



Nutrition and Health Claims

Learning from the challenger brands

Agenda

- 1 How do we develop products?
- 2 What environment do we operate in?
- 3 How do we make nutrition and health claims?
- 4 How do we achieve our claims?
- 5 How does Leatherhead work in this area?

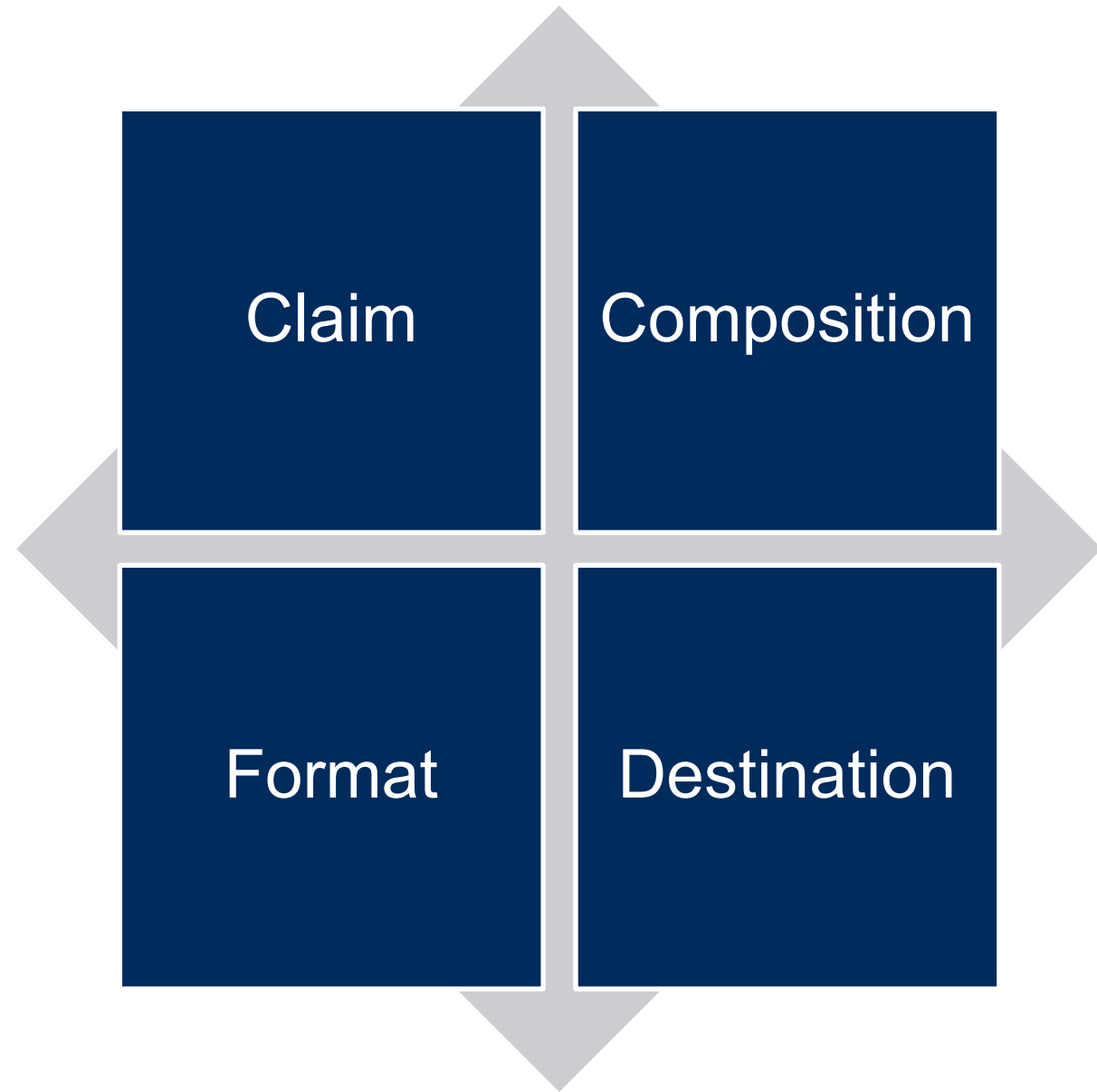
How do you ensure the development of a successful product?

