Údarás Sábháilteachta Bia na hÉireann
Food Safety Authority of Ireland

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Guidance for Preparing an Article 4 Request to Ireland Under the Novel Food Regulation (EU) 2015/2283

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Food Safety Authority of Ireland
The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300
E info@fsai.ie

www.fsai.ie

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Introduction

A novel food is defined in the European Union (EU) novel food Regulation (EU) 2015/2283 as any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls within at least 1 of 10 specified food categories.

Article 4.1 of the novel food Regulation stipulates that a food business operator (FBO) must verify the novel food status of food it intends to place on the EU market. Article 4.2 states that where the FBO is unsure of the novel food status of their food, they shall consult with the Member State where they first intend to place it on the EU market (Recipient Member State) in accordance with Commission Implementing Regulation (EU) 2018/456. Article 4.3 of the novel food Regulation clarifies that when reaching a conclusion about the novel food status of a particular food, the recipient Member State **may** choose to consult with other Member States and the EU Commission. An Article 4 request can be submitted to Ireland by the FBO, or an agent acting on their behalf.

Purpose

The Food Safety Authority of Ireland (FSAI) is the competent authority in Ireland for the implementation of the novel food Regulation. As the final decision on the novel food status of a food or ingredient subject to an Article 4 request rests with the recipient Member State, it is appropriate that the FSAI provides some guidance to FBOs that may consider submitting an Article 4 request to Ireland. While this guidance is intended to assist the FBO in preparing the Article 4 request, it is important to note that the FBO is solely responsible for preparing and presenting the information to support that consultation request. This guidance also identifies some information that could be of use to an FBO before considering Ireland as the recipient Member State for an Article 4 request. An Article 4 request can only be submitted to one Member State authority, **that being where it is to be first placed on the EU market** (Article 4.2 of Regulation (EU) 2015/2283). Where the food of interest is to be placed on the EU market in more than one Member State initially, the Article 4 request must only be submitted to one Member State authority (Article 3.2 of Regulation (EU) 2018/456).

IMPORTANT

By submitting an Article 4 request to the FSAI, the FBO acknowledges that they are familiar with this guidance and accepts the standards and principles set out herein.

The novel food Regulation (EU) 2015/2283 does not apply in the following situations:

- Products that do not meet the definition of "food" under the general food law Regulation (EC) No 178/2002
- Food that does not fit within any of the 10 categories listed in Article 3.2. of the novel food Regulation (EU) 2015/2283
- Food established as not novel through a previous Article 4 consultation
- Food established as not novel on the basis of information available in the updated Novel Food Status Catalogue on the EU Commission website
- Reformulations and recipe changes involving established non-novel foods
- Genetically modified food and feed falling within the scope of Regulations (EC) No 1829/2003
- Food enzymes falling within the scope of Regulation (EC) No 1332/2008
- Food additives falling within the scope of Regulation (EC) No 1333/2008
- Food flavourings falling with the scope of Regulation (EC) No 1334/2008
- Extraction solvents falling within the scope of Directive 2009/32/EC
- Products within the scope of Directive 2001/83/EC and Regulation (EU) 2017/745 that are regulated by the Health Products Regulatory Authority in Ireland
- Cosmetics within the scope of Regulation (EC) 1223/2009 that are regulated by the Health Products Regulatory Authority in Ireland
- Tobacco and related products falling within the scope of Directive 2014/40/EU
- Narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic drugs 1961, the United Nations Convention on Psychotropic Substances 1971, the Irish Misuse of Drugs Act 1977 and the Irish Criminal Justice (Psychoactive Substances) Act 2010
- Animal feed products falling within the scope of Article 3.4 of Regulation (EC) 178/2002.

Before an Article 4 request is submitted to Ireland, the FBO should be satisfied that the food of interest does not fall within the scope of other specific EU food legislation, for example food additives covered by Regulation (EC) No 1333/2008. Where the FSAI has any doubt about the specific legislation a particular food product could fall under, the relevant section of the EU Commission and other EU Member States will be consulted before Ireland can validate an Article 4 request for that food product.

Before an Article 4 request is submitted to Ireland, the FBO should check the publicly available information regarding novel foods on the Commission website (Novel Food - European

Commission) where the novel food status of the product of interest could already be evident in one or more of the following lists:

1. Novel food status catalogue: https://food.ec.europa.eu/food-safety/novel-food/novel-food-status-catalogue_en
2. Union List of authorised novel foods: https://food.ec.europa.eu/food-safety/novel-food/authorisations/union-list-novel-foods_en
3. List of Article 4 consultations: https://food.ec.europa.eu/food-safety/novel-food/consultation-process-novel-food-status_en
4. Novel food application terminations: https://food.ec.europa.eu/food-safety/novel-food/decisions-terminating-procedure_en

If the FBO is still unsure about the novel food status of the food of interest, they could consider an Article 4 request, taking into account the following principles applicable to Article 4 submissions to Ireland.

