

DATE	Original date: 25 <sup>th</sup> October 2019, updated: 20 <sup>th</sup> November 2019 <sup>1</sup> , 9 <sup>th</sup> December 2019, 28 <sup>th</sup> September 2020. (All updates in red font)
SUBJECT	Information note: Latest regulatory developments regarding the establishment of EU import conditions for insects intended for human consumption.
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## 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) to verify 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).
- The production and commercialization insects as food are currently not allowed across the EU territory, in the absence a novel food authorisations granted for such products under the EU [Novel Food Regulation](#). Only the EU countries applying the so-called novel food transitional measure (e.g. Finland, Denmark, the Netherlands, Czech Republic, Belgium, certain States in Germany ) are currently allowing their commercialisation, including (in the case of Finland and Denmark according to our knowledge) when originating from EU third countries.
- Yet, the above-mentioned countries will be impacted by the entry into force of the new OCR legislation, which establishes, for the first time, some specific import conditions for insect products, 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 \(EU\) 2019/628](#): establishes a Model official certificate for insects as food imported into the EU.
  - [Regulation \(EU\) 2019/626](#) draws a list of third countries authorised to export insects into the EU: this list which is currently composed of 3 countries- i.e. **Canada, South Korea and Switzerland** - has become effective **as from 14 December 2019**<sup>2</sup>. In more concrete terms, EU Member States benefiting from the so-called ‘novel food transitional measure ’<sup>3</sup> and allowing imports of insects (as food) from EU third countries (i.e. Finland and Denmark according to our knowledge) will have to cease imports of insect food products if not originating from the three EU third countries above-mentioned. However, the European Commission services intend 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 would have submitted a questionnaire to several other non-EU countries’ competent authorities). **Thailand and Vietnam have provided sufficient safety and hygiene guarantees on the insect production and control and will be added to the list. However, they will only be allowed to import in the EU once they have been added on the list and the amending Regulation comes into force.**
    - [Commission Implementing Regulation \(EU\) 2019/1981 of 28 November 2019 amending Implementing Regulation \(EU\) 2019/626 as regards lists of third countries and regions thereof authorised for the](#)

<sup>1</sup> IPIFF met the DG SANTE on 20<sup>th</sup> November 2019 in order to discuss the implementation of the OCR Regulation and the ‘list of countries’ authorised to import insects as food into the EU.

<sup>2</sup> The date of application for the text remained uncertain and a possibility to be postponed, approximately by a few days or weeks, due to delays in the settlement of the new EU Commission was foreseen. However, the official text for the amended Implementing Regulation was adopted and published on 28<sup>th</sup> November 2019.

<sup>3</sup> For more details, see 4.8. Transitional measures - [IPIFF Briefing paper on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU](#)

## 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.*

## 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 abovementioned products, please consult the European Commission’s Directorate-General for Health and Food Safety (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<sup>4</sup>, and of treated, but not processed insects<sup>5</sup> (e.g. frozen insects) as

<sup>4</sup> PAP: Processed Animal Proteins

<sup>5</sup> The import of treated, but not processed insects (e.g. dry frozen insects), - according to Regulation (EC) No 1069/2009 (later referred as ‘ABP Regulation’) -

