

Annual Trends Report 2022
Using regulatory insight to drive R&D strategy

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Foreword

Aligning regulatory and commercial strategies

Current geopolitical events will continue to place immense pressure on the global trading system in 2023. The resultant instability is keenly felt by the food and beverage industry. Conversations with our members indicate that these are challenging times.

Food and beverage businesses all over the world are dealing with serious supply chain issues, increased inflation and rising costs. These issues come hot on the heels of the upheaval caused by the COVID-19 pandemic, and their impact will be felt for years to come. Alongside this, major concerns surrounding sustainability, innovation, consumer health, and food safety are still high on the agenda.

The global regulatory landscape also continues to evolve and divergence in the demands of different markets remains a challenge. Food and beverage businesses need to keep up to date with current requirements and ongoing regulatory discussions. Meanwhile, they must ensure new products (or changes to existing products) are compliant with rules that will be applicable at time of launch in different markets.

Despite these difficulties, the sector remains buoyant. A report by accountancy firm Grant Thornton¹ says that food and beverage businesses are "staying resilient in the face of larger macroeconomic challenges". The firm highlights innovation, new industry trends and a well-established focus on sustainability as key factors that will help the sector ride the current storm.

This year's Annual Trends Report sheds light on some of the emerging, evolving and newly established regulations that will impact the sector in the short to mid-term. Our aim is to help you take an informed and proactive stance, ensuring your regulatory strategy supports your commercial roadmap, whatever lies ahead.

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Introduction

Three drivers of food and beverage regulatory trends

Our regulatory experts and scientists have conducted in-depth analysis of current global trends, and we've also asked members about their regulatory challenges and priorities. The information and insights gathered from these activities point to three overarching drivers of regulatory change for the food, beverage, and supplement sector:

- 1. Environmental sustainability
- 2. Health and wellness
- 3. Quality and safety

We spoke with members from a cross-section of ingredients, food, and beverage companies to ensure our Annual Trends Report reflects real-world needs. Interviewees held senior roles within baked goods, snacks, confectionery, soft drinks, out of home/fast food, ingredients, dairy and potato-based product companies.

The report summarises key macro and micro-trends related to the three drivers, with deep dives into selected areas that members highlighted as important. To support strategy development, it is vital to understand that regulations will be at different levels of maturity in different markets, as shown in Figure 1.

The birth of regulations

	Emerging		Establised
Definition	The potential to regulate/intervene in a particular area has been raised or discussed. Studies may have been initiated or business /NGO views requested.	Activities to regulate /intervene in a particular area have occurred and target dates have been mentioned, but details and timeframes are not finalised.	Activities to regulate /intervene in a particular area have been finalised. Details and timeframes are known.
Examples	Green papers Consultations Minutes from regulatory meetings Surveys/studies initiated	Whitepapers Draft regulation /standards/guidance /codes of practice Consultation outcomes Survey/study outcomes Published opinions (e.g. EFSA)	New legislation Amends to existing legislation Published standards /guidance/codes of practice New/amended authorisations

Figure 1: Effective regulatory strategy development is rooted in awareness of emerging and evolving articles, as well as regulations that are fully established. Regulations are generally conceived from earlier discussions about pertinent issues, and there are usually opportunities for industry players to be involved in the process.

It's important to note that regulatory trends may be at different stages in different countries and regions. Something that's established in China may still be evolving in Latin America, or vice versa. Similarly, it's often the case that where an overarching regulatory framework has been established, specific requirements are still evolving. This is particularly true in the EU and US where member states or states may interpret and implement rules in their own way.

Report objectives

The goal of this report is to aid business planning around innovation, reformulation, new product launches and global expansion in light of regulations. Applying a regulatory lens to new products at the front-end innovation point reduces the risk of problems further down the line, and plays a crucial role enabling seamless entry into new markets. It's about ensuring regulatory strategy and business planning are fully aligned, and a two-pronged approach is required.

Firstly, during the concept ideation process, it's advisable to determine compliance with the national regulations of a primary market. Prioritising this at the front-end innovation point enables the concept to be fine-tuned before it enters prototyping or the formal product development phase. This de-risks the overall process, saving time and money in the short- to medium-term as well as reducing the risk of big losses if unexpected obstacles arise later.

Secondly, it's useful to ascertain any harmonisation (or disharmony) between different national regulations that may influence decisions surrounding a single global launch versus a multi-phased one. Companies' specific needs and concerns vary on a case-by-case basis, determining single or multi-launch plans. For example, as one of our members explains, "APAC is a growing area for us, but we have fewer regulatory people on the ground there, which makes it challenging". Others cite the regulatory complexity of certain markets, language barriers, and the fact that English versions of new standards are often delayed, as factors that can hinder global activity.

For the purposes of this report, our multilingual team has reviewed documentation for regulations across some of the markets within the EU, APAC, the Middle East, Africa and the Americas, combining these insights with our horizon scanning, frontend innovation assessment, and dossier support capabilities. Our aim is to reduce uncertainty so you can navigate today's complex and volatile global requirements with greater confidence.

Five key takeaways

- Three industry drivers environmental sustainability, health and wellness, quality and safety pose challenges and opportunities for food and beverage businesses at present.
- 2 Health, sustainability issues and climate concerns, along with novel production techniques, are leading to regulatory changes and a volatile regulatory landscape.
- 3 Complexity and disharmony in requirements at a global level make it harder to conduct risk-based planning, but businesses need to avoid analysis-paralysis.
- 4 The three drivers present many opportunities for innovation surrounding new products or the evolution of existing products, to earn greater market share and consumer loyalty.
- 5 Businesses that align their commercial roadmaps with a robust regulatory strategy are set to flourish in the coming years.

