A person wearing a VR headset is sitting on the floor, holding a controller. In front of them is a bowl of popcorn and a pencil holder filled with colorful pencils. The background is a blurred indoor setting.

# Regulatory Concept Review and Harmonization

# Agenda

- 1 Focus on innovation
- 2 Tools to leverage the innovation process
  - Regulatory horizon scanning
  - Regulatory concept review
- 3 Summary

# Innovation

# Is innovation important?

80% of executives think their current business models are **at risk of being disrupted in the near future**

McKinsey

84% of executives say that innovation is **important to their growth strategy**

Accenture, McKinsey

Innovation seems to be **the leading cause of economic growth**

OECD



# Is it worth the risk?

‘On average, the **cost of launching a new product** is around \$15 million’

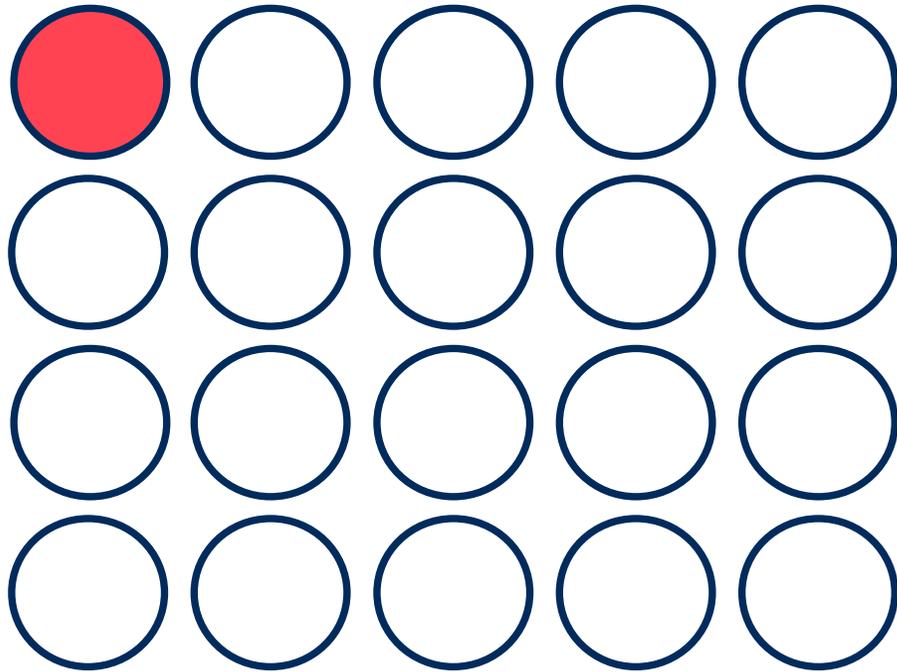
Forbes

‘**95% of consumer products fail** in the market’

