



New Regulation on Novel Foods

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Content

- *Background*
- *Definition of a novel food*
- *New procedures*
- *Traditional food from non-EU countries*
- *Transition to the new system*

Background (1):

- *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*

Background (2):

- *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)**

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" will not change!*

Clarification of the categories

Definition

- *Food not used for human consumption to a significant degree before 15 May 1997*
- *and that falls under at least one of the ten categories described in the Regulation*



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Union list of authorised and new novel foods

- ***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 (generic authorisation)*

Centralised procedure

- Applications/notifications to the Commission
- Applicant-Means a EUMS, non-EUMS or the interested party which may represent several interested parties
- Information to public-Summaries
- Evaluation by the European Food Safety Authority
- Authorisation by the Commission
- Time limits for each step



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Authorisation process and updating the Union list of authorised novel foods

Application¹ or COM initiative

COM²

Publicly available summary

Information to MS

EFSA not consulted⁴

EFSA consulted

COM

Applicant & MS

COM

Endorsement by MS

Endorsement by MS

Update of Union list

Update of Union list³

¹Applicant may withdraw its application at any time

²COM may terminate the update at any stage

³Generic authorisation, except if authorisation based on protected data

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

Data protection

- *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***

Confidentiality

- *An applicant may request confidentiality on the information in the application– harming of the competitive position*
- *Certain information can never be confidential (e.g. any prohibition or restriction imposed in respect of the food by a third country)*
- *Other information can be asked to be confidential*
- *In case of disagreement between the applicant and COM, COM shall decide what information can be kept confidential*
- *Possibility for detailed rules (implementing act) on the application of confidentiality*

Traditional food from a third country

Main improvements:

- *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 does not charge fees for handling notifications*
- *Guidance made especially for traditional food from third countries*

Traditional food from a third country

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

Traditional food from a third country

***Traditional food from a third country** is a food derived from primary production with a history of safe use in a third country.*

➤ Traditional food can be

- **Produced from plants/animals/micro-organisms etc.**
(juice of the fruit of *Morinda citrifolia* L)
- **From primary production** (chia seeds)
- **Processed or unprocessed** (baobab dried fruit)

➤ Traditional food cannot be

- **New molecules; from mineral origin; from a new process; from engineered nanomaterial; already authorised vitamins; minerals for which a new process has been applied or contains engineered nanomaterials; food used only in food supplements**

Traditional food from a third country

Authorisation

➤ **Fast and simplified**

- *Notification evaluated by MS and EFSA*
- *If no duly reasoned safety objections, the COM updates the Union list **immediately** and the product may be placed on the market*

➤ **In case of duly reasoned safety objections**

- *the COM informs the applicant immediately*
- *the notification may be turned into an application, evaluated by EFSA and authorised by COM*



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Authorisation process

(Traditional food from a third country)

Notification

COM

MS & EFSA 4 months for objections

No objections

COM updates the Union list immediately

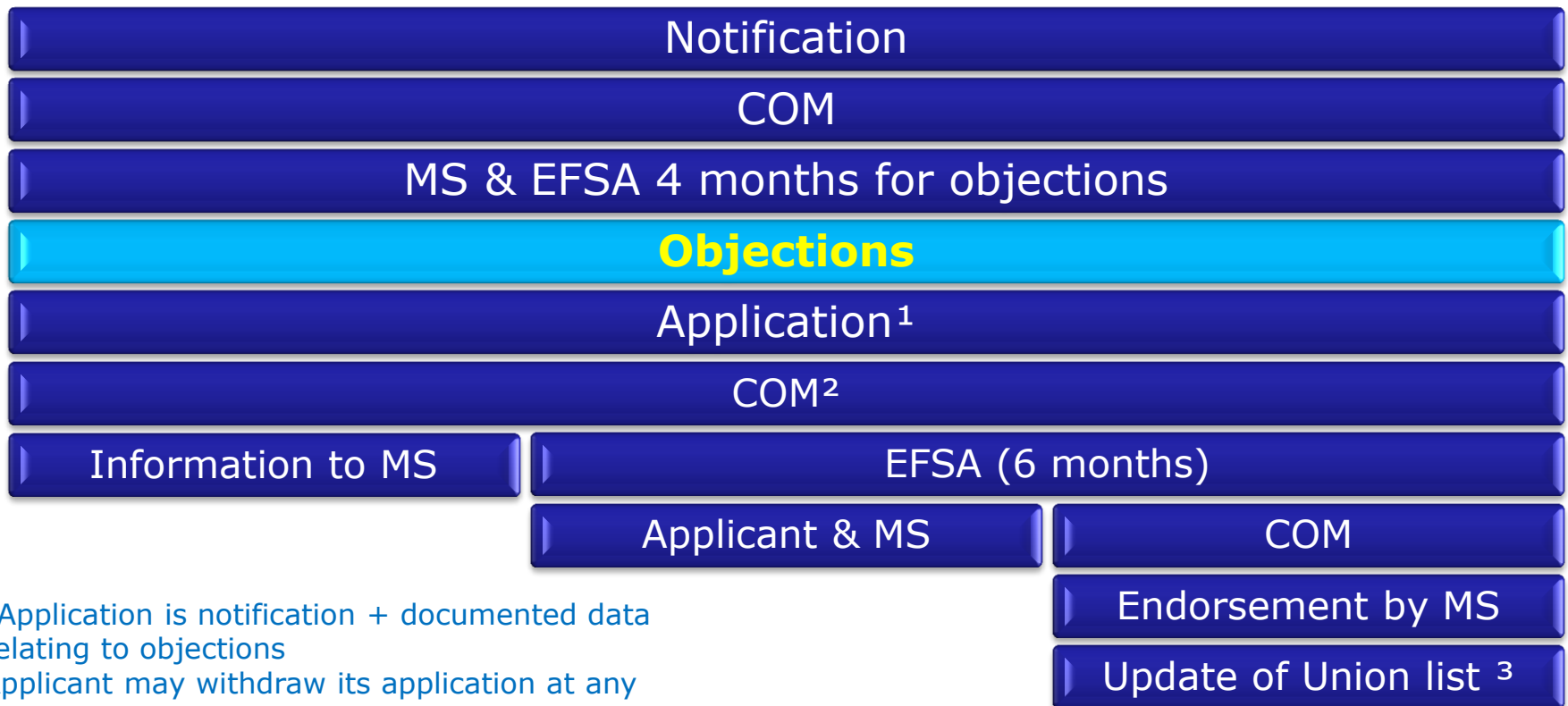
Update of Union list of authorised novel foods¹

¹Generic authorisation



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Authorisation process (Traditional food from a third country)



¹Application is notification + documented data relating to objections
Applicant may withdraw its application at any time

²COM may terminate the update at any stage

³Generic authorisation

Transition

Current rules under Regulation (EC) No 258/97 are applicable **until 31 December 2017**

New rules fully apply from **1 January 2018**

- *Applications/notifications can only be 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, will be governed by the new Regulation*

COM work within next 2 years

"Guidance"

- *Administrative requirements for "normal" applications and for **"traditional foods from third countries"***
 - ✓ *The procedural steps for the exchange of information with the Member States and with EFSA for submitting reasoned safety objections on third country notifications*
- *Scientific part – EFSA guidance (ready by September 2016)*

COM work within next 2 years

- *Guidance of the consultation process on the determination of the status of novel food*
- *Initial establishment of the Union list on already authorised novel foods*
- *Update of the definition of engineered nanomaterial to technical and scientific progress*



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