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
- Precision bred organisms (PBOs)

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.

Requests for further information

Importance of submitting a complete application

The FSA expects applications to be complete and to contain all the necessary information when they are submitted. 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.

For guidance on what constitutes a complete application, refer to earlier sections of this page: What is needed for an application and Advice on providing a valid application.

If you have any questions about application requirements you can contact us at regulatedproducts@food.gov.uk.

Incomplete applications are likely to be delayed and/or deemed invalid. 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.

You can find information and advice on FSA's expectations when we request information, which may be different from other regulators, in the following section.

Responding to requests for information at the validation stage

Once you have submitted your application it will go through a series of checks before it can be validated. To pass the validation stage applications should not require significant additions.

If information is found to be missing or incomplete, we may send you a request for further information and we will pause the application until the information is received. Each request will explain what information must be provided and will clearly specify a deadline by which it must be received. If you need more time, you should respond as early as possible within the specified period to propose an alternative deadline, explaining the reasons why. We will then consider your request.

Your responses to our requests for information should be thorough and address each point we have raised or provide a reasonable explanation for not doing so. Please keep the following points in mind:

- We will not ask the same question twice, so, you should not expect us to send follow up requests to chase information that we have already asked for if it is still missing after the deadline.
- We might ask you to clarify the information you do submit to us.

If the deadline for submitting the information expires and you have not sent us the information we have asked for, then the decision on validation will be based on the information that you have already provided to us.

Responding to requests for information at the assessment stage

If and when your application is deemed valid and moves to the assessment stage, you may be asked to provide additional information considered necessary by the relevant expert team or scientific advisory committee to support the assessment. We will pause the application until it is received.

Each request will set out the information that must be provided and the deadline for doing so. If you need more time, there will be an opportunity to propose an alternative deadline. However, prolonged timelines to conduct additional studies are unlikely to be accepted if it is reasonable to expect that the information should have been submitted upon application. To avoid this situation, applicants should thoroughly review the relevant regime guidance on our website before submission.

You must provide the information requested by the deadline. Late or incomplete responses are likely to result in your application being assessed on the available information.

Further considerations

Applicants should review the request for information to ensure they thoroughly understand what is being asked. If after consulting the relevant guidance there are any remaining questions, these should be raised as soon as possible. If there are any complex technical matters that cannot be resolved through written communication, in exceptional circumstances we may arrange a meeting, provided the issues have been clearly articulated in writing first.

As outlined above, applicants are expected to submit complete applications, and requests for information will be issued at the discretion of the FSA. Decisions regarding the timeframes for

responding to requests for information, and the adequacy and completeness of responses, also remain at the FSA's discretion.

We will consider circumstances on a case-by-case basis, including the extent to which FSA guidance has been complied with, and will strive to ensure consistency and fairness for applicants whilst facilitating a timely and efficient authorisation process.

Make a regulated product application

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