Evira's role related to Health Claims

Seminar on Health Claims

Senior officer Sari Sippola
Control department
Product safety unit

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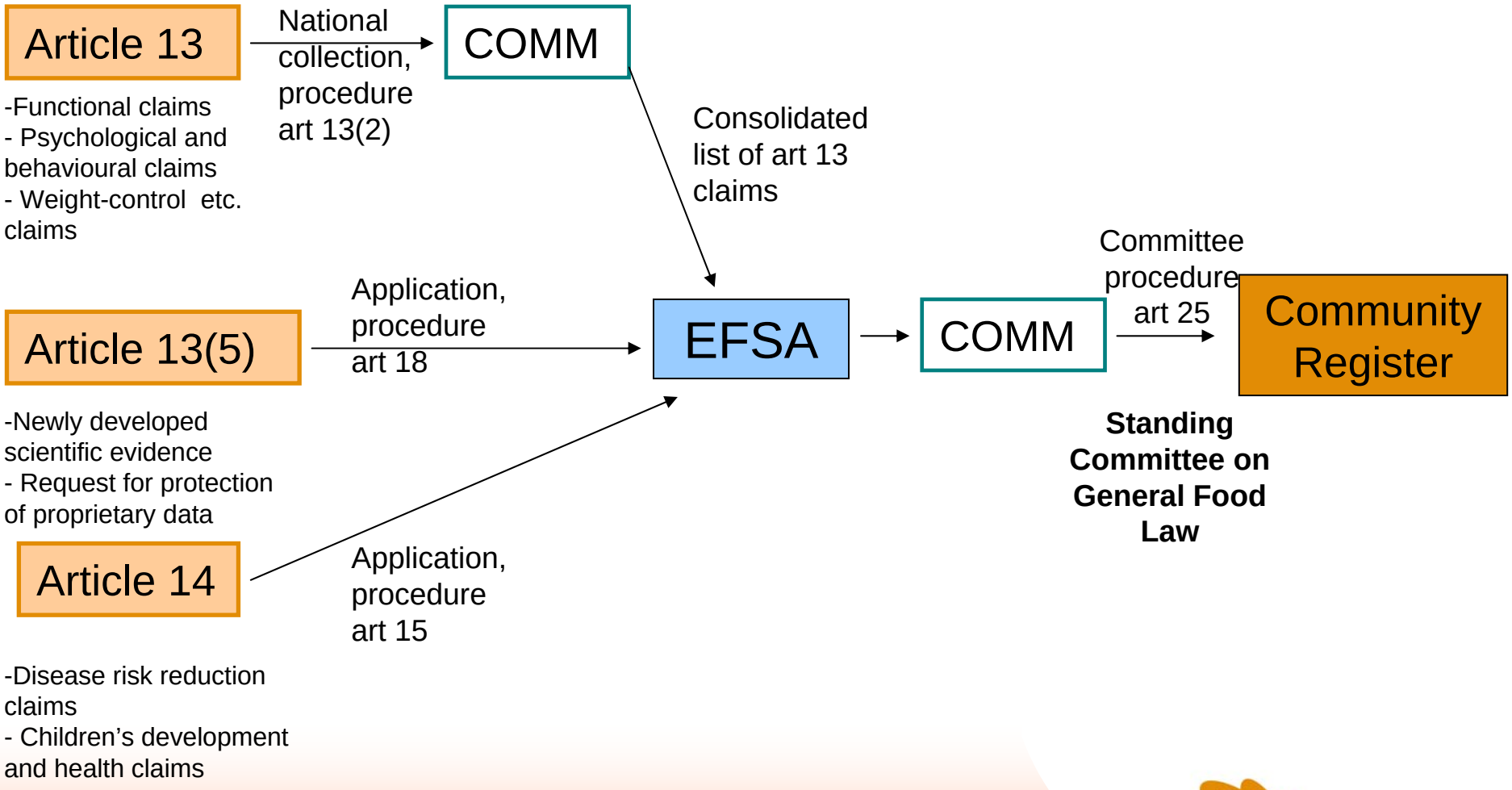
Health claims ways to Community Register of Nutrition and Health claims made on food



Competent Authorities role in health claim applications

- **Article 13(5) claims** (article 18(2))
  - The application shall be submitted to the national Competent Authority of a Member State which shall

    - Acknowledge receipt of the application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application.
    - Send the **valid** application and any information supplied by the applicant without delay to the Authority for a scientific assessment as well as to the Commission and the Member States for information.

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Competent Authorities role in health claim applications

- **Article 14 claims** (article 15(2))
  - The application shall be sent to the national Competent Authority of a Member State.

    The national competent authority shall:
    i. acknowledge receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
    ii. inform without delay the Authority; and
    iii. make the application and any supplementary information supplied by the applicant available to the Authority;

  - The application submitted to the Authority should also be valid because in Article 16 (1) it is stated that "In giving its opinion, the Authority shall respect a time limit of five months from the date of receipt of a valid application".
    - Clarified to member states in the meeting of Commission's working group on Health Claims on 4.7.2008

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What is a valid application?

1. **Application contains:**
   - Actual application form including the check list
   - The summary of the application (as well as an electronic file with the summary of the application only for publication purposes)
   - paper copy and one electronic copy of the complete application (the electronic and paper forms must be identical).
   - The full-text of all references identified as relevant to the substantiation of the health claim and organised by alphabetical order of first authors
   - All information in English

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What is a valid application?

2. Application follows as much as possible

a) the Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

b) the EFSA's guidance "Final scientific and technical guidance for applicants for preparation and presentation of the application for authorisation of a health claim"

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What is a valid application?

3. **Only one clearly defined food/constituent responsible for the claimed effect is applied**

4. **Only one well-defined claimed effect (= health relationship) is applied**

5. **Application contains only one proposal for the wording of the health claim**

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What is a valid application?

5. **Applied health claim actually falls under the scope of either**
   - Article 13.5 (function claims based on newly developed science or asking for data protection) or
   - Article 14 (reduction of disease risk or children's development and health)
     - European Commissions Guidance on the implementation of Regulation (EC) No 1924/2006 published on 14.12.2007

6. If protection of proprietary data requested, application contains **appropriate justification for the claiming of proprietary/confidential data**.
   - Sections of the application containing confidential/proprietary data are clearly identified.

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Experiences with applications

- Evira has submitted 6 health claim application to EFSA of which
  - 3 article 14 application
  - 3 article 13(5) application

- For 2 application recommended rewording because the claim wasn't seen to fit under the scope of definition
    - Claims did not mention a reduction of a disease risk factor

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Disease risk reduction claims

- According to Regulation (EC) No 1924/2006 article 2(6) a reduction of disease risk claim means
  - any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.
- Such claims can be for example,
  - “lowers high cholesterol” or ”lowers elevated blood pressure”
    - both are known and generally accepted risk factors to cardiovascular diseases.
- A claim “reduces the risk of [*name of the disease*]”, doesn’t describe the reduction of a disease risk factor.
  - Can’t be seen to fit under the definition of article 2(6)
  - It can be seen as medical claim because it conveys the image of prevention of a disease.
  - According to the Finnish Food Act (23/2006, §9) food must not be presented as having properties related to prevention, treatment or curing of human diseases or refer to such information.

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