Health Claims:
Experiences and Expectations from Industry

Mella Frewen

Director General, CIAA

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CIAA

Background

- CIAA supports the basic principle that all nutrition and health claims should be allowed if they can be scientifically substantiated, are not misleading and are well understood by consumers

- **Scientific substantiation:** sound scientific basis for claims is essential
  - Need to set out a common approach/set of criteria for the substantiation of all claims

- **Not misleading:** Consumer confidence in claims is critical; claims must therefore be honest, credible and truthful

- **Well understood:** the wording of claims should be clear and easy to understand by all consumers

Correct implementation of Regulation (EC) 1924/2006 is key;
Continuous dialogue between the European Commission, Member States, EFSA and the industry is indispensable

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Some History …

- **The European food and drink industry has been involved and engaged from the start**
  - CIAA's first position on health claims dates back to 1996
- **Comprehensive internal discussions have taken place on several aspects of claims**
  - Not always easy, sometimes leading to differing views among food companies, sector associations and national federations;
- **New process <u>for everyone;</u> therefore, the system was unlikely to be perfect from the start**
- **CIAA has always engaged constructively and assisted where possible**
  - Contributing to stakeholder consultations prior to and during the legislative drafting process
  - Coordinating the development of the industry list of Art. 13.1 health claims

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Some History …

- **In 2005, before guidance was forthcoming from EFSA and the Commission, CIAA took the initiative and developed a coordinated industry list with ERNA, EHPM and EBF of Article 13.1 health claims**

- **Purpose:**
  - To develop an approach based on existing work (WHO, US FDA CFSAN, etc.)
  - To identify and collate supporting evidence and to prepare the list, thereby assisting EFSA and the Commission in their tasks as risk assessor and risk manager respectively
  - To proactively engage in constructive dialogue with other stakeholders

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Some History …

- **Scientific screening of the claims, by independent experts, before being included on the Industry list**
- **Workshop was held in March 2006 to clarify the list with Commission, Member States representatives and others**
- **Final Industry list included 776 health claims was then sent, via the Member States**
  - Included in EFSA Register of Questions with identical “Stakeholder Code”

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An update…

First Batch (1 October 2009)

- 523 claims assessed by EFSA
- Opinions on 91 CIAA claims
  - 1 inconclusive;
  - 12 negative;
  - 78 positive.
- Amongst others: biotin, calcium, copper, zinc, vitamin A, vitamin C, vitamin D, beta carotene, gamma-linoleic acid, EPA, DHA, DPA, botanicals…

Second Batch (25 February 2010)

- 416 claims assessed by EFSA
- Opinions on 40 CIAA claims
  - 1 inconclusive;
  - 34 negative;
  - 4 positive (out of 8 positive in total);
  - 1 non-compliant with Reg. 1924/2006;
- Amongst others: Camelia sinensis, vitamin D, potassium, alpha-lipoic acid, sugar-free chewing gum, linoleic acid, betalains, lutein,…

3rd and 4rd Batch??

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Looking back – What could have been done better…

- Insufficient guidance for applicants
  - e.g. on scope, level of evidence, characterisation, type of study, target population, etc.
- Process too complicated
  - e.g. filing under Article 13.1, 13.5 or 14?
  - e.g. format for completing an application is rather laborious with a certain amount of duplication
- Expectations, on all sides, differed
  - e.g. with regard to totality and weight of evidence

Looking back – What could have been done better…

- More transparency and legal certainty needed
  - E.g. in terms of timeline and batch-wise publication, data protection
- More dialogue needed
  - Between applicant and risk assessor; between industry and risk manager
- No impact assessment of the legislation
  - Possible impact on food and drink industry

Looking back – What went well…

- Process of claims submission through CIAA-EHPM-ERNA-EBF list
- Dialogue with EC and EFSA during this process
- EFSA has to be congratulated for the task of reviewing so many health claims in such a short time

Looking **forward** – learning from the past…

Greater guidance on applications

- **Possible discussions with EFSA prior to dossiers being submitted (similar to what is allowed by US FDA)**
  - An applicant can lose time and energy undertaking costly studies and writing a dossier that is incorrect
  - Bilateral meetings/presentations become particularly relevant for dossiers related to ‘new and emerging science’ (Art. 13.5, Art. 14)
  - It would help applicants to be able to determine the level of evidence required, types of study, target groups etc.
- **Greater insight from EFSA when evaluation of dossiers receive 'insufficient'**

Looking **forward** – learning from the past…

- **Greater guidance during and after assessment phase**
  - **Need for transparency and objectivity in the weighing of the scientific evidence**
  - **At the June 2009 EFSA Technical Meeting, commitments were made for greater dialogue/greater accessibility with EFSA during the assessment phase; this still needs to be improved**
    - E.g. similar to what is allowed for novel food applications
    - Applicants should feel more informed about the progress of a specific application

Looking **forward** – learning from the past…

- **More clarity on EFSA publication time frames**

- **More dialogue between risk managers and industry on conditions of use and wording of positive claims**
  - EFSA not responsible for communication to consumers
  - Industry able to assist risk managers in setting appropriate conditions of use and provide input on more consumer friendly wording
  - Consistent but flexible enough

Conclusions

- Health claims process was new to everyone involved; therefore, the system was unlikely to be perfect from the start

- CIAA has always co-operated and engaged constructively to rationalise the system as best as possible

- After 3 years, we believe that improvements to the implementation process of the Regulation can certainly be made

- Particularly more guidance and dialogue on applications during and after the assessment phase are needed

- CIAA at the disposal of EU risk manager and risk assessor to pro-actively and constructively help improving the process