ANNEX II							
FRESH MEAT							
PART I							
List of third countries, territories and parts thereof <sup>(1)</sup>							
ISO code and name of third country	Code of Territory	Description of third country, territory or part thereof	Veterinary certificate		Specific conditions	Closing date <sup>(2)</sup>	Opening date <sup>(3)</sup>
			Model(s)	SG			
1	2	3	4	5	6	7	8
AL – Albania	AL-0	Whole country	—				
AR – Argentina	AR-0	Whole country	EQU				
	AR-1	The Provinces of: Buenos Aires, Catamarca, Corrientes (except the departments of Berón de Astrada, Capital, Empedrado, General Paz, Itati, Mburucuyá, San Cosme and San Luis del Palmar) Entre Ríos, La Rioja, Mendoza, Misiones, Part of Neuquén (excluding territory included in AR-4), Part of Río Negro (excluding territory included in AR-4), San Juan, San Luis, Santa Fe, Tucumán, Córdoba, La Pampa, Santiago del Estero, Chaco, Formosa, Jujuy and Salta, excluding the buffer area of 25 km from the border with Bolivia and Paraguay that extends from the Santa Catalina District in the Province of Jujuy, to the Laishi District in the Province of Formosa	BOV	A	1		18 March 2005
			RUF	A	1		1 December 2007
	AR-2	Chubut, Santa Cruz and Tierra del Fuego	BOV, OVI, RUF				1 March 2002
	AR-3	Corrientes: the departments of Berón de Astrada, Capital, Empedrado, General Paz, Itati, Mburucuyá, San Cosme and San Luis del Palmar	BOV RUF	A	1		1 December 2007
	AR-4	Part of Río Negro (except: in Avellaneda the zone located north of the Provincial road 7 and east of the Provincial road 250, in Comesa the zone located east of the Provincial road 2, in El Cuy the zone located north of the Provincial road 7 from its intersection with the Provincial road 66 to the border with the Department of Avellaneda, and in San Antonio the zone located east of the Provincial roads 250 and 2) Part of Neuquén (except in Confluencia the zone located east of the Provincial road 17, and in Picum Leufi the zone located east of the Provincial road 17)	BOV, OVI, RUF				1 August 2008

Figure 1. Extract List of third countries, territories and parts thereof authorised for import of fresh meat into the EU.

feed<sup>6</sup> are allowed only if originating from countries listed in [Part I of Annex II to Regulation \(EU\) No 206/2010](#) (List of third countries, territories and parts thereof authorised for import of fresh meat into the EU) and accompanied by a health certificate, in line with the model health certificate laid down in [Chapter I of Annex XV to Regulation \(EC\) No 142/2011](#). 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).

## Current EU Imports rules applying to insects as food

The import for insects as food from third countries broadly depend on two sets of legislations, one to authorise insects as a novel food <sup>7</sup> on the EU market and once authorised, to regulate its import from non-EU countries<sup>8</sup>. 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.

### 1. 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 replaces the currently applicable regulatory framework on official controls ([Regulation \(EC\) No 882/2004](#)) and will mainly come into force on 14 December 2019 <sup>9</sup>. 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) <sup>10</sup>Moreover, the EU legislator foresaw a transitional period<sup>11</sup> to apply - i.e. period during which those animal-based products 'not covered by EU harmonised rules' could continue to be imported in certain EU countries until the entry into force of the new OCR legislation.

#### Scope of OCR

- Food and food safety
- Feed and feed safety
- GMOs
- Animal health
- Animal welfare
- Animal by-products
- Plant health
- Plant protection products
- Organic production
- PDOs, PGIs, TSGs

### 2. EU Novel Food Legislation

is allowed for pet food or technical applications; however, in the absence of health import requirements laid down in the ABP Regulation, the import of treated but unprocessed insects for the manufacturing in the EU territory of processed animal protein for food producing animals is currently not permitted.

<sup>6</sup> PAP derived from insects cannot be fed to farmed animals, other than fur animals and aquaculture in the EU.

<sup>7</sup> Novel food legislation - i.e. [Regulation \(EU\) 2015/2283](#)

<sup>8</sup> EU Official Controls Regulation [i.e. Regulation 2017/625](#) which also encompass import conditions.

