Committed *since 2002*
to ensuring that Europe's food is safe

Guidance for submission for Food Additive evaluations by the ANS Panel

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Stakeholders workshop
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History (I) - Guidance by SCF

1. Guidelines for the safety assessment of food additives from 1980

2. Guidance on submission for food additive evaluations from 2001

Purpose of the SCF guidelines/guidance History (II)

efsa
European Food Safety Authority

To give guidance to petitioners and other interested parties wishing to:

- introduce new additives into the EU market,
- or seeking to revise existing provisions regulating individual additives already authorised within the EU,
- or seeking confirmation that an already approved additive made from a new source or by a new method of production is acceptable.

Why to have guidance
History (III)

In the European Union (EU), substances proposed as food additives may only be authorised for use if:

- a reasonable case of technological need can be demonstrated,
- they do not mislead the consumer
- they present no hazard to the health of consumers at the level of use proposed.

History (IV) – Guidance

- Helpful tool to design testing to demonstrate safety of a food additive

- Description of a toxicological testing

- The **aim** of toxicological testing:

  to determine whether the substance, when used in the manner and in the quantities proposed, would pose any appreciable risk to the health of consumers.

History (V) - Guidelines

- SCF guidance from 2001 outlined a framework of core toxicological tests generally required for safety evaluation of a food additive according to valid standards at the time.

- Within EFSA, **the SCF guidance 2001 was endorsed by**:
  - Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food **(AFC)** in 2003
  - Scientific Panel on Food Additives and Nutrient Sources added to Food **(ANS)** in 2008

Guidance on Food Additives
by ANS Panel

SELF TASK MANDATE

In 2009 decision to develop a new guidance on data necessary for safety assessment of a food additive

RATIONALE

- Reflect Panel's experience in evaluation of safety of food additives
- Reflect scientific developments in (food) toxicology and risk assessment
- Reflect EFSA Scientific Committee decision on/and developing of Guidances in several areas of food safety
- Addressing the animal welfare: Reduction, Refinement & Replacement (3Rs)

Terms of Reference

- **The European Food Safety Authority asked the ANS Panel to develop a guidance on submission for food additives evaluation, considering especially the following aspects:**
  - **Chemistry of the substance and specifications**
  - **Proposed uses and exposure assessment**
  - **Toxicokinetics and toxicity**
- **The ANS Panel would work in close collaboration with the Scientific Committee in order to take into account the ongoing developments on issues related to the guidance and to contribute to them.**

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TIMELINE

- **Mandate approved:** **26 March 2010**
- **Endorsed for public consultation:** **25 October 2011**
- **Public consultation:** **15 November 2011 - 15 January 2012**
- **Adoption:** **7 June 2012**
- **Publication:** **18 July 2012**

Key changes to SCF Guidance, 2001

- **Toxicological testing requirements**
  - flexible tiered approach (vs. core and additional studies in SCF 2001)
  - no standard testing requirements

- **Toxicological studies changes on:**
  - genotoxicity
  - carcinogenicity
  - reproductive toxicity

- **New Exposure assessment tool (FAIM)**
  - developed by EFSA
  - harmonisation of data submission

Time frame for applicability of a new Guidance

New EFSA Guidance replaces SCF (2001) Guidance

-EFSA recognises the timeframe necessary for development of the new additive and the need for a transition period

-EFSA recognises: new and old guidance have the same intention:

To indicate which information is necessary to demonstrate safety in use of a food additive

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Thank you for your attention