European Commission

Novel Food Regulation

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

DG Health and Food Safety,
Unit E2 "Food processing technologies and novel foods"

Explanatory meeting on the EU acquis
21 February 2019

Health and Food Safety

European Commission

Content of the presentation

1. *Background*
2. *The new Novel Food Regulation*
3. *Applications*
4. *Notifications for traditional foods from TC*
5. *Confidentiality and data protection*
6. *Transition to the new system*
7. *Work undertaken by COM and EFSA*
8. *Union list*
9. *E-submission system*

Health and Food Safety

1. BACKGROUND

- *2004 Evaluation Report on the Novel Food Regulation 258/97*
  - ***Report underlined the importance of further clarifying and updating the Regulation***
- *2006 Interactive Policy Making (IPM) online consultation*
- *2008 Impact Assessment*
  - ***Adjusted safety assessment and management for traditional food from third countries (non-EU countries)***

Conclusion: *The novel food legislation needs to be reviewed, clarified and updated taken into consideration scientific and technological developments*

- *2008 Proposal for the Regulation on novel food*
- *2011 Failure of the agreement on the proposal*
- *2013 Revised proposal*
- ***25 November 2015 adoption of Regulation (EU) 2015/2283 (Applicable from 1 January 2018)***

2. THE NEW NOVEL FOOD REGULATION

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Regulation (EU) 2015/2283 of the European Parliament and of the Council

Purpose

*"The purpose of novel food Regulation is to ensure the effective functioning of **the internal market** while providing a **high level of protection of human health and consumers' interests**."*

***NB!** The general concept of the "novel food" has not changed!*

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Scope of the Regulation

It does not apply to

(a) ***genetically modified foods*** *falling within the scope of Regulation (EC) No 1829/2003*;

(b) ***foods*** *when and in so far as they are used as:*

(i) ***food enzymes*** *falling within the scope of Regulation (EC) No 1332/2008;*

(ii) ***food additives*** *falling within the scope of Regulation (EC) No 1333/2008;*

(iii) ***food flavourings*** *falling within the scope of Regulation (EC) No 1334/2008;*

(iv) ***extraction solvents*** *used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.*

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Clarification of the categories

Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of the following categories:

(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;

….

(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC

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Novel foods in the Union list

- ***Conditions for inclusion***
  - ✓ *Safe, do not mislead consumer, no nutritional disadvantage*
- ***Generic authorisation****, except if data protection granted for 5 years*
- ***Initial establishment of the Union list***
  - ✓ *Already authorised novel foods and the foods notified as being substantially equivalent*

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3. APPLICATIONS FOR AUTHORISATION OF NOVEL FOODS

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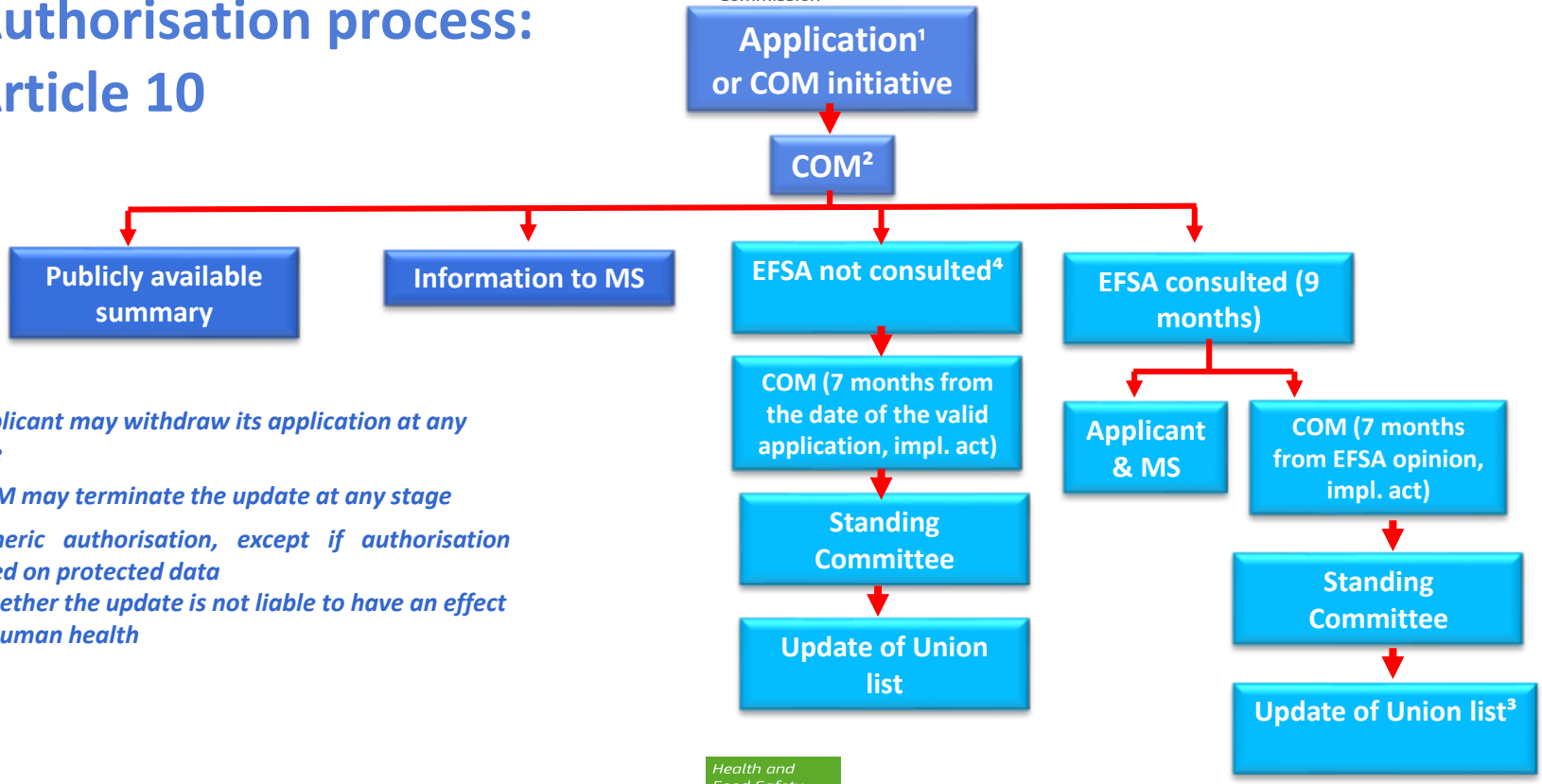
Applications (Article 10)

