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# **Novel foods in the EU Challenges & Changes**

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# Regulation (EC) 258/97

Introducing a safety assessment for 'novel' products entering the EU

## Scope

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- 1997** ■ **Initial scope**
- Foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC
  - Foods and food ingredients produced from, but not containing, genetically modified organisms
- 2002** ■ **GMO removed from the scope (separate legislation)**
- 2011** ■ **'Revised' scope**



# Regulation (EC) 258/97

- **Current scope** (4 categories)
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- Foods and food ingredients with a **new or intentionally modified primary molecular structure**
  - Foods and food ingredients consisting of or isolated from **micro-organisms, fungi or algae**
  - Foods and food ingredients consisting of or isolated from **plants** and food ingredients isolated from **animals**, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use
  - Foods and food ingredients to which has been applied a **production process not currently used**, where that process gives rise to **significant changes in the composition or structure** of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.



# Regulation (EC) 258/97

Applies to the placing on the market of foods and food ingredients which have not been used for human consumption to a **significant degree** within the EU before 15 May 1997 (date of entry into force) and belonging to one of the 4 categories

(excluding food additives, flavourings, processing aids...)

**Draft Guidance Document on the Implementation of Regulation (EC) N° 258/97  
as regards the concept  
« Human Consumption to a Significant Degree »**

- ▶ **To consider: documentation, geographical aspects, quantity of use, intended purpose, specific population groups / context of use, use of other forms / parts of a food / new technologies, availability (how, where and for how long)...**

# Examples (novel or not)

## NOT NOVEL

- A change of recipe
- A change to the production process (e.g. switch to production under a protected atmosphere)
- GMO
- Using a 'new' flavouring or additive

## GREY ZONE

New  
extraction  
or  
isolation  
method

New extract

?

## NOVEL

- Same use of an ingredient authorised for Novel Foods
- Different use of an ingredient authorised for Novel Foods (e.g. phytosterols in a soft drink)
- Use of an ingredient in PARNUTS, only used in food supplements prior to May 1997
- Use of a technological additive, authorised before May 1997, for its nutritional purposes



# Procedures

A food/food ingredient not used for human consumption to a significant degree in the EU before 15 May 1997

Substantially equivalent to existing foods ?

YES

NO

## SIMPLIFIED PROCEDURE

Substantially equivalent as regards:

- composition
- nutritional value
- metabolism
- intended use
- content of undesirable substances

## FULL PROCEDURE

Initial evaluation by the Member State

If one of the other 26 Member States objects

EFSA +  
Commission Decision



# Revision of the novel foods Regulation

- Proposal adopted in January 2008 by the Commission
- To be reviewed and adopted by the Council and European Parliament (co-decision)

**Novel food =** food that was not used for human consumption to a significant degree in the EU before 15 May 1997, including:

**food of animal origin (non-traditional breeding technique not used for food production within the Union before 15 May 1997), and food derived from the offspring of these animals;**

**food of plant origin (non-traditional breeding technique ...) if the non-traditional breeding technique applied to a plant gives rise to significant changes in the composition or structure of the food, which affect its nutritional value, how it is metabolised or the level of undesirable substances;**

**food (new production process...) if the production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, how it is metabolised or the level of undesirable substances;**

...

## Revision of the novel foods Regulation

...

food containing or consisting of engineered nanomaterials;

traditional food from a third country; and

food ingredients used exclusively in food supplements within the Union before 15 May 1997, if they are to be used in foods other than food supplements.



# Revision of the novel foods Regulation

- Work to define human consumption to a significant degree is ongoing
- Procedure for collection of information regarding the use of a food for human consumption (+ NF catalogue)
- Approved novel foods will be included in a Community list (no exclusivity)
- **Simplified procedure for traditional food from countries outside the EU  
→ notification (4 months) accompanied by documented data demonstrating the history of safe food use + SPECIFIC LIST**
- Possibility for data protection in justified cases (↔ generic authorisations)  
→ for newly developed scientific evidence and proprietary scientific data
- Nanotechnology (expected guidelines) and cloning (EC wants separate legislation) under discussion

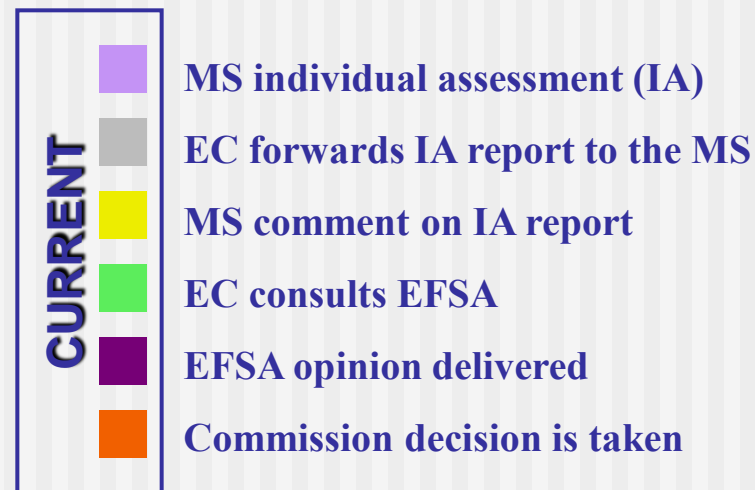


# Current versus proposed timing

(in average days)



## Current timing in practice



## Proposed theoretical timing?

- ! centralised EFSA assessment (no initial MS assessment)
- timelines (9 months for EFSA, 9 months for Commission draft Regulation)

In practice...?

# Expectations – less barriers to innovation?



- **Centralised authorisation procedure**
- **Simplified procedure for traditional ingredients from 3rd countries**
- **Increased transparency (community list of novel foods)**



- **Scope of the decisions is general**
- **Data protection**
- **Novel food catalogue**



- **No clarification on terms such as: significant degree and one generation?**
- **Ingredients used in food supplements before May 1997 => full NF approval for other food applications**



# Issues for Fruit Juices

The source / raw material

Stevia



Noni fruit – approved in 2002



Camu camu



Baobab dry fruit and pulp



Nangai nut

Pitanga



Rambutan

Jack fruit



Mangosteen – not novel (peel issue)





# Issues for Fruit Juices

**The process**

**Less an issue – if the final product is not different**

**Any process not used before 1997**

**Significant changes to the final product (e.g. molecular level)**

**Process + Final product different**

**Process + Raw material (peel, seed etc.)**



# Questions?

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# Thank you

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