



# Botanical Ingredients in the European Union, USA and China

Annie-Laure Robin, Senior Regulatory Consultant (Food & Beverage)

# Case Study: *Adansonia digitata* (Baobab) dried fruit pulp

## Origin

South Africa, Botswana, Namibia, Mozambique and Zimbabwe, India, Sri Lanka, Malaysia, China and Jamaica.

## Traditional uses

- Extensive history of consumption amongst indigenous Africans, also in Australia
- Consumed as such, in drinks or used as an ingredient in other foods



## Ingredient approval process



## Food & Beverage Applications

- Smoothies
- Cereal bars
- Health food product
- Biscuits
- Confectionary

# Botanical ingredients in the EU, USA and China

- 1 Why the demand for botanical ingredients?
- 2 What factors should we be considering when using botanicals in food and beverage applications?
- 3 Where do we go from here?





## Why the demand for botanical ingredients?



# Why the demand for botanical ingredients?

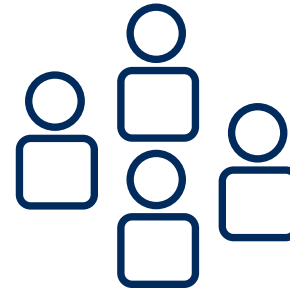
There is currently a global trend showing a significant increase in consumer demand for use of **plant-based** botanicals in food and beverage applications

## Plant-based

- From plants, herbs, spices and their oils/extracts
- Roots, bark, leaves, seeds, fruits or flowers

## Powerful marketing tools

- 'Derived from nature'
- Health benefits
- Clean label
- Vegan



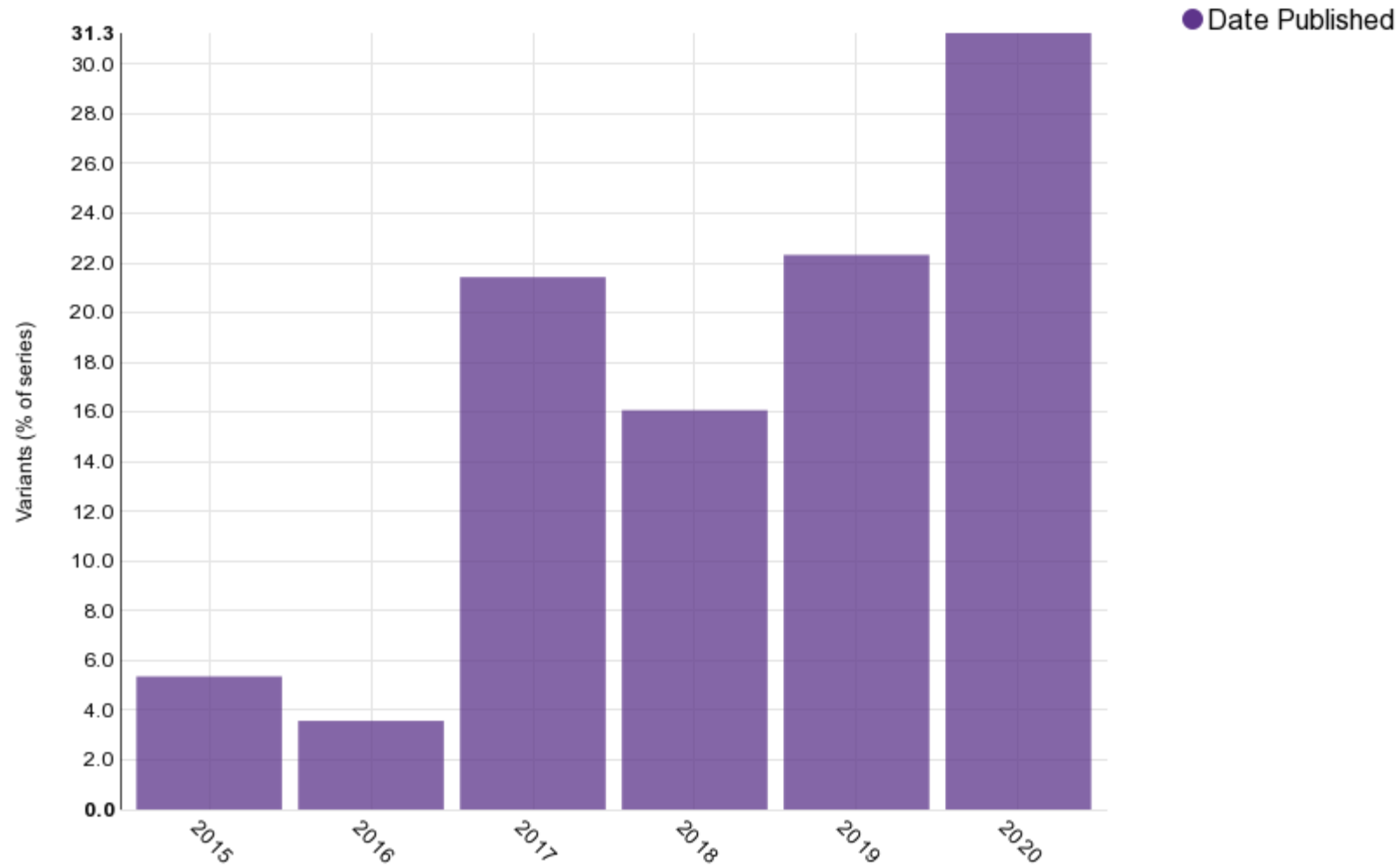
Consumers



A hot topic these days....

