

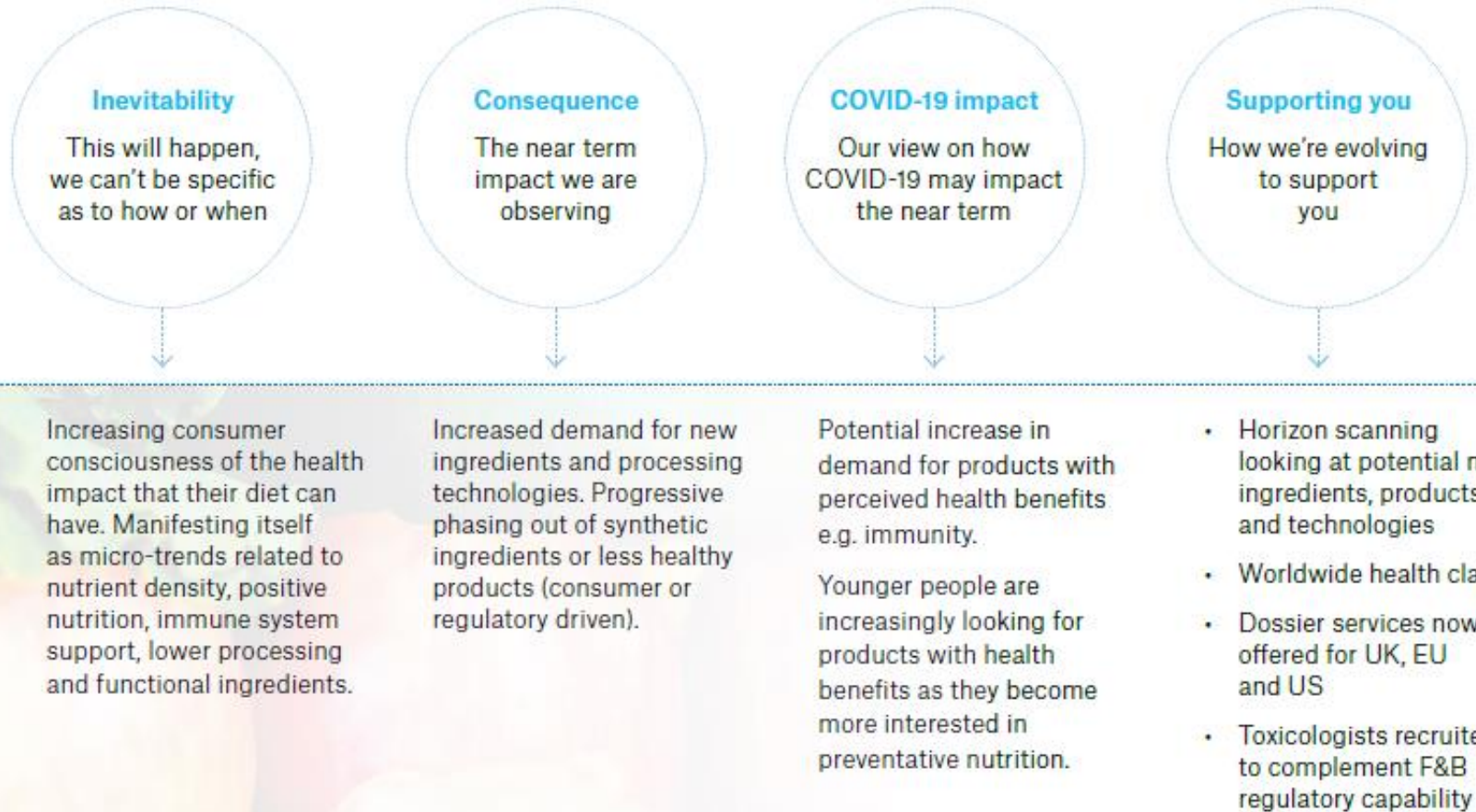


# New and emerging ingredients: A focus on cognitive, gut, stress and skin health

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# COVID-19 is accelerating consumer demand for “natural” and “novel” ingredients to support health & wellbeing

- Health & Wellbeing remain the key innovation trend for the food & beverage industry
- This could lead to increased regulatory divergence and gaps between innovation demands and regulatory permissibility
- Leading regulatory functions will enable ‘compliance by design’; transforming from a review-centre to a strategically focussed enabling function



HEALTH

# Determining the concept for delivery of functional ingredients at point of inception

## Point of inception

A consumer/ science and technology and regulatory lens at point of inception will de-risk the investments in the innovation & marketing processes.



