EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Regulation (EC) No 1924/2006 – nutrition and health claims on foods

Basil Mathioudakis
Food law, nutrition and labelling
DG SANCO – European Commission

Objectives of the Regulation

- To achieve a high level of consumer protection
- To improve the free movement of goods within the internal market
- To increase legal security for economic operators
- To ensure fair competition in the area of foods

- Adoption of Regulation 1924/2006 in second reading 20 December 2006
- Entered into force 19 January 2007
- Applicable from 1 July 2007

- Difficult process ➔ Need for combined effort of
  - Commission
  - EFSA
  - Member States
  - Stakeholders

- Different roles ➔ different responsibilities

- Commission's effort to:
  - Provide platforms to listen / discuss (e.g. Seminar 9 March 2010)
  - Provide clarification to stakeholders and Member States
    - **Guidance document** on interaction with other Community legislation, comparative claims, classification of claims (December 2007)
    - **Implementing measures** (Commission Regulations 353/2008 and 1169/2009) setting rules on individual applications, conditions of use, validity checks from national authorities and withdrawal of individual applications
    - **New guidance documents in the pipeline** on MS validity check and correct use of authorised claims

Health claims ***shall,*** *inter alia*:

- "***be based on and substantiated by generally accepted scientific evidence***" (art. 6.1)

Recital 17 "*Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence*"

Recital 23 "*Health claims should only be authorized for use in the Community after a scientific assessment of the highest possible standard*"

Recital 26 " *Health claims other than those referring to the reduction of disease risk and to children's development and health, based on generally accepted scientific evidence, should undergo a different type of assessment and authorisation*"

- **Be understandable for the average consumer** (art. 5.2)

Health claims ***shall not*** (art. 3):

- "*be false, ambiguous or misleading*"
- "*give rise to doubt about the safety and/or the nutritional adequacy of other foods*"
- "*encourage or condone excess consumption of a food*"
- "*state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general*"
- "*exploit fear in the consumer*"

Specific conditions – health claims

Health claims ***shall*** be accompanied by information on (art. 10):

- Importance of balanced diet / healthy lifestyle
- Where appropriate, persons who should avoid using the food
- Appropriate warning related to excess consumption of the food
- Quantity of the food / pattern of consumption required to obtain the claimed effect

Health claims ***shall not*** (art. 12):

- Suggest that health could be affected by not consuming the food
- Make reference to rate or amount of weight loss
- Make reference to recommendations of individual doctors or health professionals

Reduction of disease risk factor claims shall bear a statement indicating that the disease to which the claim refers has multiple risk factors and that altering one may or may not have a beneficial effect (art. 14.2)

Community lists

- Foods can only bear claims that are included in lists of permitted claims
- **Nutrition claims -** List of permitted claims in Annex of Regulation
- **Health Claims** – Lists of permitted claims
  - **"Function" claims:**
    - Art. 13 procedure => Community list
    - Additions: art. 18 procedure - "*new developed scientific evidence and/or based on proprietary data" (art. 13.5)*
  - **Reduction of disease risk claims and claims referring to children's development and health:**
    - Art. 15, 16, 17 and 19 procedure => Individual authorisation => Community list

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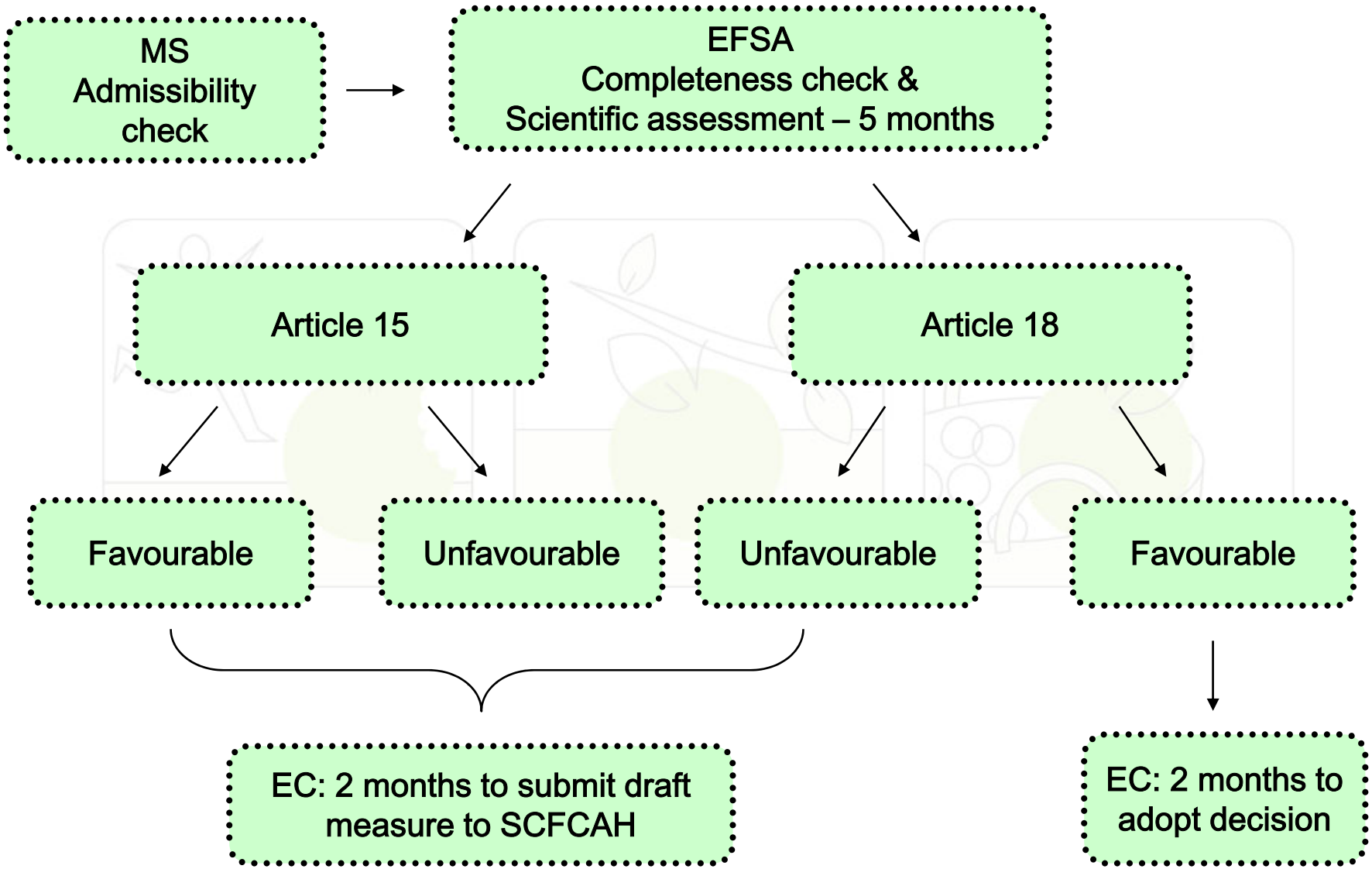
Individual Authorisation procedures
Art. 14 and 13(5)