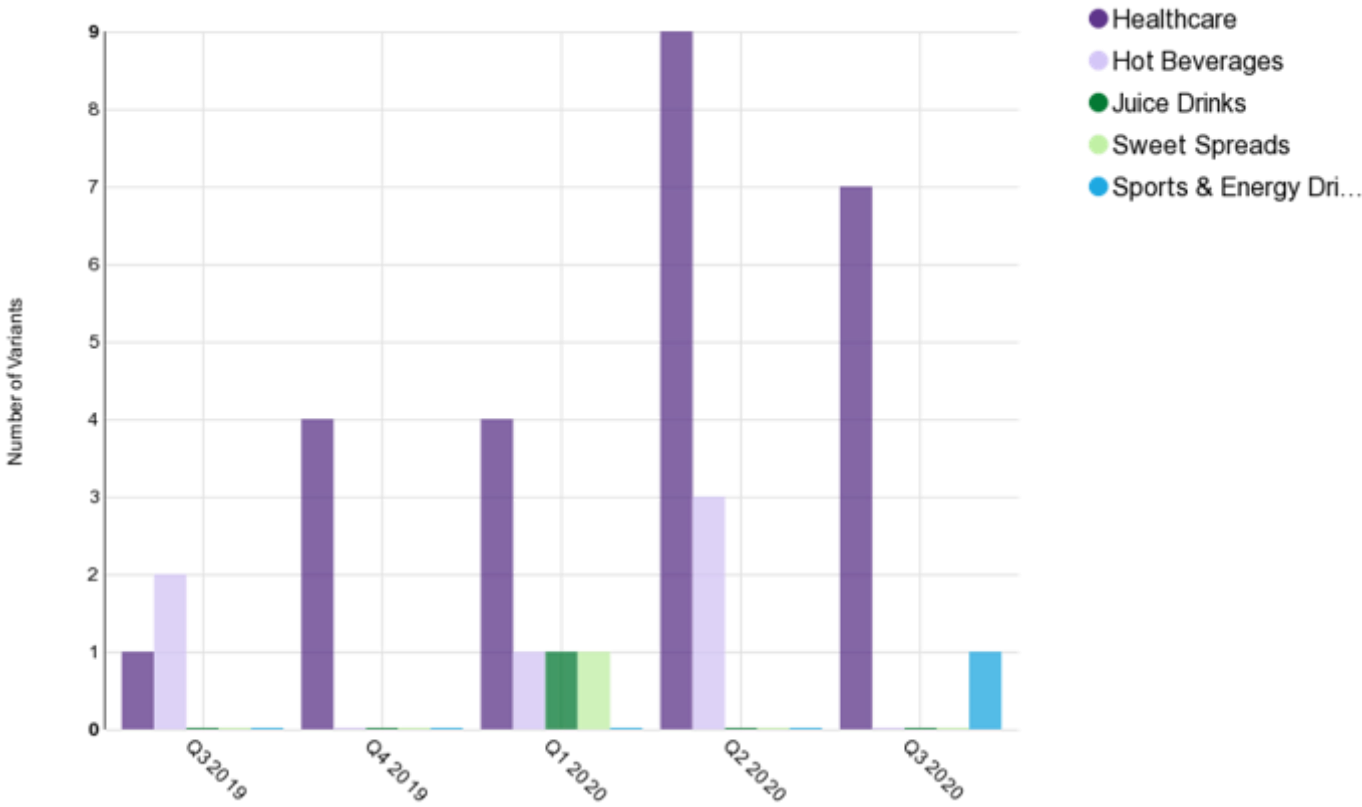
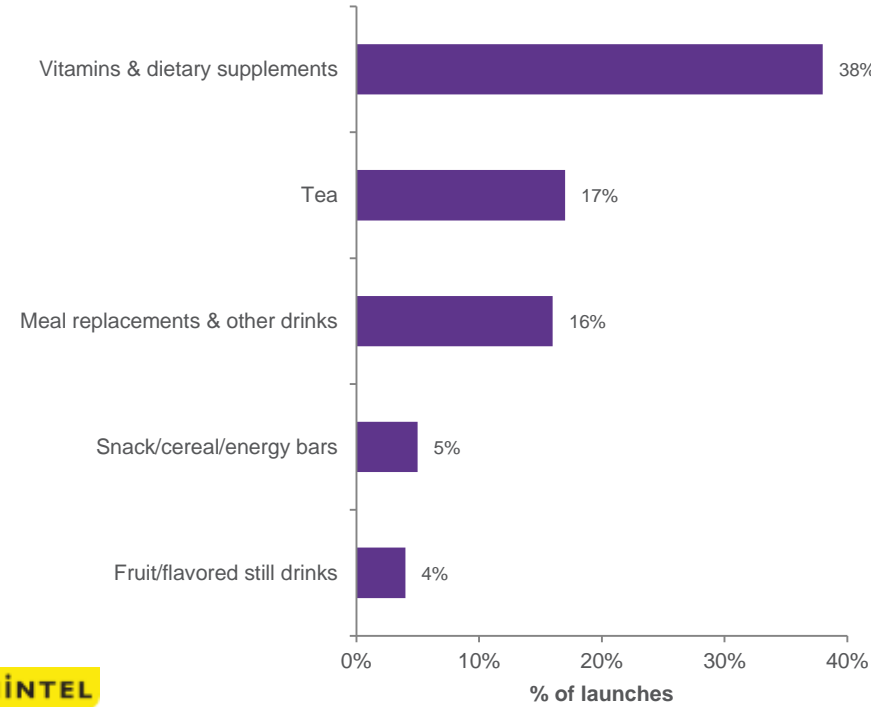


