

Food contact materials authorisation guidance

Food contact materials authorisation requirements and what you need to submit as part of your application.

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)

FCM authorisations

Regulated food contact materials need to be authorised before they can be used and placed on the market in Great Britain (GB). All FCMs must comply with the requirements of assimilated [Regulation 1935/2004](#), which sets out the general framework. 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 [The Materials and Articles in Contact with Food \(England\) Regulations 2012](#), [The Materials and Articles in Contact with Food \(Scotland\) Regulations 2012](#) and [The Materials and Articles in Contact with Food \(Wales\) Regulations 2012](#)

The FSA is required to maintain lists of authorised FCMs as determined by the appropriate authority (ministers) in England, Scotland and Wales.

Active and intelligent materials (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, responsible parties will need to ensure that they adhere to the relevant legislative requirements set out below.

AIMs

In the absence of authorisations in GB, these products may be placed on the market in GB if they meet the following:

- the applicable requirements under assimilated [Regulation 450/2009](#); and
- the applicable requirements under assimilated [Regulation 1935/2004](#). 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. These products must also be manufactured in compliance with Good Manufacturing Practices as described in assimilated [Regulation 2023/2006](#).

Local authorities are responsible for enforcing FCM legislation. They have the power to carry out documentary checks and serve enforcement notices in the case of suspected non-compliance with FCM legislation.

There may be additional considerations before making a regulated product application or placing on the market. For example, if AIMs contain a [biocidal substance](#), the active substance may need to be assessed and authorised by the Health & Safety Executive (HSE) to determine whether it is suitable for food contact material use in the first instance. The specific product type (PT) under the Biocidal Products Regulation will be dependent on the type of biocidal substance and proposed conditions of use. For example, PT4 biocides can be used for direct contact with food: disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed for humans and animals, and to impregnate materials which may enter into contact with food.

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. We are currently working on a timetable and on further guidance on establishing positive lists for these regulated products.

Recycled plastic processes

In the absence of authorisations in GB, recycled plastic processes may continue to operate, and recycled plastic produced from them may be placed on the GB market, if they meet the following:

- the applicable requirements under assimilated [Regulation 282/2008](#) (for recycling processes) and assimilated [Regulation 10/2011](#) (for general requirements on plastic food contact materials); and
- the applicable requirements under assimilated [Regulation 1935/2004](#). 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. These products must also be manufactured in compliance with Good Manufacturing Practices as described in assimilated [Regulation 2023/2006](#).

Local authorities are responsible for enforcing food contact material legislation. They have the power to carry out documentary checks and serve enforcement notices in the case of suspected non-compliance with food contact material legislation.

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 recycled plastic processes. We are currently working on a timetable and on further guidance on establishing positive lists for these regulated products.

EU applications/notifications under Commission Regulation 2022/1616

There is a separate application process to ensure compliance with the EU requirements under Commission Regulation 2022/1616 and must not be confused with the regulated product market authorisation process or compliance with assimilated Regulation 282/2008 in GB. Commission Regulation 2022/1616 is not applicable in GB but is applicable in Northern Ireland under the Windsor Framework arrangements.

The European Commission has established its [Plastic Recycling](#) webpage which provides advice and instructions to plastic recycling operators, whether it is a novel or a suitable technology. The European Commission is also responsible for maintaining its registers.

The FSA is the official competent authority in respect of the requirements set out under Commission Regulation 2022/1616. Please ensure that relevant documents and updates are submitted to recycledplastic-notifications@food.gov.uk.

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 FCM, use our [regulated products application portal](#). 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 4.1.8, 4.3, 7 and 5.5 of [Note for Guidance for Food Contact Materials](#)
- appropriate contact details of responsible person/s for making the 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 portal](#).

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

EFSA has previously developed technical guidance on the requirements of application dossiers which is also applicable for dossiers submitted in GB. However, 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 FCM 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 portal](#). 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 GB and you don't need to apply for a new authorisation.

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

You can now use our online service to [make a regulated product application](#).