Regulated products application guidance

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

Important: market authorisation process reform

On 1 April 2025, the market authorisation process for regulated products was amended by legislation covering Great Britain (GB) which:

1. removed requirements for the periodic renewal of authorisations for feed additives, smoke flavourings and food or feed containing, consisting of or produced from genetically modified organisms; and
2. allows authorisations to come into effect following ministerial decision and then be published in an official register or list, rather than being prescribed by statutory instrument (SI).

Our guidance was amended to take these changes into account. You may wish to refer to further information on the reforms and how they relate to specific product types.

Before you start

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

Before you begin the application process, please consider if you do need to apply for a regulated product market authorisation. This page explains the application requirements and will help you to work out if you need to make an application.

You need to apply for a regulated product authorisation if you wish to place one of the following product types on the market in Great Britain (GB). Follow the links for specific FSA guidance according to each product type ('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)

In addition, if you wish to apply for an authorisation of a cannabidiol (CBD) product, you can find more information in our?CBD guidance.

If you wish to apply for an authorisation of a cell-cultivated product (CCP), you can find more information in our?CCP guidance.

Existing authorisations

If your product or process was authorised by the European Commission (EC) before 1 January 2021 and the necessary legislation applies, that authorisation remains valid in GB.

Placing your product on the Northern Ireland market

Applicants wishing to place regulated products on the Northern Ireland (NI) markets continue to follow the EU authorisation process. However, regulated products authorised in Great Britain (GB) may also be placed on the NI market, provided they are eligible for, and are moved through, the Northern Ireland Retail Movement Scheme (NIRMS).

The application process

Once you've established that the product you wish to market is a regulated product that is not already authorised in GB, you must review the information on this page and the guidance specific to your regime before you submit your application, to ensure you have all the required information.

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.

The?registers of regulated products lists the regulated products permitted for use in GB and provides references to their terms of authorisation.

Important:

The quality of the dossier, and the information provided, will significantly affect?the time needed for assessment and authorisation.?We encourage applicants to follow the guidance and provide all the required information to ensure we can process your application as efficiently as possible. Incomplete applications are likely to be delayed and/or deemed invalid or refused.

For an overview of the authorisation process, please refer to our?regulated product process flowchart?and?risk analysis process flowchart.

For most regulated product types, once products or processes are authorised, they are listed in online registers which also set out how they can be used.

The registers for the following substances or processes have not yet been established:

- food enzymes
- food contact materials - recycled processes
- food contact materials - active and intelligent materials

Until the registers are in place, these products may be placed on the market if they meet requirements of:

- the General Food Law
- the relevant general criteria in the food enzyme and food contact material legislation

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 authorisation process

In assessing your application, we will take into account assimilated law and the relevant guidance previously developed by?the European Food Safety Authority (EFSA), as outlined in the regime-specific guidance pages.

After you submit your application, we will carry out initial checks to make sure it contains all the necessary information. The FSA, with Food Standards Scotland (FSS), will then carry out an assessment to decide if the product or process is safe to be placed on the market in England, Wales and Scotland. This may involve risk assessment by one of our?Joint Expert Groups and/or Scientific Advisory Committees and a consideration of?other legitimate factors?(for example, risks to the environment). These will be combined to form an evidence package.

Based on this evidence, we will consider possible risk management options and make a recommendation to ministers. There will be an opportunity to comment on the application by taking part in a consultation during the risk management process and before the final recommendation is made. The ministers will then decide whether the product should be authorised for use in England, Scotland and Wales. If a decision is taken to support an authorisation, the relevant register will be updated to reflect the change.

The timing of the full risk analysis process will depend on how complex the application is and on the type of product. For some products, the deadlines are set in legislation.

The quality of the dossier, and the information provided, will significantly affect?the time needed for assessment and authorisation. We encourage applicants to follow the guidance and provide all the required information to ensure we can process your request as efficiently as possible.

Ongoing applications to the European Union (EU)

If you submitted your application to the EU before 1 January 2021 and the assessment process has not been completed, you will need to submit your application to us using our application portal. Please include your?EFSA?question number in your submission.

We may take into account the published?EFSA?opinion and the outcome of any risk management discussions at the end of the transition period (31 December 2020),?but in some cases we may still need to carry out a full risk assessment and consider risk management options.

How to apply

Applications are made via?our online application 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 genetic modification, 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 EFSA where it remains relevant.

As detailed 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. The?application portal?includes a checklist to help you ensure your dossier is complete when you submit it. You should not submit your application unless you have all the supporting information necessary for your application and have uploaded this to the online application portal.

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.

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 clearly list all the data provided and explain how it supports the application.

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?FSA's regime-specific guidance. 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.

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.

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 is lost. Dossiers which do not clearly state each file's role will 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 any of 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 the following file types:

.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.

Large file uploads

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

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. This is particularly recommended for GMO

applicants before uploading their files.

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. Applicants should always refer to regime-specific guidance for clarification, as relevant guidance is reviewed as needed to maintain appropriate standards and support high-quality dossiers.
- 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 specific 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.
- we advise following the headings and subheadings given in the relevant EFSA guidance, to aid validation. All sections must be completed by the applicant to be considered a valid dossier. If a section given in the guidance is not appropriate for the product, the dossier should include a reasoned justification as to why that is the case (e.g. history of use).
- 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. Applications with fewer batches than specified in the guidance must provide a full justification for the number submitted.
- 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.

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.

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.

Below you can find information and advice on FSA's expectations when we request information, which may be different from other regulators.

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 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 application portal to?make a regulated product application.

Getting help

If you have any questions about authorisations of regulated products or, having consulted the registers, have general questions concerning whether a product is permitted in GB, please contact us at?regulatedproducts@food.gov.uk?before starting an application.

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.

Providing information on authorised regulated products

If you need to contact us about an existing authorisation, please email us at regulatedproducts@food.gov.uk. You should use this route to notify us of any new or developing safety concerns about an authorised product such as if you become aware of anything new casting doubt on a previous safety assessment..

Additionally, you must (where required) use this route to send us post-market monitoring reports, post-market environmental monitoring reports, updates or changes to analytical or detection methods, and any other information related to an existing authorisation.?

When emailing, please mention the authorisation or product you are referring to, what type of information you are providing, and include the RP number if applicable.? ?

Businesses are legally required to report to the FSA/FSS if they have reasons to believe that placing the food or feed product on the market could do harm to consumers.

You must report any food safety incidents to the FSA in England, Wales or Northern Ireland. If you are in Scotland, or the incident relates to a business in Scotland then please report the incident to FSS. ?