22, 2015).

10 Maria B. Nielsen et al., *Nanomaterials in the European Chemicals Legislation – Methodological Challenges for Registration and Environmental Safety Assessment*, 8 ENV'T SCI.: NANO 731, 735–38 (2021); JOINT RSCH. CTR., SAFETY ISSUES AND REGULATORY CHALLENGES OF NANOMATERIALS, 1, 6–9 (Juan Riego Sintes et al. eds., 2012), https://publications.jrc.ec.europa.eu/repository/bitstream/JRC76862/lbna25673enn.pdf [https://perma.cc/3V5Q-A39R].

11 MARIA LEE, EU REGULATION OF GMOS: LAW AND DECISION MAKING FOR A NEW TECHNOLOGY 11–15 (2009).

12 Irina Guseva Canu et al., *Methodological, Political and Legal Issues in the Assessment of the Effects of Nanotechnology on Human Health*, 72 J. EPIDEMIOLOGY & CMTY. HEALTH 148, 150–52 (2018); Rajpal et al., *supra* note 2, at 25; Huang et al., *supra* note 2, at 18–30, 27–29.

of a product. This approach can be costly for countries that frequently develop and test new technologies. It may be suitable for very new industries, but not for industries with many diverse products. According to this approach, each product must undergo a risk assessment. Assessing the safety of ENMs in the food processing industry has been challenging due to the large quantity of nanoparticles the industry uses. Producers can modify nanoparticles differently and combine the distinct characteristics of bulk chemicals at the nanoscale, further complicating the assessment process.[13] In the EU, conducting a substance-by-substance risk assessment of bulk chemicals with nanoparticles was nearly impossible.[14] As a result of initiatives from the European Parliament, some industries that use nanomaterials in their products have been subjected to regulations. For example, cosmetics companies in the EU must comply with the provisions of the Cosmetics Regulation,[15] which is specifically designed to address the potential hazards of nanoparticle-based cosmetics to human health. However, the outcomes of the European Parliament initiative are unpredictable and vary based on the size and strength of the specific product industry. Today, there are only two nano-specific regulations in the EU: the Cosmetics Regulation and the Biocide Regulation.[16]

The proactive approach to regulating ENMs presents technical and political challenges. Currently, there are no techniques to effectively monitor the release of ENMs into the air, water, and soil.[17] Regulating

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13 Suman Das & Iqtiar Md Siddique, *Navigating the Nanoscale: Challenges and Opportunities in Nanomaterial Science*, 11 EUR. J. ADVANCES ENG'G & TECH. 32, 35–37 (2024); Furkan Eker et al., *A Comprehensive Review of Nanoparticles: From Classification to Application*, 29 MOLECULES 3482, 3485–88 (2024).

14 Virginia Rodriguez Unamuno, Eur. Chems. Agency, Nanomaterials Risk Assessment – A Regulatory Framework, Presentation at SETAC Europe Annual Meeting (2025), https://echa.europa.eu/documents/10162/28801697/nanomaterials_risk_assessment.pdf (on file with the Oregon Review of International Law); Kathrin Schwirn et al., *Environmental Risk Assessment of Nanomaterials in the Light of New Obligations Under the REACH Regulation: Which Challenges Remain and How to Approach Them?*, 16 INTEGRATED ENV'T ASSESSMENT & MGMT. 706, 706–17 (2020).

15 *See* Commission Regulation 1223/2009 of Nov. 30, 2009, Cosmetic Products, 2009 O.J. (L 342) 59, art 16 (replaces Cosmetics Directive 76/768/EC).

16 *See generally* Regulation 528/2012 of May 2012, Concerning the Making Available on the Market and Use of Biocidal Products, 2012 O.J. (L 167) (EU) (relating the Biocides Regulation, which has been operative since 2013 and still awaits a thorough evaluation of its performance in practice, to the production and marketing of the biocidal products with nano particles).

17 Racliffe W.S. Lai et al., *Regulation of Engineered Nanomaterials: Current Challenges, Insights and Future Directions*, 25 ENV'T SCI. & POLLUTION RSCH. 3060,

ENMs in food involves addressing various problems throughout the nanoparticles' life cycle. This requires changing definitions, processes, and guidelines for nanoparticle-related activities. However, whether this piecemeal approach will lead to a sustainable solution is uncertain.

The precautionary approach to regulation entails developing a regulatory framework that thoroughly considers the benefits and risks of new technology.[18] This approach regulates nanotechnology-based industries in the United States. While this approach was demanded in nanotechnology-related regulations in the EU, the European Commission decided to stick with the incremental approach after finding that the relevant authorities had made significant changes to existing nanotechnology-related legislation.[19] Implementing this approach in the regulatory framework requires a deep understanding of the new technology, the ability to predict the technology's future, and resources to cover the costs of legislative changes and legal administration. Companies that are heavily reliant on the technology face additional compliance requirements. Moreover, this approach necessitates industry-specific research and the sharing of scientific information with public agencies. In the EU, courts can impose strict requirements on new technology-based industries,[20] potentially hindering investment and innovation. As such, adopting this regulatory approach could be challenging for countries experiencing financial distress and striving to achieve ambitious public policy goals.

3062–64 (2018); Michelle Romero-Franco et al., *Needs and Challenges for Assessing the Environmental Impacts of Engineered Nanomaterials*, 8 BEILSTEIN J. NANOTECHNOLOGY 101, 105–07 (2017) (Ger.); *Sustainable Monitoring: Ensuring Air, Water, and Soil Quality*, VERT ENV'T (Mar. 23, 2024), https://www.vertenviro.com/en/blog/sustainable-monitoring-ensuring-air-water-and-soil-quality [https://perma.cc/X6DC-36JL].

18 For details of this approach in regulation, see generally Ger. Advisory Council on the Env't [SRU], *Precautionary Strategies for Managing Nanomaterials* (2011).

19 For details of the European Union resolution supporting the precautionary approach, see generally Parliament Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials, PARL. EUR. DOC. (2008/2208(INI) (2009). The European Commission did some assessments of the regulations' approaches and decided to remain with the incremental approach. This is mainly due to the creation and application of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). REACH is a vital part of the chemical regulation in the EU, and it has been effective in terms of providing some tools necessary for nano-industry regulation. Nevertheless, there are some serious bottlenecks in REACH, and it is now under continuous scrutiny. For details, see Vogelezang-Stoute, *supra* note 9, at 220–24.

20 *See generally* Case C-558/07, S.P.C.M. et al. v. Sec'y of State for the Env't, Food and Rural Affs., 2009 E.C.R.; Case C-180/96, UK v. Comm'n 1998 E.C.R.; Case T-13/99, Pfizer Animal Health v. Council, 2002 E.C.R.; Case T-392/02, Solvay Pharm. v. Council, 2003 E.C.R.; Case T-74/00, Artegodan v. Comm'n, 2002 E.C.R.; Case C-236/01, Monsanto Agricoltura Italia et al. v. Presidenza del Consiglio dei Ministri et al., 2003 E.C.R.

The gap between innovation and regulation is a persistent challenge due to regulators' limited legal and scientific resources in addressing the rapidly evolving field of technology, including the technology for creating nanoparticles. While the jurisdictions pioneering these technological innovations are experimenting with their approaches to regulating the disruptions generated by those technological innovations, most countries in the world are struggling to determine the basis for regulating the risks and benefits of new technology-based products and services. Australian regulators are no exception to this.

Australia has a significant problem balancing the regulation of new technology and innovation.[21] The rapid advancement of digital platforms, artificial intelligence, nanotechnology, and other emerging technologies has outpaced existing regulatory frameworks, creating challenges for policymakers.[22] For instance, fraud, money laundering, and market manipulation are common issues Australian regulators have to deal with in the crypto domain. The Australian government is taking steps to mitigate these issues since Medibank and Optus were victims of severe cyberattacks.[23] The problem is that the regulators find it extremely difficult to govern the misuse or malicious use of technologies, because they also wish to encourage innovation like blockchain and cryptocurrency technologies. This has also been the case with the Australian Competition and Consumer Commission's inquiry on consumer protection within the digital platform ecosystem.[24]

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21 The Treasury (Austl.), Regulating Digital Asset Platforms – Exposure Draft Legislation, TREASURY.GOV.AU, https://consult.treasury.gov.au/c2025-701519 (exploring an ex ante regime and the design problem of addressing harms/market power while avoiding unnecessary impediments to innovation); *Harnessing Data and Digital Technology*, AUSTL. GOV. PRODUCTIVITY COMM'N, https://www.pc.gov.au/inquiries-and-research/data-digital/ (last visited Mar. 25, 2026) [https://perma.cc/E2AY-MLEX] (framing reforms around enabling innovation while managing risks/trust in the digital economy).

22 Editoria, *The Impact of Technology on Regulation: Transforming Legal Landscapes*, L. & MORE (Jun. 15, 2024), https://lawsandmore.com/impact-of-technology-on-regulation [https://perma.cc/HHS8-N3DL]; Kirsten Webb, *Australia's AI Regulatory Landscape: Are Existing Laws Enough?*, CLAYTON UTZ (Nov. 13, 2024), https://www.claytonutz.com/insights/2024/november/australia-s-ai-regulatory-landscape-are-existing-laws-enough [https://perma.cc/2EDM-XPBS]; Kayleen Manwaring, *Kickstarting Reconnection: An Approach to Legal Problems Arising from Emerging Technologies*, 2222 DEAKIN L. REV. 53, 56 (2017).

23 *How Technology Regulation in Australia Will Affect Your Business*, FTI CONSULTING (Nov. 22, 2023), https://www.fticonsulting.com/australia/insights/articles/how-technology-regulation-australia-affect-business [https://perma.cc/CQ6P-KCFA].

24 *New Technology and Digital Disruption Bring New Challenges for Consumer Regulator*, AUSTL. COMPETITION & CONSUMER COMM'N (March 15, 2017), https://www

There has been a sharp uptake of "Buy Now, Pay Later" services like Afterpay and Zip in Australia. At the same time, the policymakers in the country face the dilemma of allowing these services to flourish while safeguarding consumers from getting overindebted.[25] The interfaces between the high rise of fintech and slow growth of complementary regulations have underscored the necessity for more effective and comprehensive regulation. An important report from the Australian National University's Tech Policy Design Centre has argued for a novel approach to technology regulation which includes a rotating cabinet specialist committee and an expert committee.[26] This model captures the importance of political will, greater accountability, and cooperation among the state, the private sector, and the citizens. The objective of this model is to ensure that the regulatory framework supports innovation but can also respond to the threats posed by new technologies.[27]

In this context, understanding how various countries regulate the use of ENMs in food is essential for proposing approaches Australia might consider for regulating foods containing ENMs. After a comprehensive assessment of the regulatory frameworks governing ENMs in food in the United States, the United Kingdom (UK), and the European Union (EU), this study finds that the basis of their regulatory approaches is quite similar and often complementary rather than contrasting. Based on this finding, we recommend that Australia begin to develop its regulatory framework centered on principles that aim to mitigate risks, encourage innovation, and promote cohesiveness. This recommendation is significant as it will help Australian regulators move past indecision and effectively manage the impacts of novel innovations on public health and safety. Given the rapid pace of innovation, and the substantial disruptions it brings, regulators have

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.accc.gov.au/media-release/new-technology-and-digital-disruption-bring-new-challenges-for-consumer-regulator [https://perma.cc/S7QS-6F3R].

25 Vanessa Ho, *The Regulatory Challenges of Evolving Technology and Financial Services Law*, AUSTL. L. REFORM COMM'N (Nov. 29, 2023), https://www.alrc.gov.au/news/the-regulatory-challenges-of-evolving-technology-and-financial-services-law/#:~:text=The%20regulatory%20challenges%20of%20evolving%20technologies,legislation%20should%20regulate%20new%20technologies [https://perma.cc/3ZB4-QM37].

26 *ANU Invests in National Tech Policy Capability*, AUSTL. NAT'L UNIV. (Feb. 7, 2024), https://www.anu.edu.au/news/all-news/anu-invests-in-national-tech-policy-capability [https://perma.cc/DN6K-YC9Q].

27 *Better Coordination of Tech Policy Urgently Needed: Report*, AUSTL. NAT'L UNIV. (Feb. 21, 2023), https://reporter.anu.edu.au/all-stories/better-coordination-of-tech-policy-urgently-needed-report [https://perma.cc/JK5L-SBFY].

limited flexibility in responding to these changes. Australian regulators face the same challenges.

This Article is structured as follows: Part I provides a brief overview of nanoparticles, engineered nanoparticles, and engineered nanomaterials in food, along with the potential impacts of using these materials in food products. Part II serves as the core of the Article; it critically evaluates the approaches for regulating ENMs in food within the European Union, the United States, and the United Kingdom. Part III analyzes the foundational principles that these countries rely on for their regulatory approaches. Part IV discusses the regulation of ENMs in food in Australia and is divided into two Sections. The first Section examines Australia's current regulation of food with ENMs and highlights its existing framework's shortcomings. The second Section proposes approaches Australia should adopt to develop a regulatory framework for ENMs in food.

I
CONCEPTUAL UNDERSTANDING

A. Meaning of Nanomaterials for Regulatory Purposes

The size range of nanomaterials is important in both scientific and legal contexts. In a legal context, the size of nanomaterials ranges between 1–100 nanometers (nm).[28] In science, however, this criterion for defining nanomaterials can be construed loosely; materials that fall slightly outside this range may still be considered nanomaterials if they exhibit unique nanoscale properties.[29] The scientific definition emphasizes the distinct physical, chemical, and biological contents that arise at the nanoscale, which often differ significantly from those of the same material at a larger scale. On the other hand, legal definitions often adhere strictly to the 1 to 100 nm size range, even though the

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28 Commission Recommendation 2022/C 229/01 of June 10, 2022 on the Definition of Nanomaterial, 2022 O.J. (C 229) 1, 2–3.; Kirsten Rasmussen et al., *How Nanoparticles Are Counted in Global Regulatory Nanomaterial Definitions*, 19 NAT. NANOTECH. 132, 134–36 (2024).

29 *Nanomaterials: What Are the Key Criteria for Defining Nanomaterials?*, EUR. COMM'N SCI. COMM., https://ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterials2012/en/l-2/3.htm (last visited Mar. 25, 2026) [https://perma.cc/49WM-GQYN]; Shengjie Peng & Peng Li, *Basic Concepts of Nanomaterials*, *in* NANOMATERIALS AND THEIR APPLICATIONS 1, 3–6 (2024), https://link.springer.com/chapter/10.1007/978-981-97-8433-2_1 [https://perma.cc/36WG-7EPV].

development of a widely accepted regulatory standard is ongoing.[30] Moreover, some regulations specify that a certain percentage (often fifty percent or more) of the particles in a material must fall within this size range. The regulatory definitions are designed to identify materials requiring specific safety assessments due to their nanoscale properties. In contrast, the legal standard focuses on potential impacts on human health and the environment, requiring clear and enforceable definitions.

ISO/TS 80004 defines a nanomaterial as a material with any external or internal surface structure in the nanoscale, ranging from about 1–100 nm.[31] Nanomaterials come in various forms, such as nanoparticles, nanowires, nanotubes, and nanosheets, each tailored for specific applications. Their unique characteristics make them highly valuable in various fields including medicine, electronics, energy, and environmental science. They enable advancements like more effective drug delivery systems, improved electronic devices, more efficient energy storage solutions, and better environmental remediation techniques.

Amongst the three broad categories of nanomaterials (natural, incidental, and engineered/manufactured), engineered/manufactured nanomaterials (ENMs) are a primary focus of regulation and risk assessment.[32] ENMs are materials purposefully designed and manipulated at the nanoscale to exhibit specific properties or functions. Unlike naturally occurring nanomaterials, ENMs are synthesized through various physical, chemical, or biological processes to achieve desired characteristics such as enhanced strength, electrical conductivity, thermal stability, or catalytic activity.[33] ENMs, which are 100 nm or less, are synthesized from numerous nanomaterials.[34] The intentional design of ENMs allows for precise control over their size, shape, surface properties, and composition, enabling innovations

30 Rashi Malik & Sharvil S. Patil, *Nanotechnology: Regulatory Outlook on Nanomaterials and Nanomedicines in United States, Europe and India*, 7 APPLIED CLINICAL RSCH., CLINICAL TRIALS & REGUL. AFFS. 225, 225–26 (2020).

31 *ISO/TS 80004-1:2015(EN) Nanotechnologies – Vocabulary – Part 1: Core terms*, ISO, https://www.iso.org/obp/ui/#iso:std:iso:ts:80004:-1:ed-2:v1:en [Archival] (last visited Mar. 25, 2026) [https://perma.cc/FQ9M-MCB2].

32 *See Nanomaterials*, EUR. CHEM. AGENCY, https://echa.europa.eu/regulations/nanomaterials [https://perma.cc/4WRB-EE9Y] (last visited March 25, 2026).

33 Carlos M. Portela et al., *Extreme Mechanical Resilience of Self-Assembled Nanolabyrinthine Materials*, 117 PROCS. NAT'L ACAD. SCIS. 5686, at 5686–93 (2020).

34 Sarabjeet Singh Suri, Hicham Fenniri & Baljit Singh, *Nanotechnology-Based Drug Delivery Systems*, 2 J. OCCUP. MED. & TOXICOLOGY, no. 16, 1 Dec. 2007, at 1, https://occup-med.biomedcentral.com/articles/10.1186/1745-6673-2-16 [https://perma.cc/N4LH-WEHZ].

across a wide range of industries.[35] For example, in medicine, ENMs are used for targeted drug delivery, improving the precision and efficacy of treatments while minimizing side effects.[36] In electronics, ENMs contribute to developing smaller, faster, and more efficient components.[37] In environmental science, ENMs aid in pollution control and water purification by providing high surface area and reactivity.[38] The ability to engineer nanomaterials opens up new possibilities for technological advancements and solutions to complex challenges in various fields.

ENMs may also result in harmful effects on the environment. They may unintentionally arise as byproducts of mechanical or industrial activities, including combustion and vaporization. Unintentional nanoparticles can originate from sources such as vehicle engine exhaust, smelting, welding fumes, household solid fuel heating, and cooking. For instance, fullerenes—a type of nanomaterial—can form during gas combustion, biomass, and when burning candles.[39]

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35 Gagan Kant Tripathi, *Engineered Nanomaterials and Their Properties: A Review*, 12 BIOSCIENCE BIOTECHNOLGY RSCH. COMMC'NS 764, 769 (2019), https://www.researchgate.net/publication/336369975_Engineered_Nanomaterials_And_Their_Properties_A_Review [https://perma.cc/V6N8-79WM].

36 Suri, Fenniri & Sing, *supra* note 34, at 1.

37 *Nanomaterials in Electronics: Smaller, Faster, Better*, FREE SCIENCE INFO, https://freescience.info/nanomaterials-in-electronics-smaller-faster-better/ (last visited Mar. 25, 2026) [https://perma.cc/ZV3X-JWM3].

38 Elena Vargas, *Nanomaterials in Environmental Pollution Control: Strategies and Techniques*, 4 AM. J. NANO SCI. & TECH. 1708, 1708–10 (2023), https://www.australiansciencejournals.com/ajnst/article/view/1708 [https://perma.cc/QXM3-VM68] (ENMs provide high surface area and reactivity primarily due to their extremely small size and large surface-to-volume ratio. As particles shrink to the nanoscale (1–100 nm), a much larger proportion of their atoms are exposed on the surface compared to bulk materials. This dramatically increases the available surface area for interactions. With more atoms at or near the surface, ENMs have more active sites for chemical reactions, making them highly reactive. This is especially useful in applications like catalysis, drug delivery, and sensors); For details, see generally Kelvin Bassey et al., *From Waste to Wonder: Developing Engineered Nanomaterials for Multifaceted Applications*, 2 (2024), https://www.researchgate.net/publication/384329348 [https://perma.cc/3S93-HJFX]; V. Alcolea-Rodriguez et al., In Chemico *Methodology for Engineered Nanomaterial Categorization According to Reactive Surface Sites*, 11 ENV'T SCI. NANO 3744, 3745 (2024), https://pubs.rsc.org/en/content/articlehtml/2024/en/d3en00810j [https://perma.cc/G7VD-QNTF].

39 DAMIÀ BARCELÓ & MARINELLA FARRÉ, ANALYSIS AND RISK OF NANOMATERIALS IN ENVIRONMENTAL AND FOOD SAMPLES 291 (2012) (Neth.).

B. Nanomaterials in Food

Emerging technologies are crucial for raising and enhancing food accessibility and sustainability when considering problems like global population growth, environmental threats, climate change, energy scarcity, and the loss of arable land. Nanomaterials are one such emerging technology, helping to increase food accessibility and sustainability. Engineered nanomaterials (ENMs), with their distinct and diverse chemical properties, have found numerous applications in food and feed processing at many levels, including manufacturing, packaging, storage, value addition, and transportation.[40] For example, systems designed for delivering color and flavor additives, preservatives, and nutrients use nanomaterials. Food scientists use nanomaterials to modify the optical and textural properties of different foods.[41]

In the food industry, nanotechnology can help solve difficulties related to food safety, food processing, and food packaging through creative initiatives.[42] Nanomaterials also encapsulate bioactive components such as vitamins, antioxidants, and other nutrients to enhance their bioavailability.[43] Nanomaterials that exhibit antimicrobial activity are used as additives to enhance food preservation and extend shelf life.[44] This occurs as food scientists or engineers use ENMs in active packaging products to prevent the passage of oxygen, carbon dioxide, and moisture into the food.[45] To

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40 Kangran Han et al., *Advances in Nanotechnology Research in Food Production, Nutrition, and Health*, 17 NUTRIENTS 2443, 2445–47 (2025), https://www.mdpi.com/2072-6643/17/15/2443 [https://perma.cc/6WQK-MEN3]; Michael J. Walker, *Nanotechnologies in Food: What, Why and How?*, *in* NANOTECHNOLOGIES IN FOOD 1, 3–5 (Qasim Chaudhry et al. eds., 2d ed. 2023), https://books.rsc.org/books/edited-volume/566/chapter/238893/Nanotechnologies-in-Food-What-Why-and-How [https://perma.cc/99EV-345E].

41 David Julian McClements & Hang Xiao, *Is Nano Safe in Foods? Establishing the Factors Impacting the Gastrointestinal Fate and Toxicity of Organic and Inorganic Food-Grade Nanoparticles*, 1 NATURE PARTNER J.: SCI. FOOD 1, 1 (2017).

42 *See generally* Zahra H. Mohammad et al., *Application of Nanotechnology in Different Aspects of the Food Industry*, 2 DISCOVER FOOD 1, 1 (2022).

43 *See generally* Akhilesh Kumar Singh et al., *Development of "Smart Foods" for Health by Nanoencapsulation: Novel Technologies and Challenges*, 20 FOOD CHEMISTRY: X 1 (2023).

44 Rachana Jadhav et al., *An Overview of Antimicrobial Nanoparticles for Food Preservation*, 72 MATERIALS TODAY: PROCEEDINGS 204, 205 (2023).

45 Oumar Fofana, *Nanotechnology in Packaging: Enhancing Barrier Properties and Shelf Life*, PACKAGING GATEWAY (Apr. 29, 2024), https://www.packaging-gateway.com/features/nanotechnology-in-packaging-enhancing-barrier-properties-and-shelf-life [https://perma.cc/T645-U2NS]; Shweta Kumari, *Active Packaging: Oxygen Absorbers and*

attain optimal benefits, multiple types of nanotechnologies using different engineered nanomaterials are employed at different stages of the food supply chain.[46]

With the rapid increase in the use of ENMs in all stages of the food supply chain, there are growing concerns about their toxicity and negative impacts on health and the environment. Most notably, since nanoparticles can travel through humans' gastrointestinal, cutaneous, and respiratory systems, there is a risk of toxicity[47] when ENMs are present in food or food packaging.[48] Numerous studies have shown that inorganic nanoparticles (e.g., silver, iron oxide, titanium dioxide, silicon dioxide, and zinc oxide) and organic nanoparticles (e.g., lipid-based, protein-based, and carbohydrate-based nanoparticles) can potentially cause harmful health effects.[49] The harmful effects of the above inorganic nanomaterials include oxidative stress, gastrointestinal toxicity, and cellular damage.[50] These inorganic materials can also potentially accumulate in tissues, leading to long-term health risks.[51] Likewise, organic nanomaterials may alter allergen responses, disrupt gut microbiota, and negatively affect digestive processes.[52]

ENMs in food and food packaging can pose health risks, potentially leading to various diseases and conditions. The health risks associated with nanomaterials in food depend on several factors, including the type of nanomaterial, its size, shape, surface properties, and the extent of exposure.[53] Potential risks include gastrointestinal disturbances,

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Moisture Control, FOOD INFOTECH (Nov. 21, 2024), https://www.foodinfotech.com/active-packaging-oxygen-absorbers-and-moisture-control [https://perma.cc/EB44-83PB].

46 Walker, *supra* note 40, at 3–6.

47 *See generally* Shahidul Islam et al., *Engineered Nanomaterials: Understanding Their Toxicity and Environmental Impacts*, FRONTIERS TOXICOLOGY (Jul. 31, 2025), https://www.frontiersin.org/research-topics/68829/engineered-nanomaterials-understanding-their-toxicity-and-environmental-impacts [https://perma.cc/ZBC6-DMFG].

Toxicity is a measure of the harmful effects that a substance can have on living organisms, including humans, animals, and plants. Toxicity can result from exposure to chemicals, physical agents, or biological agents, and it can occur through various routes including ingestion, inhalation, or skin contact.

48 *See* Shivendu Ranjan et al., *Toxicity and Regulations of Food Nanomaterials*, 17 ENV'T CHEMISTRY LETTERS 929, 929-944 (2019).

49 McClements & Xiao, *supra* note 41, at 10.

50 Yanchen Li et al., *Assessing Inorganic Nanoparticle Toxicity Through Omics Approaches*, 16 NANOSCALE 15928, 15930–32 (2024), https://pubs.rsc.org/en/content/articlehtml/2024/nr/d4nr02328e [https://perma.cc/RH88-DN5M].

51 *Id.*

52 *Id.*

53 Ranjan et al., *supra* note 48, at 929.

immune system modulation, cellular toxicity, genetic damage, and organ-specific effects.[54] Cosmetics, personal care products, and food items are the most common direct routes of nanomaterial exposure through inhalation, ingestion, or dermal exposure.[55]

II
REGULATORY FRAMEWORK FOR ENGINEERED NANOMATERIALS (ENMS) IN FOOD

Like the short description of nanotechnology in this Article, it would be worth providing a short note on regulation. There is no clear and overarching definition of "regulation."[56] The term encompasses state control over social and economic activities to prevent undesirable behavior and promote desirable actions.[57] Legal regulation includes government policies, norms, legislation, and international covenants.[58]

The use of ENMs has increased in various consumer products with the advancement of nanotechnology. Industries such as medicine, cosmetics, and food are investing in nanomaterials. As a result, regulations for these technology-based products have also increased, with most developed countries having some form of legal regulation.[59]

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54 Elena Molina & Sara Benedé, *Is There Evidence of Health Risks from Exposure to Micro- and Nanoplastics?*, 9 FRONTIERS IN NUTRITION 4–6 (2022), https://www.frontiersin.org/journals/nutrition/articles/10.3389/fnut.2022.910094/full [https://perma.cc/Z7ZG-267K] [https://doi.org/10.3389/fnut.2022.910094]; *Addressing Food Safety Concerns and Risks of Nanomaterials in Food*, FOOD SAFETY INST. (May. 14, 2025), https://foodsafety.institute/emerging-trends-food-technology-safety/food-safety-nanomaterials-risks/ [https://perma.cc/P5T4-G52V].

55 Ranjan et al., *supra* note 48, at 930.

56 *See generally* A READER ON REGULATION (Robert Baldwin et al. eds., 1998); Julia Black, *Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World*, 54 CURRENT LEGAL PROBS. 103, 141–42; Christine Parker, *The Pluralization of Regulation*, 9 THEORETICAL INQUIRIES L. 349, 350 (2008).

57 David Levi-Faur, *Regulation and Regulatory Governance*, *in* HANDBOOK ON THE POLITICS OF REGULATION 3, 5–6 (David Levi-Faur ed., 2011); Cary Coglianese & Evan Mendelson, *Meta-Regulation and Self-Regulation*, *in* THE OXFORD HANDBOOK OF REGULATION 146–49 (Robert Baldwin et al. eds., 2012).

58 Anne Peters, *The Refinement of International Law: From Fragmentation to Regime Interaction and Politicization*, 15 INT'L J. CONST. L. 671, 673–75 (2017); Nicolas de Sadeleer & Ivana Damjanovic, *The Rule of Law Between National and International Contexts: Introduction to the Special Issue on International Economic Law and the Rule of Law*, 15 EUR. J. RISK REGUL. 477, 478–480 (2024); Kostiantyn Gorobets, *The International Rule of Law and the Idea of Normative Authority*, 12 HAGUE J. ON RULE L. 227, 229–32, (2020).

