



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Health and food audits and analysis

QUESTIONNAIRE

**FOR THE EVALUATION OF THE REGULATORY AND
CONTROL SYSTEMS GOVERNING THE PRODUCTION OF
INSECTS FOR FOOD INTENDED TO BE EXPORTED FROM
THIRD COUNTRIES TO THE EUROPEAN UNION**

Explanatory notes:

All third countries seeking market access to the European Union (EU) for animals and animal products must have an appropriate regulatory framework and official control system in place which allows the competent authority of the third country to certify that the exported animals and products satisfy EU animal health and public health requirements. Information on the applicable conditions for market access to the EU is available on the website of the European Commission's Directorate-General for Health and Food Safety here: http://ec.europa.eu/food/safety/international_affairs/trade_en

The Commission has designed this **questionnaire**, with the purpose to assess the above systems as regards insects and insects derived materials for human consumption. The completion of this questionnaire is an integral part of the application for market access, and will be assessed by the European Commission's Directorate-General for Health and Food Safety.

Note to the competent authority for the completion of this questionnaire

- The requested information should be provided in one of the official languages of the EU - preferably in English - and should be submitted by email to:

Dr. Eric Thévenard (Head of Unit G4, Food Hygiene) European Commission, Crisis Management in Food, Animals and Plants Directorate, Rue Breydel 4, Office 03/116 B-1000 Brussels, BELGIUM Email: sante-consult-G4@ec.europa.eu

- The provided information should be as complete as possible and where relevant, should include related documents, linked to the specific question(s). Upon assessment of this questionnaire, the Commission services may require further supporting information.
- In order to avoid an unnecessary burden to your services, you may refer to national official websites where the requested information can be consulted by the Commission. An explanatory note should be provided describing the best way in which this information can be accessed and understood by the Commission. References should be provided where available as separate files/documents or website addresses.
- References to supporting legislation should be included in the information provided.
- If you require any further information or clarifications, please contact:
sante-consult-G4@ec.europa.eu

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Abbreviations and Definitions

ABBREVIATIONS	
EC	European Community
EU	European Union
HACCP	Hazard Analysis Critical Control Point
ISO	International Organisation for Standardisation
OIE	World animal health organisation

Definitions

‘Insects’ means insects as defined in point (17) of Article 2 to Regulation (EU) 2019/625.

Full legal references to European Union legislation relevant for insects and insect-derived food commodities covered at the moment of application of the relevant import conditions (December 14th 2019) are listed in the Annex to this questionnaire. Legal acts quoted in this questionnaire refer, where applicable, to the latest amended version.

1. General information

1.1. Name of country

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1.2. Details on insect commodities for which EU market access is sought and list of establishments

Insect species	Name and address of the operator (including registration/approval number)	Type of activity (rearing, processing/treatment* (if applied), trade, import)	Product and CN¹ code

* Alternatively provide "technical/ customer specification fiches" as an annex to this document as a way to explain the type of product being exported to the EU.

2. National legislation

2.1. Provide a list of relevant national legislation laying down the public health conditions for the production and trade of insects and insect-derived materials intended for food in your country.

These should cover

- The designation and powers of the competent authority responsible for the supervision of business operators producing insects and their products for food.
- International health certification covering insects and insect-derived materials.
- Food business operators' responsibilities
- The importation of insects and insect derived materials from other countries

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¹ See list of applicable Combined Nomenclature (CN) codes in Article 3 of Regulation (EU) 2019/625

3. Competent authorities

- 3.1. Name and address of competent authorities responsible for (a) carrying out official controls on insects and insect-derived materials intended for food and (b) certifying that insects or products derived therefrom, intended for export to the EU as food comply the requirements laid down in the model certificate for insects intended for human consumption in Part XIII of Annex III to Regulation (EU) 2019/628.

Name:	
Address:	
Telephone:	
Email:	

- 3.2. Briefly describe the structure of the competent authorities above and provide the legal basis for it carrying out official controls on the production of insects and insect-derived materials intended for food.

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- 3.3. Are official controls (on insects) delegated to bodies² other than the competent authority? If so, please provide the following details.

Name of delegated body:	
List of tasks delegated:	
List of criteria to be met before delegation:	
Description of the supervisory role of the competent authority including whether audits or inspections of those delegated bodies are carried out.	

