

Bird & Bird & Edible Insects

Regulation of edible insects across Europe



Novel Food's Brave New World?

The new European Regulation on novel foods, which was adopted on 25 November 2015, updated the definition of 'novel food' and clarified its scope.

While the text entered into force on the last day of 2015, most of the regulation provisions will only become applicable from 1 January 2018. However, the Commission is in charge of enacting several implementing measures by the time the regulation becomes fully applicable, notably in respect of:

- the procedure for the determination of novel food status, in particular the consultation between food business operators and Member States, between Member States and the Commission and between the Member States amongst themselves;
- the administrative and scientific requirements for new novel food applications and for applications concerning traditional foods from third party countries; and
- a list of already approved novel foods.

Even though the regulation will only be effective as of 2018, food business operators need to be aware of some crucial changes which the regulation brings.

Definition of 'novel food'

The concept of novel food now explicitly encompasses whole insects and their parts, as well as food consisting of certain micelles or liposomes. Detailed categories are provided for in the regulation that include, for example, food with a new or intentionally modified molecular structure, food from cell or tissue cultures derived from animals, plants, microorganisms, fungi or algae, food from microorganisms, fungi or algae and food from material of mineral origin.

Furthermore, under the regulation, a food will be considered a novel food where it results from a production process not used for food production within the EU before 15 May 1997, which gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances. Such processes include, for example, nanotechnology.

Current approach to edible insects across Europe

Although insects fall within the scope of the new novel food Regulation, their classification under the old Novel Food Regulation (Reg. 258/1997/EC) – applicable until December 31, 2017 – was quite controversial. These uncertainties have led the European Member States to adopt different approaches to their classification and consequent placing on the market. The 'novel food status', in fact, entails the necessity that the novel food is authorized before being placed on the market.

We have created this country-by-country guide to provide a comparison of the scope and national interpretation of Reg. 258/1997/EC in six European countries. This includes a summary of any specific national rules and existing policy or guidance documents.

Finally, it shall be noted that according to the new Novel Food Regulation (Reg. 2015/2283/EU), companies that are currently marketing insects and their parts, can legally continue the sales until 1 January 2021 as provided by the transition rules. After this date, the authorization under the new novel food Regulation will be required.

Get in touch

Nicolas Carbonnelle
Senior Associate

Tel: +32 (0)2 282 6040
nicolas.carbonnelle@twobirds.com



Please refer to the Contacts page at the end of this document to find the details of food & beverage regulatory experts across our international offices.

Current approaches in Europe

<i>Are whole insects included in the concept of 'novel food'?</i>		
	Denmark	In Denmark it has been discussed whether whole insects are included in the concept of 'novel foods' due to the uncertainty of the wording in the EU Novel Food Regulation no. 258/97 Article 1(2)(d), food ingredients 'isolated from animals'. The Danish Food Authority (Fødevarestyrelsen) estimates that this wording cannot be interpreted as containing ingredients consisting of whole insects, even if the insects have been chopped or comminuted - provided that it can be proved that whole insects are used and that no parts thereof have been removed. The Danish Food Authority currently does not include whole insects in the concept of novel foods under the EU Novel Food Regulation no. 258/97.
	Germany	In Germany the question of whether whole insects are subject to the current Novel Food Regulation [(EC) 258/97] is discussed controversially, since Article 1 (2)(d) only refers to food ingredients isolated from animals. German authorities such as the German Federal Agency for Consumer Protection and Food Safety (<i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit</i>) therefore conclude that, from a food law perspective, whole insects are currently a grey area. Thus, as of now, there is uncertainty as to whether whole insects will be treated as <i>novel food</i> or not. However, according to the view of the German authorities, whole insects will be captured once the new Novel Food Regulation [(EU) 2015/2283] has entered into force on 1 January 2018. The new Article 3 (2)(a)(v) provides that food consisting of (whole) animals or their parts qualify as <i>novel food</i> if they were not used for human consumption to a significant degree within the Union before 15 May 1997.
	Italy	On October 29 2013, the Ministry of Health published a circular on 'Official control on the use of insects as food, with specific reference to the applicability of Reg. 258/1997/EC on novel foods'. The circular states that ' <i>insects, being animal origin products lacking of a long history of consumption, fall within the scope of the Regulation and therefore they cannot be placed in the Italian market</i> '. It follows that insects cannot be placed in the Italian market unless authorized.
	Belgium	The Belgian competent authorities tolerate on the national territory the commercialization of ten species of whole insects. Placing either of these ten species of whole insects (or products derived from these whole insects) on the Belgian market requires complying with general food law, including good hygiene practices, traceability, labelling, chemical and microbiological risk management and setting up an auto control system based on the principles of HACCP. Any other species of insects is considered as novel food.