59 Ibtisam Abbasi, *Global Nanomaterial Regulation: A Country-by-Country Comparison*, AZONANO (Apr. 24, 2025), https://www.azonano.com/article.aspx?ArticleID=6885 [https://perma.cc/WTU2-ETPP].

Notably, the European Union, the United States, and the United Kingdom have robust regulatory frameworks for ENMs in food.[60] This Article aims to provide an overview of these regulations worldwide. It extensively assesses the regulatory frameworks for ENMs in food in these three jurisdictions.

A. European Union (EU)

The European Union (EU) has various legal instruments to achieve its goals and ensure that those goals are consistently applied among the member states.[61] These instruments include legislation, directives, and decisions. The EU implements its legislation in all its regions. Directives state the objectives that every country in the EU must fulfill, but each country is free to create laws to achieve these goals.[62] Decisions bind the addressed parties and are self-executing. Furthermore, the EU uses nonbinding recommendations; these recommendations serve as expressions of the EU's attitude or course of action to be taken.

The EU has several public organizations that contribute to novel food regulations. The European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) are key institutions that ensure the safety of engineered nanomaterials employed in food and feed.[63] Moreover, there is the Joint Research Centre (JRC) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), which are independent bodies of the European Commission that conduct scientific studies and risk analyses of safety issues related to different particles, including ENMs, in food.

The main public agency within the EU food regulation framework is the European Food Safety Authority (EFSA).[64] Regulation (EC) No 178/2002 established the EFSA to monitor potential threats that could

60 *Id.*

61 *Types of Legislation*, EUR. UNION, https://european-union.europa.eu/institutions-law-budget/law/types-legislation_en (last visited Mar. 27, 2026) [https://perma.cc/QHD4-2ET4].

62 *EU Legal Instrument*, EUR. UNION: EUR-LEX, https://eur-lex.europa.eu/EN/legal-content/glossary/eu-legal-instruments.html (last visited Mar. 27, 2026) [https://perma.cc/G3T4-YGVD].

63 Hubert Rauscher et al., *Regulatory Aspects of Nanomaterials in the EU*, 89 CHEMIE INGENIEUR TECHNIK 224, 226 (2017) (Ger.).

64 Sevasti Chatzopoulou et al., *Improving Risk Assessment in the European Food Safety Authority: Lessons from the European Medicines Agency*, 11 FRONT. PLANT SCI. 1, 2 (Apr. 6, 2020), https://www.frontiersin.org/articles/10.3389/fpls.2020.00349/full [https://perma.cc/2ZBN-M5J6].

affect the safety of food products, both directly and indirectly.[65] The EFSA is also responsible 1for conveying scientific research and guidance on prevalent threats affiliated with the food industry hierarchy.[66] The EFSA has a Scientific Committee and panels established with independent experts to convey scientific research on new ingredients and associated risks, including nanomaterials in food.[67] The committee furnishes scientific opinion through a structured and open-ended protocol, starting from the EC's intimation process, which includes publishing a final opinion report. Constant monitoring of any new updates follows the publishing of a final report[68]

In 2009, EFSA's scientific committee published a scientific evidence-based report concerning the potential risk exposure to nanomaterials in food products.[69] In addition to ensuring consumer safety from risks closely linked with nano-food items, the EFSA furnishes an exhaustive regulatory framework that includes a risk assessment strategy, scientific guidance, data collection, research, and stakeholder participation.[70] The EFSA recently implemented two fundamental directives related to nanotechnology in the food industry: (1) *Guidance on Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain* (2018) and (2) *Guidance on Technical Requirements for Regulated Food and Feed Product Applications to Establish the Presence of Small Particles Including Nanoparticles* (2021).[71]

The European Chemicals Agency (ECHA) is the authoritative body of the EU region operating to ensure the safe use of chemicals.[72] The

65 Council Directive 178/2002, art. 22, 2002 O.J. (L 31) 15 (EC).

66 Oriol Ribó et al., *Role of the European Food Safety Authority (EFSA) in Providing Scientific Advice on the Welfare of Food Producing Animals*, 8 IT. J. ANIMAL SCI. 9, 9–17 (2009).

67 Council Directive 178/2002, *supra* note 65, art. 28.

68 *Id.* at sec. 4.

69 *The Potential Risk Arising from Nanoscience and Nanotechnologies on Food and Feed*, 7 EUR. FOOD SAFETY AUTH. J. 1, 1 (2009).

70 *See generally* Council Directive 178/2002, *supra* note 65.

71 *See generally* European Food Safety Authority Scientific Committee, *Guidance on Risk Assessment of Nanomaterials to Be Applied in the Food and Feed Chain: Human and Animal Health*, 19 EFSA J. 6768 (2021), https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6768 [https://perma.cc/34QS-9ZQB]; *see also* European Food Safety Authority Scientific Committee, *Guidance on Technical Requirements for Regulated Food and Feed Product Applications to Establish the Presence of Small Particles Including Nanoparticles*, 19 EFSA J. 6769 (2021), https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6769 [https://perma.cc/BYL2-Y7E3].

72 *What We Do*, EUR. CHEM. AGENCY, https://echa.europa.eu/about-us/what-we-do (last visited Mar. 27, 2026) [https://perma.cc/ZN76-4RJZ].

ECHA was established by the EU Regulation (EC) No 1907/2006 to regulate chemical substance manufacture, cross-border permits, and consumer-level use.[73] The European Court of Auditors has quoted the mandate of the ECHA in the following fashion:

> To ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards relating to substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.
>
> To ensure that chemical legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public.
>
> To coordinate communication concerning the REACH Regulation and its implementation.[74]

Broadly, the ECHA's functions can be categorized into four groups: (1) registering, evaluating, authorizing, and restricting chemicals; (2) classifying, labeling, and packaging substances and mixtures; (3) implementing prior informed consent; and (4) controlling hazardous chemicals, and the Substance of Concern In Product (SCIP) database.[75] The mechanisms above, controlled and overseen by ECHA, ultimately ensure a stringent hedge for human health and ecological balance from the risk posed by chemical substances—including nanomaterials—in food.[76] Additionally, the Classification, Labeling, and Packaging (CLP) strategy adopted by the REACH is regulated under the authority of ECHA.[77] Besides, the ECHA plays a significant role in developing independent scientific and technical opinions[78] and acting to reduce chemical pollution in the EU.[79]

The Commission Recommendation 2011/696/EU defines nanomaterials among the regulations related to the regulation of ENMs

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73 EU Regulation 1907/2006, 2024 (EC).

74 Eur. Court Auditors Press Release ECA/12/39, Management of Conflict of Interest in Selected EU Agencies: Special Report No. 15, at 41 (Oct. 11, 2012).

75 *See generally* Commission Regulation 1907/2006, 2006 O.J. (L 396) (EC) (REACH Regulation).

76 Tony Musu, *The European Chemicals Agency, Keystone of REACH*, 34 HIGHER ED. STAT. AGENCY NEWSL. 8, 11 (2008).

77 Malik & Patil, *supra* note 30, at 230.

78 *See generally* EUR. CHEM. AGENCY, *supra* note 72 (explaining ECHA's role in providing independent scientific opinions to guide chemical risk management in the EU).

79 *About Us*, EUR. CHEMICALS AGENCY (describing ECHA's purpose as: "We protect health and the environment through our work for chemical safety"), https://echa.europa.eu/about-us [https://perma.cc/6XMQ-NER8] (last visited Mar. 27, 2026).

in food in the EU.[80] Althoug1h the definition has no binding force, it creates a guideline for adopting a unique definition of nanomaterials, especially for policy-making purposes within EU regions.[81] The General Food Law applies to all food categories, including nano-food; the general definition, safety assessment, and guidance of the aforesaid regulation also apply to food containing nanomaterials.[82] On the other hand, the Novel Food Law Regulation expressly defines engineered nanomaterials as novel food. Hence, the ENMs fall under the direct purview of the Novel Food Law Regulation.[83] Starting in 2018, safety assessment mandated directives and authorization as food, with a prospective application. The EU defines nanomaterial in documents of regulatory significance, including a comprehensive nonbinding recommendation approved by the EC in 2011[84] along with multiple sector-specific legislations.

To foster uniformity in defining nanomaterial for policy and legislative purposes in the EU, the European Commission (EC) presented a *Recommendation on the Definition of Nanomaterial*.[85] In this recommendation, the EC highlights three basic elements of nanomaterials.[86] These are (1) the source of materials, (2) the state of nature, and (3) the size of the particles.[87] Based on these elements, nanomaterials stem from three particular sources: natural, incidental, or manufactured;[88] they contain a minimum of half of the constituent

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80 *See generally* Commission Recommendation 2011/696 of Oct. 18, 2011, on the Definition of Nanomaterial, 2011 O.J. (C 229) (EU).

81 *See generally* Claudia Baumung et al., *An Update Of Definitions and Regulations Regarding Nanomaterials in Foods and Other Consumer Products*, *in* NOVEL APPROACHES OF NANOTECHNOLOGY IN FOOD 1, 1–19 (Alexandru Mihai Grumezescu ed., 2016).

82 *See* Council Directive 178/2002, *supra* note 65, art. 4 (applicable to all food including nano-food).

83 *See generally* Commission Regulation 2015/2283, 2015 O.J. (L 327) 1–22 (EU); Regulation 1169/2011, 2011 O.J. (L 304) 18–63 (EU); Regulation 258/97, 1997 O.J. (L 43) 1–6 (EC); Commission Regulation 1852/2001, 2001 O.J. (L 253) 17–18 (EC).

84 Commission Recommendation 2011/696, *supra* note 80, at 80.

85 *See generally* Commission Recommendation 2022/C 229/01, *supra* note 28.

86 *Id.*

87 Commission Recommendation 2011/696, *supra* note 80; HUBERT RAUSCHER ET AL., GUIDANCE ON THE IMPLEMENTATION OF THE COMMISSION RECOMMENDATION 2022/C 229/01 ON THE DEFINITION OF NANOMATERIAL 6–9 (2023).

88 Michael F. Hochella et al., *Natural, Incidental, and Engineered Nanomaterials and Their Impacts on the Earth System*, 363 SCI. 1414, 1414–15 (2019), https://www.science.org/doi/10.1126/science.aau8299 [https://perma.cc/L5AU-J3ZC]; Jaison Jeevanandam et al., *Review on Nanoparticles and Nanostructured Materials: History, Sources, Toxicity, and Regulations*, 8 BEILSTEIN J. NANOTECHNOL. 1686, 1687–88 (2017), https://www.beilstein-journals.org/bjnano/articles/8/168 [https://perma.cc/6UJD-9G3R].

particles, representing one or more outer dimensions in the 1 and 100 nm range,[89] and they can stay in an "unbound [state] or [as] part of aggregates or agglomerates or aggregates."[90] According to the Joint Research Centre (JRC)—the EC's science and knowledge service provider—materials with a specific surface area by volume greater than 60 m^2/cm^3 are also considered nanomaterials unless they are not deliberately manufactured and contain nanomaterials solely as impurities or byproducts.[91]

In the context of specific binding legislation, the Novel Food Regulations[92] expressly define ENMs.[93] However, the definition does not include a percentage threshold for the content in particles of less than 100 nm above which materials are to be classified as nanomaterials.[94] The definition of engineered nanomaterials in Regulation (EU) No 2015/2283 and Regulation (EU) No 1169/2011 provides a clear and specific framework for identifying and regulating nanomaterials in novel foods and food labeling purposes. The REACH Regulation does not explicitly define nanomaterials and instead regulates them as chemical substances.[95] Hence, nanomaterials are subject to the same rigorous registration, evaluation, and safety requirements as other chemical substances.

The EFSA has prepared an extensive guideline for risk assessment of ENMs-based attributes.[96] It provides a structured strategy for the risk assessment of nanoparticles associated with food products.[97] In addition, the potential threat of exposure of nanomaterials in food items

89 Commission Recommendation 2022/C 229/01, *supra* note 28.

90 Valeria Amenta et al., *Regulatory Aspects of Nanotechnology in the Agri/Feed/Food Sector in EU and Non-EU Countries*, 73 REGUL. TOXICOLOGY & PHARMACOLOGY 463, 465 (2015).

91 RAUSCHER ET AL., *supra* note 87; ROEBBEN ET AL., TOWARDS A REVIEW OF THE EC RECOMMENDATION FOR A DEFINITION OF THE TERM "NANOMATERIAL" 38–40 (Gert Roebben & Hubert Rauscher eds., 2014).

92 Commission Regulation 2015/2283, *supra* note 83.

93 *Id.* at art. 3(2)(a)(viii).

94 Baumung et al., *supra* note 81, at 8.

95 Commission Regulation 1907/2006, *supra* note 75. Substances refer to chemical elements and their compounds in their natural state or obtained through any manufacturing process, including any necessary additives to preserve stability and any impurities derived from the process.

96 *See* Eur. Food Safety Auth. Sci. Comm. et al., *Guidance on Risk Assessment of Nanomaterials to be Applied in the Food and Feed Chain: Human and Animal Health*, 19 EUR. FOOD SAFETY AUTH. J. 1, 6–15 (2021).

97 *Id.* at 3–5.

is properly and effectively eva1luated during the assessment process.[98] The said risk assessment guidelines apply under the General Food Law and Novel Food Regulation.[99] The guidance offers an action-oriented modality for measuring latent threats from nanoscience and nanotechnologies in food additives, enzymes, flavorings, food contact materials, novel foods, feed additives, and pesticides.[100] The ECHA guideline—*Guidance on Information Requirements and Chemical Safety Assessment*—addresses chemical safety assessment (CSA) under the REACH Regulation.[101] The CSA process includes hazard identification, exposure assessment, and risk characterization, and ends with a detailed chemical safety report. Furthermore, the ECHA has established a dedicated Nanomaterials Working Group to address scientific and technical queries and provide guidance regarding ENMs under REACH and CLP.[102]

The Novel Food Regulation (Regulation (EU) No 2015/2283) outlines a regulatory framework for the safety assessment and authorization of novel foods, including ENMs. This framework ensures the safety of customers by requiring a combination of pre-market approval and post-market surveillance.[103] The pre-market authorization process involves the following steps: (1) application submission, (2) scientific evaluation by the EFSA, (3) a risk-management decision by the European Commission, and (4) authorization and inclusion in the regulatory frameworks of EU member countries.[104] At the post-market monitoring stage, food business operators should report

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98 *See* Eur. Food Safety Auth. Sci. Comm. et al., *Guidance on Technical Requirements for Regulated Food and Feed Product Applications to Establish the Presence of Small Particles Including Nanoparticles*, 19 EUR. FOOD SAFETY AUTH. J. 1, 48 (2021); Reinhilde Schoonjans & José Tarazona, *Annual Report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2020*, 18(3) EUR. FOOD SAFETY AUTH. SUPPORTING PUBL'N 1, 12 (2021).

99 *See* Council Directive 178/2002, *supra* note 65, art. 37, 95, 133, 152(4)(b); Commission Regulation 2015/2283, *supra* note 83.

100 Eur. Food Safety Auth. Sci. Comm. et al., *supra* note 96, at 6–15.

101 *Guidance on Information Requirements and Chemical Safety Assessment*, EUR. CHEMS. AGENCY (Dec. 2011), https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment [https://perma.cc/2BDK-WSBF].

102 *Guidance on Information Requirements and Chemical Safety Assessment: Appendix R.10-2 Recommendations for Nanomaterials*, EUR. CHEMS. AGENCY, 6–10 (2012), https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Publikationen/EN/REACH/ECHA/IR-CSA/ECHA_Leitlinie_Guidance_on_information_requirements_and_chemical_safety_assessment_Appendix_R10-2 [https://perma.cc/74WB-56AC].

103 Commission Regulation 2015/2283, *supra* note 83.

104 *Id.* at 9.

updated information on the novel food's protection measures, including any adverse effects.[105] Food additives, enzymes, and flavorings have been subject to an EU-wide standard evaluation and authorization process before being used in commercial foods, and a consistent approach is outlined in Regulation (EC) 1331/2008.[106] The authorization procedure should ensure the safety of ingredients in food and feed based on scientific risk assessment. A fresh safety review must be performed to improve the first substance used in the additive manufacturing process (such as changing the particle size), as the prevailing authorization process does not address those modifications.[107]

The EU has implemented extensive frameworks to guarantee consumer protection and food safety, especially regarding cutting-edge technologies like nanotechnology. The General Food Law and the Novel Food Regulation are two key legislative measures that address food safety but with different scopes and mechanisms.[108] Since the General Food Law Regulation applies to all food, nanomaterial-based food products are also governed accordingly. Although not all nanomaterial-based foods are harmful, it is crucial to undertake a safety assessment to protect human health from any probability of hazardous effects.[109] The EFSA provides detailed guidance on the risk assessment of nanomaterials used in the food supply chain.[110] This assessment process includes characterizing nanomaterials, assessing exposure, identifying and characterizing hazards, and managing risks.[111]

The Chemical Substances Risk Assessment under Regulation (EC) No 1907/2006 (REACH Regulation) plays a vital role in the EU's novel food regulation. The REACH Regulation's functions include registration, evaluation, authorization, and restriction of chemicals; classifying, labeling, and packaging substances and mixtures; establishing informed consent; and controlling hazardous chemicals

105 *Id.*

106 Amenta et al., *supra* note 90, at 467.

107 *Id.*

108 *See* Council Directive 178/2002, *supra* note 65; Commission Regulation 2015/2283, *supra* note 83.

109 Mansi Mishra et al., *Prospects, Challenges and Need for Regulation of Nanotechnology with Special Reference to India*, 171 ECOTOXICOLOGY & ENV'T SAFETY 677, 680 (2019).

110 Eur. Food Safety Auth. Sci. Comm. et al., *supra* note 96.

111 *Id.*

through the SCIP database.[112] The Regulation (EC) No 1907/2006, commonly known as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), is a cornerstone of the EU's legislative framework for chemical safety.[113] Although REACH primarily addresses the management of chemicals broadly, it has significant implications for the regulation of nanomaterials, considering them as unique chemical substances, including their use in food.[114]

REACH applies horizontally to all chemical compounds to better protect the environment and human health from the potential hazards of substances.[115] REACH excludes chemicals found in food or feeding supplies from the registration process.[116] Nevertheless, ENMs used as food-contact substances or in industrial sectors are not barred from REACH registration, therefore, the REACH regulations still apply to them.[117] Although ENMs are not specifically mentioned in the regulatory provisions of REACH, since they cover chemicals of any size, shape, or physical form, REACH rules protect ENMs.[118] Comprehending the innate characteristics of chemical substances at the earlier stage and subsequently taking the appropriate measures per those findings serves the intended goal of REACH. Two additional objectives have been incorporated in the design of the Regulation: (1) encouraging the creation of substitute, nonanimal techniques for assessing the risks associated with chemicals and (2) encouraging innovations and competitiveness of substances in the domestic market through free circulation.[119] Notably, the precautionary principle avails the foundation for REACH's requirements,[120] and

112 *REACH Legislation*, EUR. CHEM. AGENCY, https://echa.europa.eu/en/regulations/reach/legislation (last visited Mar. 27, 2026) [https://perma.cc/X8C8-DZ6M].

113 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 O.J. (L 396) 1, https://eur-lex.europa.eu/eli/reg/2006/1907/oj [https://perma.cc/QC6Y-4GJR].

114 *See* Commission Regulation 1907/2006, *supra* note 75, at 3–5; ELENA DONCHEVSKAYA, REACH (REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS) 36 (2009) (Ukr.).

115 Amenta et al., *supra* note 90.

116 *Id.*

117 *Id.* at 468.

118 *Id.*

119 *Id.*

120 *See* Commission Regulation 1907/2006, *supra* note 75, at 4.

precisely four categories of entities are the target group of the Regulation: (1) manufacturers, (2) importers, (3) downstream users, and (4) distributors.[121]

To monitor the harmful effects of chemical substances manufactured, imported, or used in EU territory, REACH is formulated with four stringent safety measures: (1) registration, (2) evaluation, (3) authorization, and (4) restriction. The European Chemicals Agency (ECHA) plays a key role in carrying out the obligation of REACH.[122]

The REACH Regulation requires manufacturers and importers to register substances (nanoparticles are considered chemical substances) manufactured or imported in volumes of one ton or more per year.[123] The registration procedure of chemical substances under the REACH can be discussed under two headings: (1) substances on their own or in preparations,[124] and (2) substances in articles.[125] Manufacturers and importers must submit a registration dossier to the agency for the former. The registration dossier has two main components: (1) a Technical Dossier and (2) a Chemical Safety Report.[126]

The evaluation process empowers the authorities to request additional details from registrants and, in a few cases, downstream users.[127] The evaluation process comprises two different areas: (1) dossier evaluation and (2) substance evaluation.[128] The dossier evaluation process encompasses two distinct duties: (1) the compliance check, and (2) the testing proposal.[129] The ECHA uses the compliance check function to verify that registration dossiers meet the standards

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121 VERIFICATION RSCH., TRAINING & INFO. CENTRE, A MANUAL OF BEST PRACTICE: A SYSTEM OF CHEMICALS REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION 6 (2021).

122 *See* Commission Regulation 1907/2006, *supra* note 75, at 57.

123 *Id.* at 10–11.

124 *Id.* art. 6.

125 *Id.* art. 7.

126 *Id.* tit. VI, ch. 1–4.

127 *See* ENTER. & INDUS. DIRECTORATE & ENV'T DIRECTORATE GEN. & EUR. COMM'N, REACH IN BRIEF 11 (2006), https://www.fecc.org/wp-content/uploads/2020/01/reach_in_brief_dec06.pdf [https://perma.cc/VX7C-B7RR].

128 *See* Commission Regulation 1907/2006, *supra* note 75, tit. VI.

129 *See Evaluation Process*, EUR. CHEMS. AGENCY, https://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure/phase-1 (last visited Mar. 27, 2026) [https://perma.cc/55QK-UH9M]; *Dossier Evaluation & Examination of Testing Proposals*, REACH METALS GATEWAY (Aug. 4, 2025), https://www.reach-metals.eu/reach/reach-specific-processes/evaluation/dossier-evaluation-examination-of-testing-proposals [https://perma.cc/9BUU-RQ4L].

outlined in the Regulation for registration. Throughout the screening process, the ECHA considers th1e crucial components of the registration dossiers including the identification of chemicals, the reliability of the supplied information, and the suitability of the risk control strategies. The mechanisms of the substance evaluation process also have two strategies: (1) substance risk assessment and (2) the Community Rolling Action Plan.[130] After evaluation, if the particle (including nanomaterials) is identified as a "Substance of Very High Concern," it either obligates authorization for a particular user or is restricted altogether.[131]

The Regulation (EC) No 1272/2008—the Regulation on Classification, Labelling, and Packaging (CLP)—furnishes an extensive regulatory framework for the safe use of nanoparticles in food. It highlights the detection of hazards, communication through labeling, and secure packaging practices.[132] The CLP aims to safeguard human health and the environment while allowing the free movement of chemicals, compounds, and products.[133] It is designed to detect the inherent risks linked to substances and compounds while informing concerned users about the probable risks of using those products.[134] Under the CLP, the classification can be made through self-assessment or by undertaking a harmonized strategy at the EU level.[135]

Regulation EC 1333/2008, Active Intelligent Materials Regulation, helps ensure (EC 450/2009) and General Food legislation (EC 178/2002) affect the aforementioned standard.[136] The Regulation establishes mechanisms for communicating food information and ways

130 *Community Rolling Action Plan*, EUR. CHEMS. AGENCY, https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan (last visited Mar. 28, 2026) [https://perma.cc/DM8H-JEMH]; Chemradar, *ECHA Releases 2025–2027 Substance Evaluation Rolling Plan (CoRAP) 28 Substances Listed*, CIRS: REGULATORY NEWS (Apr. 2, 2025), https://www.cirs-group.com/en/chemicals/echa-releases-2025-2027-substance-evaluation-rolling-plan-corap-28-substances-listed [https://perma.cc/A73W-UVNG].

131 EUR. CHEM. AGENCY, *supra* note 130.

132 Council Regulation 1272/2008, art. 95, 2008 O.J. (L 353) 1, 3–5 (EC); *see Regulation (EC) No 1272/2008 – Classification, Labelling and Packaging of Substances and Mixtures (CLP)*, EUR. AGENCY FOR SAFETY & HEALTH WORK (Mar. 14, 2024), https://osha.europa.eu/en/legislation/directives/regulation-ec-no-1272-2008-classification-labelling-and-packaging-of-substances-and-mixtures [https://perma.cc/Q9DL-9CJU].

133 Council Regulation 1272/2008, *supra* note 132.

134 For details, see generally EUR. AGENCY FOR SAFETY & HEALTH WORK, *supra* note 132.

135 *Id.*

136 Mishra et al., *supra* note 109.

to ensure consumers access.[137] This Regulation applies to food service providers throughout all the phases of the food supply chain.[138] The Regulation requires food items containing explicitly engineered nanomaterials to be clearly and transparently labeled.[139] A specific definition of ENMs has also been supplied in the Regulation:[140]

> "[E]ngineered nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 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-nano form of the same material.

To ensure consumers are fully informed about the presence of nanomaterials in the foods they purchase, the regulation mandates that all engineered nanomaterials used in food must be listed in the ingredients followed by the word "nano" in brackets.[141] For example, if a food product contains silver nanoparticles, the label should read "silver [nano]." This labeling requirement empowers consumers to make informed choices and reflects the EU's commitment to transparency in food information.

B. United States of America

The regulatory framework in the United States does not provide an express definition of the concepts "nanotechnology," "nanomaterial," "nanoscale," or other related terms. However, the National Nanotechnology Initiative Program defines nanotechnology as the understanding and control of matter at dimensions between approximately 1 and 100 nanometers.[142]

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137 Regulation 1169/2011, *supra* note 83, art. 1.

138 *Id.*

139 *Id.* art. 18.

140 *Id.* art. 2(2)(t).

141 Amenta et al., *supra* note 90, at 469.

142 Malik & Patil, *supra* note 30.

The Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) and the Toxic Substances Control Act of 1976 (TSCA), which are overseen by the Food and Drug Administration and the Environmental Protection Agency, respectively, do not explicitly describe "nanomaterials" in their provisions.[143] However, the FDA defines nanomaterials as substances with at least one dimension at the nanoscale, generally ranging from 1 to 100 nanometers.[144] In contrast, the EPA has developed guidelines and regulatory approaches to address nanomaterials under the TSCA framework.[145] Furthermore, though the Consumer Product Safety Act of 1972 does not include a specific definition, it protects the safety of consumer products within its framework, which may include products containing nanomaterials.[146]

Three key regulatory bodies in the United States govern nanotechnology in the food industry: the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Food Safety and Inspection Service (FSIS).[147] Their functions revolve around governing food safety from hazardous threats, communicating consumer information through product labeling, and advancing environmental protection. Additionally, the Consumer Product Safety Commission, the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health

143 Lynn L. Bergeson, *TSCA and Nanotechnology: EPA's Approach to Nanoscale Materials*, 5 NANOTECH. L. & BUS. 339, 340–41 (2007), https://www.actagroup.com/uploads/docs/00010729.pdf [https://perma.cc/Q6X8-EHZ9]; Gwendolyn McClung, *Regulation of Genetically Engineered Microorganisms Under FIFRA, FFDCA, and TSCA*, *in* REGULATION OF AGRICULTURAL BIOTECHNOLOGY: THE UNITED STATES AND CANADA 85, 87–88 (2012), https://www.academia.edu/78986455 [https://perma.cc/ZJR5-RMS8].

144 *Considerations for Drug Products That Contain Nanomaterials*, FDA, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/considerations-drug-products-contain-nanomaterials [https://perma.cc/CX5G-TMXC].

145 *See* 40 C.F.R. § 704.20 (2025); *Control of Nanoscale Materials Under the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY (Aug. 8, 2025), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under [https://perma.cc/6F5S-VF6P].

146 *See The Consumer Product Safety Improvement Act (CPSIA)*, U.S. CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/Regulations-Laws—Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act (last visited Mar. 28, 2026) [https://perma.cc/F7U9-MCMC] (amended several times, including a massive update through the Consumer Product Safety Improvement Act 28).

147 Jean C. Buzby, *Nanotechnology for Food Applications: More Questions Than Answers*, 44 J. CONSUMER AFF. 528, 540 (2010).

