

**Impact of the Health Claims Regulation –  
Industry View**  
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**Industry welcomes Nutrition and Health Claims  
Regulation**



→ Objectives of the Nutrition & Health Claims Regulation:

- Accurate information to consumers.
- Creation of level playing field
- Encourage innovation in the food industry.

→ Industry welcomes Nutrition & Health Claims regulation.

- Enables consumers to make healthy food choices
- Consumers are protected from incorrect claims.
- Industry encouraged to develop healthy food (ingredients)



***Industry supports a strong and transparent regulatory framework***

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## Current concern from Industry (1/2)

- Of the so far 60 assessed article 13.5 & 14 claims, 10 have obtained positive Opinions from EFSA
- The submitted scientific evidence has been evaluated against the highest possible standards, i.e. evidence is rejected if not considered 'convincing'.
- Currently EFSA is in the process of evaluating > 4000 "article 13.1-claims"
- The Commission and EFSA has informed that they will use the same review-criteria for the 13.1 claims
- If this criteria will be used also for the article 13.1 claims, very few of the >4000 claims will be approved.

### Consequences:

- **Healthy food products will potentially be taken off the market**
- **The predictability of the Regulation is low. Industry makes significant investments in R&D targeted for the European market without being able to predict the outcome of the Regulatory process.**

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## Current concern from Industry (2/2)

- EFSA Opinions of the > 4000 "article 13.1-claims" is said to be published in July, November and TBD
- The occurrence of the claims in the three groups appear to be random
- The Regulation of all >4000 claims is said to be published in January 31, 2010.
- The Commission and EFSA admit publicly that the January 31, 2010 deadline will be difficult.
- However, the publication of the EFSA Opinions is still scheduled for July, November and TBD.

### Consequence:

- **Staggering of the publication of Opinions will cause an unlevel playing field and distortion of competition as some companies will have their claims rejected, while others will still be able to use theirs (not yet assessed) claims.**

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## Way forward? - Suggestions

- Recital 26 of the Regulation opens a possibility for a modified assessment different from "gold standard":  
***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.***

### We propose:

- **A system of grading the evidence based on scientific significance should be applied during the EFSA evaluation. The Opinions should clearly state the grade of evidence and could propose appropriate claim wording e.g. by the use of appropriate language in accordance with the evidence. The publication of the Art 13.1 Opinions should be postponed in order to give EFSA sufficient time to assess all submissions following these criteria.**
- **The Opinions should be published together rather than staggered at three occasions**

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## Conclusions

- The N&H Claims Regulation has created a lot of expectations from consumers and interest from industry
- Industry welcomes a strong and transparent regulatory framework on health claims, but it should be predictable
- We suggest to focus more look on the totality of the evidence, and to include also studies demonstrating emerging science in the assessment.
- Industry does not object to a delay of the article 13.1 Opinions, if this would result in a fairer and graded procedure for assessment of submissions.
- Staggered publication of the Opinions will cause unfair competition in the marketplace.

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