Sustainability has been on the food and beverage industry agenda for decades, and many of our members have wellestablished targets and initiatives in place. However, as the urgency of environmental issues escalates, there is increasing pressure to make material gains. In addition to the net zero targets that apply to all industries, many markets are introducing measures that specifically target food and beverage businesses. The EU's Farm-to-Fork strategy, which forms part of the Green Deal, is a prime example. It covers various regulatory and nonregulatory initiatives across the entire supply chain, from production to processing to consumption.

In the mid-term, we expect the Farm-to-Fork Strategy to influence ongoing development of regulatory models for sustainability in other parts of the world. Nevertheless, there is a significant lack of global harmonisation in sustainabilityfocused guidance and regulation at present. Conversations with members indicate that the complex landscape is causing a high level of confusion and uncertainty. Businesses are keen to drive meaningful progress, but it can be hard

to determine the best way forward. As one food manufacturer explained, "one of the biggest challenges will be to get industry and governmental consensus on what 'sustainable' means for all facets of the food chain". Several members highlighted the US as an especially difficult market with "so many regulations at all levels, from county to city", and one acknowledging that "managing different requirements across 50 states will be difficult".

There are never any easy solutions when it comes to sustainability, and regulatory divergence intensifies the challenges facing our members. Recognising this, in 2022 we joined forces with our sister companies, Sagentia Innovation and TSG Consulting, to launch a sustainabilityfocused offering that encompasses management and strategy, product innovation, and product stewardship (sustainability.sciencegroup.com). The goal is to help businesses navigate sustainability opportunities and challenges by leveraging the wideranging experience and expertise held within Science Group as a whole.

Macrotrends in sustainability

Analysis of global regulations linked to sustainability reveals three macrotrends currently shaping requirements (Figure 2). The mitigation of plastic pollution dominates, and we explore this in the 'deep dive' below. Additional areas attracting the attention of NGOs, activists, scientists and regulators are water waste and pesticide pollution.

Activity surrounding water wastage is less advanced than that for plastics and pesticides. What's more, the impact of emerging and evolving articles for mitigating plastic pollution will be broad and far-reaching, affecting all aspects of the food supply chain, whereas the impact of pesticide mitigation activities will be more nuanced.

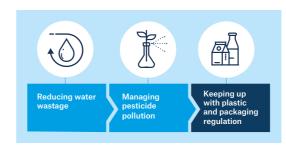


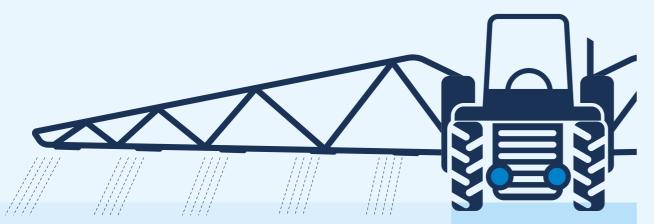
Figure 2: Top-line overview of key macrotrends for sustainability

Reducing water wastage

Water scarcity is set to become a significant problem in the coming years, and strategies for its re-use could ease some of the challenges. However, re-use isn't always feasible due to consumer attitudes, technical viability and regulatory policy. For instance, a consumer survey in the US identified 'disgust', 'neophobia' and 'safety concerns' as issues hindering consumer acceptance². At present, the global regulatory landscape is immature, and the pace of policy change is slow. A major obstacle is the lack of common definitions and parameters for 'fit-forpurpose', 'clean', 're-use', 'reclaimed' and 'recycled' water. We recently published a members' whitepaper looking at global policies for water re-use in food and agriculture, available via the members area of our website.

Managing pesticide pollution

Regulatory activity surrounding the reduced use of pesticides is a little further ahead than that for water re-use. However, as Figure 3 illustrates, regulations are still under development in many markets. There are two microtrends at play here: restricting the amount of pesticides used, and enabling the development and use of biopesticides.



RESTRICTING AND REDUCING PESTICIDE USE



Canada

In 2022, stakeholders were invited to submit comments for a consultation on the Targeted Review of the Pesticide Control Products Act. This is being handled by the Pest Management Regulatory Agency (PMRA).



The Ministry of Agriculture's Agricultural Research Institute (INIA) is thought to be working on a programme to reduce pesticide use in small- and medium-scale agriculture.



legally binding target to reduce overall use and risk of pesticides by 50%, and the use of more hazardous pesticides (those meeting the cut-off criteria) by 50% by 2030. An Integrated Pest Management Framework



mandates that chemical pesticides are used as a last resort.









regulation/

The Farm-to-Fork Strategy set a



INNOVATING BIOPESTICIDES



A National Strategy has been established to reduce the environmental and health risks caused by the handling of pesticides.



Following the UK's EU exit in 2021, HSE, the UK competent authority, is developing a National Action Plan to establish a framework for community action to achieve the sustainable use of pesticides.



The EPA is expected to release proposed interim decisions related to certain neonicotinoid pesticides in 2023. Mitigation measures will be finalised in the interim decisions which are expected in 2024.

Deep dive: plastic and packaging regulations

Challenges surrounding sustainable packaging were mentioned by all the members we spoke with when preparing this report. Diverse and rapidly changing global requirements related to single-use plastic, recycling and labelling are just part of the problem. A lack of consensus over what constitutes 'sustainable' or 'recyclable' packaging and a shortage of suitable recycled content for packaging materials compounds the issue.