Administration (OSHA) also play crucial roles in regulating nanotechnology in the food industry.[148]

The primary food regulatory agency in the United States is the FDA, established under the Department of Health and Human Services.[149] The FDA regulates drugs, cosmetics, medical services, veterinary products, and other areas related to public health.[150] Its responsibilities include ensuring the safety and security of public health by overseeing biological products, medical devices, food supplies, and cosmetics. Additionally, the FDA promotes public health by encouraging advancements that make foods and medications more safe, effective, and cost-efficient. Moreover, the FDA educates the public with accurate, fact-based guidance on using foods and medications to improve well-being.[151] The FDA is the primary agency responsible for assessing the safety of food nanomaterials and constructing regulatory protocols for their beneficial transactions.[152] More precisely, the functions of the FDA—including the governance of nanomaterials in food—encompass the creation of regulatory framework and guidance documents, the performance and monitoring of safety assessment processes, the initiation and conveyance of research and collaboration, the organization of public communication, and ensuring transparency. Any ingredients, including nanomaterials, used as a food additive require a premarket approval certificate from the FDA.[153] To obtain a premarket approval certificate, manufacturers must submit a Food Additive Petition to the FDA.

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148 Xiaojia He et al., *Regulation and Safety of Nanotechnology in the Food and Agriculture Industry*, *in* FOOD APPLICATIONS OF NANOTECHNOLOGY 517, 524 (Gustavo Molina et al. eds., 2019).

149 *FDA Organization*, FDA, https://www.fda.gov/about-fda/fda-organization (last visited Mar. 28, 2026) [https://perma.cc/DP9Y-Q354].

150 *What We Do*, FDA, https://www.fda.gov/about-fda/what-we-do (last visited Mar. 28, 2026) [https://perma.cc/DU78-KR6F].

151 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99 (1938) (amended by Food Additives Amendment of 1958).

152 FDA, *FDA's Approach to Regulation of Nanotechnology Products*, https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products (last visited Mar. 28, 2026) [https://perma.cc/7BZC-H5L4]; Singh, R. & Kumar, S., *FDA/EFSA – Regulatory and Safety Concerns Regarding the Use of Active Nanomaterials in Food Industry*, FOOD COMPLIANCE (Aug. 30, 2023), https://foodcomplianceinternational.com/industry-insight/scholarly-articles/3684-fda-efsa-regulatory-and-safety-concerns-regarding-the-use-of-active-nanomaterials-in-food-industry [https://perma.cc/4UKC-M3EE].

153 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348 (1938).

The FDA also requires that the manufacturers submit a Food Contact Notification. Through this process, the FDA ensures that the informed chemical is safe for its intended use.[154] The FDA makes guidelines available to industry stakeholders to help them understand regulatory issues with nanoparticles. The FDA assists industry stakeholders in comprehending the effects of major modifications to the production process, including cutting-edge technologies like nanotechnology, on the safety and legal status of chemicals that come into contact with food and its constituents.[155] The FDA carries out and funds research to comprehend the properties and actions of nanoparticles in food.[156] This public agency collaborates with federal agencies, such as the National Institute of Standards and Technology, to share knowledge and resources.[157] The FDA also works with international organizations, such as the World Health Organization (WHO) and the European Food Safety Authority (EFSA), to harmonize research efforts and regulatory standards.[158] The FDA also arranges public consultation by engaging stakeholders, including consumers, industry representatives, and academic researchers.

The Environmental Protection Agency (EPA) is a U.S. federal agency established to protect humans and the environment from potential health risks, to conduct research, and to implement ecology-based regulations.[159] The EPA has primarily based its authority on two crucial legislations: the Toxic Substances Control Act of 1976 (TSCA)

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154 Onyeaka et al., *supra* note 1, at 771.

155 Valeria Amenta et al., *Regulatory Aspects of Nanotechnology in the Agri/feed/food Sector in EU and Non-EU Countries*, 73 REGUL. TOXICOLOGY & PHARMACOLOGY, 463, 469 (2015); Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives, 79 Fed. Reg. 36533 (June 27, 2014).

156 *Center for Food Safety and Applied Nutrition Nanotechnology Programs*, FDA, https://www.fda.gov/science-research/nanotechnology-programs-fda/center-food-safety-and-applied-nutrition-nanotechnology-programs (last visited Mar. 28, 2026) [https://perma.cc/8E2M-XH6D].

157 U.S. FOOD & DRUG ADMIN., NANOTECHNOLOGY—OVER A DECADE OF PROGRESS AND INNOVATION: A REPORT BY THE U.S. FOOD AND DRUG ADMINISTRATION (July 2020), https://www.fda.gov/media/140395/download [https://perma.cc/2BC2-QKUM].

158 *Nanotechnology Programs at FDA*, FDA, https://www.fda.gov/science-research/science-and-research-special-topics/nanotechnology-programs-fda (last visited Mar. 28, 2026) [https://perma.cc/MH6X-7JK4].

159 *See Our Mission and What We Do*, U.S. ENV'T PROT. AGENCY (Oct. 20, 2025), https://www.epa.gov/aboutepa/our-mission-and-what-we-do [https://perma.cc/FMM6-L2GK] (describing the EPA's role in protecting human health and the environment through research, regulation, and enforcement).

and the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA).[160] In the context of regulating nanotechnology in food, the EPA under FIFRA assesses and authorizes pesticides using nanoparticles, ensuring they do not pose unreasonable risks to human health or the environment.[161] The EPA also assesses nanomaterials under the TSCA, where manufacturers must submit detailed information about their properties, uses, and potential risks.[162] This includes evaluating the environmental impact, persistence, and bioaccumulation of these nanomaterials.[163] Furthermore, the EPA contributes to research initiatives and develops guidelines to comprehend and control the threats related to nanomaterials.[164] The EPA also conducts studies on the environmental fate of nanomaterials to assess their potential to contaminate soil, water, and air.[165]

The Food Safety and Inspection Service (FSIS) is an agency of the United States Department of Agriculture (USDA) that ensures public

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160 Toxic Substances Control Act, 15 U.S.C. §§ 2601–2697 (2022) (originally enacted in 1976, this Act authorizes the EPA to regulate the manufacturing, processing, distribution, use, and disposal of chemical substances); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136(y) (2022) (originally enacted in 1947; this Act empowers the EPA to oversee the registration, distribution, sale, and use of pesticides to prevent unreasonable risks to human health and the environment in the United States); *Summary of the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY (Aug. 25, 2025), https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act [https://perma.cc/PUL5-AC6C] (explaining the TSCA's scope and the EPA's authority to require reporting, testing, and restrictions); *EPA History: Federal Insecticide, Fungicide and Rodenticide Act*, U.S. ENV'T. PROT. AGENCY (Nov. 6, 2025), https://www.epa.gov/history/epa-history-federal-insecticide-fungicide-and-rodenticide-act [https://perma.cc/S2RH-ZQ2S] (describing FIFRA's evolution and the EPA's role in pesticide regulation).

161 Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136(y) (2022) (authorizing the EPA to regulate the sale, distribution, and use of pesticides, including those with nanoscale ingredients, to prevent "unreasonable adverse effects" on human health and the environment); *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act*, U.S. ENV'T PROT. AGENCY (Apr. 25, 2025), https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act [https://perma.cc/XC4V-CSRH] (explaining that the EPA must determine whether a pesticide "will not generally cause unreasonable adverse effects on the environment" before registration).

162 *Control of Nanoscale Materials Under the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under [https://perma.cc/BGS9-ZQXN] (last visited Mar. 28, 2026).

163 Toxic Substances Control Act, 15 U.S.C. §§ 2601–2697 (2022) (authorizing the EPA to require reporting, testing, and restrictions on chemical substances, including nanoscale forms, to prevent unreasonable risks to health and the environment).

164 *Research on Nanomaterials*, U.S. ENV'T PROT. AGENCY (Jun. 3, 2025), https://www.epa.gov/chemical-research/research-nanomaterials [https://perma.cc/5LBT-FZPK].

165 *Id.*

health by preventing diseases caused by meat, poultry, and egg products.[166] It is a science-based central inspection authority focusing on food safety and defense.[167] Although the FSIS does not have rules devoted exclusively to nanomaterials, it is responsible for ensuring that any new technology, including the use of nanoparticles, conforms with current food safety laws. The FSIS generally assesses the safety and efficacy of substances including nanomaterials employed during food processing, packaging, and additive use.[168] Moreover, the FSIS evaluates its coherence with existing food safety standards if any new technology is applied.[169] Through inspections, the FSIS ensures that introducing nanomaterials does not compromise the safety and quality of the food products under its jurisdiction.[170]

The Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Consumer Product Safety Commission (CPSC) comprise three fundamental U.S. national bodies that have distinct roles of ensuring the safety of different sectors, including the safety of the domain of nanomaterials in food.[171] OSHA and NIOSH primarily focus on worker safety, while the CPSC is concerned with consumer safety.[172] In the context of nanotechnology, OSHA is empowered to frame rules and regulations to safeguard workers from feasible threats of hazards associated with nanomaterials.[173] The regulations protect workers who

166 Buzby, *supra* note 147, at 540.

167 *See generally FSIS Protects Public Health by Preventing Illness from Meat, Poultry, and Egg Products*, FOOD SAFETY & INSPECTION SERV., https://www.fsis.usda.gov/about-fsis [https://perma.cc/79LH-Q3QB] (last visited Dec. 30, 2025).

168 *Food Safety Assessment Methodology – Revision 6*, FOOD SAFETY & INSPECTION SERV., https://www.fsis.usda.gov/policy/fsis-directives/5100.1 [https://perma.cc/MYJ5-3FR3] (last visited Mar. 28, 2026).

169 U.S. DEP'T OF AGRIC. FOOD SAFETY AND INSPECTION SERV., FOOD SAFETY AND FOOD SECURITY: WHAT CONSUMERS NEED TO KNOW (Sept. 2003), https://www.sbcounty.gov/uploads/dph/EHS/Documents/USDA-FSIS-What-Consumers-Need-to-Know.pdf [https://perma.cc/4GKA-V2A8].

170 Fred Fung, Huei-Shyong Wang & Suresh Menon, *Food Safety in the 21st Century*, 42 BIOMEDICAL J. 88, 88–95 (2018).

171 *Working Safely with Nanomaterials*, OCC. SAFETY & HEALTH ADMIN., https://www.osha.gov/sites/default/files/publications/OSHA_FS-3634.pdf (on file with the Oregon Review of International Law); *Nanotechnology Research Center*, NAT'L INST. OCC. SAFETY & HEALTH & CTRS. OF DISEASE CONTROL & PREVENTION, https://www.cdc.gov/niosh/centers/nanotechnology.html [https://perma.cc/2DYA-4KV7] (last visited Mar. 28, 2026); *2019 CPSC Nanomaterial Statement*, CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/s3fs-public/CPSC-Nanomaterial-Statement-final-10-7-19.pdf?MIogdiCH9NCngHES1iCAwC2ce6RiVkK0 [https://perma.cc/E36P-VNVS] (last visited Mar. 28, 2026).

172 OCC. SAFETY & HEALTH ADMIN., *supra* note 171.

173 *Id.* at 1–3.

work with nanomaterials during food production, processing, and packaging.[174] Conversely, NIOSH conveys scientific research with nanotechnology industries and recommends how to prevent work-related diseases and injuries.[175] Against this backdrop, NIOSH researches the potential occupational health risks associated with engineered nanomaterials, including those used in food production and processing. NIOSH guides employers and workers on best practices for handling nanomaterials in the workplace, including risk assessment, exposure monitoring, and control measures to minimize potential health hazards.[176] It is worth noting that the scientific studies completed by NIOSH are based on regulations set by OSHA.[177] The CPSC is primarily responsible for ensuring the safety of consumers from risks associated with consumer products.[178] Consumer safety can be achieved through implementing safety standards, conducting research, and providing consumer information.[179] While the CPSC primarily focuses on consumer products, its connection with engineered

174 Xiaojia He et al., *supra* note 148.

175 Rosemary K. Sokas et al., *Recognizing and Preventing Occupational and Environmental Disease and Injury*, *in* PREVENTING OCCUPATIONAL DISEASE AND INJURY (7th ed. 2017).

176 Eileen D. Kuempel, *NIOSH Risk Assessment of Engineered Nanomaterials*, U.S. CTRS. OF DISEASE CONTROL & PREVENTION (June 3, 2024), https://www.cdc.gov/niosh/bulletin/2024/nano_20_risk.html [https://perma.cc/VP7T-ABDT]; OCC. SAFETY & HEALTH ADMIN., *supra* note 171, at 1–3; ENERGY FACILITY CONTRACTOR'S GROUP, BEST PRACTICE #267: UNBOUND ENGINEERED NANOPARTICLES (UNPS) GUIDANCE DOCUMENT, 1, 4–7 (2016), https://efcog.org/wp-content/uploads/Wgs/Safety%20Working%20Group/Best%20Practices/Worker%20Safety%20%20Health/Industrial%20Hygiene%20-%20Safety/BP%20267%20UNBOUND%20ENGINEERED%20NANOPARTICLES%20%28UNP%29%20Guide.pdf.

177 *NIOSH Health Hazard Evaluation Program*, U.S. DEP'T OF LABOR OCC. SAFETY & HEALTH ADMIN., https://www.osha.gov/complianceassistance/hhe-program [https://perma.cc/7VFL-4U87] (last visited Mar. 28, 2026); *OSHA Standards Development*, U.S. DEP'T OF LABOR OCC. SAFETY & HEALTH ADMIN., https://www.osha.gov/laws-regs/standards-development [https://perma.cc/W6TL-T54M] (last visited Mar. 28, 2026).

178 *Regulations, Laws & Standards*, CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/Regulations-Laws--Standards (on file with the Oregon Review of International Law). *See Duty to Report to CPSC: Rights and Responsibilities of Businesses*, CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/Duty-to-Report-to-the-CPSC-Your-Rights-and-Responsibilities [https://perma.cc/7DX5-ZPUT] (last visited Mar. 28, 2026).

179 *See generally FDA's Approach to Regulation of Nanotechnology Products*, U.S. FOOD & DRUG ADMIN. (Mar. 23, 2018), https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products https://perma.cc/6LYA-QW9B]; *Nanotechnology Guidance Documents*, U.S. FOOD & DRUG ADMIN. (Mar. 23, 2018), https://www.fda.gov/science-research/nanotechnology-programs-fda/nanotechnology-guidance-documents [https://perma.cc/6LV6-7N8A].

nanomaterials in food relates to ensuring the safety of packaging materials containing nanomaterials.[180]

The National Nanotechnology Initiative (NNI) and FDA Nanotechnology Task Force are two key and complementary initiatives with momentous roles in promoting and regulating nano-based technology within U.S. regions.[181] The NNI is a research and development initiative that provides a framework for coordinating nanoscale research and resources among various U.S. federal government agencies and departments.[182] The NNI's goal is to ensure nanotechnology's safe and effective use in FDA-regulated products.[183] Through the NNI, the United States is the "first nation to establish governmental initiatives towards nanoscale research."[184] The NNI task force focuses on risk assessment, regulatory guidance, interagency collaboration, stakeholder engagement, research, and education.[185] By addressing nanomaterials' unique challenges and opportunities in food, the task force helps protect public health while promoting innovation in the food industry.

While several public institutions are contributing to novel food regulation in the United States, the United States does not have any legislation that specifically deals with the issues related to ENMs. However, the issues of ENMs in food may relate to some provisions of existing legislation in the United States. Amongst this legislation, the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), the Food Additives Amendment Act of 1958, and the Toxic Substances Control Act of 1976 are noteworthy.[186] The other laws that could be related to

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180 Md Abdus Subhan & Tahrima Subhan, *Safety and Global Regulations for Application of Nanomaterials*, *in* NANOMATERIALS RECYCLING 83, 94 (Mahendra Rai & Tuan Anh Nguyen eds., 2022).

181 *About the National Nanotechnology Initiative (NNI)*, NAT'L NANOTECHNOLOGY COORDINATION OFF., https://www.nano.gov/about-nni/ (last visited Mar. 28, 2026).

182 *National Nanotechnology Initiative*, NAT'L NANOTECHNOLOGY COORDINATION OFF., https://www.nano.gov/national-nanotechnology-initiative/ [https://perma.cc/FTV9-4CQT] (last visited Mar. 28, 2026).

183 *Nanotechnology Task Force*, U.S. FOOD & DRUG ADMIN. (Mar. 12, 2024), https://www.fda.gov/science-research/nanotechnology-programs-fda/nanotechnology-task-force [https://perma.cc/V7BN-LY85].

184 C. Ramkumar, Angadi Vishwanatha & Rahul Saini, *Regulatory Aspects of Nanotechnology for Food Industry*, *in* NANOTECHNOLOGY APPLICATIONS IN DAIRY SCIENCE 169, 178 (2019).

185 NAT'L NANOTECHNOLOGY COORDINATION OFF., *supra* note 182.

186 *The 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), https://www.fda.gov/about-fda/histories-product-regulation/1938-food-drug-and-cosmetic-act [https://perma.cc/99B2-DZFL]; Food Additives Amendment of 1958, H.R.

these issues would be the Federal Meat Inspection Act of 1906, the Poultry Products Inspection Act of 1957, the Egg Products Inspection Act of 1970, the Occupational Safety and Health Act of 1970, and the Consumer Product Safety Act of 1972.[187]

The FFDCA prohibits the adulteration or misbranding of any food.[188] On the other hand, the Food Additives Amendment Act mandates that food manufacturers ensure that products are protected from being contaminated by hazardous substances.[189] The Food Additives Amendment Act requires a rigorous premarket approval process in case any external substance, including a nanomaterial, is intended for use in food.[190] The premarket approval process is initiated by submitting a food additive petition to the FDA.[191] The premarket approval process is initiated by submitting a food additive petition to the FDA. Once that petition is approved, the entrepreneurs can submit that premarket approval application to the FDA. The FDA then reviews the application and, if approved, issues new regulation.[192]

Manufacturers and other interested parties are authorized to submit the petition.[193] The PMA petition must be accompanied by the necessary data representing the safety of the nanomaterials used for food additives, including detailed information on the chemical identity

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13254, 85th Cong. (1957–1958); *Summary of the Toxic Substances Control Act*, U.S. ENV'T. PROT. AGENCY (Feb. 23, 2026), https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act [https://perma.cc/ABG8-BJ3C].

187 *See generally Federal Meat Inspection Act*, 21 U.S.C. §§ 601–695 (2025); *Poultry Products Inspection Act*, 21 U.S.C. §§ 451–472 (2025), https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act [https://perma.cc/W599-H7JM]; *Egg Products Inspection Act*, 21 U.S.C. §§ 1031–1056 (2025), (summarized at 9 C.F.R. §§ 412–500 (2026)); *Occupational Safety and Health Act of 1970*, 29 U.S.C. §§ 651–678 (2025); *Consumer Product Safety Act of 1972*, 15 U.S.C. §§ 2051–2089 (2025).

188 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348 (1938).

189 H.R. 13254, 85th Cong. (1958).

190 U.S. Food & Drug Admin., *Safety Evaluation of Food Contact Substances Containing Nanomaterials*, 4 (Oct. 11, 2022), https://www.fda.gov/media/166988/download [https://perma.cc/6748-6NUR].

191 H.R. 13254, 85th Cong. (1958); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 409(b)(1)–(2) (1938).

192 *See* 21 C.F.R. § 814.20 (2024); 21 C.F.R. §§ 814.40–814.45 (2024) (outlining FDA's review procedures, panel involvement, and approval or denial process); U.S. Food & Drug Admin., *Premarket Approval (PMA)*, FDA (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma [https://perma.cc/KY2L-LHHU].

193 *Guidance for Industry: Questions and Answers About the Food Additive or Color Additive Petition Process*, FDA (Sept. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-about-food-additive-or-color-additive-petition-process [https://perma.cc/WV37-MAW2].

and composition of the additives, the method of producing and processing the additives, safety information, labeling data, etc.[194] Once the petition is accepted, the FDA starts its review process, which involves administrative review, scientific evaluation, and expert opinions.[195] Administrative scrutiny mainly verifies the petition requirements. The Center for Food Safety and Applied Nutrition (CFSAN) evaluates the petition scientifically. That process involves toxicological information, exposure levels, and the potential impacts of the additives.[196] The toxicological review assesses the safety data to evaluate the probable health risk. This is followed by exposure assessment, which determines the certainty of human exposure to the additive. Eventually, the risk assessment process fuses the toxicological data and exposure assessment report to calculate the total risk, and to establish whether additives are safe for their intended application.[197] After completing the review process, the FDA determines the issuance of the regulation.[198] When the FDA determines that an additive is safe for its intended application, the FDA issues a regulation outlining the specific, approved uses for that additive. Conversely, if the additive is unsafe, or the petition does not provide sufficient evidence of safety, the FDA can deny the petition.[199]

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194 Food Additive Petitions, 21 C.F.R. § 171 (2025).

195 *See* 21 C.F.R. § 10.30(e) (2024) (mandating FDA response timelines for citizen petitions); 21 C.F.R. § 10.70(a) (2024) (describing the contents of the administrative file, including scientific evaluations and expert input); Mukesh Kumar, *Resolving Scientific Disputes with FDA: Regulatory Processes and Practical Tips*, 23 (2024), https://fdamap.com/wp-content/uploads/2025/03/dispute_resolution_with_fda.pdf [https://perma.cc/FP8F-W5ZE]; *Product Application and Petition Review Process*, FDA (Feb. 20, 2025), https://www.fda.gov/industry/fda-basics-industry/product-application-and-petition-review-process [https://perma.cc/L5ZK-QNVY].

196 *See generally FDA-TRACK: Human Foods Program – Pre-market Review*, FDA (Feb. 19, 2026), https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-center-food-safety-and-applied-nutrition-pre-market-review [https://perma.cc/AV2M-SQXR]; Peter Pressman et al., *Food Additive Safety: A Review of Toxicologic and Regulatory Issues*, 1 TOXICOLOGY RSCH. & APPLICATION 1, 3–7 (2017).

197 *See Risk and Safety Assessments (Food)*, FDA (June 6, 2024), https://www.fda.gov/food/science-research-food/risk-and-safety-assessments-food [https://perma.cc/8DJP-AQR3]; *Evaluating the Safety of Direct Food Additives*, FOOD SAFETY INST. (June 15, 2024), https://foodsafety.institute/food-toxicology-public-health/evaluating-safety-direct-food-additives [https://perma.cc/QFN5-536L].

198 *FDA Rules and Regulations*, FDA, https://www.fda.gov/regulatory-information/fda-rules-and-regulations [https://perma.cc/Z3V4-FZ7C] (last visited Mar. 28, 2026).

199 H.R. 13254, 85th Cong. (1958).

The Food Additives Amendment of 1958 launched the idea of food additives being Generally Recognized as Safe (GRAS).[200] All additives introduced after the Amendment need to be assessed using the new criteria.[201] The GRAS status supports the idea that any substance intentionally added to food is considered a food additive and thus requires premarket review and approval by the FDA.[202] However, if qualified experts generally consider a substance to be safe for its intended use, the substance is exempt from FDA review.[203] A GRAS determination can be self-affirmed, or qualified nongovernmental experts can notify the FDA.[204] Regardless of whether the GRAS determination is derived from self-affirmation or expert opinion, the recognition process must be based on scientific evidence.[205] Sometimes, the process involves rigorous review and often includes detailed safety assessments to account for the unique properties of food containing nanomaterials.[206] The manufacturer may self-determine that a substance is GRAS for its intended application. That conclusion must be based on the opinions of certified experts trained to assess the safety of additives used in food.[207] Manufacturers may voluntarily notify the FDA of their GRAS self-determination by submitting a GRAS notice. The FDA evaluates the GRAS notice to ascertain whether the self-determination is based on sound scientific evidence and expert consensus.[208]

The Toxic Substances Control Act of 1976 (TSCA) is primarily responsible for governing "the production, importation, use, and

200 *How U.S. FDA's GRAS Notification Program Works*, FDA (Feb. 9, 2018), https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works#authors [https://perma.cc/L4K4-ND8R].

201 *Understanding How FDA Regulates Food Additives and GRAS Ingredients*, FDA (June 6, 2024), https://www.fda.gov/food/food-additives-and-gras-ingredients-information-consumers/understanding-how-fda-regulates-food-additives-and-gras-ingredients [https://perma.cc/62AW-5ZKG].

202 *Generally Recognized as Safe (GRAS)*, FDA (Oct. 17, 2023), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras [https://perma.cc/NLU8-4L9N].

203 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348 (1938).

204 FDA, *supra* note 201.

205 FDA, *supra* note 202; *Guidance for Industry: Best Practices for Convening a GRAS Panel*, FDA (Dec. 20, 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-best-practices-convening-gras-panel [https://perma.cc/3Z27-BK2S].

206 FDA, *supra* note 205.

207 H.R. 13254, 85th Cong. § 21 (1958).

208 FDA, *supra* note 202.

disposal of chemical substances, including nanomaterials, in the United States." Although food regulation is not the explicit purpose of the TSCA, its regulations may influence nanomaterials that end up in food-related applications.[209] Under the TSCA, any new chemical substance, including nanomaterials, must undergo a pre-manufacture notification process before it can be manufactured or imported into the United States.[210] The applicant submits information to the EPA about the chemical's properties, production volume, intended use, and potential health and environmental impacts.[211] A premanufacture notice (PMN) must be presented to the EPA by manufacturers or importers at least ninety days before the beginning of their intended manufacture or import of a new chemical substance not included on the TSCA Inventory.[212] The EPA evaluates the PMN during the ninety-day review period to determine whether the chemical compound poses an unreasonable risk.[213]

If the EPA detects any probable threats, it can settle with the notifier to implement a consent order that sets out prohibitions or supplementary requisites for handling those risks.[214] In contrast, for existing chemicals, if a nanomaterial is intended to be used in a way that is significantly different from its previously reported uses, the EPA

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209 Bergeson, *supra* note 143, at 617.

210 *Control of Nanoscale Materials Under the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY (Aug. 8, 2025), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under [https://perma.cc/9UPC-9FKU]; *Filing a Pre-manufacture Notice with EPA*, U.S. ENV'T PROT. AGENCY (Sept. 23, 2025), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa [https://perma.cc/7X2D-82FZ].

211 *TSCA Inventory Status of Nanoscale Substances–General Approach*, U.S. ENV'T PROT. AGENCY (Jan. 23, 2008), https://www.epa.gov/tsca-inventory/nanoscale-substances-tsca-inventory [https://perma.cc/ZU9V-59M5]; Alex Stanton & Jim Alwood, *TSCA 101: What to Expect for Your Nanomaterial Submittal*, U.S. ENV'T PROT. AGENCY 3–7 (Feb. 27, 2022), https://cdn.ymaws.com/www.thegraphenecouncil.org/resource/resmgr/webinars/2023-02_epa/EPA-Graphene_Council_Februar.pdf [https://perma.cc/4TXM-RWE4].

212 U.S. ENV'T PROT. AGENCY, supra note 210 ("Anyone who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose is required to submit a pre-manufacture notice (PMN) at least 90 days prior to the manufacture of the chemical."); Ryan W. Trail, *EPA Issues TSCA PMN Guidance: Pointers for Submitters*, WILLIAMS MULLEN (Oct. 1, 2018), https://www.williamsmullen.com/insights/news/legal-news/epa-issues-tsca-pmn-guidance-pointers-submitters [https://perma.cc/6HPJ-XJYT].

213 Trail, *supra* note 212.

214 *See* 40 C.F.R. § 720.22(a) (2024) ("Any person who intends to manufacture or import a new chemical substance for a non-exempt commercial purpose must submit a notice to EPA at least 90 days before commencing manufacture or import.").

can issue a Significant New Use Rule (SNUR).[215] This requires manufacturers to notify the EPA before commencing the new use, allowing the agency to assess potential risks.[216] If a SNUR covers a chemical, anyone who plans to produce, import, or process it for a specified substantial new use must notify the EPA at least ninety days before the planned new use by submitting a Substantial New Use Notice.[217] New chemical compounds, such as nanomaterials, need a Pre-Manufacture Notification (PMN).[218] The EPA assesses the distinct qualities and possible hazards connected to nanoparticles, which may differ from those of their bulk equivalents.[219] However, for nanomaterials already listed on the TSCA Inventory, the EPA has the authority to issue SNURs, which must be reviewed before new uses are implemented.[220]

The primary objective of the TSCA risk assessments is to ascertain whether a chemical material poses an excessive risk of harm to the environment or human health.[221] The evaluation process encompasses testing chemical substances and mixtures and regulating hazardous chemicals.[222] The EPA is responsible for developing processes to

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215 Significant New Uses of Chemical Substances, 40 C.F.R. § 721.

216 *See* 15 U.S.C. § 2604(a)(1)(B) (2022) (authorizing EPA to require notification for significant new uses of existing chemical substances); 40 C.F.R. § 721.1(c) (2024) (defining "significant new use" and outlining EPA's authority to issue SNURs).

