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Cardiovascular benefits from food bioactives

BRITISH Nutrition FOUNDATION

Health claims regulation – opportunities and challenges in Europe – examples from the Bacchus project

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- Superfoods – missing link between diet and health or just hype and a distraction?
- Regulatory framework
- EU Bacchus project

Lots of claims out there but are they legal?

- Claims about ‘superfoods’ - are they supported by **robust evidence?**
- Tests carried out on vitamin and mineral supplements by West Yorkshire councils have shown that **88% of products used illegal health claims** (2014)
  - e.g. for digestive support and joint pain
- Small businesses particularly susceptible as they may lack the necessary expertise in food law and in nutrition science.

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Saskatoon Berries

"Grow your own super-food collection of highly nutritious berry plants"

- "[These] are amazingly rich in antioxidants," says the holistic nutritionist. "What gives them that beautiful purple-blue colour are anthocyanins, which are amazingly good for heart health, so they're very anti-inflammatory." They're also high in fibre.

Nutrition and health claims regulation

- The use of nutrition claims and health claims in the UK is controlled by a European Regulation (EC 1924/2006).
- Provides a comprehensive approach to the control of these claims
  - Ensures they are scientifically valid
  - Harmonises claims across the European Union
- The overall aims are to:
  - Provide useful and reliable information to consumers
  - Encourage innovation in food industry.
- Enforcement – via Member States

- Covers all foods, drinks and supplements sold in the EU
- Applies to all commercial communications, including food labels, advertorials and other promotional materials.
- Not covered – claims about preventing, treating or curing disease; claims on alcoholic beverages (>1.2% alcohol)

General principles

In addition to being **scientifically valid**, the following **five** principles must be followed. The claim **must not**:

- Be false or ambiguous
- Give rise to doubt about the safety and or the nutritional adequacy of other foods
- Encourage excess consumption
- State, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general
- Refer to changes in bodily functions which could give rise to fear in consumers.