Harvard Business School



# Are there opportunities still to be had?

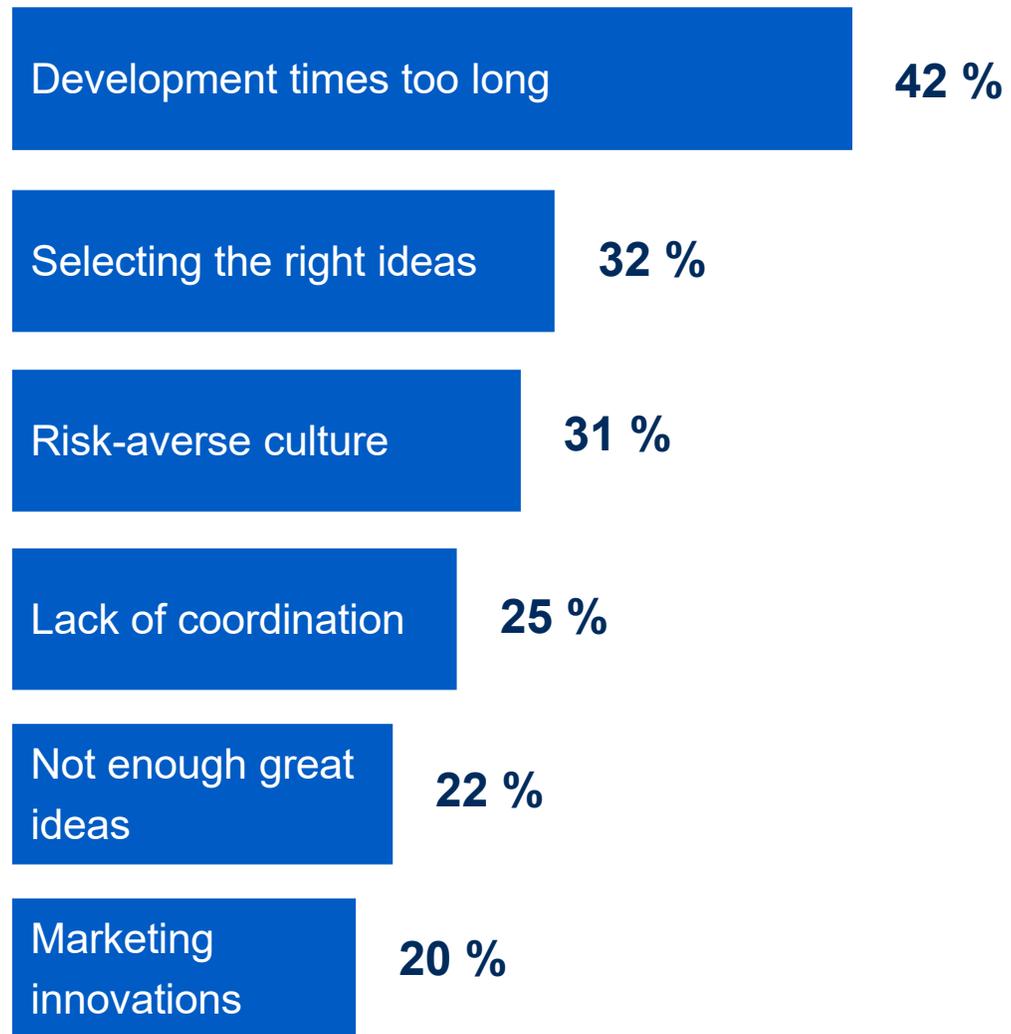


19 out of 20 product innovations fail

Organizations are missing  
72% of crucial growth opportunities

# The top six obstacles for innovation performance

## The symptoms of poor innovation



Source: [BCG Global](#)



# Innovation in food and beverage

# The trends driving change in our world

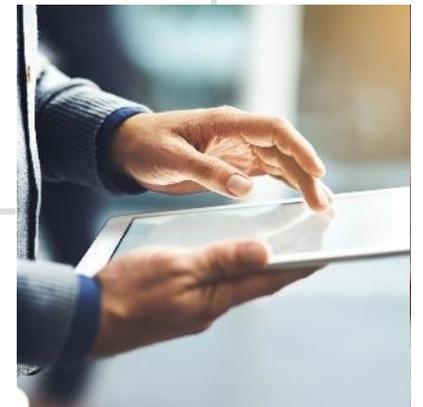
Millennials, elders, globalization, urbanization, etc.



Sustainability and environment



Internet technology and e-commerce. Processing technology



# How this manifests itself in our everyday requests

- I want to sell my product in a **new market**
- Because of consumer demand for **healthier** products, I need to develop a **new ingredient**
- I am not satisfied with the **sales volume** of my product; why am I behind my competitors?
- I want to make a health **claim** to increase added value and to access a **new consumer group**





# Tools to help



# Tools that can help

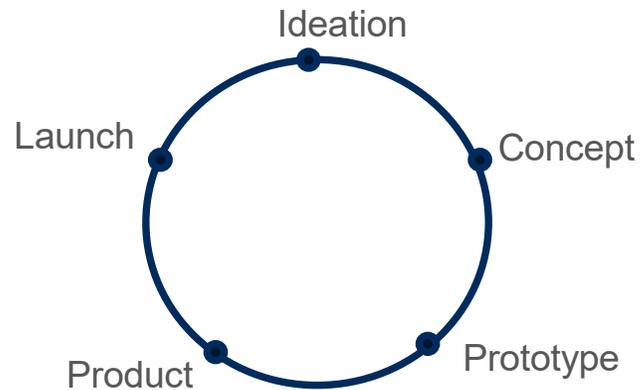
## Horizon Scanning

A process that enables you to prepare for and influence regulatory and/or policy change in order to gain a market advantage

