



# Regulation (EU) 2015/2283 on novel foods

Briefing paper on the provisions relevant  
to the commercialisation of insect-based  
products intended for human consumption  
in the EU

V.3  
Brussels,  
September 2021



International Platform  
of Insects for Food and Feed

# Regulation (EU) 2015/2283 on novel foods

## Briefing paper on the provisions relevant to the commercialisation of insect-based products intended for human consumption in the EU

### Preliminary remarks on the objectives and proposed use of this document

This briefing paper sets out the **administrative steps** to be followed by insect producers intending to submit an application for **authorisation of an insect/insect product as novel food** within the European Union. It is intended to be used as a practical guide to the EU legislative texts that are applicable to their activities, namely Regulation (EU) 2015/2283 on novel foods and its implementing measures (see section 1.1 for further information).

This briefing paper may also serve as guidance for other stakeholders, including all food business operators using insect products (i.e. by incorporating the insect raw material into food preparations) for final sale to consumers.

This briefing paper has been drafted by the **IPIFF Secretariat**, in collaboration with the Food law team of law firm **Bird & Bird LLP**.

### DISCLAIMER

This briefing paper is a non-binding document that is intended to facilitate the interpretation and application of the legislation on novel foods and does not constitute legal or professional advice. It does not necessarily reflect the official position of the European institutions (e.g. European Commission) the European Food Safety Authority, nor of IPIFF or its members.

The binding interpretation of legislation is the exclusive competence of the competent national and European jurisdictions. The views expressed in this guidance document do not constitute legal advice and cannot prejudice the position that the authors of this briefing paper might take before the jurisdictions.

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# 1. Legislation and guidance documents cited in this briefing paper and abbreviations

## 1.1 Legislation and guidance documents

### “Regulation (EU) 2015/2283”

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.

### “Transparency Regulation”

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

### “Implementing Regulations” collectively refers to:

### “Implementing Regulation (EU) 2018/456”

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.

### “Implementing Regulation (EU) 2017/2470”

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.

### “Implementing Regulation (EU) 2017/2469”

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.

### “Implementing Regulation (EU) 2017/2468”

Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

### “General Food Law”

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

## “Official Controls Regulation”

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC.

## “Regulation (EC) No 258/97”

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

## “EFSA Guidance on Applications for Authorisation”

Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1), published on 26 March 2021.

## “EFSA Guidance on Applications and Notifications of Traditional Food”

Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1), published on 26 March 2021.

## 1.2 Abbreviations

**EU:** European Union

**EC:** European Commission

**MS:** Member States

**DG SANTE:** The Directorate-General for Health and Food Safety

**EFSA:** European Food and Safety Authority

**EU:** European Union

**GMP:** Good Manufacturing Practices

**HACCP:** Hazard Analysis and Critical Control Point

**ISO:** International Organisation for Standardisation

**NFD:** Novel Food Dossier

**SCoPAFF:** Standing Committee on Plants, Animals, Food & Feed



## 2. Background on Regulation (EU) 2015/2283

Regulation (EU) 2015/2283 has become applicable on 1 January 2018. It repeals and replaces Regulation (EC) No 258/97, that has been in force until 31 December 2017.

The Novel Food Regulation applies to **certain categories of foods**, including foods originating from plants, animals, microorganisms, cell cultures or minerals (e.g. botanical extracts, insects, vitamins, minerals, food supplements, etc.) **that were not used for human consumption to a significant degree within the EU before 15 May 1997**, or resulting from production processes or practices not commonly used before that date (i.e. 'novel foods').

The Novel Food Regulation sets out **harmonised rules** for the placing on the market of these products in the EU.

With the recast of the legislation on novel foods, the EU legislator introduced, for the first time, **a centralised authorisation procedure** that is managed by the Eu-

ropean Commission and relies on the European Food Safety Authority (EFSA) as sole risk assessment body. Under Regulation (EC) No 258/97, the initial steps of the approval procedure were decentralised.

Under Regulation (EU) 2015/2283, whole insects and their preparations are considered as novel food and must thus be authorised under the new EU novel food system with the view to be lawfully marketed within the EU. The qualification of whole insects as novel foods was legally uncertain under Regulation (EC) No 258/97, and this has led to diverging approaches among EU Member States thereby generating a contrasted impact of the transitional provisions provided for under Regulation (EU) 2015/2283 (see below, section 4.8.).

Yet, this uncertainty has now been partly resolved since the ruling of the European Court of Justice in the Entoma case (C-526/19 Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation, judgment of 1 October 2020). In this Decision, the Court ruled that whole insects did not fall within the scope of that regulation and could thus be placed on the market without a premarket authorisation.

In light of this ruling, Member States should now, in principle, give full effect to the transitional measure foreseen in article 35.2 of the Regulation (EU) 2015/2283 provided that the conditions for applying it are met. For a more precise analysis, please refer to section 4.2 below.

Currently (end of August 2021), there have been over twenty applications submitted for authorisation of insects as novel foods or as novel food ingredients. The first decision granting authorisation of an insect as novel food has been adopted by the Commission on 1 June 2021<sup>1</sup>. Other currently pending applications for authorisation relate to *Acheta domesticus* (house cricket), *Alphitobius diaperinus* (lesser mealworm), *Gryllobius sigillatus* (crickets), *Hermetia illucens* (black soldier fly), *Locusta migratoria* (migratory locust), *Tenebrio molitor* (mealworm) and *Apis mellifera male pupae* (honey-bee drone brood). The summaries of some of the applica-

### Regulation (EU) 2019/625 – Article 2 Definitions

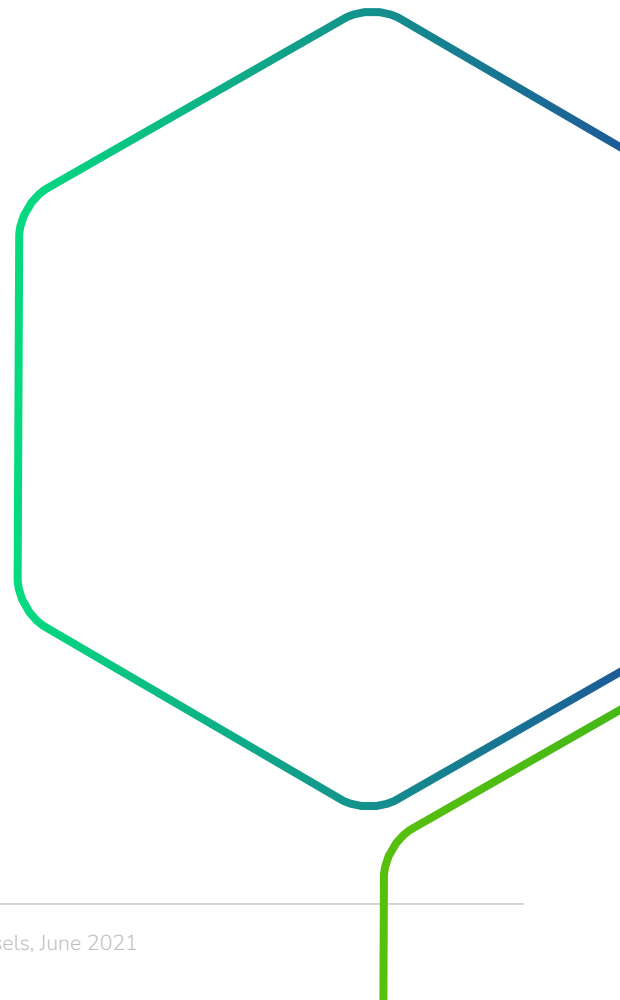
'insects' means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Implementing Regulation (EU) 2017/2470;

<sup>1</sup> Commission Implementing Regulation (EU) 2021/882 of 1 June 2021 authorising the placing on the market of dried *Tenebrio molitor* larva 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, O.J., L 194, 2 June 2021.



tions have been published on the European Commission (EC) web portal under the section novel food: [https://ec.europa.eu/food/safety/novel\\_food/authorisations/summary-applications-and-notifications\\_en](https://ec.europa.eu/food/safety/novel_food/authorisations/summary-applications-and-notifications_en).

As of 30 August 2021, EFSA has received a total of 17 insect novel food applications of which five are under 'completeness/suitability check' (see section below: EFSA Administrative guidance on the submission of applications for authorisation of a novel food), eight applications are currently in the 'risk assessment phase', for four applications EFSA has published its opinion (i.e. dried yellow mealworm, locusta migratoria, *Acheta Domesticus*, frozen and dried formulations from whole yellow mealworm) of which one application has lead to an authorisation (i.e. dried yellow mealworm). The first authorisation of an insect as novel food is an important step towards the wider commercialisation of insects for consumption and insect based foods in the European Union. With the Commission and EFSA becoming more familiar with insect-related application dossiers, the evaluation of applications related to other species could be facilitated in the future, at least in respect of certain aspects of the safety assessment where insect species share common characteristics.



### 3. How to use the briefing paper

In the present briefing paper:

- Elements included in **green frames** contain information on **legal provisions** extracted from the Novel Food Regulation and its Implementing Regulations.
- The above provisions are further **explained** throughout the present document, in order to **facilitate their implementation 'on the ground' by insect producers.**
- The content of this briefing paper is partially based on **official communication documents** (e.g. European Commission website, including press releases, EFSA guidance documents).

## 4. EU regulatory requirements applicable to the placing of insects as food on the EU market

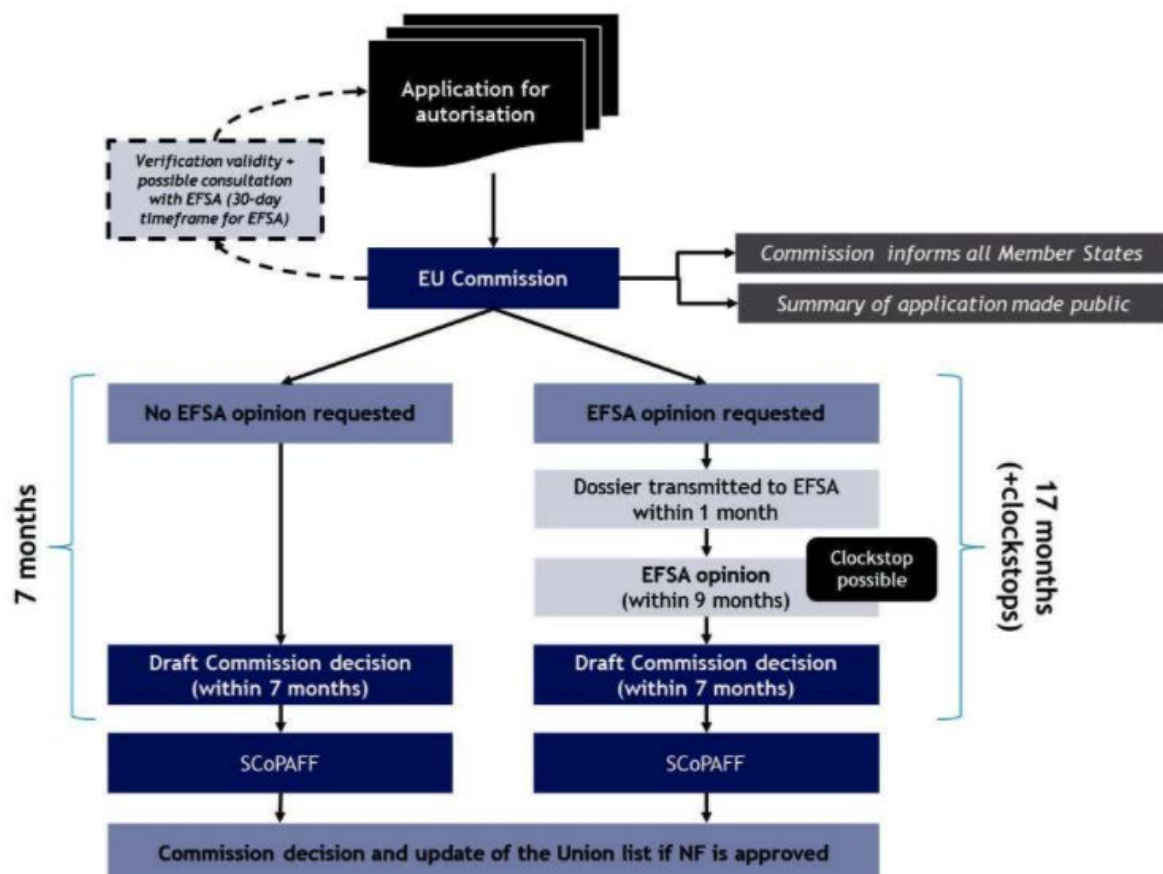
### 4.1. Outline of novel food authorisation procedures

Regulation (EU) 2015/2283 sets out the requirements for the placing of 'novel food' products on the EU market: notably these requirements concern the content of the application for authorisation which applicants must conform with (see section 4.5.) and the procedural steps to be followed by the EC, the EU Member States and the EFSA in the authorisation process. The different steps of the authorisation procedure are laid down in **chapter III of Regulation (EU) 2015/2283**.