A soft drinks manufacturer we interviewed highlighted poor clarity over deposit return scheme (DRS) labelling as a major concern:

"DRS comes into force in Scotland and Ireland soon yet there's still no clarity on what is required on the packaging. This poses a real risk as we potentially need to re-do all our labelling. Small labels may not have sufficient space to add the necessary information or logos for all markets and in all languages. It doesn't look like we're going to be able to use a single label for multiple markets."

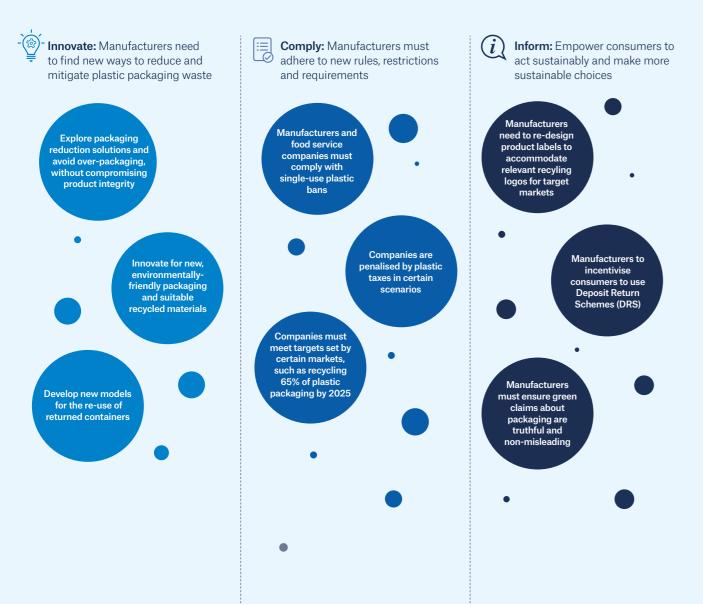
This is just one example of the packaging regulation repercussions felt by food and beverage businesses. In this environment, it's difficult to make informed risk-based decisions. Yet decisions do need to be made, using whatever information is available. Our regulatory specialists have identified noteworthy developments across several markets.



Packaging regulation: a global perspective

The 'Reduce, Reuse, Recycle' mantra remains central to packaging sustainability initiatives, but there is increasing pressure to place more emphasis on reduction and re-use, as well as to improve and accelerate the outcomes of recycling. Regulations can be used to incentivise or motivate manufacturers and consumers, as demonstrated in Figure 4.

Figure 4: How regulations are incentivising manufacturers and consumers, using three different approaches - innovate, comply and inform



Reduce

China is one market that recognises the value of legislating around packaging reduction. In August 2021, it issued the revised National Food Safety Standard on Requirements for Restricting Excessive Packaging - Foods and Cosmetics, with a transitional period until September 2023. This compulsory national standard provides stipulations for excessive packaging restrictions. For example, it restricts grains and processed products to three layers of packaging, and other commodities are limited to four layers. The standard also outlines a spatial coefficient for calculating the interspace ratio (i.e., the ratio of necessary space occupied by the product itself to the total volume of package). In October 2021, South African authorities published a draft Guideline on Recyclability by Design for Packaging and Paper. Its main purpose is to reduce the volume of packaging through measures such as improved product design, better understanding of the environmental impact of packaging design and promotion of good environmental practices.

Further to this, several countries are planning or have already introduced bans on single-use plastic. **India** banned items such as single-use plastic cutlery, plates

and cups on July 1, 2022. Colombia also published a law in July this year banning and reducing the production of certain single-use plastic items (e.g., plastic bags, straws, oxo-degradable plastics). The aim is to regulate the characteristics, requirements and certification of products that will replace single-use plastic by July 2023, and technical labelling regulations for single-use plastic will also be issued. Meanwhile, South Africa is considering an upstream plastic tax and a single-use plastic tax.

Since July 2021, each EU member state needs to have implemented the Single-Use Plastic Directive, which looks at limiting plastic marine litter and promoting the transition to a circular economy. EU member states should have brought into force the necessary regulations and administrative measures to ban single-use plastic plates, cups, cutlery, straws, containers made with expanded polystyrene and all products made with oxo-degradable plastic (with delays until 3 July 2024 for Article 6, and 31 December 2024 for parts of Article 8). See our whitepaper on the EU's Single Use Plastic Directive for more information, which can be accessed via the members area of our website.

Reuse and recycle

India has published draft regulations which will allow the use of recycled plastic packaging for ready-to-consume food and beverage products. Notably, this authorises the use of recycled polyethylene terephthalate (rPET) which was not allowed previously, although it is widely accepted in the US, EU and Japan. In contrast, the use of rPET is still not common practice in China. Reuse is also mentioned in EU targets for packaging and packaging waste. However, leaked European Commission proposals generated strong criticism in October 2022, especially from beverage associations including the European Fruit Juice Association and UNESDA Soft Drinks Europe. The leaked version indicated that the revision of the EU's Packaging and Packaging Waste Directive (EU 2018/852) will advise a 75% reuse target for drinks packaging by 2040 and 20% by 2030^{4,5}. The Draft Revision of the EU Packaging and Packaging Waste Directive published in November 2022 cited different targets and obligations, such as 65% and 70% recycling targets across all packaging by 2025 and 2030 respectively, but it has not allayed the controversy and criticism, surrounding issues such as a lack of appropriate conditions, processes, and enabling tools.

The **UK**'s voluntary on-pack recycling logo has recently changed from a three-option recycling message to a simple binary (recycle/don't recycle) message, which will be implemented from January 1, 2023. The **UK** authorities have also indicated the adoption of a single mandatory labelling scheme to support Extended Producer Responsibility (EPR) and the use of a "recycle now" swoosh logo in addition to the recycle/don't recycle message. This would be applicable to all packaging types except plastic films and flexibles from March 2026, with all plastic films and flexibles following from March 2027.

