

**Stakeholders workshop on
Guidance for submission for food additive evaluations
New applications**

**21 September 2012
10h00- 17h00**

**Conference Center Albert Borschette,
rue Froissart 36, 1040
Brussels**

Agenda

Welcome and introduction 10h00-10h15

(Claudia Heppner – Head of FIP unit, EFSA) (Chair)

1. New applications

- **Introduction**
(Wim Debeuckelaere – European Commission, DG SANCO)
10h15-10h30
- **EFSA Application desk**
(Karine Lheureux – Head of Application Desk unit, EFSA)
10h30-10h50

2. Guidance for submission for food additive evaluations - Overview

- **Scope and objective of the Guidance document for food additives**
(Alicja Mortensen – Chair of the ANS Panel)
10h50 - 11h05
- **The principle of the risk assessment paradigm and the tiered approach**
(David Gott – Vice chair of the ANS panel)
11h05 - 11h30

**Coffee break
11h30-11h45**

3. Chemistry & Specifications

(Ivan Stankovic – member of the ANS panel)
11h45 - 12h15

4. Proposed uses and Exposure assessment

(Jurgen Konig – member of the ANS panel)
12h15 - 13h00

- **General considerations**
- **Introduction of the FAIM template**
- **Q&A**

Lunch break
13h00-14h15

5. Toxicokinetics (ADME)

(David Gott - Vice chair of the ANS panel)

14h15-14h45

- General considerations
- Tiered approach to toxicokinetic testing
- Q&A

6. Genotoxicity

(Riccardo Crebelli - member of the ANS panel)

15h15-15h30

- General considerations
- Tiered approach to genotoxicity testing
- Q&A

7. Toxicity (subchronic, chronic, carcinogenicity)

(Ruud Woutersen - member of the ANS panel)

14h45-15h15

- General considerations
- Tiered approach to chronic toxicity/carcinogenicity testing
- Q&A

Coffee break
15h30-15h45

8. Reproductive toxicology

(Ine Waalkens-Berendsen - member of the ANS panel)

15h45-16h10

- General considerations
- Tiered approach to reproductive toxicity testing
- Q&A

9. Other information – General discussion

(Anastasia Kesisoglou – Scientific Officer, FIP/ANS Unit, EFSA)

16h10-16h30

- Additional information on toxicological studies
- General discussion
- Q&A

10. Any other business

16h30-17h00