

Introduction to supplementary guidance to applicants for assessment of Cell Cultivated Products (CCP) in food: Allergenicity & Nutrition

Purpose and summary information relating to the supplementary guidance to applicants for assessment of Cell Cultivated Products (CCP) in food

Revision number	Date	Purpose of revision	Revised by
1.0	04 December 2025	First version published	FSA/FSS

Purpose

This document outlines the scientific requirements for evaluating the allergenicity and nutritional aspects of Cell Cultivated Products (CCPs) when seeking market authorisation as novel foods in Great Britain. This is supplemental guidance to the 2016 EFSA technical guidance which supports applicants through assimilated Regulation (EU) 2017/2469 -which details administrative and scientific requirements for novel food applications under Article 10 of assimilated Regulation (EU) 2015/2283 for novel foods.

This guidance aims to help applicants understand how the allergenicity and nutritional sections of Article 10 of assimilated Regulation (EU) 2015/2283 and the 2016 EFSA technical guidance apply to CCP safety assessments, specifically regarding the risks of nutritional disadvantage and allergenicity and how to evidence this within a CCP novel food application.

Summary

Through the CCP sandbox programme (Feb 2025- Feb 2027), the FSA and FSS will fast-track our knowledge about CCPs and use this to produce guidance on a range of topics relevant to these products. The guidance aims to better guide companies on how to make products in a safe way and how they can demonstrate this to us. The FSA and FSS are using the learnings from the CCP sandbox programme alongside expert elicitation and literature review to publish these guidance documents to provide clarity to businesses on the path to market.

This supplementary guidance provides detailed scientific considerations for assessing the nutrition and allergenicity of CCPs, supporting the general requirements of assimilated Regulation (EU) 2015/2283. It describes the safety assessment process applicants should follow when preparing a CCP dossier for regulatory review.

By following this guidance, applicants can address common issues, ensure their submissions are comprehensive, and facilitate efficient regulatory evaluation. The goal is to support the development and authorisation of CCPs that are safe, accounting for risks associated with