A distinction must be drawn between the 'standard' authorisation procedure and the specific rules applying to traditional products from third countries (the so-called 'Notification procedure').

**Note:** the present chapter provides a general description of the authorisation procedure applying to traditional food from a third country, but it does not address in detail the aspects related to the preparation of notification dossiers.

#### 'Standard' procedure for novel food authorisation





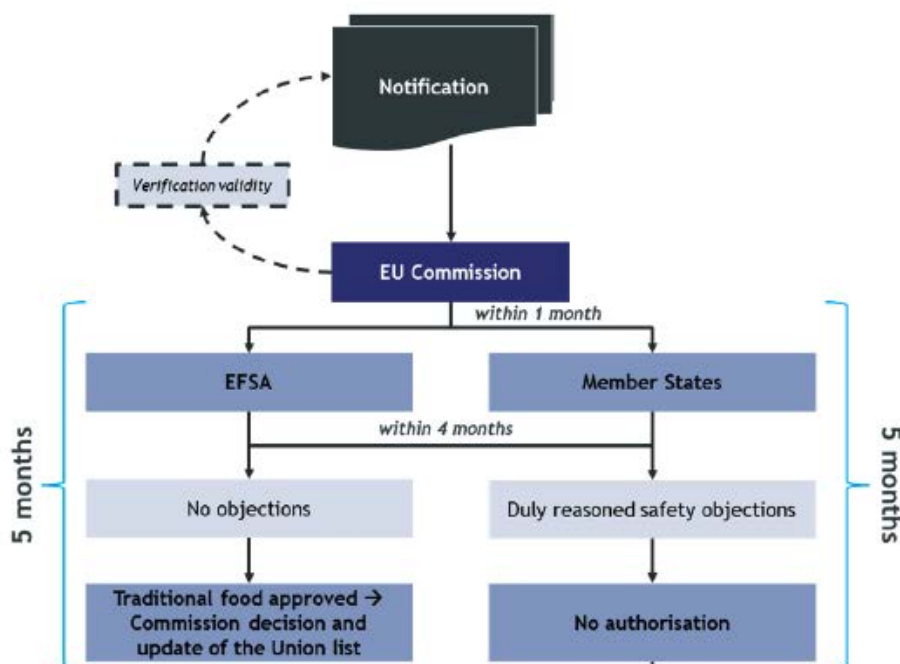
## Notification of a traditional food from a third country (and where, applicable, authorisation procedure)

Articles 14 et seq. of Regulation (EU) 2015/2283 introduce a simplified and 'fast track route' to lawfully place novel foods on the EU market for which an history of consumption can be demonstrated in a non-EU country (third country). This procedure is called 'notification of a traditional food from a third country' (hereafter referred to as 'the Notification Procedure').

Under the Notification Procedure, a traditional food may be allowed to be placed on the European Union market after only four months from the date of submission of a valid and complete notification by the European Commission to the Member States and EFSA, provided that no safety concerns ('duly reasoned safety objections') are raised by any Member State or EFSA during that period. In case such objections are raised, an authorisation procedure similar to the 'standard' procedure, but with shorter timeframes, is open to the entity that had unsuccessfully filed a notification. An overview of the procedural rules applicable to the Notification Procedure is provided below.

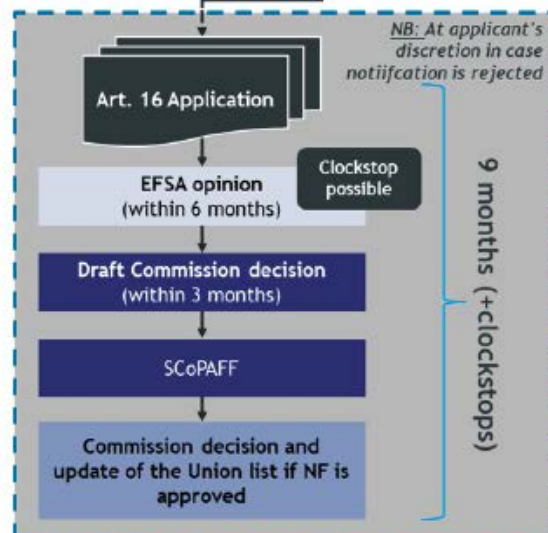
Novel Food applications for authorisation and notification concerning traditional products from third country must be submitted to the European Commission services, through the **e-submission system**, which is available on the DG SANTE website (European Commission) through the following link: <https://webgate.ec.europa.eu/esfc/>

Practical guidance on how to submit an application is provided in the **e-submission user guide**, which is available through the following link: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6488>



### 'Stop-the-clock'

When EFSA is conducting its risk opinion during an authorisation or notification procedure of a novel food application, EFSA may ask for additional information in order to complete its evaluation. When this happens, the clock on the regulatory timetable for the risk assessment is stopped until the new data is supplied. This mechanism aims to ensure that applications are assessed on a case-by-case basis in the most time-efficient way. However, this mechanism does not pre-judge on 'quality of the 'dossier' submitted, but rather aims to collect additional evidence or documentation for EFSA to develop its opinion. The eight applications 'in the pipeline' (mentioned in section 2.: Background information) have been subject to 'stop the clock' mechanism which explains the delay in EFSA's opinion corresponding to the aforementioned time frame of 9 months.'



## 4.2. Material scope of Regulation (EU) 2015/2283 and applicability to insect products

### Categories of food covered under the definition of 'novel food' in Regulation (EU) 2015/2283 vs. in Regulation (EC) No 258/97

While Regulation (EC) No 258/97 included a category of novel foods covering “food ingredients isolated from animals”, the definition of this category has been clarified and extended under Regulation (EU) 2015/2283. Per Article 3(2)(a) of Regulation (EU) 2015/2283, novel foods include “food consisting of, isolated from or produced from animals or their parts”. Indeed, the narrow definition of ‘novel food’ provided in Regulation 258/97 had **led to diverging opinions among national competent authorities as to the qualification of whole insects as novel foods**: several authorities and stakeholders argued that foods or food ingredients consisting of whole insects did not constitute ‘novel food’ under the Regulation (EC) No 258/97 (see section 4.8 below).

By including both whole animals and their parts in the material scope of application of Regulation (EU) 2015/2283, the legislator clarified **that this category therefore encompasses whole insects and insect-derived products**.

#### Regulation (EU) 2015/2283 - Article 3(2)(a)

‘**novel food**’ means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

[...]

(v) food consisting of, isolated from or produced from animals or their parts, except for animal-sobtained 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; [...]

The legislator even included a **specific reference to whole insects and their parts in Recital 8** of Regulation (EU) 2015/2283, that now places the qualification of whole insects as novel foods beyond question.

#### Regulation (EU) 2015/2283 - Recital 8

“The scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) No 258/97. However, on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. Those categories **should cover whole insects and their parts.**”

Although Regulation (EU) 2015/2283 brought clarity on the question as to whether whole insects or parts of whole insects should be considered as novel foods, this question remained relevant even after the entry into force of the Regulation (EU) 2015/2283 -notably in light of the applicability of the transitional regime provided by the Regulation (EU) 2015/2283. Indeed, according to Article 35 (2) of the Regulation (EU) 2015/2283, foods not falling within the scope of Regulation (EC) No 258/97, which were lawfully placed on the market by 1 January 2018 and which fall within the scope of Regulation (EU) 2015/2283, may remain on the market until a decision is adopted following an application for authorisation of a novel food -or a notification as the case may be-, provided such application or notification is made before a date that the Commission set to 1 January 2019.

In its Entoma ruling<sup>2</sup>, the European Court of Justice finally clarified the scope of the Regulation (EC) No 258/97. According to the Court, Article 1(2)(e) of Regulation (EC) No 258/97 must be interpreted as meaning that foods consisting of whole animals intended to be consumed as such, including whole insects, do not fall within the scope of that regulation.

As a first part of its reasoning the Court applied a literal interpretation of the concerned provision. First, the Court affirms that term 'food ingredients' refers in general to a component of a larger, composite end product, in essence, a 'foodstuff' (or a 'food'). Consequently, an ingredient is not, in principle, a product intended to be consumed in and by itself, but rather a substance or a product to be added to other substances to create a food. Secondly, the Court clarifies that the expression "isolated from" animals, refers to a process of extraction from the animal. Therefore, interpretation of that expression may not result in a reference to a whole animal.

The interpretation given by the Court has retroactive effect. It clarifies the scope of the Regulation (EC) No 258/97 as it should have been understood and applied from the date on which the rule interpreted entered into force. Given this retroactive effect, national authorities have, in certain situations the obligation to retract/with-

draw administrative decisions that are contrary to the European provision as interpreted in the Entoma ruling (for more information see section 4.8 of this paper).

That said, as recalled by the Court, the fact that foods consisting of whole animals intended to be consumed as such, including whole insects, do not fall within the scope of the Regulation (EC) No 258/97 does not mean that the Member States are not empowered to take decision restricting the placing into the market of these products. On this ground, some Member States could adopt national measures prohibiting or strictly restricting the placing into their national markets foods made of whole insects and, possibly, to attach to these measures a retroactive effect. However, the chances that such measures will be legally valid are low; such measures should comply with strict legal requirements (see in that regard section 4.8 of this paper.)

Nevertheless, it remains uncertain whether parts of whole insects and ingredients processed from whole insects, such as insect powders fall outside the scope of Regulation (EC) No 258/97. The Entoma ruling did not address this question specifically.

From the Entoma ruling, arguments can be deducted that would justify the idea that whole insects powder could also fall outside the scope of Regulation (EC) No 258/97. Several Member States follow this approach since the Entoma ruling, and grant ingredients made of whole insects the benefit of the transitional measures defined under Regulation (EU) 2015/2283.

A reasoning supporting this position can notably be elaborated based on the condition, spelled out under the definition of 'novel food', that a food must have been "isolated from" animals to fall under the scope of the regulation - which implies the implementation of a selective extraction process. Following a literal interpretation of this condition, it can be inferred that parts of whole insects and ingredients processed from whole insects such as powders from whole insects are not extracted and would therefore fall outside the scope of Regulation (EC) No 258/97.

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2 Case C 526/19 (Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation), 1 October 2020

## Summary overview of the respective scopes of Regulation (EC) No 258/97 and Regulation (EU) 2015/2283 in respect of whole insects, parts of whole insects and insect-based preparations

	Regulation (EC) No 258/97	Regulation (EU) 2015/2283
Whole insects	✗ Not in scope	✓ In scope
Parts of whole insects and ingredients processed from whole insects (e.g. whole insects flour)	✗ Not in scope*	✓ In scope
Ingredients other than (parts of) whole insects (e.g. insect extracts)	✓ In scope	✓ In scope

\* Diverging national interpretations – Some Member States did consider these categories of products as novel food under Regulation (EC) No 258/97, the Entoma ruling did not clarify this aspect. Several EU Member States have nevertheless extended the scope of the transitional measures to these products as well.

### Is there evidence supporting a significant consumption of insects within the European Union before 15 May 1997?

The category of novel foods defined under Article 3(2) (a)(v) excludes “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”.

Furthermore, a given food or ingredient only qualifies as ‘novel food’ under the condition that it “was not used for human consumption to a significant degree within the Union before 15 May 1997”.

The qualification as ‘novel food’ is therefore **not ‘automatic’** but results from the **absence of tangible information to substantiate ‘relevant’ consumption levels in Europe** before that date.

Yet, none of the surveys so far conducted by EU Member States competent authorities<sup>3</sup> concluded to the existence of such history of consumption in relation to insects. There is also no history of traditional breeding practices for insects that would have been used in the EU before 15 May 1997.

While operators are still in time to submit information to substantiate ‘history of consumption in Europe before 1997’, to the best knowledge of the authors of this document, no tangible information has been identified that would enable to substantiate such consumption levels. It is therefore very unlikely that European insect producers can benefit from an exemption to the application of the EU novel foods legislation to their products (i.e. exemption based on a demonstrated significant consumption or traditional breeding within the Union before 15 May 1997).

<sup>3</sup> See Surveys conducted by Belgium (Federal Agency for the Safety of the Food Chain) and the UK (Food Standards Agency) authorities in 2014 and 2015.

## 4.3. May insects qualify as ‘traditional food from a third country’?

The Notification Procedure (see section 4.1. above for more details) constitutes an opportunity for the authorisation of insects and insect ingredients produced outside the EU, **in third countries/regions** in which **insects form part of the traditional diets of local populations**.