Health claims in Europe

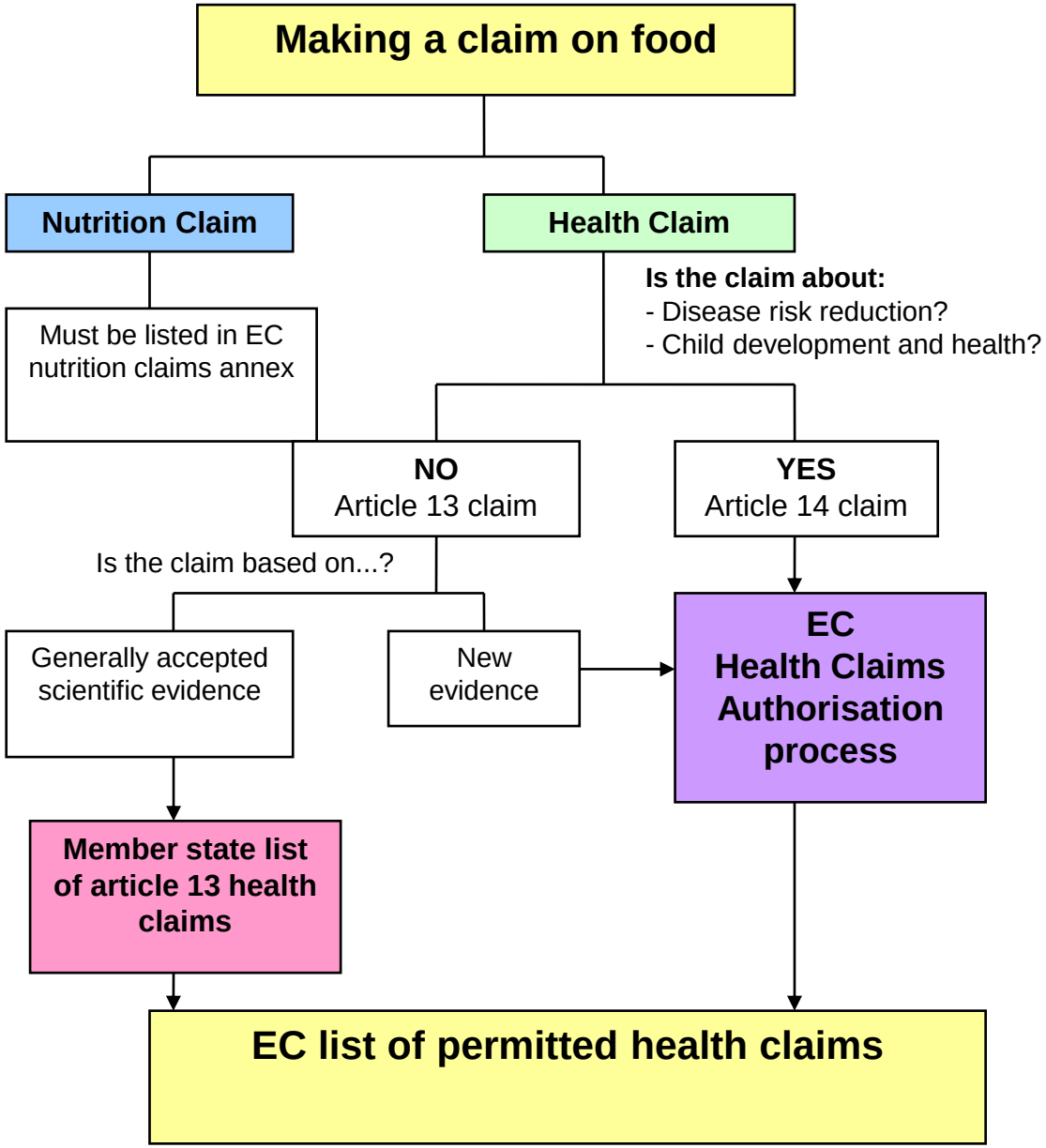
A **health claim** may be featured on the packaging if a food or one of its ingredients has been agreed by EFSA experts and the EC to provide health benefits.

A list of permitted and rejected health claims was published in November 2011 by the European Commission. This is now available on the online register at http://ec.europa.eu/nuhclaims/

In order to make a claim, the amount present of the nutrient, substance or food must fulfil the **conditions of use** of the claim.

Health claims

- **Article 13.1** are those based on generally accepted scientific evidence (*e.g.* calcium contributes to normal muscle function)
- **Article 13.5** are those based on newer evidence (*e.g.* cocoa flavanols help maintain endothelium-dependent vasodilation which contributes to healthy blood flow)
- **Article 14** are those relating to either:
  - Reduction in disease risk (**14a**) (*e.g.* plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease)
  - Children's health and development (**14b**) (e.g. iodine contributes to the normal growth of children).



Examples of health claims

- *Folate contributes to maternal tissue growth during pregnancy.*
- *Calcium is important for normal growth and development of bones in children.*
- *Oat beta-glucans have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.*
- *Cocoa flavanols help maintain endothelium-dependent vasodilation, which contributes to normal blood flow.*

Complete list: EU register of nutrition and health claims
http://ec.europa.eu/nuhclaims/

What does the regulation cover?

- All food, drinks and dietary supplements
- All ‘commercial communications’

- **Not permitted:**
  - Medicinal claims about preventing, treating or curing a disease.
  - Claims on alcoholic beverages (more than 1.2% alcohol), other than low/reduced alcohol or energy.
  - Claims that suggest health could be affected by not consuming the food.
  - Claims that make reference to a rate or amount of weight loss.
  - Claims that make reference to recommendations of individual doctors and health professionals.