# A growing market for plant-based botanicals globally



# Ashwangandha: an exotic botanical for stress, sleep and energy support

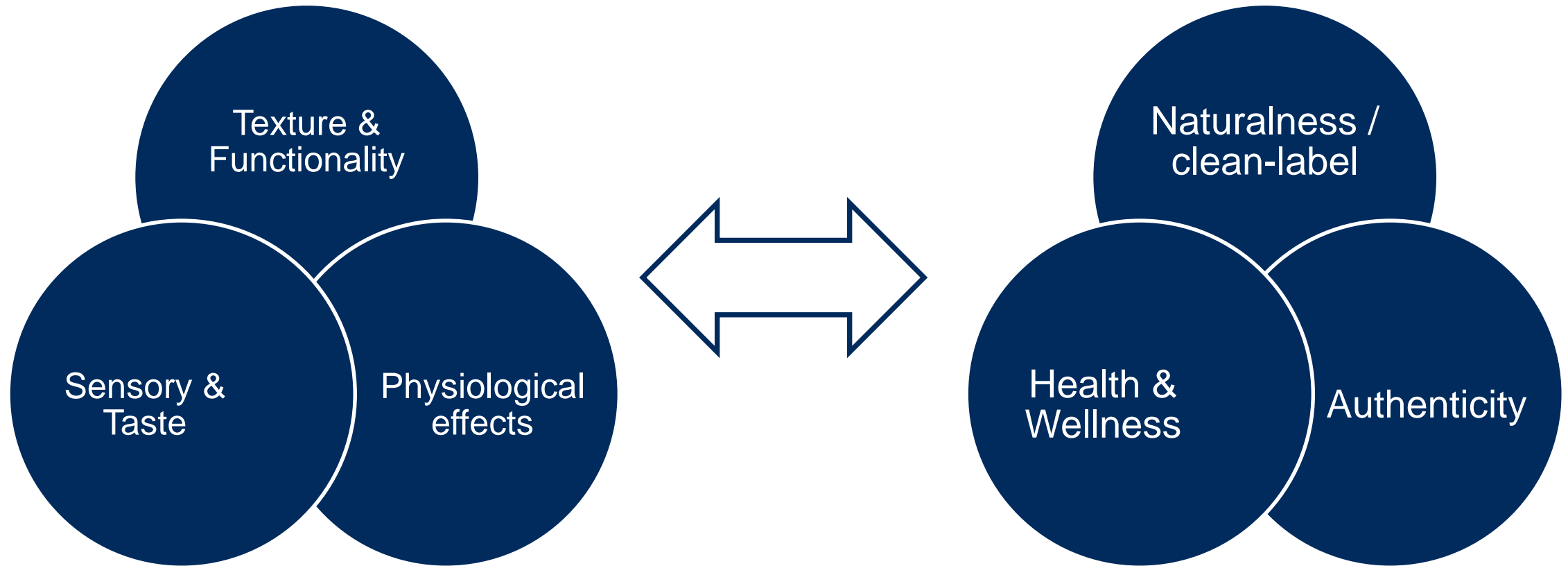
Global: share of ashwagandha-containing food/drink/VMS launches, by sub-category, Apr 2015-Mar 2020



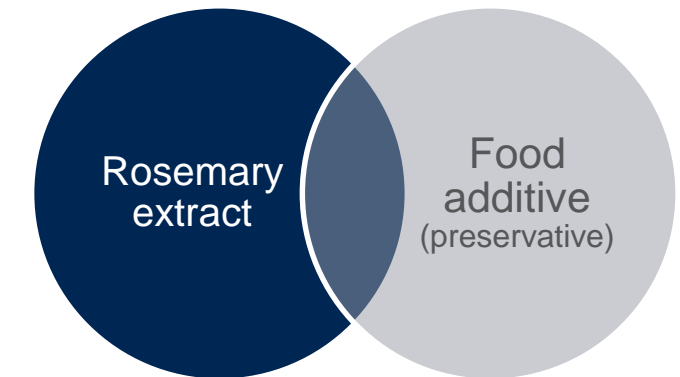
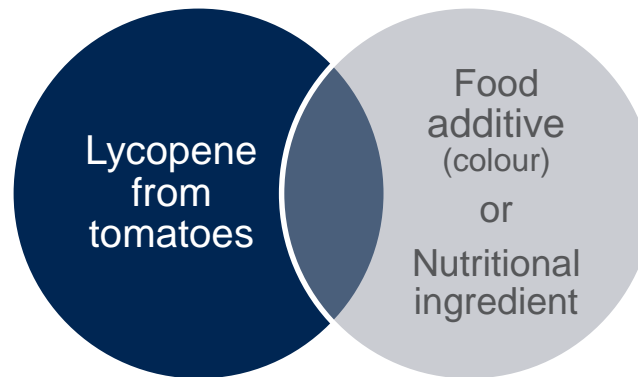
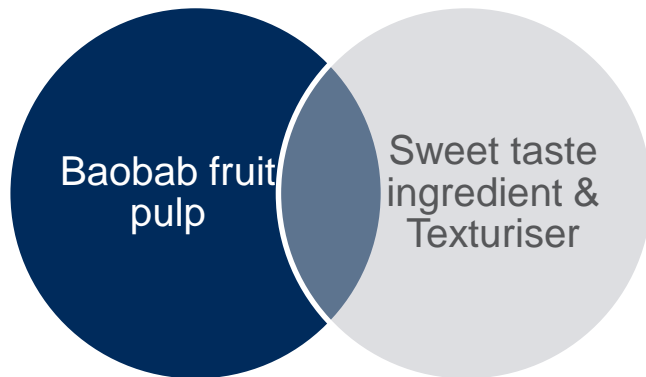
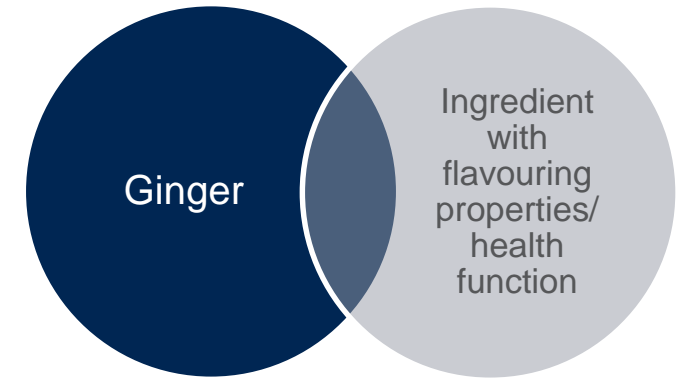
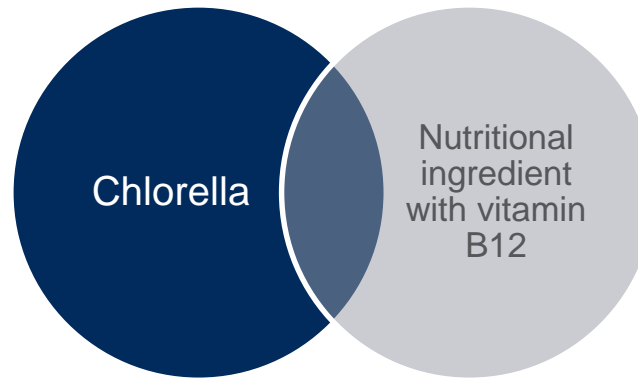
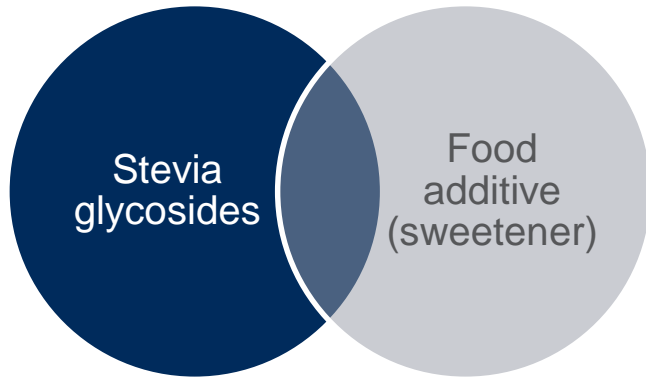
**Mintel**  
Read on [mintel.com](https://www.mintel.com)