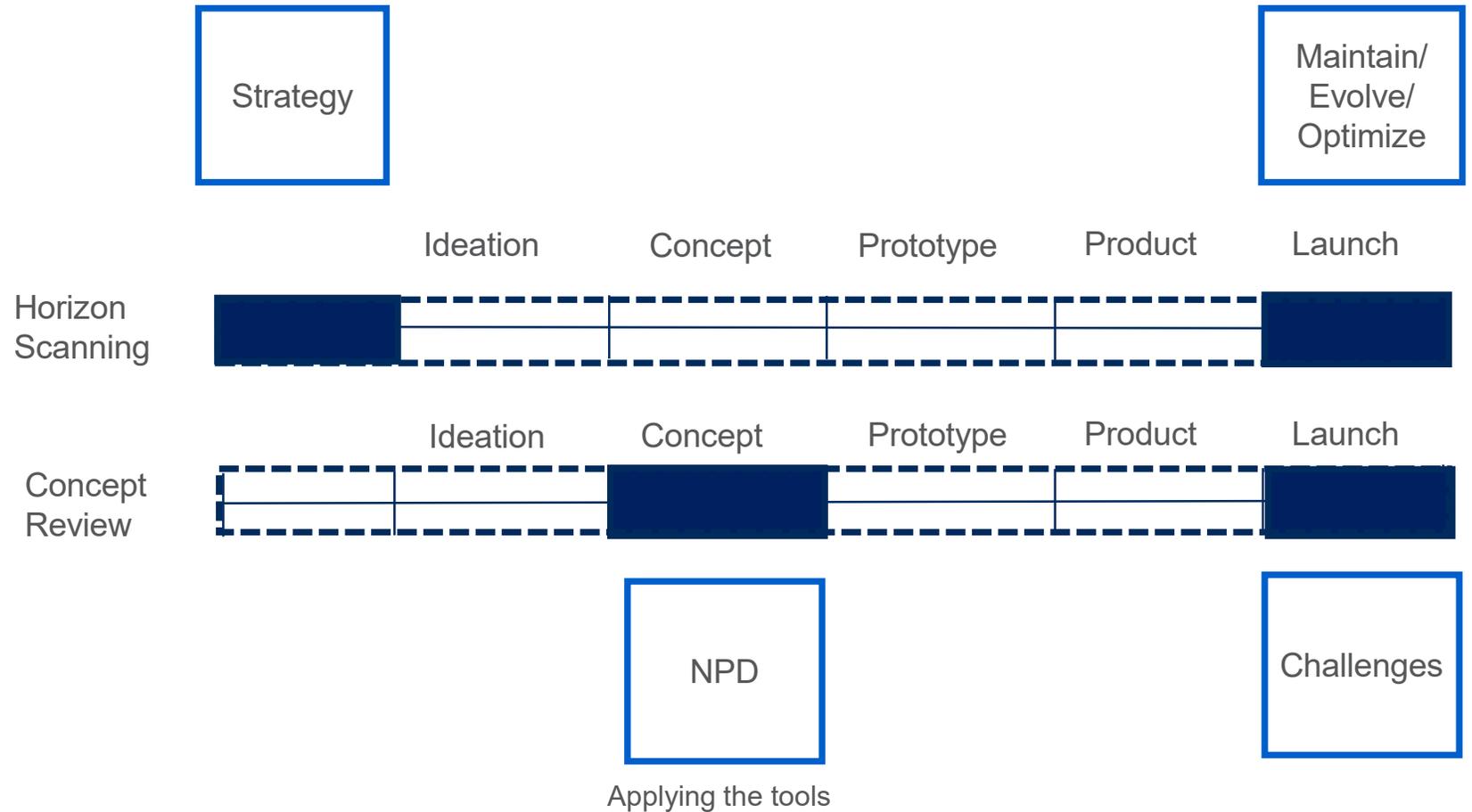
## Regulatory Concept Review

An audit framework used to evaluate the commercial relevance of a product against clearly defined business objectives

# Applying our innovation tools



US Regulatory Event:  
regulatory concept review and  
harmonization



A woman with dark hair, wearing a blue sleeveless top, is looking through a pair of black binoculars with orange lenses. She is positioned in the center-left of the frame against a light blue, textured background. To her right, a white rectangular box contains the text 'Regulatory horizon scanning' in a dark blue, sans-serif font.