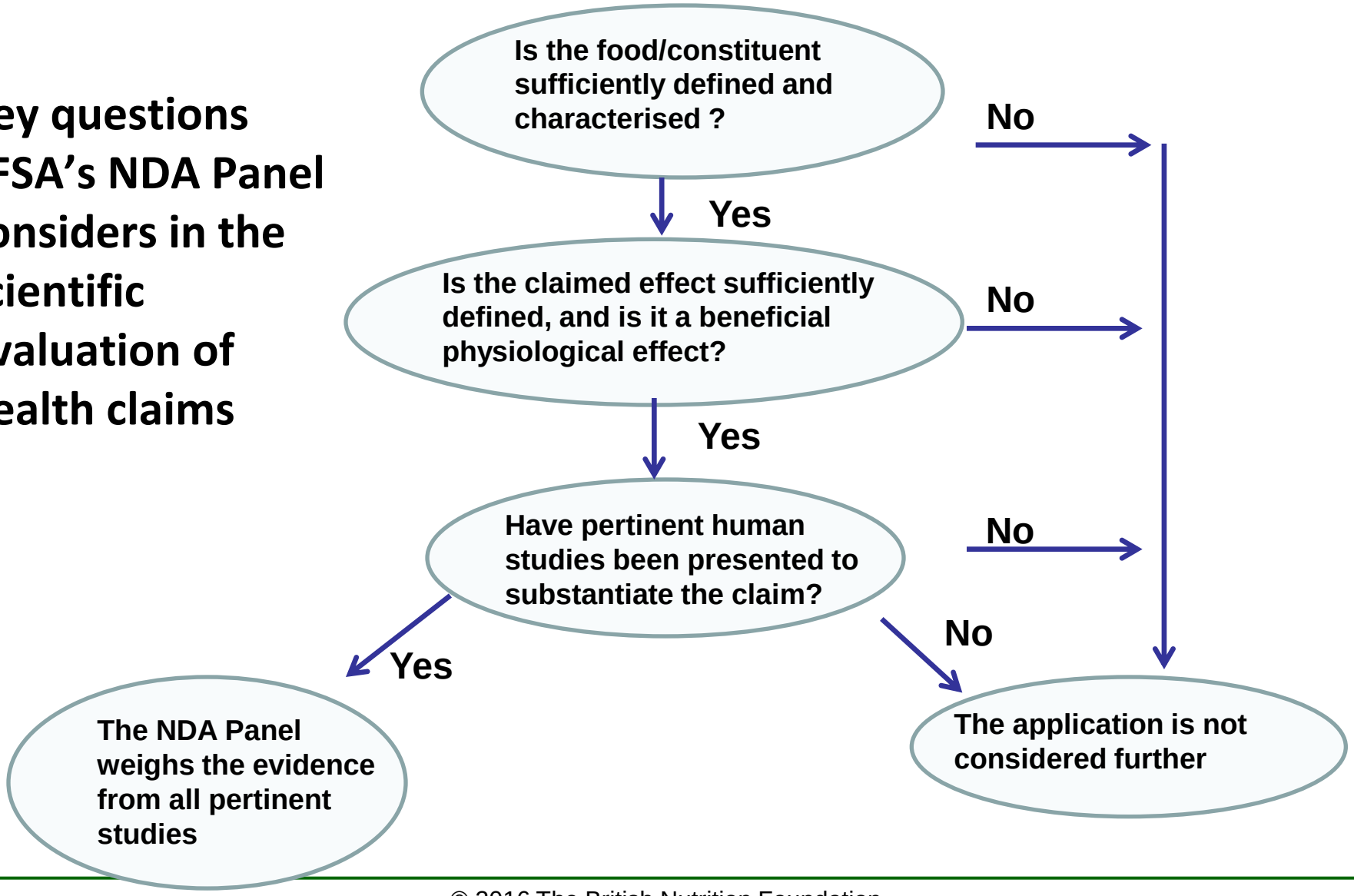
- The **five principles** listed earlier apply to all claims

Approval process for Article 13.5 and 14 claims

- EFSA NDA panel provides scientific opinion on the proposed claim dossier [NDA panel = Dietetic products, Nutrition and Allergies Panel]
- EC considers EFSA opinion and also the likely consumer understanding of the proposed wording and gives final decision on approval/rejection
- Claim and the associated 'conditions of use' are published on the approved list