217 *Filing a Significant New Use Notice (SNUN) Under TSCA*, U.S. ENVTL. PROT. AGENCY (Dec. 22, 2025), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-significant-new-use-notice [https://perma.cc/9YH2-PE73] ("Under section 5(a) of TSCA and 40 CFR part 721, if EPA promulgates a Significant New Use Rule (SNUR), a manufacturer or processor wishing to engage in a designated significant new use must submit a Significant New Use Notice (or 'SNUN') to EPA at least 90 days before engaging in the new use.").

218 U.S. ENV'T PROT. AGENCY, *supra* note 210.

219 *Fact Sheet: Nanoscale Materials*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/fact-sheet-nanoscale-materials [https://perma.cc/N5V5-ZTGB] (last visited Oct. 25, 2025); *Exposure Assessment Tools by Chemical Classes – Nanomaterials*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-nanomaterials [https://perma.cc/QQW3-NQG6] (last visited Mar. 28, 2026); U.S. ENV'T PROT. AGENCY, *supra* note 164.

220 Substances Control Act (TSCA) § 5(a)(2), 15 U.S.C. § 2604(a)(2) (authorizing EPA to determine that a use of a chemical substance is a "significant new use" and to require submission of a notice before manufacturing/processing for that use).

221 Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74292 (Oct. 30, 2023) (to be codified at 40 C.F.R. pt. 702).

222 *Assessing and Managing Chemicals Under TSCA*, U.S. ENV'T. PROT. AGENCY, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca (last visited Mar. 28,

assess and mitigate risks to human health and the environment posed by "new chemicals" (i.e., chemicals not yet on the market) and "existing chemicals."[223] Furthermore, in the context of nanomaterials intended for use in food, the EPA can conduct risk evaluations to detect whether nanomaterials present an unreasonable risk to health or the environment under the conditioned use.[224] The EPA has the authority to impose restrictions or prohibitions on the production, processing, distribution, or disposal of nanoparticles used in food if it discovers any possible risks arising from such.[225]

The Pure Food and Drug Act of 1906 created and empowered the FDA to regulate food safety.[226] The United States Department of Agriculture (USDA), created by legislation of Congress in 1862, supports and promotes the interests of American agriculture.[227] These two organizations primarily govern the Hazard Analysis Critical Control Points (HACCP) system created by the U.S. government.[228] The FDA oversees HACCP regulations for seafood and juice products under the Federal Food, Drug, and Cosmetic Act (FD&C Act).[229] The USDA regulates HACCP systems for meat, poultry, and processed egg

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2026); *Risk Evaluations for Existing Chemicals Under TSCA*, U.S. ENV'T. PROT. AGENCY, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca [https://perma.cc/KJB8-RVFZ] (last visited Mar. 28, 2026).

223 Swati DG Rayasam et al., *Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States*, 56 ENV'T SCI. & TECH. 11969, 11970 (2022).

224 U.S. ENV'T. PROT. AGENCY, *supra* note 143.

225 *Id.*

226 *Part I: The 1906 Food and Drugs Act and Its Enforcement*, FDA (Apr. 24, 2019), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement [https://perma.cc/4YX2-FRVD]; *The Pure Food and Drug Act*, U.S. CAPITOL VISITOR CTR., https://www.visitthecapitol.gov/exhibitions/congress-and-progressive-era/pure-food-and-drug-act [https://perma.cc/E9XD-WRTR] (last visited Mar. 28, 2026); *Pure Food and Drugs*, NAT'L LIBRARY OF MED., https://www.nlm.nih.gov/exhibition/phs_history/foodanddrugs.html [https://perma.cc/3LZH-5TLU] (last visited Oct. 25, 2025).

227 *USDA Celebrates 150 Years*, U.S. DEP'T OF AGRIC., https://www.usda.gov/about-usda/general-information/usda-celebrates-150-years [https://perma.cc/4888-XT5V] (last visited Mar. 28, 2026); Megan Slack, *From the Archives: President Abraham Lincoln Creates the Department of Agriculture*, WHITE HOUSE (May 15, 2012), https://obamawhitehouse.archives.gov/blog/2012/05/15/archives-president-abraham-lincoln-creates-department-agriculture [https://perma.cc/PS9P-6WGG].

228 HACCP regulations for FSIS are codified in Hazard Analysis and Critical Control Point (HACCP) Systems, 9 C.F.R. Pt. 417 (2026).

229 *Hazard Analysis Critical Control Point (HACCP)*, FDA (Feb. 25, 2022), https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/hazard-analysis-critical-control-point-haccp [https://perma.cc/WQ4B-69XF] (explaining FDA's role in implementing HACCP regulations for seafood and juice products under the FD&C Act).

products under the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) systems final rule, codified in 9 CFR § 417.[230]

HACCP[231] is a system based precautionary modality designed to ensure food safety from "biological, chemical, and physical hazards in production processes."[232] The HACCP system can be applied throughout the food supply chain, from production and preparation to packaging and distribution.[233] Although the system does not explicitly govern nanoparticles in food, HACCP guidelines may be used to ensure that these materials are safely introduced into the food supply chain.[234] The HACCP system is based on seven systematic principles that are used to identify, assess, and control risks associated with food safety: "(1) Conduct a hazard analysis, (2) Determine the critical control points (CCPs), (3) Establish critical limits, (4) Establish monitoring procedures, (5) Establish corrective actions, (6) Establish verification procedures, and (7) Establish record-keeping and documentation procedures."[235]

A hazard analysis (Principle 1) aims to create a list of hazards likely to result in harm or disease if they are not appropriately managed.[236] The aspects taken into consideration during the analysis include the skill level of employees, the high degree of food handling and contact, etc.[237] The following phase is to ascertain whether the factors might

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230 *Guidebook for Preparation of HACCP Plans*, USDA FOOD SAFETY & INSPECTION SERV., https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Guidebook-for-the-Preparation-of-HACCP-Plans.pdf [https://perma.cc/4TA5-PZF8] (last visited on Mar. 28, 2026).

231 *HACCP Principles & Application Guidelines*, FDA (1997), https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines [https://perma.cc/Q4PV-DT4B].

232 *Id.*

233 *HACCP Principles and Application Guidelines*, U.S. FOOD & DRUG ADMN. https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines (last visited Oct. 25, 2025); FDA, *supra* note 231.

234 U.S. DEP'T OF AGRIC., *supra* note 233.

235 FDA, *supra* note 231.

236 *Id.*; 9 C.F.R. § 417.2 (2026).

237 *Conduct a Hazard Analysis - Step 6, Principle 1*, FOOD & AGRIC. ORG. OF THE U.N. (2023), https://openknowledge.fao.org/server/api/core/bitstreams/9ed4db66-c4d0-46fb-8f20-2b5ca6e33cb4/content [https://perma.cc/22SU-PRU8] (describing how hazard analysis evaluates food contact and operational risks); *Understanding HACCP Principle 1: Conduct a Hazard Analysis*, SGS (July 7, 2025), https://www.sgs.com/en-ae/news/2025/07/understanding-haccp-principle-1-conduct-a-hazard-analysis [https://perma.cc/3Q4K-X3L8] (listing biological, chemical, and physical hazards in food production).

affect the severity and likelihood of the danger that has to be controlled.[238] In food production, a critical control point (Principle 2) is a phase when control can be deployed and, thereby, a food safety hazard averted, removed, or lowered to an acceptable level.[239] CCPs can take the following forms: "thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing products for metal contaminants."[240] A critical limit (CL) (Principle 3) is the highest and/or lowest value that a biological, chemical, or physical characteristic can have at a CCP in order to avoid, eradicate, or minimize the possibility of danger to food safety to a permissible degree.[241] Monitoring actions are required to ensure the process is under control at every crucial control point (Principle 4). The FSIS mandates in the United States, that the HACCP plan include a list of all monitoring procedures and their frequency.[242] Corrective actions (Principle 5) must be implemented if monitoring shows an excursion from a defined critical limit.[243] The verification procedure (Principle 6) describes actions taken, apart from monitoring, to determine if the HACCP plan is authentic and if the system functions as intended.[244] HACCP plan validation usually calls for two types of information: (1) scientific research and expert guidance and (2) in-plant observations, measurements, and assessments.[245] As the HACCP law mandates (Principle 7), all facilities must keep specific records. These records may include a hazard analysis, a written HACCP plan, documentation of monitoring critical control points and critical limits, verification activities, and management of processing deviations.[246]

C. The United Kingdom (UK)

The UK regulatory system employs a mixed approach based mainly on prescriptive and principles-based regulatory elements.[247] This

238 FOOD & AGRIC. ORG. OF THE U.N., *supra* note 237.

239 FDA, *supra* note 231.

240 *Id.* at 12.

241 *Id.*

242 9 C.F.R. § 417.2(c)(4) (2026) (HACCP plan must "list the procedures and frequency that will be used to monitor CCPs.").

243 *Id.*

244 *Id.*

245 *Id.*

246 9 C.F.R. § 417.2 (2026).

247 *New Approach to Ensure Regulators and Regulation Support Growth*, GOV. U.K. (2024), https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth/new-approach-to-ensure-regulators-and-regulation-support

combination framework allows flexibility and adaptability and ensures that regulatory frameworks can be tailored to specific sectors while maintaining high standards.[248] Post-Brexit, the UK has retained many EU regulations through the European Union (Withdrawal) Act of 2018 but has also introduced new regulatory principles to foster innovation, reduce red tape, and boost competition.[249] Although it is based on laws and stakeholder capacities, the UK's regulatory system is a comprehensive framework designed to ensure the proper functioning of various sectors and to protect public interests.[250] The UK framework encompasses various regulatory bodies overseeing specific areas such as finance, healthcare, environment, and education.[251] To regulate new technologies and novel foods, the UK has several laws, public institutions, and private bodies working together in any sector. The nano food industry is no exception to this.[252]

-growth-html [https://perma.cc/ZEZ4-G8SQ] (describing the UK's commitment to regulatory stability, predictability, and innovation); Tania Van den Brade, *Rules-Based Versus Principles-Based Regulation*, OFCOM (2024), https://www.ofcom.org.uk/about-ofcom/what-we-do/rules-versus-principles-based-regulation [https://perma.cc/96BL-G8RU] (exploring the trade-offs between prescriptive rules and flexible principles in UK regulatory design); Baker McKenzie, *UK Government Confirms Principles-Based Approach to Regulating AI*, CONNECTONTECH (2024), https://connectontech.bakermckenzie.com/uk-government-confirms-principles-based-approach-to-regulating-ai [https://perma.cc/P9PA-M9D2].

248 Christopher Decker, *Goals-Based and Rules-Based Approaches to Regulation*, *in* BEIS RSCH. PAPER 43–44 (2018).

249 Davor Jancic, *Regulatory Strings That Bind and the UK Parliament After Brexit*, 20 COMPAR. EUR. POL. 566, 567 (2022); Pedro Schilling de Carvalho, *Retaining Influence in Post-Brexit International Financial Regulation: Lessons from the UK's FinTech Framework*, 8 J. FIN. REGUL. 104, 107 (2022).

250 *Principles of Effective Regulation: A Summary Guide for Regulators and Policymakers*, NAT'L AUDIT OFF. 3–6 (2021), https://www.nao.org.uk/wp-content/uploads/2021/05/Principles-of-effective-regulation-interactive-accessible-Summary.pdf [https://perma.cc/MXK6-TUYU]; *New Approach to Ensure Regulators and Regulation Support Growth*, GOV. U.K. (2024), https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth/new-approach-to-ensure-regulators-and-regulation-support-growth-html [https://perma.cc/3PWG-434J]; Peter Lunt & Sonia Livingstone, *Regulation in the Public Interest*, 17 CONSUMER POL'Y REV. 4, 7 (2023).

251 Karen Yeung, *The Regulatory State, Regulatory Scholarship and Regulatory Space: Reflections on the UK Experience*, 30 L. & POL'Y 450, 460–63 (2008), https://doi.org/10.1111/j.1467-9930.2008.00289.x [https://perma.cc/G9RR-3YDV]; *United Kingdom: OECD Regulatory Policy Outlook 2025*, OECD, https://www.oecd.org/en/publications/oecd-regulatory-policy-outlook-2025_56b60e39-en/full-report/united-kingdom_6eb126ee.html [https://perma.cc/G9RR-3YDV] (last visited Mar. 28, 2026).

252 *Risk Assessment of Nanomaterials*, PARLIAMENTARY OFF. OF SCI. & TECH. (Oct. 2017), https://researchbriefings.files.parliament.uk/documents/POST-PN-0562/POST-PN-0562.pdf [https://perma.cc/TDU8-9YMV].

The regulatory instruments and agencies at the core of the UK's regulation of foods with ENMs include the Novel Foods Regulation (EU) 2015/2283, the Food Safety of Act 1990, and the Food Standard Agency.[253] The Section below discusses how these legislations and institutions affect the regulation of foods with ENMs.

In the UK, the definition of "nanoparticles" for regulatory purposes is primarily guided by the EU Recommendation 2011/696/EU, which has been retained in UK law post-Brexit. According to this recommendation, a nanomaterial is defined as a natural, incidental, or manufactured material containing particles in an unbound state or as an aggregate or agglomerate, where fifty percent or more of the particles in the number size distribution have one or more external dimensions in size range of 1 nm to 100 nm.[254] This definition is crucial for regulatory frameworks concerning the safety and use of nanomaterials in various sectors, including food, cosmetics, and medical devices.[255]

The Food Safety Act of 1990, which incorporates the comprehensive system of food safety and hygiene rules in compliance with EU regulations, is primarily responsible for implementing the UK's food safety standards.[256] Although an express provision to govern nanofood is absent, the scope of regulating nanomaterials and nanotechnology used in food or food-related products indicates the meaning of food, food additives, and food technologies. Concerning European Commission Regulation Number 178/2002, the Food Safety Act of 1990 defines food as involving "any substance or product, whether processed, partially processed or unprocessed, intended to be, or

253 Ritika Kumari et al., *Regulation and Safety Measures for Nanotechnology-Based Agri-Products*, 5 FRONT. GENOME ED. 1 (2023), https://www.frontiersin.org/articles/10.3389/fgeed.2023.1200987/full [https://perma.cc/LKA8-YAYU] (last visited Mar. 28, 2026); Alexandra Molitorisova and Kai Purnhages, *Regulatory Sandboxes for Novel Foods*, 14 EUR. J. RISK REGUL. 1063, 1063–1081(2023), https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/regulatory-sandboxes-for-novel-foods/D8A2B8E29D2F32DE0334DBCE9AF27188 [https://perma.cc/4278-C4C3] (last visited Mar. 28, 2026).

254 BOWMAN, *infra* note 403; Md Ershadul Karim et al., *Nanotechnology Within the Legal and Regulatory Framework: An Introductory Overview*, 3 MALAYAN L.J. 4 (2014).

255 *See generally Nanoscience and Nanotechnologies: Opportunities and Uncertainties - Two-year Review of Progress on Government Actions: Joint Academies' Response to the Council for Science and Technology's Call for Evidence*, ROYAL ACAD. OF ENG'G (Oct. 2006), https://raeng.org.uk/media/r5fdd4q1/nanoscience_nanotechnologies_response.pdf [https://perma.cc/64JF-FH5Y].

256 *UK Regulation After Brexit*, UK IN A CHANGING EUR. (2021), https://media.ukandeu.ac.uk/wp-content/uploads/2021/02/UK-regulation-after-Brexit.pdf https://perma.cc/RDS7-BGU8].

reasonably expected to be ingested by humans."[257] Since nanoscale-based components are categorized as substances under the broad definition of food, the Food Safety Act of 1990 can also be applied to regulate nanomaterials used in food.

The Act's definitions of "food" and "safety" allow it to encompass all substances, including nanomaterials, that may pose a risk to human health.[258] According to Section 8 of the Food Safety Act of 1990, adding any material—including nanomaterials—to food that might endanger human health is a serious offense.[259] This broad provision covers any potentially harmful effects of nanomaterials. The Act also prohibits the false or misleading description of food.[260] This includes ensuring that any use of nanomaterials is accurately described and not misleading to consumers.[261]

Local authorities enforce the Food Safety Act of 1990 at the ground level.[262] This involves checking food businesses to make sure safety regulations are followed. All facets of food safety are inspected, including the use of nanoparticles in food preparation and packaging.[263] The Act imposes strict penalties for noncompliance, including fines and imprisonment.[264] Food businesses that fail to meet safety standards for nanomaterials may face legal action, creating a strong incentive for compliance with food safety regulations.

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257 Council Directive 178/2002, art. 2, 2002 O.J. (L 31) 15 (EC).

258 The Food Safety Act of 1990, c. 16, §§ 7–8 (Eng.).

259 *Id.* § 8.

260 *Id.* § 15.

261 *See* Food Safety Act 1990, c. 16, §§ 14–16 (UK), https://www.legislation.gov.uk/ukpga/1990/16/contents [https://perma.cc/37C9-U2YM] (last visited Mar. 28, 2026); *Novel Foods Authorization Guidance*, FOOD STANDARDS AGENCY, https://www.food.gov.uk/business-guidance/novel-foods-authorisation-guidance [https://perma.cc/HJ9G-NAYG].

262 Food Safety (Enforcement Authority) (England and Wales) Order 1990, SI 1990/2462, https://www.legislation.gov.uk/uksi/1990/2462/contents/made [https://perma.cc/KB54-EEN7] (last visited Mar. 28, 2026); *Food Safety Inspections and Enforcement*, FOOD STANDARDS AGENCY, https://www.food.gov.uk/business-guidance/food-safety-inspections-and-enforcement [https://perma.cc/2D3Y-3BDH] (last visited Mar. 28, 2026).

263 *Food Law Practice Guidance 2025 (England)*, FOOD STANDARDS AGENCY, https://www.food.gov.uk/sites/default/files/media/document/Food%20Law%20Practice%20Guidance%20%28England%29.pdf [https://perma.cc/2E7J-JNDC]; Alan Williams, *First Evidence That Plastic Nanoparticles Can Accumulate in the Edible Parts of Vegetables*, UNIV. PLYMOUTH (Sept. 17, 2025), https://www.plymouth.ac.uk/news/first-evidence-that-plastic-nanoparticles-can-accumulate-in-the-edible-parts-of-vegetables [https://perma.cc/3WBY-AL33].

264 The Food Safety Act of 1990, c. 16, § 35 (Eng.).

Nanomaterials often fall under the category of novel foods. The Novel Foods Regulation (EU) 2015/2283, which still applies in the UK post-Brexit, mandates that any new food ingredient or technology, including nanomaterials, must undergo a safety assessment before it can be marketed.[265] Applying this law the UK is crucial to ensure that novel foods are safe before they enter the market. Post-Brexit, UK law has retained this regulation, ensuring continuity in the regulatory framework. Novel foods are defined as foods not significantly consumed by humans in the EU or UK before May 15, 1997. This includes newly developed foods, foods produced using new technologies, and foods traditionally consumed outside the EU.[266]

To place a novel food on the market in the United Kingdom, businesses must submit an application to the Food Standards Agency (FSA). The application must include comprehensive data on the safety, the composition, and the intended use of the novel food. After the application is received, the FSA conducts a thorough risk assessment to ensure that the novel food poses no health risks to consumers before it authorizes placing it on the market. There are two main routes for authorization: (1) the traditional food notification route, which applies to foods with a history of safe use outside the EU; and (2) the full application route, which applies to all other foods.[267]

In the UK, novel foods are governed by the Novel Foods (England) Regulations 2018. This legislation outlines the liabilities for food-producing and marketing companies and the agencies responsible for

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265 Food Standards Agency, *Annex Regulation (EU) 2015/2283 Novel Foods*, 327 OFF. J. EUR. UNION 1 (2015), https://www.food.gov.uk/sites/default/files/media/document/annexd_regulation_eu2015_2283.pdf [https://perma.cc/566P-PG2H] (describing safety assessment protocols and post-market monitoring for nanomaterials); *Revision of the Definition of Engineered Nanomaterials*, EUR. COMM'N (NOV. 17, 2023), https://food.ec.europa.eu/document/download/b0a8581e-aed6-44b5-a09e-68e5d9e80eeb_en?filename=adv-grp_plenary_20231117_pres-04.pdf&prefLang=et [https://perma.cc/4QL6-FDGZ] (clarifying the scope and regulatory implications of nanoscale ingredients under the Novel Foods framework).

266 *Novel Foods Authorizarion Guidance*, FOOD STANDARDS AGENCY FOOD GOV'T U.K (Sept. 19, 2025), https://www.food.gov.uk/business-guidance/regulated-products/novel-foods-guidance [https://perma.cc/6LPU-KR93] ("Novel foods are any food that was not used for human consumption to a significant degree within the United Kingdom (UK) or the European Union (EU) before 15 May 1997."); *Embracing the Future of Food: Is the Regulation of Novel Foods About to Change?*, WALKER MORRIS (Sept. 19, 2024), https://www.walkermorris.co.uk/newsletters/newsletter-items/embracing-the-future-of-food-is-the-regulation-of-novel-foods-about-to-change [https://perma.cc/U8HH-HN3F]; Taly Dvork & Roland Scarlett, *UK and EU Regulatory Divergence in Food Law*, FIELDFISHER (Aug. 8, 2025), https://www.fieldfisher.com/en/insights/uk-and-eu-regulatory-divergence-in-food-challenges [https://perma.cc/H2VK-3J3D].

267 FOOD STANDARDS AGENCY FOOD GOV'T U.K., *supra* note 266.

ensuring compliance. The main aim of this legislation is to ensure that novel foods comply with safety standards before being marketed. The FSA maintains a register of authorized novel foods, which provides transparency and helps businesses understand which novel foods are permitted for use in the UK.[268]

The United Kingdom government also adopted the Hazard Analysis and Critical Control Point (HACCP) system to manage food safety hazards.[269] The HACCP system is a preventive approach to food safety that identifies, evaluates, and controls hazards throughout food production. As stipulated by the Food Safety and Hygiene (England) Regulations 2013,[270] and by equivalent regulations in Scotland, Wales, and Northern Ireland, all UK food businesses must apply HACCP principles. These regulations require food-related businesses to implement and maintain hygiene procedures based on HACCP principles.[271]

The HACCP system involves several steps: (1) conducting a hazard analysis to identify potential food safety hazards, (2) determining critical control points (CCPs) where these hazards can be controlled or eliminated, (3) establishing critical limits for each CCP, (4) implementing monitoring procedures to ensure CCPs remain under control, and (5) establishing corrective actions if monitoring indicates a CCP is not under control.[272] Verification procedures confirm that the

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268 *Guidance on Using the Register of Novel Foods*, FOOD STANDARDS AGENCY & FOOD STANDARDS SCOT. FOOD GOV'T U.K. (Apr. 1, 2025), https://data.food.gov.uk/regulated-products/novel_authorisations/guidance [https://perma.cc/2SN3-9YQ2].

269 Food Standards Agency, *Hazard Analysis and Critical Control Point (HACCP)*, FOOD STANDARDS AGENCY FOOD GOV'T U.K. (Oct. 22, 2024), https://www.food.gov.uk/business-guidance/hazard-analysis-and-critical-control-point-haccp [https://perma.cc/SB32-59BY]; Hyde R. Hoflund et al., *One HACCP, Two Approaches: Experiences with and Perceptions of the Hazard Analysis and Critical Control Point Food Safety Management Systems in the United States and the EU*, 48 ADMIN. & SOC'Y 962, 968 (2014).

270 The Food Safety and Hygiene (England) Regulations 2013, SI 2013/2996, https://www.legislation.gov.uk/uksi/2013/2996/contents [https://perma.cc/W8C5-9XQP].

271 *Id.* at 4–6.

272 *What Are the 7 Principles of HACCP?*, EHACCP.ORG (Jan. 10, 2023), https://ehaccp.org/what-are-the-7-principles-of-haccpwhat-are-the-7-principles-of-haccp/10/01/2023/10/46/ [https://perma.cc/BY5X-T84F] (explaining critical limits, monitoring, and corrective actions); *What Are the 12 Steps of HACCP?*, EHACCP.ORG (Jan. 10, 2023), https://ehaccp.org/what-are-the-12-steps-of-haccp/10/01/2023/11/00/ [https://perma.cc/88G6-V8C3] (providing a detailed overview of hazard analysis, CCPs, and monitoring procedures).

HACCP system is working effectively, and documentation and recordkeeping demonstrate compliance.[273]

In the UK, the FSA helps food businesses implement HACCP by providing guidance and support. The FSA's MyHACCP tool is a free web-based resource that helps small food manufacturing businesses develop a food safety management system based on HACCP principles. This tool helps businesses identify and control food safety hazards and ensures that their procedures match the size and scale of their operations.[274]

Applying the HACCP system is particularly critical in high-risk sectors.[275] For example, meat-processing plants must implement and maintain hygiene procedures based on HACCP principles to control microbiological, chemical, and physical hazards.[276] The Hygiene Assessment System (HAS) monitors hygiene control in *abattoirs* and meat-cutting plants, ensuring that HACCP principles are effectively applied to reduce the risk of foodborne illnesses.[277]

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273 *Principle 7: Establish Documentation and Record Keeping*, FOOD.GOV.UK, https://myhaccp.food.gov.uk/help/guidance/principle-7-establish-documentation-and-record-keeping [https://perma.cc/3J39-QBLU] ("Documentation and record-keeping should be . . . sufficient to assist the business to verify that the HACCP controls are in place and being maintained."); *HACCP: Documentation and Record-Keeping* 12, FOOD & AGRIC. ORG. OF THE U.N., https://openknowledge.fao.org/server/api/core/bitstreams/eb1721f0-6962-47a7-ad28-ae651d67a9af/content [https://perma.cc/Y5RR-B3NT] ("Records allow the food business to easily and confidently confirm that its HACCP plan is effective."); *HACCP - 5 Record Keeping Best Practices to Ensure Compliance*, COMPLIANCEONLINE, https://www.complianceonline.com/resources/haccp-5-record-keeping-best-practices-to-ensure-compliance.html [https://perma.cc/EQ8Q-43AX] (last visited Mar. 28, 2026).

274 *New HACCP Web Tool for Your Business*, NEW FOOD MAG. (May 30, 2014), https://www.newfoodmagazine.com/news/14002/new-haccp-web-tool-for-your-business/ [https://perma.cc/CT3W-BDTK].

275 Jeff W. Savell, *Introduction to HACCP Principles in Meat Plants*, INT'L HACCP ALL. (1995), https://www.haccpalliance.org/wp-content/uploads/2022/01/HACCPintro.pdf [https://perma.cc/UF4X-E77Z].

276 Shai Barbut, *HACCP in Cooked Meat Operations*, *in* SCI. OF POULTRY AND MEAT PROCESSING (2015); RB Tompkin, *The Use of HACCP in the Production of Meat and Poultry Products*, 53 J. FOOD PROT. 795 (1990).

277 *Meat Hygiene Assessment* 4–7, DEP'T OF AGRIC., FISHERIES & FORESTRY, https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/aqis/exporting/meat/elmer3/index/methods-microbiological-test-meat/meat_hygiene_assessment_2nd_ed.pdf [https://perma.cc/B2XY-7KGK]; *Modernising Food Safety Monitoring for Australian Processors*, AUSTL. MEAT PROCESSOR CORP. 3–5 (Jan. 24, 2025), https://ampc.com.au/news-events/news/modernising-food-safety-monitoring-for-australian-processors [https://perma.cc/74AN-B7Q9]; FOOD AND AGRIC. ORG., CONTROL SYSTEM FOR PROCESSING OPERATIONS: THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM 12–15 (2024), https://www.fao.org/4/y5454e/y5454e 12.pdf.

General food labeling regulations apply to all food; labels must be accurate and not deceptive.[278] By law, food labels and packaging must also include certain descriptive information: the name of the food; a list of ingredients, including nanomaterials; a quantitative declaration of ingredients (QUID); storage conditions; date labeling; preparation instructions; and other required details.[279] The labeling of foods containing nanoparticles is subject to the Food Information to Consumers (FIC) Regulation (FIC No1169/2011, which was retained in the UK following Brexit). This regulation requires that any food containing engineered nanomaterials be labeled appropriately. The word "nano" must appear in brackets following the ingredient name in the list of ingredients.[280] This requirement enhances transparency and allows consumers to make informed decisions about the products they purchase.

