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SUBJECT	<b>Information note: Latest regulatory developments regarding the establishment of EU import conditions for insects intended for human consumption</b>
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### Information Note on the establishment of EU import conditions for insects intended for human consumption

#### Disclaimer

This document aims to explain the established and future EU regulatory provisions applying to imports of insects intended for human consumption. It does not represent in any way the views of the IPIFF organisation on this subject. This document is partially constructed on the information of ‘informal nature’ (e.g. informal legal texts) and based on bilateral exchanges with the European Commission services. Therefore, IPIFF may not guarantee the accuracy of all elements outlined in the document nor the completeness of the information provided.

#### Summary

- The European Union (EU) is a major importer of food and feed products. Stringent import rules are imposed at EU level with the view to guaranteeing that imports from these products fulfil equivalent high standards as those originating from the EU itself.
- The EU Official Controls Regulation (OCR) - [Regulation \(EU\) 2017/625](#) provides the framework for the EU Member States (MS) ensuring that Agri-food businesses comply with European food and feed safety standards. European food and feed safety standards also cover import conditions on animals and goods entering the EU from ‘third countries’ (countries outside the EU).
- **Following the authorisation of dried yellow mealworm for the placing on the market of dried Tenebrio molitor larvae as a novel food and against the background of an increasing number of EU Member States applying the so-called novel food transitional measure** (e.g. Finland, Sweden, Denmark, the Netherlands, Czech Republic, Belgium, Estonia, Lithuania, **Latvia, Portugal**), the OCR legislation, which establishes, for the first time, specific import conditions for insect products, **becomes increasingly important for business food operators who aim at importing edible insects into the EU**. The import conditions are specified notably through the following legal acts:
  - [Regulation \(EU\) 2019/625](#) foresees that imported insects as food must comply with EU requirements for food and food safety.



- [Regulation \(EU\) 2020/2235](#) laying down the applicable Model official certificate for insects as food imported into the EU. **Yet, in that regard, it should be noted that the Commission has tabled a draft Implementing Regulation aiming at extending the transitional provisions outlined under art. 35 of the same Regulation, which concerns certificates issued in accordance with the models laid down in Regulation (EU) No 28/2012 and Implementing Regulation (EU) 2019/628, until 15 March 2022.**
- [Regulation \(EU\) 2021/405](#) draws a list of third countries authorised to export insects into the EU: next to Canada, South Korea, Switzerland, Thailand, and Vietnam, **it will also be possible to export edible insects from the UK (excluding Northern Ireland) to the EU, as of 31 August 2021.** In more concrete terms, EU Member States applying the so-called ‘transitional measure’ and allowing imports of insects (as food) from EU third countries will have to cease imports of insect food products if not originating from the countries above-mentioned. However, the European Commission services intends to widen up this list to a larger number of countries, provided that they receive sufficient data and information about insect production activities in those countries (for that purpose, the European Commission services submit a questionnaire to several other non-EU countries’ competent authorities).

## Introduction and background on current EU imports rules for food and feed products

### 1. Overall EU Framework

The European Union (EU) is a major importer of food and feed products. Stringent import rules, including border checks, are imposed at EU level with the view to guaranteeing that imports fulfil equivalent high standards as products from the EU itself. EU control checks and more generally import conditions vary from one sector to another. - e.g. differences between live animals, products of animal origin, plants, and plant products, due to differentiated sanitary risks associated with these products. For further information about the specific EU import rules applying to the above-mentioned products, please consult the European Commission Directorate-General for Health and Food Safety’s (DG SANTE) [website](#).

### 2. Current EU import rules applying to insects as feed

Insects, just like other food and feed products are subject to EU import rules. Imports for insects as feed are already regulated within the existing EU legal framework - i.e. specific rules are established on the feed safety, substrates used to feed insects, hygiene, traceability, and manufacturing requirements. Furthermore, the imports in the EU of insect PAP, and of treated, but not processed insects (e.g. frozen insects) as feed are allowed only originating **from third countries as indicated in [Regulation \(EU\) 2020/692](#)** and if accompanied by a health certificate, in line with the model health certificate laid down in [Chapter I of Annex XV to Regulation \(EC\) 142/2011](#). **In April 2021, [Regulation \(EU\) 2020/692](#) replaced [Regulation \(EU\) 206/2010](#)** which listed in [Part I of Annex II](#) third countries, territories and parts thereof authorised to import fresh meat into the EU. The positive lists of eligible non-EU countries for imports are established by the EC once they have fulfilled the necessary criteria’s put forth (further explained below).

### 3. Current EU Imports rules applying to insects as food

The import for insects as food from third **countries broadly depends on two sets of legislations**, one to authorise insects as a novel food on the EU market and once authorised, to regulate its import from non-



EU countries. The official controls legislation and the novel foods authorisations are two subjects that apply in parallel but that are independent of each other.

- **Official Controls Legislation:** which also includes import, furthermore, define specifically the import conditions for insects as food on safety, a model certificate for import and which third countries are allowed to import insects. Allowance for third countries is based on the guarantees they can provide on their competent authorities who verify compliance with EU rules. Third countries on the list can import any insect that is authorised according to the novel food Regulations.
- **The Union list of novel foods:** It defines the list of insects as food allowed on the EU market.