Consumer



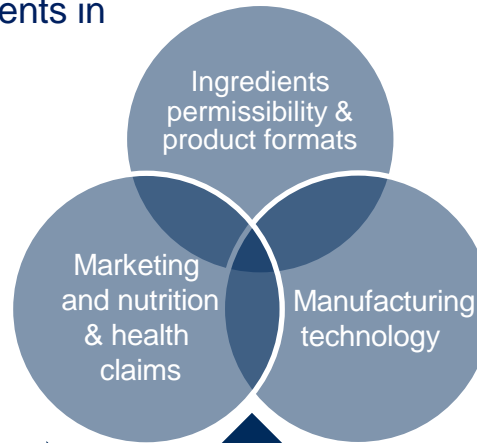
Technology



Science



Concept



Global market entry plan



## Production, marketing and sale



Label check



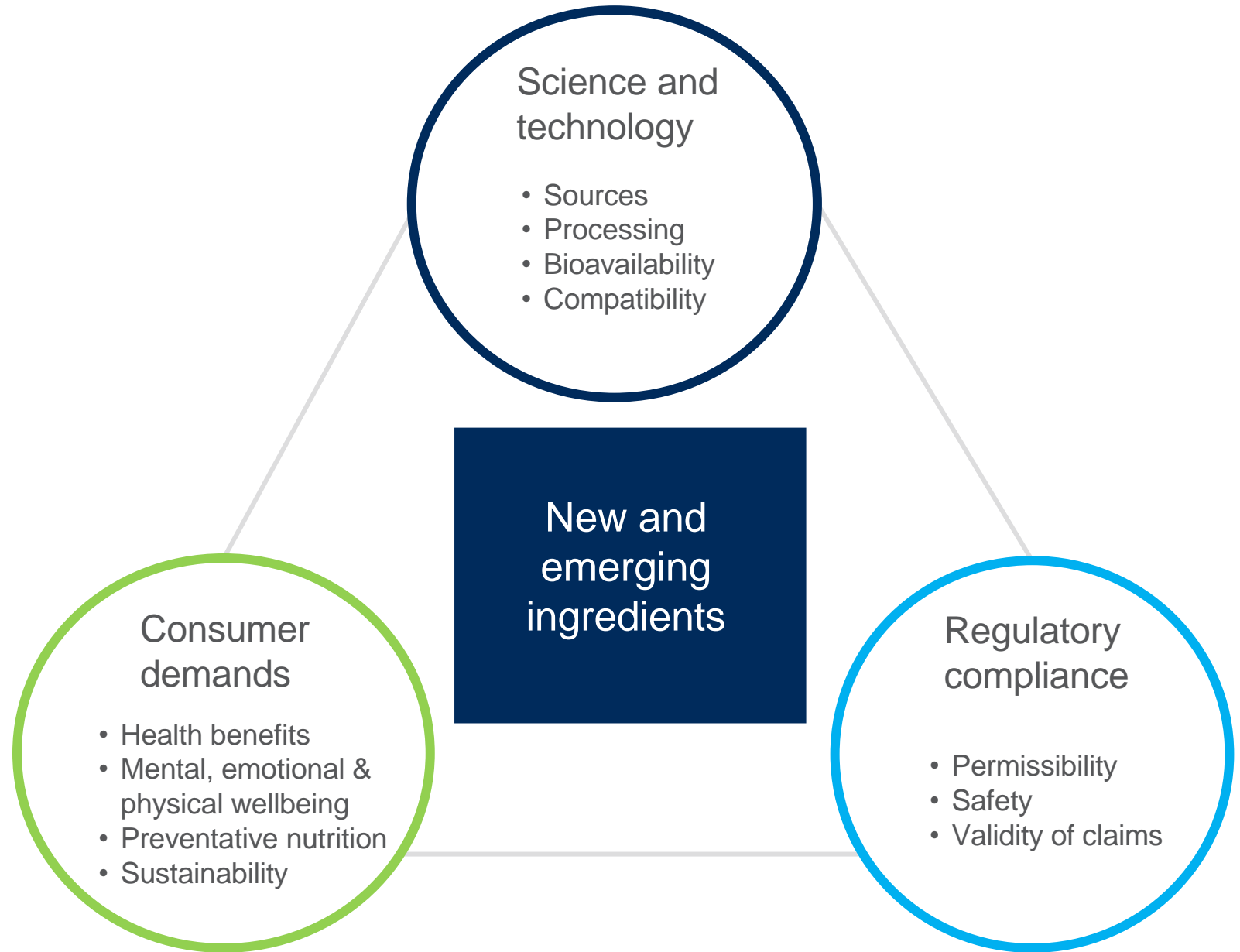
Production



Sale

# Delivering functional ingredients

A balance between consumer perception, technological success & regulatory compliance



# What are consumers looking for?

- Affordable nutrition and sustainable products
- Transparency
- Plant based
- Clean and natural
- Community

