Chapter 2.12 Edible Co-Products

This chapter details the controls required for Edible Co-Products in FSA approved establishments.

Sections

1. Introduction

In this section

1.1 Definition

An Edible Co-Product is a part of a slaughtered animal or a product of an animal that is unsuitable for human consumption at the time of production in the slaughterhouse, but which can later be processed for use in human food.

Examples of these include hides and skins later processed into gelatine and collagen, cattle feet, sheep heads and feet, bile, sheep intestines processed into sausage casings, omental fat processed into lard, etc.

Edible co-products have often been called “by-products” at the slaughterhouse, leading to the mistaken belief that these can be handled like animal by-products.

The table below includes a non-exhaustive list of items under each category.

Examples

Edible Product (Meat, offal)	Edible Co-product	Animal By-products Category 3	Animal By-products Category 2	Animal By-products Category 1	Pharmaceutical use
Wholesale and retail meat Carcase material used for meat recovery (e.g. MSM) Blood, livers and kidneys used to make edible products	Raw fatty tissues used for edible fat and greaves ("rendered animal fats and greaves"). Raw fit bones and hide splits for edible gelatine and collagen. Intestines used for edible casings. Sheep heads and feet, cattle feet and masks (e.g. scalded or depilated).	Parts of animals slaughtered and found fit, but not intended, for human consumption	Poultry dead on arrival. Many Post-mortem failures, soiled or contain medicine residues.	TSE positives. SRM.	Intestine mucosa intended for heparin production. Bile to be used on the perfume industry or like salts. Blood used for production of serum or immunoglobulins

1.2 Products covered in this chapter

- Processing of intestines, stomachs and bladders: Stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.
- Ruminant feet, heads and cattle ears (scalded, depilated). The processing of heads after skinning is not included in this Chapter.
- Cattle and sheep masks and lips (muzzles): Including cattle and sheep masks and muzzles scalded / depilated intended for human consumption.
- Bile and gallbladders, harvested for human consumption. The chapter does not cover harvesting of bile as an ABP or under the exception for pharmaceutical use.
- Gelatine and collagen:
    - Gelatine means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.
    - Collagen is the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant legal requirements.
- Rendered Animal Fats and greaves:
    - Greaves means the protein-containing residue of rendering, after partial separation of fat and water.
    - Rendered animal fats derived from rendering meat, including bones, and intended for human consumption.
- Immature eggs: harvesting of unformed eggs from spent lying hens to be used for human consumption. This does not include fertilised eggs (animal by-products, as they are embryos).

Note: This chapter does not include any reference to edible co-products from dairy industry.

1.3 Contact and useful links

- Queries regarding this chapter can be directed to the Other Products Of Animal Origin (OPOAO) portfolio group: OPOAO@food.gov.uk
- Export Health Certificates (EHCs) for the different products described in this chapter can be found by following the government guidance online.

2. Legislative References

In this section

2.1 Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe.

2.2 Regulation (EC) No 852/2004

Regulation (EC) No 852/2004 lays down the principles of food hygiene. In particular, article 5, requires FBOs to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2.3 Regulation (EC) No 853/2004

Regulation (EC) No 853/2004 lays down specific requirements for the manufacture of some edible co-products, e.g. gelatine, collagen, rendered animal fats and greaves, treated stomachs, bladders and intestines.

2.4 Regulation (EU) 2017/625, Regulation (EU) 2019/624, Regulation (EU) 2019/625 and Regulation (EU) 2019/627

These Regulations set out the official control requirements for products of animal origin for enforcement authorities. All establishments that handle edible co-products will therefore be subject to audit and inspection by the competent enforcement authority.

2.5 Food hygiene regulations

The Food Hygiene (S/NI/W) Regulations 2006 (as amended) / The Food Safety and Hygiene (England) Regulations 2013 (as amended) make it an offence for any person to contravene or fail to comply with the specified community provisions.

2.6 TSE related regulations

(EC) 999/2001 (as amended) lays down rules for the prevention, control and eradication of certain TSEs.

The Transmissible Spongiform Encephalopathies (England) Regulations 2018 and The Transmissible Spongiform Encephalopathies (Wales) Regulations 2018 implement Regulation (EC) 999/2001 in England and Wales.

2.7 Animal by-products (Enforcement) (England) Regulations 2013, Animal by-products (Enforcement) (Wales) Regulations 2014, Regulation (EC) 1069/2009 and Regulation (EC)142/2011

The Animal By-Products (Enforcement) Regulations (ABPR) apply and enforce Regulation (EC) 1069/2009 and Regulation (EC) 142/2011.

Note: References to EU legislation refer to Retained EU Law in England and Wales.

3. Products

In this section

3.1 Processing of intestines, stomachs and bladders

3.1.1 Introduction

This section covers the processing of intestines, stomachs and bladders for human consumption, i.e. stomachs, bladders and intestines that have been subjected to a treatment such as salting, heating or drying after they have been harvested and after cleaning. These processes all require approval under the regulations below.