However, Regulation (EU) 2015/2283 imposes strict conditions for producers to benefit from such regime. The concerned products must indeed, as per Article 3 of Regulation (EU) 2015/2283, meet the following cumulative conditions:

- be derived from **primary production**, i.e. the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. Primary production also includes hunting and fishing and the harvesting of wild products.
- have a **history of safe use in a third country**, i.e. 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.

Insect producers seeking a novel food authorisation through the Notification Procedure must also demonstrate **25 years of uninterrupted consumption**, to be substantiated by **both anecdotal** and documented evidence. Operators have however freedom to select the forms of materials to substantiate such a claim. Notably, the EFSA Guidance on Applications and Notifications of Traditional Food indicates that scientific publications, scientific expert opinions, monographs, information from national or international organisations, government documentation, figures on cultivation harvesting, and from sales and trade are ‘acceptable references’ to

substantiate such consumption. It also indicates that supporting documentation on the experience of the continued food use should provide a description of the extent of use of the traditional food, the population group for which the traditional food has been a part of their diet, information on its preparation and handling, its role in the diet, information on precautions. It recommends the performance of **a comprehensive literature review of human studies related to the consumption of the traditional food**.

**Insect Food business operators established within the EU may use the Notification Procedure** for authorising their products as ‘novel food’ under Regulation (EU) 2015/2283. However, where primary production takes place in the EU, it may be difficult, in practice, for the applicant to demonstrate that the traditional product that it notifies under the Notification Procedure is similar, for example in terms of preparation mode or processing methods used, to a product that is traditionally consumed in a third country.

Besides this, while all types of products are in principle eligible for the Notification Procedure, whole insects (including those subjected to limited/simple processing steps such as dehydration) are more likely to be notified than more significantly processed products. Indeed, it is less likely that a history of safe use may be established for highly processed product derived from insects (incl. insect meal products) given that the commonly known and documented traditional uses of insects generally entail minimal and/or basic processing steps.



## 4.4. Operators' responsibilities for submitting an application for authorisation or initiating a notification under Regulation 2015/2283

### Which operator(s) within the production chain is (are) responsible for submitting a novel food application for authorisation or initiating a Notification Procedure?

It is prohibited for any food business operator to place a novel food on the market if that novel food is not duly authorised or notified in accordance with Regulation (EU) 2015/2283. So in other words, the responsibility for submitting a novel food application or initiating a Notification Procedure primarily lies on actors 'placing the novel food on the market'.

#### General Food Law - Article 3(8)

'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves."

The definition of 'placing on the market' provides indications on those actors on whom the responsibility for submitting an application for authorisation (or initiating a notification procedure) mainly lies.

The first food business operator that places a novel food on the EU market is required to initiate the appropriate steps towards approval of that product, irrespective of whether the product is intended to be reused, incorporated into a final product or further processed by a subsequent food business operator further down the supply chain. In that regard, **primary producers will play a key role and will in most cases act as initial applicants.** Consequently, the main responsibility for submitting an

application will generally lie on the following actors:

- **Insect primary producers/** insect breeders who sell insects as raw material **to a subsequent producer**, who further processes and/or incorporates the material into a final product (later referred as the 'insect product user');
- **insect primary producers** who sell insects directly to consumers or through an intermediary or **distributor**.

**The central role of insect primary producers** in the approval process derives from the fact that such operators **control the farming and main production operations**, from the sourcing of the substrates fed to the insects up to the first processing activities. These operators thus determine the composition/intrinsic characteristics of the product that forms the subject-matter of the application or notification (see section 4.6. below for more details).

### Is the responsibility for submitting a novel food application for authorisation or initiating a Notification Procedure limited to operators 'placing the product on the market'?

Article 3(2)(d) of Regulation (EU) 2015/2283 defines the term 'applicant': according to this provision, the initiative for initiating the process of authorisation of a novel food also belongs to the European Commission (as per Article 10(1) of Regulation (EU) 2015/2283). This right of initiative of the Commission is not expressly provided for in respect of the Notification Procedure (see Article 14 of Regulation (EU) 2015/2283) however.



### Regulation (EU) 2015/2283 – Article 3 - Definitions

“[...]2. [...] (d) ‘the applicant’ means the Member State, the third country or the interested party, which may represent several interested parties and has submitted to the Commission an application in accordance with Article 10 or 16 or a notification in accordance with Article 14; [...]”

### Regulation (EU) 2015/2283 – Article 10 - Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list

“1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 shall start either on the Commission’s initiative or following an application to the Commission by an applicant [...]”

### Regulation (EU) 2015/2283 – Article 14 - Notification of a traditional food from a third country

“Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within the Union a traditional food from a third country, may opt to submit a notification of that intention to the Commission [...]”

The regulation thus identifies two main categories of potential applicants, namely “institutional” applicants (EU countries, non-EU countries and the Commission) and “non-institutional” applicants (food business operators). It is however expected in practice that most applications and notifications will be performed by or on behalf of food business operators, who intend to place the novel food on the EU market.

### REMARKS CONCERNING “INSTITUTIONAL” APPLICANTS

- The definition under Article 3(2)(d) of Regulation (EU) 2015/2283 entails that **EU Member States authorities** may assist companies that are active in the production of a same species, so as to prepare and submit an application on their behalf. This type of approach could be envisaged for example where insect products originating from several different insect producers are concerned, provided that these products originate from the same insect species and have similar intrinsic characteristics. This approach would then lead to a joint application.
- In practice, this option of a joint application led by an authority however seems more relevant in the case of a **third country** seeking authorisation **through the notification procedure** (as per Article 14 of Regulation (EU) 2015/2283). Indeed, national authorities in those countries where insects are traditionally consumed (e.g. South East Asia, African countries, Mexico) are sometimes ‘better placed’ than operators themselves – who very often are ‘micro scale’ farmers – to gather, collect, aggregate and analyse the data required for the compilation of the notification dossier.

- The **European Commission** has a right of initiative for the authorisation and update of authorisation of novel foods. For example, the Commission may deem it appropriate to amend a specific authorisation in consideration of public safety concerns. In such cases it is entitled to initiate a process towards amendments to the list of authorised Novel Food products. It is worth mentioning that in this process and in all procedures led and managed by the European Commission under Regulation (EU) 2015/2283, the Commission is assisted by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF).

## REMARKS CONCERNING 'NON-INSTITUTIONAL' APPLICANTS

- Any legal or natural person may be an applicant under Regulation (EU) 2015/2283. In particular, the regulation does not require that an applicant is established in the EU to the purpose of seeking an authorisation or submitting a notification. In practice, applicants may be food business operators, consultants, counsels, industry associations or any other natural or legal person.
- Applications can be filed by single applicants, or jointly by several applicants, e.g. a **joint application** could be submitted on behalf of **several producers** that are active in the production of the same product. The text of Regulation (EU) 2015/2283 leaves **freedom for operators on how to organise their collaboration**. In practice, any form of 'horizontal' structure gathering several insect primary producers of the same species or 'vertical' forms of collaboration, congregating actors at different stages of the production chain (e.g. primary producers, processors and retailers) is possible, and the choice of the **legal form to use** (e.g. joint venture, consortia, non-profit organisation or registered company) is also left to the interested parties' discretion. It is also advisable to restrict the ambit of the application to one single insect species. Furthermore, one of the practical

challenges that these actors will need to address is the precise characterisation of the product(s) that form(s) the subject-matter of their application. A particular attention will need to be reserved in that context to the production conditions and production processes used, as recorded in the product specifications. At the same time, these operators will need to demonstrate that their products have '**similar characteristics**' and/or are produced under '**similar conditions**' (see below section 4.6. Sub-section 'principle of generic authorisation' for further details). Other points of attention for operators intending to proceed with a joint application include – without limitation – the cost and profit sharing, confidentiality, regulatory data protection and antitrust compliance.

## 4.5. Content of the application for authorisation (‘standard’ procedure)

**Note:** the present briefing paper does not cover aspects related to the preparation of notification dossiers for traditional foods from a third country.

### Pre-submission advice

The Transparency Regulation inserted a new provision in the General Food Law (article 32a) concerning pre-submission advice. Since 27 March 2021, where EU law, such as the EU legislation on novel foods, contains provisions for the EFSA to provide a scientific output, potential applicants have the possibility to request general pre-submission advice (GPSA) from EFSA before submitting an application, but requesting GPSA is not mandatory.

It should be noted that the scope of the GPSA is limited and mainly relates to the:

- Applicable rules on the application procedure;
- Required content for application.

A GPSA can for example be used to seek clarifications as to the information requirements that need to be met by an application for authorisation related to an insect species or an insect-based ingredient as a novel food.

The GPSA can however not be used to seek advice regarding the following:

- design of the studies to be submitted and questions related to hypotheses to be tested, unless the advice concerns guidance documents developed by EFSA in which study design is addressed;
- risk management questions;
- any aspects going beyond the information available in the legislation, rules, guidance documents or guidelines applicable to applications.

Such advice provided by the staff of the EFSA is without prejudice and non-committal as to any subsequent assessment of applications by the Scientific Panels.

This means that if insect operators request GPSA, this advice will not be binding, but it will rather have a guiding effect.

EFSA recommends that requests for GPSA are submitted at least six months prior to the envisaged submission date for the application.

Before submitting any GPSA request, applicants need to register through EFSA’s website and obtain a pre-application ID which must be included in the application. Subsequently, the request must be submitted to EFSA by filling in a form that is available on the agency’s website: <https://www.efsa.europa.eu/en/applications/toolkit>

For more information please refer to chapter 2.1. “General pre-submission advice” of EFSA’s “Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283”, which can be found here <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6488>

Furthermore, Chapters II, III and IV of the Decision of the Executive Director of the EFSA laying down practical arrangements on pre-submission phase and public consultations provide further guidance. This decision can be consulted here [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf).

## Overall structure of the dossier and administrative requirements

While article 10(2) of Regulation (EU) 2015/2283 sets out the main components of an application for authorisation, Implementing Regulation (EU) 2017/2469 (more specifically, Articles 3 and 4 thereof) singles out more precisely the main elements to be included in the application.

### Implementing Regulation (EU) 2017/2469 - Article 3 - Structure, content and presentation of an application

1. An application shall be submitted electronically to the Commission and shall consist of the following:

- (a) a **cover letter**;
- (b) a **technical dossier**;
- (c) a **summary of the dossier**.

2. The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex I.

3. The technical dossier referred to in paragraph 1(b) shall contain:

- (a) the administrative data as provided for in Article 4;
- (b) the scientific data as provided for in Article 5.

## Notification of studies

The Transparency Regulation inserted a new article 32b in the General Food Law, that relates to the notification of studies. Potential applicants commissioning or carrying out studies as of 27 March 2021 to support an application covering insects or insect based foods have an obligation to notify EFSA without delay before the starting date of such study. The following information has to be notified to the agency:

- title and scope of study
- laboratory or testing facility
- starting and planned completion dates of the study

The same obligation applies to the laboratories and other testing facilities located in the EU for studies commissioned by potential applicants and carried out by such

laboratories and other testing facilities.

Notifications must be submitted in the database of study notifications available on the following website: <https://www.efsa.europa.eu/en/applications/toolkit>

Applicants should be aware that non-compliance with the notifications of study obligations may result in the non-validity of the application or in delays in the risk assessment process.

For more information please refer to 2.2 ("Notification of studies") of EFSA's "Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283" (see: Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283). Further guidance can also be found in the Decision of the Executive Director of the EFSA laying down practical arrangements on pre-submission phase and public consultations provide further guidance. This decision can be consulted here [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf).

## Scientific data requirements

Implementing Regulation (EU) 2017/2469, Article 5, defines the scientific data requirements to be included in the application for authorisation.

### Implementing Regulation (EU) 2017/2469 - Article 5 – Scientific data requirements

1. The dossier submitted in support of an application for the authorisation of a novel food shall enable a **comprehensive risk** assessment of the novel food.

(...)

3. The applicant shall provide a copy of **the documentation on the procedure and strategy followed when gathering the data**.

4. The applicant shall provide **a description of the safety evaluation strategy** and the corresponding toxicological testing strategy and shall justify the inclusion or exclusion of specific studies or information.

5. The applicant shall provide on request the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application. This information includes data used to generate the conclusions of the individual studies and results of examinations.

6. Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.

7. For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration. Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.

8. The applicant shall propose an **overall conclusion on the safety of the proposed uses of the novel food**. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

## Provision of evidence substantiating the absence of safety risks

### Regulation (EU) 2015/2283 - Article 10(2), (c) and (e)

“2. The application for an authorisation shall include:

[...]

(c) the description of the production process(es);

[...]

(e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;”

The production process(es) used to produce the novel food has/have to be described.