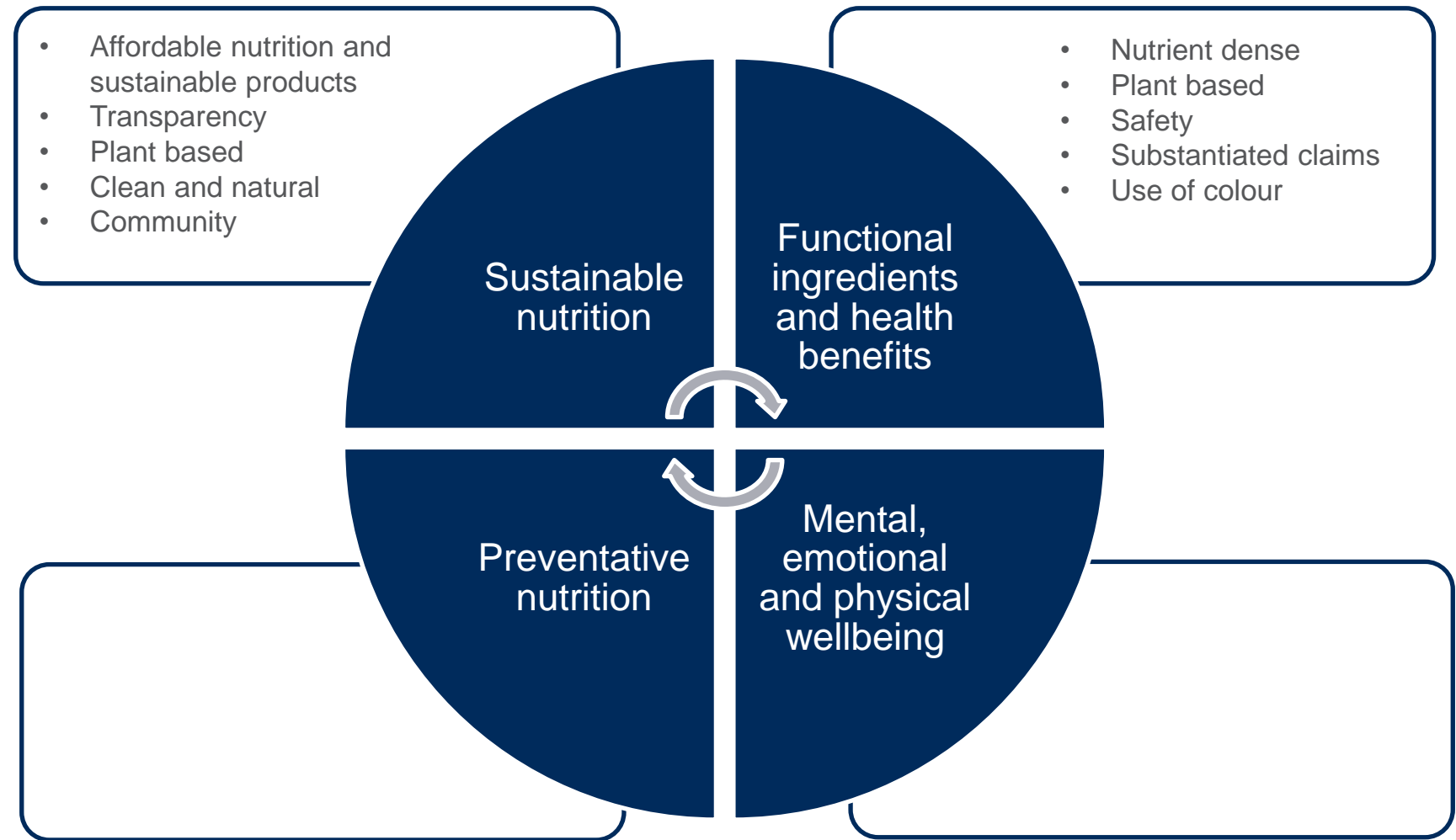
Sustainable nutrition

Functional ingredients and health benefits

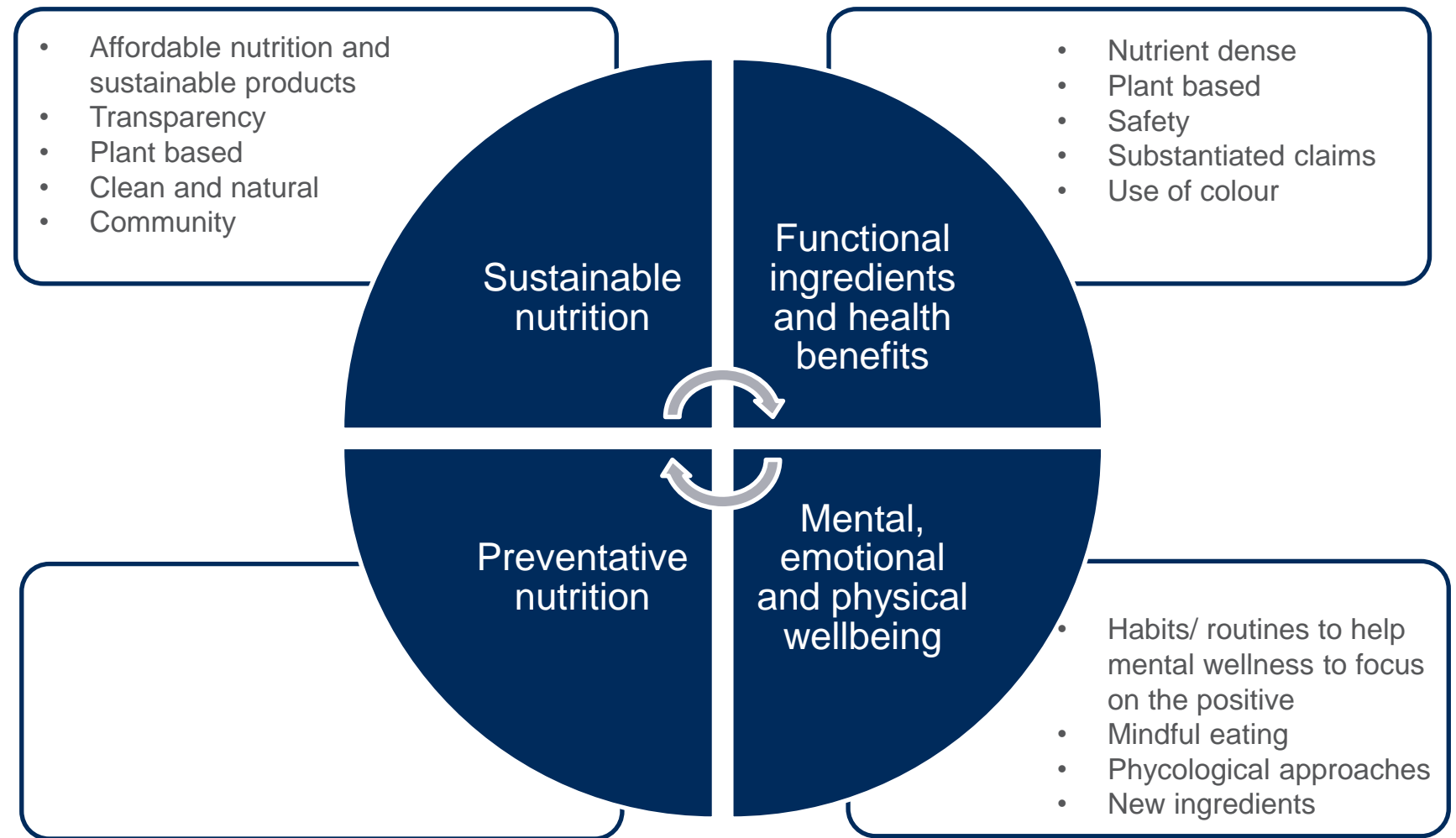
Preventative nutrition

Mental, emotional and physical wellbeing

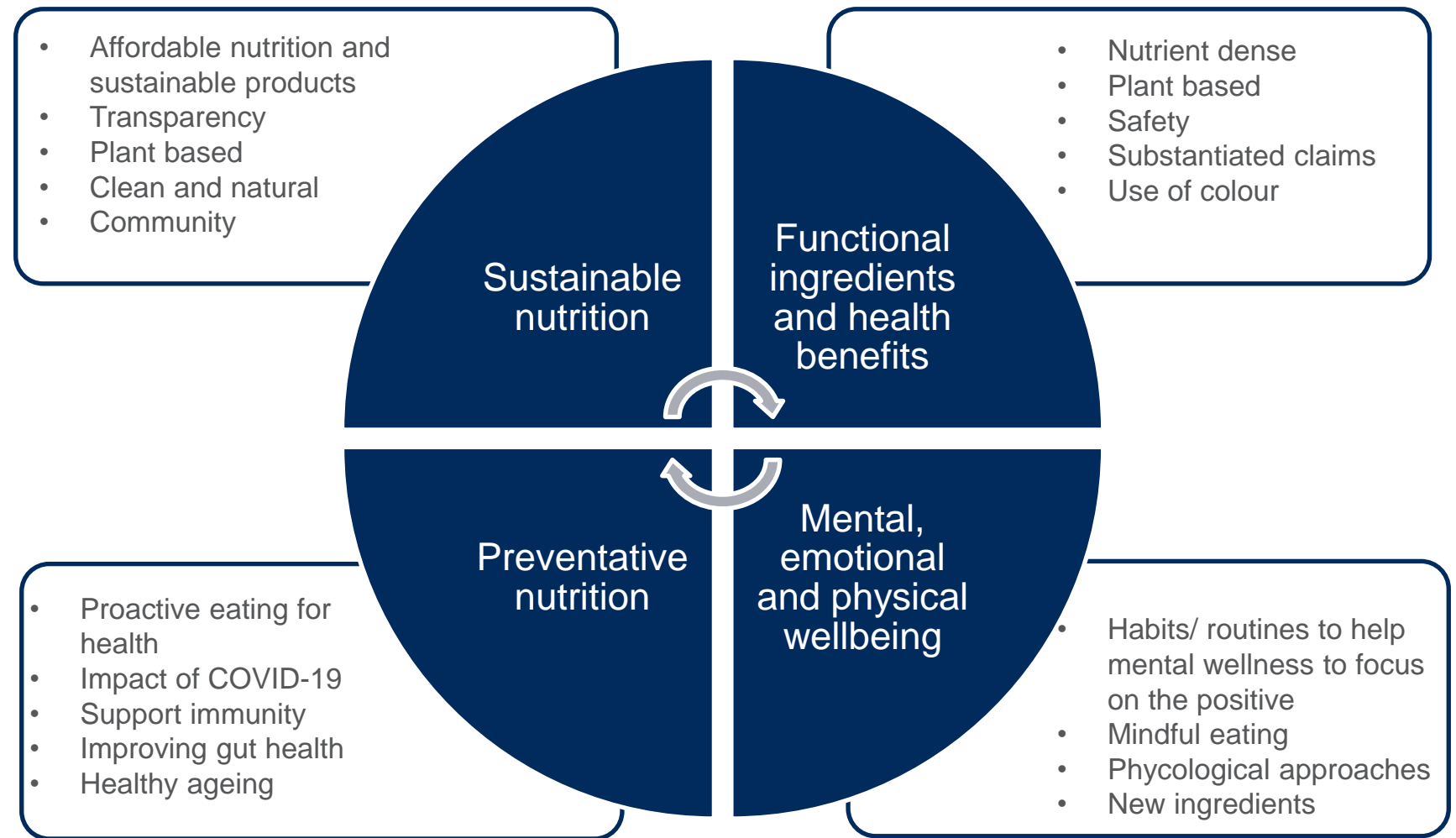
# What are consumers looking for?



# What are consumers looking for?



# What are consumers looking for?



## Science & Technology

Consumers are increasingly being aware of the role certain functional ingredients can play in their health & wellbeing

There is a growing recognition of the role certain ingredients are increasingly being recognised for their contributions to specific health areas.

Cognitive health



Gut health



Skin health



Stress health



# Science & Technology

## Functional ingredients for cognitive health



## Nootropics for cognitive health

Non-prescription substances that can enhance brain/mental performance/focus or even prevent the decline of cognitive function (dementia)

Mechanisms of Actions are still undefined, but...

Several mechanisms of action for the nootropics have been put forward.

