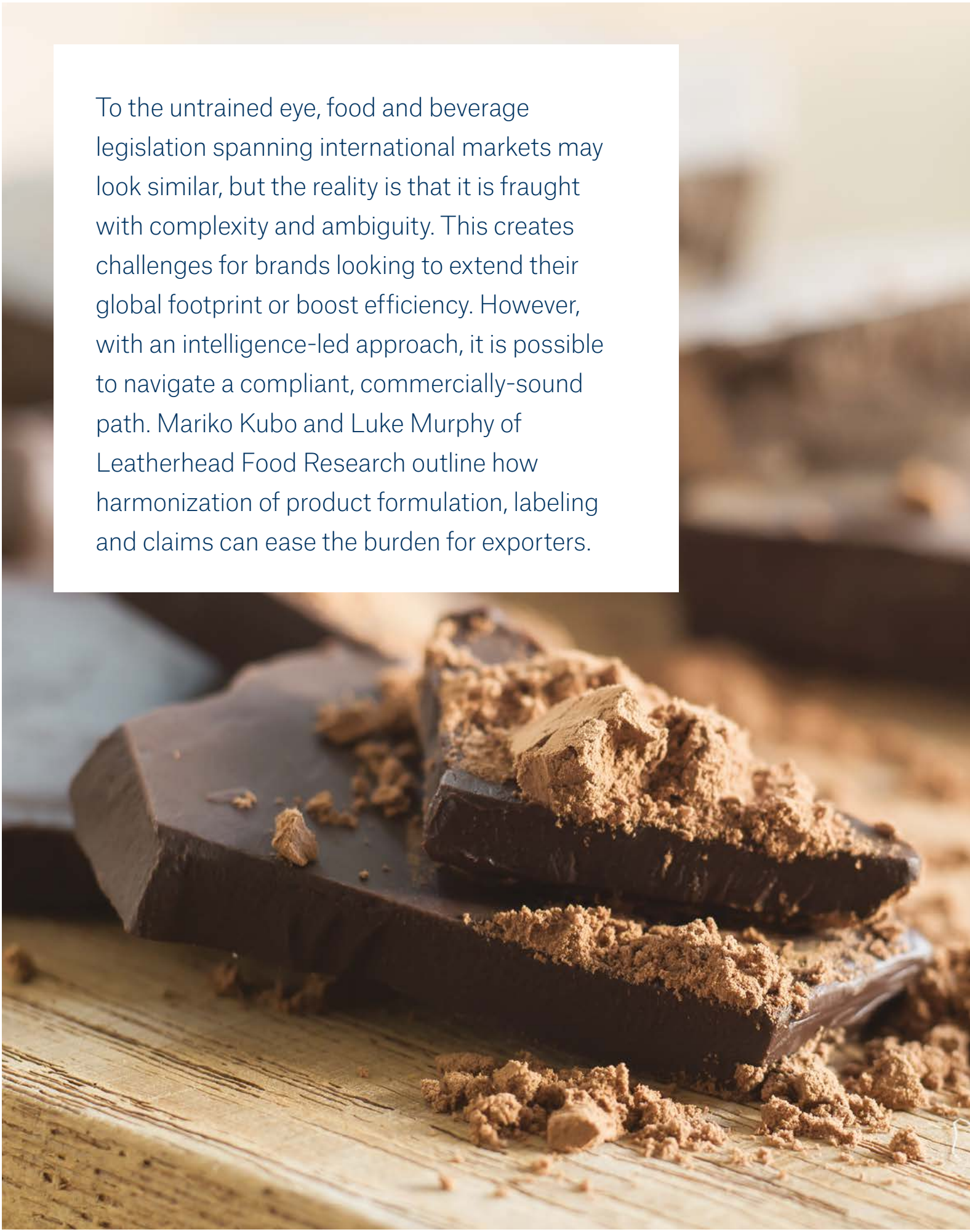
# of note

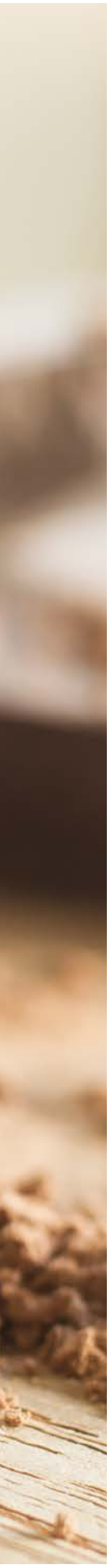
Lifting the hood on **harmonization**

leatherhead food research

a **science group** company



To the untrained eye, food and beverage legislation spanning international markets may look similar, but the reality is that it is fraught with complexity and ambiguity. This creates challenges for brands looking to extend their global footprint or boost efficiency. However, with an intelligence-led approach, it is possible to navigate a compliant, commercially-sound path. Mariko Kubo and Luke Murphy of Leatherhead Food Research outline how harmonization of product formulation, labeling and claims can ease the burden for exporters.



With food and beverage brands under ever increasing pressure to boost shareholder value, operational efficiency is moving up the agenda. For multinational companies, harmonizing product formulations and packaging across different territories can play an important role. It enables delivery of new and existing products to wider audiences more quickly and cost-efficiently. But this is not an easy task. Simply 'data sheeting' regulatory differences between countries doesn't go far enough. The situation demands a multifaceted response, with human input to rationalize decisions and offer a considered view of grey or contradictory areas.

The harmonization challenge

The global regulatory landscape is highly diverse. While sector and country-specific requirements are generally drafted with harmonization in mind, many factors can influence how the finer points are interpreted. So, even in markets such as the EU and the South American trading bloc Mercosur, where full inter-country alignment might be expected, discrepancies do exist. There may be apparent harmonization at a headline level, but specific requirements often vary country by country. These differences can be rooted in cultural, economic, environmental or historical factors. And they cannot be taken for granted.

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The EU's 'horizontal' and 'vertical' framework for food and beverage legislation highlights this lack of commonality. Horizontal categories refer to general factors, such as labeling, additives and quality indicators. They are supplemented with vertical provisions when specific rules are deemed necessary within categories. These include chocolate