

In focus

The importance
of conducting
a regulatory
environmental
review





Exposing concepts to a regulatory environment review early in the development process will help focus your efforts on products with global potential, accelerate launch timelines and align cross-functional teams. Equally applicable to challenger brand products, the exercise is designed to deliver greater efficiency, agility and profitability in the search for better products.

Developing new products is a costly and often inefficient exercise, especially when seeking to push boundaries including enabling claims, moving to natural and clean formulations. But the challenge is not just technical; the internal dynamic between stakeholders with differing perspectives, marketing, R&D and regulatory, can create a tension that is not always positive.

The benefit of a regulatory environment review?

As soon as a concept is ideated, we recommend implementing a regulatory environment review. This exposes the concept to a regulatory and policy assessment of your target markets to qualify its multi-market potential. Factors such as claims, formulation permissibility, packing, communications and manufacturing processes are all considered, enabling early identification of potential hurdles. This allows issues to be brought to the fore at an early stage, driving an evolution of the concept, it's positioning, or a complete re-think.

Clearly this is no panacea. The consumer mood in each market is not necessarily reflected in policy and regulation, but this is a quick, early-stage screening that ensures the resulting solution – a multi-market product concept – is better suited to enable the business to leverage its scale and drive

efficiencies. Furthermore, the resulting clarity on innovation boundaries channels a more targeted approach from the R&D function, which allows them to focus on the aspects of development that really matter: better products, faster to market.



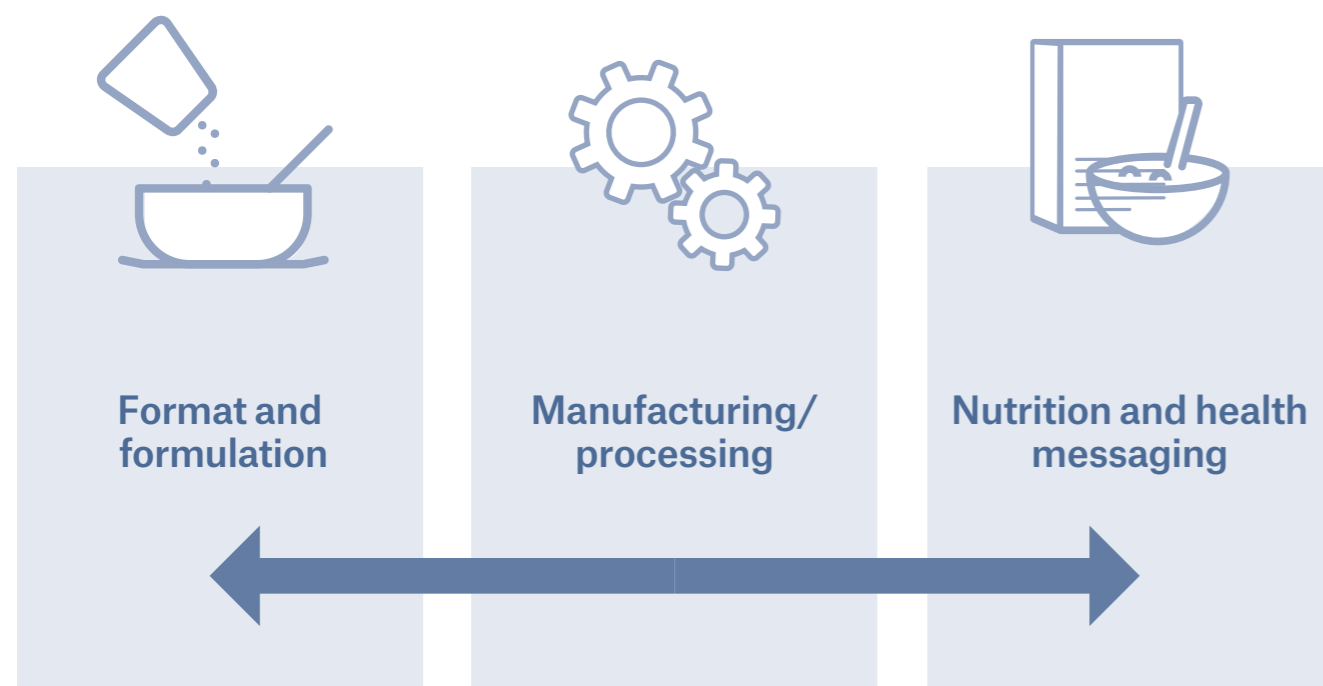
Many countries have introduced pre-market review requirements where modifications potentially affect the safety of a product. This is particularly true in the EU, where the precautionary principle remains supreme.

Qualifying challenger brands – adopt and adapt?