- Increasing the dopamine and adrenergic receptor activity and inhibiting the norepinephrine uptake
- Increasing the acetylcholine and/or glutamate reception activity and inhibiting the acetylcholinesterase

*Ginkgo biloba*

*Panax ginseng*

*Bacopa monneri*

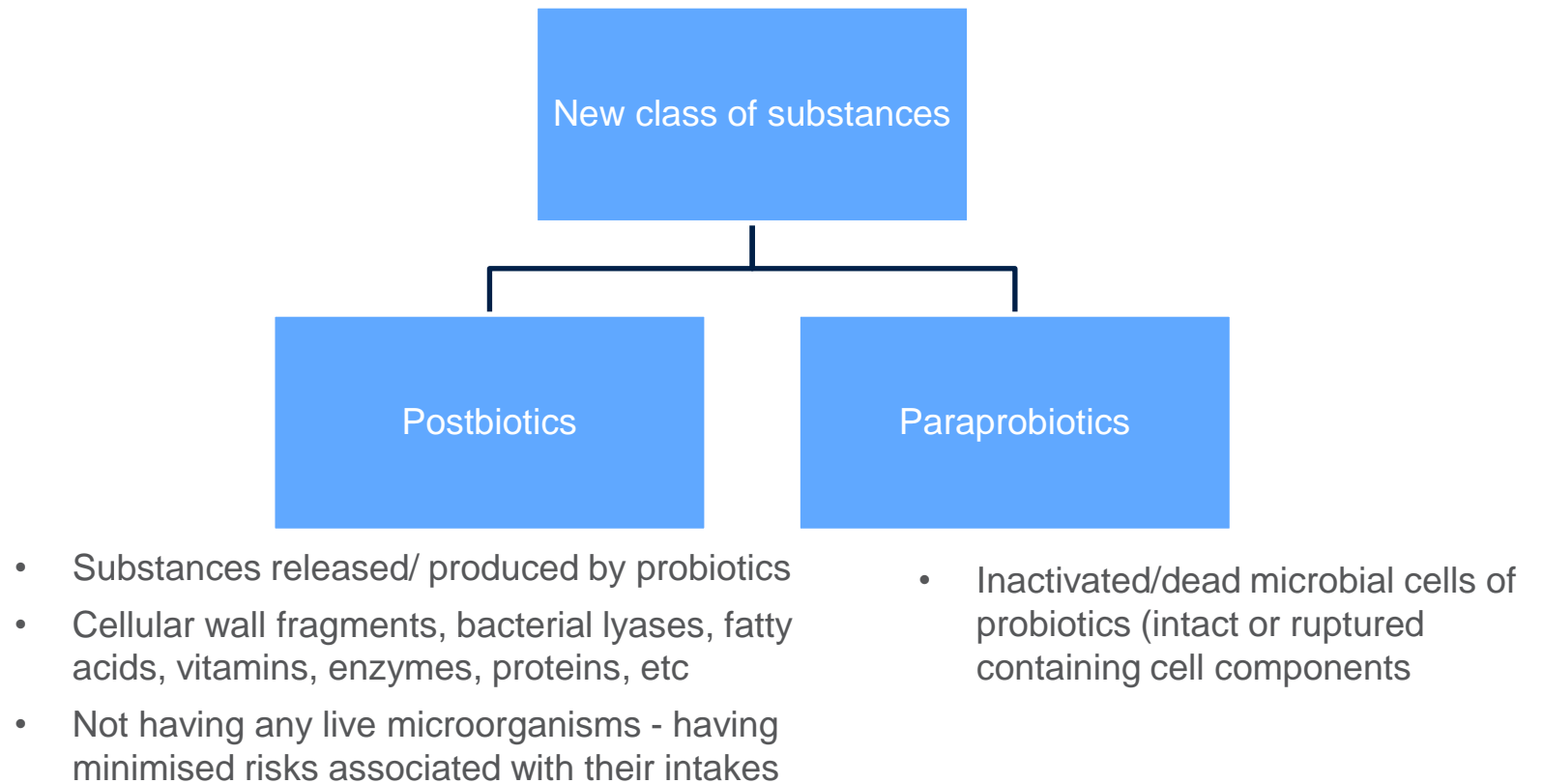
DHA (Omega-3)  
(fish & algal)

Lion's Mane  
Mushroom



## Postbiotics for gut health

Touted as a new class of substances joining probiotics and prebiotics, postbiotics and paraprobiotics will influence the gut microbiome



# Science & Technology

## Functional ingredients for skin health



## Skin microbiome for skin cosmetics

Just like the gut has a complex microbiome, the skin has its own unique microbiological ecosystem

Although studies on the skin microbiome are still in their early days, it is becoming clear that the skin microbiome indeed plays a key role in keeping skin in good condition.

The current approach is to either:

- Formulate microbiome-friendly products (i.e. products that do not sanitise the skin in excess)  
or
- Products that help balance the microbiome (prebiotics)

Emerging approaches like adding actual microbes to the products are also being explored (probiotics).

Examples of potential ingredients:

1. Carbohydrate complexes to influence the equilibrium of microbial species like *Malassezia furfur* and *Staphylococcus epidermidis* on the scalp, improving hydration and skin barrier function, which decreases flaking skin
2. Inulin, which promotes bacterial growth, may also be used to improve skin condition
3. *Lactobacillus* species are added to formulations to help rebalance the skin microbiome

# Science & Technology

## Functional ingredients for stress health



## Adaptogens for stress health

A class of herbs that help the human body adapt to stress, support normal metabolic process and restore balance

### Mechanisms of actions are still unknown

- When faced with a stressful situation - either emotionally or physically - a complex hormonal cascade occurs within a human body, resulting in the production of hormones, such as cortisol and adrenalin.
- In addition to these hormones, exposure to stress also lead to the immune system sending out inflammatory cytokines.

Tulsi (Holy Basil)

Eluthero root

Schisandra

*Rhodiola rosea*

Artic root

Maca

# Science & Technology

Embracing emerging technologies

## Emerging technologies for extracting bioactives with potential health benefits

### Extraction technologies for bioactive compounds



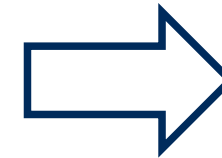
- Ultrasound-assisted extraction (UAE)
- Creates cavitation of small bubbles in the solvent due to the passage of ultrasound waves allowing for a greater penetration of the solvent within the material increasing the surface area

