

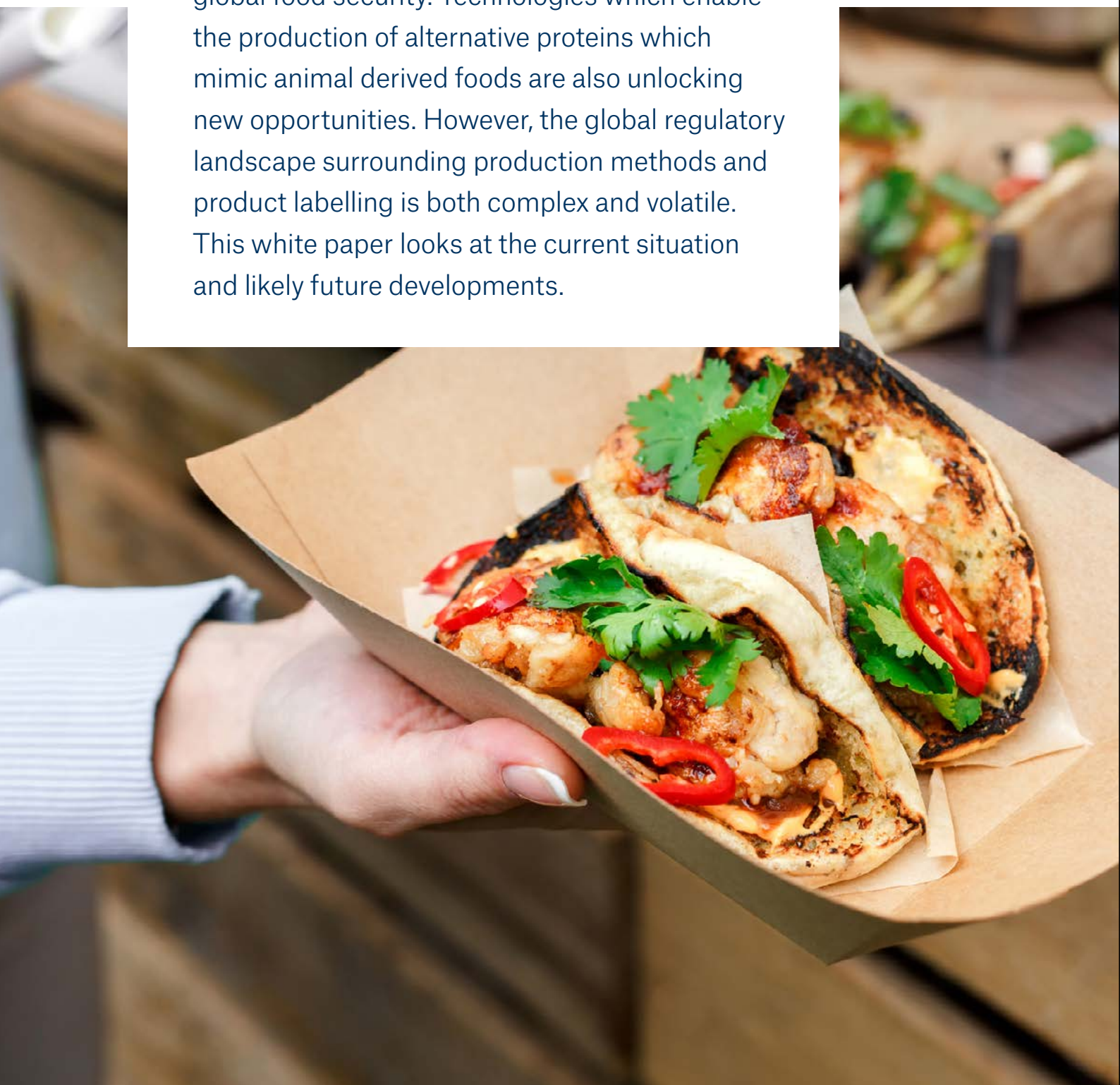
In focus

The regulatory landscape for animal product alternatives

Keep up with evolving rules for plant-based foods



The rise of the plant-based market is buoyed by many factors, from sustainability to health to global food security. Technologies which enable the production of alternative proteins which mimic animal derived foods are also unlocking new opportunities. However, the global regulatory landscape surrounding production methods and product labelling is both complex and volatile. This white paper looks at the current situation and likely future developments.