¹ Ministero della Salute, Controlli Ufficiali in merito all'uso di insetti in campo alimentare con specifico riferimento all'applicabilità del reg. (CE) 258/97 sui 'novel foods', 29 October 2013.

	<p>UK</p>	<p>The Food Standards Agency (FSA), the UK Government body for food safety and standards, states that whole edible insects are not currently included in the concept of novel food under the Novel Food Regulation [(EC) 258/97].</p>
	<p>Netherlands</p>	<p>In the Netherlands, the mealworm beetle, lesser mealworm beetle and locust are the insects currently bred and sold in the Netherlands.</p> <p>We have not found any laws or regulations on these insects but the Dutch Office for Risk Assessment & Research (Bureau Risicobeoordeling & Onderzoeksprogrammering: 'BuRo') advised the Ministers on 15 October 2014 to classify these insects as foods in the meaning of the General Food Law (Regulation 178/2002).</p> <p>So, for the Netherlands, we currently have no indication that whole insects should be regarded as novel food.</p>

Are comminuted insects included in the concept of 'novel food'?

	<p>Denmark</p>	<p>It is the assessment of the Danish food authority that there is a legal uncertainty as to whether the regulation covers chopped or otherwise comminuted insects. This is due to the fact that the categories in the regulation cover only ingredients 'isolated from animals'. According to the legal assessment of the Danish Food Authority, this cannot cover comminute insects, as these are not products isolated from animals.</p> <p>It is however a prerequisite that wings or other parts are not removed from the animal, and that it can be documented that the entire animal has been used.</p>
	<p>Germany</p>	<p>It depends. German authorities take the view that parts of insects fall within the scope of Regulation (EC) 258/97 as an ingredient isolated from animals.</p> <p>However, there is no clear guidance on whether this would also apply to whole insects that are just chopped or even pulverized. Thus, if it is still the whole insect that is used, the uncertainty described above will remain.</p>
	<p>Italy</p>	<p>The Circular of the Ministry of Health mentioned above does not make any distinction between whole and comminuted insects. It follows that both whole and comminuted insects are deemed to fall within the notion of novel food.</p>
	<p>Belgium</p>	<p>Comminuted or otherwise processed insects or ingredients made from/extracted from insects are considered as novel food.</p>
	<p>UK</p>	<p>Parts or extracts of insects are subject to the novel foods approval process and fall within the scope of the current Novel Food Regulation (EC) 258/97.</p>
	<p>Netherlands</p>	<p>No, the above mentioned advice by the BuRo does not discuss comminuted insects.</p>

What if the foodstuff, or part of the foodstuff, contains the entire insect?

	Denmark	<p><i>See above.</i></p> <p>According to the Danish Food Authority, the above mentioned uncertainty also covers whole insects.</p>
	Germany	<p><i>See above.</i></p> <p>Under the current Novel Food Regulation there can be a difference between the use of the entire insect and the use of parts of insects.</p>
	Italy	<p><i>See above.</i></p> <p>No change – insects are still included in the concept of 'novel food'.</p>
	Belgium	<p>No.</p>
	UK	<p><i>See above.</i></p> <p>Yes, under the wording of the current Novel Food Regulation [(EC) 258/97] whole insects are exempt and were not contemplated within the scope of the legislation. The new EU Directive on Novel Foods will bring whole insects within the remit of the legislation and so whole insects will, once it is in force, require a novel food safety assessment.</p>
	Netherlands	<p>No.</p>

If insects are permitted to be marketed as foodstuff under the national regulation, does any other regulation apply?

	Denmark	Besides the above mentioned regulation, the general Danish Food Legislation applies, including the companies' responsibility to ensure that the foodstuff they are marketing is not unsafe, thereby meaning hazardous to health or unsuitable for human consumption. This entails a risk analysis, described below.
	Germany	Insects (including whole insects) are subject to the same general regulations that apply to all kinds of foodstuff.
	Italy	<p>According to the circular of the Ministry of Health mentioned above, the food operator that wants to place insects or insect-based foods on the Italian market shall demonstrate that they do not fall within the scope of Reg. 258/1997/EC. Evidence of this can be provided upon presentation of: a) a certification issued by the competent authority of another Member State that guarantees that the food has been consumed in that Member State and therefore it shall not be considered as a novel food; b) documentary data certifying the presence of the product on the Community market before 15 May 1997.</p> <p>Lacking the documentation above, the food operator shall follow the procedure established by Reg. 258/1997/EC on novel foods.</p>