# Science & Technology

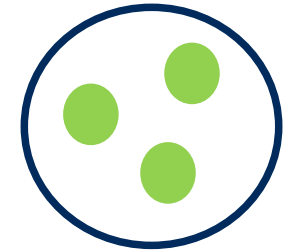
## Embracing emerging technologies

### Emerging technologies for the delivery of increased health benefits

#### Nanotechnologies for protection and accessibility



Nanocapsules



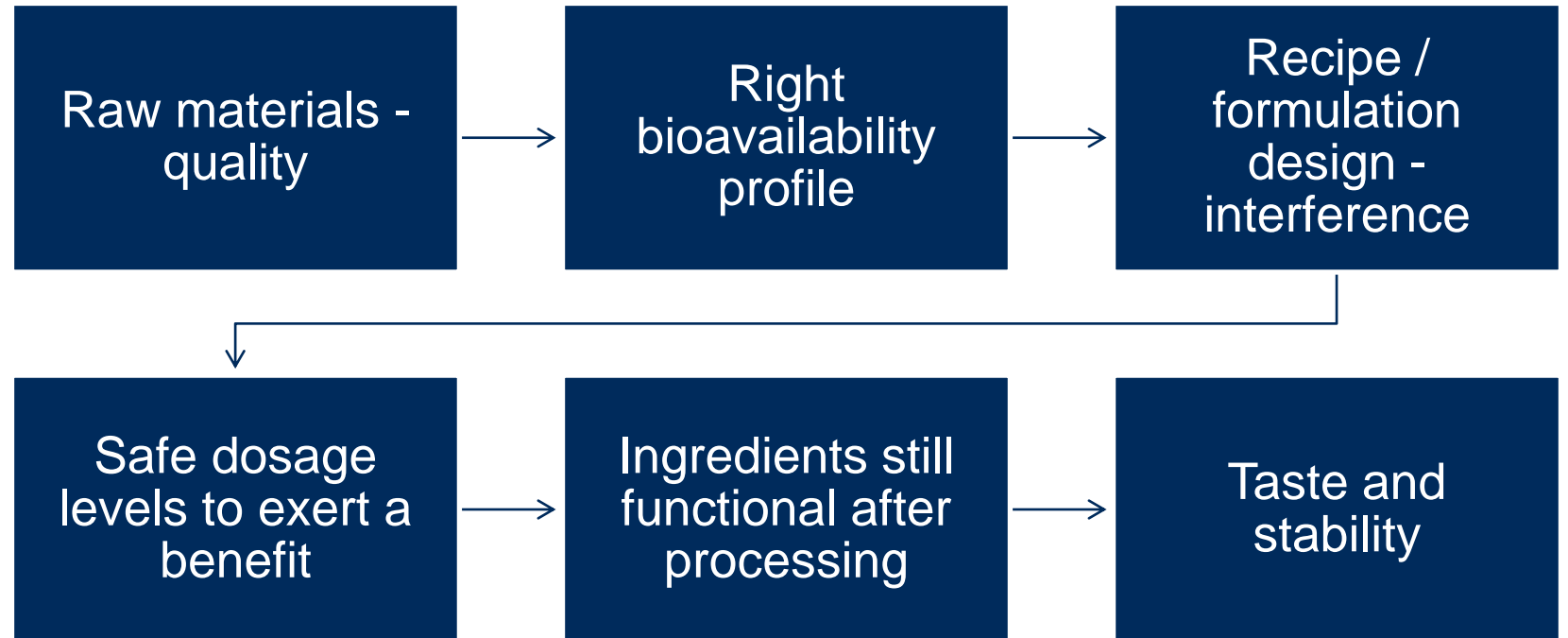
Nanospheres

- [1] The combination of the unique elements of size, surface activity and charge of nanostructures allow for exploitation of nanotechnologies to deliver bioactive compounds
- [2] The use of nanocapsules or nanospheres will allow for targeted delivery at targeted sites
- [3] Problematic issues associated with solubility of the bioactive compounds could be resolved with nanotechnologies
- [4] Nanotechnologies offer protection; for example, the stability of bioactive compounds could be protected from the acidic environment of the stomach

# Science & Technology

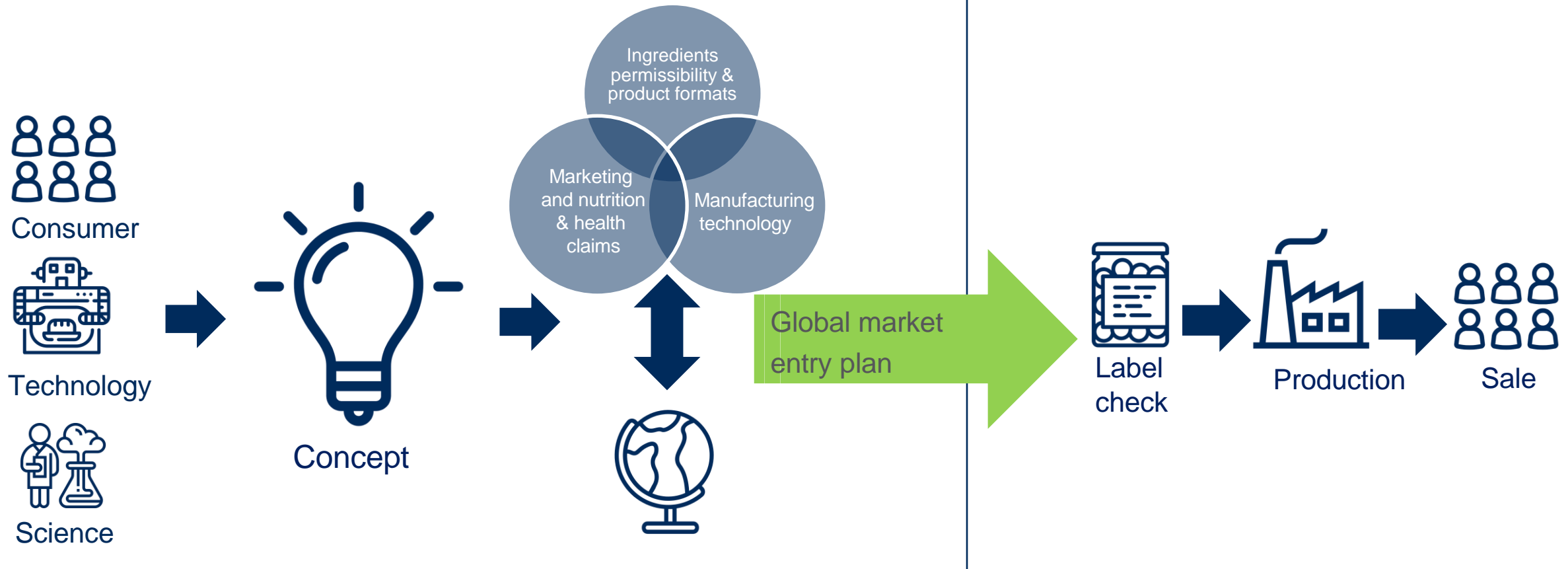
## Clever product development

Product development considerations are important  
brand reputation for delivery of said health benefits is the key



# Regulatory Considerations

A regulatory lens at point of inception will de-risk the investments in the innovation and marketing processes.