Individual Authorisation procedures Art. 14 and 13(5)

- EFSA has received approximately 300 applications
  - 219 children's claims
  - 48 risk reduction claims
  - 36 newly developed science/proprietary data
- Commission has received 85 EFSA opinions
- For the majority, the applicant/public made comments to the Commission – Article 16(6) of Regulation
- Scientific comments are transmitted to EFSA and a response is provided
- Comments and EFSA response to comments on SANCO's website: http://ec.europa.eu/food/food/labellingnutrition/claims/comments_efsa_en.htm

Individual Authorisation procedures Art. 14 and 13(5)

Until now the Standing Committee (SCFCAH) voted in favour of draft Commission Regulations that:

Permit:

- 1 claim based on proprietary data [Art. 13(5)]
- 4 reduction of disease risk claims [Art. 14(1)(a)]
- 8 claims referring to children's development and health [Art. 14(1)(b)]

Reject:

- 9 Art. 14 (1)(a) claims
- 29 Art. 14 (1)(b) claims
- 12 Art. 13(5) claims

⇒ 13 permitted and 50 rejected claims

⇒ 23 applications under consideration

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Art. 13 claims – Chronology

- **31 January 2008** - Member States submitted national lists – (44.000 entries)
- **June/July 2008** - Member States and stakeholders consulted (DG SANCO Advisory Group consulted 8 July 2008)
- **End 2008** - Consolidated list submitted to EFSA together with ToR
  - (4185 main entry claims / around 10.000 similar health relationships)
- **January 2009** – EFSA publishes database
- **2009** - Clarification process
  - 2145 health claims sent back to the MS for further information or clarification (6 criteria)
  - Continuous examination of admissibility (product specific / comparative claims)
- **March 2010** - Submission of an addendum to EFSA (452 main entry claims)
- **May 2010** – EFSA publishes consolidated database (4637 main entry claims)
  - Incorporates amendments to January 2009 database (missing and misplaced claims)
- **Approx 300 claims withdrawn so far**

- **EFSA published opinions in series**
  - First series: October 2009
  - Second series: February 2010
  - Finalisation of the assessment: end of 2011
- **Breakdown of EFSA's first two series:**
  - Substantiated claims: 182 + 10 = **192**
  - Insufficient evidence: 20 + 6 **= 26**
  - Insufficient characterisation of micro-organisms: 171 + 92 = **263**

Art. 13 – Commission's approach

Commission announced to Member States and stakeholders a process based on:

- Progressive adoption of list of permitted health claims
- Progressive removal of health claims not backed by science
- Possibility for operators to present additional data where EFSA concluded that there is:
  - Insufficient substantiation to allow a cause and effect relationship to be established
  - Insufficient characterisation of the micro-organisms claimed to have the beneficial effect

Process of further assessment

- **Limited scope**
- **Limited timeframe**
  - Avoid abuse of the procedure
- **Clarification on the procedure**
  - Under discussion with Member States
  - Preference for use of art. 18 procedure
  - To be made public on SANCO website at the latest when list is adopted

Wording of the claims

- **Importance of consumer understanding**
  - A certain flexibility provided
  - Linguistic differences may impact perception of claim
  - Final judgment on consumer understanding is made by enforcement authorities
- **Intention to follow EFSA's wording but difficulties exist**
  - Some examples on art. 13 claims…
    - *Folate contributes to normal homocysteine metabolism*
    - *Vitamin C increases non-haem iron absorption*
    - *Zinc contributes to normal acid-base metabolism*
    - *Zinc contributes to normal DNA synthesis and cell division*

Conditions of use

- **Guiding principles**
  - General ➔Non Product-specific
  - Comprehensive ➔taking different elements into account (e.g. All related claims: nutrition claims, art. 13 and art. 14 claims)
  - **Example of Omega-3 related claims**

- **Target population**
  - Sub-groups of the general population
    - Sub-groups of the general population with a disease?

- **Art. 13-specific issues**
  - Claims for which no deficiency is reported
  - Not dietary-related claims
  - Traditional use
  - Extrapolation of data from sick people
- **Other issues**
  - Borderline issues
    - Food vs. medicinal claims
  - Proprietary data – exclusive right of use

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Thank you for your attention