- *Applicant - EU MS, non-EU MS or the interested party which may represent several interested parties*
- *Information to public - Summaries*
- *Evaluation by the European Food Safety Authority*
- *COM and EFSA do not charge fees for managing applications*
- *Authorisation by the Commission and MS*
- *Time limits for each step*

Authorisation process: Article 10



[1]Applicant may withdraw its application at any time

[2]COM may terminate the update at any stage

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

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

4. NOTIFICATIONS FOR TRADITIONAL FOODS FROM THIRD COUNTRIES

European Commission

Notifications for traditional foods from third countries (Article 14)

Main improvements:

- *Eliminated substantial equivalence*
- *Setting out definitions for traditional food from third countries and history of safe use*
- *Short and simplified authorization process for traditional food from third countries*
- *COM and EFSA do not charge fees for managing notifications*
- *Guidance made especially for traditional foods from third countries*

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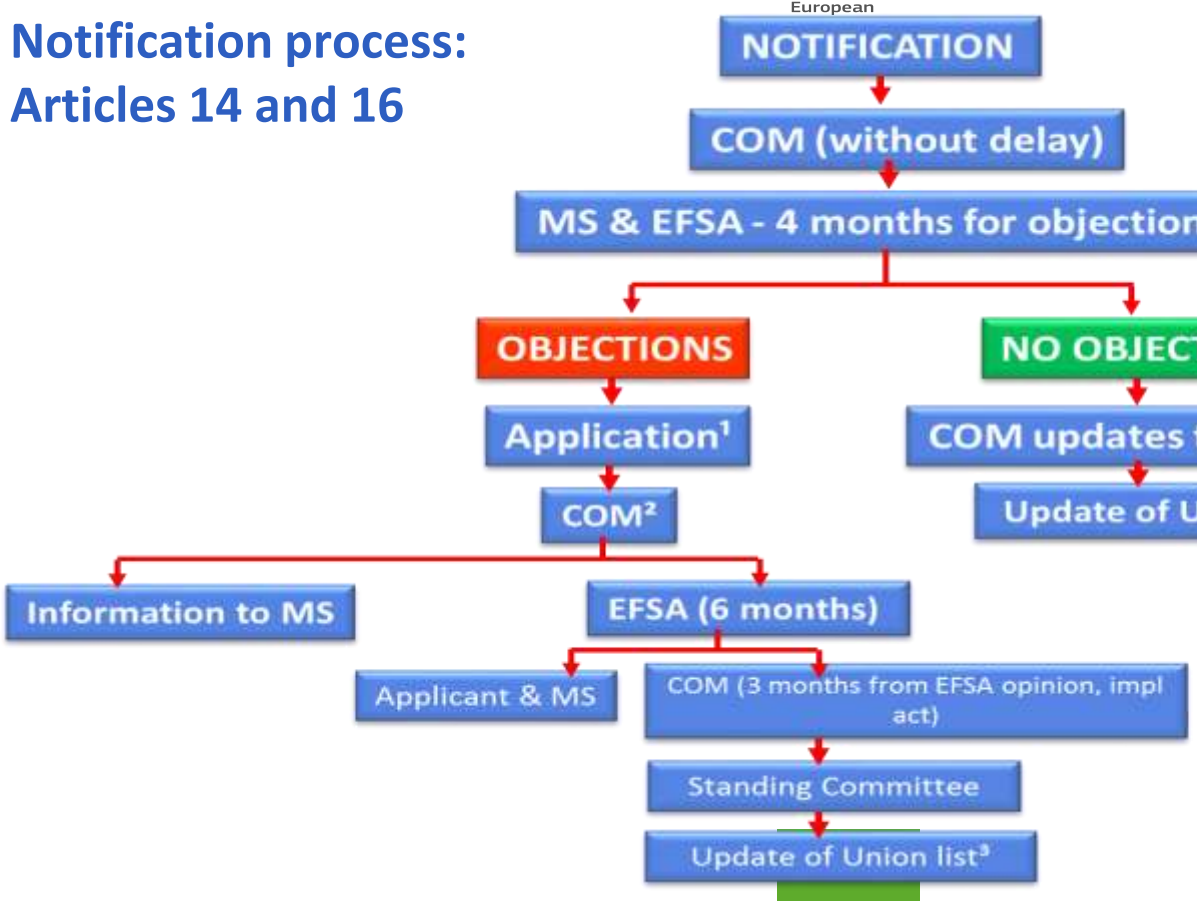
Notifications for traditional foods from third countries

