Novel foods

When placing a product on the UK or EU market, companies must do their best to ensure that the product is compliant with all relevant compositional and labelling laws.

For vitamins and minerals, it is possible to access positive lists[1,2] where the permitted vitamins and minerals and their sources can be found (also available in CRN UK's Seven Easy Steps publication). However, when it comes to substances other than vitamins and minerals, how does a company ensure that it would not be considered to be a novel food?

The UK and EU novel food laws[3,4] have 10 categories of what constitutes a novel food, as follows:

> *'novel food' means 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 under at least one of the following categories:*
>
> *(i) 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;*
>
> *(ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;*
>
> *(iii) food consisting of, isolated from or produced from material of mineral origin;*
>
> *(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:*
>
> - *traditional propagating practices which have been used for food production within the Union before 15 May 1997; or*
> - *non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;*
>
> *(v) food consisting of, isolated from or produced 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;*
>
> *(vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;*
>
> *(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;*
>
> *(viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;*
>
> *(ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:*

- *a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or*
- *they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;*

(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

It can be difficult for a company to determine whether the substance they want to use is not a novel food or whether it will fall under one of the ten listed categories.

There are some resources that are publicly available that can help a company start the process of checking whether the substance they want to use is novel or not, and these are as follows:

EU Novel food catalogue

EU Consultation process on novel food status list of decisions

In addition, the Finnish Food Authority has a list on its website of other useful resources.

These lists above are not exhaustive and queries can sometimes still remain over a substance's novel food status. There is an official route that can be followed, referred to as the Article 4 consultation process, by which companies can gain a categorical determination by the UK or EU authorities as to a substance's status in the UK or EU territories. However, many companies do not want to take that official route at an early stage in their investigations.

CRN UK has access to additional lists of other substances, including a list of established ingredients that was produced by CRN UK in 2001 and accepted, following a number of checks, by the UK Food Standards Agency (FSA) at the time. This list is still used by the FSA today in their investigation of the novel food status of substances.

CRN UK's members can obtain initial information on the status of a substance they might be considering using, which can help them determine whether:

- they are confident to proceed with using the ingredient;
- they should initiate a formal UK and/or EU consultation into its status;
- they should not use the ingredient; or
- they should consider a novel food authorisation process.

See here to find out more about membership of CRN UK.

References

1 GB: Schedules 1 and 2 of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019
2 EU/NI: Annexes I and II Directive 2002/46/EC on food supplements as amended

3 GB: Retained Regulation (EU) 2015/2283 on novel foods, as at 31 December 2020
4 EU/NI: Regulation (EU) 2015/2283 on novel foods as amended

Footnote:

Great Britain (GB: England, Wales and Scotland) currently follows retained European Union (EU) law as it stood at 23:00 GMT on 31st December 2020; GB legislation refers to this retained EU law, but future amendments will be made via GB law.

In most aspects relating to foods, Northern Ireland (NI) will continue to follow current and future EU laws, unless the political situation changes in relation to the NI Protocol.