In the case of insect products, all **measures implemented for production control and quality and safety assurance** should be described (e.g. HACCP, GMP, ISO): notably, a production flow chart may be provided, including quality and safety control checks. Adherence to **recognized professional guides of good hygiene practices** are also a critical element to substantiate product food safety.

The Scientific Opinion that EFSA published on 8 October 2015 on the risk profile related to production and consumption of insects as food and feed<sup>4</sup> identified the production conditions, including inputs during production, as main determinant of potential hazards (e.g. biological and chemical contaminants) for the use and consumption of insects.

An express reference to this Scientific Opinion is made in the EFSA Guidance on Applications for Authorisation, in the following terms (see Section 2.10.7.1 of the Guidance):

*“The EFSA Scientific Committee has identified potential hazards related to the use of farmed insects as food (EFSA Scientific Committee, 2015). These should be considered in applications for novel foods which consist of, are isolated from, or are produced from farmed insects, taking into account the species and substrate to be used, as well as methods for farming and processing. Insects collected from the wild may bear additional biological and chemical hazards which should be considered and addressed.”*

<sup>4</sup> Available at <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4257/epdf>



For more information in this regard, reference is made to the 'IPIFF report on approaches to addressing data requirements for insects as novel food' (published on 24 May 2018)<sup>5</sup>.

## Conditions of intended uses, product specifications and labelling requirements

Besides the 'scientific demonstration' (see above), the novel food specifications or 'conditions of intended use' constitute another key element to be included in the application for authorisation. These specifications **form a crucial component of the subsequent novel food authorisation** and are specified in the **Union list of novel foods**.

Article 10(2)(g) of Regulation (EU) 2015/2283 sets out these elements.

### Regulation (EU) 2015/2283 - Article 10(2)(g)

"2. The application for an authorisation shall include:

[...]

g) a proposal for the **conditions of intended use** and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary."

Careful consideration should be given by the applicant to the framing of **the conditions of intended uses** in order to ensure that they are representative enough of the product to be placed on the European Union market and that they cover **all intended uses** of the product for which an authorisation is sought by the applicant.

Any authorisation results in the inclusion of the authorised product in the Union list of novel foods, along with relevant **product specifications** that are listed in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470.

Based on the compositional data relating to the novel food, the specifications may notably include a description of the novel food and set out limits for relevant parameters. In the case of insect products, these specifications are likely to include:

- the **concentrations of the main constituents** in products (compositional requirements);
- **microbiological criteria (most likely in range values)**;
- **limits for impurities and degradation products** (e.g. residues levels from chemical and biological contaminants that may originate from the substrate used or manufacturing practices) that may be present in the final product<sup>6</sup>.
- However, according to current exchanges with the EC, no references to the production processes nor specific substrate use criterias would be included in the authorised product specifications.

These may also **include a precise description of good farming/production and hygiene practices to be followed by producers** if the risk assessment concludes that these are necessary to achieve a high level of food safety for the final product.

Compliance with the above conditions may notably be verified by **Member States authorities in the context of official controls** in relation to the applicant's product, but also in relation to products marketed by other operators relying on the same authorisation.

<sup>5</sup> A summary of the abovementioned report is made available on the IPIFF website. For more information you may contact the IPIFF Secretariat.

<sup>6</sup> 'IPIFF report on approaches to addressing data requirements for insects as novel food' (published on 24 May 2018), p 7.



## Description of the food categories for which a novel food authorisation is sought

It is important to note that any applicant is required, both in the ordinary authorisation route and the Notification Procedure, to indicate the food categories for which the use is requested (hereafter, the “food uses”), along with a proposal for the conditions of intended use of the novel food (See Articles 10(2)(g) and 14(f) of Regulation (EU) 2015/2283 and Annex I of Implementing Regulation (EU) 2017/2469 and Annexes I and II of Implementing Regulation (EU) 2017/2468). As regards the requested food uses, it is recommended to make use of the EFSA Food Classification system FoodEx2.

Any novel food authorisation or notification will be valid only for the food uses requested by the applicant. This means that food uses which are **not** listed in the approved application or notification will not be covered by this application or notification. **In case an operator seeks to commercialise a product for a food use that is not covered it will need to obtain an extension of the existing authorisation** (see section 4.6. below for more details). In practice, **joint applications** (as outlined above, section 4.4.) submitted on behalf of producers that are vertically integrated into a same structure (i.e. at different stages of production) are likely to offer valuable opportunities to tackle such situations, as insect users may anticipate and bring in food uses envisioned by insect users directly into the first, joint application.

## EFSA Administrative guidance for the preparation of applications on novel foods

The document provides administrative guidance on the preparation and submission of new applications or modifications of an existing authorisation of a novel food in the European Union. It applies to all applications submitted as of 27 March 2021. For applications submitted before that date, the previous version of the guidance applies (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1381>).

The document provides guidance to applicants submitting applications on novel foods in the European Union, which are to be evaluated by EFSA. It describes the administrative requirements for the preparation and online submission of the dossier to support an application pursuant to Article 10 of Regulation (EU) 2015/2283 such as timelines, language requirements, requirements on the structure of the dossier, etc. Annex A and B of the guidance furthermore contain a reference to the ‘completeness checklist’ and ‘summary tables’:

- Completeness checklist – which refers to the data requirements for the application. The applicant should use the checklist to verify the completeness of the data for risk assessment in the technical dossier. It should be filled in and submitted using a common word processing format (e.g. MS Word). EFSA will use the completeness checklist provided by the applicant in its technical dossier to check the completeness of the data.
- Summary tables: The applicants are encouraged to use the summary tables in order to summarise the results of the scientific studies provided in the technical dossier. These tables represent an example for the presentation of scientific data. The adherence to the common format will facilitate EFSA to carry out the risk assessment.

EFSA strongly recommends the use of the completeness checklist and summary tables when preparing an application for novel food and to upload the two documents as other relevant information through the EC e-submission system.

The documents can be accessed through this link: <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6488> (under ‘Supporting Information’)



## Stand-alone evaluation vs. grouped authorisation

Article 2 of Implementing Regulation (EU) 2017/2468 and Article 2 of Implementing Regulation (EU) 2017/2469 define the concepts of 'notification' and of 'application'.

### Implementing Regulation (EU) 2017/2469 – Article 2

'application' means a stand-alone dossier containing the information and the scientific data submitted for the authorization of a novel food pursuant to Article 10(1) of Regulation (EU) 2015/2283.

### Implementing Regulation (EU) 2017/2468 – Article 2

“(a) ‘notification’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 14 of Regulation (EU) 2015/2283.

(b) ‘application’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 16 of Regulation (EU) 2015/2283.”

The fact that an application or, where relevant, a notification constitutes a stand-alone dossier, means that each scientific evaluation conducted by EFSA is specific to the concerned product, based on the information and scientific data provided in the corresponding dossier submitted in support of the notification or the application for authorisation.

This article finds its relevance if two or more applications covering the same insect species are being examined at the same time. In that case, each application will **be evaluated individually and separate decisions to authorise the product** as novel food shall be taken based on the information and scientific evidence provided in each application.

However, **cross-references** between applications may be considered when evaluating information and evidence that are equally relevant to all products being evaluated (generic published study substantiating the safety of insects for human consumption - e.g. nutritional information history of safe use, allergenicity). Such cross-references will however be possible only where the concerned information does not benefit from regulatory data protection.

Furthermore, all products authorised and covering the same insect species may be recorded **into one single entry within the Union list of novel foods**. This entry would in such cases encompass **common specifications** applicable to all respective products authorised.

## 4.6. Extension of an existing novel food authorisation or notification

### Principle of extension of a novel food authorisation

An extension of an existing novel food authorisation or notification may be necessary where:

- certain food uses (see section 4.5. above) are not covered by an initial authorisation or notification;
- activities performed by users of insects down the supply chain (e.g. processors, who may be the direct supplier or the users or another part) may lead to substantial changes in the intrinsic characteristics of the final product, leading to modify the specifications of the product);
- an insect primary producer produces an insect species which has been previously authorised (as novel food) but using production methods that may impact its intrinsic characteristics and resulting specifications, and therefore (or otherwise) affect the results of the existing risk/safety assessment.

In most cases however, it is expected that operators down the supply chain will be able to rely on existing authorisations.

**In principle, the extension would have to follow the same procedural path as the initial authorisation.** However, pursuant to Article 3(4) of Implementing Regulation (EU) 2017/2469, where the applicant submits an application to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food, **it may not be necessary for the applicant to provide all the supporting scientific data where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the risk assessment.** Similar rule applies in respect of amendments to notifications or authorisations of traditional foods from third countries (See Articles 3(4) and 4(4) of Implementing Regulation (EU) 2017/2468).

The party applying for an extension of the authorisation (e.g. for additional food uses) may be the **initial applicant** or **another operator**. In the latter case, for novel foods other than traditional foods from third countries, due account will need to be taken with the remaining period of data protection that may cover parts of the initial dossier (see also section 4.7. below).

### Principle of generic authorisation and exceptions

Under Regulation (EU) 2015/2283, all **authorisations become 'generic'** (as opposed to the applicant-specific authorisation system on which Regulation (EC) No 258/97 was based). This means that food business operators will be entitled to lawfully place any novel food product that has been included in the Union list of novel foods pursuant to Regulation (EU) 2015/2283, as long as the authorised conditions of use, labelling requirements ([Please refer to IPIFF Food Information to Consumer guidance document for insect-based products](#)), and specifications are complied with<sup>7</sup>.

Translating this principle to the particular situation of **insects means that insect producers will be entitled to place insect-based food products on the EU market without having to prepare and submit a new novel food application or notification** (i.e. 'an extension of a novel food authorisation' as described in the above subsection) where the concerned products are made of/originate from a **previously authorised insect species** and the concerned products are covered by the existing authorisation or notification. This principle would however only apply in case **the corresponding dossier does not benefit from regulatory data protection**.

A contrario, it also means that such producers will have to submit a new application in case the intrinsic charac-

<sup>7</sup> See DG SANTE (European Commission) web page on the novel food legislation [https://ec.europa.eu/food/safety/novel\\_food/legislation\\_en](https://ec.europa.eu/food/safety/novel_food/legislation_en)

teristics of a product that these operators intend to place on the market are 'significantly distinct' from the products included in the Union list of novel foods or in case of ceasing 'protected data' to a subsequent producer in the framework of a contractual agreement with the initial applicant who has gained an authorisation.

Unlike the rules under Regulation (EC) No 258/97, there is no requirement under Regulation (EU) 2015/2283 to notify or demonstrate the **substantial equivalence** of a given product to a product that has been previously authorised for the purpose of placing that product on the market. On the other hand, only products meeting the applicable specifications, conditions of use, labelling requirements and post-market monitoring requirements as included and specified in the Union list of novel foods will be allowed on the market.

### Duty for operators to check that their product corresponds to the specifications provided for under the Union list of novel foods

Food business operators that intend to place insect products on the market need to ascertain that their products meet the conditions defined under the Union list of novel foods. This is part of their general obligation under Article 14 of the General Food Law.

The list below is a non-exhaustive list of elements that food business operators should consider to ascertain whether the conditions defined under the Union list of novel foods are met, and consequently decide whether extending an application or notification is necessary for the purpose of lawfully placing their product on the EU market.

- Do the (types of) **substrates** used by the producer **differ substantially** from a previously authorised product<sup>8</sup> (e.g. use of different arable crops or vegetable species) to the extent that these **modify sig-**

**nificantly the nutritional composition** of the final product?

- Does the product contain significantly **higher levels of contaminants** (e.g. residues of pesticides, pathogenic bacteria heavy metals, mycotoxins transmitted via the substrate), and do the levels differ to the extent that these **may have an impact on the safety of the product for human consumption?**
- Do the **manufacturing processes used** impact on the '**key characteristics**' of the final product, notably **on its nutritional composition** (e.g. dried insect, insect meal, full fat meal and defatted meal are different products even when they are produced from the same insect species) or on its **food safety?**

In case the answer provided to any of these 3 questions is affirmative, it is likely that the concerned food business operator will have to prepare and submit a new application in which this operator will need to provide evidence that the intrinsic characteristics of the concerned product – which were therefore previously assessed – do not alter the food safety of the final product. It should be borne in mind that the use of different manufacturing processes does not constitute, as such, a sufficient criterion to require the preparation of a new application. Due account must indeed be taken with the novel food approved uses and specifications as set out in the Union list as a result of the initial approval process. Different processes may result in products with specifications that meet those approved by the Commission. The concerned food business operators remain in any event responsible for ensuring compliance of their products with the requirements (see also sub-section below).

A useful tool that should be used **in case of doubt** is the procedure for determination of **novel food** status, as provided by Article 4 of Regulation (EU) 2015/2283 and as further ruled under Implementing Regulation (EU) 2018/456.