## The benefit-function synergy provided by botanicals



## Multi-functional botanicals, sourced from plants...

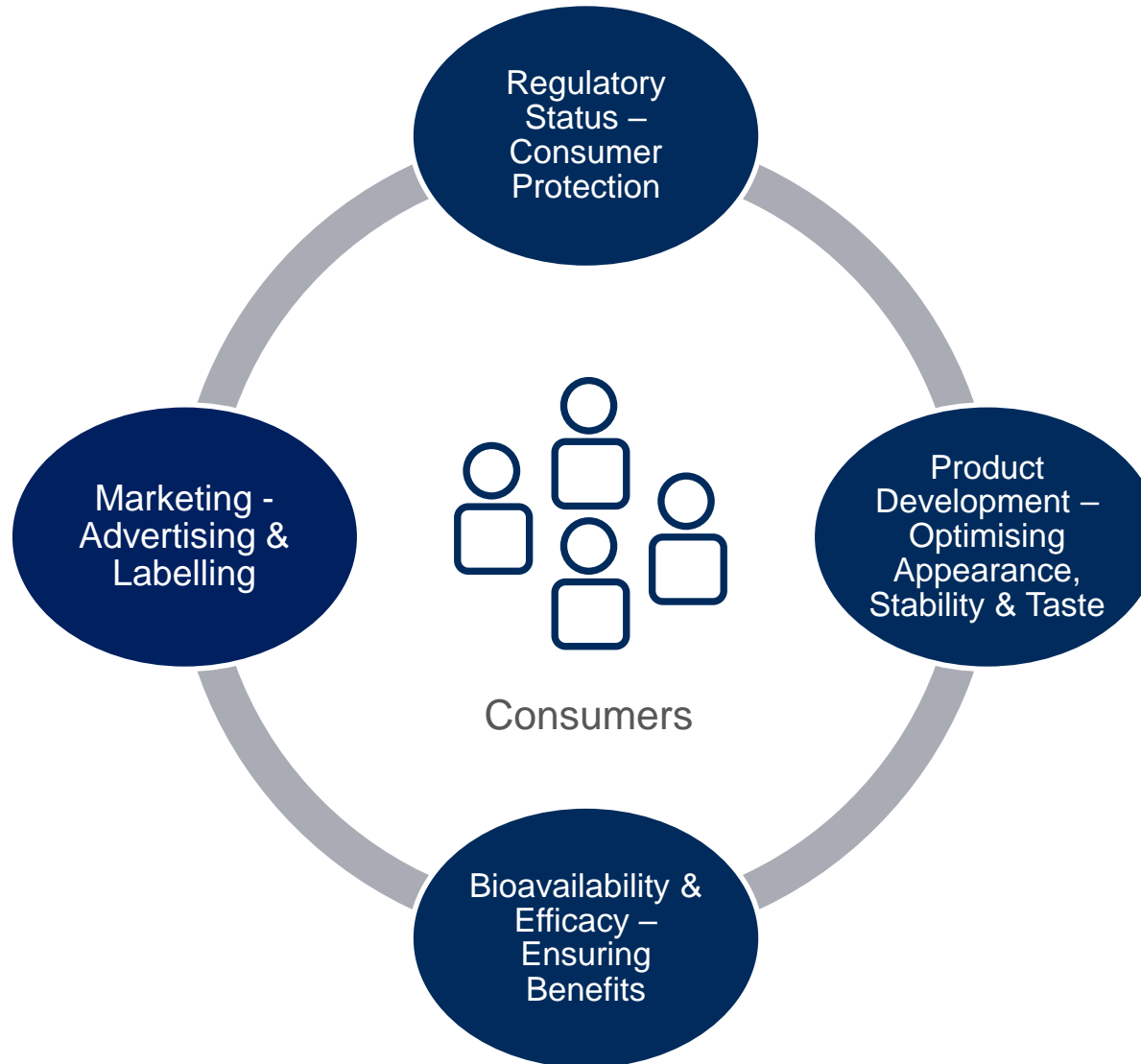


The background image shows three tall, clear glasses filled with a pinkish-red liquid, likely strawberry-infused water. Each glass is filled with ice cubes and has a red and white striped straw. The glasses are placed on a light-colored wooden surface. Several fresh strawberries are scattered around the glasses, some on the wooden surface and others on a small wooden board. The lighting is bright and natural, creating a fresh and appealing look.