The plant-based trend

Consumer awareness of the issues associated with over-production and over-consumption of meat is driving a trend for vegan, vegetarian and flexitarian diets. Growth in the global plant-based market is expected to exceed \$480 billion by 2024 with a compound annual growth rate of nearly 14% (BIS Research, 2020).

The food industry is working hard to meet growing demand for sustainable meat alternatives. Challenges related to their organoleptic profile and nutritional content, especially in products presented as animal-based alternatives, have sparked a wave of innovation. For instance, developments in production methods have unlocked new ways to create meat-free products which taste and looks just like the real meat.

However, the plant-based trend also comes with a raft of regulatory challenges related to the production and labelling of products. There is much discrepancy between global markets, and many grey areas. We've seen an increasing number of enquiries related to these issues at Leatherhead.

In this whitepaper, we look at recent developments and likely future scenarios for regulations in key markets. Food businesses that can navigate the complex regulatory landscape effectively and efficiently are set to make the most of the plant-based opportunity.

Product development & technology

A key technical challenge facing food businesses is the development of plant-based products which contain complete proteins. Food experts are investigating novel and innovative formulations to address this, for instance through the creation of an ideal protein base.

Textured proteins from vegetable sources such as soy, pea and wheat are commonly used to create complete plant-based protein. This approach uses a mechanical method to restructure protein concentrates and isolates.



Fermentation is the future of alternative protein

A new method of plant-based protein manufacture is also gaining attention: fermentation-based cellular agriculture. It uses fermentation in the production of proteins which mimic those found in dairy and egg products (PATH, 2019).

One such method involves encoding the genetic material for a desired protein and integrating it with a host organism such as yeast. This is then fermented prior to separation from the host cell followed by purification. The resultant protein matches that from the original animal-derived product. It can be used to enrich the nutritional profile, optimise functionality or improve sensory characteristics of food products (Waschulin et al. 2018).

Historically fermentation has been used safely and effectively to produce and improve a variety of foods such as bread, cheese and fruit juices. It is seen by many as the future of the alternative protein industry. However, applying the method in this way is considered novel, which brings new regulatory challenges.

Regulations for the development of animal product alternatives

There are currently no set legal provisions on the use of cellular agriculture in the major global markets of the European Union (EU) and United States of America (US).

At present, regulatory discussions surrounding tissue engineering-based cellular agriculture, also known as 'cultured meat' are ongoing in the US. Meanwhile, in the EU, the first ever investment deal for a lab-grown meat consortium project has been signed. This indicates a growing opportunity for lab-grown protein and meat alternatives.

However, no discussions are being held for products manufactured via fermentation-based cellular agriculture.

US

The US route to market for cellular foods is the Generally Recognised As Safe (GRAS) process, achieved via the Food and Drug Administration (FDA) or the manufacturer. From a legal perspective, foods produced in this way should be acceptable if they hold existing FDA GRAS approval or the manufacturer can substantiate that the food is GRAS.

An example of a GRAS approved cellular product is soy leghemoglobin, a genetically modified protein produced from the yeast species *Pichia pastoris*. Upon submission of a GRAS notice to the FDA, no questions were raised on its intended use at levels up to 0.8% to optimise flavour in ground beef analogue products for cooking.

EU

In the EU, cellular foods are likely to follow the regulatory pathway for novel foods or genetically modified foods.

Products that weren't used for human consumption to a significant degree in the EU before 15 May 1997 are classified as novel in accordance with Regulation (EU) No. 2015/2283. This applies to most foods derived from cell or tissue culture from animals, plants, microorganisms, fungi or algae, or produced by novel processes.

Such foods require pre-market authorisation and approval by the European Food Safety Authority (EFSA) prior to marketing in any individual Member States.

Alternatively, if the production method involves a genetically modified organism, the food business needs to follow the Genetically Modified Foods Regulation. So, while soy leghemoglobin is used in the US, an EU application submitted in October 2019 has not yet been actioned by the European Food Safety Association (EFSA).

This single case highlights the major discrepancies in global regulation surrounding the development and marketing of foods produced by cellular agriculture.



Regulations for plant-based product labels

Food labelling is a critical platform for marketing and regulatory requirements alike. However, definitions of plant-based products have traditionally been a grey area.

In India, legal definitions for 'non-vegetarian' and 'vegetarian' food are established under the Food Safety and Standards (Packaging and Labelling) Regulation, 2011. But this is a rare example. Most markets currently have no such legal requirements for plant-based foods.