History of safe food use in a third country

means that the safety of the food in question has been confirmed with compositional data and from 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, prior to a notification referred to in Article 14*

Notification process: Articles 14 and 16



¹Applicant may withdraw its application at any time
²COM may terminate the update at any stage
³Generic authorisation

5. CONFIDENTIALITY AND DATA PROTECTION

Confidentiality

- *On request by applicant*
- *Confidential treatment on certain information in the application– Disclosure of such info may harm their competitive position*
- *In case of disagreement between the applicant and COM, COM shall decide what information can be kept confidential*
- *Art. 23(4). Certain information can never be confidential (e.g. name of the applicant, name of the food, any prohibition or restriction imposed in respect of the food by a third country)*

Data Protection

- *On request by applicant*
- *Conditions for data protection:*

(a) the newly developed scientific evidence or scientific data was designated as proprietary;

(b) the initial applicant had exclusive right of reference to the evidence or data; and

(c) the novel food could not have been assessed by EFSA without the submission of the proprietary scientific evidence or scientific data.

- *COM can grant the individual authorization for 5 years*
- *Authorization holder indicated in the Union list*
- *Does not apply to traditional foods from third countries*

6. TRANSITION TO THE NEW SYSTEM

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Transition to the new system

Rules under Regulation (EC) No 258/97 were applicable until 31 December 2017

New rules fully already apply from 1 January 2018

- *Applications/notifications are submitted directly to the Commission from this date on and these have to comply with the new requirements*
- *Those applications, which are not finalised by the time the new Regulation applies, are treated in accordance with the new Regulation*

7. WORK UNDERTAKEN BY EFSA AND COMMISSION

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Work carried out by EFSA

EFSA has published two guidance documents on the preparation and presentation of an applications and notifications for authorisation of:

- ✓ *Novel foods*

  https://www.efsa.europa.eu/en/efsajournal/pub/4594

- ✓ *Traditional foods from TC*

  https://www.efsa.europa.eu/en/efsajournal/pub/4590

- ✓ *Administrative guidance on the submission of applications*

  http://www.efsa.europa.eu/en/supporting/pub/en-1381

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Work carried out by Commission

Adoption of 4 EU Implementing Regulations:

- *Comm. Implem. Reg. (EU) 2017/2469 of 20 Dec 2017 laying down administrative and scientific requirements for applications referred to in Article 10.*
- *Comm. Implem. Reg. (EU) 2017/2468 of 20 Dec 2017 laying down administrative and scientific requirements concerning traditional foods from third countries.*
- *Comm. Implem. Reg. (EU) 2017/2470 of 20 Dec 2017 establishing the Union list of novel foods.*
- *Comm. Implem. Reg. (EU) 2018/456 of 19 March 2018 on consultation process on NF status.*

8. UNION LIST OF NOVEL FOODS

Union list of Novel Foods

- ✓ *The initial Union list is a generic list of authorised NF*
- ✓ *established by Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods*
- ✓ *corrected by Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470*

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Union list of Novel Foods

The Union list consists of 2 tables:

- Table 1
  - ✓ Conditions under which the NF may be used (specified food category and Maximum levels)
  - ✓ Additional specific labelling requirements
  - ✓ Other requirements
  - ✓ Data protection, where necessary
- Table 2
  - ✓ Specifications