Food borne pathogens such as Salmonella, Campylobacter and E.coli commonly reside in the gut flora of animals, including those that are clinically healthy. It is therefore very important that hygiene requirements are followed by FBOs when stomachs, bladders and intestines are treated for human consumption, in order to prevent these pathogens passing into the human food chain.

3.1.2 Legislation

Regulation (EC) 853/2004, Annex III, Section I, Chapter IV, Paragraph 18 (domestic ungulates). The Food Business Operators need to make sure that when destined for further handling, stomachs must be scalded or cleaned (in the case of stomachs of young ruminants intended for rennet production the stomachs need only be emptied) and intestines must be emptied and cleaned.

Regulation (EC) 853/2004, Annex III, Section XIII. Animal intestines, bladders and stomachs may be placed on the market only if:

a) they derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;
b) they are salted, heated or dried;
c) after the treatment referred to in (b), effective measures are taken to prevent re-contamination.

Untreated stomachs, bladders and intestines are considered offal and therefore must be kept at 3°C. However, once they are treated, this requirement may no longer apply. (i.e. Salting, curing drying etc)

3.1.3 Stomachs

Harvesting and initial cleaning – Stomachs are separated from the intestines and other tissues before being opened and the contents removed. This is followed by washing: stomachs must be cleaned (visibly clean) before they leave the slaughterhouse where they were harvested.

Stomachs that have been emptied and cleaned must be kept in hygienic conditions and cooled down following a chilling curve that ensures a continuous decrease of the temperature to +3°C or below, unless they are processed without undue delay at the same establishment to obtain the final product.

After initial cleaning, stomachs may either be ‘treated’ at the slaughterhouse if approved for this purpose or transported from the slaughterhouse directly to another establishment approved for that purpose. They may also be transported frozen.

Thorough Washing - Alternatively or in addition to the previous process, stomachs can be washed at +65-70°C (sometimes lower temperatures) for between 6 and 15 minutes in order to wash the inner surface of the stomach; they are then rinsed and hung on racks to drain. Full racks are moved to the chiller for chilling to +3°C or below. They may be frozen for delivery to an approved tripe processing plant.

Scalding - involves treatment at higher temperatures, reaching normally +85-90°C for between 6 and 15 minutes to degrease and refine the outside surface of the stomach.

Note: Time/temperature parameters of washing and scalding are the most commonly used. FBOs need to identify their optimal conditions for their process based on the HACCP principles.

Note: Requirements for butcher shops selling green tripe to the final consumer

1. ‘Green tripe’ or ‘tripe’ is offal; it originates from the forestomach of ruminants.
2. Green tripe must only be sourced from an approved slaughterhouse with packaging bearing the identification mark of that establishment. The mark denotes that the product has been produced in accordance with the regulations following ante-mortem inspection of the animal from which it derived and satisfactory post-mortem inspection. The product should arrive visibly clean and should have been kept at no more than +3°C during transport.
3. As with all foods, butchers selling green tripe directly to the final consumer need to comply with the relevant requirements of Regulation (EC) No 852/2004. Appropriate food safety management procedures based on HACCP principles should be followed to minimise the potential risk of other foods stored in the shop becoming contaminated with foodborne pathogens which may be associated with this type of product.
4. A ‘one step back’ traceability trail needs to be maintained. When retailing to final consumers, customer records are not required.

5. The product should be labelled correctly with the name of the food appearing on either a label attached to the food or on a ticket or notice at the point of sale.

Food business operators must ensure that food satisfies the requirements of food law which are relevant to their activities (Article 17 of Regulation (EC) 178/2002 refers).

In addition, green tripe (untreated) can also be sold directly from the slaughterhouse to the final consumer.

Storage in cold stores is also permitted, only when intended for further processing and if the stomachs are emptied and visibly clean from extraneous contamination. It is advisable to label the product with clear information to make customers aware of the need for the product to be further processed.

3.1.4 Intestines

Harvesting - In the gut room, the small intestine is separated from the stomach; it is then separated from the mesentery and the large intestine, either mechanically or by ‘pulling’.

Manure Stripping – Intestines must be emptied and cleaned (i.e. stripped) in the slaughterhouse of harvesting. They are passed through a manure stripper (a set of rollers) to squeeze out the intestinal contents without damaging the sub-mucosa. Once the intestines are emptied of intestinal content, these are called ‘runners’. In some cases, the equipment can also act as a crusher and begin the process of removing the mucosa. After stripping, the runners are tied into hanks and put into containers of cold water, with or without salt, to await further processing – either in the same premises or in another establishment approved for that purpose.