There are so many pieces to the puzzle:

- How do we ensure the right development decisions are made?
- What does the final product look like?
- How do we plan the best route to product development?
- How do we ensure the best bang for our buck?



Areas for product development



A group of people, including a man and two women, are in a kitchen setting. They are all wearing green aprons and appear to be smiling and engaged in a cooking activity. The man on the left is looking towards the women. The woman in the center is holding a large knife. The woman on the right is wearing glasses and is also smiling. They are standing at a counter with various vegetables like tomatoes, onions, and peppers. The background is a brick wall.

What environment do we operate in?

Commercial pressures



Challenger brands

A company or product brand in an industry that is not the category leader, and has to play from a position behind the dominant leader in an industry.

Sources of inspiration
Pushing the envelope



What space do they occupy?

Increasingly influential

70% of consumer-packaged goods growth has come from small- and medium-sized brands

- Spending power of millennials who are less receptive to brands
- Market diversity - shifting gravity of sales
- Responding faster to consumer trends, more agility and increased relevance
- More opportunities for game changers

BE LIKE A START UP



It's all about the risk

“Scientists are actually preoccupied with accomplishment. So they are focused on whether they can do something. They never stop to ask if they *should* do something.”

Michael Crichton

Different levels of risk:

- Risk Awareness
- Exposure
- Reputation
- Responsibility



Global Markets/ Global Reach



Coconut Water

Functional Beverage

- Coconut Water

Benefit

- Nutrient rich
- Electrolytes

Use for

- Rehydration
- Post-workouts
- Quenching thirst
- Hangover cure

Marketing

- National sports team



How do we make
nutrition and health
claims?

Nutrition Facts
Serving Size 1 cup (228g)
Amount Per Container 2

Calories from Fat

%

Claims

- What is the nature of the intended claim?
- How is it regulated in the countries of interest?
- Is premarket assessment / approval required?
- What is required for substantiation?



Drugs vs foods

FDA

The term 'drug' means:

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals;

EC

Medicinal Product -

*Any substance / combination of substances **presented as** having properties for treating or preventing disease*

*Any substance/ combination of substances which may be used to **restoring, correcting or modifying** physiological functions by exerting a **pharmacological, immunological or metabolic** action, or to making a medical diagnosis*

Product format

The format of a product may effect its capacity to bear claims:

For example:

- dietary supplements vs conventional foods

Not all dietary supplements are foods - some are drugs by design.

- Canada regulates supplements as Natural Health Products
- Natural Health Products Ingredients Database
 - Pre-reviewed claims

Nutrition and health messaging mechanisms



Nutrient Content

Health

1. Function - 13(1)
2. Risk Reduction -14(1)(a)
3. Children's Development – 14(1)(b)

+ **Generic descriptor**



Nutrient Content

Health

1. SSA
2. FDAMA Claims
3. Qualified

Structure / Function

Different mechanisms provide different opportunities

Nutrition claims

- Closely based on nutrition labelling of countries
- References values
- Therefore dependent largely on countries nutrition labelling regulations



Health claims

- What levels of evidence is required?
- What wording is required?
- Consistent across markets?
- Consistent messaging

Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.

Foods containing at least 0.65g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ___ grams of vegetable oil sterol esters.

Designing a dietary supplement for children in the US

Initial viability assessment of three different functional packages

Vitamin and minerals quantities

Review proposed amounts in light of

1. US nutrition claims
2. Canadian NHPs requirements



Literature review

- Evidence to support Structure Function Claims
- International acceptability



Areas for investigation/ continued development

- Review Challenges in light 1 & 2
- Identify best chances of success



Fortification

Voluntary

- Fortification Policy
- Rationale of fortification legitimate
- Is only specified fortification permitted?

Mandatory

- Are mandatory fortification requirements met?
- Is fortification relevant?



How can we achieve our claims?



Voluntary formulation / reformulation – additives / ingredients

- What is the difference between an additive and ingredient?
- Are such ingredients subject to requirements for a positive listing?
- Does the legislation include applicable food standards / horizontal legislation?
- Is there applicable purity criteria?



