



Insects as food in the context of the novel food regulation

Rafael Pérez Berbejal

European Commission,
DG Health and Food Safety

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Health and
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The views expressed are purely those of the speakers and may not in any circumstances be regarded as stating an official position of the European Commission

Content

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- ✓ *Novel Food Regulation (NFR)*
- ✓ *Main changes*
- ✓ *Transition to the new system*
- ✓ *Work within next year*





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General food law in the EU (Reg. 178/2002)

- *Establishment of "from farm to fork" principle*
- *Scope covers all from Feed to Food*
- *Separation of Risk assessment from Risk management*
- *Creation of the European Food Safety Authority (EFSA)*
- *Establishment of the Rapid Alert System for Food and Feed (RASFF)*
- *Attribution of concrete responsibilities to the Feed and Food Business Operators (FFBOs) "first responsibility for safe food and feed is with the FFBOs"*

EU rules on insects as food

- **Principle of General Food Law** (Reg. 178/2002):
Food shall not be placed on the market if it is unsafe.
- **Food Hygiene Regulation** (Reg. 852/2004) applies to all FBOs and therefore also to keeping and placing on the market of insects. These acts ensure that general requirements on **safety, hygiene and traceability apply to insects.**
- **Novel Food Regulation.** Under existing Reg 258/97 and the new one (Reg 2015/2283) NF are subject to a pre-market approval. Safety assessment either by a Member State food assessment body or EFSA

Important achievements

- EFSA "Scientific Opinion on risk profile related to production and consumption of insects as food and feed" (Oct. 2015) profiles the risks and presents potential biological and chemical hazards as well as allergenicity and environmental hazards associated with farmed insects used as food and feed.
- Adoption of Circular Economy Package (Dec. 2015) aiming to generate sustainable growth and reduce food waste to which insect farming could contribute

Novel Food Regulation

Food not used for human consumption to a significant degree before 15 May 1997. Insects as food may fall under:

- ***Reg 258/97 Art 1(e)*** "food ingredients isolated from animals, except for foods and food ingredients obtained by traditional breeding practices and having a history of safe food use;"
- ***New Reg 2015/2283 Art 3(v)*** "food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union"



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Main changes

- Applications/notifications to the Commission. No fees
- 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. No fees
- Generic Authorisation by the Commission unless data protection is requested
- 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 (9 months)

COM (7 months from
the date of the valid
application, impl.
act)

Applicant & MS

COM (7 months from
EFSA opinion, impl.
act)