The FSA is legally empowered to regulate food products that incorporate nanoparticles. This power derives from key legislation, such as the Food Safety Act of 1990 and the retained Novel Foods Regulation (EU) 2015/2283. The Food Safety Act of 1990, for instance, plays an important role in ensuring that all foods containing engineered nanomaterials undergo stringent safety evaluations before being placed on the market.[281] The FSA assesses the safety of foods containing nanotechnology, ensures compliance with labeling requirements, and supervises the market for potential safety risks related to nanotechnology. The agency also advises food companies on the safe use of nanomaterials and collaborates with other regulatory agencies on nutrition to ensure high-quality food safety standards.[282]

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278 *Packaging and Labelling*, FOOD.GOV.UK (Sept. 4, 2023), https://www.food. gov.uk /business-guidance/packaging-and-labelling [https://perma.cc/9QYU-B3YH].

279 *Id.*

280 Commission Regulation (EU) 1169/2011, art. 18(3), 2011 O.J. (L 304) 18, https:// www.legislation.gov.uk/eur/2011/1169/contents [https://perma.cc/4GPW-VWD8] ("All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets."); Commission Regulation (EU) 1169/2011, 2011 O.J. (L 304) 18, https://eur -lex.europa.eu/eli/reg/2011/1169/oj/eng [https://perma.cc/NX34-GGB7] (providing the full text of the regulation, including definitions and labelling requirements for engineered nanomaterials).

281 *See generally Applications of Nanotechnology for Food Contact Materials and Food Safety*, FOOD.GOV.UK (Sept. 21, 2006), https://www.food.gov.uk/research/chemical -hazards-in-food-and-feed/applications-of-nanotechnology-for-food-contact-materials-and -food-safety [https://perma.cc/S99M-MUYT].

282 *Id.*

Moreover, the Department for Environment, Food & Rural Affairs (DEFRA) controls the use of nanomaterials in agriculture from an environmental perspective.[283] With support from the FSA and other agencies, DEFRA ensures that the use of nanotechnology in food production does not pose any adverse environmental effects.[284] The Health and Safety Executive (HSE) examines the use of nanomaterials in food industries and their occupational health impacts.[285] HSE regulations are developed to protect workers from the adverse effects associated with nanotechnology.[286]

In the UK, several private institutions also play a significant role in the regulation and research of food containing engineered nanoparticles. These organizations, including the Institute of Food Science & Technology, the Nanotechnology Industries Association, and Campden BRI, often collaborate with regulatory bodies to ensure the safety and compliance of nanotechnology in food products.[287] The Institute of Food Science & Technology is the UK's independent qualifying body for food professionals and supports the advancement and application of food science and technology.[288] The Nanotechnology Industries Association represents companies that have dominated the market for developing and commercializing nanotechnology. It advocates for the safe and responsible use of

283 Ritika Kumari et al., *Regulation and Safety Measures for Nanotechnology-Based Agri-Products*, 5 FRONT. GENOME ED. (2023), https://www.frontiersin.org/articles/10.3389/fgeed.2023.1200987/full [https://perma.cc/J2SN-ERCX].

284 *See generally* FOOD.GOV.UK, *supra* note 281.

285 UK NANOSAFETY GROUP, *Working Safely with Nanomaterials in Research & Development*, 2d ed. (2020), https://www.iom-world.org/media/1863/uknsg-guidance-working-safely-with-nanomaterials-2nd-edition.pdf [https://perma.cc/LL7U-XMTH] (last visited Mar. 29, 2026).

286 *Nanotechnology*, HEALTH AND SAFETY EXEC., https://www.hse.gov.uk/nanotechnology/index.htm [https://perma.cc/DYN8-YKLY]; SafeWork, *Nanotechnology*, NSW GOV'T, https://www.safework.nsw.gov.au/hazards-a-z/nanotechnology [https://perma.cc/U5EK-ASM3] (last visited Mar. 29, 2026).

287 Institute of Food Science and Technology is the UK's largest independent provider of scientific, technical, and regulatory support to the food and drink industry, offering research, testing, and training services. The Technology Industries Association is a global membership organization advocating for the safe, sustainable, and innovative use of nanotechnologies across industries, including food and agriculture. The Campden BRI is the UK's largest independent provider of scientific, technical, and regulatory support to the food and drink industry, offering research, testing, and training services. For details of these organizations, visit https://www.ifst.org [https://perma.cc/G93R-HZ5F], https://nanotechia.org [https://perma.cc/NU8Q-FLJ7],https://www.campdenbri.co.uk [https://perma.cc/WF5C-6W75].

288 *About the Institute*, INST. FOOD SCIENCE & TECH., https://www.ifst.org/about.

nanomaterials in food and other products.[289] Campden BRI provides market research and developmental services to the food and drink industry. It researches and evaluates nanomaterials used in food to ensure that the industry and its regulators can access sound advice and constructive guidance.[290]

IV
APPROACHES IN THE REGULATION OF FOODS WITH ENMS IN THE US, EU, AND UK

The US, EU, and UK approach regulating foods containing engineered nanomaterials differently because of their respective strategic philosophies and structures. In the US, the FDA approaches regulating nanomaterials with a science-based, product-centric strategy that places great importance on preliminary meetings with manufacturers and supports applying existing regulations to nanomaterials.[291] In the EU, the European Food Safety Authority (EFSA) has developed broad guidelines and definitions of nanomaterials that encourage risk assessment and transparency within its regulatory framework.[292] After leaving the EU, the UK still follows EU regulations but is doing additional work to fill in existing deficits in information and regulation.[293] These approaches collectively aim to

289 *Addressing Food Safety Concerns and Risks of Nanomaterials in Food*, FOOD SAFETY INST. (May 14, 2025), https://foodsafety.institute/emerging-trends-food-technology-safety/food-safety-nanomaterials-risks/ [https://perma.cc/YQ76-CMKX].

290 *Science and Technology for the Food and Drink Industry*, CAMPDEN BRI, https://www.campdenbri.co.uk/ [https://perma.cc/6UCC-2P5D]; *Publications and Guidelines*, CAMPDEN BRI, .campdenbri.co.uk/publications/index.php [https://perma.cc/J8P8-25TP]; Craig Leadley, *Food Tech: 100 Years of Innovations*, 38 FOOD SCI. & TECH. 39, 42–45 (2024) (UK).

291 *FDA's Approach to Regulation of Nanotechnology Products*, FDA (Mar. 23, 2018), https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products [https://perma.cc/5S7N-V3A2].

292 *See generally* Tannelie Blom et al., *The Politics of Information in the EU: The Case of European Agencies*, *in* THE POLITICS OF INFORMATION (2014) (discussing how European agencies manage and disseminate information within the EU regulatory framework and the political implications of such practices).

293 Joël Reland, *UK-EU Divergence Tracker Q4 2024 – Q2 2025*, UK IN A CHANGING EUR. 3–7 (Jul. 16, 2025), https://ukandeu.ac.uk/reports/uk-eu-divergence-tracker-q4-2024-q2-2025/ [https://perma.cc/5YKK-9YPR]; Joël Reland, *Regulatory Alignment: The Unspoken Part of the UK's EU Reset*, ENCOMPASS 4–6 (Dec. 2024), https://encompass-europe.com/comment/regulatory-alignment-the-unspoken-part-of-the-uks-eu-reset [https://perma.cc/8Y83-VJ4D]; *Regulating After Brexit: Written Evidence*, UK IN A CHANGING EUR, 2–5 (July 2022), https://committees.parliament.uk/writtenevidence/110151/pdf/ [https://perma.cc/CF2F-P3XN].

foster innovation while safeguarding consumers and the environment. Below, this Article details the most important aspects of each jurisdiction's approach to regulating foods containing ENMs.

The EU's policies result from legal and regulatory frameworks, economic integration, and collaboration within the member states.[294] The European Parliament and the Council of the European Union have legislative powers that serve as the foundation for regulations, harmonizing laws across all member states.[295] Economic activity within the borders of a single market necessitates regulation, which facilitates trade and competition.[296] Other public interests, such as consumer protection, environmental protection, and public health, also necessitate adopting complex regulations.[297] These factors allow regulations to be efficiently adopted, enforced, and modified without hindering economic activity as new challenges and opportunities arise.[298]

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294 *See generally* Iain Begg, *The European Union and Regional Economic Integration*, BRIEFING (Mar. 2021), https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/689369/EPRS_BRI(2021)689369_EN.pdf [https://perma.cc/AUK4-UU7Z] (providing an overview of the EU's role in fostering regional economic integration and explaining institutional mechanisms for regulatory alignment among member states); Jiyeong Go et al., *Regulatory Cooperation Through Trade: Trends, Challenges and Recommendations for Middle-Power Countries*, CITP Briefing Paper No. 19 (2025), https://citp.ac.uk/publications/regulatory-cooperation-through-trade-trends-challenges-and-recommendations-for-middle-power-countries [http://perma.cc/S9KH-AZ96] (examining how trade agreements facilitate regulatory cooperation, identifying challenges for middle-power countries, and offering policy recommendations to enhance harmonization); Joël Reland, *Regulatory Divergence and the Windsor Framework*, UK IN A CHANGING EUR. (Feb. 14, 2024), https://ukandeu.ac.uk/explainers/regulatory-divergence-and-the-windsor-framework/ [https://perma.cc/U2Q4-Z3TH] (analyzing the implications of regulatory divergence between the UK and EU post-Brexit and assessing how the Windsor Framework addresses trade and compliance issues).

295 *See generally* JOHN P. GRIFFIN, THE TEXTBOOK OF PHARMACEUTICAL MEDICINE app. 3 (John P. Griffin et al. eds., 6th ed. 2009), https://doi.org/10.1002/9781444317800.app3 [https://perma.cc/G5TC-NW6R] (providing comprehensive guidance on pharmaceutical regulation and governance, including frameworks for compliance and best practices in drug development and approval).

296 *See generally* Jacques Pelkmans, *The Economics of Single Market Regulation*, *in* MAPPING EUROPEAN ECONOMIC INTEGRATION 79 (A. Verdun er al. eds., 2013) (analyzing the economic rationale behind regulatory harmonization in the EU single market and its impact on integration and efficiency).

297 DEPARTMENT FOR ENVIRONMENT, FOOD & RURAL AFFAIRS, ENVIRONMENTAL PRINCIPLES POLICY STATEMENT 3–7 (2021) (UK); *Environmental Legislation UK – What You Need to Know*, SWEEP (Sept. 15, 2025), https://www.sweep.net/blog/environmental-legislation-uk-what-you-need-to-know [https://perma.cc/27HB-9MCJ]; UK HEALTH SECURITY AGENCY, ENVIRONMENTAL PERMITTING AND THE ROLE OF UKHSA, 2023, House of Commons 3–5.

298 Katarzyna Sum, *The Factors Influencing the EU Banking Regulatory Framework: Impediments for the New Regulations*, *in* POST-CRISIS BANKING REGULATION IN THE

Regulating engineered nanoparticles in food within the EU is a multifaceted process that seeks to ensure both food safety and consumer protection in a constantly changing environment.[299] The EU regulations define specific terms, such as "foods consisting of engineered nanomaterials," as any deliberately created substance that has one or more dimensions equal to or less than 100 nanometers (nm) or is composed of discrete functional components, many of which are equal to or less than 100 nm.[300]

The Novel Food Regulation (Regulation (EU) 2015/2283) governs the use of engineered nanomaterials in food.[301] This regulation states that any food with engineered nanomaterials should be assessed by the European Food Safety Authority (EFSA) for safety before being marketed as food.[302] The European Food Safety Authority (EFSA) conducts the risk assessment.[303] It has created specific guidance for assessing the risk of nanomaterials, which covers the assessment of possible risks and exposure levels when nanomaterials are applied to food. It also explores the unique features of nanomaterials, such as their increased reactivity and the wide variety of biological interactions they can have compared to their larger counterparts.

The EU values transparency and consumer protection. For example, EU regulations state that foods containing engineered nanomaterials

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EUROPEAN UNION: OPPORTUNITIES AND THREATS 169–207 (2016); Darren Abrahams et al., *Regulatory Landscape in the EU and the UK: Key Considerations for 2025*, STEPTOE (Jan. 16, 2025), https://www.steptoe.com/en/news-publications/regulatory-landscape-in-the-eu-and-the-uk-key-considerations-in-2025.html [https://perma.cc/5X8B-ACYR].

299 Takis Daskaleros, European Comm'n, Nanomaterials in the EU Food Regulations (April 1–2, 2019), https://www.efsa.europa.eu/sites/default/files/event/Presentation%2012%20_%20Panagiotis%20Daskaleros.pdf [https://perma.cc/ZH9F-9K4U].

300 *Id.*

301 Council Regulation 2015/2283, art. 3 & recital 8, 2015 O.J. (L 327) 1 (EU) ("Food consisting of engineered nanomaterials should also be considered a novel food under this Regulation"); Dominique Turck et al., *Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation Applications*, EFSA J., Sept. 2024, at 12–15; Ed. RIVM on Advanced Materials, *European Parliament Rejects New Nanomaterial Definition in Novel Food Regulation*, RIVM (July 17, 2024, 2:12 PM), https://www.rivm.nl/en/weblog/european-parliament-rejects-new-nanomaterial-definition-in-novel-food-regulation [https://perma.cc/3B23-NCNP] ("[I]ngredients need to be indicated as '[nano]' on the ingredient list of food packaging, as regulated by the [FIC Regulation].").

302 Council Regulation 2015/2283, art. 23, 2015 O.J. (327) 1.

303 *See generally* Dilek Ercili-Cura et al., *Food out of Thin Air*, 34 INNOVATION & COLLABORATION 44 (2020) (exploring innovative approaches to sustainable food production, including the use of advanced technologies and collaborative strategies to address global food security challenges).

should be labeled appropriately. Under the Food Information to Consumers Regulation (Regulation (EU) No 1169/2011), which requires that any engineered nanomaterials be declared in the ingredients list.[304] There are also regulations concerning food contact materials (FCMs) that use nanomaterials. The EU has specific provisions for FCMs under Regulation (EC) No 1935/2004, which governs materials intended to encounter food to prevent harmful ingredient migration. Such substances include nanomaterials whose safety evaluation is compulsory before they can be used.[305]

The EU continuously updates its regulations and guidelines to keep pace with scientific advancements and emerging risks.[306] This includes revising definitions, improving risk-assessment methodologies, and enhancing enforcement mechanisms.[307] Its aim is to ensure that the regulatory framework remains robust and effective in protecting public health.[308]

In the US, industry practices and innovations, together with public interest, results in different combinations of regulatory frameworks shaped by legislation and economic factors.[309] Congress determines the

304 Regulation No 1169/2011, art. 18(3), 2011 O.J. (L 304) 18.

305 Daskaleros, *supra* note 299.

306 *See generally* EUROPEAN COMMISSION, CROSS-BORDER AND EMERGING RISKS IN EUROPE (2024), https://op.europa.eu/en/publication-detail/-/publication/e7ccf960-1ef7-11ef-a251-01aa75ed71a1/language-en [https://perma.cc/P3G4-ZJTJ] (examining cross-border regulatory challenges and emerging risks in the EU, including strategies for coordinated risk management and policy harmonization); *EU General Risk Assessment Methodology*, EUR. COMM'N DOC. COMM'N (2016) 76, https://ec.europa.eu/docsroom/documents/17107/attachments/1/translations/en/renditions/pdf [https://perma.cc/XWC3-T34D] (providing a standardized framework for risk assessment across EU institutions to ensure consistency in evaluating hazards and regulatory decision-making).

307 *See generally* Laurens Van Kreij, *Towards a Comprehensive Framework for Understanding EU Enforcement Regimes*, 10 EUR. J. RISK REGUL. 439 (2019) (explaining that the EU's enforcement regimes are dynamic and subject to ongoing refinement, including adjustments to regulatory definitions, risk-assessment practices, and enforcement structures).

308 *Scientific Research Needed to Protect Health, the Environment and Competitiveness*, ECHA Doc. NR/25/15 (June 11, 2025), https://echa.europa.eu/-/scientific-research-needed-to-protect-health-the-environment-and-competitiveness [https://perma.cc/U5DM-U2NJ].

309 *See generally* HILARY GELFOND, EVALUATING THE ECONOMIC IMPACTS OF THE US REGULATORY SYSTEM (2020) (assessing the economic consequences of U.S. regulatory policies, including compliance costs and broader impacts on innovation and market efficiency); JOSEPH J. CORDES ET AL., REGULATORY COMPLIANCE BURDENS: LITERATURE REVIEW AND SYNTHESIS (2022) (providing a comprehensive review of research on regulatory compliance burdens, highlighting cost drivers and implications for businesses and policymakers); Jaime Bonnin Roca, *Regulatory Agencies as Innovation Enablers: A Conceptualization*, 51 SCI. AND PUB. POL'Y 1051 (2024) (conceptualizing the role of

legal bounds for regulatory agencies, requiring them to adopt enforceable rules.[310] Economic conditions, such as market stability and growth, determine the focus and intensity of different regulations to ensure the marketplace remains balanced.[311] As such, the participation of private investors and institutions in the US market is essential to creating a regulatory system.[312] Laws are part of the process, but they do not initiate and drive it. The same is true for the regulation of foods containing ENMs. While the US has no particular legally controlled regulatory system for this food, the United States Food and Drug Administration (FDA) mainly assists stakeholders and facilitates the regulation of foods containing ENMs.[313]

As with other products, the FDA oversees the marketing of food products that contain nanotechnology materials.[314] The FDA has published numerous documents detailing how it intends to implement the recommendations for overseeing the industry's use of nanotechnology. For instance, two documents—"Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and

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regulatory agencies in fostering innovation through adaptive governance and collaborative approaches).

310 MAEVE P. CAREY, CONG. RSCH. SERV., IF 10003, AN OVERVIEW OF FEDERAL REGULATIONS AND THE RULEMAKING PROCESS (2023), https://www.congress.gov/crs-product/IF10003 [https://perma.cc/WTC3-YQCZ]; *How the Federal Government Makes the Rules That Govern Your Life*, GOVFACTS (2024), https://govfacts.org/explainer/how-the-federal-government-makes-the-rules-that-govern-your-life/ [https://perma.cc/UZV5-G4F6]; *Understanding Federal Regulatory Agencies and Their Impact on Law*, LAWS LEARNED (2024), https://lawslearned.com/federal-regulatory-agencies/ [https://perma.cc/DAS6-GT9G].

311 Charles R. Shipan, *Regulatory Regimes, Agency Actions, and the Conditional Nature of Congressional Influence*, 98 AM. POL. SCI. REV. 467 (2004).

312 Timothy Spangler, *Self-Regulation and Private Actors*, *in* THE LAW OF PRIVATE INVESTMENT FUNDS 221 (3d ed. 2018); Robert DeYoung et al., *Private Equity Investment in US Banks*, *in* ELECTRONIC JOURNAL (2021); Alexandros Seretakis, *Private Equity in the United States and Europe*, *in* PRIVATE EQUITY: OPPORTUNITIES AND RISKS 32 (H. Kent Baker et al. eds., 2015).

313 *See generally* Jordan Paradise, *Regulating Nanomedicine at the Food and Drug Administration*, 21 AMA J. ETHICS 347, 348–50 (2019), https://journalofethics.ama-assn.org/article/regulating-nanomedicine-food-and-drug-administration/2019-04 [https://perma.cc/JS8P-7DNZ]; Rachel Foulkes et al., *The Regulation of Nanomaterials and Nanomedicines for Clinical Application: Current and Future Perspectives*, 8 BIOMATERIALS SCI. 4653, 4655–56 (2020), https://pubs.rsc.org/en/content/articlehtml/2020/bm/d0bm00558d [https://perma.cc/UHF4-8VS5].

314 *Nanotechnology Guidance Documents*, FDA (2024), https://www.fda.gov/science-research/nanotechnology-programs-fda/nanotechnology-guidance-documents [https://perma.cc/T8BC-UM5V].

Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives" and "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology"—assist in outlining the impact of significant alterations on safety and artificial components used in food and nutrition.[315] Through these guidelines, the FDA helps stakeholders understand the use, details, safety and compliance measures of nanotechnology.[316] The FDA insists that manufacturers meet with the agency as early as possible during the development stage to resolve all scientific and regulatory problems. Although the FDA has no mandatory requirements for labeling nanomaterials in food, it advocates providing such information to aid consumer choice.[317] The Center for Food Safety and Applied Nutrition (CFSAN) is constantly developing its regulatory science to adapt to changes in food nanotechnology.[318] This involves creating new techniques for evaluating the safety and effectiveness of nanomaterials.[319]

In the United Kingdom, legislation serves as the guiding principle for public agencies to generate rules, policies, and regulatory processes regarding financial, environmental, and consumer sustainability.[320] Legislation also exposes stakeholders to greater trust and compliance

315 *See* FDA., GUIDANCE FOR INDUSTRY: ASSESSING THE EFFECTS OF SIGNIFICANT MANUFACTURING PROCESS CHANGES, INCLUDING EMERGING TECHNOLOGIES, ON THE SAFETY AND REGULATORY STATUS OF FOOD INGREDIENTS AND FOOD CONTACT SUBSTANCES, INCLUDING FOOD INGREDIENTS THAT ARE COLOR ADDITIVES (2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-assessing-effects-significant-manufacturing-process-changes-including-emerging [https://perma.cc/C2K2-QAC3]; FDA, *supra* note 314.

316 *See FDA Use of Real-World Evidence in Regulatory Decision Making*, FDA, https://www.fda.gov/science-research/real-world-evidence/fda-use-real-world-evidence-regulatory-decision-making [https://perma.cc/545C-SYFK] (last visited Oct. 26, 2025); Rachel Foulkes et al., *The Regulation of Nanomaterials and Nanomedicines for Clinical Application: Current and Future Perspectives*, 8 BIOMATERIALS SCI. 4653, 4655–56 (2020).

317 *See* Ragini Singh & Santosh Kumar, *Regulatory and Safety Concerns Regarding the Use of Active Nanomaterials in Food Industry*, *in* NANOTECHNOLOGY ADVANCEMENT IN AGRO-FOOD INDUS. 269, 272–73 (2023) (ebook).

318 *See Center for Food Safety and Applied Nutrition Nanotechnology Programs*, FDA (Mar. 19, 2018), https://www.fda.gov/science-research/nanotechnology-programs-fda/center-food-safety-and-applied-nutrition-nanotechnology-programs [https://perma.cc/AN9A-KJGN]; FDA, *supra* note 231.

319 *See FDA's Approach to Regulation of Nanotechnology Products*, FDA (Mar. 23, 2018), https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products [on file with the Oregon Review of International Law].

320 *See* KWASI KWARTENG & LORD FROST, REFORMING THE FRAMEWORK FOR BETTER REGULATION (2021).

by emphasizing accountability and transparency in regulatory processes.[321] This legal framework allows the UK to change its regulations in response to new challenges and opportunities while balancing innovation and public interest.[322] Against this backdrop, the recent development of the UK regulatory framework is, on the one hand, shaped by the interests of the business sectors, which include fostering innovation and maintaining the economy's financial stability, while also taking into account post-Brexit bespoke policies.[323] On the other hand, a more comprehensive aim is to protect consumers and sustainability, which directly affects the efficacy and inclusivity of the regulations.[324]

The UK's regulation of engineered nanoparticles in food is designed to protect food safety and consumers' interests. Like the EU, the UK associates the term nanomaterials with materials with dimensions of 100 nanometers (nm) or less. This phrase assists in determining materials that are within the scope of regulation.[325]

Since Brexit, the UK has retained most of the EU's food-safety-related regulations and public agencies. For example, in the UK, the Food Standards Agency (FSA) is responsible for food safety issues in England, Wales, and Northern Ireland, while in Scotland, this role is reserved for Food Standards Scotland (FSS).[326] The UK further

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321 *See* Colin Scott, *Accountability in the Regulatory State*, 27 J. L. & SOC'Y 38 (2000).

322 KWARTENG & FROST, *supra* note 320.

323 *See generally* Eilís Ferran, *International Competitiveness and Financial Regulators' Mandates: Coming Around Again in the UK*, 9 J. FIN. REGUL. (2023); Schilling de Carvalho, *supra* note 249.

324 *See generally* Anton Spisak & David Britto, *After Brexit: Divergence and the Future of UK Regulatory Policy*, TONY BLAIR INST. FOR GLOB. CHANGE, at 3–6 (June 2, 2021), https://institute.global/insights/economic-prosperity/after-brexit-divergence-and-future-uk-regulatory-policy [https://perma.cc/Z8CU-GLVF]; *UK Sustainability Regulations 2025: What Your Business Needs to Know*, DECERNA (Mar. 24, 2025), https://www.decerna.co.uk/uk-sustainability-regulations-2025-what-your-business-needs-to-know [on file with the Oregon Review of International Law].

325 *See* Kay Williams, *Nanomaterials — Current UK Policy*, DEP'T FOR ENV'T FOOD & RURAL AFF., at 2–3 (June 7, 2017), https://www.rsc.org/events/download/Document/16ccc0e9-879f-41bb-b18a-b9be6e6b7c2 [on file with the Oregon Review of International Law]; *Clarification on the Definition of Nanomaterial and Cosmetic Ingredients*, COSM. TOILETRY & PERFUMERY ASSOC. (July 20, 2023), https://www.ctpa.org.uk/news/clarification-on-the-definition-of-nanomaterial-and-cosmetic-ingredients-7115 [on file with the Oregon Review of International Law].

326 *See How the FSA Has Prepared for the UK Leaving the EU and the End of the Transition*, FOOD STANDARDS AGENCY (Oct. 27, 2021), https://www.food.gov.uk/business-guidance/how-the-fsa-has-prepared-for-the-uk-leaving-the-eu-and-the-end-of-the-transition [https://perma.cc/7B7K-F7EM]; Emily Haves, LEAVING THE EU: FOOD SAFETY,

developed specific laws that regulate new technology-based products.[327] Under the Novel Food Regulation, foods containing engineered nanomaterials are considered new and must undergo premarket safety assessments and obtain authorization before being placed on the market. These steps ensure that foods containing nanomaterials are safe for human consumption.[328]

The FSA and FSS evaluate the risks associated with nanomaterials, considering their specific characteristics and possible health risks. This assessment includes evaluating risks, exposure levels, and potential harms associated with ENMs in food.[329] It is required that foods

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HOUSE OF LORDS LIBRARY BRIEFING, at 3–6 (2018), https://researchbriefings.files.parliament.uk/documents/LLN-2018-0050/LLN-2018-0050.pdf [on file with the Oregon Review of International Law]; Taly Dvorkis & Roland Scarlett, *UK and EU Regulatory Divergence in Food Law: Challenges and Opportunities Post-Brexit*, FIELDFISHER LLP (Aug. 8, 2025), https://www.fieldfisher.com/en/insights/uk-and-eu-regulatory-divergence-in-food-challenges [on file with the Oregon Review of International Law].

327 Neil Ross & Lulu Freemont, *Regulating the Digital Economy After Brexit, What Is the UK's Approach?*, TECH UK (Feb. 3, 2022), https://www.techuk.org/resource/regulating-the-digital-economy-after-brexit-what-is-the-uk-government-s-approach.html ("New rules on competition, data protection, online safety, artificial intelligence and telecommunications being introduced in the UK . . . The UK is aiming to define its own path and seeking to navigate between the global trading giants like the EU and the USA.") [https://perma.cc/DQY3-Z2LB]; Riley Cooper, *How to Understand Emerging Trends in UK Tech Law*, RSCH. STUD. PRESS (Nov. 7, 2024), https://research-studies-press.co.uk/2024/11/07/how-to-understand-emerging-trends-in-uk-tech-law/ ("The current legal framework for technology in the UK is governed by various laws and regulations, including the Data Protection Act 2018, the Computer Misuse Act 1990, and the Electronic Communications Act 2000. Emerging trends in UK Tech Law include the rise of artificial intelligence . . . [and] the Internet of Things . . . .") [https://perma.cc/JL3N-E8M6].

328 Council Regulation 2015/2283, 2015 O.J. (L 327), 1 (EU), https://eur-lex.europa.eu/eli/reg/2015/2283/oj/eng ("To ensure a high level of protection of human health and consumers' interests, food consisting of engineered nanomaterials should also be considered a novel food under this Regulation.") [https://perma.cc/CUE7-R7QJ]; Dominique Turck et al., *Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283*, EUR. FOOD SAFETY AUTH., at 1 (June 27, 2024), https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2024.8961 ("EFSA will assess the safety of the novel food under the proposed conditions of use . . . [including] absorption . . . metabolism, excretion, toxicological information . . . and allergenicity.") [on file with the Oregon Review of International Law]; Maria Abi Hanna, *Novel Foods Labeling in the EU: Regulatory Requirements*, FOOD LABEL MAKER (June 25, 2024), https://foodlabelmaker.com/regulatory-hub/ec/novel-foods/ ("Novel foods require pre-market authorization to ensure safety for consumers . . . Regulation (EU) 2015/2283 applies to novel foods in the EU and UK market.") [https://perma.cc/B6CU-ACKN].