	<p>Belgium</p>	<p><i>See above.</i></p> <p>The Belgian competent authorities tolerate on the national territory the commercialization of ten species of whole insects. Placing either of these ten species of whole insects (or products derived from these whole insects) on the Belgian market requires complying with general food law, including good hygiene practices, traceability, labelling, chemical and microbiological risk management and setting up an auto control system based on the principles of HACCP.</p>
	<p>UK</p>	<p>Insects as food would be subject to the same general regulations that apply to all foodstuffs, including the General Food Law Regulation [(EC) 178/2002], the Food Safety Act 1990 (as amended), the General Food Regulations 2004 (as amended) and the Food Safety and Hygiene (England) Regulations 2013.</p> <p>Food brought into the UK must meet Regulations under the Food Safety Act 1990 and food businesses must apply for Hazard Analysis and Critical Control Point (HACCP) procedures.</p>
	<p>Netherlands</p>	<p>The insects as mentioned above are to be considered foods in the meaning of the General Food Law (Regulation 178/2002). Besides this, insects should comply with the European hygiene regulations and all other legislation pertaining to foodstuffs.</p> <p>As far as we are aware, the production of insects in the Netherlands is based on a factual tolerance policy (gedoogbeleid), which is monitored by the Netherlands Food and Consumer Product Safety Authority ('NVWA').</p>

Is a risk assessment required before marketing insects as foodstuff?

	<p>Denmark</p>	<p>Under the EU Novel Food Regulation no. 258/97, food ingredients 'isolated from animals' are required to be risk assessed and approved before they can be marketed. It is the company responsible for marketing the foodstuffs that must assess whether the marketed foodstuffs fulfil the regulation. The company must ensure that the marketed foodstuffs are not dangerous, meaning harmful to health or unfit for human consumption.</p>
	<p>Germany</p>	<p>Under the current regime whole insects would arguably not require a risk assessment, whereas parts of insects do as part of their novel food authorization.</p> <p>However, since the question of whether whole insects are a <i>novel food</i> is subject to controversial discussion, and since according to Article 14 of Regulation (EC) 178/2002 and Section 5 of the German Act for Foodstuff and Feedstuff [<i>Lebensmittel- und Futtermittelgesetzbuch</i>] it is prohibited to market foodstuff that poses health risks, an individual risk assessment seems to be recommendable for whole insects as well. It is the manufacturer/distributor who is responsible for ensuring that this requirement is met.</p> <p>Besides, given the controversy of this question, the German Federal Agency for Consumer Protection and Food Safety strongly recommends getting in touch with the competent state authorities prior to the marketing of whole insects, in order to see how they assess the case and what requirements they will actually impose.</p>
	<p>Italy</p>	<p>Both insects and their parts must be risk assessed and approved under the Novel Food Regulation before they can be placed on the Italian market.</p> <p>The food operator must follow the procedure established by Reg. 258/1997/EC on novel foods. The Ministry of Health circular on 'Official control on the use of insects as food, with specific reference to the applicability of Reg. 258/1997/EC on novel foods' clearly stated that '<i>insects, being animal origin products lacking of a long history of consumption, fall within the scope of the Regulation and therefore they cannot be placed in the Italian market unless they are authorized.</i></p>

	<p>Belgium</p>	<p><i>See above.</i></p> <p>The Belgian competent authorities tolerate on the national territory the commercialization of ten species of whole insects. Placing either of these ten species of whole insects (or products derived from these whole insects) on the Belgian market requires complying with general food law, including good hygiene practices, traceability, labelling, chemical and microbiological risk management and setting up an auto control system based on the principles of HACCP.</p>
	<p>UK</p>	<p>Under the current regime (Novel Food Regulation [(EC) 258/97]) whole insects would not require a risk assessment as part of their novel food authorisation, whereas parts thereof do. Please note the upcoming change to this as set out in section 1 above.</p> <p>However, regardless of whether whole insects are a novel food, since they come under the definition of 'food' in Section 1 of the Food Safety Act 1999, under Section 7 of the Food Safety Act 1999 it is prohibited to market foodstuff that is injurious to health (and under Article 14 of Regulation (EC) 178/2002). Also under Section 8 of the Food Safety Act 1999 the food must comply with food safety requirements.</p> <p>In addition, food businesses must apply for HACCP procedures and to sell any foods in the EU that are or that contain products of animal origin (POAO), requires certification of the product and the premises that produce the product being licensed by the EU.</p>
	<p>Netherlands</p>	<p>According to the advice of the BuRo:</p> <ul style="list-style-type: none"> • The insects should be heated before freezing and freeze drying; • The chemical, microbiological and parasitological risks can be controlled in an adequate way by using an adequate manufacturing method; • It cannot be excluded that hypersensitivity and (serious) allergic reactions occur after the consumption of insects or insects protein; • For personnel in insect farms, there is an occupational risk on developing hypersensitivity or allergic reactions as a result of exposure to (parts of) insects; • If the expected intake of chitine via whole insects exceeds 45 gram per day, the risk of chitine intake should be re-assessed. <p>Furthermore, the BuRo advises the Inspector General of the NVWA on several matters with respect to the establishment and inspection of food safety plans and hygiene codes, but no pre-market risk assessment is described.</p>

If a risk assessment is required, does the national regulation include any guidance on the information that must be included in the assessment?