Table 1: Authorised novel foods

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 that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added N-acetyl-D-neuraminic acid within the same twenty four hour period.	
	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013	0,05 g/kg for solid foods		
	Foods for special medical purposes for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than the maximum levels specified for the category mentioned in the table corresponding to the products.		
	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		
	Unflavoured fermented milk-based products, heat treated after fermentation, flavoured fermented milk products including heat-treated products	0,05 g/L (beverages) 0,4 g/kg (solids)		

Table 2: Specifications

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:** IUPAC names: N-Acetyl-D-neuraminic acid (dihydrate) 5-Acetamido-3,5-dideoxy-D-glycero-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 Lead: < 0,1 mg/kg Residual proteins: < 0,01 % (w/w)

NOVEL FOOD

- Legislation
- Authorisation procedures
  - Union list of novel foods
  - List of authorisations under the old novel food regulation
  - Summary of ongoing applications and notifications
- Novel food catalogue
- e-submission

ALL TOPICS

Union list of novel foods

The implementing Regulation establishing the list of novel foods compiles all the authorised novel foods in the European Union to date. It includes their conditions of use, labelling requirements, and their specifications. All authorisations are generic and the Union list serves as a reference for economic operators who wish to place in the market an authorised novel food unless data protection is requested by the applicant. The Union list is updated by the Commission to add newly authorised novel foods.

Under the old Regulation (EC) No 258/97 on novel foods, 228 applications have been submitted to the Member States pursuant to Article 4 and more than 400 notifications pursuant to Article 5 of that Regulation. As a result of this legal commitment, the initial Union list contains 125 entries.

- **Union list of authorised novel foods**

Updates to the Union list of novel foods

- **Commission Implementing Regulation (EU) 2018/460** of 20 March 2018 authorising the placing on the market of *Ecklonia cava* phlorotannins as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470
- **Commission Implementing Regulation (EU) 2018/461** of 20 March 2018 authorising an extension of use of taxifolin-rich extract as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470
- **Commission Implementing Regulation (EU) 2018/462** of 20 March 2018 authorising an extension of use of L-ergothioneine as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470
- **Commission Implementing Regulation (EU) 2018/469** of 21 March 2018 authorising the placing on the market of an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470

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Union list

✓ *To date,*

- Act correcting the Union list-Commission Implementing Regulation (EU) 2018/1023
- Union list updated 24 times including 3 Traditional foods

Consultation request

✓ *9 NF status published*

9. E-SUBMISSION SYSTEM

European Commission

e-submission system for Novel Foods
User Guide

E-submission

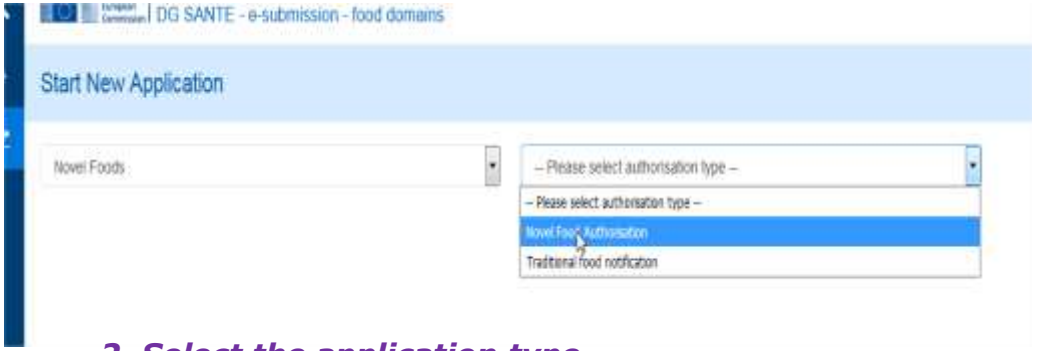
1. *System designed to allow applicants to submit novel foods applications and/or traditional foods notifications from third countries online. https://webgate.ec.europa.eu/fscap*
2. *All applicants must submit applications/notifications through that system.*
3. *All info including the user guide at https://ec.europa.eu/food/safety/novel_food/e-submission_en*

5. Content

1. Applicant

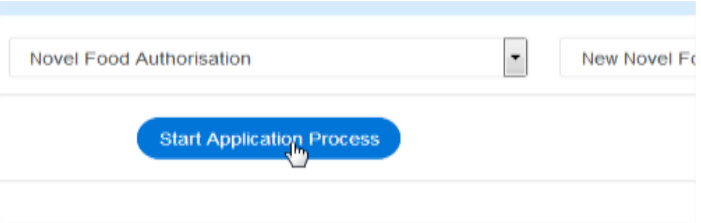
- **Select the food domain (Novel foods)**
- **Select the authorisation type**
- **Select the application type**
- **Start the application process (*a specific web form is displayed depending on the above selection*)**