329 *Chemical Hazards in Food and Feed*, FOOD STANDARDS AGENCY, https://www.food.gov.uk/research/chemical-hazards-in-food-and-feed (last visited Mar. 29, 2025) ("Undertaking research on chemicals which may be present in food and feed allows FSA risk assessors to evaluate the potential risk to health that could arise from exposure to these chemicals . . . including nanomaterials.") [https://perma.cc/K5KZ

containing ENMs bear labels that disclose this fact. This is part of the overarching Food Information Regulations, which require that any ingredient that is engineered be specified in the ingredients.[330] The provisions on food contact materials also cover nanomaterials, which must undergo a safety assessment and be approved for distribution.[331]

In contrast to a total dependence on the market and private agencies, the UK employs legal and quasilegal controls at the core of the framework for regulating ENMs in food.[332] It is a challenge to deal with

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-FYMN]; Simon More et al., *Guidance on Risk Assessment of Nanomaterials to Be Applied in the Food and Feed Chain: Human and Animal Health*, 19 EUR. FOOD SAFETY AUTH. J., June 30, 2021, at 1, https://www.efsa.europa.eu/en/efsajournal/pub/6768 ("The SC Guidance on Nano-RA . . . details aspects relating to exposure assessment and hazard identification and characterisation . . . [including] toxicokinetics, genotoxicity . . . immunotoxicity . . . [and] effects on gut microbiome and endocrine activity.") [on file with the Oregon Review of International Law].

330 Council Regulation 1169/2011, art. 18, 2011 O.J. (L 304) 18 (EU) ("All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.").

331 Raymond P. Briñas, *Safety Evaluation of Food Contact Substances Containing Nanomaterials*, FDA (Oct. 11, 2022), https://www.fda.gov/media/166988/download (evaluating whether nanomaterials used in food contact substances may migrate into food and whether such migration poses a safety concern; significant manufacturing process changes, including use of nanotechnology, may require a new food contact notification) [on file with the Oregon Review of International Law]; *Food Contact Materials*, EUR. FOOD SAFETY AUTH. (Jan. 8, 2026), https://www.efsa.europa.eu/en/topics/topic/food-contact-materials ("[EFSA's] Panel on Food Contact Materials (FCM) carries out these [safety] assessments . . . of substances used in the manufacture of FCMs . . . [including nanomaterials] . . . advice informs the legislative decisions such as setting legal [migration] limits . . . .") [https://perma.cc/BN73-KXPY]; Lisa Zimmermann, *Reviewing Nanomaterials in 2024 – Types, Migration, Toxicity*, FOOD PACKAGING F. (Nov. 12, 2024), https://foodpackagingforum.org/news/reviewing-nanomaterials-in-2024-types-migration-toxicity (explaining that nanoparticles such as silver, zinc oxide, and nanoclays are added to food packaging to enhance antimicrobial and barrier properties, and that migration testing and toxicity evaluation are essential to assess human exposure risks) [https://perma.cc/QT7R-H7N3].

332 Cent. Sci. Lab'y, *Potential Use of Nanomaterials as Food Additives or Ingredients in Relation to Consumer Safety and Regulatory Controls*, FOOD STANDARDS AGENCY (Jan. 26, 2025), https://www.food.gov.uk/research/chemical-hazards-in-food-and-feed/potential-use-of-nanomaterials-as-food-additives-or-food-ingredients-in-relation-to-consumer-safety-and-regulatory-controls ("This study . . . highlight[s] gaps in knowledge that require further research to establish whether the consumption of nanofoods may lead to any consumer health implications. The use of food additives already approved for use needs revisiting if their nano-forms are used . . . .") [https://perma.cc/WXE7-EP9H]; *Nanotechnology*, EUR. FOOD SAFETY AUTH. (Nov. 3, 2025), https://www.efsa.europa.eu/en/topics/topic/nanotechnology ("EFSA's Scientific Committee provides scientific advice on how to assess applications from food operators to use (engineered) nanomaterials in food additives,

ever-changing scientific developments and emerging issues,[333] including changing definitions, increasing methodologies for assessing risks, and altering how enforcement is done.[334] The goal is to ensure that the regulatory framework can sustain changes to protect public health.[335]

The US, UK, and EU have differing regulatory approaches toward foods that contain ENMs. In the US, the FDA focuses more on the product at hand, relying on scientific procedures and early consultation with manufacturers. Additionally, the FDA relies on case-by-case evaluations for greater granularity.[336] EFSA risk assessments and guidelines guarantee consumer protection and promote transparency in protecting consumer rights in the EU.[337] The UK, while closely following EU standards, also conducts its own studies to fill gaps and

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enzymes, flavourings, food contact materials, novel foods, food supplements, feed additives and pesticides.") [https://perma.cc/C7SK-ZSPV].

333 *See generally* Ritika Kumari et al., *Regulation and Safety Measures for Nanotechnology-Based Agri-Products*, 5 FRONTIERS GENOME ED., June 21, 2023, at 1; Foulkes et al., *supra* note 313.

334 *See generally* Mariela de Amstalden, *Developing a Smart Legal Framework for Emerging Food Technologies and Future Innovation*, UNIV. OF BIRMINGHAM (July 26, 2023), https://www.birmingham.ac.uk/documents/research/public-affairs/2023-2024/background-briefing-developing-a-smart-legal-framework-for-emerging-food-technologies-and-future-innovation [https://perma.cc/7JG5-HZUK]; *see* Aline Reichow, *Risk, Uncertainty, and Learning in Nanomaterials Regulation: An Analytical Framework*, 7 EUR. J. RISK REGUL., 502, 504–06 (2016).

335 *See* Dep't of Health & Soc. Care, *Nutrition Legislation Information Sheet*, GOV UK (Feb. 20, 2024), https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet--2 [https://perma.cc/ZTQ6-YCJK].

336 *See* FDA, *supra* note, 152; *Navigating FDA Regulations for Nanomedicines and Devices*, BLA REGUL. (Sept. 10, 2025), https://bla-regulatory.com/fda-nanomedicine-regulations [https://perma.cc/6WQG-DUFV]; *Nanotechnology*, NANOTECHNOLOGY BLOG, https://nanotechnology.blog/about/index/u.s.-food-and-drug-administration-%28fda%29 [https://perma.cc/F8KS-TA6P] (last visited Mar. 29, 2026).

337 *Transparency*, EUR. FOOD SAFETY AUTH. (Oct. 20, 2025), https://www.efsa.europa.eu/en/about/transparency ("A new regulation on the transparency and sustainability of the EU risk assessment in the food chain . . . strengthens the Authority's ability to carry out its risk assessment functions in accordance with the highest transparency standards") [https://perma.cc/8D5V-DGS9]; *The European Transparency Regulation: A New Framework for Risk Assessment and Food Safety*, ANSES (Feb. 4, 2021), https://www.anses.fr/en/content/european-transparency-regulation-new-framework-risk-assessment-and-food-safety ("Regulation (EU) 2019/1381 is improving the transparency of EU risk assessment in the food chain, as well as the reliability, objectivity and independence of the studies used by . . . [EFSA]") [https://perma.cc/H7SV-5K4T]; *New Transparency Rules for EFSA's Risk Assessment*, EUCHEMS NEWSLS. (Apr. 15, 2025), https://www.euchems.eu/newsletters/transparency-rules-efsa/ ("[The regulation] aims to increase the independence of studies, to strengthen governance and scientific cooperation and to develop a comprehensive risk communication") [https://perma.cc/89FE-JL4E].

reassure consumers of their safety. Despite their differences, all three seek to achieve an equilibrium between enabling innovation and protecting the public.[338] With this in mind, they adopt some of the following criteria for the regulation of ENM-laden food products: (1) risk mitigation, (2) transparency, (3) adaptation, (4) public agencies' voluntary guidelines, and (5) legal support.[339]

Mitigating risks while developing new technologies is essential, which helps regulate potential threats and ensure they are assessed and appropriately managed.[340] This involves taking proactive steps to reduce risks likely to emerge from adopting and using changing technologies such as AI, biotechnology, and nanotechnology.[341] Most regulations need detailed risk evaluations, strict follow-ups, and implemented safety measures to safeguard public health, the environment, and the economy welfare.[342] By focusing on risk

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338 *See generally EU vs. US Food Regulations: Understanding the Key Differences*, RDR GLOB. PARTNERS (Dec. 15, 2023), https://rdrglobalpartners.com/blog/eu-vs-us-food-regulations-understanding-the-key-differences [https://perma.cc/7DFR-GNMC].

339 *See* FDA, *supra* note 152; Kimberly Coffin, *Transparency in the Food Chain: How New Directives Are Reshaping Risk and Resilience*, LRQA US, https://www.lrqa.com/en-us/insights/articles/transparency-in-the-food-chain (last visited Mar. 29, 2025) [https://perma.cc/KR3M-XA97]; EUR. FOOD SAFETY AUTH., *supra* note 332; *Implementation of the Transparency Regulation*, EUR. COMM'N, https://food.ec.europa.eu/horizontal-topics/general-food-law/implementation-transparency-regulation_en (last visited Mar. 29, 2026) [https://perma.cc/6FS7-YU2H]; *Key Regulations*, FOOD STANDARDS AGENCY (Jan. 23, 2024), https://www.food.gov.uk/about-us/key-regulations [https://perma.cc/72SA-EVLW]; Rebecca Shipton & Thomas Samuel, *Evolving Health Regulation for the Food and Drink Industry – What Lies Ahead?*, CMS LAW-NOW (May 9, 2025), https://cms-lawnow.com/en/ealerts/2025/09/evolving-health-regulation-for-the-food-and-drink-industry-what-lies-ahead [on file with the Oregon Review of International Law].

340 *See* Jonas B Sandbrink et al., *RiskSensitive Innovation: Leveraging Interactions Between Technologies to Navigate Technology Risks*, 51 SCI. & PUB. POL'Y 1028, 1035 (2024); Monument Thulani Bongani Makhanya, *The Implications for Risk Management in the Era of Technological Advancements*, *in* THE FUTURE OF RISK MANAGEMENT (2024).

341 *See* Toby Webster et al., *Global Risk Index for AI-Enabled Biological Tools*, THE CENTRE FOR LONG-TERM RESILIENCE, Sep. 2025, at 1, 3–6, https://www.longtermresilience.org/reports/global-risk-index-for-ai-enabled-biological-tools [https://perma.cc/T986-4T3D]; Alexander K. Saeri et al., *Mapping AI Risk Mitigations*, MIT AI RISK INITIATIVE, July 2025, at 1, 4–7, https://airisk.mit.edu/blog/mapping-ai-risk-mitigations [https://perma.cc/2CCM-3CVS]; Doug Irving, *Artificial Intelligence and Biotechnology: Risks and Opportunities*, RAND (Mar. 21, 2024), https://www.rand.org/pubs/articles/2024/artificial-intelligence-and-biotechnology-risks-and.html [https://perma.cc/395P-FFP6].

342 *See generally* AUSTRALIAN GOV'T, AUSTRALIAN GOVERNMENT GUIDE TO REGULATORY IMPACT ANALYSIS 7–10 (Commonwealth of Austl. 2nd ed. 2020), https://oia.pmc.gov.au/sites/default/files/2021-06/australian-government-guide-to-regulatory-impact-analysis.pdf (last visited Sept. 28, 2025) [on file with the Oregon Review of International Law]; *see Victorian Guide to Regulation: Evaluation Toolkit*, VICTORIAN GOV'T, at 4–9

mitigation, regulators strive for a delicate balance between safety and innovation to achieve technological advancement without harming society.[343]

Regulation of a novel technology relies deeply on transparency, which ensures that new technologies are developed openly and responsibly. By providing clear and comprehensive information regarding the risks, benefits, and workings of new technologies, regulators can ensure that the public is well informed and can trust the new technology.[344] Transparency fosters accountability among all stakeholders, including the consumers, industry, and even policymakers, which makes it easier to evaluate the actions of technology developers and regulators.[345] This willingness to be accountable minimizes the chances of setting unethical standards and emphasizes that innovation should always serve society first.[346]

Rapid technological changes deeply affect the relevance and efficiency of regulatory frameworks regarding new technologies, making adaptation vital.[347] This strategy consists of modifying and developing policies on an ongoing basis to mitigate new threats, taking advantage of new opportunities, and establishing the impact of new

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(2024), https://www.vic.gov.au/sites/default/files/2024-10/2024-Evaluation-Toolkit.pdf [on file with the Oregon Review of International Law]; AUSTRALIAN CTR. FOR DISEASE CONTROL, ENVIRONMENTAL HEALTH RISK ASSESSMENT: GUIDELINES FOR ASSESSING HUMAN HEALTH RISKS 3–6 (2024), https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/Environmental-health/Health-risk-assesment/Guidelines-for-Assessing-Human-Health.pdf [on file with the Oregon Review of International Law].

343 *See Technological Risk: Innovation vs: Event Risk: The Technological Tightrope*, FASTERCAPITAL (Apr. 8, 2025), https://fastercapital.com/content/Technological-risk--Innovation-vs--Event-Risk--The-Technological-Tightrope.html [https://perma.cc/K7C8-MZR3]; Justin Kozak, *Beyond Innovation: Confronting the Complex Risks in Health Technology Development*, MEDTECH INTEL. (Dec. 5, 2024), https://medtechintelligence.com/feature_article/beyond-innovation-confronting-the-complex-risks-in-health-technology-development/ [https://perma.cc/T6J2-BCH3].

344 *See Biden-Harris Administration Announces Regulatory Framework for the Responsible Diffusion of Advanced Artificial Intelligence Technology*, BUREAU INDUS. & SEC. (Jan. 13, 2025), https://www.bis.gov/press-release/biden-harris-administration-announces-regulatory-framework-responsible-diffusion-advanced-artificial [https://perma.cc/PB8V-68MJ].

345 *See* Rebecca Williams et al., *From Transparency to Accountability of Intelligent Systems: Moving Beyond Aspirations*, 4 DATA & POL'Y 1, 4–5 (2022).

346 *See generally* Ben Chester Cheong, *Transparency and Accountability in AI Systems: Safeguarding Wellbeing in the Age of Algorithmic Decision-Making*, 6, FRONTIERS HUM. DYNAMICS, July 3, 2024, at 1; Mariana Mazzucato et al., *Governing Artificial Intelligence in the Public Interest* (UCL Inst. for Innovation & Pub. Purpose, Working Paper No. 2022/12, 2022).

347 *See* Jeroen K.G. Hopster & Matthijs M. Maas, *The Technology Triad: Disruptive AI, Regulatory Gaps and Value Change*, 4 AI & ETHICS 1051, 1055 (2024).

technologies such as AI, blockchain, and biotechnology.[348] Adaptive regulation usually incorporates innovation, such as regulatory "sandboxes" where new policies can be tried out under a certain level of supervision.[349] By permitting technological advancements to continue, regulators can maintain a more relaxed approach that promotes innovation and safeguards the public interest as regulations evolve in response to new developments.[350]

Public agencies are important for governing new technological processes because they provide comprehensive directions and information on the possibilities of new innovations.[351] Specialized bodies, offices, or even working groups focus on regulating the technologies of various national regulatory agencies' newest achievements, such as the U.S. FTC.[352] Regulatory institutes recommend procedures for forming boundaries, ethical conduct, and compliance with the goal of achieving optimal conditions that balance invention with the preservation of the public good.[353] Institutional

348 William D Eggers, Mike Turley & Pankaj Kishnani, *The Future of Regulation: Principles for Regulating Emerging Technologies*, DELOITTE (June 19, 2018), https://www.deloitte.com/us/en/insights/industry/government-public-sector-services/future-of-regulation/regulating-emerging-technology.html [https://perma.cc/2QDY-DJWZ].

349 *See generally* Sandro Mendonca, *Creative Regulatory Environments: Sandboxes at the Intersection of Regulation and Innovation in an Era of Transition*, *in* GLOBAL ENERGY TRANSITION AND SUSTAINABLE DEVELOPMENT CHALLENGES 29 (2025); Beth Do & Stacey Gray, *Balancing Innovation and Oversight: Regulatory Sandboxes as a Tool for AI Governance*, FUTURE PRIV. F. (Aug. 24, 2025), https://fpf.org/blog/balancing-innovation-and-oversight-regulatory-sandboxes-as-a-tool-for-ai-governance/ [https://perma.cc/ALQ3-53XJ].

350 *See Better Regulation and Innovation*, ORG. FOR ECON. COOP. & DEV. (July 1, 2024), https://www.oecd.org/en/topics/better-regulation-and-innovation.html [on file with the Oregon Review of International Law]; Nebojsa Stojcic et al., *Breaking or Making Futures: How Laws and Regulations Shape Innovation in Emerging Innovation Systems*, 19 REV. MANAGERIAL SCI. 1743, 1770, (2024).

351 Balázs Bodó & Heleen Janssen, *Here Be Dragons – Maintaining Trust in the Technologized Public Sector*, 41 POL'Y & SOC'Y, 414, 418 (2022).

352 *See* Stephanie T. Nguyen, *The FTC Is on the Front Lines of Tech Innovation & Regulation*, FED. TRADE COMM'N (Jan. 17, 2025), https://www.ftc.gov/policy/advocacy-research/tech-at-ftc/2025/01/ftc-front-lines-tech-innovation-regulation [https://perma.cc/TLD5-6RAP].

353 *See generally* Beverly Wagner & Nusa Fain, *Regulatory Influences on Innovation in the Public Sector: The Role of Regulatory Regimes*, 20 PUB. MGMT. REV. 1205 (2018) (exploring how regulatory regimes shape innovation in public services, emphasizing the importance of compliance structures and ethical boundaries to maintain public trust and societal benefit); Clinical Trials Toolkit, *Summary of Key Changes in the ICH E6 (R3) Guidelines*, NAT'L INST. FOR HEALTH & CARE RSCH., (Mar. 25, 2025), https://www.ct-toolkit.ac.uk/news/summary-key-changes-ich-e6-r3-guidelines (highlighting how updated

memory means that they can design policies that fit public life and opportunities brought about by new technologies.[354]

Legal directions are fundamental in shaping the regulation of new technologies.[355] These directions provide clear guidance for this technology development.[356] Such directions emerge from laws, court decisions, and administrative instructions that set the scope for the use of new technologies.[357] By establishing legal standards and compliance requirements, regulators can ensure that emerging technologies are developed responsibly and with due consideration for ethical, safety, and societal impacts.[358] This legal foundation helps to balance innovation with the public interest, fostering an environment where technological advancements can thrive while at the same time protecting consumers and maintaining market integrity.[359]

The following Part of this Article will discuss the approach Australia has taken thus far, and the approach it can take to foster its regulation of foods with ENMs. This Article will first discuss the current state of

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Good Clinical Practice (GCP) guidelines emphasize proportionality, fitness-for-purpose, and quality-by-design principles that help balance innovation with ethical oversight and public interest) [on file with the Oregon Review of International Law].

354 *See* Caitlin Connally, *Protecting Parliamentary Procedure: Bridging the Gap in Institutional Memory with Artificial Intelligence*, 40 AUSTRALASIAN PARLIAMENTARY REV., 134, 135 (2025), https://www.aspg.org.au/wp-content/uploads/2025/05/Protecting_Parliamentary_Procedure-Bridging_the_Gap_in_Institutional_Memory_with_Artificial_Intelligence.pdf [on file with the Oregon Review of International Law].

355 *See* Jordie Pettit, *How Do Laws in Australia Accommodate Changes in Technology? A Review of Australian Legislatures' Ability to Incorporate New Technologies Through Regulation*, 4–7 (Nov. 15, 2023) (MR Thesis, Macquarie University); Vannessa Ho, *The Regulatory Challenges of Evolving Technology and Financial Services Law*, AUSTL. L. REFORM COMM'N (Nov. 29, 2023), https://www.alrc.gov.au/news/the-regulatory-challenges-of-evolving-technology-and-financial-services-law/ [https://perma.cc/7P76-WJTX].

356 *See* Esther Salmeron-Manzano, *Emerging Technologies, Law and Policies*, 14 LAWS 28 (2025), https://www.mdpi.com/2075-471X/14/2/28 [https://perma.cc/9ERC-ATZZ]; *Federal Regulation: Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination*, U.S. GOV'T ACCOUNTABILITY OFF., at 5–8 (Jan. 25, 2024), https://www.gao.gov/products/gao-24-106122 [https://perma.cc/E6PD-8KGT].

357 *Technology and the Future of the Courts*, JUD. COMM'N N.S.W. (Oct. 21, 2024), https://www.judcom.nsw.gov.au/publications/benchbks/judicial_officers/technology_and_future_of_courts.html [https://perma.cc/FHD2-BKNJ].

358 *See* Sarah Kreps, *Mapping the Regulatory Landscape for New Technologies*, LAWFARE (May 26, 2024), https://www.lawfaremedia.org/article/mapping-the-regulatory-landscape-for-new-technologies [https://perma.cc/2L4N-D7JS].

359 *See* Gina Cass-Gottlieb, *Regulating for Sustainability: Business Integrity, Innovation, and Impact*, AUSTRALIAN COMPETITION & CONSUMER COMM'N (May 27, 2025), https://www.accc.gov.au/about-us/news/speeches/regulating-for-sustainability-business-integrity-innovation-and-impact [https://perma.cc/9BG7-SPMV].

regulation in this country and then discuss options it can consider for devising its regulatory framework to ensure that ENMs in foods are not counterproductive.

V
REGULATION OF FOODS WITH ENMS IN AUSTRALIA

Australia's legal system is designed for transparent, effective, and fair governance.[360] A mixture of laws, policies, and regulatory bodies form the framework of the Australian legal system, which aims to protect competitive markets and ensure the safety and health of its citizens.[361] However, Australia's approach to regulating new technological disruptions has often been characterized by indecisiveness, reflecting the complexities and rapid pace of technological advancements.[362] Australian policymakers face the challenge of balancing innovation with the need for robust oversight, often resulting in delayed or fragmented regulatory responses.[363] The subsequent discussion first analyzes Australia's current challenges in

360 *Principles of the Rule of Law*, RULE OF LAW INST. OF AUSTL., at 2–5 (2025), https://ruleoflawaustralia.com.au/principles/ [https://perma.cc/7R3M-XTNF]; *Open and Transparent Laws,* RULE OF LAW EDUC. CENTRE, at 3–6 (2025), https://www.ruleoflaw.org.au/principles/open-and-transparent-laws/ [https://perma.cc/X6UT-HKTJ]; *Rule of Law in Australia*, PARLIAMENTARY EDUC. OFFICE, at 4–7 (2025), https://peo.gov.au/understand-our-parliament/how-parliament-works/system-of-government/rule-of-law [https://perma.cc/KH3V-ZUL3].

361 *Health Regulatory Policy Framework*, AUSTL. GOV. DEPT. OF HEALTH, at 2–5 (Dec. 2020), https://www.health.gov.au/resources/publications/health-regulatory-policy-framework?language=en [https://perma.cc/7V62-N7JT]; *Public Policy for Regulators: Is "Market Failure" Passé?*, AUSTL. COMPETITION & CONSUMER COMM'N, at 3–7 (Dec. 2022), https://www.accc.gov.au/system/files/Network%20December%202022.pdf [on file with the Oregon Review of International Law]; *Public Health Law, Regulation and Policy for Prevention*, AUSTL. PREVENTION P'SHIP CENTRE, at 4–8 (2022), https://preventioncentre.org.au/wp-content/uploads/2022/12/Public-health-law-and-regulation-Synthesis-Summary.pdf [on file with the Oregon Review of International Law].

362 *The Regulatory Challenges of Evolving Technology and Financial Services Law*, AUSTL. LAW REFORM COMM'N, at 5–9 (Nov. 29, 2023), https://www.alrc.gov.au/news/the-regulatory-challenges-of-evolving-technology-and-financial-services-law/ [https://perma.cc/4SB9-H82X]; *Regulatory Policy, Practice & Performance Framework*, DEPT. OF FIN. (2025), https://www.regulatoryreform.gov.au/sites/default/files/Regulatory-Policy-Practice-and-Performance-Framework.pdf [on file with the Oregon Review of International Law].

363 John H Howard, *25 Years of Reviews and Policy Statements: What Do They Reveal About Australia's R&D Challenges?*, ACTION INST. FOR POL'Y RSCH. AND INNOVATION (Dec. 10, 2024), https://www.actoninstitute.au/post/25-years-of-reviews-and-policy-statements-what-do-they-reveal-about-australia-s-r-d-challenges [https://perma.cc/FZ5Q-RHL4].

the regulation of foods with ENMs, then it will focus on what factors the Australian government should consider in establishing its regulatory framework for foods with ENMs.

A. The Current State

Australia uses an evidence-based approach to regulate food with engineered nanoparticles.[364] This country does not have any particular legislation or designated body to regulate the use of nanoparticles.[365] It manages this issue through several provisions, including the Food Standards Australia New Zealand Act 1991, the Industrial Chemicals Act 2019, the Biosecurity Act 2015, the Competition and Consumer Act 2010, and several other pieces of legislation.

The Food Standards Australia New Zealand Act of 1991 (hereinafter the "Act") regulates food standards in Australia, including food containing engineered nanoparticles. The Act gives Food Standards Australia New Zealand (FSANZ) the authority to create and implement the Australia New Zealand Food Standards Code, which establishes rules on food safety, composition, and labeling.[366] This includes carrying out intensive scientific tests to determine whether foods with engineered nanoparticles are safe enough to be sold.[367] The Act also provides for stakeholder consultation and participation, as well as giving the public an opportunity to comment on the regulations, which makes the regulation process open and accountable.[368] The Act allows

364 *Nanotechnology and Food*, FOOD STANDARDS AUSTL. N.Z., at 2–6 (2025), https://www.foodstandards.gov.au/consumer/foodtech/nanotech [https://perma.cc/56KV-PP5E]; *Nanotechnology and the FSANZ Approach*, FOOD LEGAL, at 3–7 (Aug. 2016), https://foodlegal.com.au/inhouse/document/1526 [on file with the Oregon Review of International Law]; *Nanotechnology Regulation in Australia*, AUSTRALIAN ACAD. OF SCI., at 4–8 (2025), https://www.science.org.au/curious/technology-future/nanotechnology-regulation-australia [https://perma.cc/XS6C-QWSN].

365 *Nanotechnology Regulation in Australia*, AUSTL. ACAD. OF SCI., at 2–6 (2025), https://www.science.org.au/curious/technology-future/nanotechnology-regulation-australia [https://perma.cc/XS6C-QWSN]; *Nanotechnology and Food*, FOOD STANDARDS AUSTL. N.Z., at 2–5 (2025), https://www.foodstandards.gov.au/consumer/foodtech/nanotech [https://perma.cc/56KV-PP5E]; *Regulation of Nanomedicines*, THERAPEUTIC GOODS ADMIN. at 3–6 (Oct. 20, 2016), https://www.tga.gov.au/sites/default/files/tga-presentation-nanoparticle-therapeutics-2016-20-october-2016.pdf [on file with the Oregon Review of International Law].

366 *Food Standards Australia New Zealand Act 1991* (Cth) (Austl.), https://classic.austlii.edu.au/au/legis/cth/consol_act/fsanza1991336/ [https://perma.cc/HRC4-25SX].

367 *Id.*

368 *Id.*

the public to be sure that appropriate regulations and controls are in place regarding engineered nanoparticles in food.[369]

The Food Standards Australia New Zealand Act 1991 does not define nanomaterials, nor does it focus on the size of the material—a primary concern within the EU. Rather, it emphasizes the material's biological novelty.[370] For instance, nanoscale components that disintegrate in water or oil in the finished product are not considered nanomaterials by this Act. However, nanoscale substances, both nonbiodegradable and oil and water-insoluble, may need regulatory inspection under nanomaterials status due to their unique nature.[371]

The Australia New Zealand Food Standard Code allows the Food Standards Australia and New Zealand (FSANZ) to treat food and food-related items that include nano-materials in the same manner as non-nano particles because of the extensive definition of food under the Food Standard Australia and New Zealand Act 1991.[372] For example, due to these arrangements, fresh milk that contains nanoscale lipids in colloidal suspension is subject to the same regulations as fresh milk that does not contain nanoscale lipids in colloidal suspension.[373] Nanomaterials may be treated as food additives for regulatory purposes when they are intentionally added to food, food packaging, or contact materials from which they travel into food and serve a functional objective.[374] Conversely, nanofood additives that unintentionally enter food through food packaging or contact materials may be regulated as contaminants.[375]

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369 *Food Standards Australia New Zealand Act 1991* (Cth), § 18(1)(a)–(b), https://www.legislation.gov.au/C2004A04193/latest [https://perma.cc/4SML-W6NS].

