Health Claims: How Does The NDA Panel Work

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EFSA task on claims: who?

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- **NDA Panel**
  - 19 members: Chair (A. Flynn); Vice-chairs (H. Przyrembel; A. Palou)
  - Adopts scientific opinions and is responsible for them
  - All opinions published - EFSA Journal (web)
- **Procedure for claims**
  - NDA WG Claims prepares draft scientific opinions
  - 13 Panel members currently
  - Other independent experts will be added as needed
    - Evaluation of claims in specific areas
- **EFSA staff**
  - Support work of Panel and WG

EFSA task on claims: who?

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- **PANEL MEMBERS**

Albert Flynn -Chair of the NDA Panel , Andreu Palou -Vice-Chair
Heinonen, Karin Hulshof ,
Hannu J. Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela
Marchelli , Ambroise Martin, Bevan Moseley, Seppo Salminen J
Hendrik Van Loveren Hans Verhagen

EFSA task on claims

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- **EFSA's scientific advice on scientific substantiation of health claims**
  - Claims subject to authorisation procedure
    - EFSA Guidance to applicants for disease risk reduction claims + claims for development & health of children (Art. 14)
    - Function claims based on new science/proprietary data (Art. 18)
  - Function claims based on generally accepted scientific evidence (Art. 13)
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Guidance

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Objective: to assist applicants in preparing and presenting their applications for authorisation

- Common format - for a well-structured application
- Content - information and data required/optional
- Criteria for substantiation - the key issues to be addressed to substantiate a health claim
- To be reviewed and updated in light of experience gained in evaluation of claims

Criteria for substantiation

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Regulation - health claims should be substantiated by

- "generally accepted scientific evidence"
- "taking into account the totality of the available scientific data"
- "weighing the evidence"

Criteria:

- Relevance to human health
- Causality of the relationship
- Food quantity required for claimed effect
- Representativeness of data for target populatio

Criteria for substantiation

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Key issues

- General agreement (for decision)
- Characterization of the effect
  is it plausible and important
- Characterization of the food
- “weighing the evidence”

Criteria:

- Cause -Effect relationship established?
- Is it feasible in normal food/diet
- Scientifically established
- Defined for target population

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Example: Regulat Prokid Immune

- Fermented fruit and vegetable base with added probiotics
- Target infants and children
- Improve immune response

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Example: Regulat Prokid Immune

- Fermented fruit and vegetable base with added probiotics
- Target infants and children
- Improve immune response

- Basis for effect not sufficiently characterized
- Bacteria not characterized
- Product not tested in target population
- Cause effect:

  not demonstrated
- Proposed health claim not approved

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Example Plant Sterols

- Component well-defined
- Compound tested in several food matrices
- Results similar
- Dose response demonstrated

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Example Plant Sterols

- Component well-defined
- Compound tested in several food matrices
- Results similar
- Dose response

- Basis for effect sufficiently characterized
- Clinical studies in several countries
- Product assessed in target populations
- Cause effect demonstrated
- Proposed health claim approved but modified

Example Plant Sterols

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- Proposed: “Plant sterols are proven to lower/reduce blood cholesterol significantly. Blood cholesterol lowering is proven to reduce the risk of (coronary) heart disease”

Example Plant Sterols

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- Proposed: “Plant sterols are proven to lower/reduce blood cholesterol significantly. Blood cholesterol lowering is proven to reduce the risk of (coronary) heart disease”
- Approved: “Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease"

Example Plant Sterols

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- Comment: should be consumed only by people who need and want to lower their blood cholesterol and that patient on cholesterol - lowering medication should only consume the product under medical supervision.

Evolus product

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- Low lactose products with specific peptide composition
- Proposed claim: reduction of arterial stiffness

Evolus product

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- Product sufficiently characterized
- Not established that reducing arterial stiffness is beneficial to human health by reducing the risk of cardiovascular disease
- A cause and effect relationship has not been established
- The claim was not approved

Xylitol and Tooth Decay

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- Xylitol chewing gum/pastilles and reduction of the risk of tooth decay
- Chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol
- The claimed effect ‘reduces the risk of tooth decay’
- Target population: general population

Xylitol and Tooth Decay

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- Foods subject of the health claim (i.e., chewing gum sweetened with 100% xylitol and pastilles well characterised.
- A cause and effect relationship has been established between the consumption of chewing gum sweetened with 100% xylitol and a reduction of the risk of tooth decay in children
- Not for pastilles