Note: the term ‘cleaning’ is used for the process of removing the layers of the intestine to leave the sub-mucosa i.e. the casing, which will then be salted to become a ‘treated’ product. Treatment must take place in an establishment approved for this activity. Intestines, runners and unsalted casings are considered to be untreated and unprocessed products.

As offal, runners must be kept in hygienic conditions and cooled on a chilling curve that ensures a continuous decrease of the temperature to +3°C or below. After manure stripping and washing, runners may either be treated at the slaughterhouse, if approved for this activity, or transported directly to another establishment approved for that purpose. They may also be transported frozen.

3.1.5 Treatment

Stomachs, bladders and intestines become ‘treated’ only when they are salted, heated or dried.

Heating, salting and drying are used as a treatment/preservative method, because most bacteria, fungi and other potentially pathogenic organisms cannot survive high temperatures, a highly salty environment due to the hypertonic nature of salt, or low water activity. Any living cell in such an environment will become dehydrated and die or become temporarily inactivated. The processes of salting and drying must be included in the documented HACCP based procedures and the FBOs should have a validation system in place on the process to ensure food safety.

3.1.6 Identification marking

Stomachs, bladders and intestines despatched treated or destined for treatment should bear an appropriate Identification Mark (Annex II of Regulation (EC) 853/2004, refers).

3.1.7 Export

Untreated stomachs, bladders and intestines can be exported for further handling destined for human consumption, provided these are cleaned and fully emptied of digestive tract content. It is advised that these products are exported with clear information in the labelling, for example: “untreated stomachs, for further processing”.

For further details for export requirements refer to the export chapter.

3.2 Ruminant heads, feet, and cattle ears (scalded or depilated)

3.2.1 Introduction

This section covers the processing of ruminant heads, feet, and cattle ears for human consumption.

Note: In relation to heads, SRM requirements apply and only heads with no SRM can be destined for human consumption.

3.2.2 Legislation

Carcases and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals the heads of ovine and caprine animals and calves, the muzzle and lips of bovine animals and the feet of bovine, ovine and caprine animals. Heads, including muzzle and lips, and feet must be handled in such a way as to avoid contamination. Regulation (EC) 853/2004, Annex III, Section I, Chapter IV, Paragraph 8.

When destined for further handling, heads and feet must be skinned or scalded and depilated. Regulation (EC) 853/2004, Annex III, Section I, Chapter IV, Paragraph 18.

3.2.3 Harvesting & processing

Ruminant heads, feet, and cattle ears destined for human consumption (edible co-products), must be skinned and or scalded and depilated, and they must be subjected to PMI.

In relation to PMI, ruminants’ heads, must be presented in such a way so that PM inspection can be carried out effectively in compliance with the requirements of Regulation 853/2004 and **updated:** [Articles 20 & 21 of assimilated Regulation (EU) 219/627 to the satisfaction of the OV.]

Unprocessed ruminant feet could also be despatched to another red meat abattoir or red meat cutting plant, to be scalded and depilated or skinned there. In this case, feet must be visibly clean before being dispatched.

Heads of cattle destined for human consumption can also be despatched to a cutting plant authorised for this specific activity, but these must be skinned before they leave the establishment of slaughter
Note: (Heads of cattle 8 months old or younger can be either skinned or scalded and depilated).

Updated: [For further information on the postmortem inspection of sheep heads refer to chapter 2.4 Post Mortem Inspection.]

i. Feet processed on site:

Post-mortem inspection can be done before or after further treatment (such as dehairing) on an individual basis or in batches at the abattoir.

If post-mortem inspection takes place before treatment, a further spot check will be needed to ensure that these feet are free from any pathology.

Food grade caustic soda (sodium hydroxide) may be used as a processing aid to help in the removal of the hair of the feet. It should be thoroughly rinsed off afterwards and its use must be included in the HACCP plan for the processing operation. Caustic soda must not be used in any part of the slaughter operation or for carcase washing.

ii. Feet processed at a different approved site:

Post-mortem inspection must be done on an individual basis or in batches at the abattoir.

After treatment a further spot check will be needed to ensure that these feet are visibly clean and free from visible pathological lesions before shipping for further processing.

When authorised by the competent authority, visibly clean feet may be transported to and skinned or scalded and depilated in an approved establishment further handling the feet for processing into food (paragraph 18, Chapter IV, Section I, Annex III of Regulation (EC) No. 853/2004).

Applicable to all cases

Processed or unprocessed, ruminant heads, feet, and cattle ears, a full correlation system must be implemented by the FBO to ensure that if a carcase is detained and subsequently condemned, the entire correlated batch is disposed of as unfit for human consumption. FBOs may assist the inspection process and set aside feet with identified abnormalities.

The final product or the edible co-product destined for further handling is to be dispatched with the ID mark clearly applied according to legislative requirements to the container and/or packaging used.

There is no specific requirement to additionally authorise or approve the processing of ruminant feet, cattle ears and heads, as these activities can be considered part of the slaughter process, the exception being the processing of ruminant feet at a different establishment as detailed above.