370 *Food Standards Australia New Zealand Act 1991* (Cth), §§ 13–18; Nick Fletcher & Andrew Bartholomaeus, *Regulation of Nanotechnologies in Food in Australia and New Zealand* 2–6 (Food Safety Austl. N.Z. 2011), https://www.foodstandards.gov.au/sites/default/files/consumer/foodtech/nanotech/Documents/2011_Fletcher%20Regulation%20nanotechnolgies%20Food%20ANZ.pdf [on file with the Oregon Review of International Law]; *Nanomaterials in Food*, EURO. COMM'N, https://food.ec.europa.eu/food-safety/novel-food/nanomaterials_en [https://perma.cc/3JL9-UTZU].

371 *Food Standards Australia New Zealand Act 1991* (Cth), §§ 13–18, https://www.legislation.gov.au/C2004A04193/latest [https://perma.cc/4SML-W6NS].

372 *Id.* § 5(1).

373 KARINNE LUDLOW ET AL., A REVIEW OF POSSIBLE IMPACTS OF NANOTECHNOLOGY ON AUSTRALIA'S REGULATORY FRAMEWORK, 72 (2007).

374 *Id.* at 73.

375 *Id.*

Nanomaterials used in food may fall under the category of novel foods in Australia and New Zealand.[376] In 1999, FSANZ developed a new guideline focusing on governing novel foods.[377] Novel foods are nontraditional foods that must undergo a safety assessment by FSANZ before being introduced into the food supply.[378] In Australia and New Zealand, novel foods and their ingredients are regulated under Standards 1.1.1 and 1.5.1 in the Australia New Zealand Food Standards Code (the Code).[379] A service provider intending to sell a novel food must submit a petition before the FSANZ.[380] This petition must include a complete outline, the novel food's identification, preparation process, substance, and intended usage.[381] FSANZ's assessment of the petition considers potential risks to human health, including toxicity, allergenicity, and nutritional impact.[382] If the Australia New Zealand

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376 A "novel food" is defined in Standard 1.5.1, cl Novel Foods, (2016) § 1 –.5.1—2 AUSTL. N.Z. FOOD STANDARDS CODE as a nontraditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account:

(a) the composition or structure of the product; or

(b) levels of undesirable substances in the product; or

(c) known potential for adverse effects in humans; or

(d) traditional preparation and cooking methods; or

(e) patterns and levels of consumption of the product.

For details, *see Novel Foods*, FOOD STANDARDS AUSTL. N.Z. (June 27, 2022), https://www.foodstandards.gov.au/business/novel (on file with the Oregon Review of International Law).

377 *History of Novel Foods Standard*, FOOD STANDARDS, Mar. 22, 2013, https://www.foodstandards.gov.au/business/novel/novelhistory [https://perma.cc/N6MN-J3B3].

378 *Novel Foods*, FOOD STANDARDS AUSTL. N.Z. (JUNE 27, 2022), https://www.foodstandards.gov.au/business/novel (explaining that novel foods are nontraditional foods that require assessment by FSANZ to establish their safety before they are added to the food supply) [https://perma.cc/YFN7-YHRD]; *Advisory Committee Novel Foods*, FOOD STANDARDS AUSTL. N.Z. (NOV. 24, 2017), https://www.foodstandards.gov.au/business/novel/novelcommittee (detailing the role of the Advisory Committee in determining whether a food is "nontraditional" and whether a public health and safety assessment is required before market entry) [https://perma.cc/78WV-H5XE].

379 *Novel Foods*, *supra* note 378.

380 *Id.*

381 *Id.*; *Novel Food (Non-Traditional Food)*, DEP'T OF AGRIC., FISHERIES AND FORESTRY (July 29, 2024), https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/type/novel-food [https://perma.cc/8TVK-F33Y].

382 *Safety Assessments of GM Foods*, FOOD STANDARDS AUSTL. N.Z. (SEPT. 2, 2025), https://www.foodstandards.gov.au/consumer/gmfood/safety (FSANZ states that its safety assessments are based on internationally recognized scientific principles and include evaluations of toxicity, allergenicity, and nutritional impact. These assessments are guided by OECD, FAO, WHO, and Codex Alimentarius standards) [https://perma.cc/VH9N-TPWW]; *Risk Analysis in Food Regulation*, FOOD STANDARDS AUSTL. N.Z. (Dec. 4, 2021), https://www.foodstandards.gov.au/publications/riskanalysisfoodregulation

Ministerial Forum on Food Regulation finds the novel food safe for consumption, the FSANZ may recommend authorizing it.[383] FSANZ also conducts post-market monitoring to ensure safety and may review the approval if new evidence suggests potential risks.

The Code outlines standards for the composition, labeling, handling, and production of foods sold in Australia and New Zealand.[384] The Code addresses food additives, vitamins, minerals, processing aids, pollutants, natural toxicants, and materials that come into contact with food, as well as innovative foods.[385] Applications for new food substances created with nanotechnologies or that incorporate novel nanoscale materials are assessed according to existing standards.[386]

The Competition and Consumer Act 2010 (CCA) strives to ensure the public is not manipulated or misled by snacks engineered with nanoparticles.[387] The Australian Competition and Consumer Commission enforces this legislation.[388] Through this public agency,

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(outlining the nutritional risk analysis and the assessment of potential health risks such as toxicity and allergenicity when evaluating food-related applications) [https://perma.cc/EP4B-Z9GN].

383 The Australia and New Zealand Ministerial Forum on Food Regulation—now called the Food Ministers' Meeting—is the key decision-making body overseeing the joint food regulation system. It comprises ministers responsible for food regulation from the Australian Government, state and territory governments, and the New Zealand Government. The Forum sets overarching food policy, approves food standards, and promotes harmonized regulation across jurisdictions. For details, visit https://www.foodregulation.gov.au/activities-committees/food-ministers-meeting [https://perma.cc/8D6U-TS5X].

384 Fletcher & Bartholomaeus, *supra* note 370, at 34.

385 Standards 1.3.1, 1.3.3, 1.4.1, 1.5.1, and Schedules 3, 25, 27, 29 of the Food Standards Australia New Zealand (FSANZ), *Food Standards Code*, https://www.foodstandards.gov.au/food-standards-code [https://perma.cc/CK4K-F3R9] (last visited Mar. 29, 2026) (these Standards of this Code cover food additives, processing aids, contaminants and natural toxicants, novel foods, and materials in contact with food. Schedule 25 lists permitted novel foods; Schedule 3 outlines specifications for vitamins and minerals); *Vitamins and Minerals Added to Food*, FOOD STANDARDS AUSTL., N.Z. (JUNE 24, 2016), https://www.foodstandards.gov.au/consumer/food-fortification/vitamin-added [https://perma.cc/HW9B-MFPB]; *Additives Overview*, FOOD STANDARDS AUSTL. N.Z. (JUNE 20, 2019), https://www.foodstandards.gov.au/consumer/additives/additiveoverview [https://perma.cc/FC3G-ES8Y].

386 FOOD STANDARDS AUSTL. N.Z., *supra* note 378.

387 *False or Misleading Claims*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/consumers/advertising-and-promotions/false-or-misleading-claims [https://perma.cc/6AT4-46K6]; *Truth in Labelling, Weights and Measures and Legibility*, FOOD STANDARDS AUSTL. N.Z. (Oct. 6, 2020), https://www.foodstandards.gov.au/consumer/labelling/truth [https://perma.cc/R647-6696].

388 *Legislation We Enforce*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/about-us/accc-role-and-structure/legislation-we-enforce (last visited Mar. 29, 2026) [https://perma.cc/B5S7-9ACS].

the CCA protects consumers from risks related to engineered red flag nanoparticles and ensures a regulated market for everyone.[389]

In Australia, four primary regulatory agencies oversee nanotechnology as applied to the food sector.[390] They are the Food Standards Australia New Zealand (FSANZ), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Therapeutic Goods Administration (TGA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA).[391] Among the public organizations responsible for implementing legislation related to nanomaterials in food, the Department of Agriculture, Water and the Environment (DAWE) and the Australian Competition and Consumer Commission (ACCC) are vital.

FSANZ is the primary food regulator in Australia and New Zealand and is responsible for "protect[ing] public health and safety by ensuring a safe food supply."[392] Concerning the use of nanomaterials in food, FSANZ evaluates the food regulatory framework to deal with any risks to human health posed by nanotechnologies under the existing regulations.[393]

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389 *Compliance and Enforcement Policy*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/business/compliance-and-enforcement [https://perma.cc/NR5A-ZRAT]; *Compliance and Enforcement*, AUSTL. GOV'T, https://consumer.gov.au/legislation/compliance-and-enforcement [https://perma.cc/QP26-HQ3Z]; *see* Shaun Temby & Emma Woelke, *Current Trends in the ACCC's Enforcement of Consumer Protection*, MADDOCKS (Oct. 12, 2025), https://www.maddocks.com.au/insights/current-trends-of-accc-enforcement-of-consumer-protection [on file with the Oregon Review of International Law].

390 *Regulatory Frameworks for Nanotechnology in Foods and Medical Products*, OECD (2021), https://www.oecd.org/en/publications/regulatory-frameworks-for-nanotechnology-in-foods-and-medical-products_5k47w4vsb4s4-en.html (last visited Mar. 29, 2026) [on file with the Oregon Review of International Law].

391 *Nanotechnology and Food*, FOOD STANDARDS AUSTL. N.Z. (Sept. 28, 2022), https://www.foodstandards.gov.au/consumer/foodtech/nanotech [https://perma.cc/2QPZ-3WM3]; *Nanotechnologies for Pesticides and Veterinary Medicines: Regulatory Considerations*, AUSTL. PESTICIDES & VETERINARY MEDICINES AUTH. (2015), https://www.apvma.gov.au/sites/default/files/publication/15626-nanotechnologies-pesticides-veterinary-medicines_regulatory-considerations_july2015.pdf [on file with the Oregon Review of International Law]; *Consumer Protection (Misleading or Deceptive Conduct)*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/business/advertising-and-promotions/false-or-misleading-claims [https://perma.cc/9LQX-JDDP] (last visited on Mar. 29, 2026); *Our Portfolio*, DEP'T OF AGRIC., WATER & THE ENV'T, https://www.agriculture.gov.au/about/who-we-are/portfolio [https://perma.cc/SYQ4-JQT5] (last visited on Mar. 29, 2026).

392 *What We Do*, FOOD STANDARDS AUSTL. N.Z. (Dec. 13, 2019), https://www.foodstandards.gov.au/about-us/whatwedo [https://perma.cc/YQ5F-6V7H].

393 Fletcher & Bartholomaeus *supra* note 370, at 34–35.

As the overarching scientific authority in this binational food safety system, the principal duty of FSANZ is to protect public health and safety through the provision of a safe food system.[394] It achieves its aim by developing evidence-based standards for regulators and the industry, overseeing the food safety monitoring system, and assisting consumers by allowing them to make educated choices.[395] FSANZ also formulates and enforces the Code, which regulates the use of food ingredients, food processing aids, colorings, additives, vitamins, and minerals, as well as the composition of foods.[396] Through these standards, FSANZ guarantees that foods containing engineered nanoparticles are safe for consumption.[397]

In addition to setting standards, FSANZ manages food monitoring and recall systems in Australia and New Zealand.[398] This includes ensuring food safety within the food supply chain and dealing with incidents when they arise, including the potential risks the engineered nanoparticles pose.[399] Besides these processes, FSANZ works with other governmental bodies, like the Department of Agriculture, Fisheries and Forestry, to check if imported food products meet Australian standards.[400] By these means, FSANZ assists in ensuring high standards of safety throughout the food supply system to safeguard public health and enable consumers to have confidence in Australian food products.[401]

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), now replaced with the Australian Industrial Chemicals Introduction Scheme (AICIS), is fundamental in controlling all industrial chemicals, including those with engineered nanoparticles,

394 FOOD STANDARDS AUSTL. N.Z., *supra* note 392.

395 *Id.*

396 *Id.*

397 *The Safe Food System*, FOOD STANDARDS AUSTL. N.Z. (Jul. 13, 2023), https://www.foodstandards.gov.au/about-us/whatwedo/safefoodsystem [https://perma.cc/8UB6-LKXB].

398 *Food Recall Industry Protocol*, FOOD STANDARDS AUSTL. N.Z., (May 26, 2023), https://www.foodstandards.gov.au/food-recalls/firp [https://perma.cc/CUW2-V5RG].

399 *Id.*

400 *About the Food Regulation System*, FOOD REGULATION AUSTL., https://www.foodregulation.gov.au/about-the-system (last visited, Mar. 29, 2026), [https://perma.cc/MCP5-ZT8Q].

401 *Consumer Trust in Food Safety Holds Steady*, FOOD STANDARDS AUSTL. N.Z. (June 5, 2025), https://www.foodstandards.gov.au/news/consumer-trust-food-safety-holds-steady [https://perma.cc/75MY-SAZV]; Kim Berry, *FSANZ Releases First Consumer Insights Survey*, FOOD & DRINK BUS. (May 30, 2024), https://www.foodanddrinkbusiness.com.au/news/fsanz-releases-first-consumer-insights-survey [https://perma.cc/748F-8GVT].

in Australia. NICNAS's primary obligation and focus was on industrial chemicals contained in paints, dyes, inks, plastics, and cosmetics. Such activities encompassed examining the safety of nanomaterials and recommending appropriate measures to address them, which created an indirect influence on the food industry by ensuring the safety of materials used in food packaging and processing.[402] Through the provision of scientific evaluations and regulatory recommendations, NICNAS ensured the safe application of engineered nanoparticles through various industrial processes with minimal risk to public health and the environment.[403]

Australian Industrial Chemicals Introduction Scheme (AICIS) have replaced NICNAS in July 2020. While AICIS has no direct jurisdiction over the food sector, its work in evaluating and monitoring the levels of industrial chemicals, including nanomaterials, profoundly enhanced the safety of the entire food chain.[404] By collaborating with colleagues from other regulatory authorities, such as FSANZ, AICIS helped create Australian regulations that mitigated the legal risks of engineered nanoparticles in Australia.[405]

The ACCC is responsible for monitoring consumer protection and ensuring that businesses engage in fair trade.[406] This organization may not have direct authority over the application of nanomaterials into food, but it has an important mandate in ensuring that the goods, including food, are safe for consumption and that customers are not misled by labels.[407] The ACCC, as an independent statutory authority,

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402 *Who We Are and What We Do*, AUSTL. INDUS. CHEMS. INTRODUCTION SCHEME (May 13, 2025), https://www.industrialchemicals.gov.au/about-us/who-we-are-and-what-we-do [https://perma.cc/7ZZK-5J7T]; *Food Packaging*, Food Standards Austl. N.Z. (May 22, 2025), https://www.foodstandards.gov.au/business/food-safety/food-packaging [https://perma.cc/L4E4-KBGP]; *Food Safety in Packaging 2025: Australian Standards*, RAWSON PRINT & PACKAGING (Feb. 26, 2025), https://www.rpco.com.au/food-safety-in-packaging-2025-ensuring-compliance-with-australian-standards [https://perma.cc/7TFM-69YM].

403 Diana M. Bowman, *The Role of Soft Law in Governing Nanotechnology*, 61 JURIMETRICS 53, 68 (2020).

404 AUSTL. DEPT. OF HEALTH, *Annual Report 2020-2021*, 104, https://www.oecd.org/en/publications/regulatory-frameworks-for-nanotechnology-in-foods-and-medical-products_5k47w4vsb4s4-en.html [on file with the Oregon Review of International Law].

405 *See generally id.*

406 Amanda Smullen & Catherine Clutton, *The ACCC: Guardian of Viable Markets and Consumer Rights*, *in* GUARDIANS OF PUB. VALUE (Arjen Boin, Lauren A. Fahy & Paul 't Hart eds., 2021).

407 *Product Safety*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/consumers/stay-protected/product-safety (last visited Mar. 29, 2026) [https://perma.cc/55QU-BECZ]; *Improving Mandatory Product Safety Standards*, AUSTL.

enforces the provisions of the Competition and Consumer Act 2010, especially as related to consumer protection and other aspects of fair trading.[408] It retains the power to combat and correct overtly false or misleading behaviors in advertising and the promotion of food products.[409] This includes ensuring that any declarations made regarding the inclusion of engineered nanoparticles into food products are not false and do not misrepresent the health effects associated with those products.[410] They also play a role in the fight against deceptive promotion and guarantee that consumers have access to relevant and accurate product information in order to make informed decisions.[411]

Both the Food Standard Code in Australia and the Department of Agriculture, Water and the Environment (DAWE) regulate and are responsible for the use of engineered nanoparticles in food.[412] Like FSANZ, DAWE oversees various government stakeholders.[413]

COMPETITION & CONSUMER COMM'N, https://www.productsafety.gov.au/about-us/improving-mandatory-product-safety-standards (last visited Mar. 29, 2026) [https://perma.cc/N7YC-AUSQ].

408 *About the ACCC*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/about-us/accc-role-and-structure/about-the-accc (last visited Mar. 29, 2026) [https://perma.cc/9Y6A-EFUN].

409 *False or Misleading Claims*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/consumers/advertising-and-promotions/false-or-misleading-claims (last visited Mar. 29, 2026) [https://perma.cc/6AT4-46K6]; *Enforcement of the Food and Grocery Code*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/business/industry-codes/food-and-grocery-code-of-conduct/enforcement-of-the-food-and-grocery-code (last visited Mar. 29, 2026) [https://perma.cc/HB4M-G5TJ].

410 *False or Misleading Claims*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/consumers/advertising-and-promotions/false-or-misleading-claim (last visited Mar. 29, 2026) [https://perma.cc/6AT4-46K6].

411 *Advertising and Promotions*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/consumers/advertising-and-promotions (last visited Mar. 29, 2026) [https://perma.cc/6AT4-46K6]; *Enforcement of the Food and Grocery Code*, AUSTL. COMPETITION & CONSUMER COMM'N, https://www.accc.gov.au/business/industry-codes/food-and-grocery-code-of-conduct/enforcement-of-the-food-and-grocery-code (last visited Mar. 29, 2026) [https://perma.cc/HB4M-G5TJ].

412 *Nanotechnology and Food*, FOOD STANDARDS AUSTL. N.Z., https://www.foodstandards.gov.au/consumer/foodtech/nanotech (last visited Mar. 29, 2026) [https://perma.cc/56KV-PP5E].

413 *Purpose*, Department of Agriculture, Water and the Environment, https://www.agriculture.gov.au/sites/default/files/documents/dawe-purpose-objective-priorites-statement.pdf [on file with the Oregon Review of International Law] (last visited Mar. 29, 2026).

DAWE's policies ensure that foods consumed within Australia with engineered nanoparticles are safe.[414]

DAWE is tasked with the monitoring, regulation, and compliance of imported foods with the Australian and New Zealand food standards, including those for engineered food products.[415] The Department of Agriculture, Fisheries and Forestry (DAFF) employs an inspection scheme based on the risk attached to each food product to ensure that imported foods comply with the safety stipulations set out in the Australia New Zealand Food Standards Code,[416]and also attempts to align Australia's food standards with international standards to ease regulatory control and ensure the safety and competitiveness of Australian food products on the international market.[417] The Food Standards Code enhances consumer autonomy in making choices regarding the food they consume without compromising safety within the food value chain.[418]

B. The Way Forward

The regulation of food products with engineered nanomaterials in Australia falls under the jurisdiction of the FSANZ.[419] Under the existing law, it is the responsibility of every food manufacturer or supplier to guarantee the safety and acceptability of their products for

414 *Food Regulation and Safety*, DEP'T OF AGRIC., FISHERIES AND FORESTRY, https://www.agriculture.gov.au/agriculture-land/farm-food-drought/food/regulation-safety (last visited Mar. 29, 2026) [https://perma.cc/3ESP-FLUA].

415 *Id.*

416 *Id.*

417 *See generally Food Regulation and Safety*, DEP'T OF AGRIC., FISHERIES AND FORESTRY, https://www.agriculture.gov.au/agriculture-land/farm-food-drought/food/regulation-safety (last visited Mar. 29, 2026) [https://perma.cc/3ESP-FLUA]; *International Food Standards Initiative*, DEP'T OF AGRIC., FISHERIES AND FORESTRY, https://www.agriculture.gov.au/agriculture-land/farm-food-drought/food/ifsi (last visited Mar. 29, 2026) [https://perma.cc/6JR5-3SZM]; *Codex – International Food Standards*, DEP'T OF AGRIC., FISHERIES AND FORESTRY, https://www.agriculture.gov.au/agriculture-land/farm-food-drought/food/codex (last visited Mar. 29, 2026) [https://perma.cc/6JR5-3SZM].

418 *Mandatory Food and Grocery Code of Conduct Comes into Effect Today*, AUSTL. COMPETITION & CONSUMER COMM'N (Apr. 1, 2025), https://www.accc.gov.au/about-us/news/media-updates/mandatory-food-and-grocery-code-of-conduct-comes-into-effect-today [https://perma.cc/NKP3-XPMU]; CONSUMER AFFS. AUSTL. AND N.Z., AUSTRALIAN CONSUMER LAW REVIEW FINAL REPORT 5–9 (2017), https://consumer.gov.au/sites/consumer/files/2025-02/final-report-australian-consumer-law-review-2017.pdf [on file with the Oregon Review of International Law].

419 *Nanotechnology and Food*, FOOD STANDARDS AUSTL. N.Z., https://www.foodstandards.gov.au/consumer/foodtech/nanotech (last visited Mar. 29, 2026) [https://perma.cc/56KV-PP5E].

human consumption according to the Food Standards Code.[420] While special provisions for nanomaterials do not exist, any new food product developed with nanotechnology that raises safety issues must be subjected to a scientific safety evaluation prior to the food's distribution.[421] Such an evaluation contains information about the particle size, shape, size distribution, and any other size-dependent attribute(s).[422] In spite of these efforts, some issues still persist, such as the absence of universal definitions for nanomaterials and the ambiguity of their effects on human health over time.[423]

The landscape of rules for foods with ENMs is complex. One obvious concern is the absence of bespoke rules for nanomaterials. While it is true that regulations on food safety do exist, these regulations do not address the specific characteristics and threats posed by ENMs.[424] This situation has the potential to compromise risk assessment and management, leaving parts of consumer safety unattended.

Another issue is the lack of scientific evidence to back up one's claim, especially concerning the health issues related to ENMs. Whether it is safe to consume ENMs remains vague, and existing risk assessment approaches do not seem to address this problem adequately.[425] This ambiguity presents problems for fostering new regulations and for increasing public confidence in the domain of nanotechnology in food.

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420 *Safe Food Australia – A Guide to the Food Safety Standards*, FOOD STANDARDS AUSTL. N.Z., https://www.foodstandards.gov.au/publications/safefoodaustralia (last visited Mar. 29, 2026) (offering detailed guidance on compliance with the Food Standards Code, including responsibilities of food manufacturers and suppliers to maintain food safety) [https://perma.cc/8ABH-XQ4F].

421 *Id.*

422 *Id.*; Joe Lederman & John Thisgaard, *Nanotechnology and the FSANZ Approach*, FOODLEGAL (Aug. 2016), https://foodlegal.com.au/inhouse/document/1526 [on file with the Oregon Review of International Law].

423 Fletcher & Bartholomaeus *supra* note 370, at 3–6; AUSTL. ACAD. OF SCI., *Nanotechnology Regulation in Australia*, https://www.science.org.au/curious/technology-future/nanotechnology-regulation-australia [https://perma.cc/XS6C-QWSN] (last updated Mar. 16, 2018); Simon More et al., *Guidance on Risk Assessment of Nanomaterials in the Food and Feed Chain: Human and Animal Health*, EFSA J., June 30, 2021, at 5–9.

424 Fletcher & Bartholomaeus, *supra* note 370.

425 Kristen Lyons & Gyorgy Scrinis, *Under the Regulatory Radar? Nanotechnologies and Their Impacts for Rural Australia*, *in* TRACKING RURAL CHANGE: COMMUNITY, POLICY AND TECHNOLOGY IN AUSTRALIA, NEW ZEALAND AND EUROPE (Francesca Merlan & David Raftery eds., 2009).

Furthermore, gaps in commonly accepted rules for categorizing nanomaterials lead to various loopholes in the governing regulations.[426] The lack of clear guidance makes it virtually impossible to define or control the scope of nanomaterials,[427] which could potentially produce various forms of regulatory mischief including poor enforcement. If regulators seek trust and acceptance, it is imperative to provide consumers with information about the existence and safety of nanoparticles in food products.[428] Even so, current policies may lack transparency and the opportunity for greater public participation.

This research suggests that the strategies employed by the US, EU, and UK might not yield the results Australia desires. Australia may consider a new method for revising and developing policies, enhancing scientific inquiry, and collaborating with stakeholders on the safe and ethical use of nanotechnology in the food industry. The question, therefore, is what approach Australia should take as the core of this regulatory framework. As discussed earlier, the US, EU, and UK have several bases for building this regulation; they do not follow any particular approach, including the precautionary, product-specific, incremental, or proactive approaches.

Adaptation is the key to the incremental approach to regulation.[429] The incremental approach enables the regulatory framework to evolve with new technologies and changing risks based on the principles of adaptation.[430] Instead of making sweeping changes, incremental adjustments are implemented, allowing regulators to address specific issues without causing widespread disruption.[431] Through these incremental changes, regulators are able to collect data, evaluate the newly implemented changes, and make decisions on any necessary

426 Jorge Antonio Chávez-Hernández et al., *Safe Nanomaterials: From Their Use, Application, and Disposal to Regulations*, 6 Nanoscale Adv. 1583, 1586–89 (2024); CTR. FOR INT'L ENV'T L. (CIEL), RISK ASSESSMENT OF NANOMATERIALS IN A REGULATORY CONTEXT (2016).

427 *See generally* Fletcher & Bartholomaeus, *supra* note 370.

428 *See* David B Fischer, *Nanotechnology: Scientific and Regulatory Challenges*, 19 VILL. ENV'T L.J. (2008); Michael D. Cobb & Jane Macoubrie, *Public Perceptions About Nanotechnology: Risks, Benefits and Trust*, 6 J. OF NANOPARTICLE RSCH. 395–405 (2004).

429 Julia Black, *Paradoxes and Failures: 'New Governance' Techniques and the Financial Crisis*, 75 MOD. L. REV. 1037, 1042–45 (2012); Neil Gunningham & Darren Sinclair, *Regulatory Pluralism: Designing Policy Mixes for Environmental Protection*, 21 LAW & POL'Y 49, 52–56 (1999).

430 *See generally* Magnus Schoeller & Paul Weismann, *Economic and Monetary Union: Incremental Adaptation Under Legal and Political Constraints*, *in* EU REGULATORY RESPONSES TO CRISES: ADAPTATION OR TRANSFORMATION? (2024).

431 Black, *supra* note 429.

changes.[432] Such an approach encourages innovation by allowing new advances without causing regulatory constraints. This approach also ensures that regulations do not become outdated and ineffective by enabling continuous improvement and learning.

While the matter of regulation infused with the adaptation approach is straightforward, its execution is not so simple. One of the core problems is what some might refer to as hyperadaptability, which, while enabling flexibility, can result in regulatory volatility or instability.[433] For example, there is uncertainty for businesses and consumers when modifications are constantly introduced and altered; people may lose trust in the system, leading to avoidance or noncompliance.[434] A stakeholder's or investor's ability to plan and make investments in the long run becomes much more complex because regulatory forecasting is challenging.[435] One also needs to consider that adaptive regulation, which requires sustained concentration, data gathering, and process study, is resource intensive and can strain regulatory agencies, taking their focus away from earmarked vital matters.[436] Of equal concern are continuous changes, which can fragment implementation across sectors or regions and make compliance impossible.[437] When dealing with adaptive regulation,

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432 Jeroen van der Heijden, *Adaptive Governance for a Resilient Digital Society*, *in* GOVERNANCE FOR DIGITAL TRANSFORMATION 1, 4–9 (2024); Shahana Akther & James Evans, *Emerging Attributes of Adaptive Governance in the Global South*, 12 FRONTIERS ENV'T. SCI. (2024).

433 Jeroen van der Heijden, *The Limits of Adaptive Governance*, 54 REGUL. & GOVERNANCE 1, at 4–8 (2023); Asress Adimi Gikay, *Risks, Innovation, and Adaptability in the UK's Incrementalism Versus the European Union's Comprehensive Artificial Intelligence Regulation*, 32 INT'L J.L. & INFO. TECH. 1, 6–9 (2024).

434 Kenan Institute, Up to Code: The cost of Regulation and Regulatory Uncertainty, https://kenaninstitute.unc.edu/kenan-insight/up-to-code-the-costs-of-regulation-and-regulatory-uncertainty (last visited Mar. 29, 2026) [https://perma.cc/RF6D-TAUA].

