

EC 1924/2006

realising innovative commercial  
opportunities

# Outline

- EC 1924/2006 overview
- Innovation imperatives
- Specific aspects of the regulation
  - Generic claims
    - » Modifications to generic list
  - Disease risk reduction claims
  - Nutrient profiles
- Substantiation of claims
- Conclusion

# EC 1924/2006 scope...

REGULATION (EC) No .../2006  
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of  
on nutrition and health claims made on foods

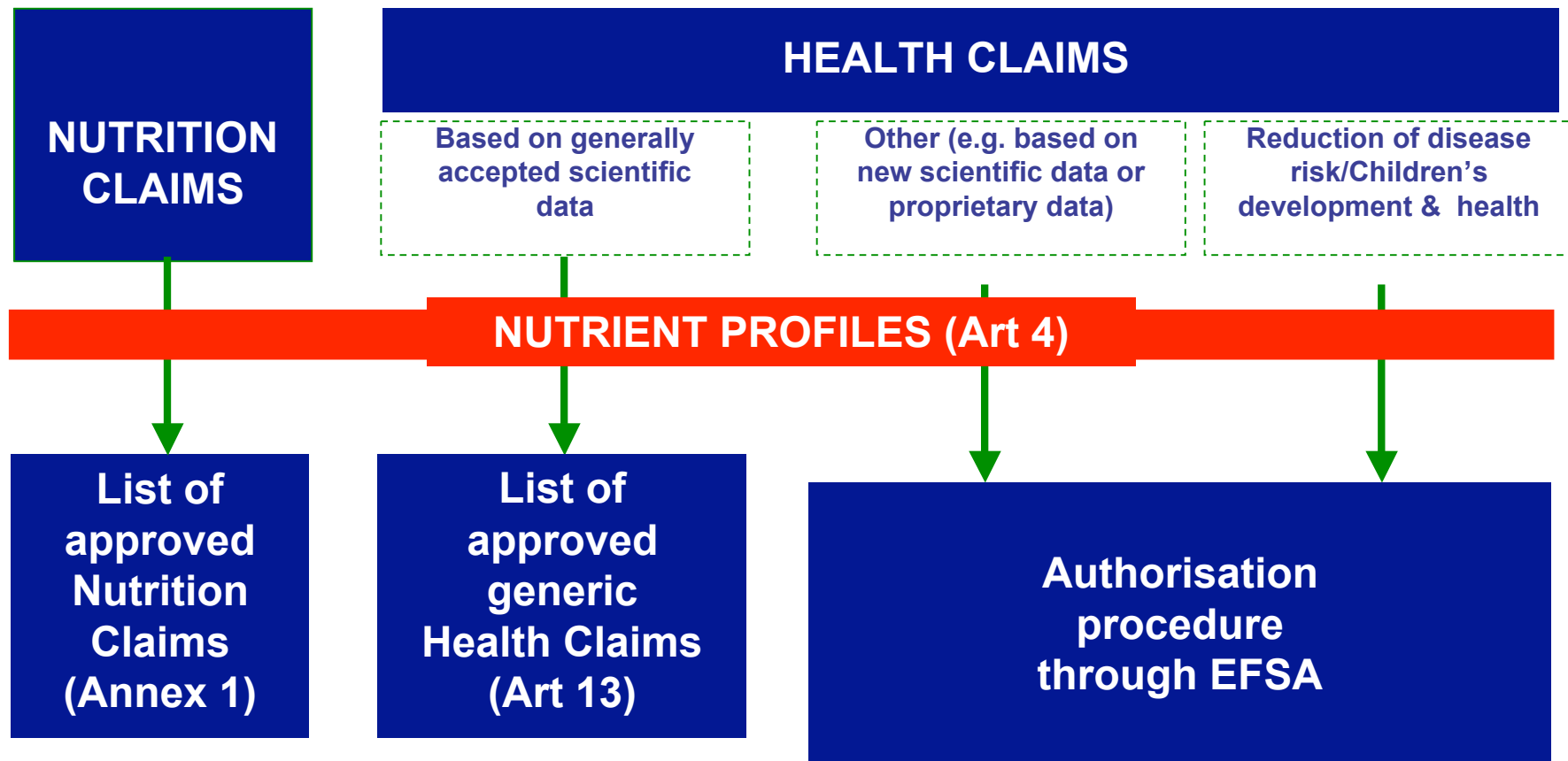
- All commercial communications (i.e. the labelling, promotional materials, web sites, and advertising)
- Foods to be delivered as such to the final consumer, including foods which are placed on the market unpacked or supplied in bulk
- Foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers

# Path of the regulation



# Regulation features linked to innovation

- Determines the claims that can be made
- Establishes the lists of generally accepted health & nutrition claims
- Establishes the procedure for the authorisation of new claims



# Fostering innovation in EC

## Imperatives:

- Vital European economy
- Vital to industry as it is the currency of competition and critical for sustainable growth
- High on EU priorities since the launch of the Lisbon strategy in 2000
- Esko Aho – 'Creating an Innovative Europe' expert report 2005



# Fostering innovation in EC

Imperative for industry:

- Critical in tackling key public health issues highlighted in Commission's Green & recent White Paper
- by development & reformulation of foods
  - that contribute to dietary improvements based on sound science
  - that reduce risk of diseases

# Innovation in the regulation

## Recitals:

- 11 – ‘nutrient profiles should allow for product innovation’
- 26 – ‘to stimulate innovation, those health claims which are based on newly developed science should undergo accelerated type of authorisation’
- 32 – ‘appropriate to protect the investment made by innovators in gathering the information and data supporting an application’

# Generic claims

Health claims describing or referring to...

- the role of a nutrient or other substance in growth, development and the functions of the body
- psychological and behavioural functions
- slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet

which are included in the Art 13 list and are...

- based on generally accepted scientific evidence and well understood by the average consumer

...may be made

# Article 13 list - 2010

## Benefits:

- Consumer confidence
- Level playing field through-out Europe
- List of claims plus conditions applying to them
- Claims based on generally accepted science
- Claims that are understood by the consumer



Innovation will rely on creative and appealing executions that maximise the relevance to the consumer

# Modifications to the list

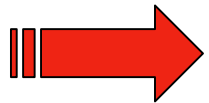
- Changes to the list
- based on generally accepted science
- Comitology procedure
- After Commission on its own initiative or following a request from a member state consult EFSA

# Modifications to the list

- Additions of claims to the list
- Based on newly developed scientific evidence and/or a request for protection of proprietary data (in order to stimulate innovation Recital 26)
- Accelerated procedure Art 18
- Exception: children's development and health claims

# Modifications to the list

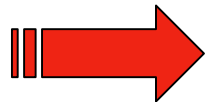
- Accelerated procedure (Art 18)
- Procedure applicable- now.....when list adopted?



- Advantages
  - Stimulate innovation and research
  - Speed to market
  - ‘Restricted for use’ status. Health claim authorised on basis of proprietary data is ‘restricted for use’ to the applicant unless another applicant obtains authorisation without reference to the proprietary data

# Disease risk reduction claims

- Any claim that states, suggests or implies, that the consumption of a food category, food or one of its constituents significantly reduces a risk factor in the development of a human disease
- Require **prior** approval on a case by case basis

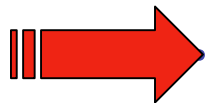


Innovative aspect: Establishes new claim opportunity; list of permitted disease risk reduction claims plus necessary conditions of use that are highly relevant to consumers and underpinned by science

# Claim classification

Example...

- Cholesterol claims- lower/reduce cholesterol
- Different opinions on classification (Art 13/14?)
- No transition period....
- Mandatory statements not considered claim (Art 2.2)

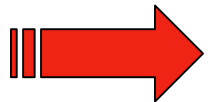


With this type of uncertainty it is difficult to focus on innovation  
– Potential re-packaging/re-labelling/resources

