

Application of ‘novel food’ regulation regarding insects for human consumption in Belgium

Questions and answers and application of the transition period

Table of contents

1. What status do insects have under the 'novel food' Regulation (EU) 2015/2283?.....	2
2. Which insects and insect-based products can be placed on the Belgian market for human consumption?	3
3. Which insects and insect-based products have been authorised?.....	3
4. What is provided by the transitional measures in Regulation (EU) 2015/2283?	3
5. Which insects and insect-based products benefit from the transitional measures in Belgium?	4
6. For which insects and products the transitional measures do not apply?	4
7. What happens when a European decision is taken for a specific insect for which the transitional measures apply?	5
8. Is the situation the same in the other Member States of the European Union?	5
9. How can authorisation be obtained for novel foods?	6
10. What information should be included in an application for the use of an insect?	6
11. Can insects be produced for human consumption that are intended for export to countries outside the European Union?	7
<i>Disclaimer</i>	8
Annex I : Authorisations granted at EU level	9
Annex II: Applications for which the transitional measures are applicable in Belgium	11



1. What status do insects have under the 'novel food' Regulation (EU) 2015/2283?

The scope of the [European regulation \(EU\) 2015/2283](#) on novel foods is very clear with regard to insects: all insect-based products (not only parts of insects or extracts, but also whole insects and their preparations) are considered as “novel foods”¹ if no evidence is available of a significant history of consumption in the European Union (EU) before 15 May 1997.

The Belgian authorities and other Member States do not have such a history of significant consumption of insects. A prior authorisation must therefore be obtained at European level before they are commercialized (see question 3 ‘Which insects and insect-based products have been authorised?’).

Due to the existence of a legal uncertainty regarding the scope of the old novel food legislation (Regulation (EC) No 258/97, which has been repealed since 1 January 2018 by the European [Regulation \(EU\) 2015/2283](#)) regarding whole insects, the Belgian Authorities tolerated the marketing of 10 species of whole insects for human consumption on the national territory. The Belgian tolerance policy was extended after 1 January 2018 for those whole insects for which a Novel Food application for authorisation was submitted before this date.

In the ruling of the [case C-526/19](#), the European Court of Justice has lifted the legal uncertainty concerning the scope and determined that whole insects are not considered as novel food under the old Regulation (EC) No 258/97.

The tolerance policy that existed in Belgium is therefore abolished and replaced by the application of the transitional measures provided for in paragraph 2 of Article 35 of Regulation (EU) 2015/2283.

¹ Extracts from regulation (EU) 2015/2283:

Whereas 8) The scope of this Regulation should in principle remain the same as that of Regulation (EC) No 258/97. However, it is appropriate to review, clarify and update the categories of foods that are novel foods based on scientific and technological developments that have taken place since 1997. Those categories should include whole insects and parts thereof. (...)

Article 3 - definitions

2. In addition, the following definitions apply:

(a) "novel foods" means all foods that were not used for human consumption to a significant degree within the Union before 15 May 1997, regardless of the dates of accession of Member States to the Union, and which fall under at least one of the following categories: (...)

(v) food consisting of, isolated from or produced from animals or parts thereof, with the exception of animals obtained by traditional breeding methods that were already used for the production of food in the Union before 15 May 1997, provided that the food from these animals is a have a history of safe use in the Union as a food.
(...)



2. Which insects and insect-based products can be placed on the Belgian market for human consumption?

Only the following insects and insect-based products may be placed on the market in Belgium:

- those which have been the subject of an authorisation at European level under European Regulation (EU) 2015/2283: see question 3;
- those benefiting from the transitional period: see questions 4 and following.

The placing on the market for human consumption of other insects and insect-based products is prohibited.

3. Which insects and insect-based products have been authorised?

Insects and insect products authorised are added to the [Union list](#) of Implementing Regulation (EU) 2017/2470.

This list includes for each authorised novel food:

- the categories of food in which they can be added and in what maximum quantity;
- the designation to be used in the labeling as well as other possible labelling information (warning, target population, etc.)
- specifications (description, characteristics, criteria of composition, purity, etc.).

Authorisations are valid for all operators, unless the application contains scientific data covered by exclusive property rights which have been deemed essential. In this case, the authorisation of the novel food is limited for five years to the operator who submitted the authorisation request. However, this exclusivity is only valid for five years, the authorisation becoming generic at the end of this period.