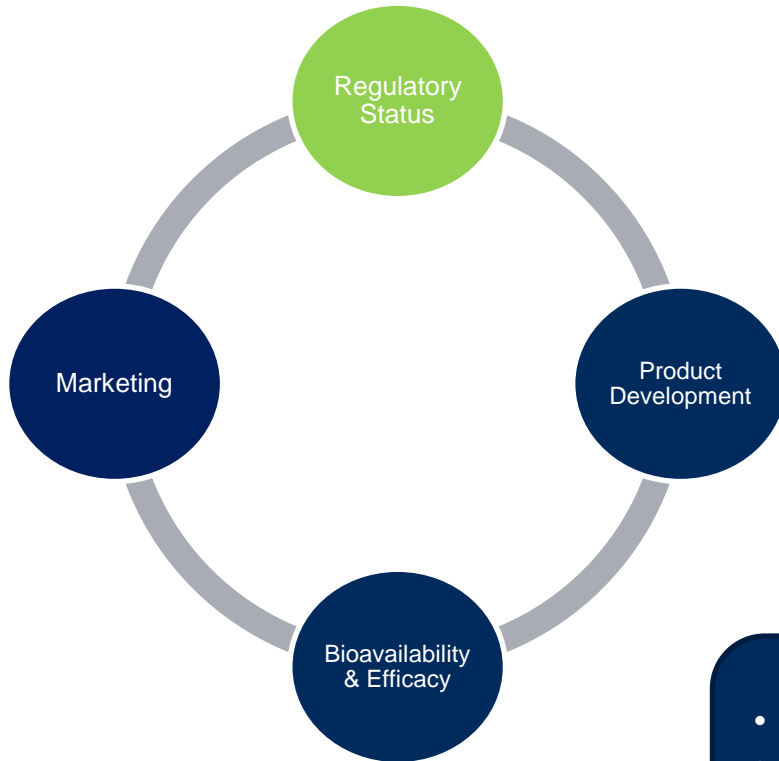
## Factors to consider when using botanicals in food and beverage applications



# Factors to consider when making a product with botanicals



# Using botanicals in food and beverages in different markets



## USA

- Flavourings
- Food additives
- GRAS substances
- Dietary ingredients
- Botanical drugs

## European Union

- Food additives (e.g. colours, preservatives)
- Flavourings
- Nutrients (e.g. food supplements or novel foods) or
- Medicine (e.g. traditional herbal medicine or medicine)

## China

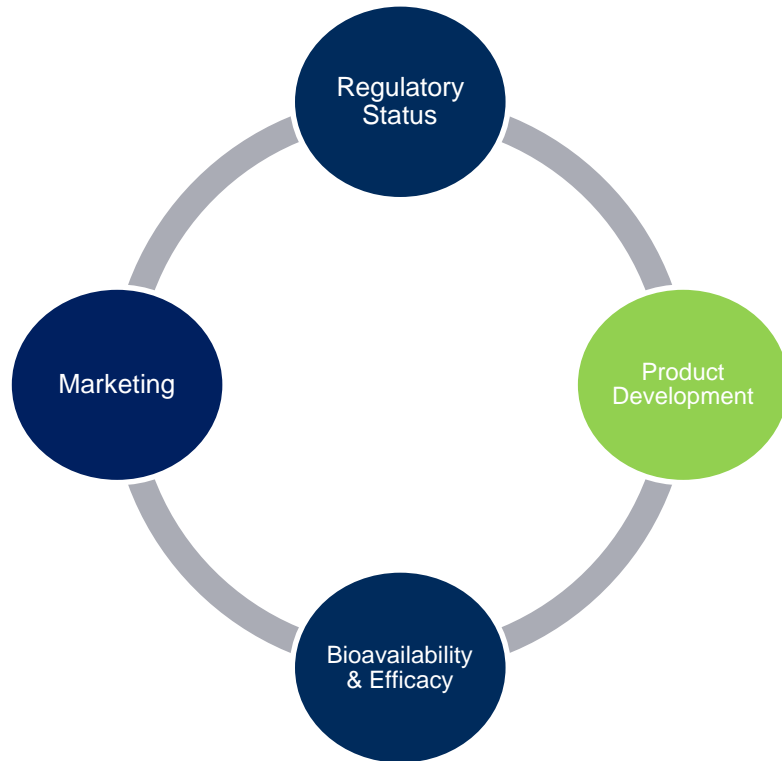
- Food additives (inc. flavourings)
- Novel foods and ingredients with medicinal properties
- Ingredients for Health foods (inc. food supplements)
- Functional food

## Case study: classification of some botanicals in the EU, USA and China differs

Botanical	EU	USA	China
Aloe vera	<ul style="list-style-type: none"> <li>• Flavouring</li> <li>• Food ingredient</li> <li>• Food supplement</li> <li>• Medicinal</li> <li>• Cosmetic</li> </ul>	<ul style="list-style-type: none"> <li>• No evidence of food use (no GRAS opinion)</li> <li>• Cosmetic Use.</li> </ul>	<ul style="list-style-type: none"> <li>• Flavouring (if extracts)</li> <li>• Novel food ingredient (Aloe Vera Gel only)</li> <li>• Food supplement (Aloe Vera Gel only)</li> <li>• Medicinal</li> </ul>
Curcumin (Turmeric)	<ul style="list-style-type: none"> <li>• Flavouring</li> <li>• Food ingredient</li> <li>• Food Supplement</li> </ul>	<ul style="list-style-type: none"> <li>• Color or coloring adjunct</li> <li>• flavoring agent or adjuvant</li> <li>• Food Supplement</li> </ul>	<ul style="list-style-type: none"> <li>• Flavouring (if extract)</li> <li>• Food additive (if extract)</li> <li>• Food ingredient (turmeric)</li> <li>• Food Supplement (turmeric)</li> </ul>
Lycopene from tomato	<ul style="list-style-type: none"> <li>• Food additive (colour) – E 160d</li> <li>• Novel foods in food and food supplements</li> </ul>	<ul style="list-style-type: none"> <li>• Flavouring</li> <li>• Adjuvant</li> <li>• Colouring FEMA GRAS</li> </ul>	<ul style="list-style-type: none"> <li>• Food additive (colour) – INS 160d(i)</li> </ul>
Noni fruit juice	<ul style="list-style-type: none"> <li>• Approved novel foods for food and food supplements</li> </ul>	<ul style="list-style-type: none"> <li>• Dietary supplement</li> </ul>	<ul style="list-style-type: none"> <li>• Approved novel food for food and food supplements</li> </ul>