3.3 Cattle and sheep masks and lips (muzzles)

3.3.1 Introduction

This section covers the processing of cattle and sheep masks and muzzles for human consumption.

Cattle and sheep masks refers to the skin of the head after flaying. It does not include the ears or the eyelids but may include lips and the muzzle of cattle and sheep. It should not include the area of skin that surrounds the bolt hole (where this method of stunning is used) as there is a risk that it will be contaminated with specified risk material (SRM). For practical purposes and to minimise the risk of cross-contamination it is advisable to remove this as soon as possible.

There is no specific requirement to additionally authorise or approve the harvesting of cattle and sheep masks and/or muzzles, as this activity can be considered as part of the slaughter process.

The cattle masks guidance can be found in Annex 1.

3.3.2 Harvesting & processing

Cattle and sheep masks and muzzle can only be harvested in approved slaughterhouses from animals that have passed both ante mortem and post-mortem inspection.

Where the masks are intended for human consumption, they must also be scalded and depilated. Only masks that have been harvested at the slaughterhouse may be processed at that slaughterhouse. Masks cannot be taken to another slaughterhouse for cleaning/processing (i.e. scalding and depilating), neither can they be brought in from another slaughterhouse or other premises – even if these other premises are in the same ownership or are very close to the slaughterhouse of harvesting. Therefore, masks for human consumption must not leave the site of harvesting until they have been adequately processed and all hair has been removed (paragraph 18, Chapter IV, Section I, Annex III of Regulation (EC) No. 853/2004).

Food grade caustic soda (sodium hydroxide) may be used as a processing aid to help in the removal of the hair of the masks. It should be thoroughly rinsed off afterwards and its use must be included in the HACCP plan for the processing operation. Caustic soda must not be used in any other part of the slaughter operation or for carcase washing.

The food hygiene legislation does not permit burning the hair from the head's skin of any animal other than for small amounts of hair that have not been removed by the scalding operation.

'Raw' (or just harvested) cattle masks waiting to be processed for human consumption are offal. As offal, the masks should be stored at no more than +3°C.

3.3.3 HACCP/SOPs

All stages of the process must be included in the food business operator's HACCP based food safety management system. The food business operator must develop and agree with the incumbent OV the relevant SOPs that ensure hygienic production. The risk of SRM contamination from eyes that are damaged during slaughter and dressing needs to be taken into consideration and masks and muzzles from heads with damaged eyes must not be harvested. Also, if a captive bolt system of stunning was used, the SOP will include trimming the area around the bolt hole.

The food business operator must also have a system to ensure that unfit product, e.g. masks and muzzles from carcases which have been considered unfit for human consumption, do not enter the food chain. If the material has been batched before inspection and cannot be correlated to the condemned carcase, the whole batch must be treated as Animal By-Products.

If the mask (or head) is separated from the rest of the carcase before completion of the post-mortem inspection, the food business operator must have a system/procedure in place to link the mask with the carcase.

3.3.4 Identification marking

Processed cattle masks and muzzles (final product) intended for human consumption leaving the slaughterhouse must be clearly marked on the container or packaging with an oval identification mark bearing the information laid down in Section I, Annex II of Regulation (EC) 853/2004.

3.4 Bile and gallbladders

3.4.1 Introduction

This section covers the harvesting, handling and despatch of bile or gallbladders for human consumption as food or as an ingredient for the pharmaceutical industry. This section also covers the process of concentrating bile for export to third countries.

There is no specific requirement to additionally authorise or approve the harvesting of bile and/or gall bladders as this activity can be considered part of the slaughter process.

To note that bile and gallbladders may also be harvested as Category 3 animal by-product, in this case all stages of this process must be kept separated from the production of bile and gallbladders for human consumption.

Where bile is being supplied as a pharmaceutical and is **not intended to be, or cannot be, used as food**, then the EU food hygiene provisions will not apply but separate authorisation under ABP /Medicinal Products legislation will most probably be required in these instances. These cases will need to be discussed with APHA and/or VMD individually.

3.4.2 Legislation

Bile is considered to have no significant use as food and as such, would require authorisation under the Novel Food Regulation 2009 before it may be placed on the market within the UK.

3.4.3 Harvesting of bile and gallbladders

Bile and gallbladders can only be harvested in approved slaughterhouses from animals that have passed both ante and post-mortem inspection. Once harvested for human consumption, bile and gallbladders must be treated as edible co-product by being stored and despatched under temperature-controlled conditions same as offal.

3.4.4 Export

Bile and gallbladder can be harvested/pre-processed for export for either food or for pharmaceutical use.

Where bile and gallbladders are intended for export for food use, it should be treated as an edible co-product with the FBO treating the harvesting, collection, storage and transport of bile and/or gallbladders in-line with the same food hygiene requirements as fresh meat/offal.

