



## Applicant Information & Guidance for Applying for EC Approval of a Food Establishment



### Introduction to approval

Regulation (EC) No 853/2004 requires that food business establishments handling food of animal origin that fall under the categories for which Annex III of Regulation (EC) No 853/2004 lays down requirements must, with some limited exceptions, be approved by the competent authority. Compliance with relevant requirements of Regulation 853/2004 is required in addition to full compliance with Regulation (EC) No. 852/2004.

Regulation (EC) No. 853/2004 provides certain exemptions from approval for some establishments. The exemptions fall into the following basic categories:

- a) Retail establishments - The exemption for retail establishments that supply food of animal origin to the final consumer and to supply other retail establishments (including caterers) food of animal origin on a marginal, localised and restricted basis.
- b) Poultry slaughter and cutting on farm - There is an exemption for producers supplying small quantities of meat from poultry and lagomorphs reared and slaughtered on their own farm directly to the final consumer and to local retail establishments directly supplying this meat to the final consumer only.
- c) Slaughter for private domestic consumption - Where slaughter is carried out for private domestic consumption and the meat is not placed on the market this activity is exempt subject to compliance with Transmissible Spongiform Encephalopathies and EU and National Animal By-Products Regulations.
- d) Wild game – There is an exemption for primary producers (individual hunters or shooting estates) supplying small quantities of wild game carcasses in fur/feather directly to the final consumer and to local retail establishments directly supplying this game to final consumers. There is also an exemption for hunters and active members of a hunting party supplying small quantities of wild game meat directly to the final consumer and to local retail establishments directly supplying this game to the final consumer.

For a more in depth explanation of the exemption thresholds and criteria you should contact your local environmental health department of Newry, Mourne and Down District Council at O'Hagan House, Monaghan Row, Newry BT35 8DJ **OR** Downshire Civic Centre, Downshire Estate, Ardglass Road, Downpatrick BT30 6GQ Tel: 0300 013 2233 Email: [health@nmandd.org](mailto:health@nmandd.org).



## Background to Food law

The EU food legislation forms the basis for UK food law which Food Business Operators (FBOs) must comply with and includes the following:

### [Regulation \(EC\) No 178/2002 – General Food Law Regulation](#)

The regulation provides a framework for food and feed law in the EU. It applies to all stages of production, processing and distribution of food and feed. The principal aim of the regulation is to protect public health and consumers’ interests in relation to food.

### [Regulation \(EC\) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs:](#)

This sets out general hygiene rules that apply to all registered and approved food businesses including structural requirements and the implementation of procedures based on hazard analysis and critical control point (HACCP) principles. The regulation sets out objectives for “good hygiene practices” to protect consumers.

### [Regulation \(EC\) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin:](#)

This includes requirements for businesses producing Products of Animal Origin (POAO) that apply in addition to those set out in Regulation 852/2004, including the requirement for establishments to be approved.

### [Regulation \(EC\) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption:](#)

This includes the specific requirement for inspection and auditing activities to be carried out by the District council in relation to establishments, which require approval under Regulation 853/2004.

### [Regulation \(EC\) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules: \*\*LINK TAKES YOU TO 853/2004\*\*](#)

This includes procedures to be followed concerning the approval of establishments as required under Regulation 853/2004.



The above Regulations contain general and specific rules on the hygiene of food for competent authorities and food business operators (FBOs) under the umbrella of the General Food Law Regulation (EC) No. 178/2002.

The Regulations lay down rules on the hygiene of foodstuffs taking into account a number of principles such as the primary responsibility for food safety resting with the FBO, the need to ensure food safety throughout the food chain starting from primary production ('farm to fork') and the implementation of procedures based on the hazard analysis and critical control point (HACCP) principles together with the application of good hygiene practices.

The Regulations provide the legal context for FBOs to be allowed to produce, transport, store, process and place on the market food for human consumption and for the competent authority to verify compliance with food law by FBOs.

### **Guidance notes for the completion of the application form**

This section provides advice on how to complete the application form for approval. Please read this document carefully before filling out the application form.

#### PART 1 – Establishment for which approval is sought

- a. Trading name is the name that the owner wishes to be known to trade under. This cannot be a different incorporated company.
- b. Address: Complete address including postcode. Make sure the full telephone number and if appropriate, fax number, including area code is included. Please also provide a full email address.