- If it's not on the list ……

Key questions EFSA's NDA Panel considers in the scientific evaluation of health claims



Current challenges include…

- There are still submitted (botanicals) claims ‘on hold’.
- Nutrient profiling process for use with claims still not in place (was scheduled for 2009); delay leads to uncertainty.
- Issues with the flexibility of wording once a claim has been approved, and suggested inconsistency between member states in the enforcement processes applied.
- Assessment of consumer understanding in the evaluation of communications in a manner that controls subjectivity, and supports the aims of the Regulation.

- Is the Regulation facilitating research and innovation, as planned?

See Buttriss 2015 (Nutrition Bulletin 40, 211-222) for a more detailed discussion of these issues

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To develop tools and resources that will facilitate the generation of robust and exploitable **scientific evidence** that can be used to support claims of a **cause and effect relationship** between consumption of bioactive peptides and polyphenols and beneficial effects related to **cardiovascular health in humans**

http://www.bacchus-fp7.eu/resources/bacchus-publications/

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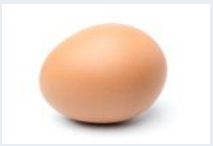
- Best Practice Guide
- Watching Briefs
- Tool kit: Best Practice Guide, Dossier template, checklists, guidance on human studies design, tool to enable exposure assessments (eBASIS composition database linked to Crème Nutrition for Bacchus).
- SME impact surveys, 2015, 2016

AIMS of Bacchus Best Practice Guide:

- Provide an introduction to the Nutrition and Health Claims Regulation
- Review relevant guidance documents
- Review health claims opinions to identify key issues
- Identify criteria for successful health claims dossiers.

Importance of characterisation of the ingredient: knowing the mechanism helps - EFSA guidance EFSA Journal 2016; 14(1):4367, 38 pp.

Food	Bioactives	Product and SME
Pomegranate 	Polyphenols e.g. ellagintannins, ellagic acid	Ellagitannin-rich extracts (ADMIRA)
Apples 	Polyphenols e.g. (epi)catechins, procyanidins (oligomers),	Evesse™ apple granules Evesse™ –EPC Evesse™-OPC (CORESSENCE)
Aronia 	Polyphenols e.g. anthocyanins, phenolic acids	Polyphenol-rich chokeberry juice (Aronia Anti-Oxi ®) (NUTRIKA)
Sweet orange 	Polyphenols e.g. flavone glycosides	Cordiart™ sweet orange extract (BIOACTOR)  
Cured pork 	Bioactive peptides (formed during curing process)	Cured hams and loins, fermented sausages, pork-containing pastes (VAQUERO, VALDYCOMER)
Eggs, egg white 	Bioactive peptides (generated by controlled proteolysis)	Tensiocontrol (BIOACTOR)

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Work-package 2
Bioactive-rich foods and placebos

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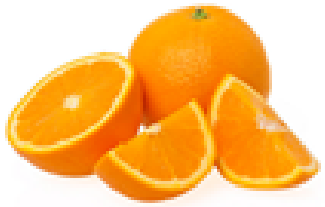



1. Development and characterisation of foods, beverages, extracts and placebos
   - Suitable bioactive content and composition
   - Placebos


2. New methods of analysis
   - Ellagitannins
   - Apple flavanols including procyanidin oligomers

3. Preparation and characterisation of foods for the RCTs

Key factors that that play a role in **successful** health claims related to polyphenols and cardiovascular disease

- Example of a successful health claim, *olive oil polyphenols contribute to the protection of LDL particles from oxidative stress*

✓ Sufficient characterisation of the food constituent (olive polyphenols)

