

Novel foods regulation: Getting your product to the UK market

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Introduction

1. Foods that fall within the definition of “novel food” must have market authorisation before they can be legally marketed in the UK. This article examines what novel foods are and the authorisation process to allow novel food products to reach the UK market. This article touches upon, but does not address at length, the process in respect of ‘traditional foods from third countries’.
2. Cannabidiol based novel foods have particular requirements which are dealt with separately below.

Legislative overview

3. Regulation 2015/2283/EU on Novel Foods (“the Novel Food Regulation”) came into force in November 2015, updating the pre-existing EU provisions on novel food. The purpose of the updating Regulation was to “*ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers’ interests*”. In particular, concern had been raised regarding the number of novel food products in the EU market and the disparity of regulation on their supply and sale across the Community. In response, the EU Commission decided to assist by harmonising the law.
4. The Novel Foods (England) Regulations 2018/154 and Novel Foods (Wales) Regulations 2017/1103 make it a criminal offence to put a novel food product on the market without authorisation, as well as allowing civil sanctions also.

5. Accordingly, the current legal position is that if you have a food product that amounts to a novel food you must obtain authorisation from the EU Commission in order to lawfully sell your product in the UK.

What is a novel food?

6. Novel food is defined at Article 3(2)(a) of the Novel Food Regulation however, the definition is unwieldy and complex. Regard should be had to the Novel Food Regulation definition where appropriate however, for the purpose of this article, an accurate summary is as follows (taken from the definition within the Novel Food Regulation):

“any food that was not used for human consumption to a significant degree within the Union before 15 May 1997...and [is food]:

- *with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;*
 - *consisting of, isolated from or produced from microorganisms, fungi or algae;*
 - *consisting of, isolated from or produced from material of mineral origin;*
 - *[derived] from plants or their parts, except when the food has a history of safe food use within the Union...*
 - *[derived] from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;*
 - *Made using production process not used prior to 15 May 1997...*”
7. It can be seen that the actual definition of novel foods is not that which is widely publicised (that it is any food that wasn't in long term or safe use prior to 1997) and that there is far more to the definition, in particular, a plethora of categories that the relevant product must also be within in order to fall under the remit of the definition.

What kinds of products would fall under this definition

8. The Union list of authorised novel foods (Commission implementing Regulation)(2017/2470/EU) provides the list of authorised novel food products within the EU and, helpfully, provide an insight into the types of products that fall within the definition and the conditions for their use. For instance:
 - a. Magnolia Bark Extract is approved for use within mints and chewing gum. Products containing it must only contain 0.2% of the extract based on a maximum mint/gum size of 1.5g and a cap of the level of extract of 3g;
 - b. Phospholipides derived from egg yolk can be used without condition;
 - c. Plum Kernel Oil can be used for frying and seasoning food in line with normal food use of vegetable oils.

9. Additionally, the EU Novel Food Catalogue contains a list of products that are considered to be novel food products and which would require authorisation in the UK prior to being marketed. Such product include, but are not limited to food products containing:
 - a. Agaricus Bisporus (Selenium and vitamin B12 mushrooms);
 - b. Cannabidiol (CBD);
 - c. Xanthoparmelia Scabrosa (lichen).

10. A word of caution for manufacturers of goods that are potentially novel foods. The burden is on the food business operator to know if what they are selling amounts to a novel food and therefore, it is sensible to seek advice on this if you believe you may be at risk of falling foul of the Novel Food Regulation. Further information can be obtained by contacting the Food Standards Agency: novelfoods@food.gov.uk.

Obtaining market authorisation

11. The EU will only approve novel foods for market in the Union where:
 - a. the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;

- b. the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
 - c. where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
12. In order to apply for authorisation, one of two processes should be followed depending on whether the particular product is a novel food product outright or, alternatively, whether it is a 'traditional food from a third country'.

Novel Food

13. The first step to take in order to make an application for authorisation is to set up an account on the [EU Portal](#).
14. The application should include:
- a. the name and address of the applicant;
 - b. the name and description of the novel food;
 - c. the description of the production process(es);
 - d. the detailed composition of the novel food;
 - e. scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
 - f. where appropriate, the analysis method(s);
 - g. a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.
15. Where the food is liable to have an impact on human health, a risk assessment will have to be carried out by the European Food Safety Authority ("EFSA"). The timescales are significant with the Commission being obliged to provide a copy of the application to the

EFSA within one month of confirming the validity of the application. The EFSA then has a further nine months to come to its opinion on the health impact of the product. This time frame can be extended where further information is subsequently requested.

16. In reaching its determination, the EFSA will, as appropriate, consider whether:
 - a. the novel food concerned is as safe as food from a comparable food category already placed on the market within the Union;
 - b. the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;
 - c. a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
17. Once complete, the EFSA provides its opinion to the Commission, the Member State and the applicant.
18. Should the application be accepted the Commission then has seven months (either running from the date of the receipt of the valid application or, where required, running from the date of the publication of the EFSA's opinion) to submit a draft implementing act allowing the placement of the novel food on the market and the amendment to the novel foods list outlined above.
19. Thereafter, the product can be placed on the market in the UK.

Traditional food from a third country

20. Where food business operators deem their food product to be traditional food from a third country a slightly different process can be followed. It is, in the author's view, crucial to obtain advice where you believe your product may fall under this category as the distinction between such products and novel foods is not at all clear.
21. The benefits of such a product however, are:
 - a. the use of a potentially more straightforward process to secure authorisation;

- b. potentially quicker approval; and
- c. the ability to avoid an EFSA Opinion.

Cannabidiol (CBD) products

22. In January 2019, CBD extract and isolate were confirmed as being novel foods. This has posed a problem for those already selling CBD based food products as the change to the status of CBD applies regardless of the fact that there are pre-existing products on the market. That there are currently no authorised CBD novel foods on the market makes the matter worse.
23. Food business operators should make sure to apply for market authorisation of any CBD based food products that they wish to continue to sell. Where products are already being sold, the deadline to submit an application for validation is 31 March 2021 following which, any CBD based food products without authorisation will have to be removed from the market.
24. Pending approval, food business operators have been advised by the Food Standards Agency that:

“We have advised local authorities that businesses can continue to sell their existing CBD products during this time, provided they are not incorrectly labelled, are not unsafe and do not contain substances that fall under drugs legislation. However, no new CBD extracts or isolates should be sold until they have the necessary authorisation”.

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