# Regulatory considerations

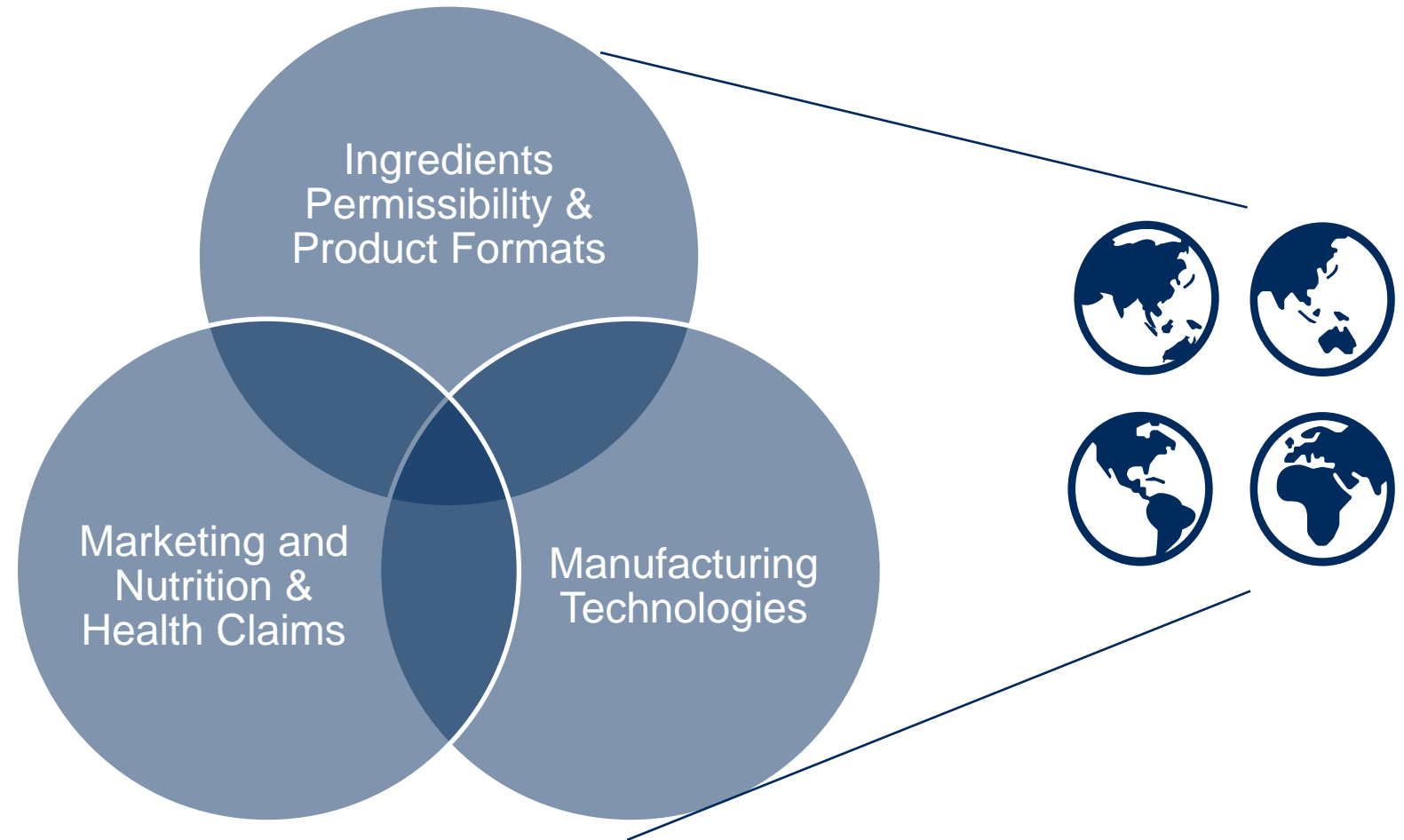
A complex quagmire



## Regulatory considerations

The three things to consider at point of inception

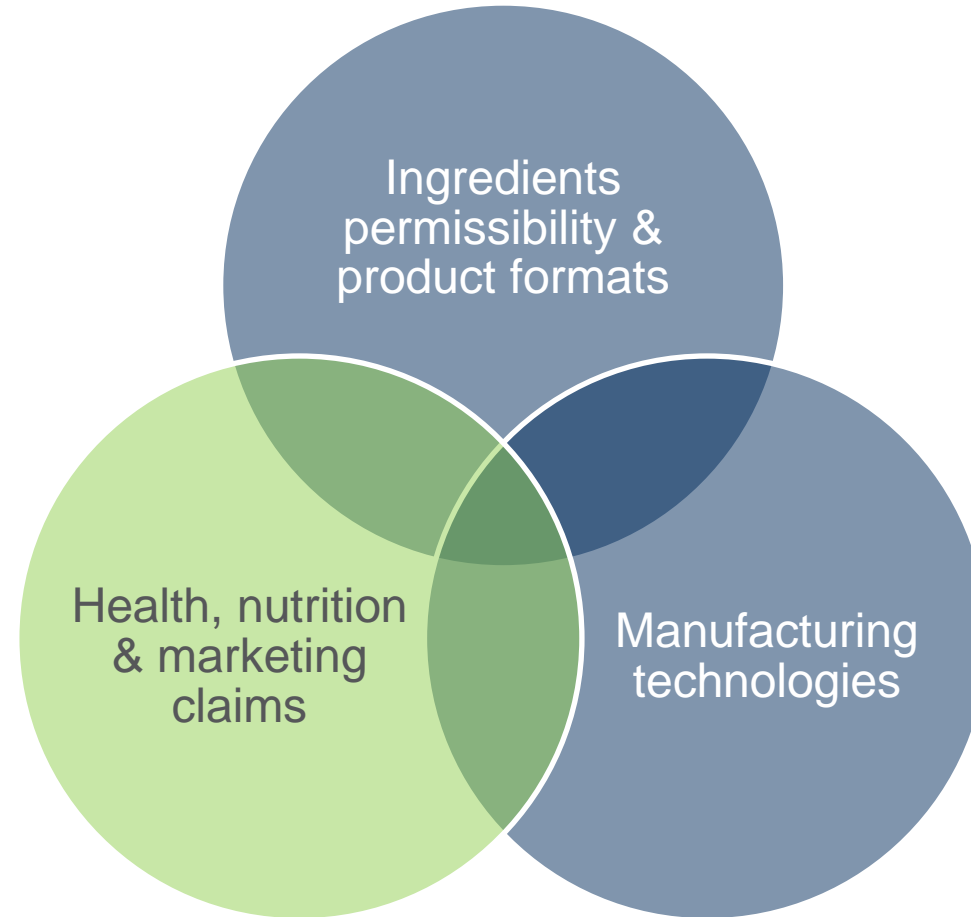
But regulations have never been more important than ever now with the emerging ingredients & technologies



## Regulatory considerations

Whilst all are important, the scope for nutrition, health & marketing claims will be discussed here

Health, nutrition & marketing claims are powerful communication tools – it is critically important that at point of inception the formulations do support the claims.



# Are we becoming medicinal?

There is a blurring boundaries between food and pharma – bioactives can be used in food supplements and food/beverage applications, but whether it becomes medicinal or not is defined by the dosage and form.



Support / Reduce the risk of /  
Maintain / Contribute / Play a role in  
the normal function of the human  
body



Treat / Cure / Prevent an  
illness/disease  
Enhance/ Stimulate/ Optimise the  
normal function of the human body



## Case study: *Gingko biloba*

Markets	Medicine or Food Supplement / Food / Beverage	Conditions
Belgium	Food supplement	Flavonol glycosides ingested cannot be greater than 21.6 mg and the amount ingested terpene lactones greater than 5.4 mg. <u>Warning:</u> "Consult your doctor if taking anticoagulants"
Czech Republic	Allowed in food supplements	<ul style="list-style-type: none"> <li>Dried leaf: up to 2500 mg in daily intake</li> <li>Standardised extract 24/6 from leaves: up to 40 mg in daily intake</li> </ul>
Finland	Medicinal	
France	Medicinal	
Germany	Could be medicinal	
Ireland	Medicinal	
Italy	Food supplement	<u>Warning:</u> Possible interaction with anticoagulants and antiplatelet drugs – consult doctor and not recommended during pregnancy and breastfeeding
Poland	Could be medicinal	
Romania	Food supplement	
Slovenia	Medicinal	
Sweden	Medicinal	
UK	Food supplement	



Cognitive function  
Blood pressure  
Cardiovascular diseases & stroke

Bleeding & clotting  
Lower blood sugar  
Headache, vomiting, diarrhoea

# Regulatory considerations

When designing a concept, the first question we should ask...