The national authorities that are responsible for this procedure are listed in the table below.

<sup>8</sup> Insects may be produced in the EU exclusively with substrates eligible as feed materials for farmed animals (products of non-animal origin or the following products of animal origin: fishmeal, blood products from non-ruminant, di and tricalcium phosphate of animal origin, hydrolysed proteins from non-ruminant, hydrolysed proteins from hides and skins of ruminant, gelatine and collagen from non-ruminants, eggs and egg products, milk, milk based-products, milk-derived products and colostrum, honey and rendered fat)

Considering the above, the conditions of intended use provided in the initial application are not only an important component of the authorisation and of subsequent controls for the novel food (see section 4.6. above, sub-section 'conditions of intended uses, product specifications and labelling requirements'), they are also crucial elements to determine the latitude for subsequent operators to benefit from a previously authorised application.

### Consequences and control measures by Member States authorities

**A food business operator claiming that his/her product should benefit from a previous authorisation may place it on the European market freely**, under the condition that this food business operator complies with conditions of intended use and labelling requirements applying the authorised novel food, as specified in the Union list of novel foods.

A preauthorisation is thus not required under Regulation (EU) 2015/2283. However, the food business operator will have to demonstrate the compliance of the concerned products in **the context of official controls** – i.e. pursuant to the Official Controls Regulation.

Different means can be used to demonstrate compliance, such as e.g.:

- **Sampling results** substantiating conformity with maximum limits for impurities and degradation products as defined in the relevant specifications;
- **Check of measures implemented for production control and quality and safety assurance** (HACCP, ISO standards, adherence to professional guide of good hygiene standards) to demonstrate conformity with the levels of food hygiene standards that allow meeting the specifications defined in the Union list as part of the approval of the application or notification.

- **Monitoring the nutritional characteristics of the products** (e.g. as resulting from manufacturing processes used) to ensure that these do not differ from the criteria defined in the Union list.

**Non-compliance with the specifications or conditions of intended use** of a previously authorised product would result in the concerned product being non-compliant with the requirements under both Regulation (EU) 2015/2283 and the General Food Law obligations. Such **infringements** are sanctioned by measures enacted at **Member State level**, namely penalties implemented pursuant to Article 29 of Regulation (EU) 2015/2283 and/or sanctions implemented pursuant to Article 55 of Regulation (EC) No 882/2004).

## LIST OF NATIONAL COMPETENT AUTHORITIES RESPONSIBLE FOR THE IMPLEMENTATION OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/456

### AUSTRIA

Bundesministerium für Arbeit, Soziales, Gesundheit und  
Konsumentenschutz  
Sektion IX, Gruppe B - Veterinärmedizin und Veterinär-  
wesen, Lebensmittelsicherheit  
Radetzkystrasse 2  
A-1030 Wien  
[https://www.verbrauchergesundheit.gv.at/Lebensmittel/  
neuartige\\_lm/neuarti\\_gelm.html](https://www.verbrauchergesundheit.gv.at/Lebensmittel/neuartige_lm/neuarti_gelm.html)  
[novelfood@sozialministerium.at](mailto:novelfood@sozialministerium.at)

### BELGIUM

Federal Public Service of Health, Food Chain Safety and  
Environment Service of Food, Feed and Other Consump-  
tion Products  
Place Victor Horta 40/10  
Eurostation II  
1060 Brussels  
Belgium  
[novelfood@health.fgov.be](mailto:novelfood@health.fgov.be)  
[http://www.health.belgium.be/eportal/foodsafety/food-  
stuffs/novelfoods/](http://www.health.belgium.be/eportal/foodsafety/food-stuffs/novelfoods/)

### BULGARIA

Ministry of Health  
5, Sveta Nedelya sq 1000 Sofia

### CROATIA

Ministry of Health Ksaver 200a  
10 000 Zagreb, Croatia  
[hrana@miz.hr](mailto:hrana@miz.hr) [www.zdravstvo.gov.hr](http://www.zdravstvo.gov.hr)

### CZECH REPUBLIC

Ministry of Agriculture of the Czech Republic  
Tesnov 65/17  
110 00 Prague 1  
Czech Republic  
[novelfoods@mze.cz](mailto:novelfoods@mze.cz)

### CYPRUS

Medical and Public Health Services Ministry of Health,  
Prodromou 1  
1449, Nicosia  
Cyprus  
[healthservices@mphs.moh.gov.cy](mailto:healthservices@mphs.moh.gov.cy)

### DENMARK

Fødevareministeriet Fødevarestyrelsen Stationsparken  
31-33  
2600 Glostrup [Novelfood@fvst.dk](mailto:Novelfood@fvst.dk)  
[www.foedevarestyrelsen.dk](http://www.foedevarestyrelsen.dk)

### ESTONIA

Veterinaar- ja Toiduamet  
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11415 Tallinn [vet@vet.agri.ee](mailto:vet@vet.agri.ee)  
[www.vet.agri.ee](http://www.vet.agri.ee)



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[www.ruokavirasto.fi](http://www.ruokavirasto.fi)

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Teledoc 223  
59, boulevard Vincent Auriol  
F-75703 Paris Cedex 13  
Tel : 01 44 97 31 51  
[Bureau-4A@dgccrf.finances.gouv.fr](mailto:Bureau-4A@dgccrf.finances.gouv.fr)

## GERMANY

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit  
Dienststelle Berlin  
Postfach 11 02 60  
10832 Berlin  
[www.bvl.bund.de](http://www.bvl.bund.de)  
[novel.food@bvl.bund.de](mailto:novel.food@bvl.bund.de)

## GREECE

Independent Authority for Public Revenue  
Directorate General of GENERAL CHEMICAL STATE  
LABORATORY Directorate of Alcohol and Foodstuffs  
An. Tsoha 16,  
GR-11521 Athens  
[www.gcsf.gr](http://www.gcsf.gr)  
[novelfood-gr@gcsf.gr](mailto:novelfood-gr@gcsf.gr)

## HUNGARY

National Food Chain Safety Office  
Hungary, 1024 Budapest,  
Keleti Károly u. 24  
[novelfood@nebih.gov.hu](mailto:novelfood@nebih.gov.hu)

## ICELAND

The Icelandic Food and Veterinary Authority  
Austurvegur 64  
800 SELFOSS  
ICELAND  
[www.mast.is](http://www.mast.is)  
[mast@mast.is](mailto:mast@mast.is)

## IRELAND

Food Safety Authority of Ireland The Exchange  
George's Dock, I.F.S.C.  
Dublin 1  
Ireland  
D01 P2V6 [novelfood@fsai.ie](mailto:novelfood@fsai.ie)  
[www.fsai.ie](http://www.fsai.ie)

## ITALY

Ministry of Health  
Off. 4 of the Directorate General Hygiene, Food Safety  
and Nutrition Via Giorgio Ribotta 5  
I-00144 Roma  
[http://www.salute.gov.it/portale/ministro/p4\\_8\\_0.jsp?lingua=italiano&label=servizionline&idMat=APINF&idAmb=Nf&idSrv=NFAC&flag=P](http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=APINF&idAmb=Nf&idSrv=NFAC&flag=P)  
[dgsan@postacert.sanita.it](mailto:dgsan@postacert.sanita.it)  
Tel : 01 44 97 31 51  
[v.digiorgi@sanita.it](mailto:v.digiorgi@sanita.it)  
(until further notice, the request needs to be done with the template available on the website and needs to be indicated as a subject the following: I5IH5- RNFS- name of the substance for which the request is done)

## LATVIA

Food and Veterinary Service  
Peldu street 30  
Riga, LV-1050  
[www.pvd.gov.lv](http://www.pvd.gov.lv)  
[pvd@pvd.gov.lv](mailto:pvd@pvd.gov.lv)

## LITHUANIA

Ministry of Health of the Republic of Lithuania  
Vilniaus str. 33  
LT-01506 Vilnius  
Lithuania

## LUXEMBOURG

Ministère de la Santé  
Direction de la Santé  
Division de la sécurité alimentaire  
Villa Louvigny Allée Marconi  
L-2120 Luxembourg  
<http://www.securite-alimentaire.public.lu/professionnel/Denrees-alimentaires/Nouveaux-aliments/index.html>  
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## MALTA

Food Safety Commission  
Continental Business Centre Cutrico Buildings  
Old Railway Track Santa Venera SVR9018 MALTA

## THE NETHERLANDS

Ministry of Health, Welfare, and Sport PO Box 20350  
2500 EJ The Hague  
The Netherlands  
Consultation requests should be sent electronically to the novel food assessment body:  
Medicines Evaluation Board (CBG-MEB)  
Novel Food Unit  
P.O. Box 8275  
3503 RG Utrecht  
[novelfoods@cbg-meb.nl](mailto:novelfoods@cbg-meb.nl)  
<https://english.cbg-meb.nl/topics/nv-determination-of-novel-food-status>

## POLAND

The Chief Sanitary Inspectorate Department of Food and Nutrition Safety  
Targowa Street 65  
03-729 Warsaw  
[www.gis.gov.pl](http://www.gis.gov.pl)  
e-mail: [inspektorat@gis.gov.pl](mailto:inspektorat@gis.gov.pl)

## PORTUGAL

Direção Geral de Alimentação e Veterinária – DGAV (Directorate-General of Food and Veterinary - of Ministry of Agriculture) Campo Grande, no 50  
1700-093 LISBOA  
Portugal  
[www.dgav.pt](http://www.dgav.pt)  
[dsna@dgav.pt](mailto:dsna@dgav.pt)

## ROMANIA

Ministry of Health  
General Directorate of Healthcare and Public Health  
Cristian Popisteanu str, No. 1-3, 010024  
Bucharest,  
Romania  
[www.ms.ro](http://www.ms.ro)  
email: [anita@ms.ro](mailto:anita@ms.ro)

## SLOVAK REPUBLIC

Public Health Authority of the Slovak Republic  
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826 45 Bratislava  
[www.uvzsr.sk](http://www.uvzsr.sk)  
[podatelna@uvzsr.sk](mailto:podatelna@uvzsr.sk)

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Ministry of Agriculture, Forestry and Food  
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Safety, Veterinary Sector and Plant Protection  
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## SPAIN

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Ministerio de Sanidad, Consumo y Bienestar Social.  
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## UNITED KINGDOM

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## NORWAY

The Norwegian Food Safety Authority (Mattilsynet),  
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Food Department, Labelling and Quality Section  
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N – 2381 Brumunddal  
Norway  
[postmottak@mattilsynet.no](mailto:postmottak@mattilsynet.no)

## 4.7 Transparency requirements, confidentiality and data protection

### Transparency requirements

The Transparency Regulation became applicable on 27 March 2021 and introduced a general principle of automatic and proactive disclosure of information, studies and data by the EFSA, submitted to support a request for a scientific output by EFSA, which is the case for novel foods applications.

The information that is now published proactively includes:

- All scientific outputs of EFSA, including the opinions of the Scientific Committee and the Scientific Panels after adoption, minority opinions and results of consultations performed during the risk assessment process
- Scientific data, studies and other information supporting applications for scientific outputs of EFSA
- Summary of the advice provided to potential applicants at pre-submission phase

In principle, such disclosure takes place automatically. However, if confidential treatment has been requested for certain information, the EFSA (or the Commission) can decide to not make this confidential information public (see below).

The principle of proactive transparency is included in the General Food Law, as well as in a specific provision in the Regulation (EU) 2015/2283.

As regards information related to novel foods and traditional foods applications and notifications, the provisions of the Transparency Regulation will apply on such applications and notifications submitted as of 27 March 2021.

### Confidentiality

Article 23 of Regulation (EU) 2015/2283 provides for confidentiality rules in respect of information relating to the applications of novel foods and notifications of traditional foods submitted to EFSA and the Commission, which are subject to the proactive disclosure of the EFSA. It should be noted that the Transparency Regulation replaced the content of the previous article 23 of Regulation 2015/2283, which means that this new provision applies on applications and notifications submitted as of 27 March 2021.

The novelties in relation to confidentiality for novel foods applications are not limited to the new article 23; this provision needs to be read in conjunction with articles 39 to 39e of the General Food Law on confidentiality requests.

An important aspect regarding the new confidentiality provisions is that it is now specified to which kind of information the confidentiality request can relate.

First of all, the applicant should justify that the disclosure of the information harms the applicant's interests to a significant degree. EFSA has adopted Practical arrangements on pre-submission phase and public consultations, and practical arrangements concerning transparency and confidentiality that set out the criteria that EFSA intends to apply in relation to the applicant's confidentiality requests.