Insects and their products that have been the subject of an authorisation are listed in Annex I of this document. It is specified there whether the authorisation benefits from exclusivity.

Both for the production (breeding) of insects for human consumption and for the eventual placing on the market of these insects, the general principles of the applicable food law must be complied with, including the application of good hygiene practices, traceability, compulsory notification, labelling, control of chemical and microbiological hazards and the implementation of an auto-control system based on the HACCP principles. For more information you can consult the [website of the FASFC](#).

4. What is provided by the transitional measures in Regulation (EU) 2015/2283?

The transitional measures provided for in paragraph 2 of Article 35 of Regulation (EU) 2015/2283, stipulate that foods that do not fall within the scope of Regulation (EC) No 258/97, but are now considered as novel food (which is the case for whole insects), may continue to be marketed until a decision has been taken regarding their approval as a novel food, under the following cumulative conditions:

- the foodstuffs in question were legally placed on the market before 1 January 2018, and



- an application for authorisation as a novel food was submitted by 1 January 2019 at the latest.

5. Which insects and insect-based products benefit from the transitional measures in Belgium?

Whole insects meeting the criteria of the transitional period of paragraph 2 of Article 35 of Regulation (EU) 2015/2283 (because they were legally placed on the market before 1 January 2018 and because an application for authorisation was submitted by 1 January 2019 at the latest) are the following:

Acheta domesticus (house cricket)
Alphitobius diaperinus (lesser mealworm)²
Gryllodes sigillatus (banded cricket)³
Locusta migratoria (African migratory grasshopper)
Tenebrio molitor (yellow mealworm from yellow meal beetle)

The transitional measures only apply to whole insects and their respective uses that are included in the applications (see Annex II of this document). Thus, not only are the insect species and its development stage (larva, adult) considered, but also the technological treatment applied to the whole insect as well as the categories of products in which they are used.

The transitional measures apply to the placing on the market of whole insects or products thereof:

- by Belgian operators; or
- from other Member States of the European Union, provided that they have been legally marketed in these Member States for human consumption; or
- from third countries that are authorised for export to the EU (these are countries outside the EU that are included in a European list of countries authorised for export to the EU) and in accordance with the applicable legislation (the insects sent to the EU must be accompanied by a European ad hoc certificate correctly completed). More information is available on [the website of the FASFC](#).

Both for the production (breeding) of insects for human consumption and for the eventual placing on the market of these insects, the general principles of the applicable food law must be complied with, including the application of good hygiene practices, traceability, compulsory notification, labelling, control of chemical and microbiological hazards and the implementation of an auto-control system based on the HACCP principles. For more information you can consult the [website of the FASFC](#).

6. For which insects and products the transitional measures do not apply?

The transitional measures do not apply to insects and their products:

- that do not appear in Annex II of this document;

² Applications on the basis of this insect do not longer benefit from the transition period as a decision has been taken.

³ This application does not longer benefit from the transition period as the file has been withdrawn.



- that are not used in their entirety;
- for which an application for authorisation was submitted after 1 January 2019 (the operators who submitted these files will have to wait for the possible authorisation of their products as novel foods before they can be marketed);
- from Member States of the EU where they are not legally marketed;
- from third countries (countries that are not members of the EU), which do not meet the conditions of the applicable European legislation (in particular regarding the list of third countries that received approval to export insects to the EU) and the conditions of the FASFC. More information is available on the [FASFC website](#).

7. What happens when a European decision is taken for a specific insect for which the transitional measures apply?

The transitional measures will be terminated when a decision on an application for authorisation has been taken by the European Commission. The consequences depend on the decision taken.

In case of a positive decision and the granting of an authorisation, the insects and their products that comply with the conditions and specifications laid down in the [Union list](#) of Implementing Regulation (EU) 2017/2470, can continue to be placed on the market. It is however possible that certain specific uses for which an authorisation is requested are not included in the final authorisation. Specific uses which are not covered by the granted authorisation are then prohibited.

This authorisation is valid for all operators, except if the file contains scientific data that are protected by exclusive proprietary rights and considered essential. In that case, the authorisation to market the novel food is reserved for five years to the operator who submitted the application. As a consequence, other operators placing the same insects and products thereof on the market based on the transitional measures will have to stop the marketing (unless they are the subject of another application that still benefits from the transitional measures and for which no decision has yet been taken). The protection of property rights is only valid for five years, after which the authorisation becomes generic. The files for which exclusive proprietary has been requested are indicated in Annex II to this document.

