

## **INFO SHEET**

### **TYPES OF NOVEL FOODS AUTHORISATIONS**

#### **GENERIC & DATA PROTECTED**

## **THE DIFFERENT TYPES OF EDIBLE INSECT'S NOVEL FOOD AUTHORISATIONS**

- ✚ The scope and implications of an authorisation granted for an insect food product depend on whether this authorisation has been based on proprietary scientific evidence or scientific data (later referred to as 'protected data') or not.
- ✚ Under the 'new' novel food legislation ([REGULATION \(EU\) 2015/2283 OF 25 NOVEMBER 2015](#)), applicants may request that the data included in the application shall not be used for the benefit of a subsequent application during a period of five years.<sup>1</sup>

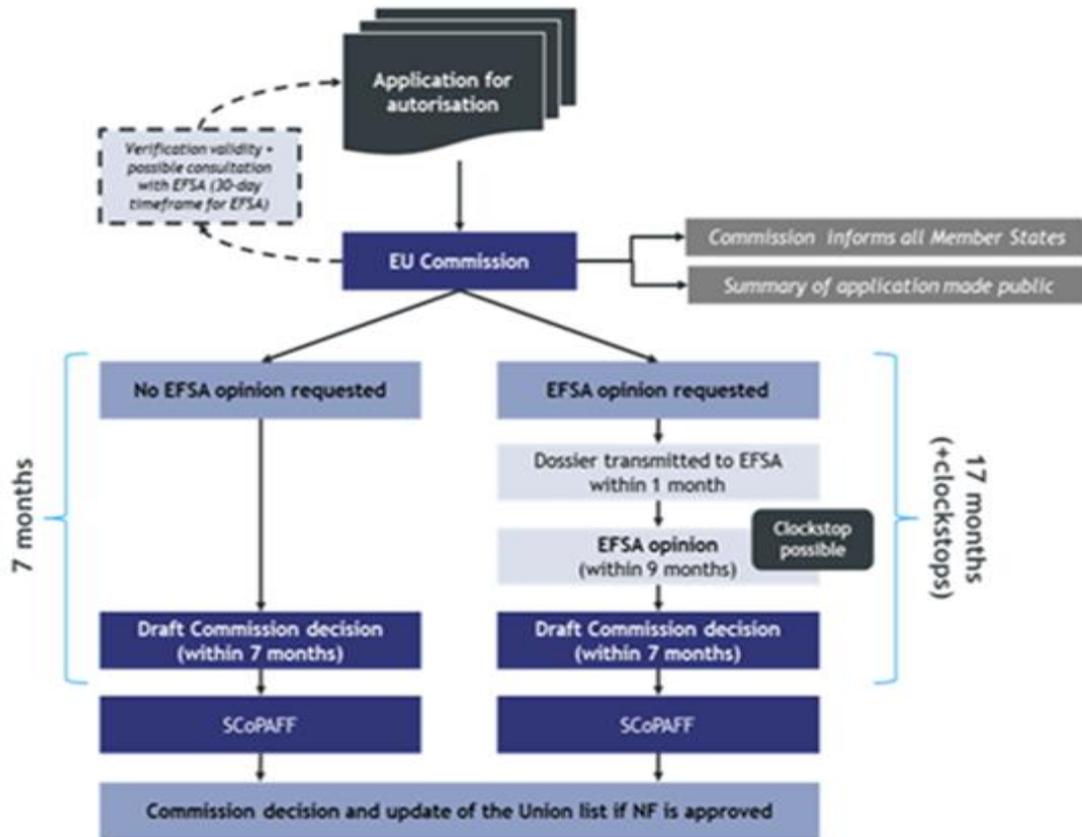
### **1. GENERIC AUTHORISATION**

- ✚ Although insect-producing companies must receive an a 'priori' authorisation prior to commercialising the concerned product on the EU market, authorisations may be 'generic', which means that subsequent operators producing this authorised insect product are entitled to place the concerned product freely on the EU market.

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<sup>1</sup> Article 26.1 and Chapter V of Regulation (EU) 2015/2283).