To incentivise recycling, Brazil published two federal decrees in April 2022: the National Solid Waste Plan (Planares) and the Recycling Credit Certificate (Recicla+). The latter is designed to encourage private investment in the recycling of products and packaging discarded by consumers. Meanwhile, **Chile** has published a Supreme Decree on waste collection. recovery targets and associated packaging obligations. Some of the provisions will be enforced from September 2023. In 2021, the Chilean legislature unanimously passed comprehensive single-use and recycled plastics regulations. These ban single-use plastic within a food establishment and

compel markets and convenience stores to only sell recyclable beverage containers, which must contain plastic collected and recycled within Chile. These regulations will come into effect over a three-year period. Meanwhile. China has introduced a revised national standard which is planned to come into force early next year. Amongst other requirements this sets out conditions for the recycling logos displayed on recyclable packaging materials and abolishes the recycling logo for biodegradable plastic packaging while introducing new logos for glass and composite-material packaging.

Recycling logos - a dilemma for food and beverage manufacturers

In the absence of harmonised rules for recycling information, several EU countries are developing their own logos and stipulations. This creates a difficult situation for food and beverage businesses that sell products across different markets. We recently published a members' whitepaper outlining current requirements for recycling logos in Europe (available via the members area of our website).

<u>leatherhead</u> food research

Here to help: Our strategic horizon scanning service helps clients navigate dynamic sustainability regulations and policies to create strategic R&D programmes.

CASE STUDY | HORIZON SCANNING



Client challenge:

concerns surrounding a key ingredient regulatory changes were on the horizon.



Key question:

What are the and how will they impact my business?



Leatherhead response phase 1:

and bans for this



Leatherhead response phase 2:



Outcome:

Insights and analysis enabled design of strategic product development and market programmes.

Avoiding greenwashing

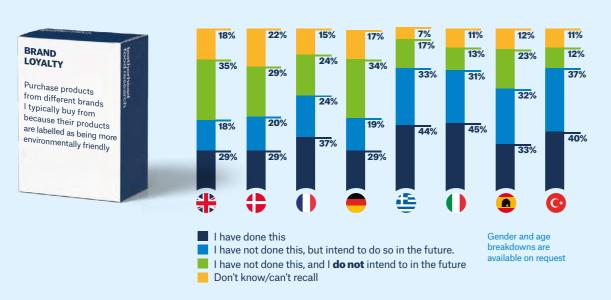
We recently commissioned a study of more than 10,000 adults across Denmark, France, Germany, Greece, Italy, Turkey, UK and Spain to gain deeper understanding of how environmental or green claims influence consumer behaviour³. The findings indicate the powerful influence of these claims on consumer behaviour and the associated commercial advantage for manufacturers.

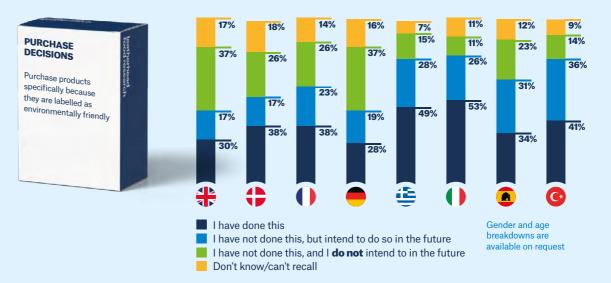
Overall, 37% of respondents say they have purchased grocery

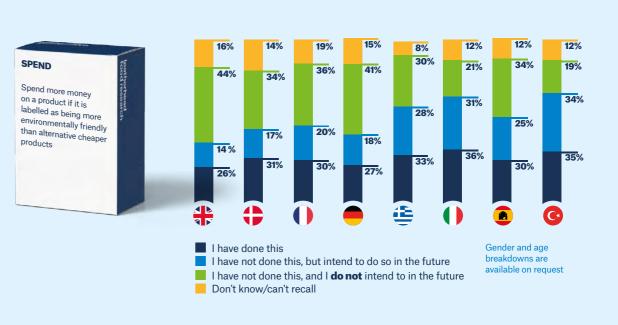
products specifically because they are labelled as environmentally friendly. What's more, 30% have spent more on a product labelled as environmentally friendly, while 34% have purchased products from a different brand to usual for this reason. Figure 5 illustrates the variations on a country-by -country basis.

Sustainability has become a key product differentiator, and many food and beverage companies are keen to position products as being environmentally friendly. However, this has given rise to regulatory concern about greenwashing – where brands make unsubstantiated or misleading claims to imply a product has superior environmental qualities. As green claims come under the spotlight, it's important to ensure they are holistic, specific and verifiable. We've published guidance on how to avoid problems with green claims, available via the members area of our website.









2. Health and wellness

Health and wellness for the food beverage and supplement industry broadly falls into two camps. There are products which contain functional ingredients to confer positive health benefits, leading to a new niche area of pharmafoods. And there are those products deemed 'less healthy' which face scrutiny in many parts of the world. At present, the latter is occupying the attention of regulatory bodies worldwide.

Less healthy products

Businesses manufacturing or selling products that are high in fat, salt and sugar (HFSS) face a rapidly changing patchwork of global regulations. Much of the activity is aligned with governmental strategies to tackle obesity.

This is a thorny area for companies operating in the soft drinks, snacks and confectionery categories. As one of our members puts it: "Due to the nature of our product we won't meet the HFSS targets. What will be the impact of this?" Others are working hard to improve the health profile of products without compromising product stability or consumer enjoyment: "We are trying to become as healthy as possible as a brand, adding vitamins to our products and trying to reduce the calories."