Ensuring the quality and stability of botanicals, when exposed to processing, packaging and storage conditions is a must to ensure brand reputation



Quality and safety of  
raw materials

Processing  
Technologies for  
Product Manufacture

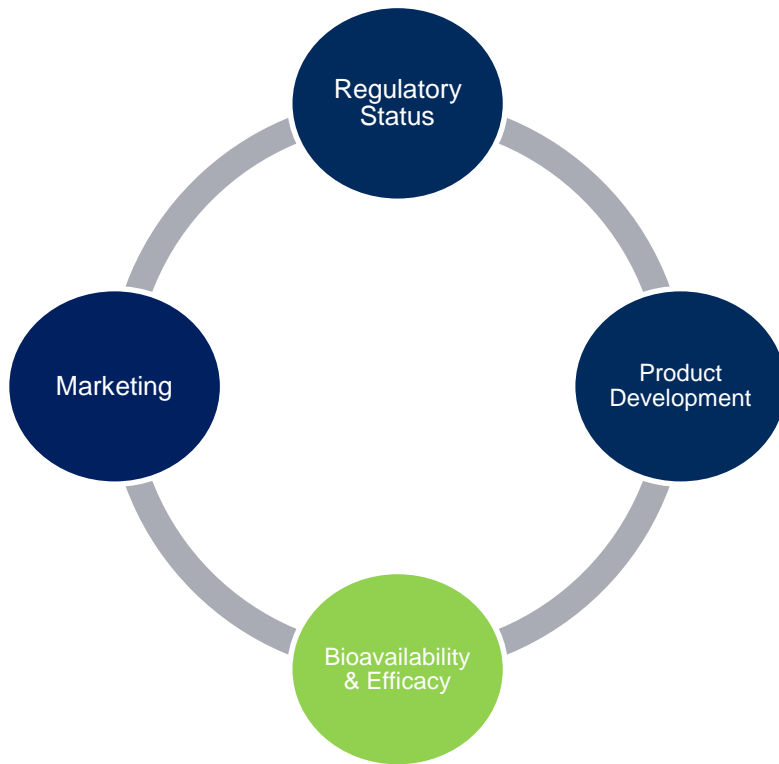
Interactions with Other  
Ingredients

Packaging & Storage  
Conditions

Microbiological  
Stability

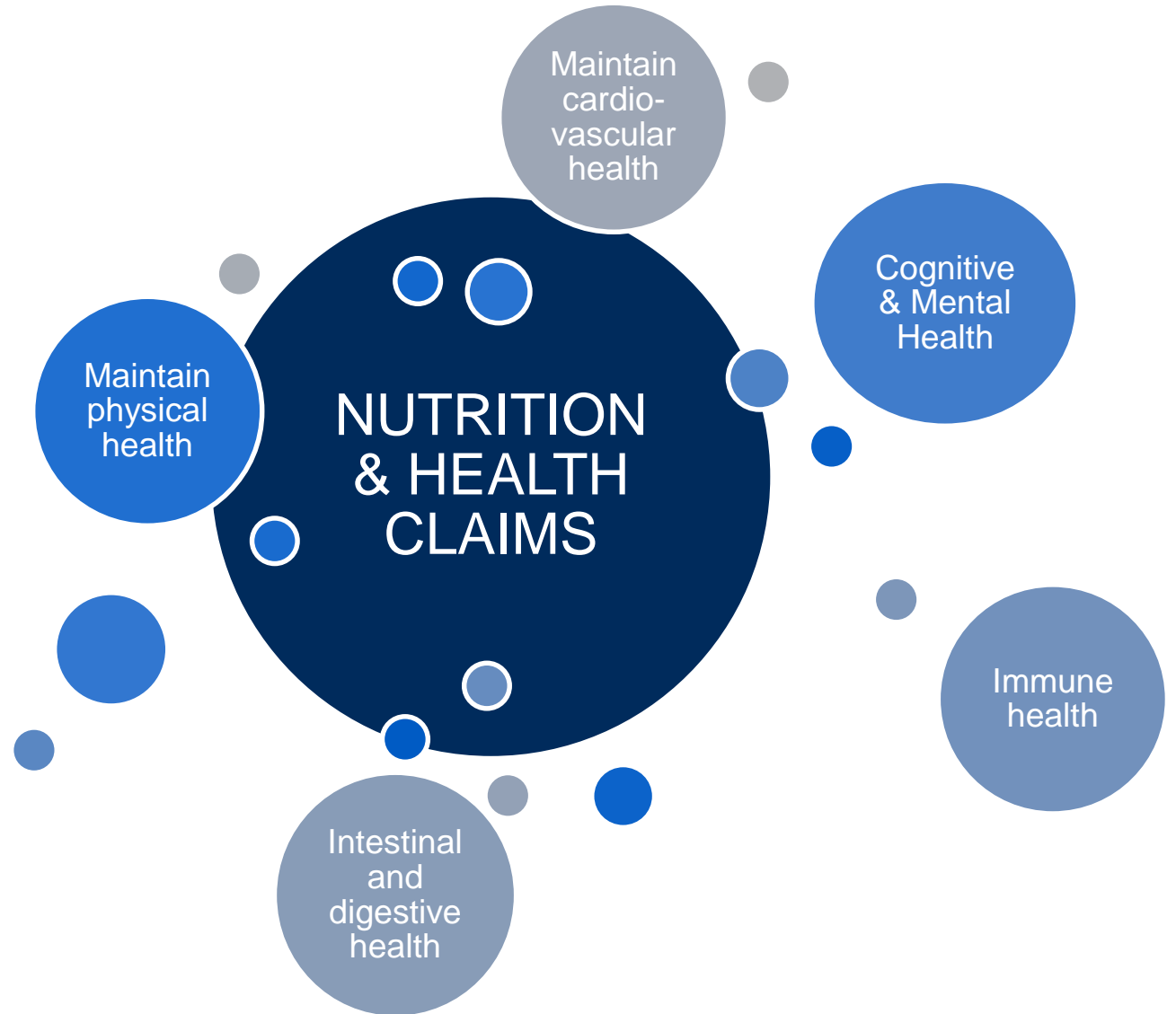
Determine botanical  
overage

# Validating the bioavailability and efficacy profiles of botanicals in product applications



- Characterisation of botanicals (plant part(s), Latin name);
- Human study data showing health effect(s) and any conditions of use (dosage) authorities or knowledgeable organisations
