



# SICHERHEITSBEURTEILUNG VON ZUSATZSTOFFEN

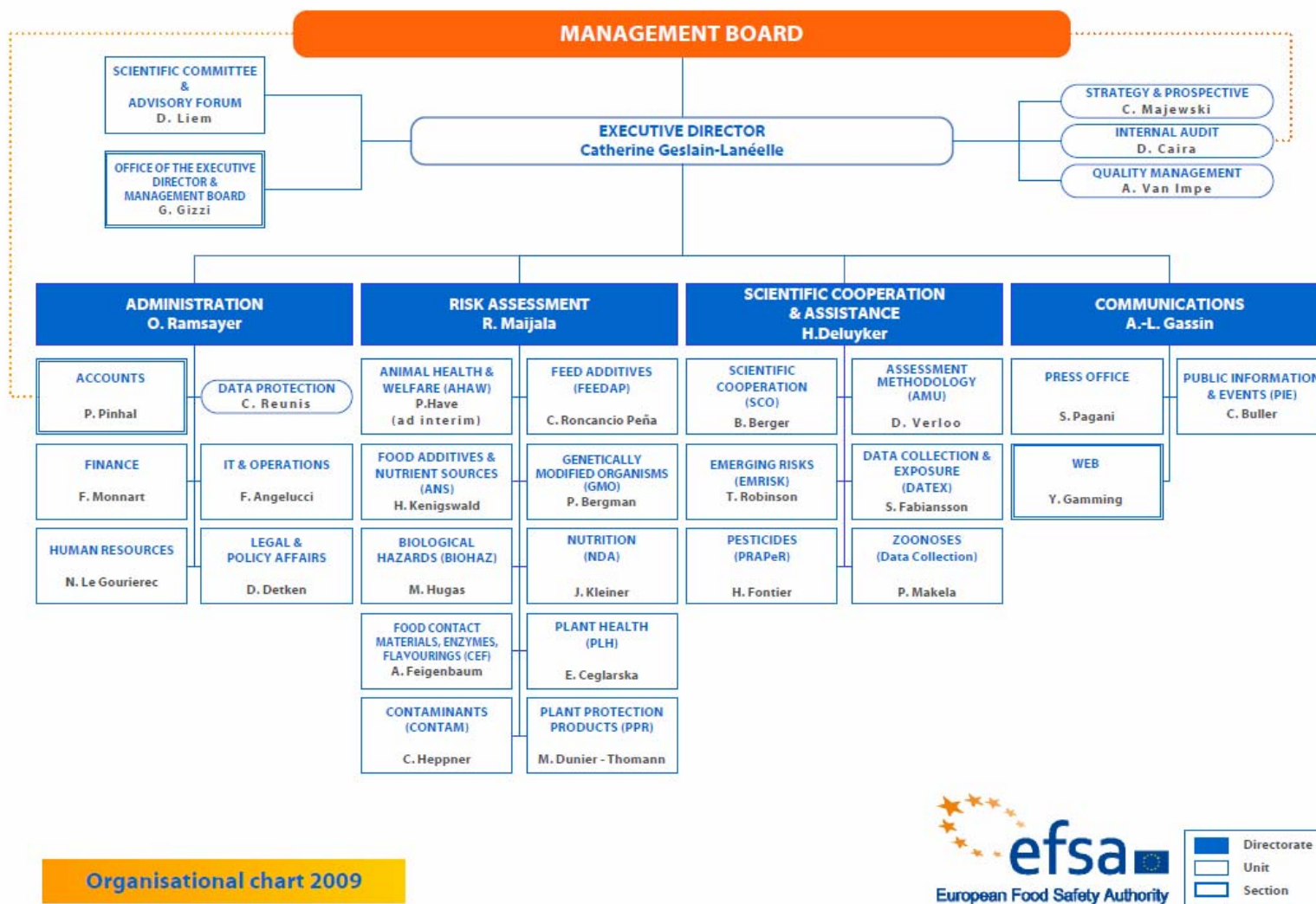
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# European Food Safety Authority

The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.



# European Food Safety Authority



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National authorities





# **SUBMISSION FOR FOOD ADDITIVE EVALUATIONS**

# || Safety Evaluation

New food additives or nutrients added to foods have to be evaluated by the EFSA ANS panel. Submissions for this evaluation have to follow the guidance on submission for food additive evaluations.