#### PARTS 2, 4, 5, 6, 7 & 9 Type of establishment(s) and activities for which approval is sought

- a. You will need to specify the type of operations the establishment is requiring approval for. This includes full details of the specific activities, products, species and approximate quantities.

#### PART 3 – Food Business Operator (FBO) details and Business structure

- a. The Food Business Operator (FBO) is the legal entity of the company and can be an incorporated company that is registered with Companies House or the name of the owner(s) if a partnership or sole trader.
- b. It is vital that the details in this section are correct. If you have any doubt as to the structure of your business seek legal advice or contact Companies House.



- c. Only complete section 3a if you have been given Incorporated/ Limited Company status. Make sure the company registration number is completed in full. When submitting your application, please also enclose a copy of the Company Registration Certificate and a company letterhead/business card.
- d. Details for the Company Directors should be listed in full. This does not include senior management. If necessary please continue on a separate sheet and attach.
- e. Only complete section 3b if you are trading as a Partnership or Sole Trader. You should list the details accurately including telephone numbers, fax number, home address and email. If necessary please continue on a separate sheet and attach.

### PART 3 – Establishment managers and contacts

List all the relevant managers and staff who will hold a position of responsibility:

For a Limited company, a Duly Authorised representative of the FBO should be entered. For Partnerships/Sole Traders a Duly Authorised representative of the FBO only needs entering if different to the individuals listed in Part 3b.

### PART 8 – Information and documentation

The following examples are intended as guidance on the type of information and documentation which is to be provided in support of your approval application.

- a. Every business varies considerably in its complexity and therefore the extent and detail of the documentation that is required will also vary. It is very important that the information you do provide has sufficient detail to enable a proper assessment to be made. All documents should be up-to-date. Copies of each document are sufficient as you should retain any originals.
- b. In each section below examples are given of the type of information which is required. The information and documentation should be clear and legible. Your inspecting officer may determine that further information is needed and will contact you accordingly.

### **Submission of information**

A change to any aspect of your food business operations that may affect the approval must be authorised by the council prior to making those changes and both copies of the approval file should be updated accordingly.



1. A detailed scale plan of the establishment showing the location of rooms and other areas to be used for the storage and processing of raw materials, product and waste, and the layout of facilities and equipment.

Easily understood plans showing the following are required: -

- a. A clear and fully labelled layout of the premises indicating the activities carried out in each area including external rooms, storage areas and structures.
- b. The location of working equipment including tables and fittings such as wash hand basins, sinks etc. Each should be clearly labelled.
- c. Drainage plan for the premises, which should indicate location of drains and the direction of flow for drains.
- d. Movement of personnel throughout the premises to include high and low risk areas (where appropriate), the flow of raw ingredients and other materials such as packaging, work in progress, finished product and waste.
- e. A plan of the water supply indicating pipe-work, location of cisterns and storage tanks whether internal or external. Water sampling points such as at equipment or sinks should be indicated. These are locations from which water may be drawn for the purposes of food production or cleaning. The location of any non-potable water source or supply should also be clearly shown.

It will normally be easiest to provide a separate plan or sketch plan indicating each of the above points a) to e). For example, provide a copy of the architect's dimensioned drawing of the whole food premises.

2. A description of the (proposed) food safety management system based on HACCP principles.

Ensure that your HACCP document is up to date, covers all current activities and provide a copy. Your HACCP should include details of the intended review date(s) and name of the person responsible.

3. A description of the (proposed) establishment and equipment maintenance arrangements.

The maintenance procedures for the premises and for equipment should be included. This procedure should detail what maintenance is routinely carried out and the frequency in addition to what arrangements are in place with regard to proactive maintenance. It



should describe the contracts that you have in place, who does the maintenance, their contact details including arrangements for emergency call out and proof of any relevant accreditation (e.g. for the calibration of equipment which is necessary for safe food production). Areas to consider include gas, refrigeration, electricity, water supply and drainage etc.

4. A description of the (proposed) establishment, equipment and transport cleaning arrangements.

You should have a cleaning policy including schedules, this should be sufficiently detailed to describe: -

- What is to be cleaned, (e.g. food contact equipment, wall, floors, ceilings, vehicles, water storage tanks etc.)
- How it is cleaned
- What equipment you use to clean with
- How often each item is cleaned
- The chemicals that are used

The 'specification' for each cleaning product should also be provided. Please note that these are often separate from the safety data sheet which is provided for health and safety purposes. The specification sheet will describe what the product is suitable for, e.g. for food use, and indicate dilution rates, method of application and whether rinsing is necessary, etc.