Businesses that are innovating or reformulating to improve health and wellness credentials would benefit from applying a regulatory lens to products at the earliest possible stage to reduce risk of failure later. Indeed, we regularly support our sister company Sagentia Innovation to facilitate this in reformulation projects for leading brands.

Macrotrends in health and wellness

New and forthcoming measures and regulations cover everything from nutritional labelling to advertising restrictions and sugar taxes. There are two macrotrends at play here (Figure 6); one focuses on guiding and empowering consumers to make healthier choices (i.e., front-of-pack labelling), the other looks to penalise or control the actions of manufacturers (i.e. taxation). We have also provided an overview of the microtrends, deep-diving into food composition for you.



Figure 6: Overview of key macrotrends and microtrends for health & wellness, deep-diving into food composition

Topic of interest: pharmafoods

Innovation in pharmafoods, supplements and functional ingredients is widespread, and boundaries between food and pharma are starting to blur. This poses the risk of food and beverage products straying into the territory of medicine regulations. There are two key challenges when it comes to designing and launching these products:

- 1 With increased development of functional ingredients from new sources, using new technologies, or with enhanced bioavailability, there is a need to check permissibility and restrictions in target markets. Pre-market approvals may be required to ensure products satisfy consumer safety and toxicology standards. It should be noted that a functional ingredient which is permissible under one country's food and beverage regulations may be restricted or classified as 'novel' by another. If this is an important area for your business, we recommend our members' whitepaper looking at how to leverage functional ingredients without falling foul of regulation, which is available via the members area of our website.
- 2 The promotion of such products can be supported through health-related claims on packaging, However, requirements for such claims and the associated substantiation of efficacy vary greatly between different markets. This can lead to confusion and complexity when establishing claims for a single global market launch. For instance, a 'Health Claim' in the US, which has the highest level of substantiation requirement (i.e., the gold standard), is equivalent to the 'Foods For Specified Health Uses (FOSHU)' in Japan. On the other hand, US 'Structure-Function Claims' require less stringent substantiation and would be equivalent to Japan's 'Foods with Functional Claims (FFCs)'.

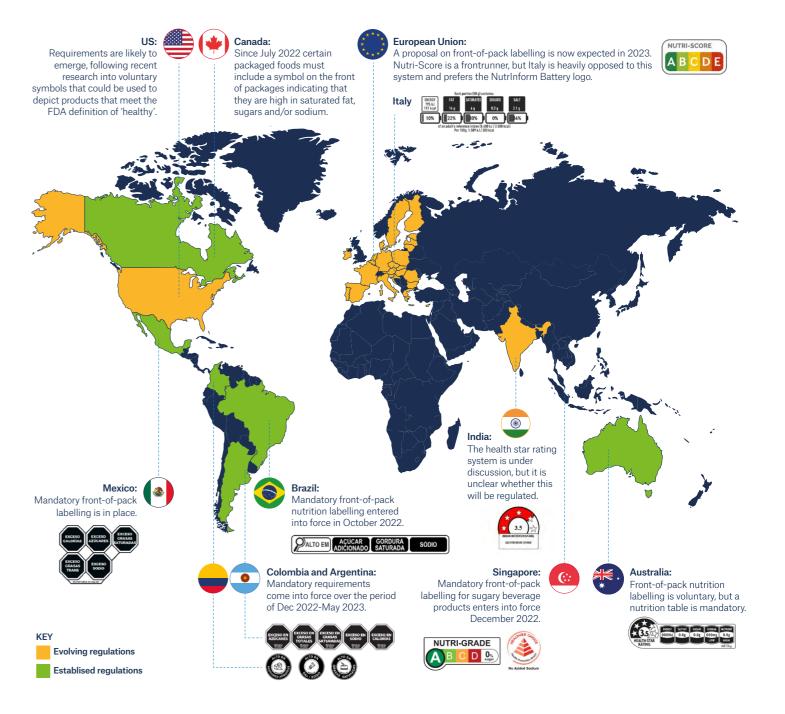
Front-of-pack nutrition labelling

The global situation for front-of-pack nutrition labelling is summarised in Figure 7.

In the **EU**, the Farm-to-Fork Strategy states that harmonised mandatory front-of-pack nutrition labelling is a key priority. One aspect of this is the introduction of icons or logos that convey product information in a simple, accessible format. The well-known Nutri-Score system is strongly backed by many **EU** member states such as **France**, but others are opposed. **Italy** favours its own 'Nutrinform Battery' system, claiming that Nutri-Score discriminates against single-ingredient products such as olive oil, parma ham and cheese⁶. This EU situation is still evolving, with a proposal now expected in 2023.

Other markets have already established front-of-pack nutrition labelling requirements, including Canada, Singapore, Mexico, Brazil, Colombia and Argentina. With respect to China, a draft is currently in existence and the authorities are still finalising the national legislation; the timescale for the final version is currently unknown. Requirements are likely to emerge in the US too, following recent research into voluntary symbols that could be used to depict products that meet the FDA definition of 'healthy'. In India discussions are underway to determine a format that would be easily understood by consumers. The Food Safety and Standards Authority of India (FSSAI) held a review meeting on this matter in February 2022, but it is still unclear whether the authority will draft a regulation to reflect the latest discussions. In South Africa, a draft regulation for front-of-pack nutrition labelling has existed for many years, but has yet to be implemented.

Figure 7 (opposite): There's a varied picture for front-of-pack nutrition labelling around the world



Government-led restrictions

Many governments are introducing rules and policies that aim to reduce consumption of HFSS products by control of product placement and the encouragement of healthier choices. However, despite the shared global goal of reducing obesity, the regulatory picture is complex and fragmented.