It will be necessary for the FBO responsible for exporting the product to demonstrate that the product they produce complies with any legal requirements that might exist for this product in the country of destination. The OVs will want to satisfy themselves that the products to be exported do comply with the requirements in the country of destination in the same way as for any product exported to a third country.

In addition to the requirements of the importing country, the product must not be injurious/harmful to human health. The UK competent authority responsible must request evidence from the food business operator that the product is safe, e.g. does not contain excessive levels of heavy metals or other contaminants. It has also been reported that gall bladders can also act as a reservoir for Salmonella. Therefore, the FBO should consider all these factors during the hazard analysis.

Where activities include concentrating the raw material for export, there is an expectation that the food business operator should be able to provide evidence on how any food safety risks associated with the final product have been assessed under the HACCP based principles. In addition, verification by the relevant UK competent authority is required prior to the operations commence.

There might be instances where the FBO will also need an Export Health Certificate for this product. If more advice is required, then contact should be made with APHA.

3.5 Gelatine and Collagen

3.5.1 Introduction

This section covers the manufacture of gelatine and collagen for human consumption as well as the collection and storage of raw materials intended to be used for the manufacture of gelatine and collagen for human consumption.

Gelatine can be used for pharmaceutical or photographic processes whilst Collagen may be produced also for medical and cosmetic purposes. Those are not included in the scope of this chapter.

Establishments that generate or process raw material for the production of gelatine or collagen for human consumption must be registered, approved or specifically authorised by the competent authority.

Approval will not be required however if the premises carry out only transport operations or storage of products not requiring temperature-controlled storage conditions (Regulation (EC) 853/2004, Article 4.2).

3.5.2 Legislation

Regulation (EC) No 853/2004:

Annex I, point 7.7 - definition for gelatine: ‘Gelatine’ means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.

Annex III, Section XIV, Chapter I, Paragraph 3 – raw materials for the production of gelatine.

Annex I, point 7.8 - definition for collagen: ‘Collagen’ means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation.

Annex III, Section XV, Chapter I, Paragraph 3 – raw materials for the production of collagen.

Regulation (EC) No 2073/2005

Annex I, Chapter 1, point 1.10 - Food Safety Criteria (Salmonella), for edible gelatine/collagen.

International trade:

- **Regulation (EU) 2019/625**, Article 7 (e), quotes that in order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent, products from establishments manufacturing raw materials intended for the production of gelatine and collagen, should only be allowed entry into the Union if these establishments appear on lists drawn-up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission.
- Import of Gelatine and Collagen for Human Consumption from Third Countries (February 2020)

3.5.3 Raw material

Raw materials for the manufacture of gelatine or collagen for human consumption may include:

- Bones, other than specified risk materials as defined in Article 3(1)(g) of Regulation (EC) No. 999/2001.
- Hides and skins of farmed ruminant animals.

- Pig skins.
- Poultry skin.
- Tendons and sinews.
- Wild game hides and skins.
- Fish skin and bones (not covered in this MOC Chapter)

Such raw material can originate from approved (e.g. slaughterhouses, cutting plants), registered (e.g. butcher shops, establishments handling fishery products) or specially authorised sites (e.g. collection centres and tanneries) complying with Reg. (EC) 852/2004 and fulfilling the requirements laid down in Reg.853/2004 (see subchapter 3.5.2).

The registration/approval/special authorisation number of those sites will be recorded in the document accompanying the raw material (see Annex 2 of this MOC chapter).

Raw materials must derive from animals that have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante-mortem and post-mortem inspection (including a negative result from the BSE test where this is required by Community legislation) or, in the case of hides and skins from wild game, found fit for human consumption.

The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed. For the purpose of this section, ‘tanning’ means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

When hides and skins are not intended for the production of edible gelatine or collagen, then they become animal by-products. They must be handled and stored separately from hides and skins destined for the production of edible gelatine/collagen.

If the raw materials (e.g. hides) are separated from the carcase before completion of the post-mortem inspection, the operator must establish a system to ensure that if a carcase is declared unfit for human consumption or it is detained, any body parts from that carcase are also declared unfit or are detained.

If it is impossible to identify the hide or other body part from a particular carcase declared unfit, the entire batch of hides or other body parts derived from that carcase must be declared unfit.

3.5.4 Treatment

Examples of treated raw materials for the production of edible **gelatine** and details on the applicable treatments are listed in Regulation (EC) No 853/2004, Annex III, Section XIV, Chapter I, Paragraph 4.

Treatment requirements for the manufacture of gelatine (production process for gelatine) are quoted in Regulation (EC) No 853/2004, Annex III, Section XIV, Chapter III, Paragraph 1.

On a similar note, examples of treated raw materials for the production of edible **collagen** and details on the applicable treatments are listed in Regulation (EC) No 853/2004, Annex III, Section XV, Chapter I, Paragraph 4.