5. A description of the (proposed) waste collection and disposal arrangements.

The description of waste handling arrangements should include a description of the categories of waste produced and of the waste containers that are used (e.g. marked for waste use, leak proof, lidded). Copies of waste transfer documents for animal by-products or receipts from companies receiving other waste materials should be provided.

6. A description of the (proposed) water supply.

Detail what type of supply is used and whether water is stored in tanks or cisterns for use in the production process or for cleaning purposes. Is a non-potable water supply used for any purpose, e.g. washing, firefighting? If so a clear distinction should be made on the plan referred to in point 1 above.

7. A description of the (proposed) of the water quality testing arrangements.



If water is from a mains supply only, are arrangements in place with the water board to inform you in the event of any contamination issues?

Do you rely solely on the water service for sampling and are the results available to you?

Contact details - 'Waterline' Phone: 08457 440088, Email: [waterline@niwater.com](mailto:waterline@niwater.com)

Do you carry out your own water testing? If so include a copy of your sampling policy and program.

Is the laboratory used for testing of water accredited? You should obtain an up to date copy of the accreditation certificate, which should be forwarded to this department and should include accreditation details of those tests carried out on your behalf.

8. A description of the (proposed) arrangements for product testing.

This refers to any microbiological or chemical testing that may be carried out. You should make yourself aware of the type (if any) of testing that you may be required to carry out. This may include batch testing, shelf life testing, or swab testing that is carried out for the purpose of checking the standard of cleaning regimes.

To satisfy this requirement, provide details of the testing that will be carried out by the business if any. A copy of your sampling schedule should be included.

Is the laboratory used for testing of raw material/product accredited? If so, an up to date copy of the accreditation certificate should be forwarded to this department, which should include accreditation details of those tests carried out on your behalf.

9. A description of the (proposed) pest control arrangements.

Provide details of your pest control arrangements. If you have a pest control contract this should include a statement of treatments and areas covered by the contract and a copy of the baiting plan for the premises including any external baiting points. The description should indicate whether the pest control company is responsible for servicing electronic fly killers and that suitable arrangements are in place with the pest control company to provide an emergency response service.

10. A description of the (proposed) monitoring arrangements for staff health.

This should include your staff hygiene policy and any surveillance/monitoring that you carry out or would intend to carry out with regard to new employees. It should also detail any questionnaires that you require your staff to complete employment questionnaire or after a period of sickness. Any arrangements such as health



declarations required by contractors or visitors to your establishment should also be included in this section.

11. A description of the (proposed) staff hygiene training arrangements.

This should list all of the staff that you have working in the premises both permanent and temporary and detail any food hygiene training that they have received. You should also include a copy of your up to date hygiene training policy that should detail any induction or on the job training that is given. You should state the frequency of any refresher training that is required.

12. A description of the (proposed) arrangements for record keeping.

This includes all records kept in relation to your HACCP, your product traceability records and any other records that are relevant to food safety or food standards such as sample results, complaints etc. It should detail those responsible for ensuring that the records are completed as well as the person(s) responsible for filing, how the records are stored (electronically, paper files, etc.) and for how long the records are kept.

13. A description of the (proposed) arrangements for applying the identification mark to product packaging or wrapping.

The regulations require that products from approved establishments placed on the market must bear an identification mark.

You are required to provide details of: -

- All packaging, labels or commercial documentation that bear the identification mark
- How and where the identification mark is applied, whether pre-printed or printed-on-demand
- Details of where and how the materials bearing the identification mark are securely stored and name of the person(s) that have access.
- The name of the person(s) that are responsible for issuing pre-printed materials or print-on-demand labels
- Describe how damaged or redundant materials bearing the identification marked are securely disposed of.





## **Additional information**

### **Traceability System - Regulation (EC) No178/2002**

Provide evidence that you can identify your suppliers, any raw material specification (i.e. what you expect with regards to quality and quantity from each supplier) and details of any supplier's audits you carry out. A supplier list along with details of the foods and ingredients that they supply would help to satisfy this requirement.

Provide evidence that you can identify all other businesses to which you supply your products such as a customer list including details of the products that you supply them with.