1. Select the domain (Novel foods) & authorisation type



2. Select the application type

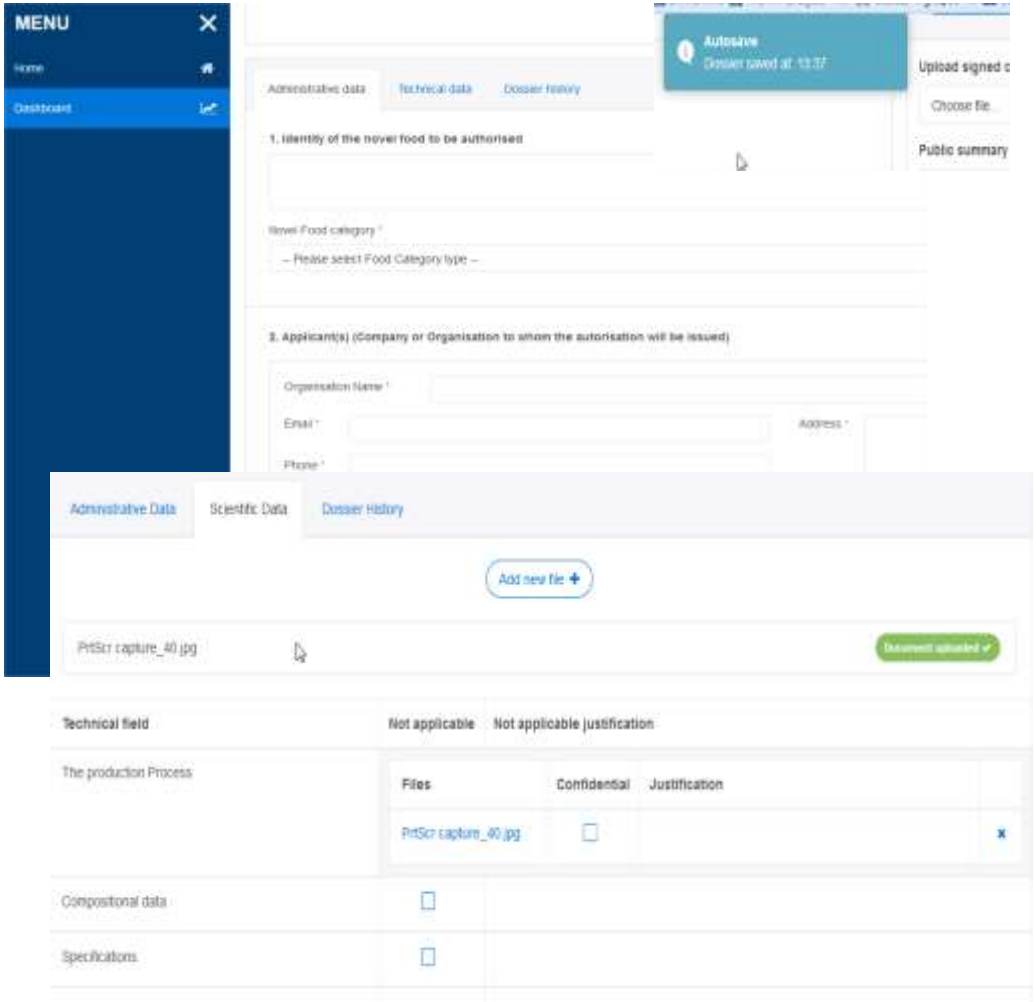
3. Start the application process



5. Content

1. Applicant

- **Fill in an application form for novel foods (with auto save option)**
  - Administrative data
  - Scientific data
  - Cover letter
  - Public summary
- **Submit the application to the European Commission**

