NOVEL FOODS in the European Union

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OUTLINE

1. Definition and EFSA's role
2. Current procedure
3. New Regulation – new procedures
4. Traditional foods from 3rd countries
5. Other novel foods

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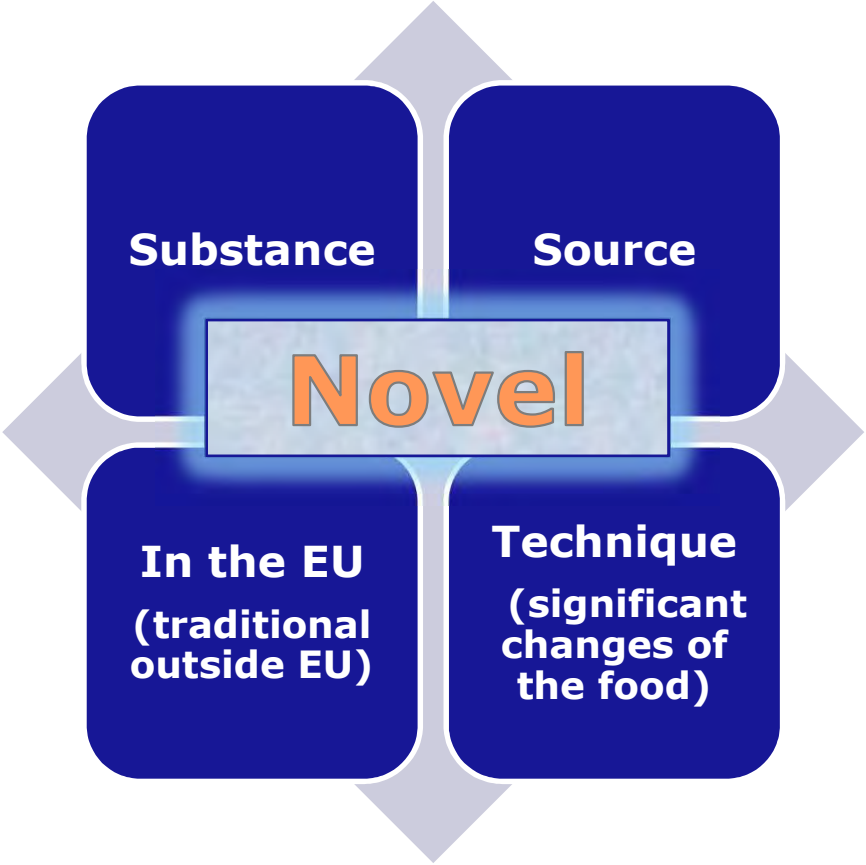
WHAT IS A „NOVEL“ FOOD IN THE EU?