Taxation, frequently targeted at soft drinks, is seen as a win-win for governments looking to raise money and take a visible stance against obesity. Other restrictions surround advertising and product placement. Our members' whitepaper on anti-obesity strategies, available via the members' area of the website, covers this in more detail.

For advertising, there are discussions about putting advisory statements on product labels and in promotional materials to help consumers make healthier choices. For instance. China has drafted a new version of the Nutrition Labelling Standard (GB28050), issued in September 2021, which proposes to mandate that prepackaged foodstuffs indicate that children and teenagers should use caution when choosing foods with excessive salt, fat and/ or sugar. The timeline for implementation is unknown.

Food compositi on is another governmentled factor, as covered in the deep dive below.

Deep dive: regulations related to food composition

The regulatory agenda for 'unhealthy' food and beverage products has been heavily occupied with sugar and salt in previous years. Now, attention is turning to fats, particularly trans-fats.

It's four years since the World Health Organization (WHO) released its REPLACE action package to eliminate industrially-produced trans-fatty acids from the global supply chain⁷. With trans-fat intake thought to be responsible for approximately 500,000 premature deaths each year, the WHO wants to achieve global elimination by 2023. REPLACE includes an overarching technical document providing a rationale and framework for an integrated approach to trans-fat elimination along with resources to facilitate implementation.

Country-specific compositional requirements

From January 2026, Canada has mandated that products high in sodium, sugars and saturated fats (exceeding 15% daily value) should carry a front-of-pack label, as shown in Figure 8. However, some products such as fruits and vegetables without added sodium, plain yoghurt and cheese, raw single ingredients (e.g. meat, sugar, salt) and butter are exempt.



Figure 8: Front-of-pack label example informing consumers on product composition

Several South American countries are introducing mandatory and voluntary measures surrounding the composition of food and beverage products. In Brazil, voluntary agreements based on Commitment Terms have been established between the Ministry of Health and food industry representatives. Commitment Terms for sodium reduction are already established, but the phased entry of sugar restrictions is ongoing. Several target limits have been set for the end of 2022, including a maximum sugar content for soft drinks of 10.6g per 100ml.

The regulatory situation for product composition is also evolving in Argentina. Its government closed a public consultation in May 2022 regarding the expansion of

established trans-fats limits. Under the proposed regulation, use of partially hydrogenated oils and fats would also be banned in the production of foods, ingredients, and raw materials. In addition, discussions are underway to restrict the content of industrially produced trans-fatty acids from 5% to 2% in all foods. These measures would be subject to a two- or four-year transitional period depending on the provisions made. Another public consultation held in 2022 looked at further reductions of sodium levels in snacks and biscuits.

An earlier WHO proposal, the 2004 Global Strategy on Diet, Physical Activity and Health, recommended limiting all sodium intake. Based on this, Colombia recently published guidance regarding the implementation of its Resolution 2013 regarding Maximum Sodium Content in Processed Foods, Annexes to the Resolution include a list of products for which a maximum content of sodium is established. There are two sodium thresholds listed, with the first applying from November 2022 and the second from November 2024. Affected products include dehydrated soups and broths, some cereals, some cold meats, peanuts, other savoury snacks, some sauces. some bakery products and some cheeses.

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Topic of interest: ultra-processed foods

Discussions surrounding ultra-processed foods, and how these impact the wellbeing of populations, are taking place around the world. There is growing evidence of a link between high consumption of ultra-processed foods and non-communicable diseases, such as obesity, heart disease, nutritional deficiencies and diabetes. One recent study suggests there may also be a link between consumption of ultra-processed foods and adverse mental health symptoms⁸.

The NOVA Food Classification System developed by Brazil's University of São Paolo groups all foods according to the nature, extent and purpose of any industrial process they undergo. These include physical, biological and chemical techniques used after harvest and before consumption or preparation. However, controversy surrounds its use, with some experts considering the tool 'qualitative and imprecise'⁹. Nonetheless, Brazil has proceeded with the creation of a Food Guide for its population, and NOVA has been used in many other countries too. The UK, Sweden and India have used it in public health studies to investigate the relationship between ultra-processed food and population health.

Further information can be found in our dedicated NOVA whitepaper, available via the members area of the website, but it is anticipated that further discussions for the control of ultra-processed foods are imminent. Stakeholders such as the Food and Agriculture Organization of the United Nations (FAO), the World Food Programme (WFP), WHO and Global Alliance for the Future of Food are said to be "...considering the need of deploying public policies to inhibit several categories of processed foods from having negative impacts on human health, including advocating restriction and sales of foods classified as ultra-processed because they are high in calories and have minimal nutritional value..."10. Canada's recently implemented front-ofpack symbol warning consumers of foods high in saturated fat, sugars, and/or sodium (Figure 8) is an example.

leatherhead food research Here to help: Our concept and label review services are beneficial for companies looking to support their concept convergence process at the front-end innovation point.

CASE STUDY | CONCEPT REVIEW













Client challenge:

Selection and development of new products that would achieve strong differentiation in the highly-competitive market through use of permitted nutrition and health claims.

Key question:

Which of the prototype recipes would be compliant with multi-market regulations in terms of ingredient/ botanical permissibility and use of nutrition and

Leatherhead response phase 1:

We reviewed to recipes accord to ingredient permissibility boundaries of could be claim target markets.

Leatherhead response phase

We identified alternative ingredients and ingredient formats to maximise bioavailability and compliance.

Outcome:

Selection of optimal recipes for formal product development, applicable across all markets of interest.

Compliant health-related claims, as dictated by national legislations.

Robust multi-market entry plans.

