



EFSA's current role on Novel Foods

by Bevan Moseley, Chair of the NDA Panel

Regulation (EC) 258/97 concerning novel foods and novel food ingredients

1. To harmonise national rules
2. To ensure that novel foods and food ingredients are subject to a single safety assessment through a Community procedure in order to protect public health
3. Novel foods and food ingredients are defined as those which have not hitherto been used for human consumption to a significant degree within the Community (in practice before 1st May 1997)

Categories of novel foods

1. Foods (and food ingredients) containing or consisting of genetically modified organisms (GMOs)
2. Foods produced from but not containing GMOs
3. Foods with a new or intentionally modified primary molecular structure
4. Foods consisting of or isolated from microorganisms, fungi or algae
5. Foods consisting of or isolated from plants and food ingredients isolated from animals except for
6. Foods to which has been applied a production process not currently used and where that process gives rise to significant changes in the composition or structure of the foods which affect their nutritional value, metabolism or level of undesirable substances

The safety assessment

Foods and food ingredients falling within the scope of the Regulation must not:

- present a danger for the consumer
- mislead the consumer
- differ from foods which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer

SCF Guidelines 1997

Guidelines of the Scientific Committee for Foods (SCF) concerning the scientific aspects and the presentation of information necessary to support NF applications

97/618/EC: Commission Recommendation of 29/07/97

Classes of Novel Foods

1. Pure chemicals or simple mixtures
2. Complex NF
3. GMO classes (superceded by GMO Regulation)
4. Ditto
5. Ditto
6. Novel processes

Data Requirements

- I. Specification of the NF
- II. Effect of the production process
- III. History of the organism used as the source of the NF
- IV. to VIII Related to GMOs
- IX. Anticipated intake/extent of use of the NF
- X. Previous human exposure to the NF or its source
- XI. Nutritional information
- XII. Microbiological information
- XIII. Toxicological information

Current Application Procedure

Manufacturer:

- ➔ Member State (MS): Initial assessment (3 months)
- ➔ all other MSs (26 now) for Comments/Concerns/Objections (60 days)
- ➔ EFSA: additional safety assessment and scientific opinion
- ➔ European Commission & MSs: Authorisation decision.

- Phytosterols (in a number of foodstuffs)
- Noni juice (juice of the fruits of *Morinda citrifolia*)
- Ice structuring protein