ANNEX I

TEMPLATE COVER LETTER ACCOMPANYING A CONSULTATION REQUEST FOR DETERMINATION OF THE NOVEL FOOD STATUS

Competent authority of the Member State

Date: …

Subject: Consultation request for determination of the novel food status of …

…

The Food business operator(s)/consulting party:

Company: …

Address: …

Telephone: …

Email: …

Contact person: …

submit(s) the present consultation request in order to determine the novel food status of …

Yours sincerely,

Signature …

Enclosures:

Technical dossier

Documents in support of the consultation request

Explanatory note

ANNEX II

TEMPLATE TECHNICAL DOSSIER

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

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

For all foods, Section 1 must be completed.

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

For foods resulting from a production process not used for food production within the Union 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 UNION 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])	
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 Union 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 Union before 15 May 1997**	
5.1	To what extent was the food consumed to a significant degree throughout the Union before 15 May 1997? Details shall be provided.	
5.2	To what extent was the food consumed to a significant degree in one Member State before 15 May 1997? Details shall be provided.	
5.3	Was the food consumed only regionally/on a small local scale in the Union before 15 May 1997? Details shall be provided.	
5.4	Was the food available before 15 May 1997 in the Union as an ingredient designed for specific target population (e.g. food for a special medical purpose)? Details shall be provided.	

6. Consultations on availability in the Union

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 Union 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 Union? Details should be provided.	

7. Additional information

7.1	Is there any information that the product concerned is used within the Union as medicinal product in accordance with Directive 2001/83/EC ([2])?	
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 shall 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 shall be provided.	
8.2	Specification of the extract. Details shall 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 shall be provided.	

SECTION 3: FOODS RESULTING FROM A PRODUCTION PROCESS NOT USED FOR FOOD PRODUCTION WITHIN THE UNION 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 shall be provided.	
9.3	Is the food produced from a source that in itself is not normally consumed as part of the diet? Details shall be provided.	

([1]) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/456. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.