Contemporary challenges for Novel Foods in EU

Prof.Dr. Hans Verhagen
Melle, Belgium
4 May 2022

FSNConsultancy@hotmail.com
hansver@food.dtu.dk
h.verhagen@ulster.ac.uk

1

1976-1983 University Nijmegen/Paris
•Chemistry
•Toxicology

1989 PhD Maastricht University
•Food toxicology

1990 → Board-certified toxicologist

1990's TNO (CRO)
•Head genetic toxicology
•Head food analysis lab

2000-2005 Unilever
•Scientific & regulatory affairs

2005-2015 RIVM
•Head Centre Nutrition and Health
•Senior Scientific advisor

2005 → Board-certified nutritionist

2009 → visiting professor food safety & nutrition University of Ulster

2015-2020 EFSA
•Head of Department Risk Assessment
•Senior Scientific Officer

2006-2015 EFSA NDA Panel Health claims
Novel Foods

2020 "retirement"
•Professor →
•Consultancy →

2021- …
UK Advisory Committee
Novel Foods and Processes

2021 → visiting professor Risk-benefit of food safety & nutrition DTU

FOOD SAFETY & NUTRITION CONSULTANCY

2

Novel Foods - definition

Novel Foods ……. are
food or food ingredients ……
that were

"not used for human consumption ……. to a significant degree …… in the European Union (EU) …… before 15th May 1997".

3

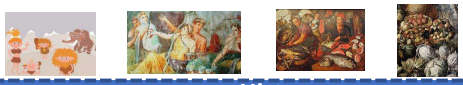
Novel Foods - history

Not novel

History

4

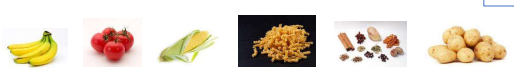
Novel Foods - history



Not novel

History

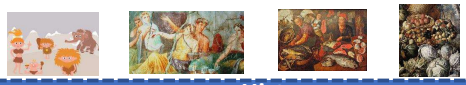
Not novel



15 May 1997

5

Novel Foods - history



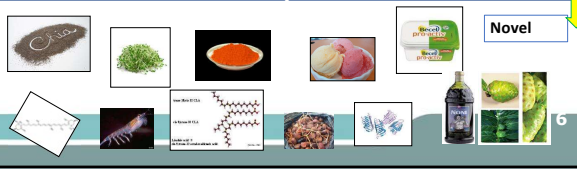
Not novel

History

Not novel

15 May 1997

Novel



6

Novel Foods - categories

- food ingredients with a new or intentionally modified primary molecular structure
- micro-organisms, fungi, algae or cell culture
- plants or animals
- food produced by new production process that significantly changes the product nutritionally or in relation to the food safety risks
- minerals or engineered nano-materials

7

Regulation 258/1997

REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 January 1997
concerning novel foods and novel food ingredients
(OJ L 43, 14.2.1997, p. 1)

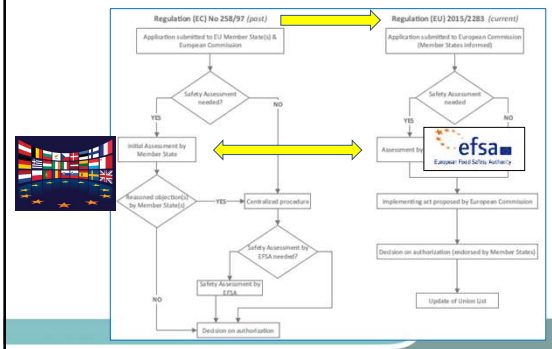
- Extensive and time consuming authorisation procedure
- Complaints from non-EU countries regarding hurdles for their "traditional foods" to enter EU market

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

- In place from 1 Jan 2018
- Novel Foods & Traditional Foods from Third Countries
- 2 new EFSA Guidance documents
- Adjacent Regulations

8

Main steps of the past and current EU novel food regulations



E. Vavreis, et al. *Food Research International* 137 (2020) 109515

9

Goal of a novel food application/notification

- **Establish that the Novel Food is "safe under the proposed conditions of use"**
- **Convince the evaluation body:** efsa European Food Safety Authority
  (& Member States)

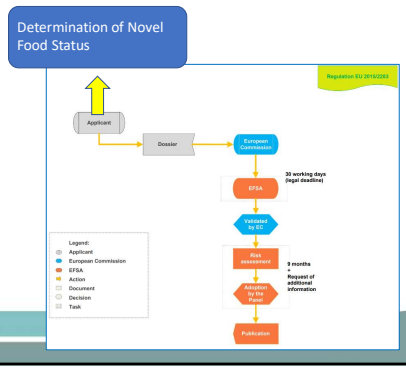
10

Regulation (EU) 2015/2283: applications and notifications

- **All** to the European Commission
- **Applications**: EC → EFSA
- **Notifications**: for traditional foods from third countries: EC → to EFSA and Member States.
  - Member States and EFSA have 4 months to present *duly reasoned safety objections*.