- Await guidance document

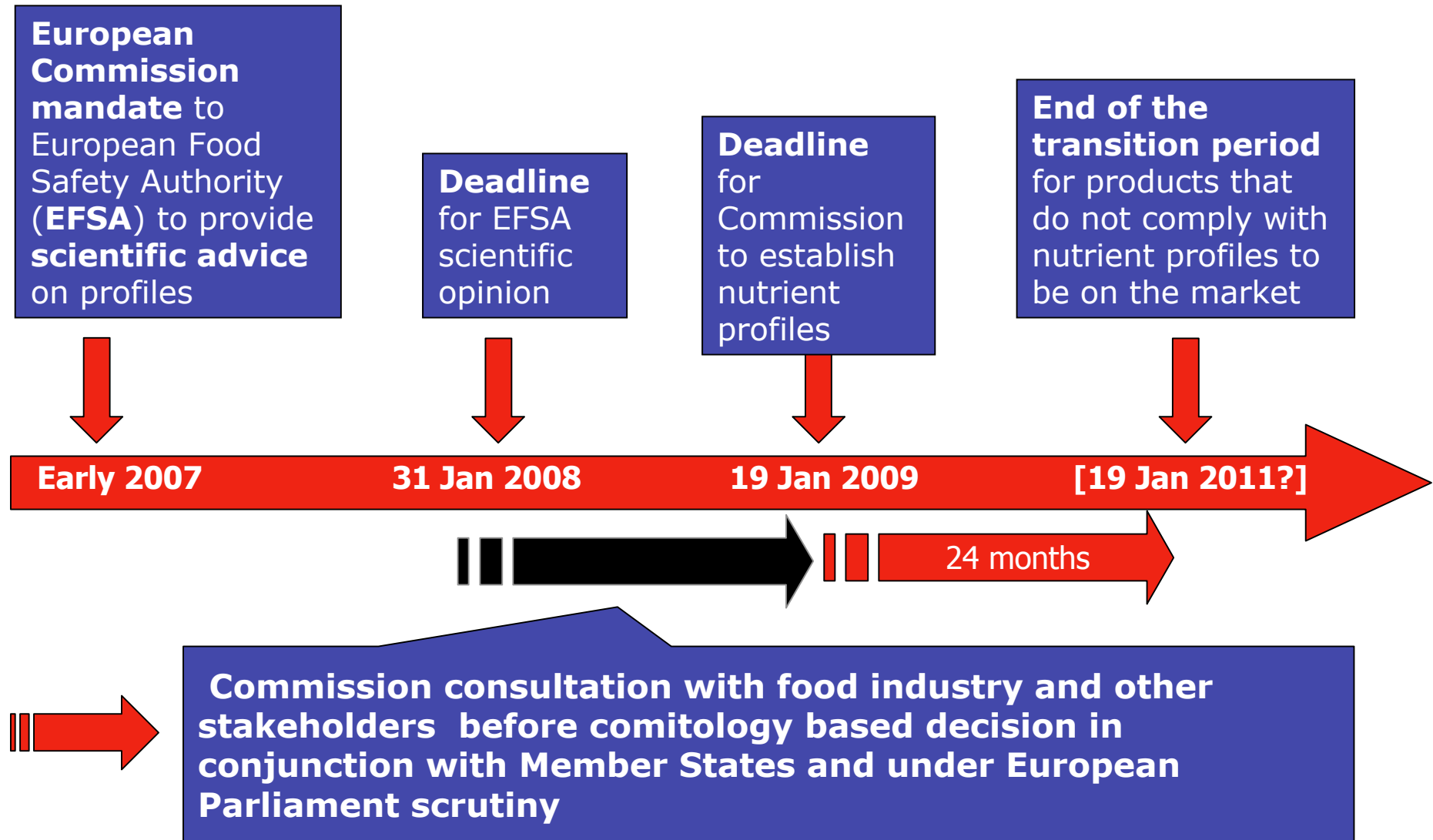
# Nutrient profile issues

- Whether profiles will be set for food in general and/or categories of food
- The choice and balance of nutrients that will be taken into account
- The choice of reference quantity/basis for profiles
- The approach to the calculation of the profiles
- Exemptions.....



Impact on current R&D & NPD projects for future launches

# Nutrition profiles



# Substantiation of claims

- Pre approval requirement impacts on timelines/critical path from research to launch
- Biomarker development & validation
- Data management
  - Confidentiality
  - Ownership of data
  - Proprietary data

# Innovation & regulation

## Principles of better regulation

- Accountability
- Transparency
  - understandable, practical, predictable
- Proportionality
- Targeting
- Consistency

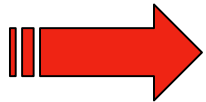
*After Lord Haskins*

*(former Chair, UK Better Regulation Task Force)*

# Innovation & regulation

Claims 'Reward' for

- Innovation in product development
- Investment in R&D



***Implementation*** of a clear predictable regulatory framework will help ensure that food products can make claims when justified scientifically and foster innovation.

# Regulation as a facilitator of innovation?

**“There are known knowns;**

there are things we know we know.

**We also know there are known unknowns;**

That is to say we know there are some things we do not know.

**But there are also unknown unknowns:**

The ones we don't know we don't know.....

It's the latter category that tend to be the difficult ones”

*After Donald Rumsfeld*



**EC 1924/2006**  
**realising innovative**  
**commercial opportunities**

**Thank You**