



# *Review of the ‘Novel Food’ Regulation*



# Background

## ● Article 14 - Novel Food Regulation

No later than five years from the date of entry into force (15 May 2002), and in light of the experience gained, the Commission shall forward a report on the implementation of the Regulation to the European Parliament and the Council.

## ● GM-food

COM(2001) 425 of 25 July 2001 on genetically modified food and feed. Parliament's opinion (1st reading) delivered in July 2002. Council reached political agreement in November 2003. Parliament's opinion (2nd reading) expected in July 2004.



# What is a 'novel food' ?

## ● Food that:

- were not used for human consumption to a significant degree,
- within the Community,
- before 15 May 1997,

## ● and which fall within one of the following categories:

- with a new or intentionally modified molecular structure;
- consisting or isolated from plants and ingredients from animals;
- isolated from, micro-organisms, fungi or algae;
- a new production process resulting in significant changes in the composition or structure of the food, which affects its nutritional value, metabolic effect or level of undesirable substances.



# What is not a 'novel food' ?

## ● Food that:

- were used for human consumption to a significant degree within the Community before 15 May 1997;
- are outside the scope ('novel food' categories);
- are exempted from the Regulation (i.e. additives, flavourings and extraction solvents);
- new food formulation - but with familiar ingredients.

## ● Discussion:

- substances used as 'food supplements';
- exotic fruits, nuts, etc.



# Criteria for authorization

## ● Novel food must not:

- present a danger for the consumer; or
- mislead the consumer; or
- differ from foods or food ingredients that they are intended to replace to an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

## ● Discussion:

- compare with (political agreement on) GM food : 'danger' v. 'unacceptable risks';
- 'mislead' the consumer ?



# Procedure: notification

## ● **Products eligible:**

those which are 'substantially equivalent' to existing foods as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained.

## ● **Assessment:**

on the basis of the scientific evidence available and generally recognised or on the basis of an opinion from a MS competent authority.

## ● **Assessment:**

notification by the applicant to the Commission, who informs the Member States.



# Procedure: authorization

## ● **First phase:**

- application to and initial assessment by the competent authority of a Member State (six months)
- Member State informs the Commission

## ● **Second phase:**

- Commission circulates initial assessment;
- other Member States and Commission may raise objections or make comments (two months)



# Procedure: Community decision

## ● If objection raised:

- SCF - EFSA may be asked for opinion, if 'public healthy' is at stake;
- opinion of Standing committee on the food chain;
- decision by the Commission.

## ● Discussion:

- individual v. general decisions
- maintain 'substantial equivalence' ?
- streamline procedure...



# Novel food in practice

## ● Authorized:

- phospholipids from egg yolk;
- yellow fat spreads with added phytosterol esters;
- dextran produced by *Leuconostoc mesenteroides*;
- pasteurised fruit-based preparations produced using high pressure pasteurisation;
- trehalose;
- coagulated potato protein.

## ● Not authorized:

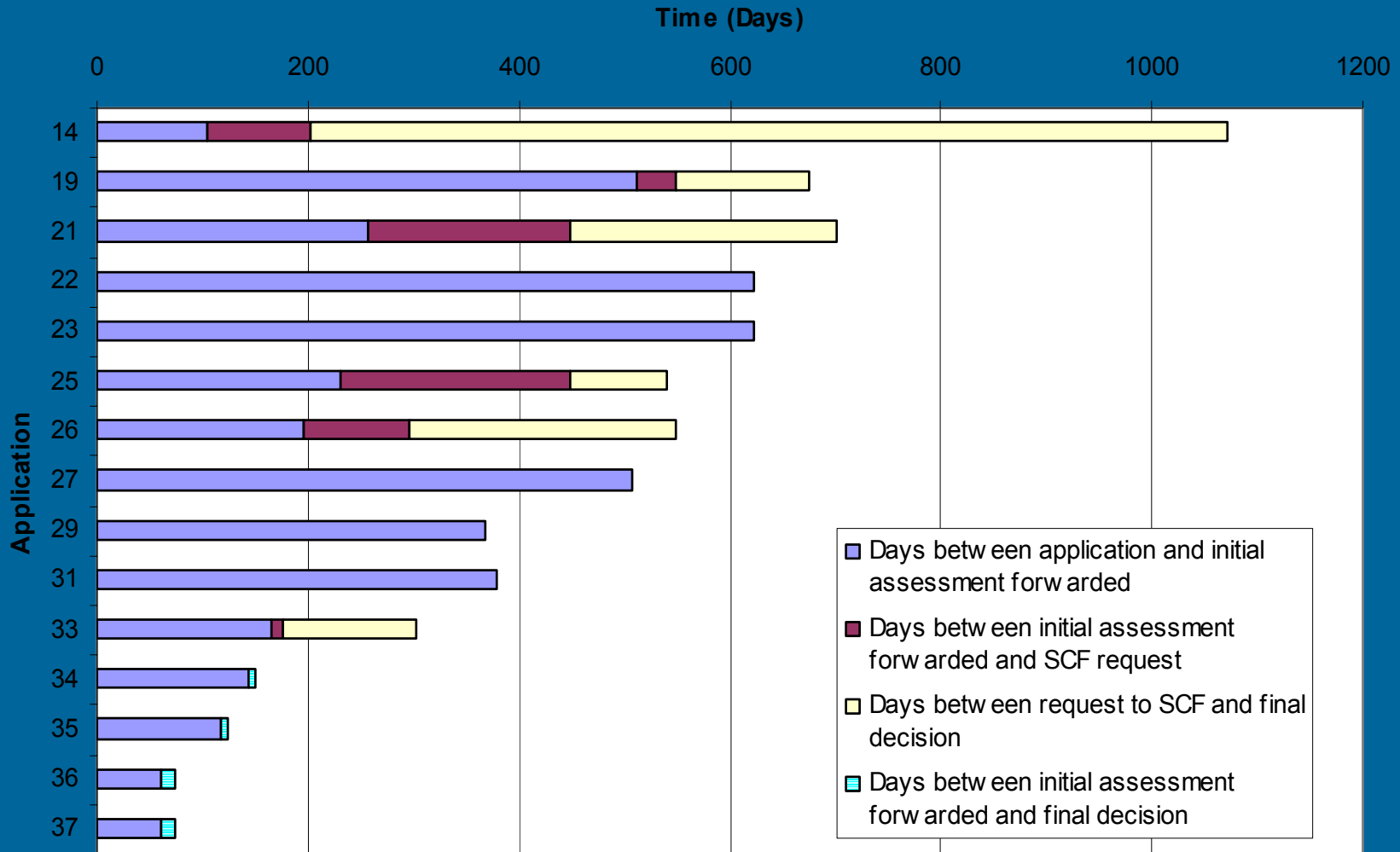
- *Stevia rebaudiana* Bertoni, plants and dried leaves;
- Nangai (Ngali) nuts (*Canarium indicum* L.).



# EUROPEAN COMMISSION

## Health and Consumer Protection DG

**SANCO.D.4**  
Food Law &  
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## Main issues for reform

- **Scope**
- **Different categories of 'novel food'**
- **Different procedures / decisions**
- **Centralised Community procedure**
- **Protection of data - market exclusivity**
- **Labelling**
- **Transparency, public information and confidentiality**