435 Edward Venter et al., *Rethinking Regulatory Investment: Unlocking Value Beyond Compliance in Banking*, DELOITTE (April 28, 2025), https://www.deloitte.com/uk/en/services/consulting/blogs/2025/rethinking-regulatory-investment-unlocking-value.html [https://perma.cc/FA2F-KF6H]; *The Impact of Regulatory Environment on Investments*, FASTERCAPITAL (April 6, 2025), https://fastercapital.com/content/The-Impact-of-Regulatory-Environment-on-Investments.html [https://perma.cc/5S8B-M4MM].

436 Claudio Radaelli & Lorenzo Allio, *What Is the Future of Regulatory Policy?*, THE REGUL. REV. (Dec. 19, 2022), https://www.theregreview.org/2022/12/19/allio-radaelli-regulatory-policy/ (last visited Mar. 29, 2026) [https://perma.cc/97VA-CVPV]; Rebecca Schmidt & Colin Scott, *Regulatory Discretion: Structuring Power in the Era of Regulatory Capitalism*, 41 LEGAL STUD. 3 (2021).

437 Joseph Kalmenovitz, Michelle Lowry & Ekaterina Volkova, *Regulatory Fragmentation*, 80 J. FIN. 1081 (2025).

flexibility needs to be tempered with predictability. This type of regulation requires resources that are not easily acquired.

Risk mitigation transforms the foundation of the precautionary approach to regulation, and initiates a systematic method of identifying potential dangers that need evaluation and manages new technologies or materials that are still novel in nature.[438] This precautionary approach highlights the necessity of preventive action in the context of scientific ignorance and risk assessment before widespread implementation.[439] Through risk evaluation, regulators and subject matter experts are able to predetermine the possible effects, likelihood, severity, and means to mitigate factors that pose risk.[440] This approach aids in enhancing public health and environmental protection while being careful about innovation.[441] Thus, the precautionary principle ensures safety whenever there is incomplete scientific evidence.[442]

Developing a system for risk evaluation is extremely difficult but remains a vital part of the precautionary principle for effective and efficient regulation. A lack of understanding of the long-term consequences of new technologies presents an emerging issue—how should we cope with the resulting scientific uncertainty?[443] This can

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438 Deryck Beyleveld, and Roger Brownsword, *Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning*, 4 L. INNOVATION & TECH. 35, 65 (2012); European Commission, *Communication from the Commission on the Precautionary Principle*, at 3–6 COM (2000)1 final (Feb. 2, 2000).

439 The Rio Declaration on Environment and Development princ. 15, June 13, 1992, 31 I.L.M. 814 ("Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"); European Commission, *Communication from the Commission on the Precautionary Principle*, at 3–6 (Feb. 2, 2000).

440 Organisation for Economic Co-operation and Development [OECD], *Framework on Management of Emerging Critical Risks*, at 5–9 (June 19, 2024), https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/06/framework-on-management-of-emerging-critical-risks_7924458a/2f2eddd8-en.pdf [on file with the Oregon Review of International Law]; Panagiotis Isigonis et al., *Risk Governance of Emerging Technologies Demonstrated in Terms of Its Applicability to Nanomaterials*, SMALL 1, 3–5 (2020).

441 Andrea Fabrizi et al., *The Impact of Environmental Regulation on Innovation and International Competitiveness*, 31 J. INT'L ECON. 1123, 1125–30 (2024); Daniele Sofia et al., *Mitigation Strategies for Reducing Air Pollution*, 27 ENV'T. SCI. & POLLUTION RES. 8654, 8656–62 (2020).

442 European Commission, *supra* note 438, at 3–6.

443 DEBORAH C. PETERSON, PRECAUTION: PRINCIPLE AND PRACTICE IN AUSTRALIAN ENVIRONMENTAL AND NATURAL RESOURCE MANAGEMENT 3–6 (Annette Weier et al. eds., 2005); David Lindenmayer & Rhett D. Martin, *Applying the Precautionary Principle to Hidden Collapse*, SUSTAINABILITY 4–7 (May 2, 2024), https://doi.org/10.3390/su16103904 [https://perma.cc/E8C7-LUMA]; Aoife Nolan, *Precautionary Principle and Impact Assessment: The Case of School Closures During the Pandemic in Ireland*, 14 EUR. J. RISK REGUL. 1, at 5–9 (2023).

result in overly cautious choices that may cripple innovation and growth in new technologies.[444] The prolonged and resource-heavy processes of risk evaluation can also impede other crucial areas within regulatory agencies, including limitations on risk scrutiny and management resources.[445] In addition, an overreliance on the precautionary principle risks undue or excessive damages because it may constrain new technology beyond the level of danger anticipated, contravening the original intention of the principle.[446] Finding the effective mixture between restricting actions leading to risk, fostering innovation, and market enrichment remains the most difficult aspect of these regulations.[447]

Transparency is vital in tracking product-specific regulations because it makes sure that product-related information and information pertinent to safety, efficacy, and the environment are accessible to various stakeholders.[448] This approach requires the product to be

444 *See generally* Cass R. Sunstein, Beyond the Precautionary Principle, John M. Olin Program In Law & Econ. Working Paper No. 149, 2002), https://chicagounbound.uchicago.edu/law_and_economics/87/ (critiquing strong forms of the precautionary principle as paralyzing and highlighting how excessive caution can hinder innovation and growth) [https://perma.cc/W3LH-72YX].

445 OECD, *Regulatory Policy Outlook 2021*, at 112–15 (Oct. 6, 2021), https://www.oecd.org/content/dam/oecd/en/publications/reports/2021/10/oecd-regulatory-policy-outlook-2021_c5274577/38b0fdb1-en.pdf [on file with the Oregon Review of International Law].

446 Yorgos Marinakis et al., *The Precautionary Principle: What Is It, Where Did It Come From, How Should We Use It?*, 3 J. INT'L & INTERDISC. BUS. RSCH. 1, 10–12 (2016); Robert W. Hahn & Cass R. Sunstein, *The Precautionary Principle as a Basis for Decision Making*, 2 ECONOMISTS' VOICE 1 (2005).

447 Kevin A. Bryan & Florenta Teodoridis, *Balancing Market Innovation Incentives and Regulation in AI: Challenges and Opportunities*, BROOKINGS INST. (Sept. 24, 2024), https://www.brookings.edu/articles/balancing-market-innovation-incentives-and-regulation-in-ai-challenges-and-opportunities/ [https://perma.cc/QV3T-YMP6]; Betsy Vereckey, *Does Regulation Hurt Innovation? This Study Says Yes*, MIT SLOAN SCH. OF MGMT. (June 7, 2023), https://mitsloan.mit.edu/ideas-made-to-matter/does-regulation-hurt-innovation-study-says-yes [https://perma.cc/Y4X9-5GRZ]; Philippe Aghion, Antonin Bergeaud & John Van Reenen, *The Impact of Regulation on Innovation*, 113 AM. ECON. REV. 2894 (2023); Yafit Lev-Aretz & Katherine J. Strandburg, Bulletin, *Regulation and Innovation: Approaching Market Failure from Both Sides*, YALE J. ON REGUL. 1, 1 (2020), https://openyls.law.yale.edu/bitstreams/e2e0e89f-338b-4bd9-b462-7227e1b18b0d/download [on file with the Oregon Review of International Law].

448 *See generally* Muralikrishna Gangadharan Komala et al., *Investigating the Regulatory Process, Safety, Efficacy and Product Transparency for Nutraceuticals in the USA, Europe and Australia*, FOODS 1 (Jan. 16, 2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC9857896/pdf/foods-12-00427.pdf [on file with the Oregon Review of International Law]; Joshua M. Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug*

labeled accurately, documented appropriately, and have data made available at every stage of the product's life cycle, including data related to the product's risks.[449] Regulators are able to build trust and accountability through the provision of accurate and complete information that enables consumers to make rational choices and encourages companies to adhere to the regulations set out.[450] When some of these measures contribute to better transparency, regulative bodies are able to track compliance with regulations and quickly rectify any problems.[451] In the end, this principle allows regulatory innovation while continuing to protect the health and safety of the public and other stakeholders.

Although transparency is critical, it brings forth important challenges. One significant problem within regulation is the risk of stakeholders being overwhelmed by excessive data disclosures, which can make critical information virtually unidentifiable.[452] Furthermore,

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Administration: Recommendations to Advance the Development of Safe and Effective Medical Products, 45 J.L. MED. & ETHICS 7 (2017).

449 *See* Christiane Arndt et al., *2015 Indicators of Regulatory Policy and Governance: Design, Methodology and Key Results* 12–15 (OECD Regulatory Policy Working Papers Nov. 1, 2015), https://www.oecd.org/content/dam/oecd/en/publications/reports/2015/12/2015-indicators-of-regulatory-policy-and-governance_g17a2744/5jrnwqm3zp43-en.pdf [on file with Oregon Review of International Law]. *See generally* Raman Maroz & Luisa Daniela Dyer Melhado, *Data-Driven Transparency: The Need for Easy Access to Laws and Regulations for Businesses*, WORLD BANK BLOGS (Dec. 19, 2024), https://blogs.worldbank.org/en/opendata/data-driven-transparency--the-need-for-easy-access-to-laws-and-r [https://perma.cc/S9VK-S9QG]; U.N., Economic & Social Council, Economic Commission for Europe, Executive Committee, Draft Recommendation No. 49: Transparency at Scale, U.N. Doc. ECE/TRADE/C/CEFACT/2024/6 (July 3, 2024); Frieder Rubik, *Life Cycle Management: Labelling, Declarations and Certifications at the Product Level – Different Approaches*, *in* LIFE CYCLE MANAGEMENT (Guido Sonnemann & Manuele Margni eds., 2015).

450 Consumer Compliance, BD. OF GOVERNORS OF THE FED. RSRV. SYS. (July 27, 2018), https://www.federalreserve.gov/supervisionreg/consumer-compliance.htm (explaining that regulators promote compliance and consumer trust by providing accurate information, guidance, and supervisory resources to enable informed consumer choices and ensure adherence to regulatory standards) [https://perma.cc/JC82-DHTX].

451 *Id.*

452 *See generally* CARY COGLIANESE, HEATHER KILMARTIN & EVAN MENDELSON, TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RULEMAKING PROCESS: A NONPARTISAN PRESIDENTIAL TRANSITION TASK FORCE REPORT (July 2008), https://hepg.hks.harvard.edu/sites/g/files/omnuum10586/files/hepg/files/transparencyreport.pdf (discussing how excessive disclosure can undermine meaningful participation by overwhelming stakeholders with information) [on file with the Oregon Review of International Law]; U.S. GOV'T ACCOUNTABILITY OFF., https://www.gao.gov/federal-information-transparency (last visited Mar. 29, 2026) (explaining that while transparency promotes accountability, agencies face challenges ensuring data is usable and not overwhelming for stakeholders); MEDIA FREEDOM & INFO. ACCESS CLINIC, YALE L. SCH.,

there is the confidentiality versus transparency dilemma that businesses must deal with, where it is hard to appreciate proprietary data while still making it publicly available. This issue stems from the fact that companies are often unwilling to provide sensitive information that can put them at a competitive disadvantage.[453] In addition, larger organizations often bear the burden of increased organizational complexity that ultimately deteriorates transparency. This may curb innovation and entry into the industry for small and medium sized enterprises.[454] Accordingly, transparency cannot be ensured at the expense of efficiency or competitiveness.

The principle of *voluntary guidelines* is the cornerstone of the proactive approach to regulation. Following this principle, regulators solicit voluntary compliance from regulated businesses by encouraging cooperation and responsibility.[455] This principle assists the business in organizing its internal strategies and, at the same time, guides public

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ABRAMS INST., ALGORITHMIC ACCOUNTABILITY: THE NEED FOR A NEW APPROACH TO TRANSPARENCY AND ACCOUNTABILITY WHEN GOVERNMENT FUNCTIONS ARE PERFORMED BY ALGORITHMS (Jan. 18, 2022), https://law.yale.edu/sites/default/files/area/center/mfia/document/algorithmic_accountability_report.pdf (highlighting that current disclosure practices often fail to provide clarity, creating transparency without true accountability) [on file with the Oregon Review of International Law].

453 *Id.*

454 *See generally* Vereckey, *supra* note 447 (summarizing research showing that as firms grow and cross regulatory thresholds, added compliance obligations dampen innovation and create organizational complexity); Tyler Hoguet, *Estimating the Impact of Regulation on Business*, THE REGUL. REV. (Feb. 28, 2024), https://www.theregreview.org/2024/02/28/hoguet-estimating-the-impact-of-regulation-on-business/ (reviewing findings that regulatory compliance costs disproportionately burden medium-sized firms, complicating transparency and inhibiting growth and market entry) [https://perma.cc/QFQ6-S9KK]; *Better Regulation and Innovation*, OECD, https://www.oecd.org/en/topics/better-regulation-and-innovation.html (last visited Mar. 29, 2026) (setting out OECD guidance that overly complex or poorly designed regulatory governance can stifle innovation and should be risk-based and agile to avoid unnecessary burdens on firms, including SMEs) [on file with the Oregon Review of International Law].

455 *See generally An Overview of Voluntary Remediation Programs*, DOWNSTREAM STRATEGIES (Sept. 18, 2024), https://downstreamstrategies.com/an-overview-of-voluntary-remediation-programs/ (explanatory parenthetical) [https://perma.cc/8DFB-L5GB]; United States-Mexico-Canada Agreement, ch. 28, July 1, 2020, https://ustr.gov/sites/default/files/files/agreements/ FTA/USMCA/Text/28_Good_Regulatory_Practices.pdf (outlining principles of good regulatory practices, including voluntary cooperation and regulatory alignment to reduce burdens and promote compliance) [on file with the Oregon Review of International Law]; *Compliance Guidelines*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., https://oig.hhs.gov/compliance/compliance-guidance/ (last visited Dec. 2, 2025) (providing voluntary compliance program guidance for healthcare entities to encourage proactive adherence to regulations and ethical standards) [https://perma.cc/ZMV3-TFPT].

agencies in establishing institutional standards and best practices in business organizations without the need for constant supervision or monitoring. As much as this principle aims to create behavioral change, the regulatory approach based on voluntary guidelines creates goodwill between the regulators and the businesses as they attempt to promote accountability and compliance. It allows regulatory authorities to use their time and resources more effectively by concentrating on more serious problems while doing away with tedious and expensive enforcement. Voluntary guidelines from public agencies achieve rapid compliance with regulations in highly advanced economies while fostering competition, innovation, and safeguards for the public, people, and industry.[456]

While voluntary guidelines promote innovation and cooperation, they also have various problems. One of the biggest problems is that compliance is not guaranteed, and therefore it becomes difficult to enforce. This would result in scant adherence from diverse organizations.[457] This may compromise the effectiveness of the guidelines and further create an imbalanced system. Furthermore, self-management in an industry may go too far and lead to some businesses taking actions that are against public health and safety.[458] Moreover, the absence of rigid standards can easily lead to a lack of accountability, thus compounding the problems associated with noncompliance and corrective measures.[459] These limitations emphasize the need to combine voluntary guidelines with some legal provisions to achieve flexibility and accountability.

Safeguarding these new issues and opportunities brought about by new products is best achieved through the use of different criteria and

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456 CHARLOTTE WOOD ET AL., APPLICATIONS OF RESPONSIVE REGULATORY THEORY IN AUSTRALIA AND OVERSEAS 3 (2010); AUSTL. GOV'T DEP'T OF FIN., REGULATORY POLICY, PRACTICE & PERFORMANCE FRAMEWORK, 4–6 (2024); NSW GOV'T, COMPLIANCE AND ENFORCEMENT APPROACH, 5–8 (2025).

457 *See* HOWARD BEALES ET AL., REGUL. TRANSPARENCY PROJECT, GOVERNMENT REGULATION: THE GOOD, THE BAD, & THE UGLY (2017).

458 *See generally* AUSTL. COMM'N ON SAFETY AND QUALITY IN HEALTH CARE, NATIONAL SAFETY AND QUALITY HEALTH SERVICE STANDARDS (2nd ed. 2021), https://www.safetyandquality.gov.au/sites/default/files/2021-05/national_safety_and_quality_health_service_nsqhs_standards_second_edition_-_updated_may_2021.pdf (explanatory parenthetical) [on file with the Oregon Review of International Law]; Stephen R. Finger & Shanti Gamper-Rabindran, *Testing the Effects of Self-Regulation on Industrial Accidents*, 43 J. REGUL. ECON. 115, 115–46 (2013).

459 Finger & Gamper-Rabindran, *supra* note 458.

approaches, especially concerning new technology based products.[460] Various emerging technologies, such as artificial intelligence, biotechnology, and nanotechnology, each possess different features and impacts that call for different approaches to regulation.[461] As discussed above, while the regulatory approaches of the UK, US, and EU are promising, an approach based on a single principle is not ideal for regulating foods with ENMs.[462] Each approach, based on a particular principle, has its own drawbacks. A regulatory approach that can hold the abovementioned principles would be the ultimate approach for regulating foods with ENMs.

When dealing with new innovations, Australia employs strategies that best suit its specific context, be it economic, social, or environmental.[463] Unlike in other countries where either laws or voluntary guidelines are the norm, Australia incorporates more flexibility and adaptability into its regulatory frameworks,[464] enabling businesses to experiment with new technologies at a specific level of restricted regulation. Also, the Industry and Skills Council's regulatory bodies in different Australian states work on proactive industry reform to support innovation while controlling risk.[465] Australia hopes to strike

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460 Jerry Wind & Vijay Mahajan, *Issues and Opportunities in New Product Development: An Introduction to the Special Issue*, 34 J. MKTG. RSCH. 1, 1–3 (1997).

461 *See generally* William D. Eggers et al., *The Future of Regulation: Principles for Regulating Emerging Technologies*, DELOITTE (June 19, 2018), https://www2.deloitte.com/us/en/insights/industry/public-sector/future-of-regulation/regulating-emerging-technology.html (noting that emerging technologies differ significantly in their characteristics, risks, and societal implications, requiring tailored regulatory approaches rather than a single uniform model) [https://perma.cc/2QDY-DJWZ].

462 Simon More et al., *Guidance on Risk Assessment of Nanomaterials to Be Applied in the Food and Feed Chain: Human and Animal Health* 1, 6–10 (2021).

463 *See* DEBORAH C. PETERSON, PRECAUTION: PRINCIPLE AND PRACTICE IN AUSTRALIAN ENVIRONMENTAL AND NATURAL RESOURCE MANAGEMENT 3–6 (2006); INNOVATION & SCI. AUSTL., AUSTRALIA 2030: PROSPERITY THROUGH INNOVATION 18–22 (2017).

464 AUSTRALIAN DEPARTMENT OF INDUSTRY, SCIENCE AND RESOURCES, *infra* note 469, at 12–15; OECD REGULATORY POLICY OUTLOOK, OECD at 218–19.

465 *See generally Jobs and Skills Councils*, AUSTL. GOV'T DEP'T OF EMP. & WORKPLACE RELS., https://www.dewr.gov.au/skills-reform/jobs-and-skills-councils (last visited Mar. 29, 2026) (explaining that the new Jobs and Skills Councils (JSCs) are industry-owned/led bodies tasked with workforce planning, developing responsive training products, and stewardship—giving industry a stronger voice to drive reform of the VET system in partnership with governments) [https://perma.cc/FY4C-92QK]; *Industry Engagement Reforms: Frequently Asked Questions*, AUSTL. GOV'T DEP'T OF EMP. & WORKPLACE RELS., https://www.dewr.gov.au/download/15005/industry-engagement-reforms-frequently-asked-questions/34701/industry-engagement-reforms-frequently-asked

a balance between growth and innovation, on the one hand, and public safety and confidence on the other.[466] To achieve this goal, it collaborates with all stakeholders, engages them, and promotes a responsive regulatory policy.

Against this historical context, Australia should implement a holistic risk management strategy specifically designed for regulating nanoparticles in food, without compromising the unique qualities of the materials at hand. It should provide thorough assessments of the health and environmental risks associated with the behaviors of ENMs.

Australia can benefit from the public's engagement in its regulatory policies.[467] For this, the Australian government should emphasize proper disclosure and labeling for foods that contain ENMs to instill confidence in the public that the food they consume is safe. This will empower the public to participate in regulation.[468] By creating an open regulatory atmosphere, Australia can foster informed consumer participation and a greater appreciation of the use of other technologies in the food industry through nanotechnology. Furthermore, Australia should enact progressive regulations to align with the fast-changing dynamics of nanotechnology, on top of allocating funds to research. Developing custom research programs and allocating grants to understand nanoparticles' impacts over time will enable informed regulatory actions.[469] Sandboxes are examples of more advanced adaptive regulatory frameworks that permit controlled testing of new

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-questions/PDF (last visited Mar. 29, 2026) (detailing how strengthened industry engagement via JSCs is designed to address strategic workforce risks and accelerate qualification updates, embedding proactive, evidence-based reform processes) [hereinafter *Industry Engagement Reforms*] [on file with the Oregon Review of International Law].

466 *Industry Engagement Reforms*, *supra* note 465.

467 *See* Caron Molster et al., *Informing Public Health Policy Through Deliberative Public Engagement: Perceived Impact on Participants and Citizen–Government Relations*, 17 GENETIC TESTING AND MOLECULAR BIOMARKERS (2013); Peta Ashworth et al., *Turning the Heat on: Public Engagement in Australia's Energy Future*, *in* RENEWABLE ENERGY AND THE PUBLIC (2014).

468 *Principles on Open Public Sector Information*, OFF. OF THE AUSTL. INFO. COMM'R (May 25, 2011), https://www.oaic.gov.au/about-the-OAIC/information-policy/information-policy-resources/principles-on-open-public-sector-information [https://perma.cc/3V6R-TACD]; *Open Government, Open Data & Public Participation*, INFO. AND PRIVACY COMM'N, https://www.ipc.nsw.gov.au/information-access/open-government-open-data [https://perma.cc/2X2G-ELQD].

469 Umme Thayyiba Khatoon & Aditya Velidandi, *An Overview on the Role of Government Initiatives in Nanotechnology Innovation for Sustainable Economic Development and Research Progress*, 17 SUSTAINABILITY 1250, 1252–53 (2025); FDA, *FDA's Approach to Regulation of Nanotechnology Products* (Mar. 23, 2018), https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products [https://perma.cc/7BZC-H5L4].

technologies and progressive alterations to regulatory norms.[470] This more comprehensive approach will position Australia to effectively deal with new developments and risks as they arise, informing other aspects of Australian public health and safety networking regulations.

Australia needs an approach that holds the principles of transparency, adaptability, risk minimization, regulation of independence, and legal compliance in its regulation of foods with ENMs. While there are some options of regulatory approaches to serve this need, this Article suggests a meta-regulation approach, which would be the most appropriate for Australia's regulatory needs.

Meta-regulation merges reflexive and responsive regulations.[471] Despite the increasing interest from policymakers and scholars in meta-regulation, a universal definition has yet to be established. Consequently, the definitions of meta-regulation vary. For instance, Bronwen Morgan defines meta-regulation as the ability to "manage the tension between the 'social' and 'economic' goals of regulatory politics".[472] Others adopt a broader perspective, using meta-regulation to refer to interactions among different regulatory actors or levels of regulation. Furthermore, Parker describes meta-regulation as regulating the regulators, whether public agencies, private corporate self-regulators, or third-party gatekeepers.[473] Braithwaite and Parker characterize institutional meta-regulation as the regulation of one institution by another.[474] Additionally, Morgan argues that meta-regulation captures a desire to think reflexively about regulation, such that, rather than regulating social and individual actions directly, the regulation process becomes regulated.[475] Commenting on the process, Parker and others noted that in meta-regulation, each layer [of regulation] regulates the regulation of each other in various

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470 Dirk A. Zetzsche, *Building Fintech Ecosystem: Regulatory Sandboxes, Innovation Hub and Beyond*, 23 EUR. BUS. ORG. L. REV. 1, 3–7 (2022).

471 Mia Mahmudur Rahim, *A Meta-Regulation Approach to Laws to Incorporate CSR Principles in Corporate Self-Regulation*, *in* LEGAL REGULATION OF CORPORATE SOCIAL RESPONSIBILITY: A META-REGULATION APPROACH OF LAW FOR RAISING CSR IN A WEAK ECONOMY 129, 139 (2013).

472 *Id.* at 137.

473 Christine Parker, *Meta-Regulation: Legal Accountability for Corporate Social Responsibility*, 29 LAW & POL'Y 1, 3 (2007).

474 JOHN BRAITHWAITE, RESTORATIVE JUSTICE AND RESPONSIVE REGULATION, 254 (2002).

475 *See* BRONWEN MORGAN, SOCIAL CITIZENSHIP IN THE SHADOW OF COMPETITION: THE BUREAUCRATIC POLITICS OF REGULATORY JUSTIFICATION 2 (2017) (ebook).

combinations of horizontal and vertical influence.[476] The essential characteristics of any regulatory instrument or approach are fourfold: target, regulator, command, and consequences.[477] In the case of meta-regulation, the regulators may be multiple, and the sources of command can be multidirectional.

Among various versions of meta-regulation, Parker emphasizes the legal pluralism of regulatory governance, viewing it increasingly as involving "collaborations," "partnerships," "webs," or "networks." In Parker's model, laws play a less critical role, and the government's primary role is to coordinate and facilitate stakeholders in regulatory frameworks. Consequently, multiple stakeholders—including consumer society, media, nongovernmental organizations, and even international institutions—create and implement regulations. Within this flexible yet indirectly balanced regulatory framework, all the regulated parties can contribute their resources to advance a public policy goal; they can devise competitive strategies to achieve this goal in pursuit of incentives, recognition, and credits from public agencies and systems. Parker finds that a regulatory framework based on the meta-regulation approach enables large companies to enhance their internal capacity with the support of other stakeholders, ultimately allowing them to internalize corporate conscience in their business activities without jeopardizing their primary commercial objectives.[478] She also argues that individuals directly involved in specific situations should play a significant role in enhancing the integration of social responsibility into corporate practices.[479]

476 John Braithwaite, REGULATING LAW 6 (Christine Parker et al. eds., 2004).

477 Cary Coglianese, *Engaging Business in the Regulation of Nanotechnology*, *in* GOVERNING UNCERTAINTY: ENVIRONMENTAL REGULATION IN THE AGE OF NANOTECHNOLOGY 46, 50–51 (Christopher J. Bosso ed., 2010).

478 Parker, *supra* note 473, at 7–10.

479 *Id.*

CONCLUSION

> *"No regulatory tool is perfect, especially under every condition. The appropriate test for a regulatory option is not whether it is perfect. It is whether that approach is better than the alternatives—including the alternative of doing nothing."*[480]

The rapid growth of the engineered nanomaterials (ENMs) industry poses significant challenges for effectively regulating foods that incorporate these substances. Current regulatory methods—which range from deterrence to prescription and private ordering—have proven costly and ineffective in addressing the complexities of this technology driven market. To navigate these challenges, it is crucial to modernize and harmonize regulations, improve risk assessment methodologies, and significantly enhance transparency and stakeholder engagement in regulating foods containing ENMs. This effort is particularly urgent as technological advancements outpace the development of adequate information and strategies to mitigate potential risks.

Leading jurisdictions in producing and managing nanotechnology-based products typically use one of four regulatory approaches: incremental, product-specific, proactive, or precautionary. These approaches rely on foundational principles such as adaptation, risk minimization, transparency, and self-regulation. While each principle has its benefits, they also come with inherent limitations. A synergistic application of these approaches could minimize their drawbacks, creating a more robust regulatory framework. Thus, a regulatory approach that integrates all these principles is essential for effectively overseeing the challenges presented by engineered nanotechnology.

These authors advocate for a meta-regulation approach within Australia's framework for regulating foods with ENMs. This strategic approach empowers the food industry to devise effective self-regulation strategies that significantly minimize health risks associated with ENMs. Rather than creating an entirely centralized or decentralized regulatory landscape, meta-regulation seeks a balanced framework that incorporates both elements in a meaningful way.

Under this meta-regulation approach, Australian laws could empower regulatory agencies to tap into resources from private corporations and civil society to tackle uncertainties associated with

480 Cary Coglianese & Evan Mendelson, *Meta-regulation and Self-regulation*, *in* THE OXFORD HANDBOOK OF REGULATION 1, 26 (2010).

ENMs in food. This collaborative approach is vital: Scientific uncertainties should not reside solely with public agencies, nor can private entities shoulder the burden of ensuring public safety alone. By decentralizing regulatory power, stakeholders—including large chemical and food producers—can better align their operations with consumer interests, thereby enhancing industry regulation. This delegation of regulatory authority enables food manufacturers and associated stakeholders to effectively confront the challenges posed by engineered nanomaterials, driving the development of innovative solutions to mitigate potential risks to public health and the environment.