Where potential harm is demonstrated, confidentiality can be granted if the disclosure concerns the following information:

(a) the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;

- (b) commercial links between a producer or importer and the applicant, where applicable;
- (c) commercial information revealing sourcing, market shares or business strategy of the applicant; and
- (d) quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

More specifically, for applications and notifications in the framework of the Regulation 2015/2283, confidentiality can also be granted for the following information, unless that information is relevant to the assessment of safety:

- (a) detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food;
- (b) detailed analytical information on the variability and stability of individual production batches.

### General Food Law - Article 39

Article 23 of Regulation 2015/2283 refers to articles 39 to 39 e of the General Food Law.

Articles 39a to 39e of the General Food Law include the procedural aspects of the confidentiality requests. These procedural aspects are further elaborated on in the Decision of the Executive Director of the EFSA laying down practical arrangements concerning transparency and confidentiality.<sup>9</sup>

The provisions regarding the procedure for the confidentiality requests are mainly focussed on situations where the European Commission requests the opinion of EFSA in accordance with Article 10(3) and Article 16 of the Regulation 2015/2283 in case of an application for the authorization of a novel food or an application for the authorization of a traditional food.

For applications where no opinion of the EFSA has been requested or for traditional foods notifications in accordance with article 14 of the Regulation 2015/2283, the confidentiality request is treated by the Commission, and only certain provisions regarding the procedure apply (article 39, 39a and 39d of the General Food Law).

<sup>9</sup> EFSA, Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning transparency and confidentiality, ver. X - 18.01.2021, [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/210111-PAs-transparency-and-confidentiality.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf)

All parts of an application or notification that the applicant deems confidential must be marked as such. For each information requested to be considered as confidential, the applicant must specify the legal basis for the confidentiality claim, and provide a valid justification. These elements constitute a specific annex of the dossier, that is updated each time an applicant submits a request for information to be treated as confidential.

When an applicant requests the confidential treatment of certain parts of the dossier, the EFSA assesses the justification submitted and takes a decision as to whether or not it accepts to treat the concerned information confidentially. Depending on whether the Commission requests an opinion of the EFSA or not, it shall be the Commission that treats the confidentiality requests. In case the EFSA disagrees, in whole or in part, with the confidential character of certain information, the applicant has the possibility to withdraw the pending application within two weeks or state its view on the disagreement. Pending this, the confidentiality of the information provided will be maintained. If after that period the concerned applicant has not withdrawn the application, and in case of disagreement, the EFSA is competent to decide which parts of the information are to remain confidential and, in case a decision has been taken, notifies the Member States and the applicant accordingly of its reasoned decision<sup>10</sup>. In case an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and the Authority have a duty not to disclose confidential information, including the information whose confidentiality is or was the subject of disagreement between the EFSA or Commission and the applicant.

In all cases, certain parts of the dossier will not be considered as confidential, namely those listed under paragraph 4 of Article 23 of Regulation (EU) 2015/2283 (see above).

## Data protection

In the context of an application for authorisation of a novel food other than a traditional food for a third country, applicants may apply for a five-year period of regulatory data protection.

### Regulation (EU) 2015/2283 – Article 26

1. On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1), newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.
2. The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met:
  - (a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
  - (b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
  - (c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant. However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used."

<sup>10</sup> This part of the procedure is not applicable on notifications for traditional foods and situations where no EFSA opinion was requested.



The period of data protection that can be granted has a duration of **five years** and is not renewable. Only the data that meets the three cumulative conditions listed under paragraph 2 of Article 26 can be eligible for data protection, i.e.:

1. the data must consist of newly developed scientific evidence or scientific data that the applicant has designated as proprietary upon the first application; and
2. at the time the first application was made, the initial applicant had an exclusive right of reference to data; and
3. the novel food could not have been assessed by the EFSA and authorised by the Commission without the submission of the concerned data by the initial applicant.<sup>11</sup>

It is the competence and responsibility of the European Commission to decide on the grant of data protection. With respect to the handling and use of proprietary data by EFSA, where evidence for the safety of a novel food includes a request for the protection of proprietary data, the EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) considers in its opinion whether the safety of the novel food could have been assessed without the data claimed as proprietary by the applicant or not: this element is indeed crucial in the context of the Commission's decision-making relating to the grant of data protection or not.

In practice, where data benefits regulatory data protection, other applicants will not be entitled to refer to these data for the purpose of obtaining a novel food authorisation. **The applicant that has obtained an authorisation on the basis of protected proprietary data indeed benefits from a market exclusivity** in respect of those data and of the product to the extent the protected data is relied upon for the sake of placing the product on the market. In cases where data protection is granted, the Union list specifies it, and indicates that during the period of data protection the novel food is au-

thorised for placing on the market within the Union only by the initial applicant, unless a subsequent applicant obtains authorisation for the novel food without reference to the protected data or with the agreement of the initial applicant.

It is thus important to note that the **grant of data protection does not prevent other applicants to submit their own data** (i.e. data that is not covered by the protection), nor to reference to the non-protected parts of dossiers that have previously been approved. No provision under the Novel Food regulation prevents a reference to be made to the parts of the dossier that are not covered by data protection. Article 26(2) in fine expressly provides for the possibility for the initial applicant to agree with (a) subsequent applicant(s) on the use of the data that benefits data protection. The terms under which such agreement is reached are however not further defined by the regulation and are left to the discretion of the concerned applicants. This can notably be done by means of a letter of access. However, if the initial applicant agrees with (a) subsequent applicant(s) on the use of the data that benefits from 'data protection', the latter must file a separate authorisation application to the EC (or request an extension of this novel food authorisation – see Chapter 4.6 for more details) accompanied by the agreement made by the two parties to benefit on placing the said product on the market. Alternatively, if the initial applicant does not agree to a reference being made to the data benefitting from data protection, the subsequent applicants may submit an own set of data to "fill the gap" of the data that is protected. They will however not be eligible for a separate data protection period for these data, as the data protection mechanism only benefits the initial applicant.

As indicated above, **no data protection can be applied for in respect of the notification of a traditional food from a third country** (as per Article 26(3) of Regulation (EU) 2015/2283).

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11 See IPIFF position paper - implementation of EU Regulation 2015/2283 on 'novel foods' (19 November 2016)

## 4.8. Transitional measures

### Objectives and measures provided as transitional provisions under the Article 35(2) of Regulation (EU) 2015/2283

Article 35(2) of Regulation (EU) 2015/2283 provides for transitional measures that aim to ensure that products that were lawfully commercialized in a Member State of the EU before Regulation (EU) 2015/2283 became applicable (i.e. before 1st January 2018) may remain on the market of this particular Member State for a given period of time, subject to certain conditions.

Transitional measures are usually intended to avoid situations where a product that is lawfully on the market becomes unlawful and needs as a consequence to be withdrawn or suspended from the market as a result of the entry into force of a new legislation. Avoiding such situations is in the interest of all stakeholders, including industry (legal certainty), authorities (reduce administrative burden) and consumers (confidence that products on the market are safe).

Regulation (EU) 2015/2283 provides for such measures for products that did not fall under the scope of application of Regulation (EC) No 258/97 and that do fall under the scope of application of Regulation (EU) 2015/2283. This is the case for whole insects and may be the case for products made of/from whole insects (see section 4.2. above and below).

Article 35(2) of Regulation (EU) 2015/2283 defines the criteria that must be met in order for food business operators to benefit from the transition measures and sets out its implementation modalities.

### Regulation (EU) 2015/2283 - Article 35 (2) - Transitional measures

The application of the above transitional measure is of particular relevance for insect producers, since it guarantees that operators are not compelled to discontinue the production and/or marketing of their products whilst they prepare and submit their application for authorisation or notification in accordance with Regulation (EU) 2015/2283<sup>12</sup>. These operators are allowed to continue placing their products on the market until a final decision has been adopted in respect of their application or notification, i.e. until the European Commission adopts a decision (see section 4.1. above).

While Article 35(2) provides that the transition period may benefit to operators who submit an application for authorisation or a notification for their lawfully marketed product until 2 January 2020, the same article however empowered the European Commission to set a shorter deadline. Such shorter deadline was in fact defined by the Commission through Implementing Regulation (EU) 2017/2469, that was adopted on 20 December 2017 following unanimous approval by Member States). Implementing Regulation (EU) 2017/2469 sets **1st January 2019 as final deadline for the submission of applications** eligible for the benefit of the transitional period. Article 11 of Implementing Regulation (EU) 2017/2468 sets an identical deadline in respect of traditional foods from third countries.

<sup>12</sup> See letter from the Commissioner for health and food safety Vytenis Andriukaitis to IPIFF (8 December 2017)

### **Implementing Regulation (EU) 2017/2469 - Article 8(5) – Transitional measures**

The deadline for the submission of the applications referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be 1st January 2019.”

### **Implementing Regulation (EU) 2017/2468 - Article 11 – Transitional measures**

“The notifications as referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be submitted to the Commission not later than 1 January 2019.”

The European Commission considers that the application of such deadline to the case of insects is adequate to ensure “timely certainty about the legality of products on the EU market (both for consumers and food business operators)”<sup>13</sup>. Taking into account the timeframes imposed under Regulation (EU) 2015/2283, the expected timeframe for the adoption of a final decision on an application for authorisation is estimated between 18 months and 24 months (in the absence of repeated ‘stop the clock ’). In fact, the adoption of the final decision on the application covering dried yellow mealworm, which was submitted by the French company SAS EAP Group Agronutris, took 39 months in total.

Insect food operators who lawfully marketed insects as novel foods in compliance with the national legislation and for which an application was submitted for authorisation of the product as a novel food before 1 January 2019, should continue to benefit from the transition regime until an authorization decision has been made. (This information has been notified and discussed by

the European Commission with the respective Member States at the Working Group on ‘Food Safety’ held on 2/3 July 2019). If a data protected application is authorised, other insect operators producing the same product/species can continue to benefit from the transitional measure provided that there is at least one outstanding application covering the same species and a product with similar characteristics and provided that this application complies with the requirements outlined in article 35.2 of Regulation (EU) 2015/2283. Once there is no other outstanding application covering the product in question, the other operators may no longer benefit from the transitional measure for the product in question and may therefore no longer sell it.

If a non-data protected application is authorised, all operators from the EU would benefit from it, therefore the transitional measure for the said product becomes irrelevant.

### **Eligibility of insect products for the transitional measure provided for under Regulation (EU) 2015/2283**

- Article 35(2) of Regulation (EU) 2015/2283 provides that the first eligibility criterion for the benefit of the transitional measures is that the concerned foods did not fall within the scope of Regulation (EC) No 258/97. As explained above (see section 4.2.), it is arguable that whole insects and their preparations did not fall within the scope of Regulation (EC) No 258/97, given that the latter applied – in respect of animal-derived foods and food ingredients – solely to “food ingredients isolated from animals”, thereby excluding from its scope of application whole animals – such as whole insects. An interpretation according to which whole insects were not falling within the scope of Regulation (EC) No 258/97 can thus reasonably be followed.

<sup>13</sup> See letter from the Commissioner for health and food safety Vytenis Andriukaitis to IPIFF (8 December 2017)

- The **second eligibility criterion** for the benefit of the transitional measures is that the products were **lawfully placed on the market by 1 January 2018**. In practice, such decision lies with each EU Member State. **The final decision of those countries** regarding the lawful placing on the market of such products was essentially based on **their classification or not as 'novel food'** (i.e. their 'novel' status) under Regulation (EC) No 258/97. Member States that regarded the concerned products as 'novel' under Regulation (EC) No 258/97 therefore consider that the product was not (and still not is) 'lawfully placed on the market' if such product has not been authorised in accordance with Regulation (EC) No 258/97. In practice, no novel food authorisation has been granted for any insect product under Regulation (EC) No 258/97.

However, difficulties may arise in the Member States where the possibility for insect producers to benefit from the transitional measures is inexistent. This is due to the fact that insect products are considered by those authorities as not fulfilling the necessary conditions to become eligible for the transitional measure (i.e. they consider whole insect to fall under the old novel food regulation, thus not fulfilling the eligibility to benefit from the transitional measure).

Considering the restrictive definition of 'novel food' as provided for under Regulation (EC) No 258/97, that did not cover whole animals, the legality of the position of a Member State who denies the benefit of the transitional measures to whole insects and their derived products on the ground that these should already have been considered (in the view of these Member States) as 'novel food' under Regulation (EC) No 258/97 was questionable for a long time. In its Entoma ruling of 1 October 2020 (see section 4.2 above), the European Court of Justice clarified that foods consisting of whole animals intended to be consumed as such, including whole insects, do not fall within the scope of the 'old' novel food regulation'.

