Collegio Europeo di Parma

EU legal framework for Novel Food

Prof. Patrick Deboyser

Regulation (EU) 2015/2283

- Adopted in **2015**

REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 November 2015

on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes sig-

Definition / Scope

- **Concept** of Novel Food **unchanged:**
  - food
  - that was not used for human consumption
  - to a significant degree
  - in the EU
  - before 15 May 1997
- **Out of scope**
  - genetically modified food
  - food additives, flavourings, enzymes, extraction solvents.
- **Update of definition**
  - by delegated act of the Commission
  - in light of the scientific and technical progress

Novel food categories

- **New** or modified **molecular structure**
- Food **consisting** of, **isolated** from or **produced** from:
  - microorganisms, fungi, algae
  - material from mineral origin
  - plants or their parts without history of use
  - animals or their parts without history of use
  - cell or tissue cultures
- Food produced with a **novel method** which significantly changes the food's **composition** or **structure**
- **Nanomaterials**
- Prior use only in/as **food supplements**
- **Vitamins** and **minerals** (new method or in nanoform)

Determination of novel food status

- **Economic operators** are responsible for determining whether or not the food they intend to place on the European Union market is novel.
- In case of doubt, they should check the status of their food in the **Member State** in which they plan to place the food on the market **first**.
- The Member State concerned can **consult** the **other Member States** and the **Commission.**
- Commission to lay down **consultation procedure** and means to make the **status publicly available** by implementing regulation (not yet done).

Generic authorizations

- Under the new novel food regulation, authorizations are **no longer applicant-specific**.
- **Authorizations granted** under the old novel food regulation, and their conditions of use remain valid, but they **become generic** following their inclusion in the **Union list**.
- **New** authorizations will also be **generic**.
- Once a novel food is authorized, **any economic operator** can place the novel food on the EU market, provided that the conditions laid down in the authorization are met.

Union List of novel food

- Commission Implementing **Regulation (EU) 2017/2470**

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

of 20 December 2017

establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (1), and in particular Article 8 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission has to establish the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council (2).

(3) The Union list of novel foods is to apply without prejudice to other provisions laid down in sector specific legislation.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on

Table 1: Authorised novel foods

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Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
N-Acetyl-D-neuraminic acid	Infant and follow-on formulae as defined by Regulation (EU) No 609/2013 (1)	0,05 g/L of reconstituted formula	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'N-acetyl-D-neuraminic acid' Food supplements containing N-acetyl-D-neuraminic acid shall bear a statement	
	as defined by Regulation (EU) No 609/2013	0,05 g	added N-acetyl-D-neuraminic acid within the same twenty four hour period.	
	Foods for special medical purposes for	In accordance with the particular nutri-		
	Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	0,2 g/L (drinks) 1,7 g/kg (bars)		
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 (2)	1.25 g/kg		
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,05 g/L		

Authorised novel food

Additional labelling requirements

Conditions under which the novel fo

Other requirements

Specified food category | *Maximum level*

Table 2: Specifications

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Authorised Novel Food	Specification
N-Acetyl-D-neuraminic acid	**Description:** N-Acetyl-D-neuraminic acid is a white to off-white crystalline powder **Definition:** **Chemical name:** …drate) …ro-D-galacto-non-2-ulopyranosonic acid (dihydrate), Synonyms: Sialic acid (dihydrate) **Chemical formula:** $C_{11}H_{19}NO_9$ (acid) $C_{11}H_{23}NO_{11}$ ($C_{11}H_{19}NO_9$ * $2H_2O$) (dihydrate) **Molecular mass:** 309,3 Da (acid) 345,3 (309,3 + 36,0) (dihydrate) **CAS No.:** 131-48-6 (free acid) 50795-27-2 (dihydrate) **Specifications:** Description: white to off-white crystalline powder pH (20 °C, 5 % solution): 1,7 – 2,5 N-Acetyl-D-neuraminic acid (dihydrate): > 97,0 % Water (dihydrate calculates to 10,4 %): ≤ 12,5 % (w/w) Ash, sulphated: < 0,2 % (w/w) Acetic acid (as free acid and/or sodium acetate): < 0,5 % (w/w) **Heavy Metals:** Iron: < 20,0 mg/kg

Authorised novel food

Specification

Authorization procedure

- **Two** possibilities:
  - Commission's **initiative**
  - **application** to the Commission
- **Implementing Regulation (EU) 2017/2469**

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469

of 20 December 2017

laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (1), and in particular Article 13 and Article 35(3) thereof,

Authorization procedure

- Must be submitted **electronically**
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ANNEX I

Template cover letter accompanying an application for novel food

Article 4

Article 5

Scientific data requirements

1. The dossier submitted in support of an application for the authorisation of a novel food shall enable a comprehensive risk assessment of the novel food.

2. Where the application for the authorisation of a novel food involves the use of engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283, the applicant shall provide detection and characterisation test methods in compliance with the requirements of Article 10(4) of that Regulation.