# Regulatory horizon scanning

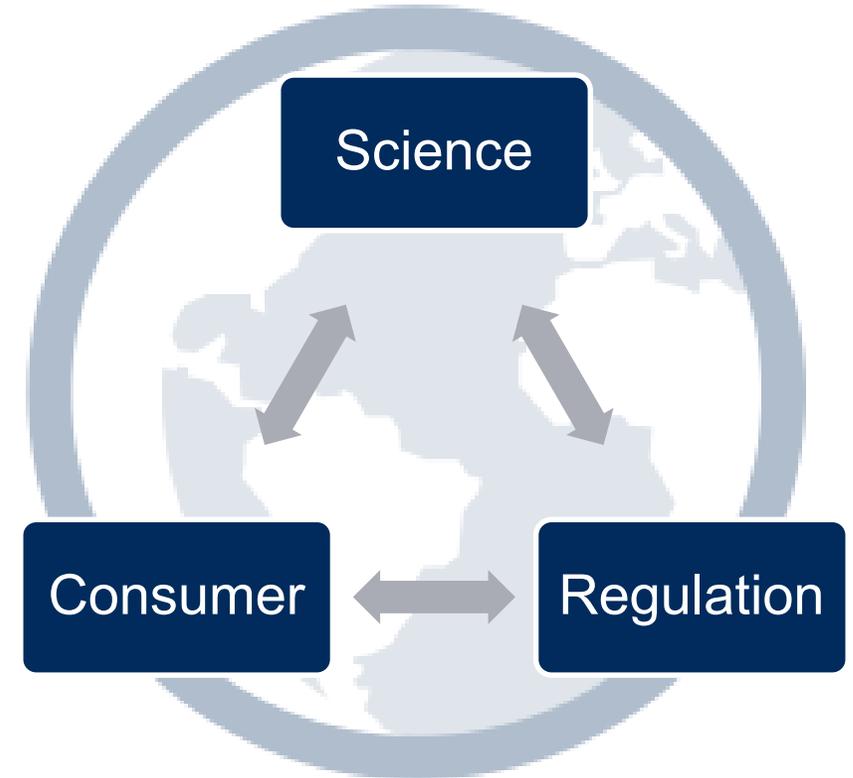
# What is horizon scanning?

Horizon scanning is a technique used to identify emerging opportunities, and potential threats and risks based on the regulatory, science and consumer landscape.

## Benefits:

Provides insight at an early stage, allowing the business to think and proactively engage (not just react)

- You gain time to evolve your strategy
- Provides you flexibility to plan your advocacy
- You can gain advantage in the market by preparing your product portfolio.