## Food & beverage or supplement?

Categorisation of product at the **point of inception** is crucial as the regulations for food/beverage products and for food supplements products can differ, depending on the markets.

Same Regulations



Separate Regulations



## Regulatory considerations

The second question to ask is the type of claims to make

Claims are powerful marketing tool that are legal and regulated to protect the consumers



Nutrition Claims

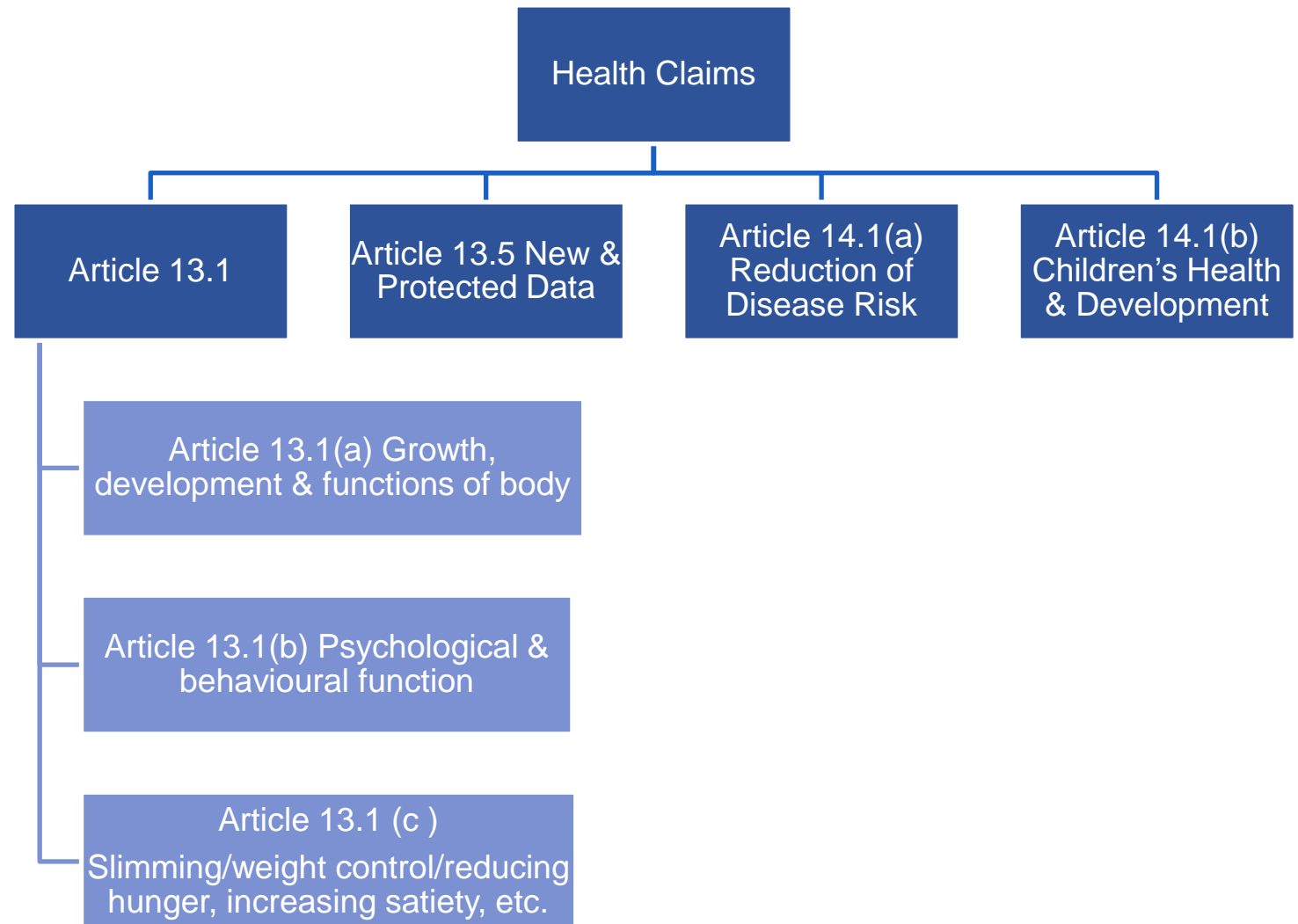
Health Claims

Marketing Claims

## Regulatory considerations: EU



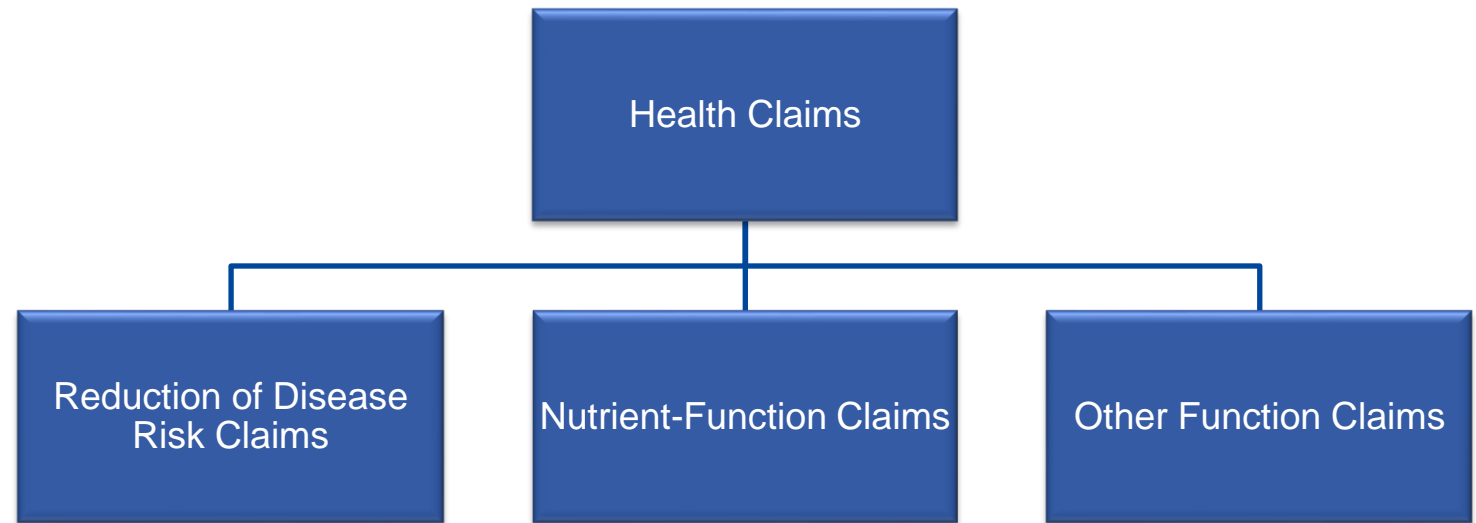
## Health claims – a powerful marketing tool