You should also provide an explanation of the batch marking system that you use, which would facilitate product withdrawal or recall should food which you supply be found not to be in compliance with the food safety requirement. This should information on what a 'batch' consists of e.g. number, weight, etc.

### PART 10 – Application

If you fail to complete all relevant parts of this form may result in a delay in the approval process.

- a. Make sure the name is completed in BLOCK LETTERS, dated, and a signature supplied.
- b. If completed on screen, please print off a copy, sign and date and either post or submit scanned copy by email to the address as detailed in the application form.

### **Application process explained**

(subject to variation dependent on the complexities of an individual case)

When the application and site plans are received by the District Council, an authorised officer who will contact you to discuss your approval requirements.

Where required the authorised officer of the District Council will arrange an on-site advisory visit to assist you in identifying any problems in the areas of structure, maintenance and food safety management. This is in order to avoid any potential difficulties when the establishment is assessed for approval.

When you consider the establishment to meet all the requirements for approval, an approval visit will be undertaken by an authorised officer to assess the establishment.

Conditional approval may be granted if the establishment meets all the infrastructure, and equipment requirements. The establishment may not be able to demonstrate the documented



HACCP based procedures but the planned method of operation must not constitute a risk to public health and there must be adequate provision to control any hazards that have been identified.

A further visit will take place by the authorised officer within 3 months of a conditional approval being granted. This visit is to observe activities in operation and to assess whether deficiencies identified at conditional approval have been rectified (e.g. amendment required to the HACCP based procedures).

- a. If you have made clear progress but the establishment still does not meet all of the relevant requirements (e.g. required paperwork not fully completed, activities have not all been seen in operation), conditional approval may be extended. This extension will not exceed 3 months.
- b. If there is insufficient evidence to demonstrate that necessary work will be completed at the end of the three month period of extended conditional approval, approval will be refused.
- c. Conditional approval will expire if either the establishment ceases operations or a visit could not be undertaken.

A final approval visit by the authorised officer will take place within 6 months from the original date conditional approval was granted.

Full approval will be granted if, following conditional and/ or extended conditional approval, you comply with all the relevant requirements of food law (infrastructure, equipment & operational requirements) and operations have been observed and found to be compliant.

Conditional approval will be refused if there are structural or equipment deficiencies at the initial approval visit.

Extended conditional approval will be refused, if at the end of 3 months insufficient progress has been made to meet all the requirements in full.

Full approval will be refused, if at the end of 6 months there is insufficient compliance with structural, equipment or operational requirements and other relevant requirements of food law, including the implementation of an effective food safety management system based on HACCP principles.

When refused approvable activities must not be undertaken.



## Appeals

In accordance with the Official Feed and Food Controls Regulations (Northern Ireland) 2009, any person who is aggrieved by a decision taken by the FSA in respect of an establishment subject to approval may appeal to a court of summary jurisdiction if such an appeal is lodged within one month of the decision being notified.

## Definitions of activities

<b>Activity for which approval is sought</b>	<b>Definition</b>
<b>Minced meat</b>	Boned meat that has been minced into fragments and contains less than 1% salt.
<b>Meat preparations</b>	Fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasoning or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus eliminate the characteristics of fresh meat.
<b>Mechanically separated meat (MSM)</b>	The product obtained by removing meat from flesh bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.
<b>Processing plant</b>	An establishment where POAO are either treated, processed (heating, smoking, curing etc) and wrapped or undergoes one or more of those handling activities
<b>Meat products</b>	Processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.
<b>Ready to eat food</b>	Food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing
<b>Rendered animal</b>	Fat derived from rendering meat, including bones and intended for human consumption (e.g. lard). Greaves is the protein



<b>fats and greaves</b>	containing the residue of rendering after partial separation of fat and water (e.g. pork crackling)
<b>Treated stomach, bladders and intestines</b>	Treated stomach, bladders and intestines that have been submitted to treatment such as salting, heating or drying after they have been obtained and after cleaning
<b>Gelatine</b>	Natural, soluble protein obtained by the partial hydrolysis of collagen produced from bones, hides, skins, tendons and sinews of animals (e.g. used in production of jelly)
<b>Collagen</b>	Protein based product derived from animal bones, hides, skins and tendons (e.g. used in food additives).
<b>Re-wrapping</b>	Wrapping means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself. There-fore re-wrapping means the replacement of initial wrapping or initial container, which is in direct contact with the product.