## The Entoma ruling and its practical implications

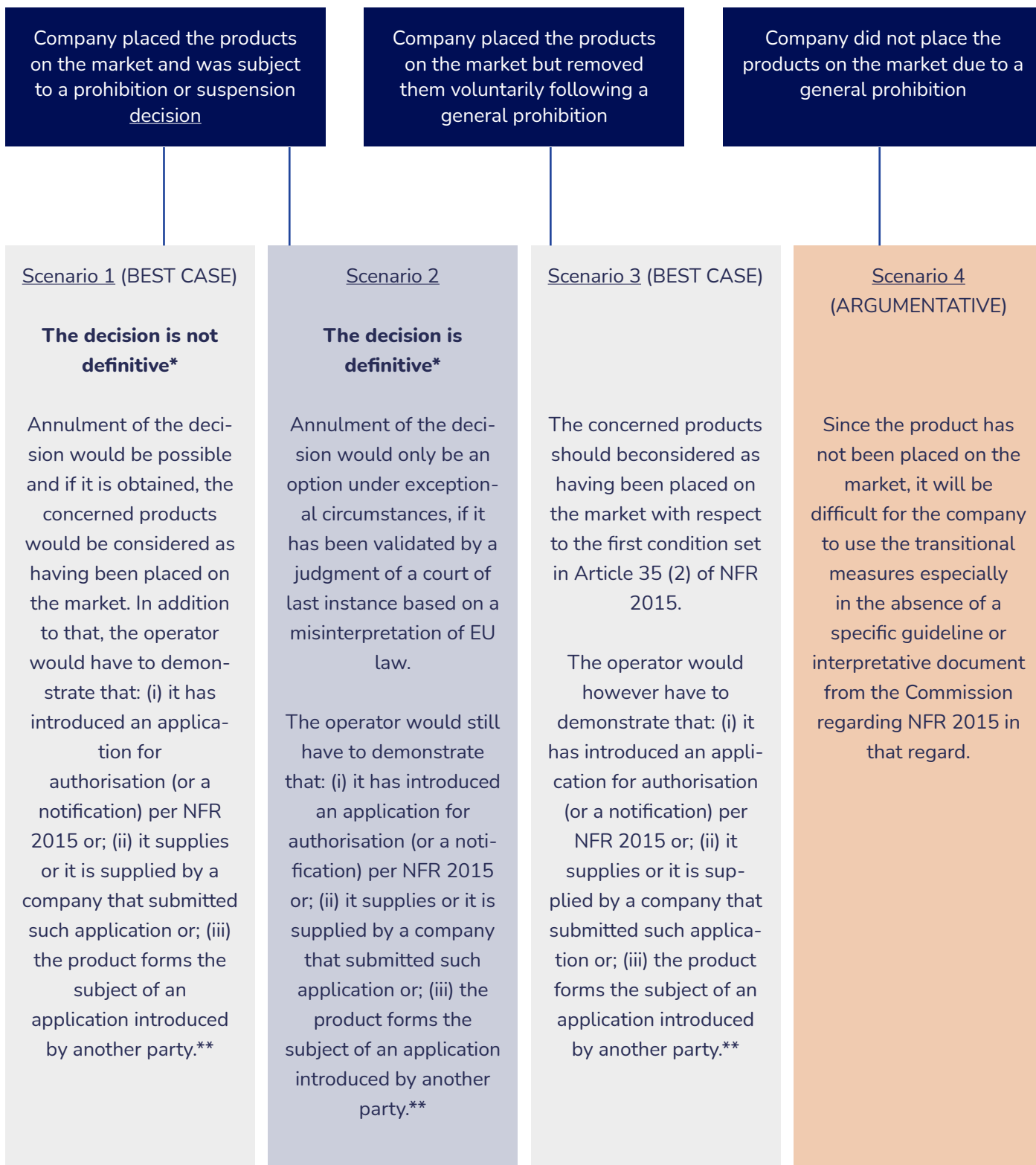
The interpretation given by the Court has retroactive effect. This means that in certain situations where the transitional regime fully applies, national authorities have the obligation to retract/withdraw administrative decisions that are contrary to European law, as interpreted by the Court in the Entoma ruling.

Such obligation will apply in several scenarios, including the following:

- a product has been placed on the market and has been subjected to a prohibition or suspension decision that has not become definitive. The concerned operator can seek the annulment or withdrawal of the decision - once obtained, the concerned product will (retrospectively) have to be considered as having been placed on the market.
- a product has been placed on the market and has been subject to a prohibition or suspension decision that has become definitive. In that case, the annulment of the decision would only be an option under exceptional circumstances, if it has been validated by a judgment of a court of last instance based on a misinterpretation of EU law. This scenario requires a careful assessment based on the relevant national law and procedural rules.
- a product has been first placed on the market before 1 January 2018, and then withdrawn from it on the basis of a general prohibition or an information note coming from national authority. In that case, the concerned products should be considered as having been placed on the market for the purpose of the transitional measures.

It is important to note that in addition to the requirement that the product must have been lawfully placed on the market before 1 January 2018, the product must also be covered by an application (or notification) filed before 1 January 2019 in order to benefit from the transitional provisions.

Hereunder a Diagram with the scenarios is presented.



\* The decision should be considered as not definitive if it is still possible to use legal remedies in order to obtain its annulment or withdrawal under national law.

\*\* As far as the hypothesis (iii) is concerned, the operators will have to be able to demonstrate that both products are the result of the same production process and have the same detailed composition/meet the same specifications.



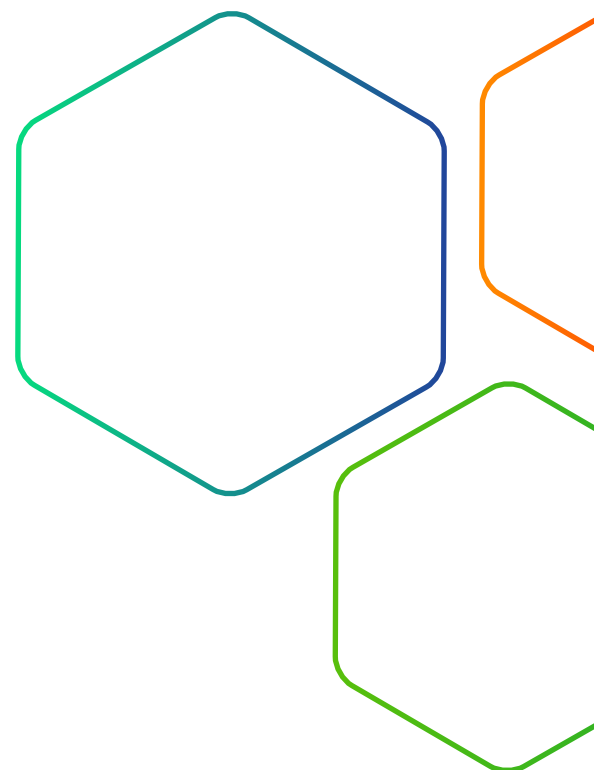
## EU Member States' approaches following the Entoma ruling

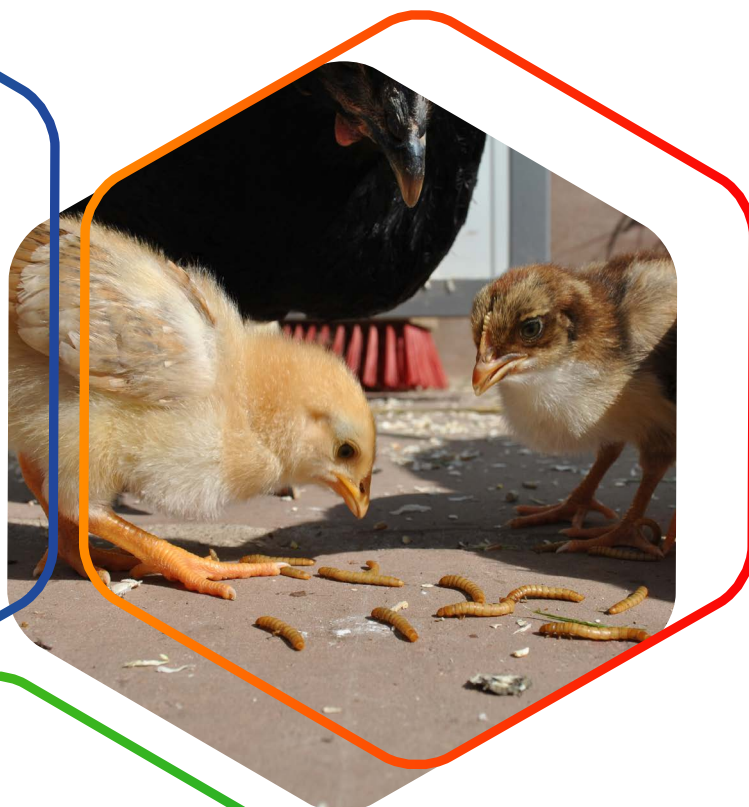
As recalled by the Court, the fact that foods consisting of whole animals intended to be consumed as such, including whole insects, do not fall within the scope of the Regulation (EC) No 258/97 does not mean that the Member States are not empowered to take decision restricting the placing into the market of these products. On this ground, some Member States might be keen to adopt national measures prohibiting or strictly restricting the placing into their national markets foods made of whole insects to ensure the safety of the consumers and, possibly, to attach to these measures a retroactive effect.

However, should a Member State adopt such retroactive measure, it should be borne in mind that the powers of Member States to do so are extremely limited as such powers are strictly framed by European legislation and general principles, such as the principle of mutual recognition and the principles of legitimate expectations and legal certainty. Furthermore, Member States should demonstrate that the insects are unsafe in accordance with Article 14 of the General Food Law, i.e. only if the product is (i) injurious to health and (ii) unfit for human consumption, it is forbidden to place the product on the market.

As a consequence, only in very rare cases, Member States would have the possibility to issue new retroactive measures undermining the interpretation pronounced by the Court in its Entoma ruling.

Finally, as explained in section 4.2. above, it remains unsure whether products derived from whole insects such as insect powders would fall out of the scope of Regulation (EC) No 258/97 as the Entoma ruling did not address this question expressively.





The map below outlines the novel food status of whole insects and their preparations in most EU countries.

## NB:

1. This map does not refer to the position of Member States regarding the novel status of ingredients derived from insects (i.e. ingredients other than made from whole insects), as these products undoubtedly fall within the scope of Regulation (EC) No 258/97 and are thus not eligible for the transitional measures foreseen under article 35(2) of Regulation (EU) 2015/2283;
2. Given the absence of univocal position in relation to the interpretation to be given to the material scope of application of Regulation (EC) No 258/97, diverging approaches have been adopted by the Member States, resulting in a legal patchwork.

## Legend

- Countries indicated in **green** are those in which the **national authorities agreed to grant the transitional measure** to whole insects and/or their derived products;
- Countries indicated in **yellow** are countries in which national authorities have applied the transitional measure, but **have imposed specific conditions** (e.g. the transitional measure only applies to whole insects and not to powder derived from it, the implementation of the transitional measure is limited to certain administrative regions);
- Countries indicated in **orange** correspond to EU countries in which national authorities took the position to **deny the implementation of the transitional measure** (or applied it restrictively) and whose position may possibly evolve, following the Court of Justice of the European Union ruling;
- EU Member States coloured in **white** are those countries whose position is **unknown** to the authors at the time of drafting this document;
- Countries coloured in **grey** are non-EU countries from which insects as food may not be placed on the EU market;
- Countries indicated in **purple** are non-EU Member States from which Insect food products may be placed on the market of those EU Member States which apply the transitional measure under national legislation. Once a novel food authorisation has been granted for a specific product, it can be exported to the entire EU.