Treatment requirements for the manufacture of collagen (production process for collagen) are quoted in Regulation (EC) No 853/2004, Annex III, Section XV, Chapter III, Paragraph 1.

A food business operator may produce and store both gelatine/collagen intended for human consumption and gelatine/collagen not intended for human consumption in the same

establishment, provided that the raw materials and the production process comply with the requirements applying to gelatine/collagen intended for human consumption.

3.5.5 Temperature controls

Raw material for the production of gelatine/collagen for human consumption must be transported and stored chilled (to below +3°C) or frozen, unless they are dispatched and processed within 24 hours after their production.

However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

3.5.6 Identification mark

When delivered to a collection centre or tannery, the raw material used in the manufacture of gelatine or collagen must, instead of carrying an identification mark, be accompanied by a document containing the information set out in the Appendix to Annex III of Regulation (EC) No. 853/2004. This document can be found in Annex 2 to this MOC chapter.

Collection centres and tanneries supplying raw material to a gelatine or collagen processing establishment must ensure that the raw materials are accompanied by the document described above.

Once produced, the gelatine/collagen must bear an identification mark containing the approval number of the gelatine/collagen plant where they were produced.

3.5.7 Labelling

Wrapping and packaging containing gelatine must bear the words “gelatine fit for human consumption” and must indicate the date of minimum durability (Regulation (EC) 853/2004, Annex III, Section XIV, Chapter V).

Wrapping and packaging containing collagen must bear the words “collagen fit for human consumption” and must indicate the date of preparation (Regulation (EC) 853/2004, Annex III, Section XV, Chapter V).

3.6 Rendered animal fats and greaves

3.6.1 Introduction

Rendering is the process of extracting fat for human consumption from meat by melting (heat treatment), with the greaves being the protein containing the residues of the rendering process.

3.6.2 Legislation/Approval of premises

Food business operators must ensure that establishments collecting or processing raw materials for the production of rendered animal fats and greaves and preparing rendered animal fats and greaves, comply with the requirements laid down in Regulation (EC) No. 853/2004, Annex III, Section XII.

Establishments that collect or process raw material to produce rendered animal fats and greaves must be approved by the competent authority. Approval will not be required if the premises carries out only transport operations, or the storage of products not requiring temperature-controlled storage conditions.

3.6.3 Raw materials

Raw materials must:

- derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection
- consist of adipose tissues or bones which are reasonably free from blood and impurities; and
- come from establishments registered or approved under Regulation (EC) No. 852/2004 or Regulation (EC) No. 853/2004.

3.6.4 Processing and temperature controls

Raw material for the production of rendered animal fats and greaves (unless the fat is rendered within 12 hours after the day on which they were obtained) must be transported and stored at an internal temperature no greater than +7°C.

Centres for the collection of raw materials and further transport to processing establishments must be equipped with facilities for the storage of raw materials at a temperature of not more than +7°C.

However, the above refrigeration facilities are not necessary if the arrangements for the supply of raw materials ensure that they are either (a) never stored or transported without active refrigeration, or (b) rendered within 12 hours after the day on which they were obtained.

Greaves intended for human consumption must be stored in accordance with the following temperature requirements:

a) When greaves are rendered at a temperature of not more than +70°C, they must be stored: at a temperature of not more than +7°C for a period not exceeding 24 hours; or at a temperature of not more than –18°C.
b) When greaves are rendered at a temperature of more than +70°C and have a moisture content of 10% (m/m) or more, they must be stored: at a temperature of not more than +7°C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee; or at a temperature of not more than –18°C.
c) When greaves are rendered at a temperature of more than +70°C and have a moisture content of less than 10% (m/m), there are no specific requirements.

During the rendering of raw materials, the use of solvents is prohibited. Rendered animal fat, depending on the type, must meet the standards laid down in the table in point 4 of Chapter II of regulation (EC) 853/2004, Annex III Section XII.

Please be aware that temperature requirements are now different for Northern Ireland.

As per Regulation (EU) 2021/1374 (which amended Reg 853/2004) There are no longer any temperature requirements for the storage of greaves. *Technological developments have allowed certain packaging techniques, such as vacuum-packaging for which the specific temperature requirements are not needed to ensure the safety of food derived from greaves. Food business operators should ensure the safety of food derived from the greaves by good hygiene practices and procedures based on Hazard Analysis and Critical Control Point (HACCP) principles.*

3.6.5 Identification mark

Both the raw material (i.e. the fat and/or bones) and the final product (i.e. the rendered animal fats and greaves) must bear an identification mark showing the approval number of the establishment

where they were produced.

