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

Guidance for submission for Food Additive evaluations

Welcome & introduction

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Stakeholders workshop on "Guidance for submission for food additive evaluations", Brussels, 21st September 2012

Workshop on new guidance for submission for food additive evaluations

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WELCOME!

47 participants from stakeholder organisations (BEUC, CEFIC, ELC, FoodDrinkEurope, NATCOL,), European Commission, experts from the Panel on Food additives and nutrient sources added to food (ANS) and EFSA staff

Introduction – external evaluation

- EFSA´s second external evaluation report was recently published.
- Key assessment criteria: relevance, efficiency and effectiveness-added value.
- The evaluation underlines that EFSA operates to the highest standards, particularly with regard to the quality of scientific opinions and risk assessment methodologies.
- Independence, transparency and openness are core values upon which the Authority is built. The review acknowledges that our culture and safeguards in this respect are among the most rigorous of any comparable organisation.

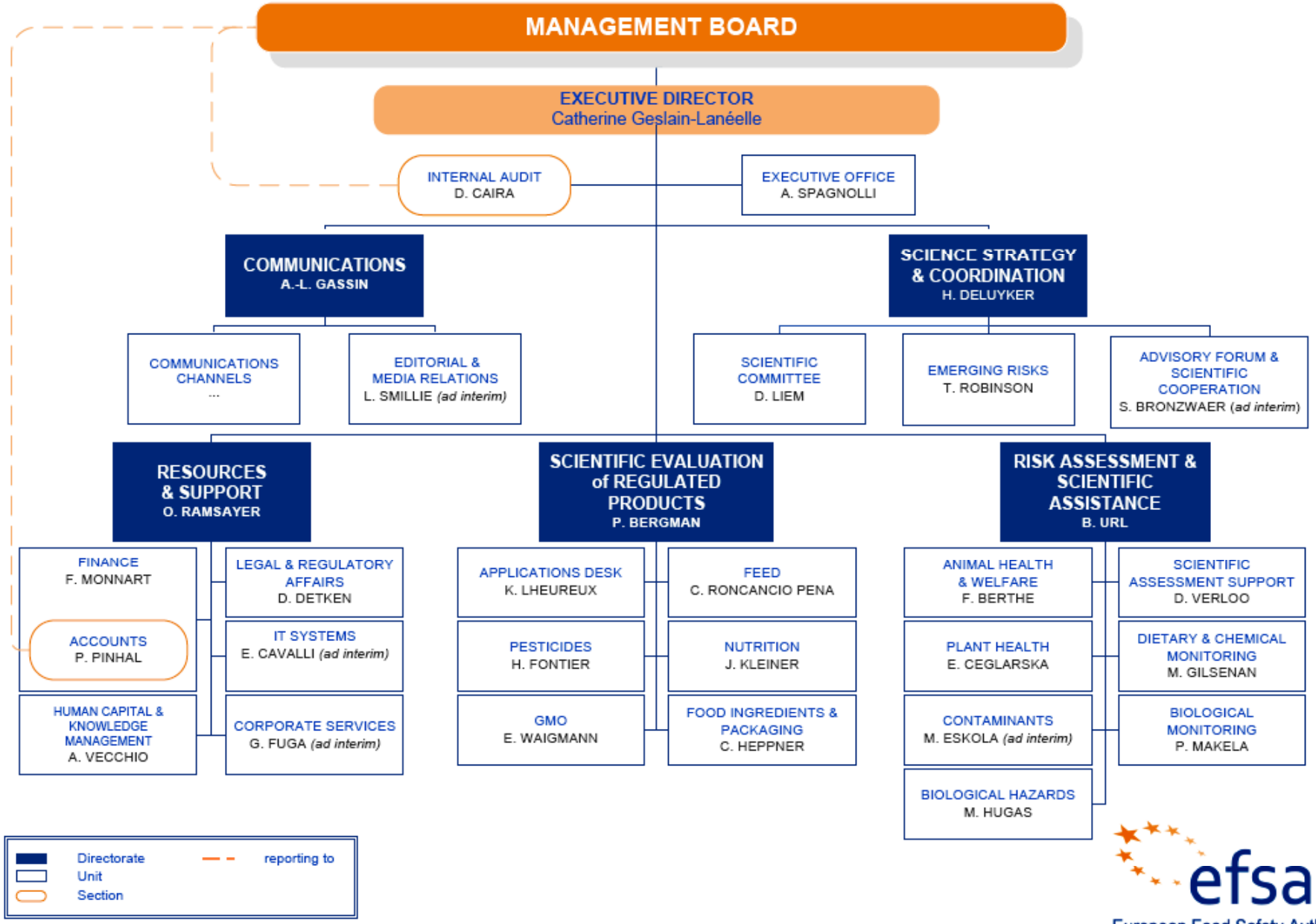
Introduction – external evaluation

- The evaluation recommends that EFSA should
  - enhance transparency in some decision-making processes;
  - build better links with Member States;
  - increase its planning and prioritisation capacity;
  - improve the clarity of its communications;
  - develop its data collection practices.
- These proposals will make an important contribution to shaping future development of the organisation.
- The follow up process with EFSA´s key stakeholders (staff, management board, advisory forum, scientific committee, stakeholder platform) is currently ongoing.

Introduction – transparency

Todays workshop on “Guidance for submission for food additive evaluations” is part of EFSAs activities to outline in a transparent manner the steps and content of the new guidance document for the submission for food additive evaluations to its external stakeholders.

Organisational Structure on 01/07/2012



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REPRO – Application areas

Food & feed regulatory areas	Scientific Panel	Supported by
