EFSA - Stakeholders workshop on ANS Guidance for food additives

Introduction

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Health and Consumers

European Commission

Regulatory framework

Regulation (EC) No 1333/2008 on food additives:

- **A food additive may be included in the Union lists if it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;**

- **The Union lists shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings**

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Regulation (EC) No 1331/2008

Procedure for the assessment and authorisation of food additives

- The Commission shall seek the opinion of EFSA
- For removing substances, changing conditions of use or changing specifications, the Commission shall not be required to seek the opinion of EFSA if the updates in question are not liable to have an effect on human health.

Requires the adoption of an implementing measure (I.M.)

I.M.: REGULATION (EU) No 234/2011

Implementing Regulation (EC) No 1331/2008

- the content, drafting and presentation of the application
  - Data required for risk assessment, (scientific opinion on 9 July 2009 on data requirements for the evaluation of food additive applications)
  - Data required for risk management
- arrangements for checking the validity of applications
- type of information that must be included in the opinion of EFSA
- Applies since 11 September 2011

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I.M.: REGULATION (EU) No 234/2011

- The applicant shall take into account the practical guidance on the submission of applications made available by the Commission (Art. 3.1.)
- The applicant shall take into account the latest guidance documents adopted or endorsed by EFSA available at the time of the submission of the application (Art. 5.3.)
- In case of an application for a modification of the conditions of use or of specifications of an already authorised food additive all the data mentioned may not be required. The applicant shall submit a verifiable justification why the proposed changes do not affect the results of the existing risk assessment (Art. 2.4. & 2.5.)

I.M.: Data for risk management (Art. 7)

- For risk management additional data on technological need, efficacy, advantages and benefits for the consumer and possible misleading of the consumer are required
- Data on exposure assessment:

➔Commission advises to follow the guidance and to use the tools of EFSA.

I.M.: Validity check (Art 12)

1. Commission verifies applications:
   - Whether it falls in the scope of the food additives legislation
   - Contains all required elements
2. Commission requests EFSA to verify suitability of data and to prepare, if appropriate, an opinion
3. EFSA informs Commission about suitability of data (30 working days, 9 months timeline for opinion starts)
4. Additional data may be requested by the Commission
5. Commission may consider an application as not valid

European Commission

Commission guidance

Commission website on Food Additives, Enzymes and Flavourings - Applying for an authorisation:

http://ec.europa.eu/food/food/fAEF/authorisation_application_en.htm

Practical guidance for applicants for addresses, contact points and the relevant documents for risk assessment

Health and Consumers