Compliant market entry road-maps and claims for multi-market launches.

3. Quality and safety

The members we interviewed unanimously said that safety is always at the top their agenda. Comments included "safety is our biggest priority and has been for a long time", "safety is a high priority for all parts of the business", and "we're investing even more in safety at the moment". It's important to sustain a progressive attitude to quality and safety, because as the industry evolves, new concerns and challenges arise.

Macrotrends in quality and safety

Based on our regulatory research, three key macrotrends are apparent at present (Figure 9). We'll touch on issues related to plant-based products and allergens, with a deep-dive into genetic technologies.



Figure 9: An overview of the global macrotrends supporting the quality & safety driver:

- Rapid growth in the plant-based category is attracting the attention of regulators and bringing implications for product names and labels in many markets
- 2. Increased focus on allergens has resulted in new global requirements
- 3. Progress in genetic technologies (one of the pillars to support sustainable food production) is bringing new quality and safety considerations to the fore

Rapid plant-based category growth - labelling is a key challenge

In the past 12 months, several markets have moved quickly to regulate labelling for plantbased products. In South Africa, authorities published a letter to stakeholders, importers and manufacturers stating that terminology associated with processed meat must be removed from the packaging of plant-based foods on 22 June, 2022. Earlier in June authorities also stated that plant-based egg substitutes cannot use the term 'egg'. Paraguay also established a new law regulating the term 'meat' on plant-based and cellular meat products this year. On 3 August, 2022 Argentina introduced a resolution to regulate terms including 'plant-based', 'vegan' and 'vegetarian'; it also specified that these products must not use the regulated names associated with foods of animal origin. India published new regulations on vegan food in June 2022, defining vegan food as containing no animal products whatsoever with no animal ingredients used during production or processing. Following this, in September 2022, a dedicated logo was published which must be displayed on the packaging of approved vegan food.

Discussions are ongoing in other markets. **Belgium** plans to publish guidelines on the labelling of plant-based food, banning some terminologies. A ban on terms including 'steak' and 'sausage' for plant-based foods was planned for implementation in France in October 2022, but it has now been suspended by the Order of 27 July, 2022. The **US** FDA is also planning to issue guidance on the labelling of plant-based alternatives to animal-derived foods and milk. Early discussions are underway in Brazil, and Australia and New Zealand are considering a list of recommendations, including the development of a mandatory regulatory framework for the labelling of plant-based products; the timelines for these are unknown. The situation in **China** is a little ambiguous owing to its nascent plant-based food industry. Currently, animal-free products are not regulated at national level, except for a draft for terminology and product classification, although there are some voluntary association standards available. Early in 2022, the China Biodiversity Conservation & Green Development Foundation published the China Vegan Food Standards, which could be used as a guidance for developing further detailed provisions, should the Chinese government or associations decide to regulate vegan foods. As for plant-based foods, the China Institute of Food Science & Technology has published a voluntary standard whereby the terms 'chicken' or 'milk' can be used as long as it is in conjunction with 'plant-based'. This is the opposite of what is happening in other markets, including the **EU** and **USA**.

We expect to see further activity in this space, with regulators and industry players negotiating the boundaries. As a dairy industry representative we spoke to explains:

"Current US standards for plantbased yogurts were set in the 1930s and 1940s, and they haven't kept up with modern ingredients. There are many constraints which hinder product development, and discussions with the FDA surrounding yogurt's standard of identity have not yet brought the clarity we're looking for."

It's also worth noting that NGOs are following plant-based labelling protocols closely. ProVeg International recently called on governments to consult the plant-based sector before passing further regulations preventing the use of 'meaty' names, saying such restrictions are counterproductive¹¹. Figure 10 illustrates where various markets currently sit on this matter.

Figure 10: Plant-based regulations

ESTABLISHED



EVOLVING



Australia and New Zealand: Recommendations, including a mandatory regulatory framework for the labelling of plant-based products, are being considered.



₩."

Belgium: Plant-based labelling guidelines banning some terminologies are expected.



Brazil: Early discussions are underway surrounding specific plant-based legislation under the current regulatory agenda.



China: Vegan Food Standards published in 2022 may form a framework for any future regulations. A separate voluntary standard allows terms such as 'chicken' or 'milk' for vegan food providing the term 'plant-based' is also used



US: Guidance for the labelling of plant-based alternatives to animal-derived foods and plant-based milk alternatives is being developed.



Argentina: The terms 'plant-based', 'vegan' and vegetarian' have been regulated since August 2022.



France: Terms such as 'steak' and 'sausage' have been banned for plant-based foods since October 2002.



India: New regulations on vegan food were published in June 2022.



Paraguay: A new law regulates the term 'meat' on plant-based and cellular meat products.



South Africa: Authorities recently published a letter to stakeholders, importers and manufacturers stating that 'meaty' terms cannot be used on plant-based products.

The prioritised focus on allergens

The food and beverage industry takes the allergen issue very seriously, but challenges and complexities remain and there is a need for regulatory input to resolve key issues. In the UK, Natasha's Law came into effect in 2021, mandating that all prepacked food for direct sale must include a full list of ingredients, with 14 major allergens emphasised. In the **US**, sesame will be classified as the market's ninth major food allergen from 1 January, 2023.

From a labelling perspective, in Australia and New Zealand, the standard for mandatory declaration of allergens has been amended to specify that allergens must be declared in bold font, using prescribed terms and including the 'contain' statement. There is a three-year transitional period where products that do not comply with the new standard can still be sold.