Food additives Nutrient sources	Food additives & nutrient sources added to food (ANS)	FIP
Flavourings Enzymes Food contact material	Food Contact Materials, Enzymes, Flavourings & Processing Aids (CEF)	
Feed additives	Additives & Products or Substances used in Animal Feed (FEEDAP)	FEED
Genetically Modified Organisms	Genetically Modified Organisms (GMO)	GMO
Health claims Novel food Infant formulae Food allergies	Dietetic Products, Nutrition & Allergies (NDA)	NUTRITION
Plant Protection Products: active substances (PPP) and Maximum Residual Levels (MRL)	Plant Protection Products & their Residues (PPR)	PESTICIDES

FIP unit

- Food Ingredients and Packaging Unit (FIP) was established in January 2012 as a result of merging the former ANS and CEF Units.
- The FIP unit facilitates the workprogramme of ANS and CEF Panels and its 15 working groups in order ensure a timely delivery of risk assessments/safety evaluation in the area of food ingredients and packaging. The major areas of activities: chemistry and specifications, recycling material, food contact material, food processing, food enzymes, food additives, food colours, and nutritional sources.
- For 2012 the proposed revised work programme for activity 2 forsees 47 outputs: 12 by ANS Panel (mainly re-evaluation of food additives but also new food additive applications and food additive guidance document) and 35 by CEF Panel.

Workshop on guidance for FAs

OBJECTIVES

- Introdution of the EFSA Application Desk and the workflow for food additive (FA) applications.
- Present the new guidance document for submissions for food additive evaluations.
- Discuss the latest scientific developments and principles in risk assessment when designing a testing strategy prior to submission of applications.

Outline of the meeting

PART I: **NEW APPLICATIONS**

- Introduction
- EFSA Application desk

PART II: **GUIDANCE DOCUMENT - Scope and objective**

- Introduction
- Risk Assessment paradigm & Tiered approach

PART III: **GUIDANCE DOCUMENT - Technical information**

- Chemistry and Specifications
- Proposed uses & Exposure assessment
- Toxicological studies
  - Toxicokinetics
  - Toxicity
  - Genotoxicity
  - Reproductive toxicity
- Other information & General discussion




Thank you for sharing your view and wishing a fruitful and open discussion