EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10802/2017 ANNEX Rev. 1
CIS (POOL/E2/2017/10802/10802R1-EN ANNEX CIS.doc)
[…](2017) XXX draft

ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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

ANNEX

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_____
_____

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 the
_____

Yours sincerely,

Signature _____

Enclosures:

- □ Technical dossier
- □ Documents in support of the consultation request with the full information in electronic format
- □ Explanatory note

ANNEX II

TECHNICAL DOSSIER

Where applicable, the technical dossier shall contain a proposal on the category under which the novel food falls as defined in Article 3(2) of Regulation (EU) 2015/2283.

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 assessment, those parts shall be highlighted.

For foods, other than extracts and other than foods resulting from a production process not used for food production within the Union before 15 May 1997, Section 1 must be completed.

For extracts Section 1 and 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 other than extracts and foods resulting from a production process not used for food production within the Union before 15 May 1997

1.	**Description of the food**	
1.1	Name of the food	
1.2	Detailed description of the food	
1.3	Proposed category of the novel food in accordance with Article 3 (2) (a) of Regulation (EU) 2015/2283	

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	
B.	Chemical substances	
2.4	CAS number(s) (if this has been attributed)	

2.5	Chemical name(s) according to IUPAC nomenclature rules	
2.6	Synonyms, trade name, common name, where applicable	
2.7	Molecular and structural formulae	
2.8	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. Details shall be provided.	
5.2	To what extent was the food consumed to a significant degree in one Member State. Details shall be provided.	
5.3	Food consumed only regionally/on a small local scale in the Union.	
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)?	

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 shall 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 shall be provided.	
6.2	Is the food currently available on the market within the Union? Details shall 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[1]?	
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.	
8.2	Specification of the extract	
8.3	If extracted from a food source, will the intake of any extract components in the new food be higher than the intake of these components from the original food source?	

[1] 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).

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.	