4. Food business operators' responsibilities

Please indicate whether operators are responsible to implement any "own-check" systems.(e.g. HACCP based procedures, Good Manufacturing Practices, record keeping) as a condition for initial listing and remaining on the list. If so, provide supporting information

² Delegated Bodies as defined in Article 3(5) of Regulation (EU) 2017/625

5. Delivery of official controls

Official controls should follow the general principles laid down in Articles 125 to 129 of Regulation (EU) 2017/625, Delegated Regulation (EU) 2019/625 and should form the basis for official certification as per the requirements laid down in the model certificate for insects intended for human consumption in Part XIII of Annex III to Regulation (EU) 2019/628.

Registration / approval and listing of establishments producing insects for human consumption

- 5.1. With regard to the EU requirements laid down in the model certificate for insects intended for human consumption in Part XIII of Annex III to Regulation (EU) 2019/628, describe the national (legal) provisions for the approval of establishments producing insects intended for human consumption for the EU market.

- 5.2. List the criteria that must be met by establishments producing insects intended for human consumption which seek to be approved for export to the EU. Indicate how these criteria are checked by the competent authority.

Criterion	Description of how this is checked/verified by the competent authority	How many times per year is each criterion verified?

- 5.3. Provide information on the criteria used to determine the frequency of official controls carried out in each of the establishments listed in question 1.2, and whether those frequencies are met.

- 5.4. Please describe how official veterinarians are made aware of the certification requirements for insects (as food) laid down in the model certificate for insects intended for human consumption in Part XIII of Annex III to Regulation (EU) 2019/628 and are in a position to verify compliance of operators with said requirements in respect of exports to the EU.

- 5.5. Please describe how food business operators feeding insects intended for the food chain are checked by the competent authority to ensure that EU rules on eligible feedstuffs (substrates) are respected.

- 5.6. Have microbiological criteria for insects intended for food been established in your country? If so, is there an official sampling plan in place? Please describe

6. Enforcement

- 6.1. With regard to the EU requirements laid down in the model certificate for insects intended for human consumption in Part XIII of Annex III to Regulation (EU) 2019/628, describe the national (legal) provisions for taking enforcement action against operators producing insects intended for human consumption for the EU market, which do not comply with EU rules. Indicate whether the competent authority has powers to stop establishments from exporting to the EU and/or refuse certification.

7. Health certification

- 7.1. With regard to the EU requirements laid down in Article 120.2(h) of Regulation (EU) 2017/625 and in the model certificate for insects intended for human consumption in Part XIII of Annex III to Regulation (EU) 2019/628, describe the system for issuing certification. Include information on the authorisation of official veterinarians, their training and on how the competent authority assures itself that officials signing certificates are competent to do so.

8. Annex: Most relevant EU legislation

EUROPEAN LEGISLATION	OFFICIAL JOURNAL	TITLE
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1–24	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
Regulation (EC) No 852/2004	OJ L 139, 30.04.2004, p. 1	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 853/2004	OJ L 139, 30.04.2004, p. 55	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Regulation (EU) 2017/625	OJ L 95, 7.4.2017, p. 1	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 (Official Controls Regulation)
Regulation (EU) 2019/625	OJ L 131, 17.5.2019, p. 18	Commission Delegated Regulation (EU) 2019/625 of 5 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption
Regulation (EU) 2019/626	OJ L 131, 17.5.2019, p. 31	Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation (EU) 2016/759 as regards these lists.
Regulation (EU) 2019/627	OJ L 131, 17.5.2019, p. 51	Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls.
Regulation (EU) 2019/628	OJ L 131, 17.5.2019, p. 101	Commission implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation

EUROPEAN LEGISLATION	OFFICIAL JOURNAL	TITLE
		(EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates.
Regulation (EC) No 1935/2004	OJ L 338, 13.11.2004, p. 4	Regulation of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
Regulation (EU) No 10/2011	OJ L 12, 15.1.2011, p. 1–89	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
Regulation (EC) No 1069/2009	OJ L 300, 14.10.2009, p. 1	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Regulation (EU) No 1169/2011	OJ L 304, 22.11.2011, p. 18–63	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
Regulation (EU) 2015/2283	OJ L 327, 11.12.2015, p. 1–22	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