In the absence of legal requirements, various authorities publish national guidelines for terminology associated with vegan and vegetarian products to avoid confusion and misinterpretation. Canada has specific guidance on the use of claims for various genres of vegetarianism: lacto-ovo-, lacto- and ovo-vegetarian. In markets where no such guidance is available, food businesses can seek support and advice from vegan and vegetarian societies and certification bodies.

The use of meat and dairy terms on plant-based foods in the EU and US

One of the many challenges for plant-based foods is the use of terms traditionally associated with dairy and meat products, such as 'milk' or 'steak'. With dairy products for instance, there are compositional standards associated with product types, but legal requirements for plant-based foods are yet to be established. In their absence, non-misleading principles apply.

EU

EU Regulation No. 1308/2013 prohibits the use of terms such as 'cheese' and 'milk' for plant-based alternatives. So, product descriptions or names such as 'almond milk' are not acceptable, unless listed as an exemption under Commission Decision 2010/791/EU, which allows for certain dairy terms to be used for non-dairy alternatives. This exemption applies to 'coconut milk'.

In October 2020, a European Parliament plenary vote was held which could have extended this ruling to change how meat-related terms such as 'steak', 'sausage', or 'burger' can be used on food products. However, MEPs rejected the proposals to recognise such terms as exclusive to meat-based products and the amendment was voted down.

US

Since 2018, the FDA has been discussing how 'standards of identity' are regulated. It's looking at developing draft guidance to provide greater clarity on appropriate labelling of plant-based alternatives (FDA statement, 2018). While speaking about future initiatives, the FDA Commissioner at the time supported an enforcement to exercise stricter standards on milk alternatives. He famously said 'an almond doesn't lactate' sparking widespread discussions on naming protocols for non-dairy milk.

However, as of 2020, no legal enforcement has been established. It is therefore acceptable to use the term 'milk' on the labels of vegan products such as almond milk in the US, providing the source of origin is clearly distinguished.

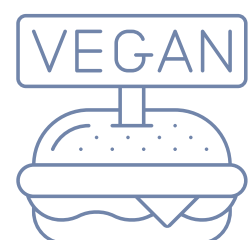
All in all, various ongoing discussions worldwide could change how meat and dairy alternatives will be labelled in the future. As a result of the recent proposal rejection in the EU, we would expect that meat related terms will continue to be acceptable in the EU provided a clear description of the product is given. However, we may see the emergence of legal restrictions on use of dairy terms in the US soon.

'Plant-based' claims

While there is consensus on what constitutes a 'vegan' or 'vegetarian' product, there is less guidance and shared understanding on 'plant-based' product claims. Individual food businesses are responsible for ensuring they don't mislead consumers. When developing a product that will be positioned as plant-based, various factors should be considered, such as:

- Should it be 100% of plant origin, or only partly?
- Must the quantitative ingredient declaration requirement in the EU be applied for the plant-based ingredients so consumers can understand the proportion of plant ingredients within the product?

There are no clearly defined answers to these questions. In fact, the interpretation of 'plant-based' can vary significantly across markets depending on dietary habits, consumer expectations and culture. Appropriate use of the claim needs to be determined on a case by case basis, with attention given to consumer assumptions and existing national authority guidelines.