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate C - Scientific Opinions  
C2 - Management of scientific committee; scientific co-operation and networks

Scientific Committee on Food

SCF/CS/ADD/GEN/26 Final  
12 July 2001

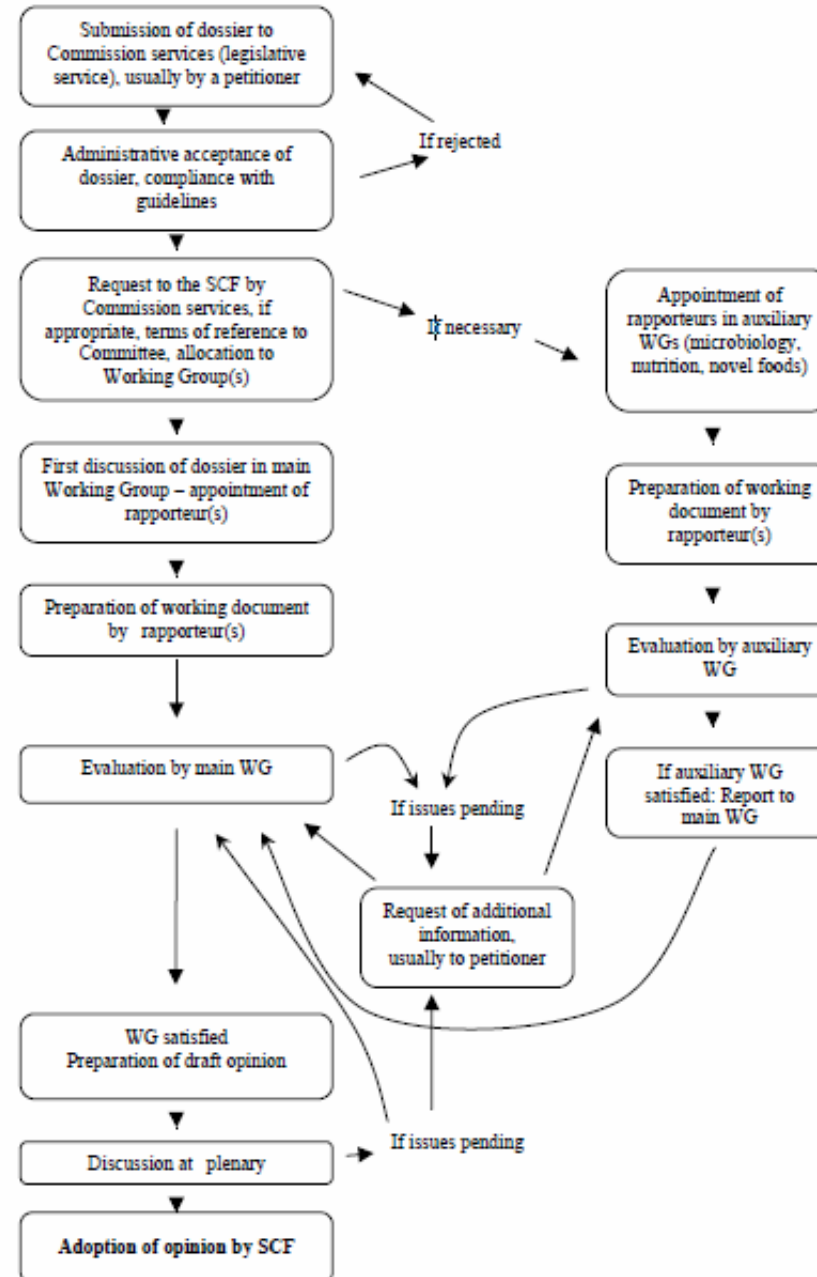
**GUIDANCE ON SUBMISSIONS FOR FOOD ADDITIVE  
EVALUATIONS  
BY THE SCIENTIFIC COMMITTEE ON FOOD**

(opinion expressed on 11 July 2001)

# Safety Evaluation

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APPENDIX I: FLOWCHART OF THE PROCESS OF EVALUATION BY THE SCF OF A DOSSIER ON A FOOD ADDITIVE



