

Urolithin A Discussion Paper

Committee Paper for Discussion - ACNFP/173/02

Advisory Committee For Novel Foods and Processes

Application for authorisation as a novel food for Urolithin A

Application Number - RP1777

Issue

An application has been received under the novel food authorisation process (assimilated Regulation 2015/2283) for urolithin A. The Committee is asked to advise on whether the available data provides an adequate basis for a risk assessment, and whether the novel food is safe and not nutritionally disadvantageous under the proposed use and use levels.

A draft Committee Advice Document (CAD) has been prepared to support the review of this novel food application. Members are asked to consider the CAD and provide comments.

Background

1. On the 25th October 2022, the FSA received the submission for urolithin A, from Amazentis SA, Switzerland.
2. The novel food is made via chemical synthesis followed by purification, filtration and drying steps to yield the novel food. The applicant intends to use the novel food in conventional foods, cereal bars, protein bars, nutrition bars targeting athletes, yoghurt products, specialised foods for adults only (meal replacements for sports people and weight loss [general weight loss and total diet replacements], nutrition drinks and powders, food supplements, and foods for special medical purposes [FSMPs]).
3. The draft CAD is attached as Annex A. The application dossier and the annexes to the dossier are attached as Annexes B and C, respectively. These

contain confidential information. The FSA's request for further information (RFI) and the applicant's response to the RFI are included as Annexes D and E, respectively. Annex E also contains confidential information.

Committee Action Required

- The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of the extension of uses for the novel food.
- If so, the Committee is asked whether it is content to recommend approval of the novel food as an ingredient to be added to the range of foods specified.
- If not, the Committee is asked to indicate what additional data would be required.

ACNFP Secretariat

September 2025

Annexes

ACNFP-173-02-Annex A – Draft Committee Advice Document

ACNFP-173-02-Annex B – Dossier and References [Confidential]

ACNFP-173-02-Annex C – Annexes [Confidential]

ACNFP-173-02-Annex D – Request for Information

ACNFP-173-02-Annex E – Response to RFI [Confidential]