

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



European Food Safety Authority

# **Guidance on food additives Chemistry & Specifications**

**Ivan Stankovic**

**Member of the ANS Panel**

**Stakeholders workshop  
21 September 2012, Brussels**

## OBJECTIVE

Identify the food additive, potential hazards (i.e. impurities) from its manufacture, and define the material tested.

## IDENTITY OF THE SUBSTANCE (I)

- **Single substances** (*sorbic acid, sodium ascorbate, glycerol...*)
- **Simple mixtures** (*sorbitol syrup, lecithins...*)
- **Complex mixtures** (*mineral hydrocarbons, beeswax, shellac...*)
- **Polymers** (*xanthan gum, pectins, modified starches...*)
- **Additives derived from botanical sources** (*steviol glycosides, rosemary extracts...*) (Guidance on Botanicals – EFSA, 2009)
  - Chemical composition of plant-derived FA (i.e. concentrations of constituents)
  - Max. levels for microorganisms, mycotoxins, pesticide residues, PAH...

## IDENTITY OF THE SUBSTANCE (II)

- **Nanomaterials** (Guidance on ENMs – EFSA, 2011)
  - Characterisation and identification of ENMs and non ENMs
- **Substances of microbial origin**
  - Info on microbial origin, QPS, production process, etc.
  - Additives of GMM origin/derivation (Guidance on GMMs – EFSA, 2011)

## SPECIFICATIONS

**Objective:** defining the identity and the purity of the food additive

- Adequate chemical characterisation
- Analytical info on at least 5 independently produced batches
- Submission in EU format (Appendix C) or other internationally recognised format
- Rationale for proposed specifications

## ❖ Specifications for additives derived from botanical sources

(Guidance on Botanicals – EFSA, 2009)

- Identity of the article of commerce, purity, validated methods, etc
- Characterisation of the composition for each production process

**\*\* Full description (100%) of the material including % of material 'not identified'**

- **MANUFACTURING PROCESS**

- method of manufacture, production controls, quality assurance
- other info on:
  - chemically-synthesised substances
  - botanical/animal/microbial-derived substances
- **confidential & non-confidential descriptions** to be provided
- existing vs new manufacturing methods

- **METHODS OF ANALYSIS IN FOOD**

- fit-for-purpose validated analytical methods  
(applicable to all food categories)
- additives made from or containing ENMs  
(EFSA Guidance on ENMs, 2011)

- **STABILITY OF THE SUBSTANCE, AND REACTION & FATE IN FOOD**

- chemical/physico-chemical stability of food additive
  - under the storage conditions
  - In processed food
- degradation products (nature, reactivity, interactions)
- technologically intended reactions in food and the resulting products