products, alcoholic beverages and non-alcoholic beverages such as fruit juice, juice drinks and flavored drinks. However, each country interprets aspects of both horizontal and vertical legislation in their own way, creating a complicated web of requirements. This causes friction for exporters targeting Europe, particularly those based in markets such as the US which have little concept of horizontal and vertical legislation. It's a situation that is replicated in different markets and across various product types around the world.

With such inconsistency, one-size-fits-all cannot be achieved at a global level. Instead, food and beverage brands need to harmonize their own approaches to create a 'best fit' for as many markets as possible. The cornerstone of this is an understanding of variations across key areas, such as ingredients, formulation, product claims and labeling.

Ingredients

Some regulations stipulate that individual ingredients must be considered in isolation, not as part of a product. This is most common with raw materials that may be at risk of contamination, such as milk.

Raw milk is often subject to rules surrounding permitted levels of pesticides or veterinary drugs. However, this requirement can manifest itself in different ways: both permitted levels and measurement units may vary. So, it quickly becomes highly complex. In the case of milk, with many markets regulating 100-150 pesticides, a review of ten markets could demand the assessment of more than 1,000 data points. Complying with the lowest permitted level might be the most straightforward option. But a commercial sense-check is required to ensure it represents the best solution from a business perspective.

There are also cases where an ingredient used freely in one market is not allowable in other regions. This is apparent in the use of monk fruit extract (luo han guo) as a zero-calorie sweetener. It's widely used in the US and Asia, but it's not permissible in Europe. The definition and use of additives and processing aids can be problematic too. One country's food coloring additive is another country's ingredient that happens to impart color. In other words, depending on its function in a given product, the same ingredient may or may not be permissible. Moreover, this impacts how ingredients need to appear on the labels in different markets, i.e. declared as a color or as a normal ingredient.