70% of consumer-packaged-goods sector growth has come from small and medium brands over recent years and challenger brands, on mass, have muted the growth of the larger players. However frustrating, these brands are highly innovative and whilst most of these innovations are founded on a local or national need, some have multi-market potential.

To this end, the regulatory environment review can be used to assess the global potential of challenger brands and their applicability to your brand strategy. Not only this, but the addition of a scientific and/or consumer lens can add further depth, again in a fast and efficient way.

The output: a clear, concise qualification as to whether to adopt and adapt the product concept or simply ignore it. This tool is particularly useful to scientific and regulatory affairs functions looking to better support marketing peers in a fast-moving landscape littered with challenger brand concepts, good and bad.



Things we think you should know...

Having completed a number of these reviews recently, there are a few things we think you should consider:

1 Don't assume permissibility in this market or the next

When challenger brands exist in the category and/or market, the default position from some stakeholders may be that permissibility of similar concepts is assured. Sadly, this is not the case. Many smaller brands take large risks in order to create a point of difference, and the diversity and dynamic nature of the regulatory landscape between markets means that permissibility in one country does not infer permissibility in the next (even within a trade bloc).

That being said, there are intelligent ways to navigate these differences that may be able to contain risk to an acceptable level. Some examples of potential adaptations are explained below.

2 Both formulations and formats will impact permissibility

Many innovations involve format or formulation modifications, for example, to make a product perceivably more ethical, natural or convenient. This often includes the substitution of one or more ingredients for new ingredients. When this is the case, it is important to ensure that the use of such components is supported by the legislation in your target markets, allowing use of the ingredient without impacting compliance with any compositional standards (assuming this is important to you).

Additives are a particularly good example of this. Their use in many countries is subject to regulation through a positive list, which means that if an additive does not feature on the list, it is generally

not considered safe and may not be used in the product (until the regulations are amended).

A common food colour, carbon black, is permitted in many markets like Australia, EU and Canada, but may not be used in the US.

Using a naturally derived extract for a specific reason will not circumvent the additive legislation in many countries.

Compositional standards allow you to use protected product names in national markets. For example, they distinguish whether you can call something 'chocolate' or 'fruit juice', and there is currently lots of debate around the term 'milk' when considering plant-based products. These requirements are set out in vertical legislation that can be highly prescriptive and often differs between markets.

Clearly, the addition of a new ingredient may either directly contradict an established standard and/or modify the physical characteristics of a product, that in turn may prohibit the use of product names.

There is typically a compromise to be achieved that supports the use of new, more consumer-friendly ingredients, realising the desired product name and achieving compliance in multiple markets as it is unlikely a silver-bullet solution can be found.

It is important to note that these requirements continually evolve, so understanding the future direction of these is as important as achieving compliance today.

3 The manufacturing process of individual ingredients is just as important as the final product

Using new technology, such as ingredients, packaging, distribution, is another method to make your product stand out from the crowd. However, if this has the potential to affect the safety of a product, you should review the impact on launch timelines.

Many countries have introduced pre-market review requirements where modifications potentially affect the safety of a product. This is particularly true in the EU, where the precautionary principle remains supreme, whilst other countries take a more liberal approach and use risk-based assessments as the basis for their decisions.

It is worth pointing out that the use of various breeding techniques to produce new crops may be regulated differently. For example, genetically modified crops may specifically require labelling and pre-market approval.