<sup>9</sup> See footnote 2

<sup>10</sup> [Regulation \(EC\) No 882/2004](#)

<sup>11</sup> [REGULATION \(EU\) 2017/185 laying down transitional measures for the application of certain provisions of Regulations \(EC\) No 853/2004 and \(EC\) No 854/2004 of the European Parliament and of the Council](#)

Under the ‘new’ EU novel food legislation - i.e. [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 the ‘old’ novel food legislation- i.e. [Regulation \(EC\) No 258/97](#), and this has led to diverging approaches<sup>12</sup> among the EU Member States (MS) thereby generating a contrasted impact<sup>13</sup> of the transitional provisions provided for under Regulation (EU) 2015/2283<sup>14</sup>. The transitional provision is eligible<sup>15</sup> and applied by the respective MS provides them with a possibility to continue to market insects and based products until authorised at an EU level. No insects as a novel food have been authorised and included in the [union lists of novel foods](#). Thus, the possibilities for importing 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 (i.e. Finland and Denmark according to our knowledge).

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

In March this year, 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 and are explained below. All these Regulations will come into effect on 14/12/2019<sup>16</sup>.

### 1. [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.

PART XIII  
MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF INSECTS INTENDED FOR HUMAN CONSUMPTION

COUNTRY		Official certificate to the EU	
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No	I.2. Certificate reference No	I.2.a IMSCC reference No
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
	I.5. Consignee/importer Name Address Postal code Tel. No	I.6. Operator responsible for the consignment Name Address Postal code	
I.7. Country of origin	ISO I.8.	I.9. Country of destination	ISO I.10.
I.11. Place of dispatch Name Address	Approval No	I.12. Place of destination Name Address	
I.13. Place of loading		I.14. Date and time of departure	
I.15. Means of transport Aeroplane <input type="checkbox"/> Vessel <input type="checkbox"/> Other <input type="checkbox"/> Road vehicle <input type="checkbox"/> Railway <input type="checkbox"/> Identification:		I.16. Entry BCP	
I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.17. Accompanying documents Type No	
I.19. Container No/Seal No			
COUNTRY		Official certificate to the EU	

Text of image

<sup>12</sup> Some MS considered whole edible insects as ‘Novel food’ under the while the others did not.

<sup>13</sup> This led to only some MS being eligible for the transitional measure (see footnote 14).

<sup>14</sup> 4.8. Transitional measures - [IPIFF Briefing paper on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU](#)

<sup>15</sup> MS are eligible for the transitional measure if they considered that the insects as food did not fall within the scope of Regulation (EC) No 258/97 (old novel food regulation) and the products were lawfully placed on the market by 1 January 2018.

<sup>16</sup> See footnote 2

2. [Regulation \(EU\) No 2019/628](#) establishes a model official certificate for animals and goods, including insects

Figure 2. Model official certificate presented in Regulation (EU) No 2019/628

A model certificate - contained in Part XIII of Annex III of Reg (EU) No 2019/628 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.

3. [Implementing Regulation \(EU\) No 2019/626](#) 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.

The adopted text from March 2019 - article 20 (see below) - only refers and not specifically identifies, third countries and regions thereof from which insects have been authorised in accordance with the novel food legislation (i.e. in other words, the EU Legislator did not necessarily intend to draw a list of authorised countries on top of restrictions imposed through the novel food legislation). However, in the recent past, the EC services found it appropriate to refer to a concrete list, following which proposed a new text (see below) that has been presented and positively voted for an amendment by EU Member States authorities this summer.

Article 20 of Regulation (EU) 2019/626

Third countries or regions thereof authorised for the entry into the Union of insects

Adopted text from March 2019

*‘Consignments of insects intended for human consumption shall be authorised for the entry into the Union only if such foods are originated in and consigned from a third country or region thereof, from which insects have been authorised in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council and listed in Commission Implementing Regulation (EU) 2017/2470 (21).’*

Will be amended to:

*‘Consignments of insects intended for human consumption shall only be authorised for the entry into the Union if such foods have originated in and been consigned from a third country or region thereof, listed in Annex IIIa.’*

**Background information:** Back in early 2018, the European Commission services (DG SANTE) had communicated about their intention to develop such a list of ‘authorised third countries’ in the case of insects as food. To this end, the European Commission - back in 2018 - had initiated bilateral consultations with several EU third countries authorities as with the IPIFF organisation<sup>17</sup>. According to the latest information received, further contacts would have been established between the European Commission services and relevant Member States authorities<sup>18</sup> a few months ago, with the view to establishing such lists.