3. The applicant shall provide a copy of the documentation on the procedure and strategy followed when gathering the data.

Authorization procedure: EFSA Guidance

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 21 September 2016

doi: 10.2903/j.efsa.2016.4504

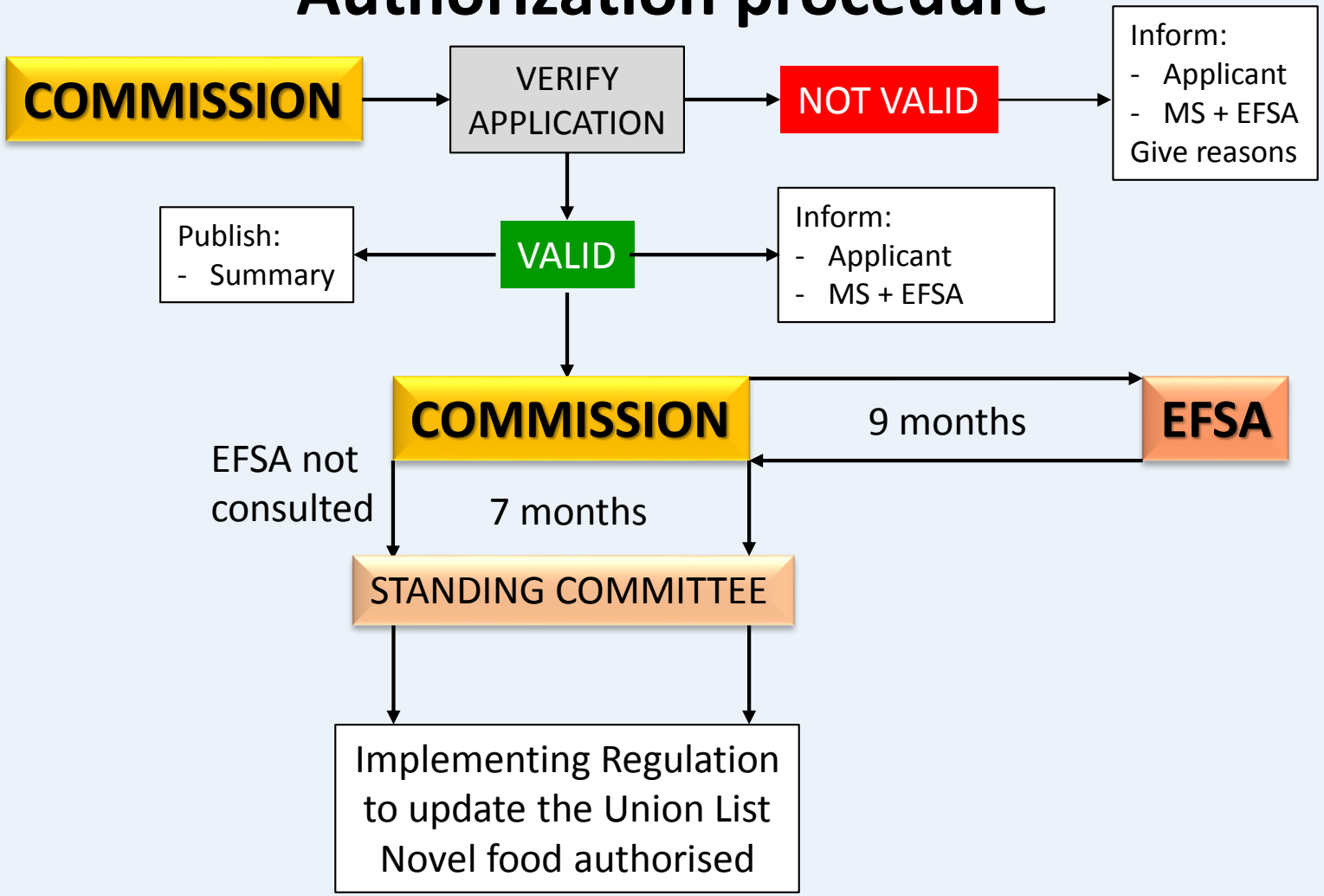
Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA),
Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean,
Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf,
Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka,
Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé,
Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Rosangela Marchelli, Annette Pöting,
Morten Poulsen, Seppo Salminen, Josef Schlatter, Davide Arcella, Wolfgang Gelbmann,
Agnès de Sesmaisons-Lecarré, Hans Verhagen and Hendrik van Loveren

Abstract

Following the adoption of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Commission requested EFSA to update and develop scientific and

Authorization procedure



Traditional foods from non-EU countries

- Faster and structured **notification system** for **traditional foods** from **non-EU countries.**
- History of safe food use in the non-EU country must be confirmed:
  - with compositional data and
  - experience of continued use for at least 25 years in the customary diet of a significant number of people

Traditional foods from non-EU countries

Implementing Regulation (EU) 2017/2468

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2468

of 20 December 2017

laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (1), and in particular Article 20 and Article 35(3) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods in the Union.