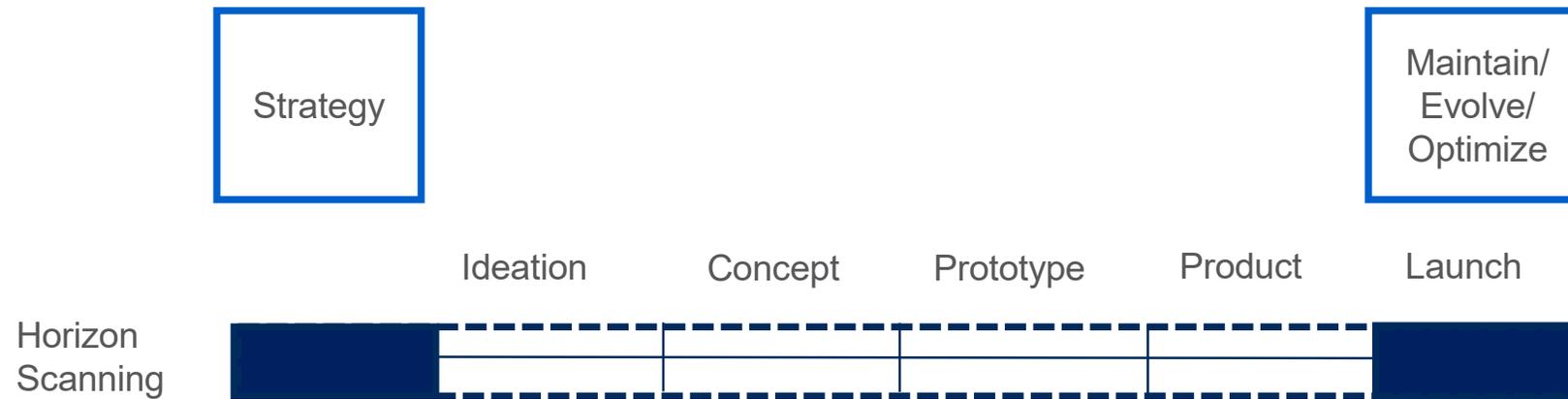
# Why you should be using it

And why we develop it

- ✓ The global regulatory landscape is poorly aligned and continues to diverge in the detail
- ✓ The mechanism for regulatory change is continuously shifting
- ✓ Smaller countries have more aggressive policy making mechanisms and are being perceived as case studies to more significant markets
- ✓ Consumers increasingly play a greater role in policy-making and the adoption of self-regulation mechanisms



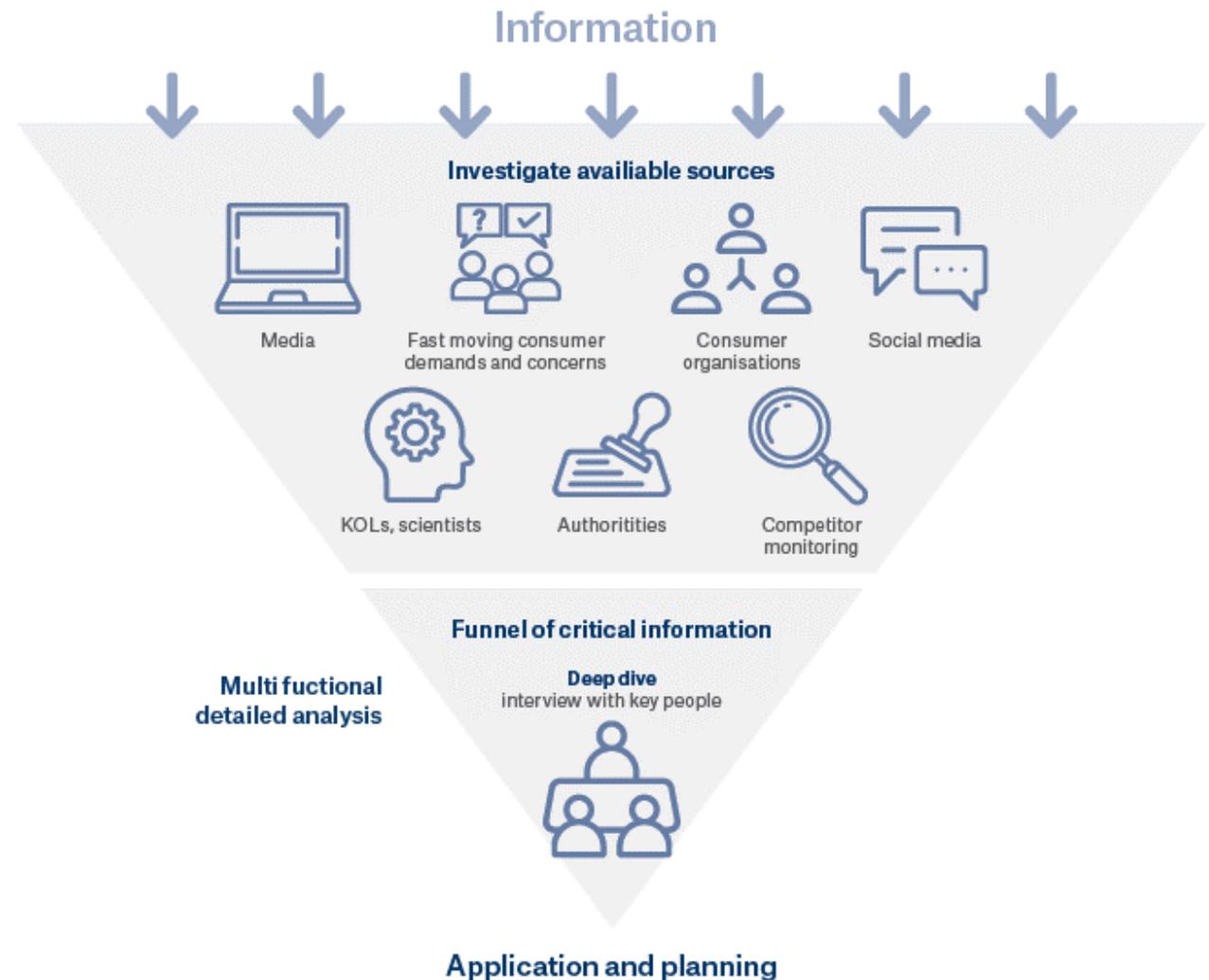
# When to use regulatory horizon scanning