- ✚ This ‘generic’ principle does not however apply when the concerned authorisation is ‘data protected’- pursuant to article 26 of Regulation 2015/2283: in such a case, its producer benefits from a market exclusivity of 5 years following the authorisation of the concerned product.
- ✚ Furthermore, the ‘generic’ principle only applies if the product forming part of the subsequent novel food application complies with the same specifications (e.g., acceptable limits of biological and chemical contaminants in the concerned product) as the previously authorised product. If that is not the case, such an operator must request a so-called ‘extension’ of a novel food authorisation, and therefore submit a ‘new’ application to the European Commission.
- ✚ Furthermore, the ‘generic’ principle only applies if the product forming part of the subsequent novel food application complies with the same specifications (e.g., acceptable limits of biological and chemical contaminants in the concerned product) as the previously authorised product. If that is not the case, such an operator must request a so-called ‘extension’ of a novel food authorisation, and therefore submit a ‘new’ application to the European Commission.



**Procedure length:** From approximately 8 months in case no opinion is requested from EFSA to 18 months where such opinion is requested, with a possibility of clock stops

<sup>2</sup> Source: IPIFF Guidance Document – the Provision of Food Information to Consumers (<https://ipiff.org/wp-content/uploads/2019/09/FIC-doc.pdf>)

## 2. DATA-PROTECTED NOVEL FOOD AUTHORISATIONS

- ✚ In case of an authorisation following an application for which data protection is requested by the applicant and granted to the latter, this initial applicant has de facto the exclusive right to commercialise the respective insect food product for five years.

### REQUIREMENTS TO BE MET FOR THE REQUEST OF A DATA-PROTECTED AUTHORISATION

- Pursuant to article 26.2 of [REGULATION \(EU\) 2015/2283 OF 25 NOVEMBER 2015](#), three cumulative conditions must be met to be eligible for data protection:
  - ✚ The data must consist of newly developed scientific evidence or scientific data that the applicant has designated as proprietary upon the first application.
  - ✚ At the time the first application was made, the initial applicant had an exclusive right of reference to the data.
  - ✚ The novel food could not have been assessed by EFSA and authorised by the Commission without the submission of the concerned data by the initial applicant.

### SUBMISSION OF AN APPLICATION FOR THE SAME TYPE OF SPECIES/EDIBLE INSECT PRODUCT FOR WHICH A FORMER APPLICANT REQUESTED DATA PROTECTION

- ✚ Other producers of the same species may apply for authorisation to place the same novel food on the market if they do not refer to the proprietary scientific evidence or information submitted as part of a previous application that requested data protection.

## EXCEPTIONS TO THE COMMERCIALISATION OF A DATA-PROTECTED AUTHORISED EDIBLE INSECT NOVEL FOOD PRODUCT

The decision on whether data protection is granted or not lies with the European Commission. However, even if data protection is granted for a novel food product, it is still possible for other operators to commercialise the same product under certain circumstances. This is the case if:

- ✚ A processing company has purchased the specific food product from the authorised applicant to process it in its own products.
  
- ✚ An agreement to use the protected data has been reached between the authorised applicant and the operator who would like to commercialise the product.
  
- ✚ The five-year period for which data protection is granted has come to an end. In that case, any operator who wishes to commercialise the authorised novel food may do so. It is then not necessary to file a new application.

## THE PROPRIETARY OF A DATA-PROTECTED APPLICATION CAN AUTHORISE THE COMMERCIALISATION OF ITS PRODUCT TO OTHER BUSINESS OPERATORS

- ✚ A former applicant whose application for a novel food edible insect was authorised, with the granted data protection, can also decide to extend the rights of commercialisation of its product to another business operator.

## **EXTENSION OF THE COMMERCIALISATION RIGHTS FROM A DATA-PROTECTED AUTHORISED NOVEL FOOD PRODUCT**

### **FROM JULY 2022**

- ✚ From July 2022, a business operator with a commercial agreement with an authorised applicant of a Novel Food product no longer must submit a different application to the EC.
- ✚ The business operator can commercialise the product in question, based on the terms defined in the agreement signed between both parties.

## **COMPLIANCE TO BE MET BY BUSINESS OPERATOR WITH THE EXTENDED RIGHT TO COMMERCIALISE AN AUTHORISED DATA-PROTECTED EDIBLE INSECT NOVEL FOOD PRODUCT**

- ✚ Notwithstanding, the business operator continues to comply with all applicable national legislation where the product is to be commercialised (e.g., hygiene standards, safety, and security).
- ✚ EU national competent entities have the authority to verify its compliance and may request the business operator to present the commercial agreement in question.
- ✚ The European Commission Directorate-General on Health and Food Safety (DG SANTE) provides an open platform with data shared from all EU Member States' competent authorities, where all existing commercial agreements can be checked.