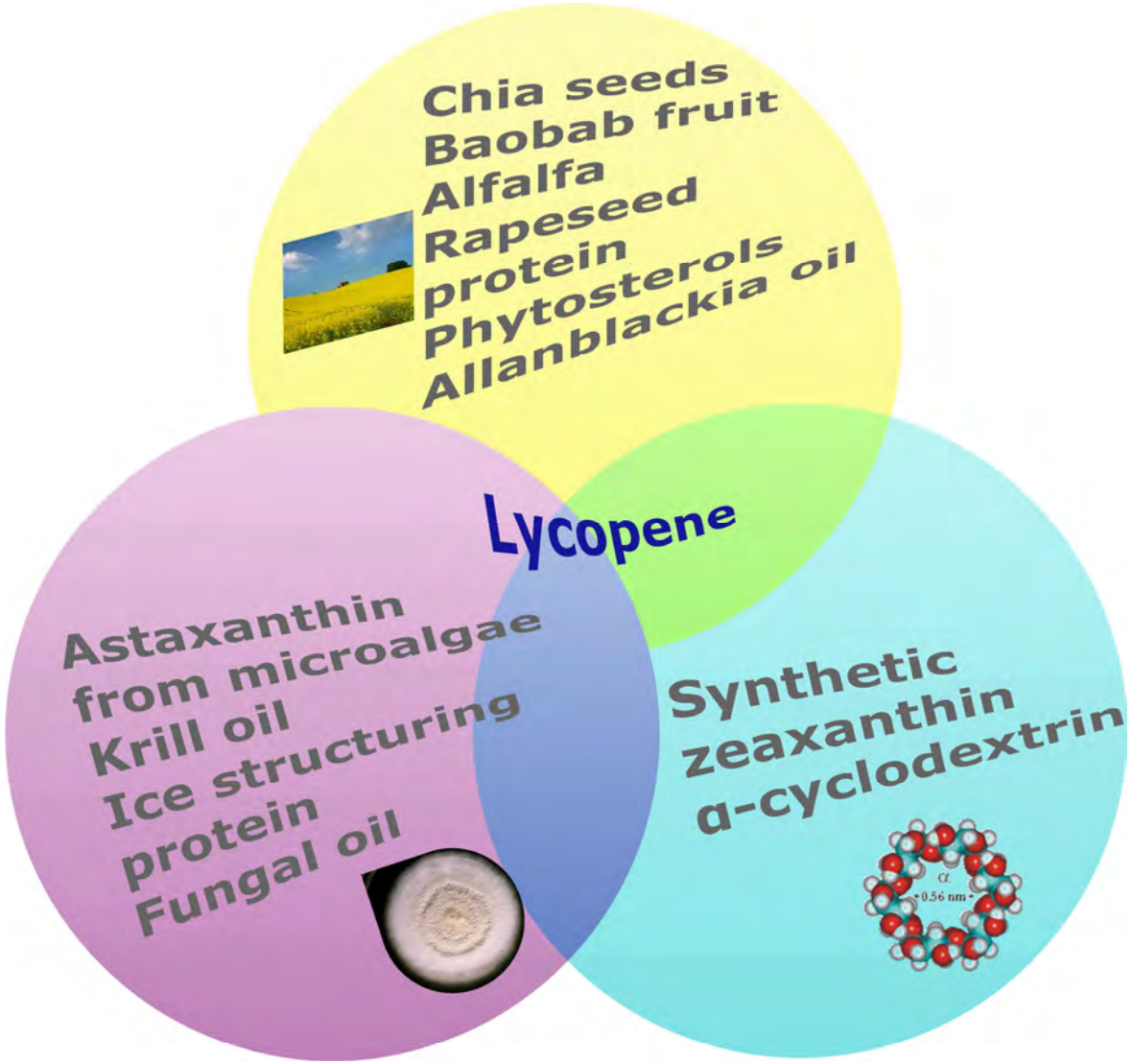
Regulation (EU) 1997/258 :

…a food (ingredient) that was *not consumed to a significant degree by humans in the EU prior to 15 May 1997.*

Regulation (EU) 2015/2283: definition unchanged



EXAMPLES FROM THE PAST



EFSA'S TASKS ON NOVEL FOODS

Not

- **Legislation**
- **Regulatory decisions**
  - classifications
  - authorisations
  - conditions of authorisations
  - labelling
  - food inspections
  - sanctions

Yes

- **Scientific advice**
- **Guidelines**
- **Safety assessment**
  - risk assessment
  - dossiers food/feed
- **Communication**
  - risk managers
  - stakeholders
- **Collaboration**

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CURRENT PROCEDURE: REGULATION (EU) 1997/258

Member State

↓

EC

↓

EFSA

↓

EC

Initial assessment (3 months)

If objections from other MSs (+2 months)

Scientific assessment

(2/3 of applications)

- **Extensive and time consuming authorisation procedure**
- **Complaints from non-EU countries**

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Scope

Applies to the placing of novel foods on the EU market (enter into force 1 January 2018)

It does not apply to

- **genetically modified foods** (Regulation (EC) 1829/2003)
- **foods when, and in so far as, they are used as:**
  - **food enzymes** (Regulation (EC) 1332/2008)
  - **food additives** (Regulation (EC) 1333/2008)
  - **food flavourings** (Regulation (EC) 1334/2008)
  - **extraction solvents** (Directive 2009/32/EC)