- **During strategy development and prior to ideation**  
e.g. to determine growth opportunities with new products or markets, or divestments
- **Post launch – an ongoing surveillance activity**  
e.g. to understand the longevity of the existing portfolio/ need to evolve

# How to use regulatory horizon scanning

- ✓ A range of information sources harnessing consumer, science and regulatory perspectives (not just regulatory documents)
- ✓ Global research (not limited to target markets)
- ✓ An ongoing process – frequency of information updates vary with pace of change
- ✓ Focussed on specific topics of interest based on ‘heat’ of interest and relevance to your business



The focus of your Horizon Scanning activity will vary, depending on your business type.

Likewise, so will your reaction.

### Ingredients/components

Enables top-line investigation and raises awareness to food safety concerns and other issues which have a regulatory change potential

e.g. nano-technology, additives

### Products

Identifies opportunities to grow and expand brands into new markets

e.g. functional ingredients for infant formula

### Key issues

Monitors driving forces and incidents which may cause regulatory change

e.g. *microplastics*

Tracks policy changes continuously (even when there are weak signals) to enable innovation

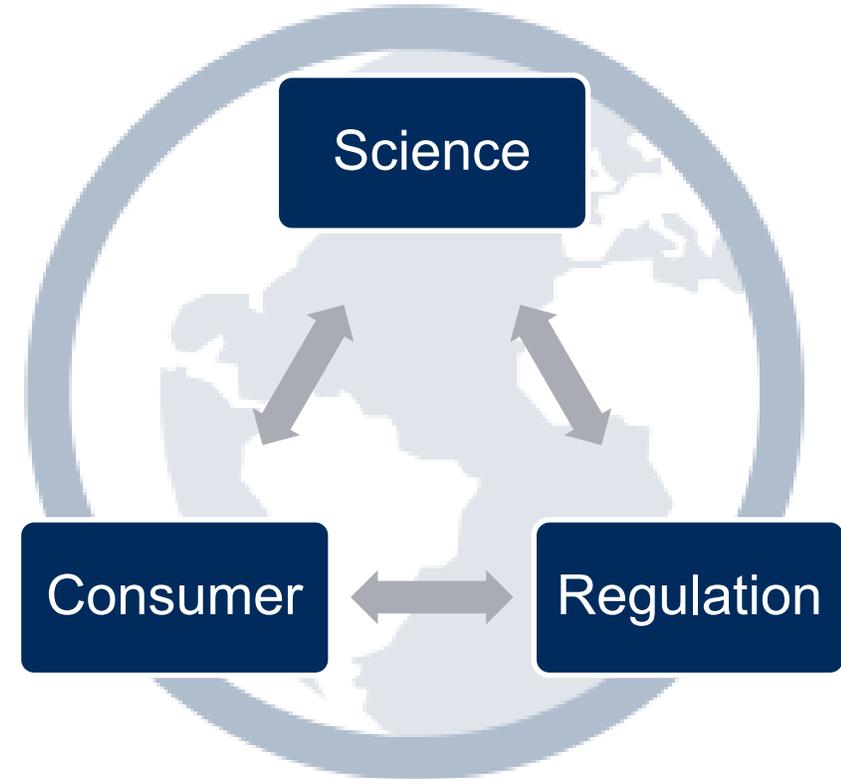
e.g. *caps for sugar content, novel flavouring solutions (such as Positive Allosteric Modulators)*