11

Novel foods – checking status (if in doubt)



12

Novel foods – checking status (if in doubt)

L 77/6 EN Official Journal of the European Union 20.3.2018

COMMISSION IMPLEMENTING REGULATION (EU) 2018/456

of 19 March 2018

on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

Applicant → Recipient Member State

- 4 months
- If novel food status confirmed:
- Into "novel food catalogue" on EC website

13

Into the Novel Foods catalogue

Regulation 2018/456 (article 4)

- Not novel
- FSs not novel Foods novel
- Novel
- Novel?

Statuses

This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EC) No. 258/97. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

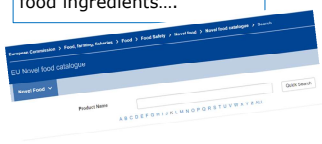
According to information available to Member States competent authorities this product was used only as or in food supplements before 15 May 1997. Any other food uses of this product have to be authorised pursuant to the Novel Food Regulation. → Foods

There was a request whether this product requires authorisation under the Novel Food Regulation. According to the information … competent authorities … → Novel application

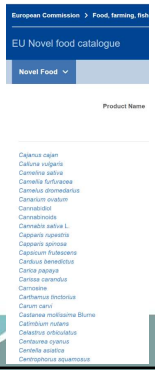
14

Novel Foods – catalogue

… an informal record of discussions at EU level about the novel food status of numerous foods and food ingredients….

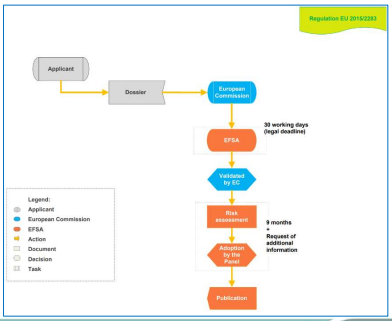


https://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm



15

Regulation (EU) 2015/2283 - applications



16

Regulation (EU) 2015/2283 – applications *e-submission*

L 351/64 EN Official Journal of the European Union 30.12.2017

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469

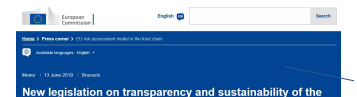
of 20 December 2017

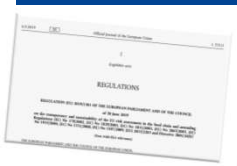
laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

https://ec.europa.eu/food/safety/novel_food/e-submission_en

17

Transparency Regulation 2019/1381





a.o. :

- Notification of studies
- Applications open unless confidentiality claimed
- Presubmission advise from EFSA

18

Novel foods – authorisation dossier
2 EFSA Guidance documents

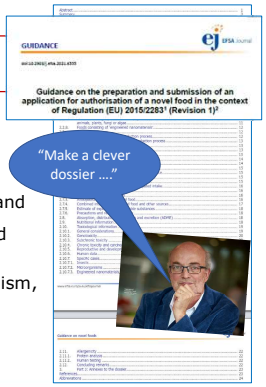
19

Characterisation of novel food
technical & scientific data

2.2. Identity of the novel food
2.3. Production process
2.4. Compositional data
2.5. Specifications

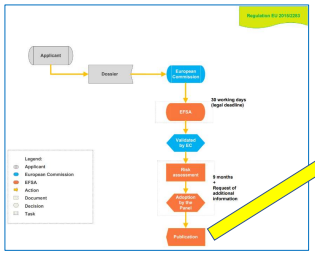
2.6. History of use of the novel food and of its source
2.7. Proposed uses and use levels and anticipated intake

2.8. Absorption, distribution, metabolism, and excretion
2.9. Nutritional information
2.10. Toxicological information
2.11. Allergenicity