In case of a negative decision (= refusal of authorisation), the whole insects and their products can no longer be placed on the market, unless they are the subject of another application that still benefits from the transitional measures and for which no decision has yet been taken. Nevertheless, the transitional measures no longer apply if the reasons for the refusal of authorisation are related to safety problems inherent to the specific insect and independent of the intended use.

In the case of voluntary withdrawal of an application for authorisation by an applicant, the consequences are the same as for a refusal of authorisation.

8. Is the situation the same in the other Member States of the European Union?

regarding the application of the transitional measures, the situation is not the same in all Member States. It is therefore recommended to check with [the competent authorities of the Member States](#) concerned



which rules and conditions apply to the marketing of insects for human consumption during this transitional period. However, the authorisations are valid for the whole of the EU.

9. How can authorisation be obtained for novel foods?

Regulation (EU) No. 2015/2283 provides for a centralized European procedure. The applications for authorisation are submitted by an operator (or a consortium of operators) to the European Commission via the “e-submission” system (https://ec.europa.eu/food/safety/novel_food/e-submission_en). The Commission is responsible for checking the validity of the application files (= validation phase). The summaries of the validated applications are published on the website of the European Commission (https://ec.europa.eu/food/safety/novel-food/authorisations/summary-applications-and-notifications_en).

The Commission sends the valid applications to EFSA, which is responsible for the scientific evaluation of the dossier. If the opinion of EFSA is favorable, the Commission, in cooperation with the authorities of the Member States, will grant an authorisation. The novel food in question will be added to the [European Union list of approved novel foods](#) (use the consolidated version). The Union list also contains the authorisations based on legislation (EC) No 258/97.

Regulation (EU) No. 2015/2283 provides that the authorisations are generic, i.e. authorised novel foods may be placed on the market by any operator, provided that the specifications and conditions of use laid down in the authorisations are complied with. There is one exception: when the authorisation file contains scientific data that are protected by exclusive proprietary rights and considered essential, the authorisation for the marketing of the novel food is limited to the operator who submitted the authorisation application. However, this exclusivity is only valid for five years, after which the authorisation becomes generic.

Under Regulation (EU) No. 2015/2283, traditional foods from third countries (such as, for example, certain insects), which can rely on a safe history of use and have been part of the normal diet for at least 25 years, can benefit from a simplified procedure, the so-called notification procedure.

More details about this can be found at the following link:

<https://www.health.belgium.be/nl/informatiebrochure-novel-food>

10. What information should be included in an application for the use of an insect?

Depending on whether it concerns a complete application or a notification of a traditional food from a third country, the files must follow the prescribed rules of the respective implementing regulations:

- [Implementing Regulation \(EU\) No. Commission 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 \(EU\) No. Commission 2017/2468 of 20 December 2017 laying down administrative and scientific requirements for traditional foods from third countries in accordance with Regulation \(EC\) 2015/2283 of the European Parliament and of the Council on novel foods](#)

The scientific content of the dossiers must also be based on the guidelines issued by EFSA, in this context for applications or notifications:

- [Guideline on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation \(EU\) No. 2015/2283](#)
- [Guidance on the preparation and presentation of the notification and application for authorisation of a traditional food from third countries in the context of Regulation \(EC\) No. 2015/2283](#)

It is also useful to consult the following scientific advice:

- [EFSA opinion on the risks of insect production and consumption;](#)
- [Joint advice of the SciCom and the SHC on the food safety of insects intended for human consumption.](#)

A file for an application for authorisation must be sufficiently specific for a particular insect species, as the evaluation is specific for a particular species.

11. Can insects be produced for human consumption that are intended for export to countries outside the European Union?

In case these insects have an authorisation for placing on the market on the basis of [Regulation EU 2015/2283](#) with regard to novel foods or if they fall under the application of the transitional measures (provided for in paragraph 2 of Article 35 of Regulation (EU) 2015/2283), the production of these insects is allowed if the applicable rules are respected. Even if the insects are exclusively intended for export to a third country, it is necessary that the producer of these insects, like any producer of insects intended for human consumption, is registered with the FASFC and will be subject to official controls (see the website of the FASFC).

