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<u>ANNEX</u>

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Template cover letter accompanying an application for novel food

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date: ...

Subject: Application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283

(Please indicate clearly by ticking one of the boxes)

 \Box Application for an authorisation of a new novel food.

□Application for adding, removing or changing the conditions of use of an already authorised novel food. Please provide a reference to that authorisation.

□Application for adding, removing or changing the specifications of an already authorised novel food. Please provide a reference to that authorisation.

□Application for adding, removing or changing additional specific labelling requirements of an already authorised novel food. Please provide a reference to that authorisation.

□Application for adding, removing or changing post market monitoring requirements of an already authorised novel food. Please provide a reference to that authorisation.

The Applicant(s) or their Representative(s) in the Union

(name(s), address(es)...)

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submit(s) this application in order to update the Union list on novel foods.

Identity of the novel food (Please provide information on the identity of the novel food depending on the category(ies) under which the novel food falls):

•••

•••

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283:

Data Protection(*). Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283:

□ Yes

* Applicant should specify the part(s) of the application which include(s) proprietary data for which protection is requested, clearly stating section(s) and page number(s). Applicant should provide verifiable justification /declaration for the proprietary claim.

Food categories, conditions of use and labelling requirements

Yes

No

No

Food category	Specific conditions of use	Additional specific labelling requirement

Yours sincerely,

Signature ...

Enclosures:

- \Box Complete dossier
- □ Summary of the dossier (non-confidential)
- □ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree
- □ Information supporting the protection of proprietary data relating to the novel food application
- □ Copy of administrative data of applicant(s)
- □ List of studies and notification reference numbers'