Food contact materials authorisation guidance

Food contact materials authorisation requirements and what you need to submit as part of your application.
This page is part of the Regulated products application guidance

Food Contact Materials (FCMs) are materials and articles that come into contact with food during its production, processing, storage, preparation or serving. Examples of FCMs include:

- containers for the transportation of food
- packaging materials
- kitchenware
- tableware

There are four categories of food contact materials which are subject to specific regulations:

- plastic monomers and additives
- active/intelligent materials ('AIMs')
- recycled plastic processes
- regenerated cellulose film (RCF)

Northern Ireland

The EU law that applies to Northern Ireland after the transition period is specified in Annex II to the Northern Ireland Protocol. This means that if you're seeking a new authorisation for an FCM to be placed on the Northern Ireland market you will have to continue to follow EU rules.

Placing FCMs on the market in Great Britain

Regulated food contact materials need to be authorised before they can be used and placed on the market in Great Britain (GB). Assimilated law outlines the authorisation requirements for these substances:

- for plastic monomers and additives in Regulation 10/2011
- for active/intelligent materials in Regulation 450/2009
- for recycled plastic processes in Regulation 282/2008
- for regenerated cellulose film in Directive 2007/42/EC

For most regulated product types, once products or processes are authorised, they are listed in relevant legislation, which also sets out how they can be used. These lists are referred to as positive lists.

AIMs and recycled plastic processes

The positive lists for AIMs and recycled plastic processes have not yet been established in legislation. Until the positive lists are in place these products may be placed on the market or continue to operate in GB if they meet the requirements of:

- the General Food Law Regulations
- any general criteria in the food contact materials' legislation - for instance, that they should not be harmful to human health, detrimentally affect the composition of food (such as alter its acidity), nor adversely affect its taste, aroma, colour or texture

There may be additional considerations. For example, if AIMs contain a biocidal substance, it may need to be assessed by the Health & Safety Executive (HSE) to determine whether it is suitable for food contact material use in the first instance.

Applications will need to be submitted for evaluation and consideration for inclusion on the positive list. There is no requirement to do this immediately for AIMs and recycled plastic processes. We are currently working on a timetable and on further guidance on establishing positive lists for these regulated products. We will in due course set out a deadline for making applications to be considered for inclusion on the first positive list.

Additives in plastic and RCF

New additives in plastic and RCF cannot be placed on the market until the authorisation process is complete.

New authorisations

To apply for an authorisation of a food contact material use our regulated products application service. This is where you will be asked to upload all the documents to support your application, which will form your dossier. There is no fee for the application.

You will also need to send a sample and accompanying information to the National Reference Laboratory (NRL) as part of the application process for the following FCMs:

- additives and starting monomers in plastic food contact materials
- additives in active and intelligent food contact materials (AIMs)
- additives in regenerated cellulose film (RCF)

Your submission to the NRL should include:

- a physical sample of the substance (250g)
- the relevant product safety sheet (in English) and spectroscopic data (if applicable)
- the analytical method(s) including performance parameters as set out in 5.1.8, 5.3,7 and 6.5 of Note for Guidance for Food Contact Materials
- appropriate contact details of responsible person/s for making the regulated product application

This information will be stored securely by the NRL.

The requested information and sample should be sent to Fera, at the following address:

Fera Science Ltd (Fera)
Food Contact Materials team
York Biotech Campus
Sand Hutton
York YO41 1LZ
United Kingdom

This should be done at the same time as the full application is made to our regulated products application service.

To avoid any potential delays in UK customs, particularly concerning the submission of physical samples from overseas, please can you pre notify Fera Science at sales@fera.co.uk or via the FERA website. Please ensure that you refer to the latest guidance on labelling and shipping of parcels to the UK.

Detailed guidance

Detailed guidance has previously been developed by the European Food Safety Authority (EFSA) and remains relevant as our current approach is based on EU processes.

When developing your dossier you should follow the relevant EFSA guideline documents (below).

You should follow the parts that relate to the development of dossiers only and not the application process.

Please also include any supplementary documentation to support your application. For example, this may include additional information/points of clarification previously requested by EFSA.

Plastic monomers and additives

- EFSA administrative guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials

Active/intelligent materials

- EFSA guidance on the submission of a dossier for safety evaluation of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food

Recycled plastic processes

- EFSA guidelines on submission of a dossier for safety evaluation of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food

RCF

Specific guidance for additives in RCF is not available, but you can use the guidance for plastic monomers and additives as a helpful guide.

Ongoing applications

If you submitted a food contact material application to the EU before 1 January 2021 and the assessment process for this application was not completed, for example an EFSA opinion was published but it was not on an authorised (positive) list, you will need to submit your application to us, using our regulated product application service. When completing the application form, you will be asked to provide your EFSA question number.

Existing authorisations

If your plastic or regenerated cellulose film additive was authorised by the European Commission before 1 January 2021 and the necessary legislation is in place, that authorisation will remain valid in Great Britain and you don’t need to apply for a new authorisation.

How long will my application take?

The law includes deadlines for key steps in the process. In most cases, applications will take up to 15 months, which includes the risk assessment and the final risk management decision. It is possible that requests for additional information from the applicant will be carried out during the risk assessment phase, and this could lead to an extension of the overall timeframe.

The quality of the dossier information provided will determine the time needed for assessment and authorisation. We therefore encourage applicants to carefully follow the guidance and provide as much relevant information as possible to ensure we can process your request as efficiently as possible.

Getting help

If you have any questions about the authorisation procedure or application requirements, you can contact us at regulatedproducts@food.gov.uk

Apply for authorisation

Apply for an FCM authorisation using our regulated products application service.