# New Novel Food Regulation

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Health and Food Safety

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# Content

- ✓ *Purpose, scope and NF categories*
- ✓ *New procedures*
- ✓ *Transition to the new system*
- ✓ *Work within next two years*

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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" will not change!*

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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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# Engineered nanomaterials

*Current situation*

- ***Nano provisions in Regulation (EU) 2011/1169 on food information to consumers (FIC)***
  - *Definition and labelling requirement*

*1 January 2018*

- ***FIC regulation***
  - *Definition will be deleted from FIC Regulation*
  - *It will replaced by a reference to the definition set out in the new novel food Regulation*
- ***New novel food Regulation***
  - *The definition is included in the novel food Regulation*
  - *Empowerment for the COM to update the definition in light of the scientific and technical progress (Revision of the Commission Recommendation from 2011)*

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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)*

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# 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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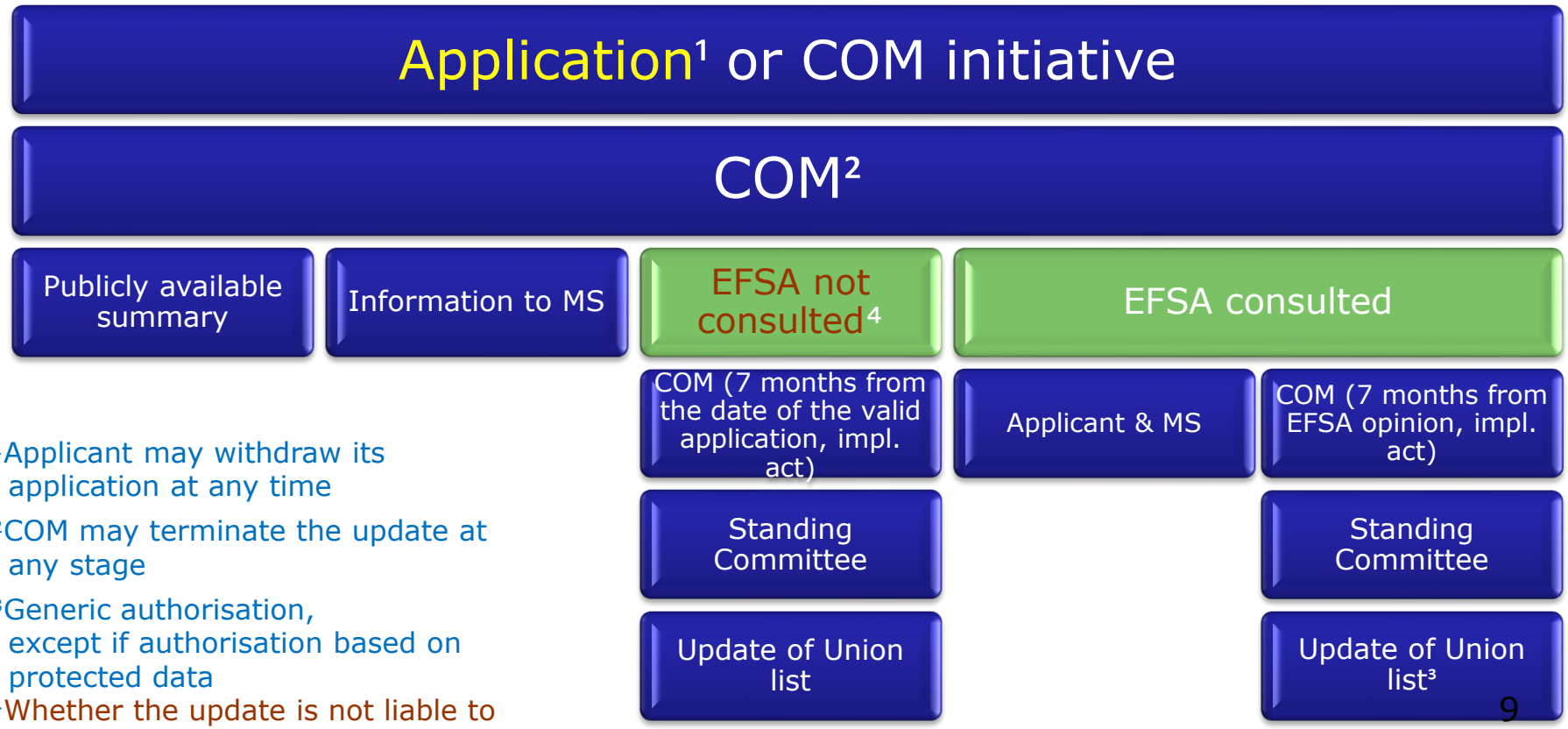
# Authorisation process and updating the Union list of authorised novel foods




