Novel foods checklist

This Food Standards Agency (FSA) checklist provides advice about online lists that you can check, as well as how to ask for information to be sent to you, which may help you to find out the novel status of a particular food.

Definition

Novel foods are defined as foods or food ingredients that do not have a significant history of consumption within the EU prior to the 15 May 1997. All novel foods are subject to a pre-market safety assessment in accordance with the Novel Food Regulation (EC) 258/97.

FSA advice

The Food Standards Agency is the UK competent authority for novel foods. The Novel Food Unit is able to advise you whether your product will require assessment under (EC) 258/97. To enable us to do this, you will first need to provide us with some basic information.

What do I need to do?

For your food not be regarded as a novel food, we will need evidence that your food or food ingredient has a significant history of consumption in the EU prior to 15 May 1997.

Significant consumption should be demonstrated by evidence of sale in the EU and EU guidance on this aspect can be found at:


The following questions may also assist you with the provision of this information.

(1) *Is your product available elsewhere in the world (e.g. USA, Australia, Japan)?*

- If so, you should ask your supplier / importer whether the novel food status has ever been confirmed within the EU. If it has not then you should make them aware that the product may require a premarket safety evaluation before it can be placed on the market in the EU.

- If it has been marketed in other **EU** Member States then you should contact the Member State in question who should be able to offer a view on whether
the food is a novel food.

- If you have approached a Member State and they have concluded that the product is not a novel food then there is no need to contact us to advise us that you are intending to market the product in the UK.

(2) Does your product appear in the EC Novel foods catalogue, Nettox list, the Italian supplements list or the Belgian Royal Decree on Plants?

- It is not possible to provide an exhaustive list of novel foods, however the status of a significant number are detailed in the European Commission’s ‘Novel food catalogue’ at:
  http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm

- Information regarding the ‘Nettox list’ (a list of 334 major European plants which were on the market in the EU before the novel food regulation entered into force) can be found at:
  www.eurofir.net/publications/eurofir_nettox_plant_list

- **Italian food supplement** lists:
  
  Plants permissible for food supplement use  
  www.salute.gov.it/imgs/C_17_pagineAreel_1268_listaFile_itemName_2_file.pdf

  Plants not permissible  
  www.salute.gov.it/imgs/C_17_pagineAreel_1268_listaFile_itemName_3_file.pdf

- Information regarding the **Belgian Royal Decree on Plants**:
  
  Plants permissible for food supplement use  
  www.health.belgium.be/eporal/foodsafety/foodstuffs/novelfoods/?fodnlang=en

(3) Is your product a herbal botanical preparation?

- A significant number of herbal ingredients may be considered medicinal in the UK. Advice on herbal food ingredients, including information to determine whether it’s status as a medicine can be found on our website at:
  www.food.gov.uk/enforcement/sectorrules/herbal/

(4) Do you need advice on food supplement?
• If your product is currently only used in the EU as an ingredient in food supplements and you would like to use it in other foods (e.g. drinks, biscuits etc) then it will need a separate authorisation under the novel food regulation unless you are able to find significant evidence of consumption in the EU prior to 15 May 1997 for ‘non-supplement’ use.

• The Department of Health holds lists of contacts who wish to receive information on particular issues including food supplements. These lists are confidential and are only used to contact you about issues that may be of importance to you. If you have any questions on food supplements, please contact the Department of Health:

  Customer Service Centre
  Department of Health
  Richmond House
  79 Whitehall
  London SW1A 2NS
  tel: 020 7210 4850
  www.info.doh.gov.uk/contactus.nsf/memo?openform

(5) Is your product an extract, isolate or concentrate of an existing food?

• If so, you must provide evidence of significant consumption for a comparable product. You cannot rely on evidence of consumption of the source material.

Additional information

If you are contacting us from another EU Member State:

• Please indicate what advice you have received from our counterparts in your country.
• If you have not sought their advice please indicate why you are seeking the view of the UK.

Next steps

In order for us to deal with your enquiry as quickly as possible, would you please ensure that that you have taken into account all of the issues detailed above.

Novel Foods Unit, Food Standards Agency

October 2013 (version 1.7)