3.7 Immature eggs

3.7.1 Introduction

OVs have observed FBOs harvesting and selling “eggs” at various stages of their development for human consumption, when “spent hens” are consigned to slaughter. This includes:

- fully formed eggs laid naturally following their consignment from a production site to a poultry slaughterhouse and during lairaging and hang on,
- what appear to be fully formed eggs “pulled” from dead birds after killing and prior to evisceration,
- what appears to be fully formed eggs with cracked shells found either in the lairage or on the evisceration line,
- nearly fully formed eggs that are harvested from the evisceration line,
- immature ova / yolks, harvested from the dead bird after PMI for sale to the Kosher market, for what are described as “traditional products”.

3.7.2 Definition

“Eggs” are defined as eggs in shell — other than broken, incubated or cooked eggs — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.

3.7.3 Legislation

Regulation (EC) 853/2004, Annex I, Point 5.1

Regulation (EC) 589/2008, Article 1(k)

For further reference please see annex 3

3.7.4 Collection of eggs

3.7.4.1 Collection at different steps in the slaughterhouse

Slaughterhouses do not satisfy the relevant definitions of “producer”, “registered production site”, “collection centre” or “a packing centre” and therefore FBOs cannot sell shell eggs. As such, those eggs will not comply with the definition of fresh eggs.

FBO will not be able to give eggs away to plant staff for free.

The only exception refers to FBO harvesting fully formed eggs for their own personal consumption.

Eggs that have not been laid prior to the animal’s death, cannot be “eggs” by definition, but would fall under the definition of “offal” - fresh meat, other than that of the carcase, including viscera and blood.

As offal, the “egg” could be harvested as an edible co-product, ID marked and sold for human consumption,

3.7.4.2 Harvest of ova/yolk

The unformed proto eggs or ova would fall under the definition of “offal”. However, harvesting such products should only be done after the completion of a successful ante and post mortem inspection at which there are no grounds to declare the carcase / offal unfit for human consumption.

The harvesting of offal is a legally permissible activity, provided that a hazard analysis has been undertaken, risks are being managed, the product is treated hygienically, appropriately chilled to 3 degrees C, ID marked and labelled correctly as a food product, with appropriate allergen labelling.

3.7.4.3 Disposal

Eggs must be disposed of as Category 3 Animal By-products.

If eggs originate from an animal rejected with a condition communicable through the egg itself to humans or animals, it would be a Category 2 ABP.

See Annex 3 for more information related to the harvesting of eggs in poultry abattoirs.

4. FBO Role

4.1 HACCP

Edible co-products can only be harvested in approved slaughterhouses from animals that have passed both ante and post-mortem inspection.

All stages of the process must be included in the food business operator’s HACCP based food safety management system, as per any other food process. The FBO has to consider hazards associated with the relevant steps and processes and subsequently implement controls to ensure food safety.

As unprocessed edible co-products might be handled in approved slaughterhouses and cutting plants, the risk of cross-contamination between these products and meat or other products must be taken into consideration.

The food business operator must also have a system to ensure that unfit product (for example co-products from carcases that have been considered unfit for human consumption), does not enter the food chain and that a clear separation is kept between products intended for human consumption and animal by-products.

If edible co-products are further processed, the process should be validated and verified under the HACCP principles.

4.2 Batching system

The FBO shall have in place a batching system when harvesting certain edible co-products (for example feet, heads, ears) in case a carcase has to be disposed of as an animal by-product.

This means that co-products must be correlated with carcases and offal. A batching system is acceptable provided that in the case of a post-mortem rejection of a carcase, the entire batch of related co-products is rejected. Any edible co-product batching system must provide full correlation with the carcasses and offal.

5. FSA Role – Inspection, Verification and Audit

5.1 Inspection duties in slaughterhouses

5.1.1 OV duties

In addition to the normal controls, the OV should carry out verification checks to ensure that the meat complies with the required regulatory regime applicable to edible co-products.

Those checks should be made to ensure:

- The overall hygiene performance around edible co-products generated and/or processed on site.
- The OV includes these as part of the off-line duties for the Official Auxiliaries
- The supervision of the hygienic processing, separation, storage, temperature requirements, packaging, wrapping, ID marking and commercial documents are included
- Production takes place in line with the on-site HACCP and all relevant legal requirements
- Edible co-products are consigned to appropriate premises (i.e. approved, registered) and that accompanying documentation is correct and has been completed accurately (for example ABP commercial documents are not to be used for the transport of edible co-products)
- With regards to segregation, ABP and co-products are clearly separated (for example hides intended for gelatine/collagen production from ABP hides).
- The product bears an identification mark in accordance with Article 5 and Annex II of Regulation (EC)853/2004. Identification marks are applied, even when the product is destined for further processing before being placed on the market for human consumption.

5.1.2 Frequency of checks

The OV is to ensure that the production of edible co-products is part of the routine hygiene verification checks. The frequency of these checks is proportionate to:

- Size of the establishment
- Volume and type of co-products
- Layout
- History of compliance (including audit score)

For further guidance, see chapter 2.4 section 12 and 13: Slaughter hygiene Verification in Red Meat and Poultry.