Scope

It does apply to

- food with a new/intentionally modified molecular structure;
- food consisting of, isolated from, or produced from microorganisms, fungi or algae;
- material of mineral origin;
- food produced from plants or their parts (with some exceptions);
- food from animals (with some exceptions)

Scope

It does apply to

- food from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae
- food resulting from a new production process (>1997)
- food consisting of engineered nanomaterials
- vitamins, minerals and other substances from a new production process or containing engineered nanomaterials;
- new uses for foods used exclusively in food supplements within the Union before 1997

WHAT IS NEW?

- Applications to the Commission
- Evaluation by EFSA - 9 *months*
- Notification for traditional foods from third countries. Member States and EFSA have *4 months* to present duly reasoned safety objections.
- Time limits for each step

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TRADITIONAL FOODS FROM THIRD COUNTRIES?

- *Novel* for EU (1997)
- Derived from microorganisms, fungi or algae; plants or animals or cell/tissue cultures
- Must derive from primary production (processed or unprocessed)
- Must have a '***History of safe food use in a third country***'
  - compositional data
  - experience of continued use (>25 years)

NEW AUTHORISATION PROCESS

Traditional Foods from Third Countries

Notification (Article 14)

European Commission (EC)

EU Member States (MS) & EFSA 4 months for objections

Immediate (generic) authorisation ← **no** ← **Objections**

↓ **yes**

Application[1] (Article 16)

European Commission[2]

Information to MS

EFSA (6 months, Panel Opinion)

Applicant & MS

EC

Endorsement by MS

Update of Union list [3]

[1]Applicant can submit an application = notification dossier plus documented data relating to objections (Applicant can withdraw its application at any time)

[2] Generic authorisation

EC MANDATE FOR EFSA GUIDANCE

Regulation (EU) 2015/2283 → EFSA shall consider:

Is **history of safe food use** in a third country substantiated?

Do composition and conditions of use **pose a safety risk?**

Nutritionally disadvantageous for the EU consumer?

EFSA was asked to prepare two guidance documents for:

- **notifications of traditional foods, and**
- **applications for novel foods.**

EFSA GUIDANCE ON Traditional Foods

General principles

Consult:

- EFSA Guidance on Traditional Foods
- Regulation (EU) 2015/2283
- Future EU guidelines and provisions
- Other relevant guidance documents from EFSA

- notification ≠ application
- applicant to provide all of the available data
- identification of data should be performed and documented
- analyses/tests should be performed in a competent facility
- justify deviations from requirements
- confidential treatment → European Commission

EFSA GUIDANCE ON TRADITIONAL FOODS

1. **Description of the Traditional Food**
2. **Production process**
3. **Compositional data**
4. **Specifications**
5. **Data from experience of continued use for at least 25 years**

"History of safe food use"

6. **Proposed conditions of use for the EU market**
   - 6.1. Target population
   - 6.2. Proposed uses and use levels
   - 6.3. Intended role in the diet
   - 6.4. Precautions and restrictions of use

SCIENTIFIC DATA - EXPERIENCE OF CONTINUED USE

5. Data from experience of use

5.1. Experience of food use in a third country

- Extent of use
- Characteristics of the population group(s) of consumers
- Role of the Traditional Food in the diet
- Precautions for the preparation and restrictions of use
- Human data (if available)

www.wien.gv.at

Type of data: include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on cultivation, harvesting, sales, trade, cookbooks, recipes, anecdotal data.

5.2. Other information (from non-food uses)

WHY ARE TRADITIONAL FOODS ASSESSED…

…while the safety of the large majority of foods in the EU was never assessed?

- **Compositional data** are available for basically all foods in the EU
- Information on **the history of use**, such as:
  - processing, preparation, handling, precautions,
  - consumer groups (all, only adults, children etc.),
  - intake levels;
- Consumers without experience and without this information may be at risk.