- Supporting data from specific intervention and observational studies (animal, in vitro cell and molecular, genotype, modelling);
- Avoid ‘non-authorized’ claim;
- Careful with claim wording

# Substantiating your labels - claims on packaging





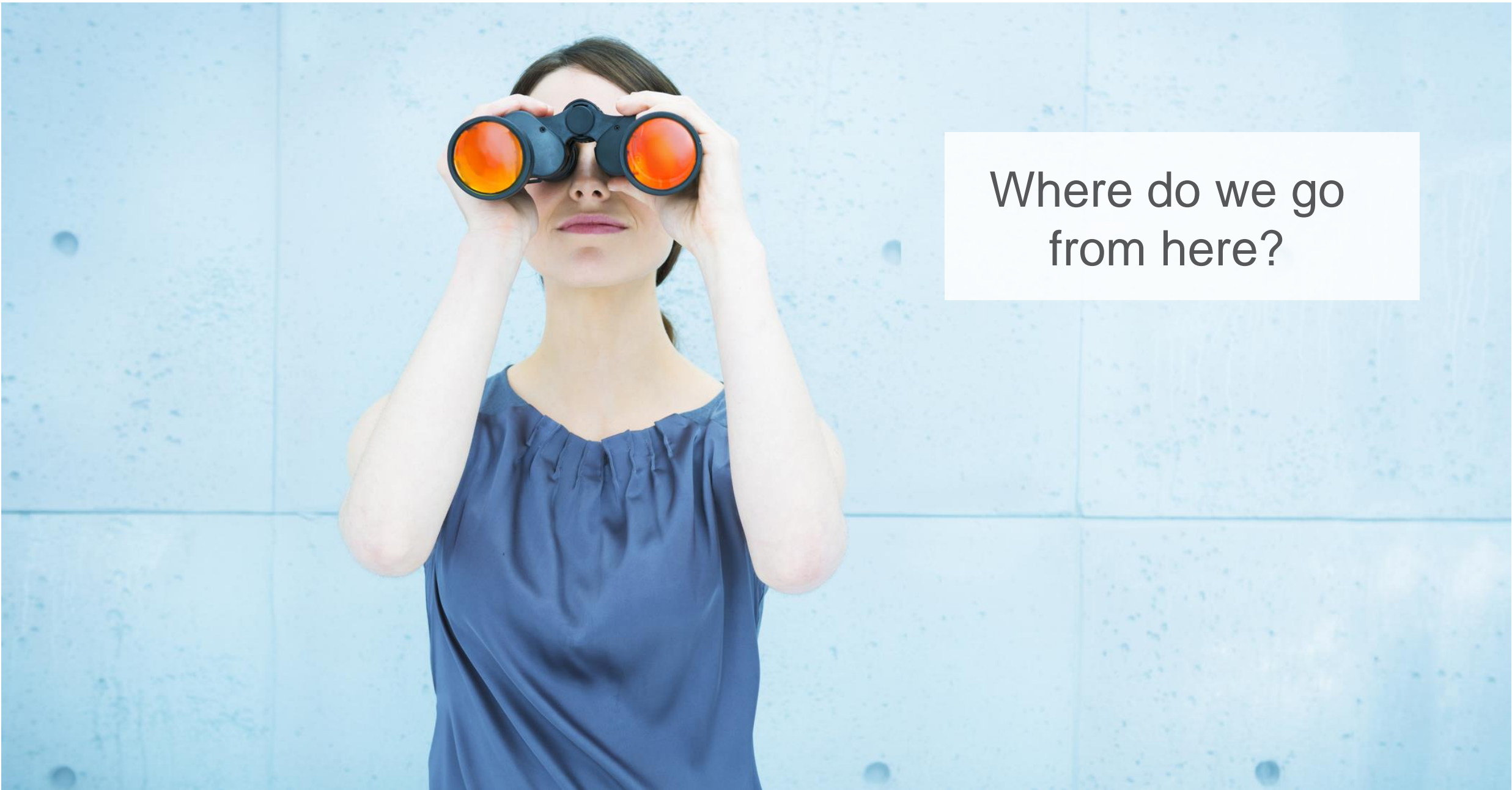
.....but claims are regulated differently in the EU, USA and China

Markets	Nutrition claims e.g. 'High in Vitamin C'	Health claims e.g. 'Maintain blood cholesterol'	Medicinal claims e.g. 'Prevent joint inflammation'
EU	Positive list	On hold for botanicals	Not allowed to be used
China	Positive list	Health Food functionality claims*	