✓ Large body of evidence from human studies

✓ Use of validated biomarker of LDL peroxidation

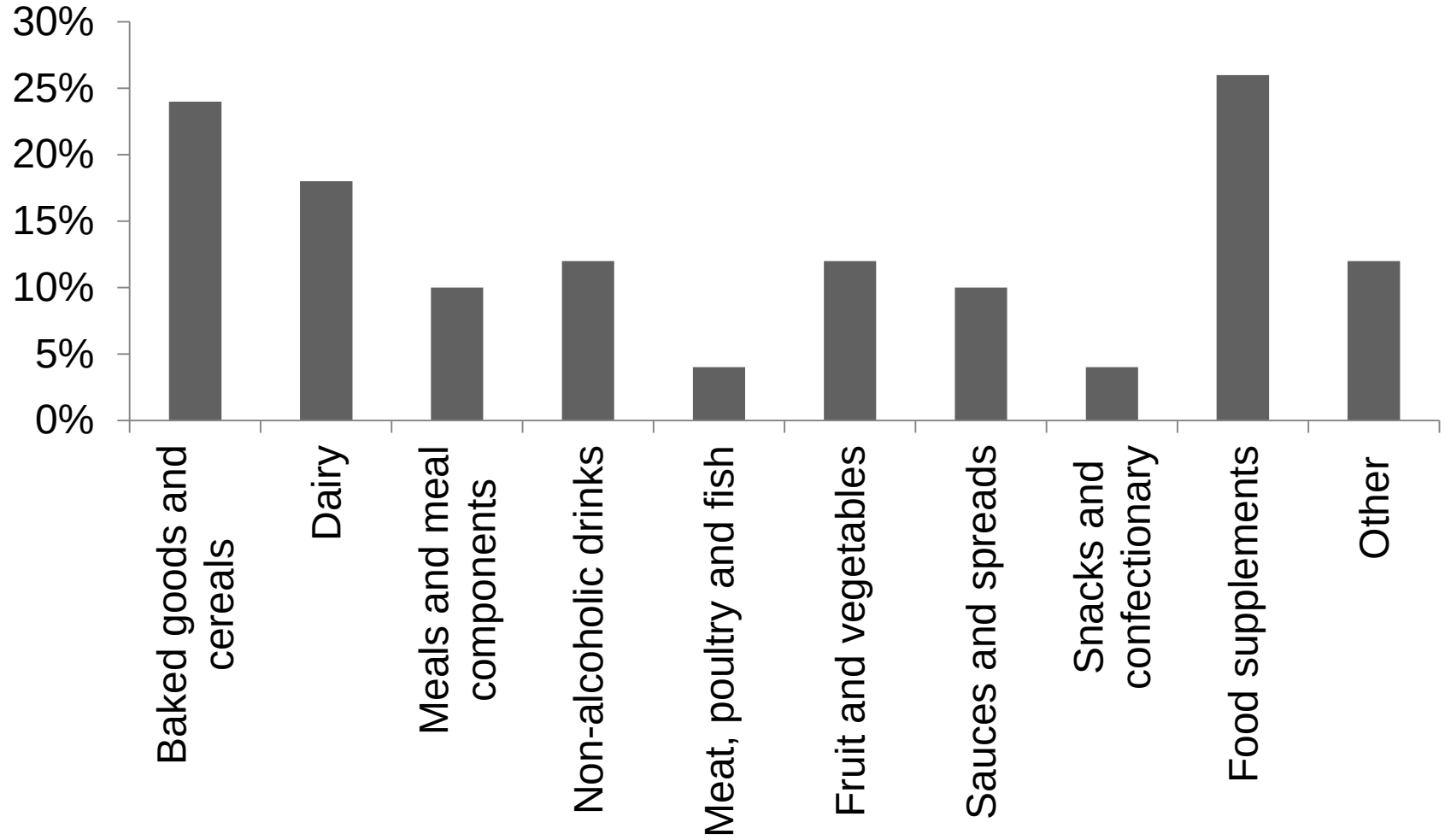
✓ Biologically plausible mechanism by which olive phenolics may protect LDL particles from LDL peroxidation

Key factors that play a role in unsuccessful health claims related to polyphenols and cardiovascular disease