# || Safety Evaluation

## **PART I ADMINISTRATIVE DATA**

## **PART II TECHNICAL DATA**

1. Identity of substance
2. Microbiological characteristics
3. Proposed chemical and microbiological specifications
4. Manufacturing process
5. Methods of analysis in food
6. Reaction and fate in food
7. Case of need and proposed uses
8. Exposure
9. Additives produced by microbiological processes
10. Additives produced from genetically modified organisms
11. Information on national authorisations



# || Safety Evaluation

## **PART III TOXICOLOGICAL DATA**

1. General framework for the toxicological evaluation of food additives
2. Study protocols
3. Toxicological section of the dossier
  1. Core studies
  2. Other studies
4. Data reporting
5. Review of results and conclusions

## **PART IV REFERENCES AND REPORTS**

1. List of references
2. Appended papers and study reports





# || Safety Evaluation

Examples:



*The EFSA Journal (2009) 935, 1-31*

## SCIENTIFIC OPINION

**The use of taurine and D-glucurono- $\gamma$ -lactone as constituents of the so-called “energy” drinks <sup>1</sup>**

**Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food**

**(Question No EFSA-Q-2007-113)**

**Adopted on 15 January 2009**

# || Safety Evaluation

Examples:



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*The EFSA Journal* (2008) 660, 1-54

**Assessment of the results of the study by McCann *et al.* (2007) on the effect of some colours and sodium benzoate on children's behaviour<sup>1</sup>**

**Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC)**

(Question No EFSA-Q-2007-171)

**Adopted on 7 March 2008**



European Food Safety Authority

ASSESSMENT METHODOLOGY UNIT

Parma, 11<sup>th</sup> March 2008  
EFSA (2008)  
EFSA/AMU/AFCA3(2008)

**Statistical Report on the study by McCann *et al.* (2007) on the effect of some colours and sodium benzoate on children's behaviour**

# || Safety Evaluation

Examples:



EFSA Journal 2009; 7(11):1331

## SCIENTIFIC OPINION

### Scientific Opinion on the re-evaluation Tartrazine (E 102)<sup>1</sup>

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food provides a scientific opinion re-evaluating the safety of Tartrazine (E 102). Tartrazine has been previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1966 and the EU Scientific Committee for Food (SCF) in 1975 and 1984. Both committees established an Acceptable Daily Intake (ADI) of 0-7.5 mg/kg bw/day. The Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that became available since then and the data available following a public call for data. New studies included a study by Sasaki *et al.* from 2002 reporting effects on nuclear DNA migration in the mouse *in vivo* Comet assay, a study by McCann *et al.* from 2007 that concluded that exposure to a mixture including Tartrazine resulted in increased hyperactivity in 3-year old and 8- to 9-year old children and studies on neurodevelopment by Tanaka. The Panel notes that Tartrazine was negative in long-term carcinogenicity studies and that the effects on nuclear DNA migration observed in the mouse *in vivo* Comet assay are not expected to result in carcinogenicity. The Panel also concurs with the conclusion from a previous EFSA opinion on the McCann *et al.* study that the findings of the study cannot be used as a basis for altering the ADI, and additionally considered that the Tanaka study can also not be used as a basis for altering the ADI. The Panel concludes that the present database does not give reason to revise the ADI of 7.5 mg/kg bw/day. The Panel also concludes that at the maximum reported levels of use, refined intake estimates are below the ADI. The Panel concludes that Tartrazine appears to be able to elicit intolerance reactions in a small fraction of the exposed population. The Panel also notes that sensitive individuals may react to Tartrazine at dose levels within the ADI.

# || Safety Evaluation

Examples:



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*The EFSA Journal* (2009) 1082, 1-39

## SCIENTIFIC OPINION

**L-selenomethionine as a source of selenium added for nutritional purposes  
to food supplements <sup>1</sup>**

**Scientific Opinion of the Panel on Food Additives and Nutrient Sources  
added to Food**

**(Question No EFSA-Q-2005-103, EFSA-Q-2006-195, EFSA-Q-2006-196,  
EFSA-Q-2006-304)**

**Adopted on 14 May 2009**



# DANKE FÜR IHRE AUFMERKSAMKEIT!

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