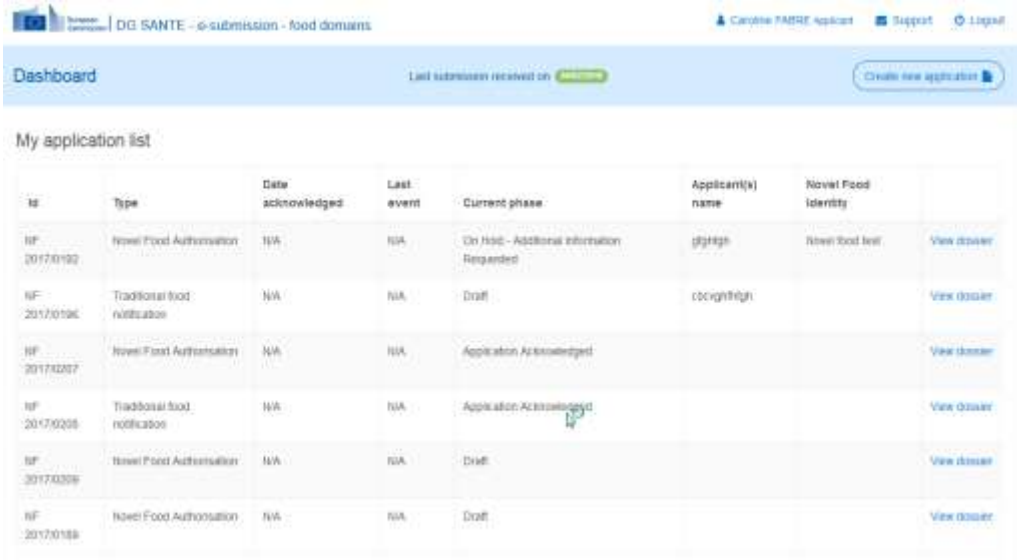


5. Content

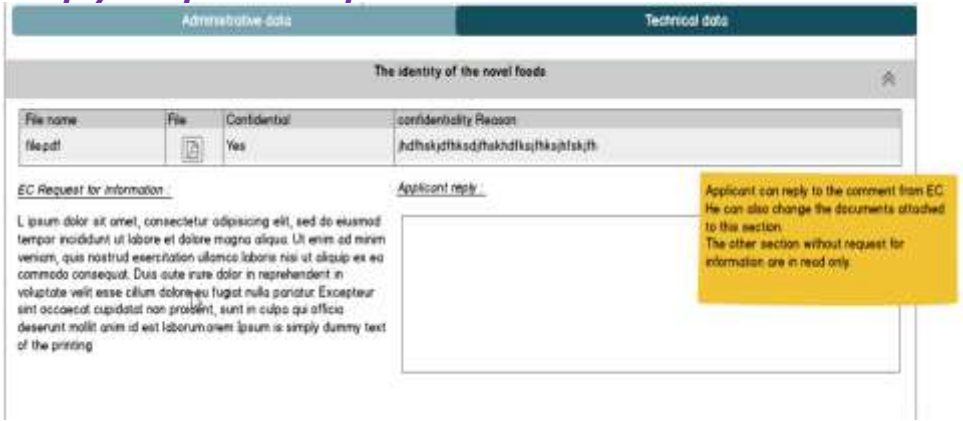
1. Applicant

- **Follow-up applications (dashboard)**
- **Receive email notifications when status of the application change**
- **Reply to request for information sent by EC or EFSA (validity check, suitability check and risk assessment)**

Follow-up applications



Reply to specific request for information

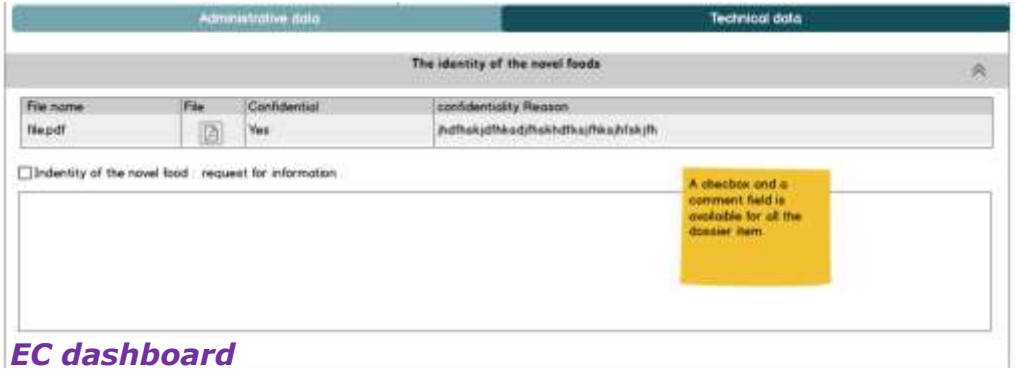


5. Content

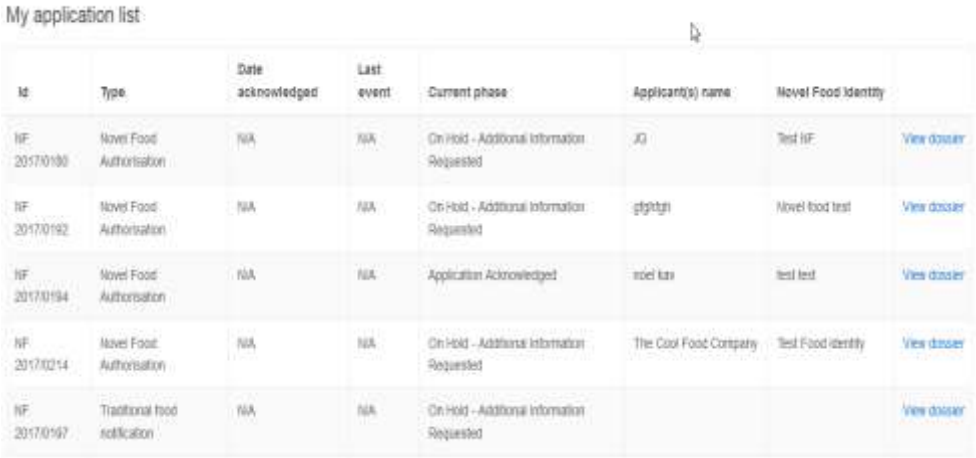
2. European Commission (EC)

