

Regulated products application guidance

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

Certain food and feed products, called [regulated products](#), require authorisation before they can be sold in the UK.

To place your regulated product on the market in Great Britain (GB), you'll need to submit your authorisation application using our [regulated products application service](#). Please note that we only accept applications in English and Welsh.

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 any business seeking a new authorisation for a regulated food and feed product placed on the Northern Ireland market will have to continue to follow EU rules.

Information you need to supply

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

The information you will need to supply to us is based on retained EU law and the same as required by the European Food Safety Authority (EFSA) and the European Commission (EC).

The requirements for each type of authorisation differ in detail and are outlined in the product type specific guidance. Generally, they cover three main areas.

Administrative information

We'll 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

This may include details about which information you'd like us to treat as confidential.

Technical information

We need this information to understand more about the product or the process and how it is intended to be used. For example for a new food additive it would be:

- the identity of the new food additive, what function it has in food and associated benefits
- the requested use levels in different types of food and the amounts people are likely to consume from their diet

This may also include data for our risk management team to assess whether all the criteria in the relevant legislation have been met, such as benefits to consumers. You should also tell us what information in the application you'd like to be kept confidential in line with the criteria set out in

the legislation.

Safety information

You should provide scientific data and information as part of your application dossier. This will allow us to carry out a thorough risk assessment, where appropriate, to ensure the product or process can be used safely.

There may be some occasions when the information or studies specified in the product type guidance may not be relevant for your application. In these circumstances you should provide clear justification for not submitting this information.

Uploading your files

When you submit an application form using our [regulated products application service](#), you will receive a secure link where you can upload your supporting documents.

You can structure your application dossier by uploading folders containing individual files. To upload your folders you can use 'drag and drop' functionality or select 'Upload' option.

Allowed file types

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, .tsv, .txt, .xls, .xlsx.

Any other file type, including zip files and images, will not be saved.

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

Naming your files

Name your files appropriately before you upload them to the service. You won't be able to change file names once they've been uploaded.

Submitting your files

Files uploaded to the service will be saved automatically. Once this is done, the name of your file will start with the word 'SUBMITTED', for example 'SUBMITTED_Application summary'.

If a file type is not allowed, the file won't be submitted. It will be deleted from the system and the file name on the list of your files will start with the words 'NOT_SUBMITTED'.

Depending on the number of documents in your application and their size, there may be a delay between uploading your files and saving them in our system. To make sure we receive your full application, check that all file names in your uploaded dossier are preceded by the word 'SUBMITTED'.

Editing, deleting or replacing your files

You won't be able to edit or delete your files once they've been uploaded to the service. If you need to replace a file, please contact us at regulatedproducts@food.gov.uk

Getting help

If you have any questions about uploading your application files, contact us at regulatedproducts@food.gov.uk

Guidance for different product types

What you need to submit with your application and when you need to apply differs depending on the type of product authorisation you require. You can find detailed information on authorisation requirements for your product type in our authorisation guidance for:

- [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](#)