Regulated products application guidance

What you need to submit as part of your regulated product application.

Before you start

Certain food and feed products, called regulated products, must go through a risk analysis process, and require authorisation before they can be sold in the UK.

Before you begin the application process, please consider if you do need to apply for a regulated product authorisation.

Our background information on placing a regulated product on the market explains the application requirements and will help you to work out if you need to make a regulated product application.

If you are still unsure or have general questions concerning whether a product is permitted in the UK, please contact us at regulatedproducts@food.gov.uk before starting an application.

If you wish to apply for an authorisation of a cannabidiol (CBD) product, you can find more information in our CBD guidance and the novel food application guidance.

For other queries, including imports and registering a food business, please read our guidance for food businesses and submit an online enquiry if you require further assistance.

Detailed information for each regulated product type

You need to apply for a regulated product authorisation if you wish to place one of the following product types on the market in the UK.

Follow the links for specific FSA guidance according to each regime. These pages also link to the relevant guidance and regulations applicable to each regime:

- extraction solvents
- feed additives
- feed for particular nutritional uses(PARNUTS)
- feed detoxification processes
- flavourings
- food contact materials
- food additives
- food enzymes
- genetically modified organisms(GMOs) as food and feed
- novel foods
- smoke flavourings

Please note

Authorisations are not generally issued for composite foods. The authorisation requirement relates to a particular substance (for example, 2'-fucosyllactose as a novel food) rather than to a composite product containing a regulated product as an ingredient (for example, a flavoured drink containing the novel food 2'-fucosyllactose). Applications for authorisations must be prepared

accordingly.

The application process

Once it is clear that the product you wish to market is a regulated product that is not already authorised in Great Britain, you should ensure that you have all the relevant information as outlined in the applicable regime regulations and guidance before you submit your application. This information is needed so that our risk assessors can assess whether the product or process is safe and to inform the decision on whether the application will be authorised. Incomplete applications are likely to be delayed and/or deemed invalid or refused.

For more details on what information you'll need to provide, please read the guidance that applies to your product type.

For an overview of the authorisation process, please refer to our background information on placing a regulated product on the market, our regulated product process flowchart and risk analysis process flowchart.

Please note

Applications are made via our online portal, where you can upload all the required information. Once your application has been submitted you will receive an email with your case reference number and a secure link where you can view your application and case history.

General advice on submitting an application

When applying for a regulated product authorisation you will have to supply administrative, technical and safety information. This information will form your application dossier.

The dossier requirements and structure are specific to each product type. You must read and follow the detailed guidance for the regime your product falls under (for example, novel foods, food additives) and submit the required data and information specified in the relevant guidance.

Some new products, particularly those produced by GM, may require applications under more than one regime. If this might be relevant to your product, you are strongly advised to contact us at regulatedproducts@food.gov.uk before starting an application.

The FSA's regime specific guidance links to parts of the technical guidance produced by the European Food Safety Authority (EFSA) where it remains relevant. For example, the EFSA guidance detailing the requirements of application dossiers for feed additives, genetically modified organisms, flavourings and food contact materials (plastic, active & intelligent materials, recycled plastics) remains relevant and will need to be considered.

Specific EFSA guidance for additives in regenerated cellulose film (RCF) is not available, but you can use the EFSA guidance for plastic monomers and additives as a helpful guide. This guidance remains relevant to GB applications, as it is based on legislation and processes that are also still largely applicable to GB. As will be made clear in the FSA regime specific guidance, you should follow the parts of the EFSA guidance that relate to the development of dossiers only (not the application process).

What is needed for an application

An application consists of two parts:

1. Administrative information

We will need to know:

- who is applying for the authorisation;
- who is responsible for the product or process;
- who we should contact if we have any questions.

It is also helpful to know the application's status in the EU, if it has been submitted there.

Applicants must provide up-to-date details to the FSA for correspondence. Failure to do so may result in the application(s) being deemed invalid.

2. Technical and safety information

The dossier needs to contain all the information that is requested within the applicable regime regulations and guidance. Failure to submit all the necessary information is likely to result in the application being delayed and/or deemed invalid or refused.

We need this information to understand more about the product or process and how it is intended to be used. This will allow us to carry out a thorough risk assessment, where appropriate, to verify whether the product or process can be used safely to inform the decision on whether the application will be authorised. The application portalincludes a checklist to help you ensure your dossier is complete when you submit it.