4 Nutrition and health claims can be realised with careful consideration

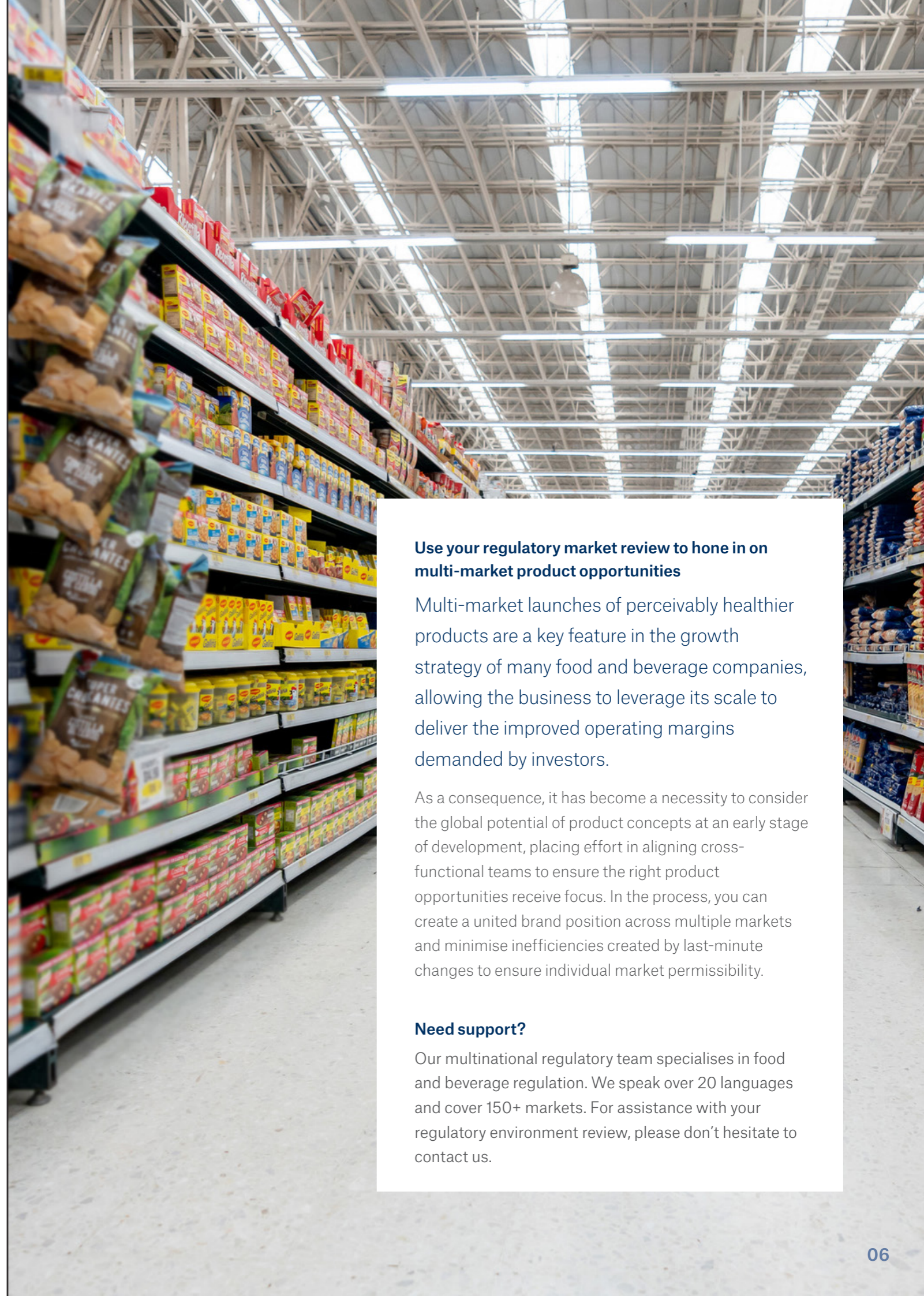
Consumers are looking for health benefits and functions from both the most indulgent and commodity foods, and, as a consequence, nutrition and health claims are aspirational elements of most new product innovations. However, as science develops and the authorities restrict unsubstantiated claims, it is becoming increasingly important to ensure yours is a legitimate one.

Furthermore, due to the differences in regulatory processes and requirements between markets, consideration should be given to launch timelines and the opportunity to develop a single body of evidence that can support claims across the markets.

– Nutritional claims
Modern nutrition labelling has created a way to convey the benefits and risks of consuming foods, with certain substances such as vitamins and minerals considered beneficial while other components are considered detrimental. Hence, it is important to consider both positive and negative messages.

You should also continue to track the evolution of nutrition labelling policy. As it is updated to provide clear and more pertinent nutrition information to consumers, new opportunities for nutrition messages emerge alongside changes to the mandatory labelling requirements.

– Health Claims
Some markets distinguish between disease and function claims, generally permitting truthful and non-misleading function claims but requiring pre-market approval for disease claims.



Use your regulatory market review to hone in on multi-market product opportunities

Multi-market launches of perceivably healthier products are a key feature in the growth strategy of many food and beverage companies, allowing the business to leverage its scale to deliver the improved operating margins demanded by investors.

As a consequence, it has become a necessity to consider the global potential of product concepts at an early stage of development, placing effort in aligning cross-functional teams to ensure the right product opportunities receive focus. In the process, you can create a united brand position across multiple markets and minimise inefficiencies created by last-minute changes to ensure individual market permissibility.

Need support?

Our multinational regulatory team specialises in food and beverage regulation. We speak over 20 languages and cover 150+ markets. For assistance with your regulatory environment review, please don't hesitate to contact us.

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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Founded in 1986, Science Group was one of the founding companies to form the globally recognised Cambridge (UK) high technology and engineering cluster. Today the Group has 12 European and North American offices.

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