Biofortified Crops

Review of the potential for the use of biofortified crops in food

Biofortified crops regulatory status

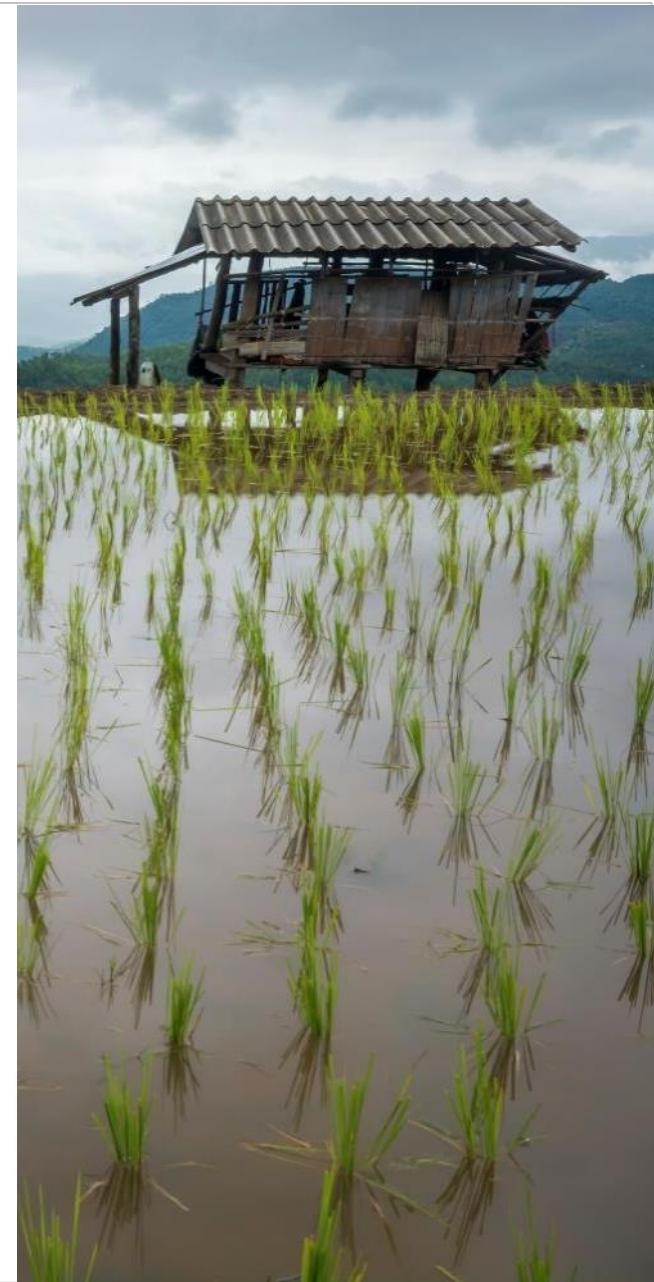
Identify are such crops regulated around the world

- Definitions of “biofortification“
- Requirements for premarket assessments/ notifications
- Potential development of regulations

Potential claims

Review potential claims in the markets of interest

- Identify nutrient content claim requirements
 - Reference Values / Amounts suitable for claim
 - Nutrient Profiling requirements
- Identify any health claims that relate to nutrients of interest
- Identify potential multicomponent foods in which the crop may be used to make claims, where levels of use of the ingredient may be sufficient to justify claims
- Potential general marketing claims



Additives / ingredients

Additive use:

- New sweetener
- New colour
- New texture

Ingredient use:

- New botanical
- New crop strain



Additive purity criteria

- Purity specified by regulation
- Purity specified by reference
 - JECFA
 - FCC
- Fortification regulations specify the form of nutrient required



Other considerations

Gluten Free

- Healthy
- 20 ppm limit
- Dietary compliance

Natural

- Healthy
- EU member States
- USDA / FDA

Organic

- Certification
- Mutual Recognition
 - Potential difference
- Logos

Non GMO / GMO Free

- Guidance
- Language
- Meaning
- Tolerances



How does Leatherhead work in this area?

Regulatory concept review

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.

Summary

- 1 Market growth is coming from challenger brands
- 2 By being agile in positioning, they have been able to provide propositions that resonate with consumers
- 3 Risks profile may be different to established brands and companies
- 4 While there may be potential pitfalls, there is still opportunity to learn from challenger brands provided concepts are appropriately managed

Thanks for listening!

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Questions

leatherhead food research

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