## EU Member States' approaches on the novel status of 'whole insects and their preparations'



	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions?	Application of the transitional measure	Import conditions	Reference document
Denmark	The Danish Veterinary & Food Administration (DVFA) considered that 'whole insects' and their parts <b>were not covered under Regulation (EC) No 258/97</b> , provided that it can be documented that whole insects are used and that no parts thereof have been removed.	Yes, if the products conform with other applicable legislations (e.g. General EU food law and EU 'Hygiene Package' requirements).	No	Yes	Imports from EU and non-EU exporting countries are allowed but subject to an import authorisation from the Danish Food Authority (DVFA). The insect product must originate from a production site that is approved or registered by the local authorities in the country of origin, as attested by official certificate) and veterinary control at border point apply.	<a href="#">Insects — farming and use as feed and food in Denmark and the EU — what's allowed and what is not?</a> (Updated 23 April 2020)
The Netherlands	The Dutch Office for risk Assessment and Research (Bureau Risicoboordeeling en Onderzoeksprogrammering – BuRo) considered that 'whole insects' and their parts <b>were not covered under the former EU 'novel food' Regulation</b> .	Yes, the products must conform with other applicable legislations (e.g. General EU Food Law, traceability and reporting obligations, labelling and EU 'Hygiene Package' requirements).	No	Yes	N/A	<a href="#">Handboek nieuwe voedingsmiddelen</a> (18 November 2020)
Finland	In September 2017, on request of the Government, the Finnish Food Safety Authority (EVIRA) changed its interpretation of the scope of the novel food legislation and considered that 'whole insects' <b>were not covered under Regulation (EC) No 258/97</b> , to the effect of considering insect production as lawful, subject to the requirements and controls under the food legislation.	Yes, provided that the products conform with other EU (e.g. General EU food law and EU 'Hygiene Package' requirements) and national (e.g. National Animal Welfare Decree 396/1996 or the Animal Diseases Act 441/2013).	No	Yes		<a href="#">Evira Guide 'Insects as food'</a> (16 March 2018)
Belgium	Following the Entoma ruling, the Belgian federal public service applies the transitional regime to whole insects.  In official guidance, the Belgian federal public service also mentions that the transitional regime applies to products thereof.	Yes, if the products conform with other applicable legislations (e.g. General EU food law and EU 'Hygiene Package' requirements).	Yes, restricted to 5 insects, ( <i>Acheta domesticus</i> (house cricket), <i>Alphitobius diaperinus</i> (lesser mealworm) <i>Grylodes sigillatus</i> (banded cricket) <i>Locusta migratoria</i> (African migratory grasshopper) <i>Tenebrio molitor</i> (yellow mealworm from yellow meal beetle).	Yes, but only for 5-insect, ( <i>Acheta domesticus</i> (house cricket), <i>Alphitobius diaperinus</i> (lesser mealworm) <i>Grylodes sigillatus</i> (banded cricket) <i>Locusta migratoria</i> (African migratory grasshopper) <i>Tenebrio molitor</i> (yellow mealworm from yellow meal beetle) based on the consideration that an application for authorisation of these species has been filed before 1 January 2018 and is thus pending. The transitional measures only apply to whole insects and their respective uses that are included in the authorization applications	Imports originating from EU Member States in which the insect products are lawfully placed on the market under national law (e.g. Finland, Denmark) are allowed.  Imports from non-EU countries or from EU Member States where such products were not lawfully on the market before 1 January 2018 are not permitted	<a href="#">Application of 'novel food' regulation regarding insects for human consumption in Belgium. Questions and answers and application of the transition period.</a> (January 2021)



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<b>Estonia</b>	N/A	Applications for the following insect species (8 species) were submitted before 1.1.2019: <i>Acheta domesticus</i> , <i>Alphitobius diaperinus</i> larvae, <i>Apis mellifera</i> pupae, <i>Gryllobates sigillatus</i> , <i>Hermetia illucens</i> larvae, <i>Locusta migratoria</i> , <i>Schistocerca gregaria</i> , <i>Tenebrio molitor</i> larvae. Estonia allows the marketing of whole insects of those species and also products made from whole insects (flour, bakery products, etc.).	N/A	Yes	N/A	N/A
<b>Latvia</b>	Latvian authorities do not consider 'whole insects' and products thereof (e.g. ground whole insects) to fall under Regulation (EC) No 285/97.	N/A	The transitional measure is not applicable to insect parts or extracts do not fall are not authorised.	Yes	N/A	N/A
<b>Lithuania</b>		Yes	Lithuania allows insect-based foodstuff which was commercialized in EU Member States before 1 January 2018 and for which a Novel Food request has been submitted in the same Member State, to be commercialized in Lithuania. Lithuania applies the transitional measure to all insect-based foodstuff, for which applications for authorisation of a novel food were submitted for EFSA evaluation.	Yes	N/A	<a href="#">Lietuvos Respublikoje auginamų vabzdžių, skirty žmonių maistui ir (ar) gyvūnų pašarams, gairės</a> (26 August 2021)
<b>Sweden</b>	Swedish authorities do not consider 'whole insects' to fall under Regulation (EC) No 285/97.	Yes	No	Yes	N/A	<a href="#">Insects - Control wiki (livsmedelsverket.se)</a>
<b>Czech Republic</b>	The Czech authorities considered that whole insects were not covered under the Regulation (EC) No 258/97.	Yes, Provided that, the food must be made of an insect species that is already being consumed in an EU Member State and sold there before 1 January 2018. Furthermore, producers are required to apply for an authorisation to the European Commission by the beginning of 2019. The current possibility of placing insects on the market is time-limited and conditional. Only those authorised, and registered on the Union list, may be sold after 2 January 2020.	The rules apply only to whole insects, possibly to insect flour, not to substances extracted from insect bodies (e.g. proteins). Species that can be legally consumed include: domestic cricket buffalo mealworm short-winged cricket migratory locust mealworm Insect foods are subject to the same legislation as any other food	In principle, yes.	N/A	<a href="#">Zásady Správné zemědělské a výrobní praxe produkce hmyzu určeného pro lidskou spotřebu</a>
<b>Portugal</b>	In the wake of the CJUE ruling on 1st October 2020, the PT authorities do not consider 'whole insects' (incl ground insects) to fall under Regulation (EC) No 285/97.	According to DGAV: the following species of insects may be produced, marketed and used in food in Portugal: <i>Acheta domesticus</i> , <i>Alphitobius diaperinus</i> , <i>Apis mellifera</i> male pupae, <i>Gryllobates sigillatus</i> , migratory locust, <i>Schistocerca gregaria</i> , <i>Tenebrio molitor</i>	(authorisation subject to certain restrictions): 'Insects can be marketed/ used, whole (not alive) and ground (by example, flour). Yet, Insect parts or extracts cannot be sold'	yes	Imports from non-EU states are only possible for countries listed in Implementing Regulation (EU) 2021/405 (Annex XV) after the products have been authorized and appear on the Union List of novel foods authorized. The following countries are currently listed: Canada, Switzerland, South Korea, Thailand and Vietnam'	<a href="#">Direcção-Geral de Alimentação e Veterinária (DGAV)</a>

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<b>Austria</b>	Yes, but only to insect species included in the list of 6 species.	Yes, if the products conform with other applicable legislations (e.g. General EU food law and EU 'Hygiene Package' requirements).	Yes, authorisation limited to 6 species (i.e. <i>Acheta domesticus</i> , <i>Gryllobes sigillatus</i> , <i>Locusta migratoria</i> , <i>Schistocerca gregaria</i> , <i>Alphitobius diaperinus</i> , <i>Tenebrio molitor</i> ).	Yes, but it is limited to those insect species that were commercialised on the Austrian market before 1 January 2018.	N/A	<a href="#">Leitlinie für gezüchtete Insekten als Lebensmittel</a> (Update 10 May 2021)
<b>Germany</b>	No official position at German federal level. Differentiated approaches among the different German Landers (e.g. authorities from the Schleswig Holstein consider that 'whole insects' including if chopped and pulverised are outside the scope of Regulation (EC) No 258/97 vs. authorities from the North Rhine-Westphalia consider that 'whole insects' should be classified as NF).	No official position at federal level. <b>Yes</b> , in certain Landers. <b>No</b> in a few others. Unclear situation in many Landers.	No	<b>Yes</b> within a few lander / <b>No</b> in several others	Imports from EU Member States are allowed. Specific import procedures (incl. veterinary border inspection via a border inspection post) apply when importing insects and their products) from non-EU countries.	
<b>France</b>	The French authorities considered that 'whole insects and their derived products' <b>shall be classified as 'novel food' under Regulation (EC) No 258/97</b> . However, in the Entoma ruling, the CJEU declared the administrative decision that considered that food insects fall under the scope of the Regulation 258/97 not compliant to EU law. The French agency for food safety (ANSES) indicated in a 2015 Opinion that the risk analysis regarding insects needed to be performed in accordance with Regulation (EC) No 258/97.	N/A	No authorisation	Currently not. Following the Entoma ruling, France did not yet adopt a new position on the transitional measures.	No imports allowed	<a href="#">DGCCRF 'information note n° 2014-157 sur la commercialisation d'insectes destinés à la consommation humaine'</a> (16 February 2016)

	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions?	Application of the transitional measure	Import conditions	Reference document
Spain	The Spanish authorities considered that 'whole insects and their derived products' were already subject to the requirements of Regulation (EC) No 258/97.	No. However, by virtue of the Principle of Mutual Recognition provided in the treaty of the European Union, it could be possible to commercialise said specific insects. The principle of mutual recognition stems from Regulation (EC) No 764/2008. It defines the rights and obligations for public authorities and enterprises that wish to market their products in another EU country. The Regulation also defines how a country can deny mutual recognition of a product.	No authorisation	No	No imports allowed	<a href="#">Situación de los insectos en alimentación humana</a>
Italy	The Italian authorities considered that 'whole insects and their derived products' <b>shall be classified as 'novel food' under Regulation (EC) No 258/97.</b>	No	No authorisation	No	No imports allowed	'Controlli Ufficiali in merito all'uso di insetti in campo alimentare con specifico riferimento all'applicabilità del reg. (CE) 258/97 sui 'novel foods' (Ministero della Salute, 29 October 2013)
Poland	N/A	N/A	N/A	N/A	N/A	N/A
Hungary	N/A	N/A	N/A	N/A	N/A	N/A
Romania	N/A			Would potentially apply the transitional measure, however, the competent authorities expected a notification/request from an operator wishing to place edible insects on their national market in parallel to a novel food application submitted to the European Commission (as having the latter only was deemed insufficient).	N/A	N/A
Bulgaria	N/A	No	Does not apply the transitional measure pointing to an absence of applications submitted before 1 January 2018.			

## 4.9. May insect-based products be lawfully exported outside the European Union?

The Novel Food Regulation does not lay down specific export requirements. The rules on export as laid down under Article 12 of the General Food Law apply:

### General Food Law – Article 12

“1. Food [...] exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health [...], food [...] can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food [...] concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.”

Exports outside the EU can only be envisaged taking into account the country of destination, in order to ascertain whether or not the requirements under the Novel Food Regulation (e.g. authorisation granted in accordance with the procedure laid down in Regulation 2015/2283) must be met for the export activity to be performed.

For products that benefit from the transitional provisions (i.e. lawfully marketed in a country of the EU, pending an EU authorisation under Regulation 2015/2283), a country-by-country assessment is required, given that the scope and extent of the transitional arrangements varies between Member States (see above, section 4.8., for more details).

## 4.10. EU import conditions for insects intended for human consumption

The import for insects as food from third countries into the EU is regulated by a comprehensive set of laws and regulations that notably includes

- Legislation in relation to novel foods; and
- Legislation in relation to official controls.

The legislation in relation to novel foods defines the list of insects that are authorized to be imported to the EU market as a food.

The legislation on official controls provides national authorities and the European Commission with the necessary powers to ensure effective enforcement of the regulatory requirements of food legislation, and thus including novel foods legislation. This legislative framework is particularly relevant in the context of border controls when foods are being imported from a third country.

This legislation defines the specific import conditions for insects as food on safety and a model certificate for import.

Furthermore, based on the official controls legislation, the European Commission also established Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 containing a list of third countries from which insects can be imported based on the appropriate evidence and guarantees submitted by those third countries that the insects comply with the requirements of EU legislation in the area of food safety.

The following countries are included in Annex XV to Commission Implementing Regulation (EU) 2021/405, thus meaning that insect food business operators from these countries may export insect food products to the EU:

- Canada
- South Korea

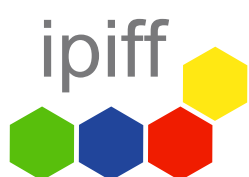
- Switzerland
- Thailand
- Vietnam
- UK (excluding Northern Ireland)

Food business operators from these countries may import into the whole EU any insect food product that is included in the Union list of novel foods and for which a 'generic authorisation' has been previously granted (as of August 2021, no insect food product has received a generic authorisation). These operators may also import insect food products to those EU Member States that apply the EU novel food transitional measure (according to article 35.2 of Reg. 2015/2283) provided that the latter countries authorise the import of such products from third countries, under their national legislation.

### Operators in the UK

Since 31 August 2021, the United Kingdom (excluding Northern Ireland) is listed in Annex XV to Commission Implementing Regulation (EU) 2021/405. UK-based operators may therefore import insect food products to the EU under the afore-mentioned conditions.

For UK-based operators wanting to market insect products in the UK, it is important to note that if an authorisation would have intervened before the UK's full withdrawal from the European Union (i.e. 1 January 2021), it would have been included within the body of UK 'retained law', meaning that this authorisation would still have been valid in the UK after 1 January 2021. The Food Standards Agency (FSA) has now made it clear that, if a novel food application was made to the European Commission before 1 January 2021 and the assessment process for the application has not been completed, applicants will need to submit their application to the FSA, using the FSA's own application service. Since insects and insect derived products had not yet been authorised by the EU before 1 January 2021, this means that the FSA will require a separate application to authorise insects and insect-based ingredients.



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