	<p>Denmark</p>	<p>The risk assessment must cover the contents of potentially harmful parts of the foodstuffs, either through natural contents or through pollution.</p> <p>Furthermore, it will be a requirement that the correct name is provided, including the Latin name of the insects, the state of evolution of the insect (eggs, caterpillars, cocoons or fully developed insects), and also which parts of the insects (body, wings, legs, the whole insect or other parts) will be used. Any processing of the insects (e.g. grinding or extraction can also be relevant. If there are special requirements concerning the correct use, such as special preparation methods, these must appear on the packaging.</p>
	<p>Germany</p>	<p>The risk assessment is made as part of the novel food authorization process.</p> <p>Further, any risk analysis should comply with the requirements under Art. 6 of Regulation (EC) 178/2002.</p>
	<p>Italy</p>	<p><i>See above.</i></p> <p>The food operator must follow the procedure established by Reg. 258/1997/EC on novel foods.</p>
	<p>Belgium</p>	<p>The Belgian authorities have issued opinions (Opinion 14/2014 of the Federal Agency for the Safety of the Food Chain and Opinion 9160 of the Superior Health Council) that address inter alia the microbiological safety and toxicity aspects to be taken into account in respect of insects intended for human consumption as food. In addition to the specific recommendations included in these opinions, companies must also take into account the recommendations applicable to all applications for the placing on the market of novel foods and novel food ingredients (currently contained in Commission Recommendation 97/618/EC) and the EFSA opinion on the Risk profile related to production and consumption of insects as food and feed (published October 8, 2015).</p>

	<p>UK</p>	<p>In the UK, the assessment on novel foods is normally carried out by an independent committee of scientists appointed by the Food Standards Agency, the Advisory Committee on Novel Foods and Processes (ACNFP). Assessments include a detailed study of potential for toxic, nutritional and allergic effects. Further guidance is available on the FSA website.</p> <p>The Novel Foods Regulation includes a simplified procedure for marketing certain types of novel food or novel food ingredient in the EU if it is considered ‘substantially equivalent’ to an existing food or food ingredient that is already marketed within the EU. In these cases, the company can submit a notification to the European Commission after obtaining an opinion on equivalence from an EU Member State. The application dossier should show how the novel food or novel food ingredient may be substantially equivalent to an existing food or food ingredient as regards to its:</p> <ul style="list-style-type: none"> • composition (such as the source organism and preparation method) • nutritional value • metabolism • intended use (such as a food ingredient or supplement) • level of undesirable substances (such as contaminants, mycotoxins and allergens) <p>Full guidance on what is required can be found in the ACNFP's guidelines on demonstrating substantial equivalence; these can be found at the link here.</p>
	<p>Netherlands</p>	<p>N/A</p>

When importing, is there a requirement for a national import permit independent of the country of origin?

	<p>Denmark</p>	<p>Importing to Denmark from both EU countries and non-EU countries requires an import authorization. The presentation of the above mentioned risk assessment to the authorities is a condition of the import authorization.</p> <p>Since insects are animal products. These products are not harmonized inside the EU (meaning that there are no common import conditions). The individual EU Member State needs to set its own conditions for importation.</p> <p>In Denmark import is only allowed after authorization by the Danish Food Authority (Veterinarian control regulations §3 on intra-Community trade and §24 on import from non-EU countries). The non-harmonized products cannot be traded freely between EU Member States, but require authorization from the competent authorities in the recipient country. Animal products are also covered by the regulation on veterinarian control on the outer borders of the EU if they are imported from non-EU countries.</p> <p>Private importation of insects is excluded from the condition of veterinarian control, as long as the insects are imported in the persons own luggage during arrival, or in immediate connection to the arrival, or are received as packages and respect the following limitations on quantity:</p> <ol style="list-style-type: none"> 1. Import from other EU Member States, Norway, Lichtenstein, Andorra and Switzerland: no quantity limitations in the Danish Food Authorities rules 2. Import from Iceland, the Faroe islands and Greenland: not more than 10 kilos per person 3. Import from all other states (i.e. except EU Member States, Norway, Liechtenstein, Andorra, Switzerland, Iceland, the Faroe Islands and Greenland): private importation not allowed. <p>(Point 2 and 3: see Community regulation no. 206/2009)</p>
	<p>Germany</p>	<p>In general, an import permit is only required for imports originating from non-EU countries. For products coming from those countries, the specific import procedures according to Directive 97/78/EC, Directive 91/496/EC and Commission Decision 2007/275/EC need to be observed when importing insects (alive or dead), parts of insects and ingredients made from insects from third countries into the EU. Thus, import is subject to veterinary border inspection and needs to be made via a border inspection post.</p> <p>Products from EU Member States may generally be freely imported into Germany. This does, however, not apply to products that do not meet the German statutory requirements for those products. In the latter case, permission needs to be obtained from German Federal Agency for Consumer Protection and Food Safety (<i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit</i>).</p>