Markets	Structure/Function Claims	Medicinal claims e.g. 'Prevent joint inflammation'
USA	<u>For conventional foods</u> : effects from nutritive value only;	Not allowed to be used
	<u>For dietary supplement</u> : effects from non-nutritive as well as nutritive values [notification]	
	Health claims = <i>Nutrition Labeling and Education Act of 1990 (NLEA) Claims, Health claims based on Authoritative Statements and Qualified Health claims</i>	

# The European Union has currently put the majority of health claims for botanicals “on hold”

	Health relationship proposed by (if any)		
Botanical substances			
Aloe vera (Aloe barbadensis)	helps to increase immunity	Not established in the food legislation	None
Curcuma domestica - common name: Curcuma, curcumin, konyak, turmeric, Indian saffron	/ "Used to facilitate the digestion" / "Helps to support normal liver function" / "Contributes to the stimulation of the production of the digestive body fluids" / "Supports the liver and biliary function" / "Contributes to the digestive comfort" / "Helps to facilitate fat digestion" / "Contributes to better fat digestion" / "Helps to support the digestion" / "Contributes to support the digestion"	Not established in the food legislation	Manufacturer needs to have substantiation of structure function claims if made on food supplements.
Lycopene from tomato	no health claim dossier submitted	Not established in the food legislation	Qualified claims regarding lycopene and cancer denied by the FDA
Morinda citrifolia-Fructus-Noni	Stimulates immunity / Antitumoral effects	Not established in the food legislation	3 FDA warning letters issued regarding Morinda citrifolia-Fructus
Caffeine	Caffeine contributes to an increase in endurance capacity Caffeine helps to increase alertness Caffeine helps to improve concentration	Not established in the food legislation	Warnings issued about pure and highly concentrated caffeine supplements



Where do we go  
from here?



# Entering markets with botanicals



- Definitions in different markets
- No harmonised rules
- Brand reputation

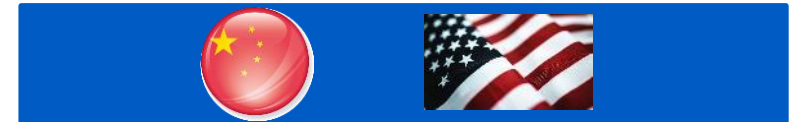


- Regulatory status
- Focused product development
- Long-term strategies to make products with claims
- Routes available for success

## Current regulatory situations for health claims on botanicals



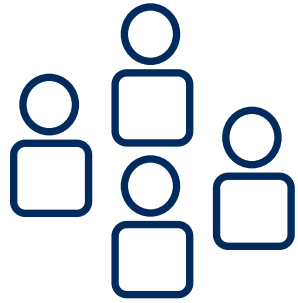
‘On hold’ botanical claims - amendment to nutrition and health claim rules?



No regulatory amendment, short term

# Where do we go from here?

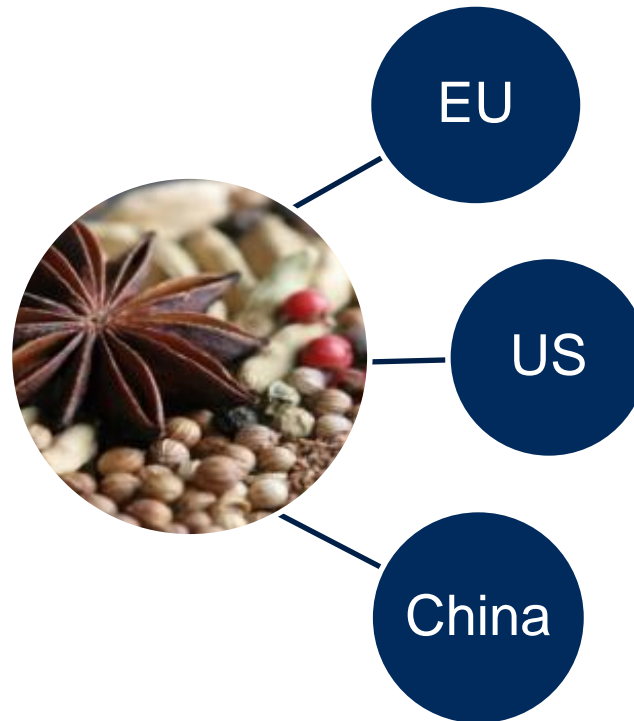
## Drivers



Consumers

- Natural / clean-label trend
- Proactive demand for “preventative” ingredients
- Increasing markets

## Identifying Market Requirements & Regulatory Complexity



## Meeting Regulatory Requirements



- Review ingredient quality, regulatory compliance, stability and shelf life
- Support from experts in toxicology, human health and global legislation

# Questions

# leatherhead food research

## Epsom

Yew Tree Bottom Road  
Epsom  
KT18 5XT  
UK

Phone: +44 1372 376761  
[help@leatherheadfood.com](mailto:help@leatherheadfood.com)

## Sacramento

980 9th Street  
Suite 400  
Sacramento  
CA 95814  
USA

Phone: +1 202 828 8990  
[help@leatherheadfood.com](mailto:help@leatherheadfood.com)



## Disclaimer

Some parts of a report of this nature are inevitably subjective and/or based on information obtained in good faith from third party sources. Where opinions are expressed, they are the opinions of the individual author and/or the relevant third party source and not those of Leatherhead Food Research or its group. Furthermore, if new facts become available and/or the commercial or technological environment evolves, the relevance and applicability of opinions and conclusions in this report may be affected.

Accordingly, while this report has been compiled in good faith, no representation or warranty, express or implied, is made by Leatherhead Food Research as to its completeness, accuracy or fairness. Except where limited by law, neither Leatherhead Food Research nor its group shall be responsible for any actions taken or not taken as a result of any opinions and conclusions provided in this report and you agree to indemnify Leatherhead Food Research, its group and/or personnel against any liability resulting from the same.