➤ According to latest/recent information collected by the IPIFF Secretariat, the EC would have transmitted a questionnaire to a wide range of national competent authorities with the view to evaluating whether the targeted country has an appropriate regulatory framework and official control system in place. Thus, allowing the EC to ensure that the exported animals and products satisfy EU animal health and public health requirements. The responses from this questionnaire would have been used by the EC to evaluate and prepare a list of authorised countries to import insects as food products into the EU.

➤ **Evaluation of responses:** According to the DG SANTE services, Switzerland (on 28 August 2019), South Korea (on 11 September 2019) and Canada (on 8 October 2019) have provided ‘sufficient guarantees’ to be authorised for the entry into the Union of insects.

➤ Consequently, the above countries have been added in a draft list of countries authorised to import insects as food, amending Article 20 of Regulation (EU) 2019/626. This draft list was discussed and voted by the EU Members States at a meeting held on 14 October 2019. The amended version of the text will be publicly accessible in the next few weeks.

General procedure for request for authorisation to export animal-based products to the EU if not in the positive list of countries authorised for imports into the EU.

The competent authority of a non-EU country must submit a written request to the Directorate-General for Health and Food Safety of the European Commission to export animal and animal products to the EU. The request should contain confirmation that the authority can fulfil all relevant legal provisions to satisfy EU requirements. Upon receipt, the Directorate-General for Health and Food Safety then sends a general and/or product-specific questionnaire to the competent authority which should be completed and returned. The completed questionnaire(s) will provide information on relevant national legislation on animal health and food hygiene, structure of the competent authorities etc.

**THIS REGULATION CAME INTO TO EFFECT FROM 14 DECEMBER 2019 <sup>19</sup>**

(October 2019) Consequently, the EU countries currently benefiting from the novel food transitional measure and allowing imports of insects (as food) from EU third countries (i.e. Finland and Denmark according to our knowledge) will have to cease, as from 14th December 2019 such imports (if any) except if originating from Canada, South Korea and Switzerland.

**Future updates of the list of ‘authorised third countries’: conditions and a forecasted timeline**

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<sup>20</sup>. Third country insect producers affected by the above restriction (i.e. if based in a country