[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



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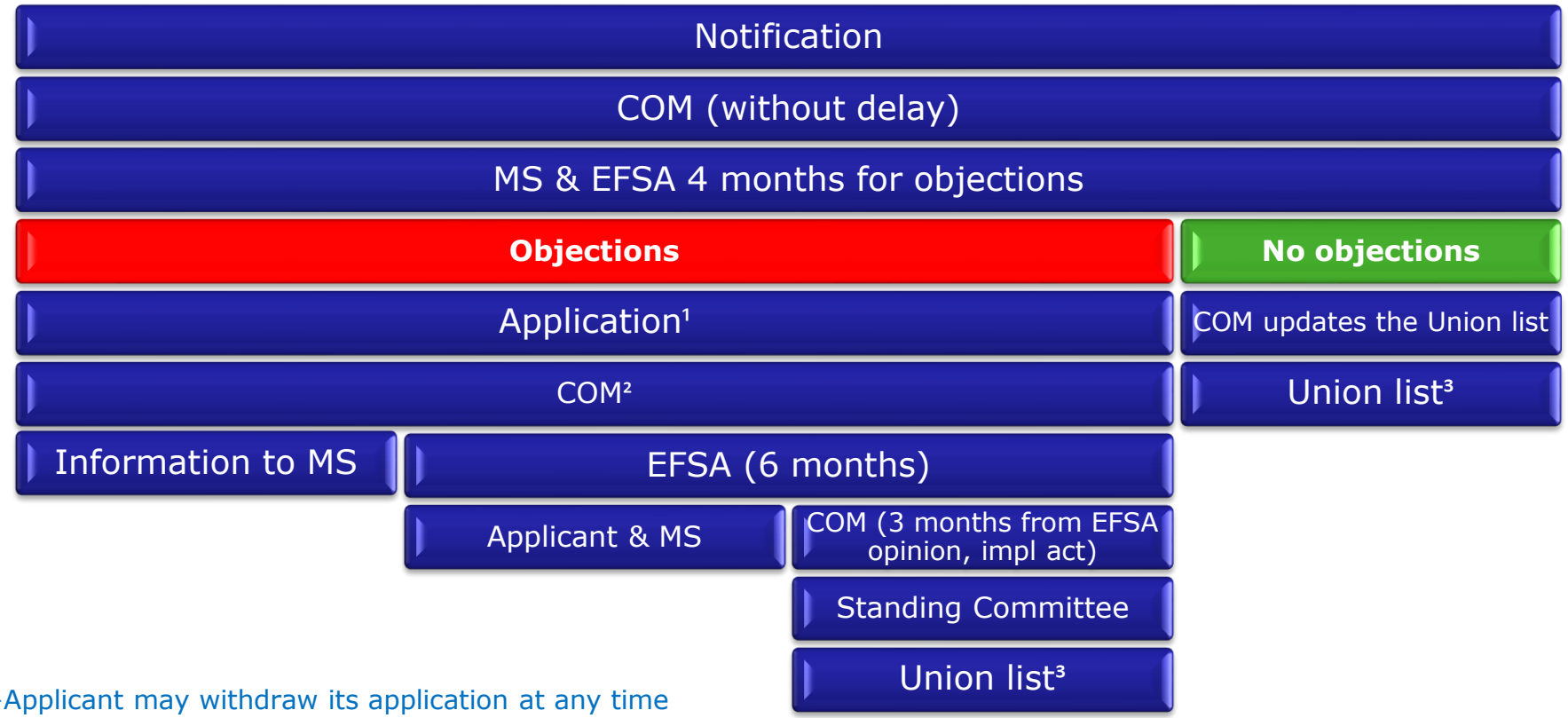
# Authorisation process (Traditional food from a third country)




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

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# 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.*** *(i.e. juice of the fruit of Morinda citrifolia L)*
  - ✓ ***From primary production*** *(i.e. chia seeds)*
  - ✓ ***Processed or unprocessed*** *(i.e. 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***

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# 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*

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# 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*

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# 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*

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# Work within next 2 years:

- *"Guidance" Implementing measure*
- *The procedural steps for the exchange of information with the Member States and with EFSA for submitting reasoned safety objections on third country notifications*
- *The procedural steps of the consultation process on the determination of the status of novel food*
- *Initial establishment of the Union list*
- *Update of the definition of engineered nanomaterial. Delegated act (It can only apply from 1 January 2018 at the earliest)*


**European Commission, DG Health and Food Safety website**
**http://ec.europa.eu/food/safety/novel_food/index_en.htm**

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