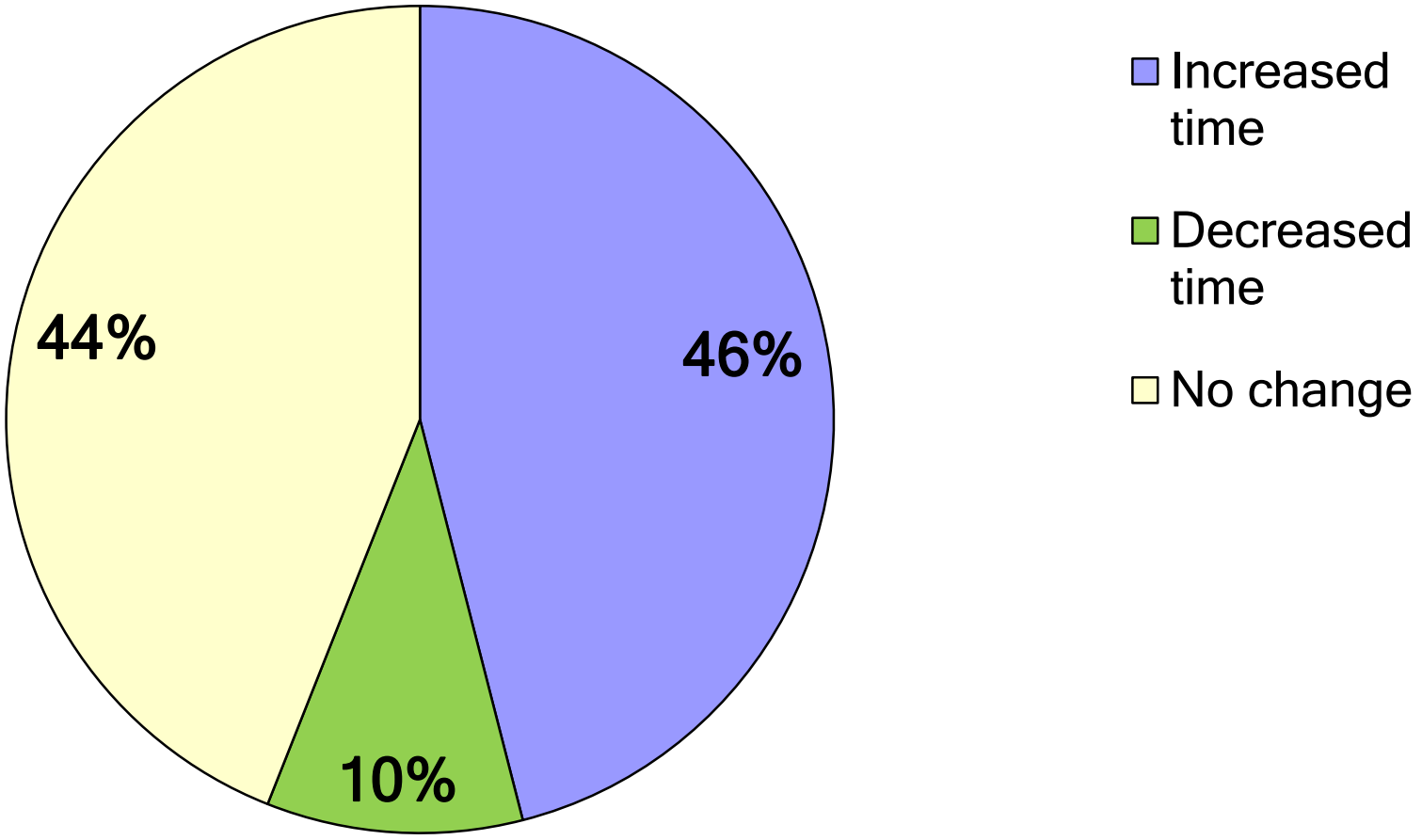
- Failure to reach a positive opinion for proposed health claims can occur for several reasons:

1. Claims submitted under an **inappropriate article**,
2. **Insufficient characterisation** of the food/constituent,
3. **Insufficient evidence provided to establish a cause and effect relationship** between consumption of the food/constituent and the claimed effect,
4. **Lack of evidence** that the claimed effect is **beneficial to the maintenance or improvements of functions** of the body,
5. Lack of **human** trials.