Legislative gaps and grey areas exist in all markets, which can be an advantage or a disadvantage. In many cases, control of coloring food falls into this category. So, the framework legislation needs to be carefully analyzed and interpreted. With experience and knowledge of the market's legislation and enforcement rules, a risk-based conclusion can be drawn. At Leatherhead we facilitate formal round-table discussions to debate, identify and propose solutions to gaps in regulatory frameworks. We also use our network of contacts in regulatory authorities to gain clarity on grey areas and better understand the enforcement rules.

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Formulation

Many products have strict compositional requirements such as physical and chemical characteristics (e.g. cocoa content in chocolate), which may differ across markets. This can have fundamental implications for the way ubiquitous products such as chocolate or fruit juice are classified and marketed. Orange juice is a prime example. Most territories legislate that it must be derived from edible parts of sound, ripe fruit, but beyond this there are many discrepancies.

Australia and New Zealand, Switzerland and Ecuador allow up to 10% of orange juice to be constituted from other similar fruit juice such as tangerine or mandarin. Italy legislates that products sold as orange juice must contain orange juice at a level not less that 20g per 100cc. And Canadian legislation demands that orange juice contains no less than 1.20 milliequivalents of free amino acids per 100 millilitres. In the US there are 12 subcategories for orange juice, ranging from pasteurized, canned and frozen to manufacturing grade. Each subcategory has various requirements surrounding factors such as the minimum Brix ratio, use of added sweeteners and substitution of orange juice with *citrus reticulata*.

So, a beverage called orange juice in one country, may not be permitted to use the name in another due to the country's specific compositional requirements. This doesn't necessarily mean that the product cannot be sold, but it can have major implications for labeling, packaging or formulation. Manufacturers need to consider their objectives and, depending on the priority, the required changes may vary. If moving into a new market is the priority, changing the legal name of the product may be sufficient. However, if it is important to sell the product as 'orange juice' in all markets, the formulation may need to be altered. Use of visual elements on packaging also needs to be considered. One market may allow the use of a picture of an orange whilst another may restrict such use or there may be associated labeling requirements.

Product claims and labeling

Claims surrounding health benefits, organic credentials or other differentiators can pose major problems for brands wanting to harmonize packaging and labeling.

In the US, self-substantiation of health claims is generally acceptable. However, in other markets there are strict requirements for all claims to be approved by an authority.

Since 2007, the EU has actively regulated nutrition claims such as 'low fat' and health claims such as 'Vitamin D is necessary for bone growth and development'. Statements of this nature must be clear, accurate and based on scientific evidence. For instance, to claim that a food is a source of omega-3 fatty acids, it must contain at least 0.3g alpha-linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal. The use of misleading claims is prohibited.

Organic certification involves challenges too, since country requirements are generally dictated at a government level by the department or ministry of agriculture. A product grown in the EU and certified under the EU Organic Program may not have identical credentials to a US product grown in line with the USDA National Organic Program.

To reduce trade barriers, organizations such as the US's Organic Trade Association orchestrate equivalency agreements between different territories. So, under an EU-US agreement, audits have led to an agreement that their respective organic programs achieve a comparable level of compliance and quality standards. Similar bilateral arrangements exist between the US and Japan, South Korea, Canada and Switzerland.

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Harmonization tactics

The inherent complexity of global food and beverage regulation means that no one product formulation or label will ever be applicable across all markets. But it is possible to rationalize the requirements and consolidate formulation/labeling to reduce the number of variations.

Best practice is rooted in large-scale 'compare and contrast' exercises at an early stage in the product development cycle. A confectionery manufacturer might use this method to identify a global formulation that can be sold in as many markets as possible. Or a company wanting to break into new markets with an existing product might use the approach to inform decision making about which markets to prioritize, or how much resource needs to be deployed to overcome barriers to trade.