# Regulatory concept review



# How to use regulatory concept review

A regulatory concept review is an audit framework used to evaluate the commercial relevance of a product against clearly defined business objectives (typically related to multiple-market compliance of formulations and on-pack communication)



# How to use regulatory concept review

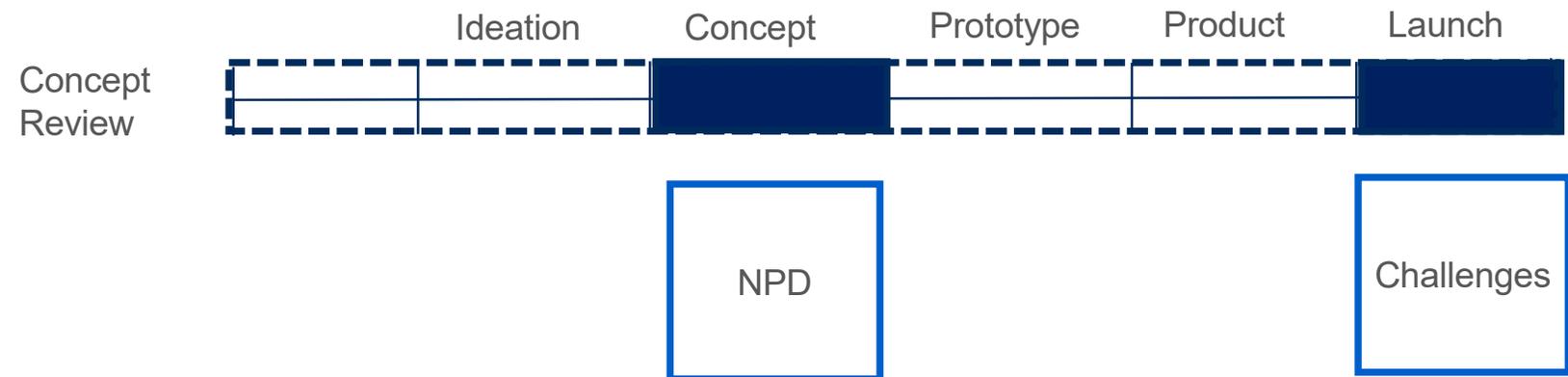
When it is performed at the very early stage it:

- Reduces the risk of time and budget overruns, and even failures
- Quickly qualifies the commercial relevance of new product concepts
- Aligns internal teams on the reality of the possible



# When to use regulatory concept review

- After ideation stage
- New market entry
- Challenger brand threat



# How to use regulatory concept review?

## FORMULATIONS AND FORMATS

An independent assessment and validation of your recipe, ensuring you are using the permitted ingredients...

- At the right levels,
- In the right formats, and
- With the right bio-availability profiles

...for the concept that you want to launch in a single market or multiple markets

Across all  
markets and all  
food, beverage  
and supplement  
categories

# How to use regulatory concept review?

## EMERGING TECHNOLOGIES

A global regulatory evaluation paired with scientific, toxicology and consumer perspectives to identify the position of emerging technologies, such as:

- Bio-fortification
- Genetic modification
- Nanotechnology
- Irradiation

All of these could enhance the nutritional, physico-chemical, textural, sensory and safety qualities of your concept

Across all  
markets and all  
food, beverage  
and supplement  
categories

# How to use regulatory concept review?

## NUTRITION & HEALTH CLAIMS

A pre-emptive collation and mapping of robust science-based evidence that could be used to:

- substantiate the desired nutrition and/or health claims
- advise on strategic reformulations or processing conditions to align more closely with the provisions of the desired claims

These will consolidate the validity of your concept in terms of product development and marketing plans

Across all  
markets and all  
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and supplement  
categories

# Mapping the opportunity for bio-fortified crops

## Opportunity Area: Bio-fortified crops

These crops are created by conventional plant breeding methodologies.