Notification procedure

- Must be submitted **electronically**
- Must consist of:
  - Application letter

ANNEX I

Template cover letter accompanying a notification for traditional food from a third country following the requirements of Article 14 of Regulation (EU) 2015/2283

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Article 5

Article 6

Scientific data to be provided in a notification or an application

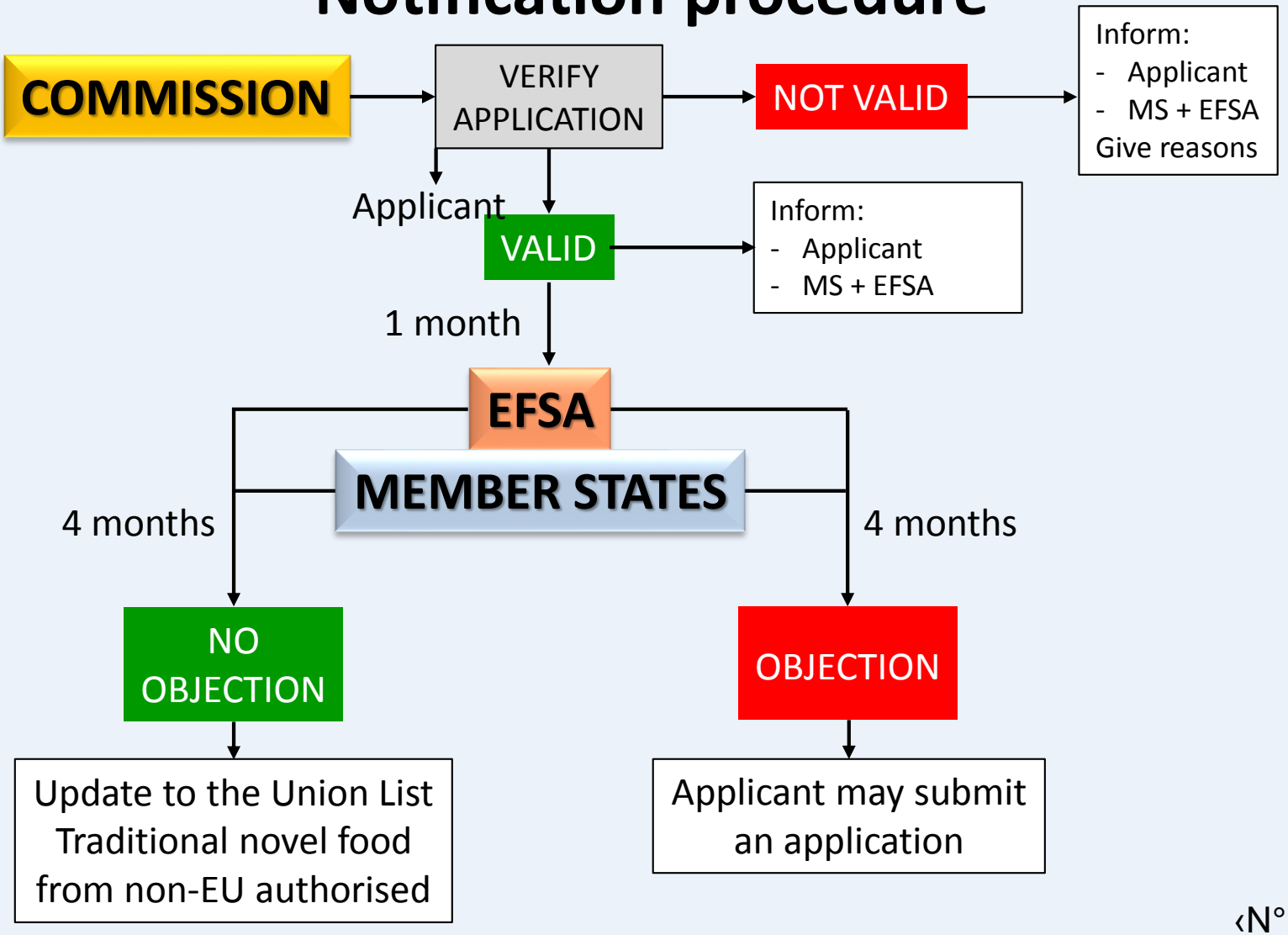
1. The dossier submitted in support of a notification or an application for the authorisation of a traditional food from a third country shall enable a history of safe use of the traditional food from a third country to be assessed.

2. The applicant shall provide a copy of the documentation on the procedure followed when gathering the data.

3. The applicant shall provide a description of the safety evaluation strategy and shall justify the inclusion and exclusion of specific studies or information.

4. The applicant shall propose an overall conclusion on the safety of the proposed uses of the traditional food from a third country. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Notification procedure



Thank You !