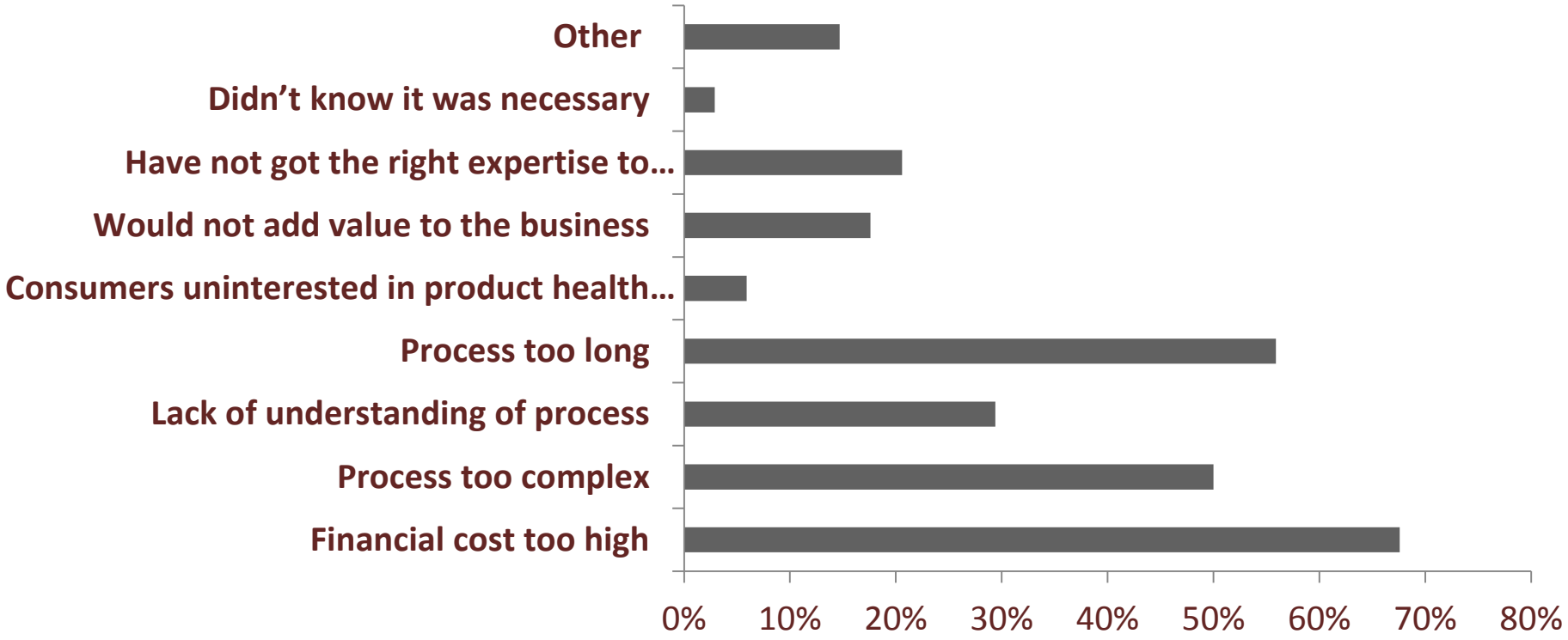
Sectors represented among the SMEs surveyed (n=50, 11 countries)



Responses to the question ‘Has the regulation affected the length of time it takes from concept to product placement in market?’



Percentage of respondents selecting each available option to the question ‘Why is it unlikely that your company will submit a health claim dossier of evidence?’



Thanks for listening!

www.nutrition.org.uk
www.foodafactoflife.org.uk