Many businesses have adopted new production processes and systems as well as labelling strategies where required. However, the lack of minimum detection limits coupled with the sensitivity of technologies used in batch testing creates a catch-22 situation. One member that traditionally operated in the dairy category explains:

"We're moving into plant-based products, which means the business is operating in a more complex allergen territory than before. We now have to consider allergens such as soy and coconut. In the US, there are no minimum detection limits, but tests can detect very small levels - down to 0.1 parts per billion - which don't pose a safety risk."

These concerns were echoed by a member specialising in baked goods who said, "there are risks of cross contamination from the source, anything coming from wheat is exposed to risk". Another mentioned a cross-contamination situation they had experienced with peanut and soy which highlighted an issue with supply-chain visibility of ingredient components.



Foreword Introduction 1. Environmental sustainability 2. Health and wellness 3. Quality and safety Conclusion

The modern biotechnology method of cell culture is gaining attention as an alternative and potentially more sustainable practice for meat and fish production. Groundbreaking 'lab-grown meat' created using cell culture techniques has been making waves in recent years, but at present it is expensive to produce commercially. What's more, research by the **UK** Food Standards Agency suggests that almost 60% of adults in England, Wales and Northern Ireland would not be willing to try lab-grown meat¹².

Nevertheless, as production costs come down and consumer acceptance increases, these products could make the transition from niche to mainstream. According to MarketsandMarkets estimates, the global cultured meat market will be valued at USD214 million in 2025 with a projection of USD593 million by 2032¹³.

Regulators are responding to these developments, but conversations with our members indicate that activity is perceived as fragmented and lacking depth of knowledge. An ingredients company points out that "novel genomic techniques are different to genetic modification, but will regulators see it that way?".

An evolving global picture

Our regulatory specialists have been analysing the latest activity around the world, and highlight the US, UK, China, and Australia and New Zealand as markets to watch.

In the **US**, the FDA has indicated that it intends to develop a draft guidance in 2022 on Foods Derived from Plants Produced Using Genome Editing. The list of intended topics for the year also includes a Premarket Consultation on Cultured Animal Cell Foods. These forthcoming guidance documents are categorised under 'food safety' and 'food additives' respectively.

Following Brexit, Great Britain's stance on gene editing regulations is diverging from that of the EU. On 29 May, 2022, the government introduced The Genetic Technology (Precision Breeding) Bill into parliament and proposes new legislation to "unlock the potential of new technologies to promote sustainable and efficient farming and food production." At the time of writing, the Bill is at the report stage awaiting a date for its third reading where the Commons will have a final opportunity to debate its contents. At present it applies to plants, but it has the possibility of being applied to animals in the future.

It's worth noting that the Bill only applies to England, as Scotland, Wales, and Northern Ireland have the right to legislate separately on food and agriculture. So, there is increasing potential of divergence not only between GB and the EU, but also within GB.

Australia and New Zealand are currently working on a proposal to update definitions for 'gene technology' and 'food produced using gene technology' in the Food Standards Code. Current definitions are considered unclear and out of date. There are also problems related to regulatory uncertainty and possible gaps in regulatory coverage of new breeding techniques. It's recognised that this could hinder innovation, so the proposal seeks to:

- Revise and expand the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding; and
- Revise the definition for 'food produced using gene technology' to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM foods

The labelling of GM food is not in the scope of this proposal.

Finally, **China** issued its first guidelines in relation to genome editing for the agricultural field in January 2020, focused on Safety Assessment of Genome Edited Plants for Agricultural Use. It contains details on the application procedures for the assessment of genome edited plants without the insertion of exogenous DNA. The guidelines don't apply to genome edited animals and microorganisms. What's more, they only apply to safety assessment, not the wider aspects of production and trade. After a safety certificate is obtained, other aspects of genome edited plants remain subject to existing relevant GM requirements.

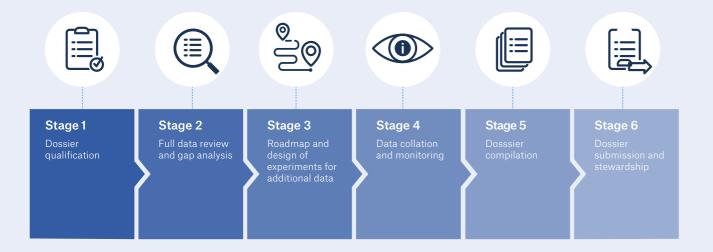


Here to help: Our dossier services support members' development of products that require pre-market approval.

CASE STUDY | DOSSIER SUPPORT

To protect consumers, the safety of novel/new ingredients and manufacturing processes for production of supplements, food and beverages must be guaranteed. Different jurisdictions around the world have different processes, but require submissions of dossiers, which can be a costly and lengthy process. To manage this, Leatherhead has a dedicated service that is split into six 'go/no-go' stages to provide control and clarity.

Applying a regulatory lens at the outset reduces risk of failure later. We use expert insights to provide a realistic estimate of resources required to submit the application.





Conclusion: Regulatory insights aid resilience

Key regulatory challenges

The current climate presents many opportunities for innovation, growth and diversification. It's our belief that organisations using regulatory insights to shape and inform shortto mid-term commercial strategies will reap the greatest benefits from this. Aligning regulatory and commercial strategies ensures better resilience in the face of evolving challenges. Accounting for regulatory factors at the outset of product innovation or market expansion makes it easier to pivot and adapt if circumstances change. This reduces risk and improves the likelihood of positive outcomes, so businesses don't just ride the storm but thrive within it.

Environmental sustainability

Regulatory divergence and ambitious, rapidly-evolving requirements.

Health and wellness

Complex global picture for rules surrounding less healthy products.

Quality and safety

Regulations are behind the curve when it comes to breakthrough food technologies.



Notes

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