Conclusion

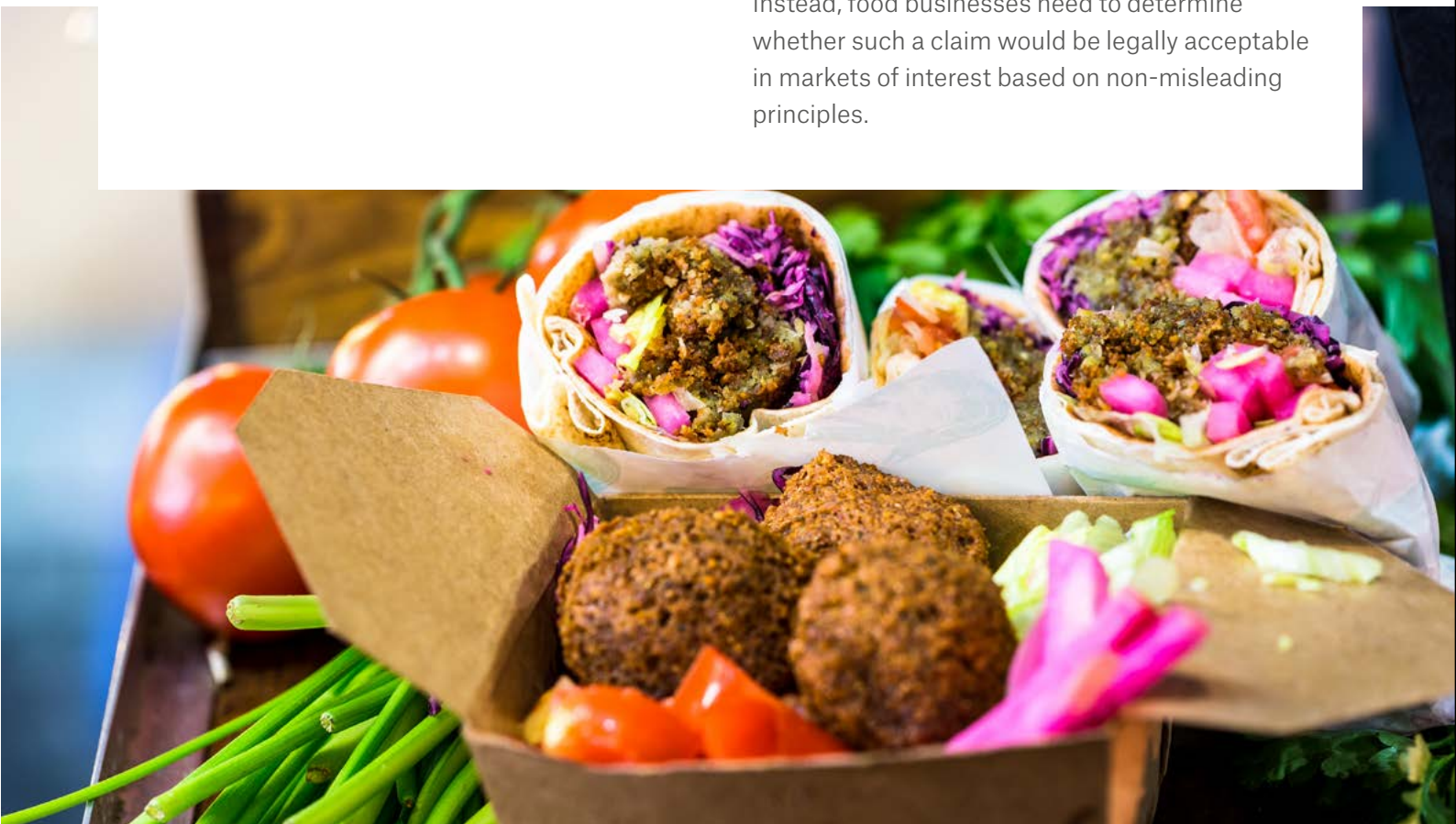
Plant-based products are set to continue as a high-growth subsector of the food industry. Rapid innovation and an evolving regulatory landscape bring both opportunities and challenges.

Our recommendation is that food businesses in this space, or planning to enter it, remain vigilant and monitor the situation closely. There are significant gaps in the legal requirements for plant-based products. Without specific and transparent regulations based on safety assessments, the onus is on food businesses to act with care and integrity as they develop and market new products.

We advise taking notice of the following:

- Technologies such as cellular agriculture are not specifically regulated and therefore foods produced by such methods may require pre-approval
- Labelling of plant-based foods remains a grey area from a regulatory standpoint. Few markets define 'vegetarian', 'vegan' or 'plant-based' products under food legislation. It remains to be seen whether major markets will define these terms

We carried out a study on the use of 'plant-based' claims on products. It concluded that without specific regulations or guidelines, it is impossible to establish when or where this claim is permitted. Instead, food businesses need to determine whether such a claim would be legally acceptable in markets of interest based on non-misleading principles.



How can Leatherhead help?

At Leatherhead Food Research, we advocate a risk-based approach to decision-making, using a logical and evidence-based rationale founded on market-specific regulations and consumer research.

- From a technology perspective, we can advise food businesses upon which regulatory pathway is required, and support with novel food dossier applications
- From a consumer perspective, we can establish consumer panels to reveal how a 'plant-based' claim is interpreted, providing substantiation for use of the claim if challenged by market authorities



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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 programme 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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