## Regulatory considerations: India



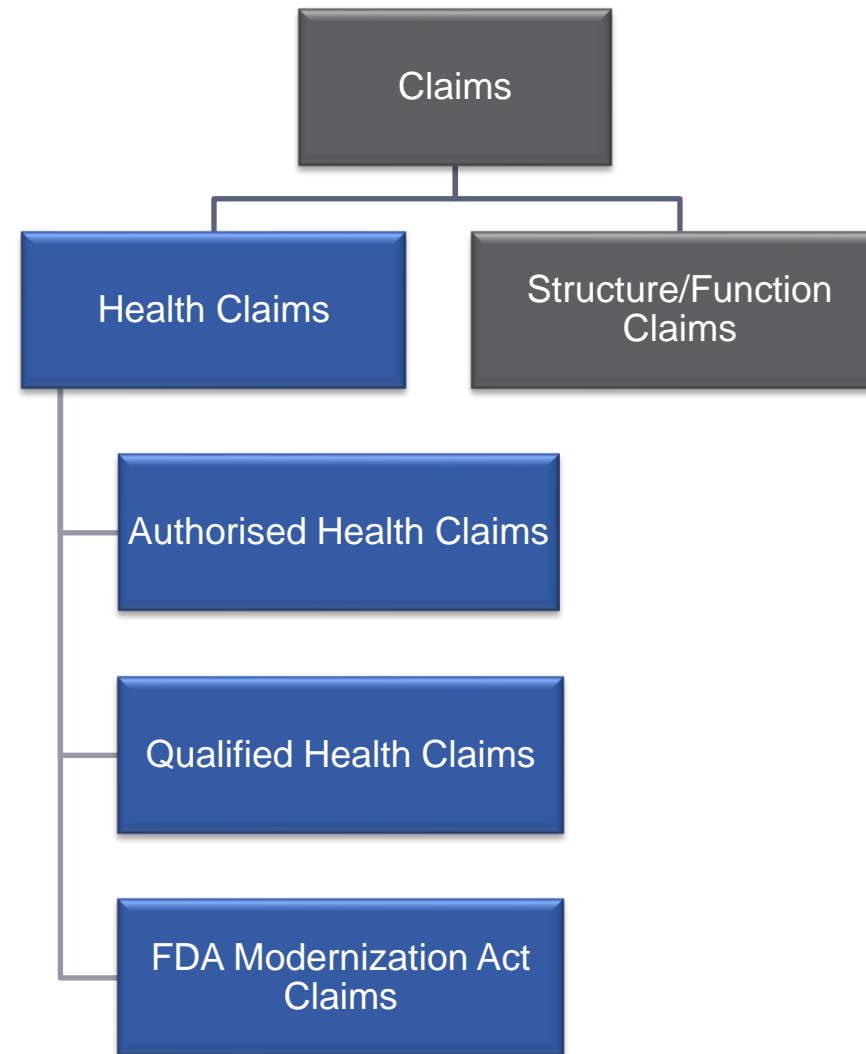
## Health claims – a powerful marketing tool



## Regulatory considerations: USA



## Health claims – a powerful marketing tool



## Regulatory considerations: China







## Health claims – a powerful marketing tool

In China, Health claims can only be used for health foods, including food supplements, and cannot be used for normal food products.

# Regulatory considerations: EU



## The use of claims in the EU is well-regulated

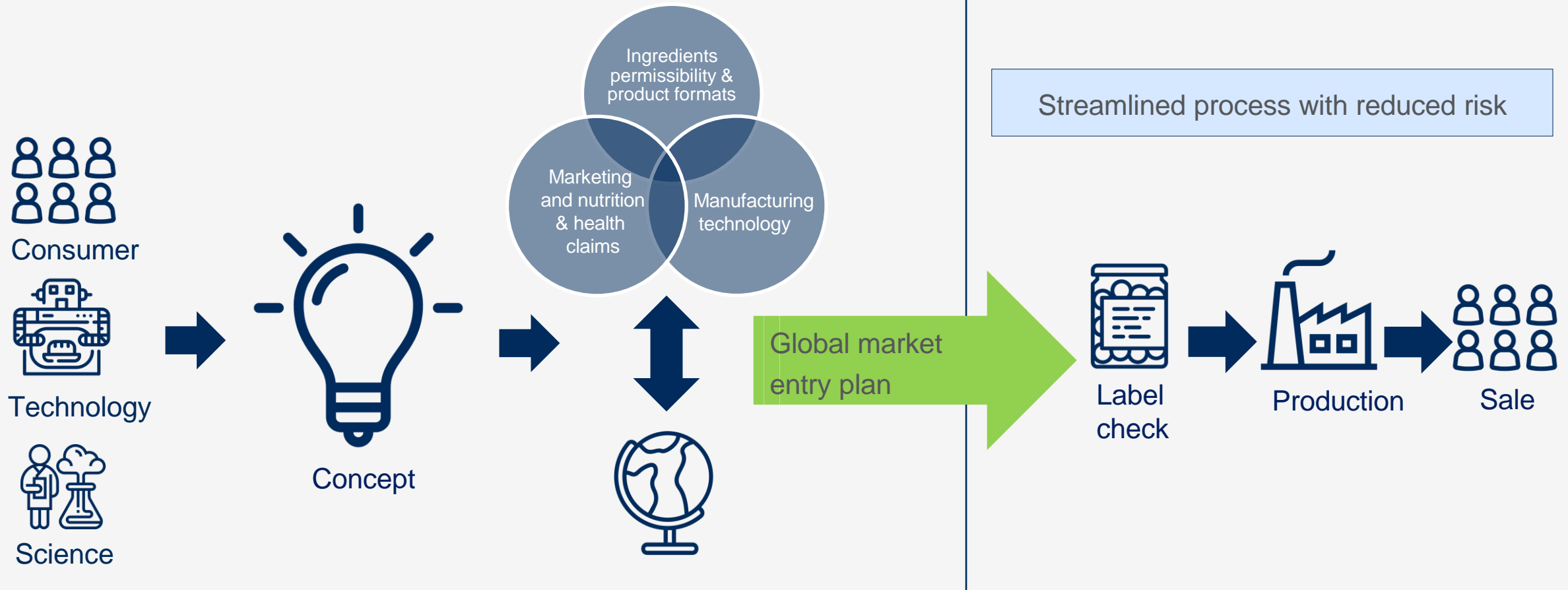
	Cognitive 	Gut 	Skin 	Stress 
Nutrition Claims	Source of / High in....			
	Omega-3-fatty acids	Prebiotics / fibres	Iodine	Chamomile
Health Claims	DHA contributes to maintenance of normal brain function	No “probiotic” claims permitted in EU, but in Switzerland	Iodine contributes to the maintenance of normal skin	Contributes to optimal relaxation
Marketing Claims	“Good for the brain”	“Good for the stomach”	“Good for your skin”	“Good for your stress levels”

A collection of clear plastic bowls filled with various nuts and seeds, including almonds, cashews, and sunflower seeds, arranged on a surface. The focus is sharp on the bowls in the foreground, while the background is blurred.

In summary

# Key consideration for concept development at point of inception

A regulatory lens at point of inception will de-risk the investments in the innovation and marketing processes.



## Key take away points

- ✓ Continuation of innovation in natural and functional ingredients
- ✓ Regulatory lens at the point of inception
- ✓ Permissibility and safety/manufacturing process of functional ingredients
- ✓ Substantiation of nutrition, health & marketing claims



# Questions

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