20

Novel foods – authorisation decision EC

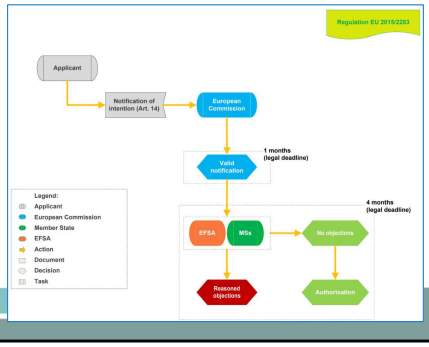


Authorisation in EC discussed in EC standing committee

Into "union list" on EC website

21

Regulation (EU) 2015/2283 - notifications
for traditional foods from 3rd countries:



22

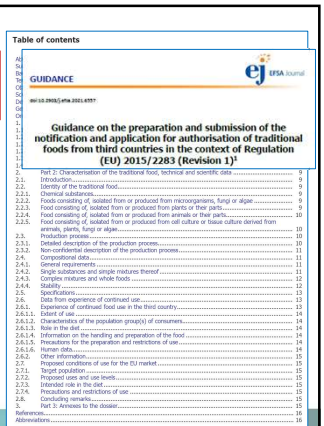
Traditional Foods from 3rd Countries

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



Outcome of a dossier evaluation

The Novel food (ingredient) is

safe / **not safe**

under the proposed conditions of use

- EFSA (& MSs) to evaluate
- EC/MSs to decide on authorisation

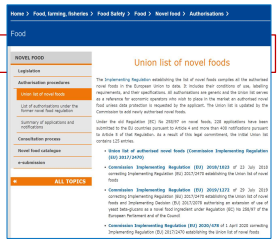
24

Union list

- **Once a food or ingredient is authorised** as a novel food, or a traditional food from a third country is successfully notified, the **Union List**, established by Commission Implementing Regulation (EU) 2018/1023, **is updated**.
- The **Union list** contains **all novel foods and traditional foods** from third countries that have been **authorised** to date in the EU and includes the name, conditions of use, labelling and other requirements as well as specifications.

25

Union list



L 351/72 EN Official Journal of the European Union 30.12.2017

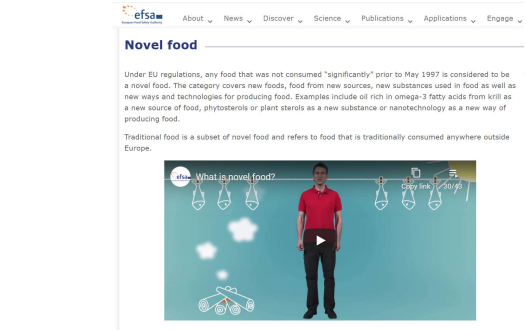
COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

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

https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en

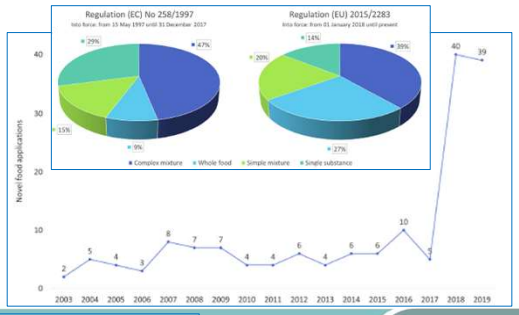
26



https://www.efsa.europa.eu/en/topics/topic/novel-food

27

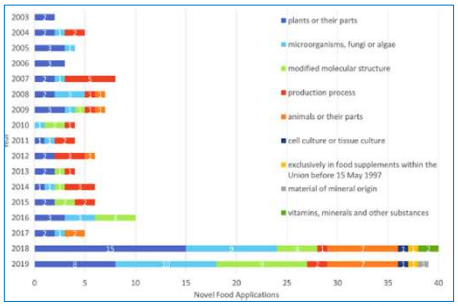
Novel food applications that entered EFSA's risk assessment



E. Ververis, et al. *Food Research International 137 (2020) 109515*

28

The nature of novel foods that entered EFSA's risk assessment



E. Ververis, et al. *Food Research International 137 (2020) 109515*

29

Mapping of **requests for additional or supplementary information** sent by EFSA.

E. Ververis, et al. *Food Research International 137 (2020) 109515*

30

Thank you ☺

Prof.Dr. Hans Verhagen
FSNConsultancy@hotmail.com
hansver@food.dtu.dk
h.verhagen@ulster.ac.uk
@HansVerhagenNL
LinkedIn hans-verhagen-617aa61
www.fsnconsultancy.nl www.fsnconsultancy.com

31