They are being developed to tackle the worrying global trend of hidden hunger and micronutrient malnutrition.

## Approach

Scope: consumer acceptability, barriers to B2B uptake, regulatory compliance (UK, EU, US) and the impact on manufacturing processes in sample recipes.

<https://www.harvestplus.org/>



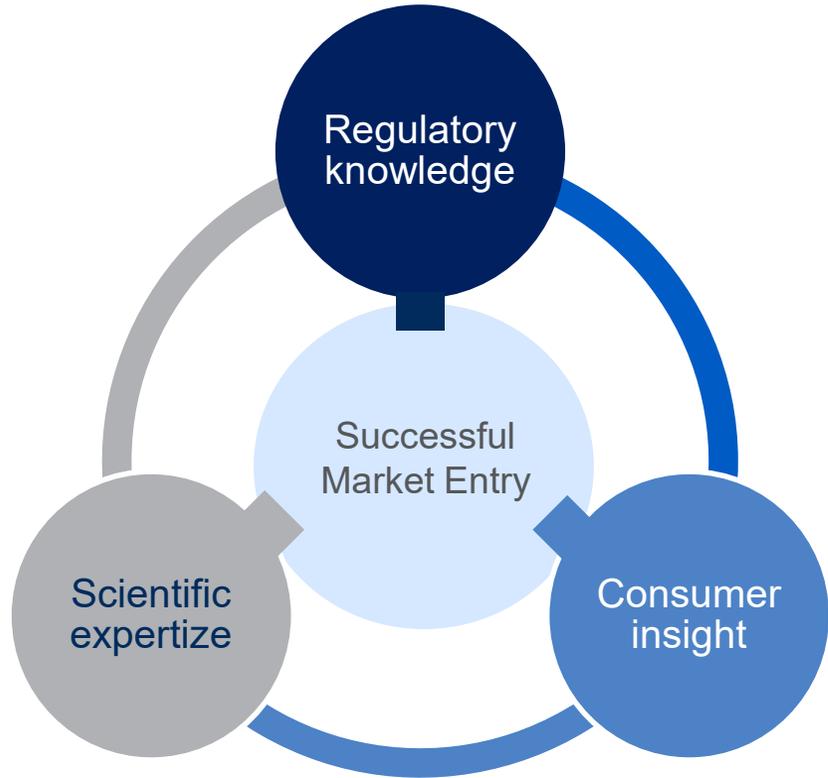
**Regulatory Landscape**  
*What is the widely accepted definition of bio fortification? What are the parameters of the definition?*

**Regulatory Framework for Labels & Claims**  
*What claims are permissible? What labelling options are possible?*

**Ingredient Supply**  
*How would the bio-fortified crops and ingredients be provided to food manufacturers?*

**Existing and New Product Developments**  
*What existing products and new concepts can these bio-fortified ingredients be used in?*

**Theoretical recipes**  
*How can the ingredients be incorporated into recipes, taking into consideration various critical factors including processing, risk assessment and nutritional profiles?*



**Qualitative research**  
*What is the perception of UK consumers to foods which are naturally higher in vitamins and minerals? What are the opportunities and challenges in driving awareness and acceptance of these foods?*

**Quantitative research**  
*Which terminology resonates best with consumers? Which product concepts excite consumers most?*

# Summary

- **Embrace and adapt external ideas:**

Innovation is as important as it always has been but our approach is letting us down. The influx of challenger brands can help us innovate better if we can embrace their concepts effectively

- **Think globally:**

The mechanisms for policy and regulatory evolution are changing quickly and therefore so must your monitoring techniques; single or multiple market focus is not enough

- **Get ahead of the pack:**

There is substantial opportunity for those organisations that can identify the early signs of regulatory and/or policy change and proactively influence and/or respond. Make sure you are one of them

# Thanks for listening!

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# Questions



# leatherhead food research

innovate | access new markets | realise global opportunities