- **Specifications** are elementary for control purposes.

ASSESSMENT BASED MAINLY ONLY ON

Compositional data and "history of use"?

Assessed under Regulation (EU) 258/1997:

- **Baobab dried fruit:** favourable UK Opinion; Member States agreed
- **Chia Seeds**: insufficient data in 2005; favourable EFSA Opinion in 2009
- ***Arracacia xanthorrhiza:*** insufficient data on description, composition and production process; no response from applicant

https://www.wikimedia.org

CHIA (*SALVIA HISPANICA* L.) SEEDS

Opinion on the safety of 'Chia seeds (Salvia hispanica L.) and ground whole Chia seeds' as a food ingredient

European Food Safety Authority (EFSA)

First published: 3 April 2009 Full publication history

Composition and production data

- ***Labiatae*** family
- **proximate parameters** (%): dry matter 92-96, protein 15-25, fat (30-33), carbohydrate 26-41, fibre (18-30);
- **fatty acid profile**: ≈ 60 % α-linolenic acid > chia seeds a particularly rich source of omega-3 fatty acids;
- analyses of **minerals** (K, P, Ca, Fe, Mg, Zn, Se, Cu) and **vitamins** (Vit A, C, E, B1, B2, niacin, B6);
- Information on possible use of **herbicide** (trifluralin), **heavy metals, mycotoxins;**
- Information on **harvesting, mechanical cleaning of seeds, quality control system** in place.

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History of (food) use

- **Use of Chia seeds by Aztecs; porridge** or made into **cakes**; beverage "**Chia fresca**", (water soaked seeds, flavoured with fruit juice).
- From 2000 onwards: **increased consumption** in North America, Asia, Australia (information provided on the tonnage, company, type of food: bars, seeds, chips, cereals, supplements).
- Two available **human studies** to investigate suposed beneficial effects → no adverse effects observed.
- **Non food use**: four feeding studies with laying hens & broilers.

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NEW CENTRALISED AUTHORISATION PROCESS

Novel Foods (Article 10)

Application[1] or EC initiative

European Commission (EC)[2]

Publicly available summary	Information to EU Member States (MS)	EFSA not consulted[4]	EFSA (Panel Opinion)	
		EC	Applicant & MS	EC
		Endorsement by MS		Endorsement by MS
		Update of Union list		Update of Union list[3]

[1]Applicant may withdraw its application at any time

[2]COM may terminate the update at any stage

[3]Generic authorisation, except if authorisation is based on protected data

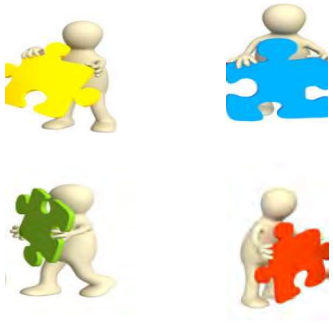
[4]Whether the update is not liable to have an effect on human health

NEW EFSA GUIDANCE ON NOVEL FOODS: APPROACH

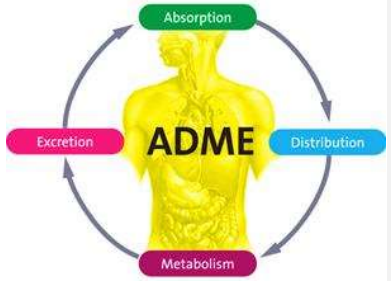
- **Starting point: Scientific Committee on Food Guidance from 1997**
- **Scientific Colloquium** *("What's new on Novel Foods", 2009)*
- **Experience gained since 1997**
- **Making use of existing EFSA Guidance** *(horizontal guidance documents and harmonisation with other guidance documents, e.g. guidance for food additives, where applicable).*
- ***In-house* consultation with other Panels**
- **Public consultation on website and in stakeholder event**
- **Info session and webinar planned for spring 2017**