Standing
Committee

Standing
Committee

Update of Union
list

Update of Union
list³

¹Applicant may withdraw its
application at any time

²COM may terminate the update at
any stage

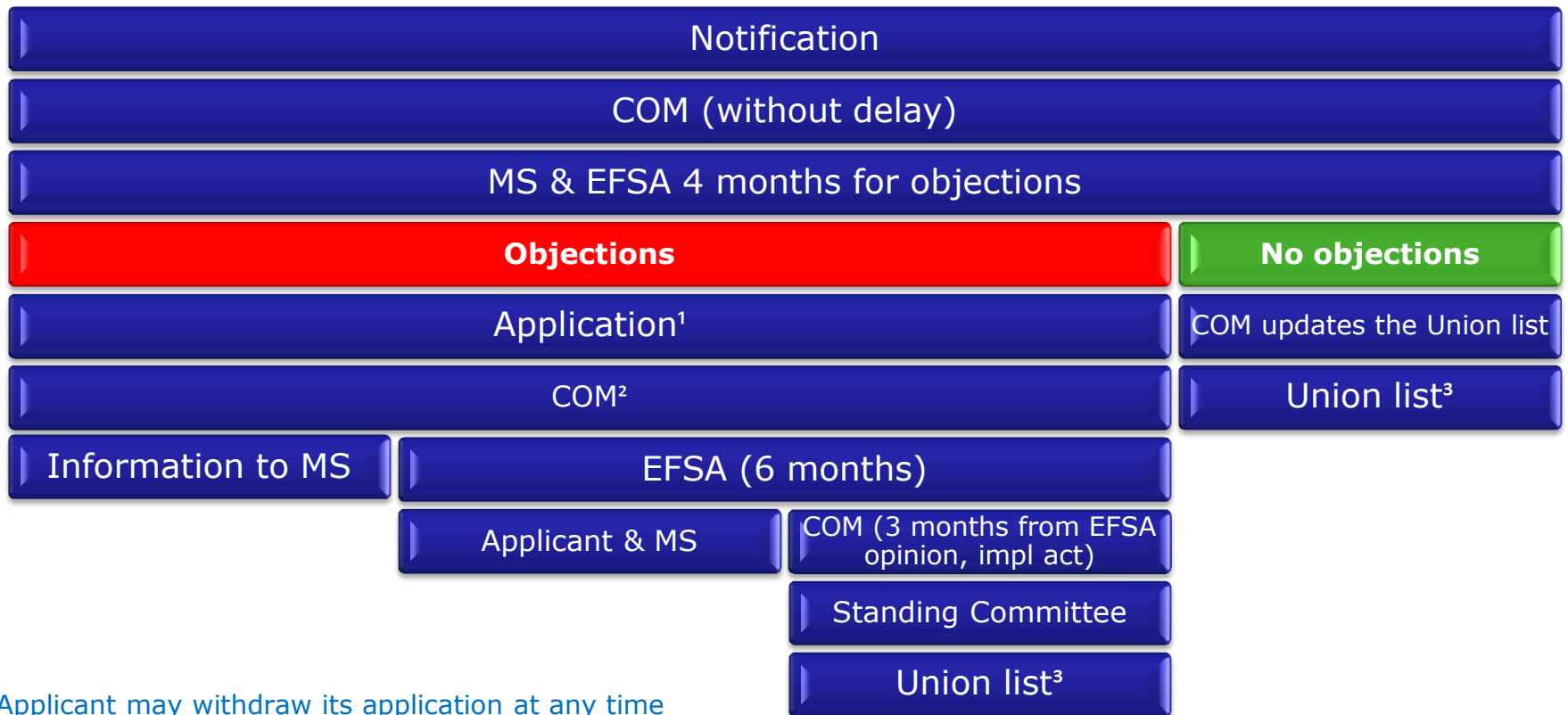
³Generic authorisation,
except if authorisation based on
protected data

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



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Authorisation process (Traditional food from a third country)



¹Applicant may withdraw its application at any time

²COM may terminate the update at any stage

³Generic authorisation

Traditional food from a third country

Traditional food from a third country is a novel food derived from primary production with a history of safe use in 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*** can be
 - ✓ ***Produced from*** plants/***animals***/micro-organisms etc. (i.e. insects)

Confidentiality and Data protection

On request by the applicant:

Confidentiality on the information in the application– harming of the competitive position

Data protection. COM can grant the individual authorization for 5 years. It does not apply to traditional foods from third countries.

Transitional Measures

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*

Transitional Measures

New rules fully apply from 1 January 2018

- ✓ *Foods not falling within the scope of Regulation (EC) No 258/97, which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation may continue to be placed on the market until a decision is taken following an application/notification submitted no later than 2 January 2020.*

EFSA guidance on novel foods

EFSA has recently published two guidance:

- 1) *Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283*
<http://www.efsa.europa.eu/en/efsajournal/pub/4594>
- 2) *Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283*
<http://www.efsa.europa.eu/en/efsajournal/pub/4590>

Work within next year

- *Implementing measures on administrative and scientific requirements for applications and traditional food 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*
- *The procedural steps of the consultation process on the determination of the status of novel food*
- *Initial establishment of the Union list*



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European Commission, DG Health and Food Safety website

http://ec.europa.eu/food/safety/novel_food/index_en.htm

Rafael PEREZ BERBEJAL (email: rafael.perez-berbejal@ec.europa.eu)