If these insects do not have an authorisation for placing on the market based on Regulation EU 2015/2283 with regard to novel foods or if they do not fall under the application of the transitional measures (provided in paragraph 2 of Article 35 of Regulation (EU) 2015/2283), the production of these insects is in principle not allowed. However, if these insects are only intended for export to a third country that allows import from Belgium and allows the consumption of these products on its territory, the interested operator can contact the local control authority of the FASFC on which he depends (consult the website of the FASFC for more information).

In all cases, it is the responsibility of the insect producers to ensure compliance with any additional requirements, specific to production, imposed by the importing country.



www.health.fgov.be

For more information, please contact: novelfood@health.belgium.be

'Novel food' team Belgium:

Isabelle Laquiere : isabelle.laquiere@health.fgov.be +32 2/524 73 64

Jean Pottier : jean.pottier@health.fgov.be +32 2/524 73 62

Disclaimer

This document is based on the Regulation (EU) No. 2283/2015 on novel foods.
The content is for informational purposes only, no rights can be derived or claimed.

Annex I : Authorisations granted at EU level

<p>The authorised food categories, quantities and specifications are included in the specific authorisations and in the <u>Union List</u> (consult the last consolidated version)</p>	<p>Temporary exclusive authorisation?</p>
<p>TENEBRIO MOLITOR (YELLOW MEALWORM)</p> <p>Specific authorisation : 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</p>	<p>Yes</p>
<p>TENEBRIO MOLITOR (YELLOW MEALWORM)</p> <p>Specific authorisation : Commission Implementing Regulation (EU) 2022/169 of 8 February 2022 authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (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</p>	<p>yes</p>
<p>LOCUSTA MIGRATORIA (AFRICAN MIGRATORY GRASSHOPPER)</p> <p>Specific authorisation : Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021 authorising the placing on the market of frozen, dried and powder forms of Locusta migratoria 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</p>	<p>Yes</p>
<p>ACHETA DOMESTICUS (HOUSE CRICKET)</p> <p>Specific authorisation : Commission Implementing Regulation (EU) 2022/188 of 10 February 2022 authorising the placing on the market of frozen, dried and powder forms of Acheta domesticus 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</p>	<p>yes</p>
<p>ACHETA DOMESTICUS (HOUSE CRICKET)</p> <p>Specific authorisation : Commission Implementing Regulation (EU) 2023/5 of 3 January 2023 authorising the placing on the market of Acheta domesticus (house cricket) partially</p>	<p>yes</p>



defatted powder as a novel food and amending Implementing Regulation (EU) 2017/2470	
<p>ALPHITOBIOUS DIAPERINUS (<i>lesser mealworm</i>)</p> <p>Specific authorisation: Commission Implementing Regulation (EU) 2023/58 of 5 January 2023 authorising the placing on the market of the frozen, paste, dried and powder forms of <i>Alphitobius diaperinus</i> larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470</p>	yes

Annex II: Applications for which the transitional measures are applicable in Belgium

Insects, their development stage and their applications in foodstuffs (different applications are submitted for the same insect)	Exclusive right requested?
<p>ACHETA DOMESTICUS (<i>house cricket</i>) Whole adult insect, eventually dried and/or ground</p> <p>As such, or used in:</p> <ul style="list-style-type: none"> ○ Pasta ○ Protein products excluding dairy analogues ○ Confectionary ○ Salads and savoury based sandwich spreads ○ Bakery wares ○ Nut spreads ○ Breakfast cereals ○ Salts, spices, soups, salads and protein products ○ Ready-to-eat savouries and snacks 	No
<p>LOCUSTA MIGRATORIA (<i>African migratory grasshopper</i>) Whole nymph or whole adult insect, eventually dried and/or ground</p> <p>As such or used in:</p> <ul style="list-style-type: none"> ○ Bakery wares ○ Salads and savoury based sandwich spreads ○ Confectionary ○ Protein products excluding dairy analogues ○ Sauces ○ Nut spreads ○ Ready-to-eat savouries and snacks ○ Soups and broths 	no
<p>TENEBRIO MOLITOR (<i>yellow mealworm</i>) Whole larvae, eventually dried and/or ground</p> <p>As such or used in:</p> <ul style="list-style-type: none"> ○ Flours and other milled products and starches ○ Pasta ○ Protein products excluding dairy analogues ○ Confectionary ○ Salads and savoury based sandwich spreads Bakery products ○ Nut spreads ○ Soups and broths ○ Sauces 	no



○ Ready-to-eat savouries and snacks	
--	--