Inevitably, there will be gaps in regulatory requirements between countries, as well as grey areas and contradictions. Expert interrogation of the rules, and insight into the rationale behind them, helps ensure a proportionate response. In situations where food safety might be compromised it is clearly essential to follow rules to the letter. But there are circumstances where common sense can prevail. One example could be the requirement for food and beverage labels in France to include a verbatim French translation of any information included in another language. In the case of alcoholic beverages, including age restrictions for countries that have a

different minimum drinking age would risk confusing the consumer.

With packaging and labeling, the ideal scenario is to facilitate use of a single piece of artwork across as many territories as possible. This enables reduction of print costs, flexibility of stock, fewer manufacturing line changeovers and other associated benefits. Label clustering can be deployed to help achieve this, whereby various requirements are mapped out and compared to find a solution that fits most markets. Where it's not possible to find a perfect fit, a risk-based system can be used to assess the significance of discrepancies, enabling more strategic decision making. Simple solutions, such as the use of on-pack stickers (where allowed), can help overcome some of the issues.

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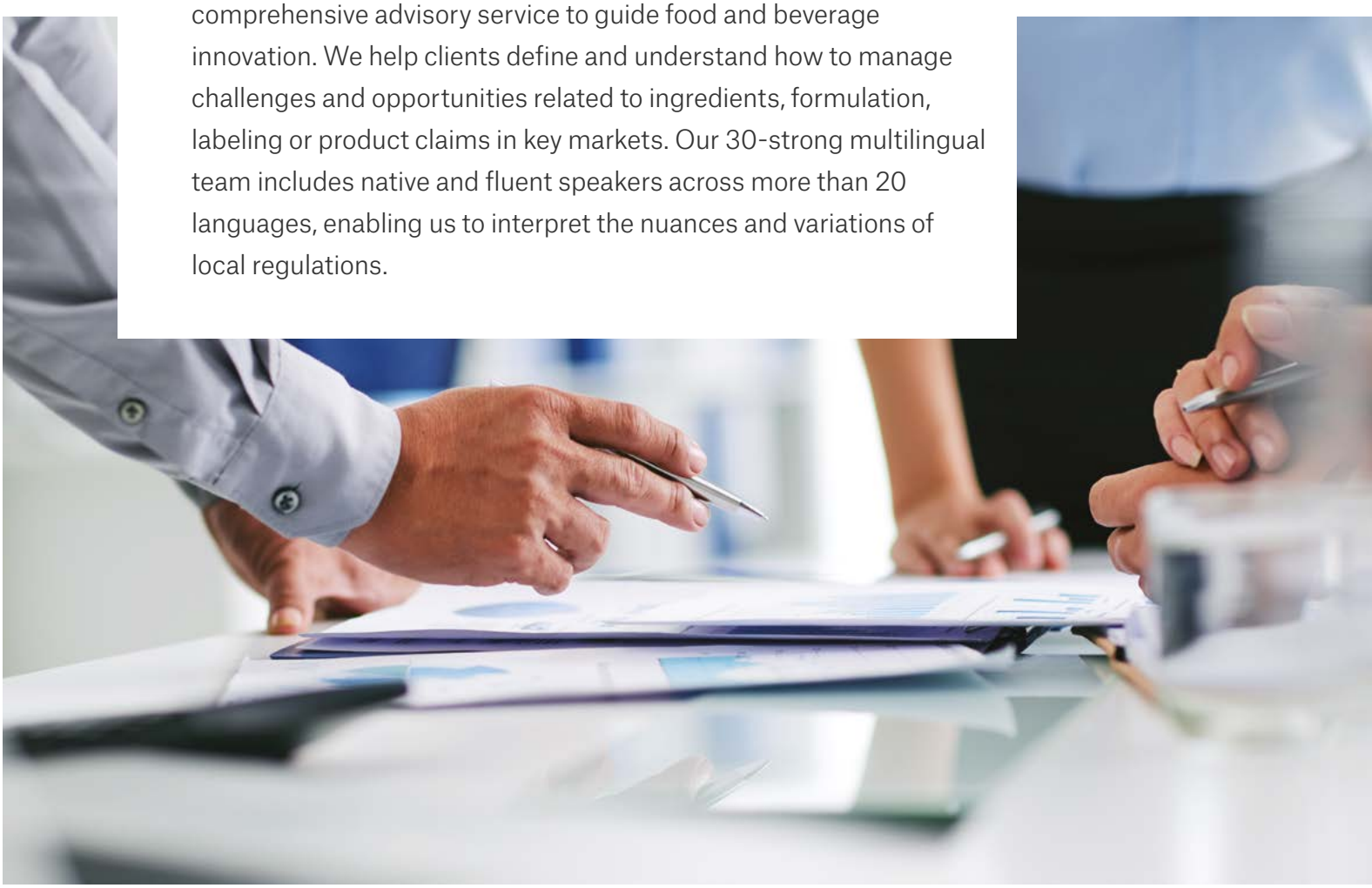
A proactive approach to harmonization is a critical tool for international food and beverage companies. Reducing the number of SKUs across markets enables economies of scale in terms of production and printing, and dovetailing formulations and label clusters with key ports of entry facilitates more efficient distribution. Global food and beverage regulation is fraught with complexity and in many cases it lacks clarity. But with a well-informed, considered approach, it is possible to devise an intelligent strategy that strikes an effective balance between compliance and commercial nous.