- **Receive applications for novel foods**
- **Perform the validity check and submit to EFSA for suitability check if necessary**
- **Request information to the applicant if needed**
- **Participate together with Member States and EFSA on the consultation period for the traditional food notifications**
- ***Perform the risk management (phase 2)***

Request for information to the applicant (for a specific part of the dossier)



EC dashboard

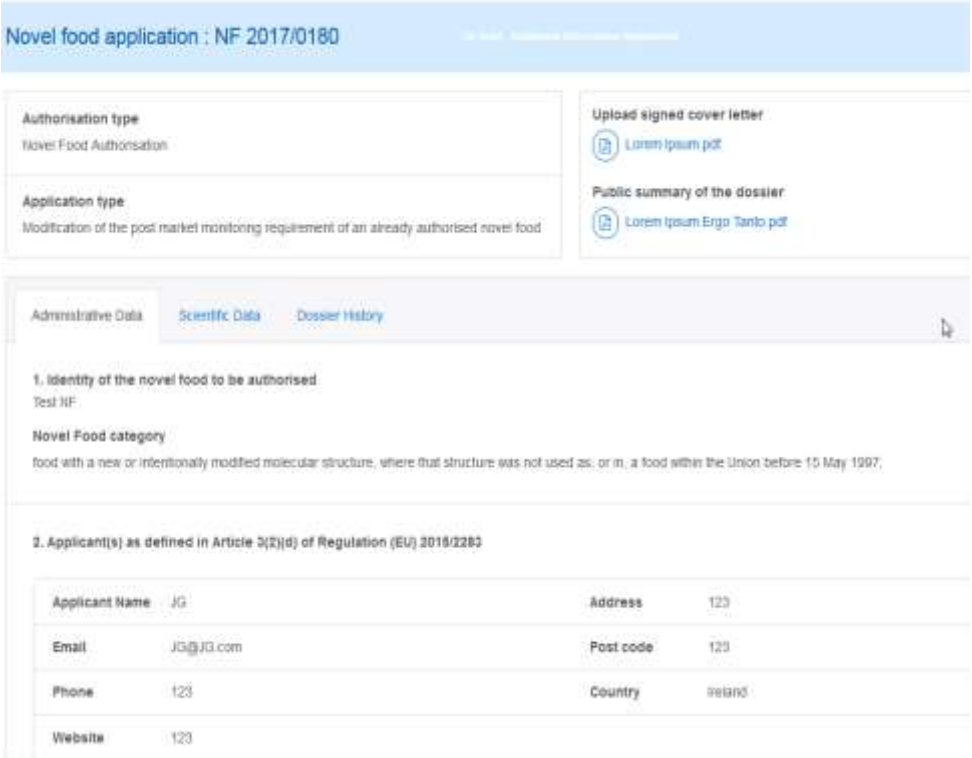


5. Content (phase 1)

3. EFSA

- **Be notified by the European Commission when an application needs a suitability check.**
- **Perform the suitability check by accessing the full content of the application**
- **Request information to the applicant if needed (same functionality for EC)**