You should clearly list all the data provided and explain how it supports the application. You must submit all relevant data, whether the results are supportive of the product or not, to demonstrate that you understand the risks and have identified how these can be managed.

You should also tell us what information in the application you would like to be kept confidential, in line with the criteria set out in the relevant legislation and FSA guidance.

You should not submit your application unless you have all the supporting information necessary for your application and uploaded this to the online portal.

Please note, our working language is English. Dossiers can be accepted in English and Welsh.

Any documents, including supporting documents such as annexes or references that are in other languages must be translated and the translation provided with the submission.

Copies of all references and a table of references should be provided, which should clearly indicate which files or parts of files are regarded as confidential and for which a data protection request has been made.

File names

Files within the dossier should be named logically. Further details are given within the checklists in the portal. This minimises the chance that key data are lost. Dossiers which do not clearly state each file's role take longer to assess. It is also important to cross reference files within the dossier where applicable and make supporting information clear.
Make sure that file names do not include the following special characters:

- " quotation mark
- * asterisk
- : colon

- < less-than sign
- > greater-than sign
- ? question mark
- / forward slash
- \ back slash
- | vertical bar
- # hash
- % percent

File types

You can only upload a maximum of 100 files at one time and uploads should not exceed 200mb in total. You may carry out multiple uploads.

You can only upload the following file types to our regulated products application service:

- .ab1
- .asc
- .bam
- .csv
- .doc
- .docx
- .faa
- .fast5
- .fasta
- .fastq
- .ffn
- .fna,
- .frn
- .gff
- .gff3
- .hdf5
- .odf
- .pdf
- .ppt
- .pptx
- .r
- .sam
- .sas
- .tsv
- .txt
- .xls
- .xlsx
- .aln
- .bai
- .fa
- .fo
- .fq
- .gbk

Any other file type, including zip files (which are not allowed for security reasons) and images, will not be saved. Only single files from the same source folder can be uploaded at a time.

If you have information that is not available in any of these formats or sizes, please contact us at regulatedproducts@food.gov.uk to discuss options.

Advice on providing a valid application

The points below will not apply to all regimes but give some general advice:

- detailed guidance is provided in the FSA guidance documents which link, where appropriate, to the relevant EFSA guidance. You should follow the relevant EFSA guidance closely, since it is still relevant to GB applications.
- you should clearly explain the product's purpose, intended use and its composition. You must provide evidence of the product's composition and how you know the product's authenticity. For example, it may be necessary to give the chemical name or scientific (Latin) name, depending on regime.
- all the necessary technical information, as outlined in the regime regulations and guidance, should be included when you submit your application. For example, appropriate validation and / or accreditation documents for methods of analysis are required for all regimes and should be included in applications when they are submitted.
- the technical dossier should explain how the product meets the criteria set out in the relevant regulation and guidance. You should clearly list all the data provided and explain how it supports the view that the product is safe. You must submit all relevant data, whether the results are supportive of the product or not.
- for most application routes, the dossier should include your assessment of the product's risk, with enough information to verify this assessment. The focus of the assessment is that you show your understanding of the risks and identified how the risks can be managed.
- where appropriate, information on the relevance and strength of the data, as well as test methods, should be included, as should an interpretation of the data. If applicable, the variability of the product should be considered when selecting the batches for testing.
- for dossiers that require completion of a production section, a Hazard Analysis Critical Control Plan (HACCP) is useful. The information in this section should identify whether there are new risks introduced by the production process and to what extent existing hazards from the starting material are managed. If the effectiveness of a step is supported by the product analytical testing, this should be clearly stated.
- all references must be provided.

We expect applications to provide all of the necessary information when they are submitted. If applications have missing or incomplete information then there will be a limited opportunity to fill gaps, within reason and at the FSA's discretion. However, these applications will be delayed by requests for additional information and if the necessary information is not provided within a reasonable timeframe then they are likely to be deemed invalid.

If and when your application is deemed valid and moves to the risk assessment stage you should provide complete and prompt responses to any requests for further information by the deadline set. If further time is required you will need to make a clearly reasoned request explaining why this additional time is needed. Late or incomplete responses may result in your application being assessed on the available information.

Please note, an authorisation for a regulated product allows the product to be used and placed on the market. However, depending on your product, you may also need to comply with other applicable legislation (for example, the requirement to register a food business and legislation concerning food hygiene and contaminants). Other legislative requirements are outlined in the guidance for food businesses.

Make a regulated product application

You can now use our online service to make a regulated product application.