How Leatherhead can help

Leatherhead Food Research's global regulatory team provides a comprehensive advisory service to guide food and beverage innovation. We help clients define and understand how to manage challenges and opportunities related to ingredients, formulation, labeling or product claims in key markets. Our 30-strong multilingual team includes native and fluent speakers across more than 20 languages, enabling us to interpret the nuances and variations of local regulations.



About the authors

Mariko Kubo, Head of Food and Beverage Regulatory

Mariko has extensive experience managing global landscaping projects on regulatory matters and devising efficient approaches to global compliance. Fluent in Japanese, English and German, Mariko also has strong analytical skills. She has a BSc in Public Health Nutrition from Oxford Brookes University and a project management qualification.

Luke Murphy, Regulatory Manager

Luke has worked in food and beverage regulation for more than a decade, and global harmonization is a specialty. Before joining Leatherhead in 2006, he held product development roles with brands including Mars Petcare and Unilever Beverages. Luke has a BSc in Food Science from the University of Leeds, he's a member of the IFST food law steering group and sits on the BRDO Business Expert Group (Food Standards and Labeling).

Interested in discussing a potential project?

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About Leatherhead Food Research

Leatherhead Food Research provides expertise and support to the global food and drink sector with practical solutions that cover all stages of a product's life cycle from consumer insight, ingredient innovation and sensory testing to food safety consultancy and global regulatory advice. Leatherhead operates a membership program which represents a who's who of the global food and drinks industry. Supporting all members and clients, large or small, Leatherhead provides consultancy and advice, as well as training, market news, published reports and bespoke projects. Alongside the Member support and project work, our world-renowned experts deliver cutting-edge research in areas that drive long term commercial benefit for the food and drink industry. Leatherhead Food Research is a trading name of Leatherhead Research Ltd, a Science Group Company.

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About Science Group plc

Science Group plc (AIM:SAG) offers independent advisory and leading-edge product development services focused on science and technology initiatives. Its specialist companies, Sagentia, Oakland Innovation, OTM Consulting, Leatherhead Food Research and TSG Consulting collaborate closely with their clients in key vertical markets to deliver clear returns on technology and R&D investments. Science Group plc is listed on the London AIM stock exchange and has more than 400 employees, comprised of scientists, nutritionists, engineers, mathematicians and market experts.

Originally founded by Professor Gordon Edge as Scientific Generics in 1986, Science Group was one of the founding companies to form the globally recognized Cambridge, UK high technology and engineering cluster. Today Science Group continues to have its headquarters in Cambridge, UK with additional offices in London, Epsom, Boston, Houston, San Mateo and Washington DC.

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