Access to all the data included in the applications received

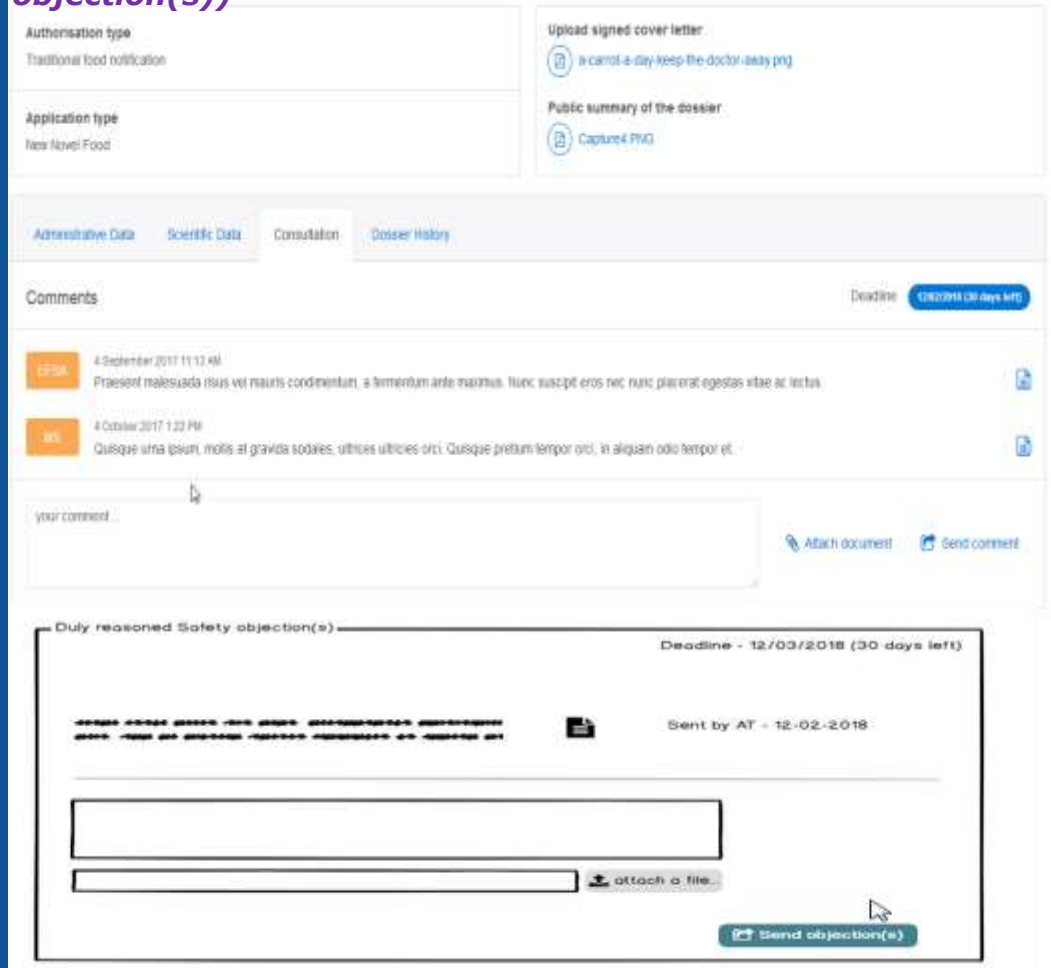


5. Content (phase 1)

3. EFSA

- **Perform the risk assessment and attach the opinion**
- **Participate together with Member States and EFSA to the consultation period (safety objection) for the traditional food notification**

Consultation period (comments + duly reasoned safety objection(s))

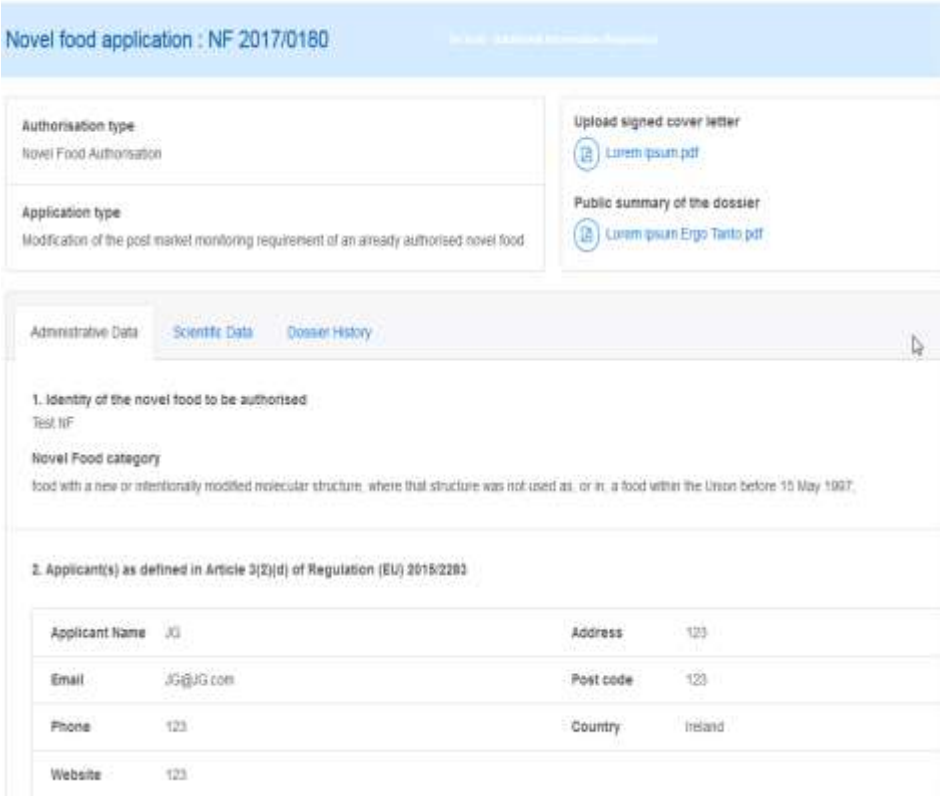


5. Content (phase 1)

4. *Member States (MS)*

- **Be notified by the system when an application is acknowledged (received by EC).**
- **Read access to all the novel foods applications**
- **Participate together with EC and EFSA on the consultation period for the traditional food notification**

Read only access to all the acknowledged applications



European Commission, DG Health and Food Safety website
https://ec.europa.eu/food/safety/novel_food_en

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