Acceptance and handling of Article 4 requests by Ireland (FSAI)

Before considering Ireland as a recipient Member State, the FBO should take into account the following points:

- The FBO must be familiar with Commission Implementing Regulation (EU) 2018/456, which sets out the procedural steps of the consultation process
- The FSAI will assist the FBO in order to achieve validation in accordance with Article 5 of Commission Implementing Regulation (EU) 2018/456
- Confidentiality requests relating to the information provided must be justified and in accordance with the criteria set out in Article 9 of Commission Implementing Regulation (EU) 2018/456
- Once an Article 4 request is validated, the FSAI will reach a conclusion based on the information prepared and presented by the FBO, and will only request further information or data in accordance with Article 6.2 of Commission Implementing Regulation (EU) 2018/456 where it is deemed necessary by the FSAI to enable it to reach a conclusion
- The FSAI will discuss the draft conclusion with the FBO before finalising the process
- Article 4 requests can only be withdrawn by the FBO before the validation process is completed. Once validated, the Article 4 process must be finalised with a conclusion
- Conclusions regarding the novel food status of the food of interest will ultimately be published on the Commission website and contain the information specified in Article 7 of Commission Implementing Regulation (EU) 2018/456

- A more detailed report and discussion on the final conclusion and how it was reached can be facilitated by the FSAI.

Evidence of a history of human consumption within the EU to a significant degree prior to 15 May 1997

This guidance is not intended as an exhaustive list of acceptable or unacceptable information that can be used as evidence of a history of human consumption to a significant degree before 15 May 1997 (HOC) in the EU. However, the following information will assist FBOs in providing appropriate information:

- Verifiable documented evidence of a HOC (e.g. sales receipts, official records, etc.) within the EU is the primary evidence accepted by the FSAI, with any other evidence possibly considered as supporting evidence on a case-by-case basis
- Evidence of a HOC in another EU Member State(s) prior to 1997 must be assessed and verified by the authorities in that EU Member State(s) before it can be accepted as evidence of a HOC in the EU by the FSAI
- Evidence of a HOC in the United Kingdom (UK) prior to 1997 must be assessed and verified by the relevant authorities in the UK before it can be considered, on a case-by-case basis, by the FSAI as possible evidence of a HOC in the EU
- Evidence of a HOC in the EU as or in food supplements only is not accepted as evidence of a HOC in the EU as or in general foodstuffs (Article 3.2(a)(x) of the Novel Food Regulation (EU) 2015/2283)
- Evidence of the sale and/or consumption of a product in the EU as or in products regulated by the Health Products Regulatory Authority in Ireland (including traditional herbal medicine) is not accepted by the FSAI as evidence of a HOC in the EU as or in general foodstuffs or food supplements
- Evidence of the sale and/or use of a product in the EU as or in cosmetics falling within the scope of Regulation (EC) 1223/2009 and regulated by the Health Products Regulatory Authority in Ireland is not accepted by the FSAI as evidence of a HOC in the EU as or in general foodstuffs or food supplements
- Anecdotal evidence of a HOC in the EU, for example, affidavits, testimonials, written survey responses or verbal communications is not accepted by the FSAI as primary evidence of a HOC, but might be accepted as supporting evidence

- Evidence of a HOC within the EU must demonstrate continuous consumption to a significant degree (to be decided by the FSAI in relation to consumption within Ireland) up to, including, and after 1997. References to truncated historical consumption (e.g. biblical references, historical texts or old recipes, etc.) in the EU before 1997 might be accepted as supporting but not primary evidence of a HOC
- An established HOC within the EU for a food might not apply to an "extract" of that food, particularly where it is obtained by a non-aqueous extraction process
- An established HOC within the EU for an extract, such as a plant or fruit extract, might not apply to the original plant or fruit
- An established HOC within the EU for defined parts of a plant or animal might not apply to other parts of that plant or animal
- An established HOC within the EU for a seed might not apply to the germinated or sprouted seed which can differ in terms of composition, nutritional value and the level of undesirable substances
- The novel food status of food products resulting from fermentations will be considered on a case-by-case basis.

Demonstrating the similarity of a food of interest to an existing non-novel food

A new food or source of food, or a food produced using a new process can fall within the scope of the novel food Regulation and an Article 4 request might be necessary to determine the novel food status. In this context, the following points are worth considering:

- Authorised novel foods are still considered novel foods and can only be placed on the EU market if they comply with the specifications and conditions of use set out in the Union List of novel foods. Any deviation from those specifications and conditions of use would require a new novel food authorisation
- An established non-novel food produced using a new production or processing technique not used in the EU before 15 May 1997, can fall within the scope of the novel food Regulation if the composition, nutritional value or level of undesirable substances in the food has been significantly altered as decided by the FSAI
- A novel food status determination based on the similarity of a food of interest to an established non-novel food will be made using the comparative information provided relating to composition, nutritional value and level of undesirable substances

- A novel food status determination based on the similarity of a food of interest to an established non-novel food might not concur with a similar assessment carried out by the UK authorities. Therefore, the UK determination in such situations might not apply within the EU
- Highly purified products (e.g. >98%) that are not significantly different when produced from different sources might not be considered novel foods, but that will be decided on a case-by-case basis and depend primarily on the content of the minor fraction(s)
- Non-selective extracts (primarily aqueous extracts) of an established non-novel food are generally regarded by Ireland as not novel, but a case-by-case determination may be required
- A selective extraction of any type (aqueous or non-aqueous) is generally regarded as producing a novel food, but would be subject to a case-by-case determination
- Different forms (e.g. isomers, enantiomers, etc.) of a pure chemical substance can have different physical or chemical properties. Therefore, a substance with an established HOC within the EU can differ significantly from the same substance in a different chemical or physical form, meaning that a case-by-case determination could be required
- Organic material (e.g. plant leaves, seeds etc) generally does not become a novel food by simple physical manipulation such as crushing, drying, rehydrating, freeze-drying, etc. However, a case-by-case determination could be required where the composition, nutritional value or level of undesirable substances of the final food is altered significantly.

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