#### a) EU Official Controls Legislation

The EU Official Controls Regulation [i.e. Regulation 2017/625](#) - provides the framework for the EU Member States (MS) to verify that agri-food businesses comply with European food and feed safety standards. The OCR Regulation which came into force on 14 December 2019 replaced [\(Regulation \(EC\) No 882/2004\)](#). European food and feed safety standards also cover import conditions on animals and goods entering the EU from third countries (countries outside the EU) (see the following chapter for more details). As insects are not covered under the current EU regulatory framework on official controls, no specific restrictions apply today in the case of imports from third countries - apart from the restrictions foreseen in the framework of the EU novel food legislation - see section 2 below).

#### b) EU Novel Food Legislation

Under the 'new' EU novel food legislation - i.e. Regulation (EU) 2015/2283 - whole insects are considered as novel food and must thus be authorised under the new EU novel food regulation (Regulation (EU) 2015/2283). **Currently, this is the case for dried yellow mealworm food products. The same applies to insect products benefitting from the transitional measures, provided that the EU country in which the food product is commercialised applies the transitional measures. Thus, whereas dried yellow mealworm can be imported to the entire EU market (under the condition of an agreement with the French company SAS EAP Group Agronutris which - following the foods product's authorisation in June 2021 - has de facto an exclusive right to commercialise this food product in the entire EU) the possibility to import other insects as food from EU third countries are restricted to these EU countries who have applied the novel food transitional measure and who also specifically allowed such imports.**

#### 4. Recent modifications introduced by the EU OCR legislation and impact for the insect sector

In March 2019, the EU Legislator has adopted a 'package' of EU Regulations - i.e. Five Regulations- which set out the import conditions for animals and goods for human consumption. These texts also address the case of insects as food specifically.

Among the five Implementing Regulation mentioned above, three acts of interest to the insect sector are explained below.

- a. [Regulation \(EU\) No 2019/625](#): The Regulation specifies that imported insects as food must comply with the following EU requirements for food and food safety. E.g:



- the establishment producing the composite products (e.g. products containing edible insects as an ingredient) fulfils hygiene standards, recognised to be equivalent to those required under EU Legislation - i.e. Regulation (EC) No 852/2004;
  - each consignment of animals and goods be accompanied by an official certificate, or official attestation or any other evidence of compliance;
  - the animals and goods shall come from a third country or region thereof listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625 - i.e. the so- called list of authorised countries.
- b. [Regulation \(EU\) 2020/2235](#) establishes a model official certificate for animals and goods, including insects
- A model certificate - contained in Chapter 48 of Annex III of Reg (EU) No 2020/2235** shall be used for the entry into the EU for placing on the market of insects intended for human consumption in order to meet the certification requirements laid down in the above-mentioned Regulation - i.e. Regulation (EU) No 2019/625. The contents of the model certificate cover information on the consigner/exporter, authorising competent authorities, country of origin, mode of transport, country of origin, essential dates, list of accompanying documents, etc.
- c. [Regulation \(EU\) 2021/405](#) establishes a list of third countries authorised for EU entry of animals and goods for human consumption

**Scope of this regulation:**

**This regulation defines a list of authorised countries to import products of animal origin** intended for human consumption into the EU. These sector-specific lists are established from a food safety perspective and include products for which no EU rules/restrictions existed before (see chapter above for more details). **A list of authorised countries for imports has newly been established specifically for insects among other products of animal origin** (e.g. reptile meat, casings).

These lists are drawn based on an in-depth evaluation of the regulatory and control systems governing the production of the respective product for food intended to be exported from third countries to the European Union: the evaluation is notably done to check whether the competent authorities provide sufficient guarantees that they comply with the requirements laid down in the EU legislation. Specific subjects evaluated include general information on the third country and the product, relevant national legislation laying down the public health conditions and official controls, structure and information on competent authorities and enforcement activities, food business operators' responsibilities and system on issuing health certification of the products.

**Article 24 of [Regulation \(EU\) 2021/405](#) refers to the list of third countries from which food business operators are allowed to export edible insects into the EU, under the conditions outlined above:**

*Consignments of insects intended for human consumption shall only be authorised for the entry into the Union if such foods are originated in and consigned from the third countries that are listed in Annex XV.*

**Annex XV currently lists Canada, Switzerland, South Korea, Thailand and Vietnam as authorised third countries. From 31 August 2021 onwards, UK will join this list.**

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This list of authorised third countries for imports of insects as food will continue to be updated based on the responses and guarantees to be provided to the EC by the third countries consulted or to be consulted. Third country insect producers affected by the above restriction (i.e. if based in a country that is not part of the above list) may, therefore, contact their respective national authorities (e.g. to check whether authorities responded to such questionnaire and/or have been part of this round of consultation). In the event other countries would provide the European Commission services with the above-requested information, the EC could update this list periodically and therefore authorise these new countries to import into the EU countries.