NEW EFSA NOVEL FOOD GUIDANCE

1. Administrative data
2.1. Introduction
2.2. Identity of the novel food
2.3. Production process
2.4. Compositional data
2.5. Specifications
2.6. History of use of the novel food and of its source
2.7. Proposed uses and use levels and anticipated intake
2.8. Absorption, distribution, metabolism, and excretion
2.9. Nutritional information
2.10. Toxicological information
2.11. Allergenicity
2.12. Concluding remarks
3. Annexes, References



2.8 ADME

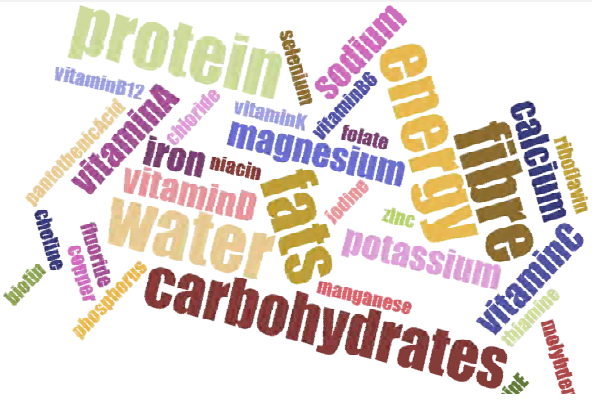


- **Critical** for the development of appropriate toxicity testing .
- **Negligible absorption:** may justify not undertaking higher tiered toxicological studies.
- **Single substances and simple mixtures:** tested according to the same principles as those applied to food additives.

  May not be feasible for all components of **complex mixtures and whole foods** → to be provided for toxicologically relevant constituents.
- Kinetic data may also be relevant for **nutritionally significant constituents**

2.9 NUTRITIONAL INFORMATION

- **Should not be nutritionally disadvantageous for consumers at the proposed conditions of use**
  - Novel food is intended to **replace another food**
  - **Novel production process** is applied
- Information required on **nutrient composition** and potential effects arising from production process
- **Anti-nutrients**, **interaction with nutrients**
- **Studies** (in vitro, animal, or human) may be needed to address possible effects of anti-nutrients and interaction



2.10 TOXICOLOGY

- **Tiered toxicity testing approach** as the default approach

  It integrates the core areas of:

  - toxicokinetics,
  - genotoxicity,
  - repeated dose toxicity testing, and
  - reproductive and developmental toxicity.

- **Additional studies** may be needed:
  - immunotoxicity,
  - hypersensitivity and food intolerance,
  - neurotoxicity,
  - endocrine activity, and
  - mechanisms and modes of action.

Deviations from this approach and/or its non-applicability should be reasoned

2.11 ALLERGENICITY

Minimum requirement: protein content, its source, production process, available experimental and human data.

- No protein → very low allergenic potential
- Contains proteins → have allergenic potential (default assumption for novel foods)
  - Further testing:
    - (a) protein_analyses
    - (b) human testing

Potential or proven allergenicity is not a reason to say that a novel food is unsafe

- Separate legislation for food allergen labelling exemption.

AND WHAT ABOUT INSECTS?

In the absence of significant consumption data (<'97) in the EU:

- Under the current Regulation (EU) 258/1997: novel food
- Under the new Regulation (EU) 2015/2283: novel food

=> but many insects have a history of food use outside the EU and may be notified as traditional foods from third countries.

FIGURE 2.1
Recorded number of edible insect species, by country

Source: Centre for Geo Information, Wageningen University, based on data compiled by Jongema, 2012.

EFSA OPINION ON INSECTS

Risk profile related to production and consumption of insects as food and feed

- Biological hazards
- Chemical hazards
- Environmental hazards
- Farmed insects
- As food and feed
- Entire chain


THANK
YOU
GRACIAS
ARIGATO
SHUKURIA
GOZAIMASHITA
EFCHARISTO
TASHAKKUR ATU
YAQHANYELAY
DANKSCHEEN
BÏYAN
SHUKRIA
TINGKI
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