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Novel Foods in the European Union

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Trusted science for safe food



- **What are “Novel Foods” in the European Union (EU) ?**
- **Novel Food Regulation (EU) 2283/2015**
procedures, timelines, types of Novel Foods
- **EFSA Novel Food Guidance (2016) and Risk Assessment**
- **Traditional Foods from Third Countries**

What are “Novel Foods” in the EU?

‘Novel Food’ (NF) means any food that was not used for human consumption to a significant degree within the Union before **15 May 1997.**

“Old” NF Regulation 258/1997 replaced by “new” NF Regulation 2283/2015.

Why a new Novel Food Regulation ?

- First Novel Food Regulation from 1997
- 2002: Separate GMO Regulation
- General EU Food Law Regulation (EU) 178/2002: EFSA
- Complains from industry about the long procedure
- Complains from countries outside the EU „barriers“

NEW in NF Regulation (EU) 2283/2015?

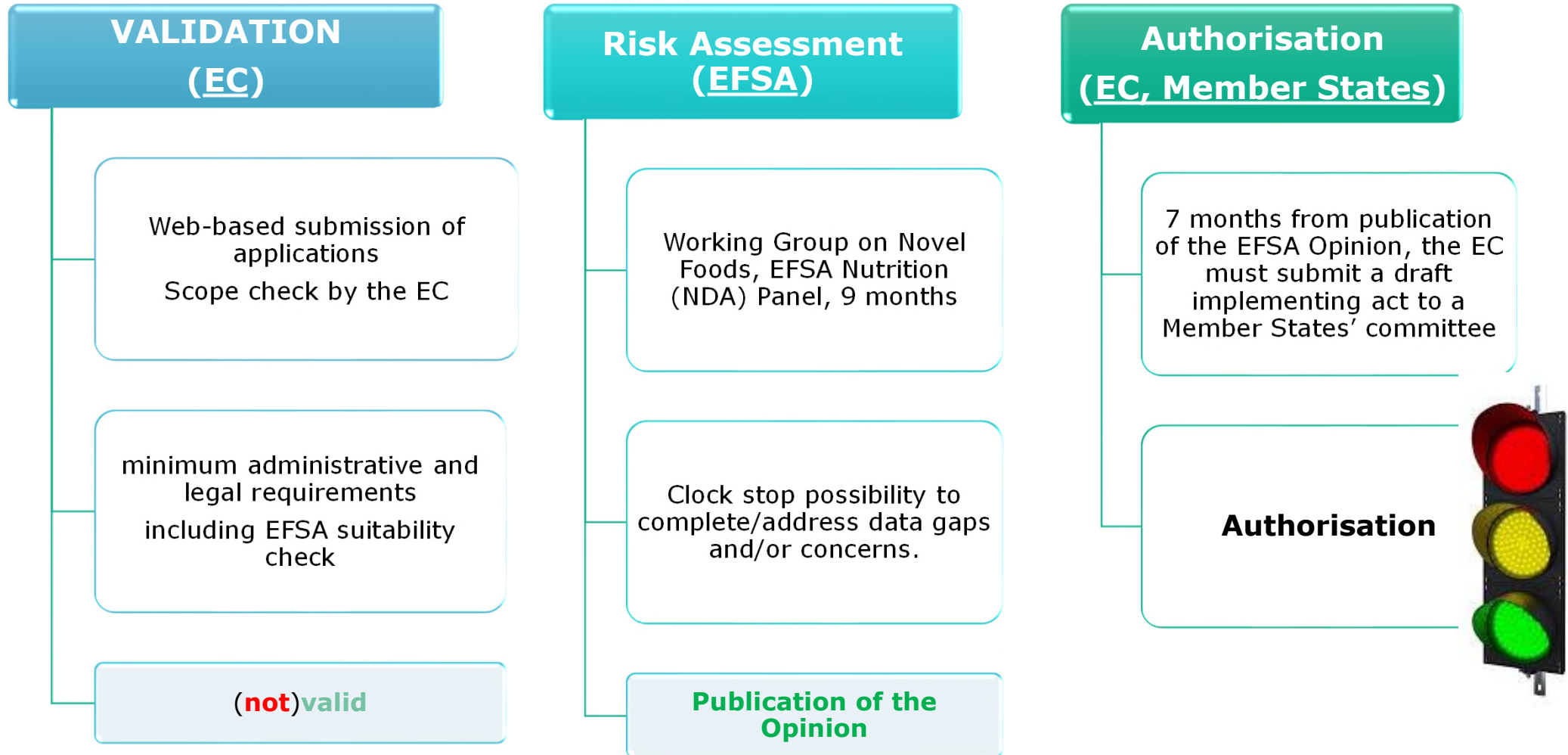
....as compared to “old” 1997 NF Regulation:

- Applications to the European Commission (EC)
- Legal deadlines: Novel Food applications (Article 10-13)
Centralised procedure: EFSA Opinion - *9 months*
- Notifications of Traditional Foods from third countries
4 months
- Generic authorisations
- 5 years “data protection”
- Clarification on insects

NOT NEW in NF Regulation (EU) 2283/2015?