	<p>Italy</p>	<p>In Italy, the import of insects and their parts is not allowed.</p>
	<p>Belgium</p>	<p>Products originating from non-EU countries may not be placed on the Belgian market under the tolerance regime described above. Imported insects or insect-based products need to follow the authorization (or notification, as appropriate) route in order to be lawfully marketed in Belgium.</p>
	<p>UK</p>	<p>In general, an import permit is only required for imports originating from non-EU countries. For products coming from those countries, the specific import procedures according to Directive 97/78/EC, Directive 91/496/EC and Commission Decision 2007/275/EC need to be observed when importing insects (alive or dead), parts of insects and ingredients made from insects from third countries into the EU. Thus, import is subject to veterinary border inspection and needs to be made via a border inspection post.</p> <p>Food imported from other EU countries must meet general food safety requirements of Article 14 of EC general Food Law Regulation (EC) No 178/2002.</p> <p>Products from other EU member states may generally be freely imported into the UK.</p> <p>When importing live insects, if these are not native to the UK then will need to apply for a license from Animal and Plant Health Agency (APHA).</p> <p>Food brought into the UK must comply with Regulation (EC) No 852/2004 to ensure that the food satisfies the relevant hygiene requirements at all stages of production. In addition if you intend to set up a business to sell food the activity has to be registered under Regulation (EC) No 852/2004 and the environmental health office of the local authority where the business is to be set up must be contacted.</p>
	<p>Netherlands</p>	<p>We have not found such a stipulation.</p>

If there is a requirement for a national import permit independent of the country of origin, what must be included in the application, and what is the relevant authority?

	Denmark	<p>The authorization must be given by the Danish Food Authority.</p> <p>To acquire the authorization, the risk assessment must be presented. The risk assessment must meet the criteria set out above.</p> <p>If the importation is private, the above mentioned quantity limitation must be respected.</p>
	Germany	<p>The contents of the import declaration follow from Annex III to Regulation (EC) 136/2004 as well as from Annex 2a to the German Foodstuff Import Regulation (<i>Lebensmitteleinfuhr-Verordnung</i>).</p> <p>The import needs to be declared at customs, and the competent German Food Authorities of the respective state will then decide whether the applicant complies with the laws on foodstuff and animal health.</p>
	Italy	<i>See above.</i>
	Belgium	The matter is under the authority and supervision of the Federal Public Service competent for health, food chain safety and environment and of the Federal Agency for the Safety of the Food Chain.
	UK	<p>For importing live insect species that are non-native to the UK the relevant authority is APHA and the license application form is the RM01 form.</p> <p>A declaration must be sent to HMRC when goods are imported into the UK from outside the EU. This is usually done using the Single Administrative Document (SAD), also known as form C88.</p>
	Netherlands	N/A

Nicolas
Carbonnelle
Senior Associate, Belgium

Tel: +32 (0)2 282 6040
nicolas.carbonnelle@twobirds.com



Lars Karnoe
Senior Counsel, Denmark

Tel: +45 39141678
lars.karnoe@twobirds.com



Christian
Lindenthal
Associate, Germany

Tel: +49 (0)89 3581 6153
christian.lindenthal@twobirds.com



Francesca Lotta
Associate, Italy

Tel: +39 06 69 66 7000
francesca.lotta@twobirds.com



Christina Pennock
Associate, UK

Tel: +44 (0)20 7415 6772
christina.pennock@twobirds.com



Hanneke Later-
Nijland
Associate, Netherlands

Tel: +31 (0)70 353 8945
hanneke.later-
nijland@twobirds.com



Amy Cowper
Senior Associate, Australia

Tel: +61 2 9226 9837
amy.cowper@twobirds.com



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