SCHEDULE Regulation 76

Wording for inclusion in Commission Implementing Regulation (EU) 2018/456 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

Commencement Information

I1 Sch. in force at 31.12.2020 on IP completion day (in accordance with 2020 c.1, **Sch. 5 para. 1(1)**), see reg. 1

"Annex 2

Template technical dossier

1. The connection between the different pieces of information must be explained in an explanatory note. In particular, as regards the evidence presented to support a human consumption to a significant degree within the United Kingdom or the EU before 15 May 1997, where documents from a range of sources must be considered to be able to reach a conclusion.

2. Where only parts of the documents are relevant for the determination of the novel food status, those parts must be highlighted.

3. For all foods, Section 1 must be completed.

4. For extracts, in addition to Section 1, Section 2 must be completed.

5. For foods resulting from a production process not used for food production within the United Kingdom or the EU before 15 May 1997, Section 1 (points 1 to 3, and point 7) and Section 3 must be completed.

Section 1: All foods (for foods resulting from a production process not used for food production within the United Kingdom or the EU before 15 May 1997 only points 1 to 3 and point 7)

1. Description of the food
1.1 Name of the food.
1.2 Detailed description of the food, including information whether the food consists of engineered nanomaterials as referred to in points (a)(viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283.
1.3 Proposed category of the novel food in accordance with Article 3(2)(a) of Regulation (EU) 2015/2283, where applicable.
2. Further characterisation of the food and/or source of the food (where relevant)
A. Organisms (microorganisms, fungi, algae, plants, animals).

2.1 Taxonomic name (full Latin name with author name).

2.2 Synonyms, other names, where applicable.

2.3 Specification of which part of the organism the use for human consumption before 15 May 1997 within the United Kingdom or the EU refers to, where applicable.

2.4 Specification about purity/concentration.

B. Chemical substances.

2.5 CAS number(s) (if this has been attributed).

2.6 Chemical name(s) according to IUPAC nomenclature rules.

2.7 Synonyms, trade name, common name, where applicable.

2.8 Molecular and structural formulae.

2.9 Specification about purity/concentration.

3. Conditions of use

3.1 How is the food intended to be used?

3.2 Type of product(s) in which the food is intended to be used.

3.3 Level/concentration (or range of levels) in the product(s) in which the food is intended to be used.

4. Production process

4.1 Detailed description of the production process. Include a flow process chart to describe the production process.

5. History of human consumption of the food within the United Kingdom or the EU before 15 May 1997

5.1 To what extent was the food consumed to a significant degree throughout the United Kingdom or the EU before 15 May 1997? Details must be provided.

5.2 To what extent was the food consumed to a significant degree in one Member State before 15 May 1997? Details must be provided.

5.3 Was the food consumed only regionally/ on a small local scale in the United Kingdom

or the EU before 15 May 1997? Details must be provided.

5.4 Was the food available before 15 May 1997 in the United Kingdom or the EU as an ingredient designed for specific target population (e.g. food for a special medical purpose)? Details must be provided.

6. Consultations on availability in the United Kingdom or the EU: where food business operators are unsure whether the information in their possession is sufficient to prove that the food concerned has been used for human consumption to a significant degree within the United Kingdom or the EU before 15 May 1997, they may consult other food business operators or food business operator federations in order to gather sufficient information

6.1 Have other food business operators or food business operator federations been consulted? Details should be provided.

6.2 Is the food currently available on the market within the United Kingdom or the EU? Details should be provided.

7. Additional information

7.1Is there any information that the product concerned is used within the United Kingdom or the EU as medicinal product in accordance with Directive 2001/83/EC?

7.2 Is there any other information which would assist in determining the novel food status? Any information which is relevant even if not specifically requested must be submitted.

Section 2: Extracts

8. Extracts

8.1 Any further details of the source material for the extract, if not provided in Section 1. Details must be provided.

8.2 Specification of the extract. Details must be provided.

8.3 If extracted from a food source, will the intake of any extract components in the food be higher than the intake of these components in the food source? Details must be provided.

Section 3: Foods resulting from a production process not used for food production within the United Kingdom or the EU before 15 May 1997

9. Production process	
9.1 Detailed description of the production process. Include a flow process chart to describe the production process.	
9.2 Is the structure or composition of the food affecting its nutritional value, metabolism or level of undesirable substances because of the process by which the food has been prepared? Details must be provided.	
9.3 Is the food produced from a source that in itself is not normally consumed as part of the diet? Details must be provided.”	

Changes to legislation:
There are currently no known outstanding effects for the The Novel Food (Amendment) (EU Exit) Regulations 2019, SCHEDULE.