- Definition of NF
- Should be safe,
- Should be nutritionally not disadvantageous
- Should not mislead the consumer

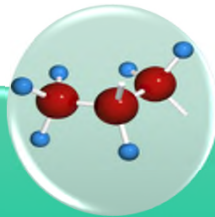
Life Cycle of an Art 10 NF Application



Novel Foods Categories



New production process



New or modified molecular structure



Micro-organisms, fungi, algae



From plants or their parts



New vitamins or minerals



Mineral origin



From animals or their parts



cell or tissue cultures



Engineered nanomaterials



Substances used only in food supplements before 197

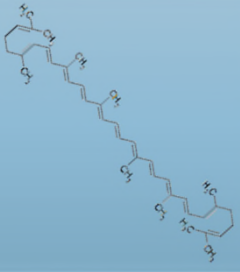

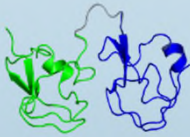



General Principles (12)

- Administrative data
- Introduction
- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and of its source
- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism, and excretion

- Nutritional information
 - Toxicological information, human data
 - Allergenicity
 - Concluding remarks
 - Annexes, references





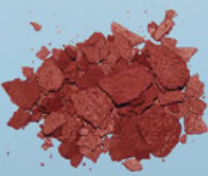

Examples of Novel Foods

newly synthesized/
isolated compounds

		
<p>Synthetic Lycopene</p>	<p>Non-sticky chewing gum base</p>	<p>Ice-structuring protein</p>
		
<p>"Fonio" (<i>Digitaria exilis</i>)</p>	<p>Cacao pulp</p>	<p>Haskap berries (<i>Lonicera caerulea</i>)</p>

traditional foods
from non-EU
countries

new processes

		
<p>UV-treated milk</p>	<p>Milk products fermented with <i>B. xylanisolvens</i></p>	<p>UV-treated yeast</p>
		
<p>Krill oil</p>	<p>Lycopene from <i>B. trispora</i></p>	<p>Astaxanthin from <i>H. pluvialis</i></p>

new sources

And what about “Traditional Foods” in the EU

Novel Foods

- Risk assessment by EFSA upon EC request

Traditional Foods

- a subset of novel foods
- EFSA may raise “duly reasoned safety objections”

What is a Traditional Food from 3rd Country

- A food not consumed to a significant degree by humans in the EU prior to 15/05/1997
- From primary production, processed or unprocessed
- From microorganisms/fungi/algae/plants/animals/cell or tissue cultures
- Must have a '**History of safe food use**' in a third country confirmed by
 - **compositional data** and
 - **experience of continued use** for at least 25 years in the customary diet of a significant number of people in at least one third country

Traditional Foods from Third countries

VALIDATION (EC)

Application submitted through the e-system of the EC, EC checks whether the item falls under the scope of the NF Regulation

EC checks whether minimum administrative and legal requirements are fulfilled

(**not**)valid

Assessment (Member States, EFSA)

Member States, EFSA Working Group on Traditional Foods, 4 months

No clock stop possibility to complete/address data gaps and/or concerns.

Publication of the EFSA Statement

Authorisation (EC)

3 months from publication of the EFSA Opinion, the EC must submit a draft implementing act to a Member States' committee

Authorisation



Traditional Foods from Third Countries

- EU Member States, EFSA scope: raising or not raising “duly reasoned safety objections”.
- **No objections** > authorisation (at least 9 months faster than Article 10 Novel Food applications)
- **Objections** > applicant can file an Article 16 application
- EFSA Guidance for Traditional Foods

General Principles (12)

- Administrative data
 - Introduction
 - Identity of the novel food
 - Production process
 - Compositional data
 - Specifications
- Data from experience of continued use
 - Extent of use
 - Characteristics of the population group(s)
 - Role in the diet
 - Information on the handling and preparation
 - Precautions for the preparation and restrictions
 - Human data
 - Other information (from non-food uses)
 - Proposed conditions of use of the TF for the EU

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EFSA Novel Foods: <https://www.efsa.europa.eu/en/topics/topic/novel-food>
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Thank you for your attention!