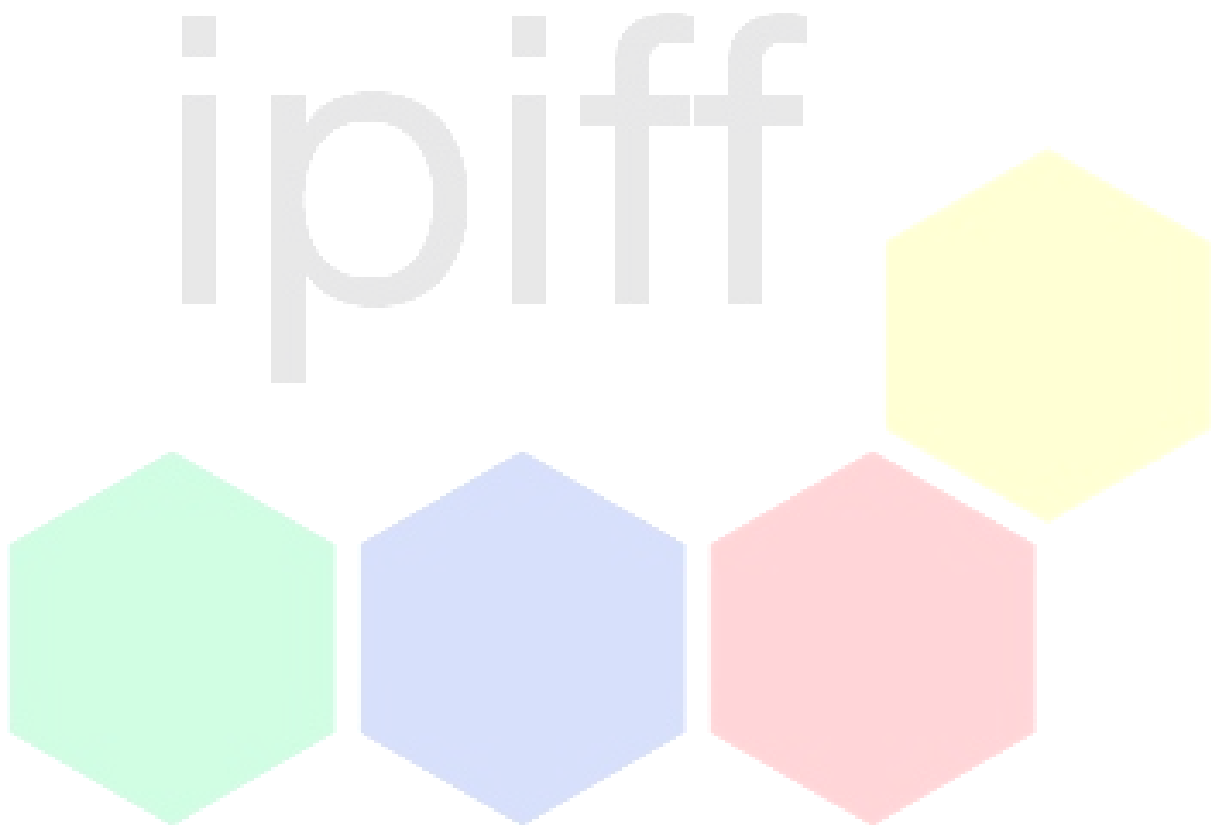
<sup>17</sup> Through bilateral discussions, IPIFF informed the DG SANTE services about the need to widen up consultation towards wider possible range of non-EU Countries, thereby giving the possibility for the EC services to evaluate thoroughly whether all countries where commercial production of insects as food exist could be part of the list of authorised countries.

<sup>18</sup> The IPIFF Secretariat does not have further information about the specific countries that have been contacted for the purpose of the above-mentioned evaluations

<sup>19</sup> See footnote 2.

<sup>20</sup> If certain ‘third countries’ have not received the questionnaire it is the responsibility of the third country to request (the questionnaire) the EC for authorisation to import into the EU.

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<sup>21</sup> and therefore authorise these new countries to import into the EU countries<sup>22</sup>. On the evaluation of the responses to the EC questionnaire (see details above), Thailand has provided sufficient guarantees on the appropriate regulatory framework and official control system in place. The EC had informed the Thai authorities (10 April 2020) of the favourable evaluation of the questionnaire. Thailand will therefore soon be included on the list of third countries authorized to export these insects to the EU, which will require amendment of Annex IIIa of Regulation (EU) 2019/626. This amendment must follow the legislative procedure, with the submission of the amended list to other Director Generals and the Member States, which may take a few months to come into force (potentially by the end of 2020) after which Thailand would be added to the list and have the possibility for Thailand to import into the EU. Similarly, Vietnam has provided sufficient guarantees in September 2020 to the EC and received a favourable evaluation. The next amendment to include Vietnam into the list of authorised countries and allowed to import into the EU remains subject to legislative procedures (potentially by mid-2021).



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<sup>21</sup> Two waves of updates to the lists are expected firstly mid-2020 and secondly towards the end of 2020 complementing the new ‘Animal Health Regulation’ to come into force in April 2020. The lists will be updated if the respective countries submit the questionnaire to the EC in due time and sufficient guarantees are provided.

<sup>22</sup> Such import authorisation would only be valid for EU countries applying the novel food transitional measure before the first novel food authorisations are granted, and in the whole EU thereafter.