Note: The FSA is no longer required to carry out 100% checks on compliance with SRM removal requirements. However, the OV must verify that the FBO has robust systems in place to ensure that meat entering the food chain is free from SRM. For example, Sheep or cattle heads containing SRM).
However, 100% verification of the removal of spinal cord SRM from relevant cattle and sheep carcases is still required.

5.2 Inspection duties in cutting plants

Some cutting plants may process edible co-products as part of their normal operation.

These operations are to be covered during the unannounced inspection (UAI) visits and under the audit scope. There is not a dedicated section in the UAI report for edible co-products, so they are to be included within the general supervision sections.

Authorised Officers inspecting this kind of plants are to be familiar with this section of the MOC and the relevant legal requirements when assessing these activities

5.3 Identification marking

Regulation (EC) 853/2004, Chapter II, Article 5, paragraph 1 states that “Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has an identification mark applied in accordance with Annex II, Section I, of this Regulation.”

Edible co-products are therefore to be dispatched bearing an ID mark even when going for further processing. The exception being the dispatch of hides for collagen and gelatine as per section 3.5.6.

AO supervising edible co-product related issues are to verify application of ID mark takes place before dispatch.

When an establishment receives raw materials for further processing as edible co-products, they are to be ID marked as per Regulations.

Note: It is important to bear in mind the ID marking requirements for liquids (i.e. bile, melted fat, etc). In particular Regulation (EC) 853/2004, Annex II, Section I, point C, paragraph 12, where it is quoted that "In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains an indication of the country of origin (GB), the approval number and be on oval shape”. That would be for instance applicable to the transport of bile if in containers.

If the edible co-products are no longer intended for human consumption or they are handled and/or stored unhygienically, they become unsuitable for human consumption and should be treated as ABPs and dealt with as such. Once they have been downgraded to ABPs, they cannot revert into the human food chain.

5.4 Audit duties

The FBO’s food safety management procedures based on HACCP principles, associated records and processes will be assessed during audit both at slaughterhouses and at cutting plants involved in the supply chain.

Information about the auditing process can be found in Chapter 4.1 There is a specific section in the FBO Audit Aide Memoire (section 3.4), that covers the handling of edible co-products.

Reference: Chapter 4.1 Audit, Annex 1 ‘Audit Aide Memoire’.

6. Enforcement

Edible co-products are food so the same hierarchy of enforcement that applies to fresh meat should be used, see Chapter 7 “Enforcement”.

Deficiencies found by the AO are to be recorded in CHRONOS and the daybook when available (i.e. slaughterhouses and VC removal authorised cutting plants).

7. Annexes

Annex 1 Guidance on the harvesting and processing of cattle masks for human consumption

Note: This Guidance is provided on the basis of current science and knowledge. It will be reviewed if new science or evidence emerges.

Introduction

1. A number of approved slaughterhouses in the UK are interested in harvesting/ processing cattle masks for human consumption. The following guidance will help those food business operators to undertake this activity hygienically. Regulations (EC) Nos. 852/2004 and 853/2004 will apply to this activity. This guidance may also be used for harvesting/processing the masks of other animals for human consumption should food business operators wish to consider doing this.
2. For ease of reference, throughout this document ‘cattle masks’ refers to the skin of the head after flaying. It does not include the ears or the eyelids but may include lips and the muzzle of cattle. It should not include the area of skin that surrounds the bolt hole (where invasive stunning is used) as there is a risk that the skin in the proximity of the bolt hole will be contaminated with specified risk material (SRM). Please refer to paragraphs 12 and 18 for further details.
3. Cattle masks for human consumption must only be harvested from heads originating from animals that have been slaughtered in an approved slaughterhouse and whose carcases have been found fit for human consumption following ante mortem and post-mortem inspection. Full traceability is required, therefore if the mask is separated from the rest of the hide, or the head is separated from the carcase before completion of the post-mortem inspection, the food business operator must have a system/procedure in place to correlate

the mask and/or the head with the carcase.

4. This must ensure that if a carcase is declared unfit for human consumption the mask and/or the head is also declared unfit and is removed from the slaughter/processing area as an animal by-product (ABP). When it is impossible to identify the head and/or the mask from a particular carcase that has been declared unfit, the entire batch of heads/masks must be declared unfit and consigned as ABP. The category of ABP will depend on the reason for rejection. Any batching system must provide full traceability with the carcass and offal of origin.
5. At no point should skins, including masks, for human consumption - or other material for human consumption - be classified as, or come into contact with, material that is not fit for human consumption or that has been labelled as ABP. Slaughterhouse procedures should be arranged so that there is clear separation and cross contamination is, at all times, avoided. If the cattle masks do come into contact with ABPs then they too should be treated as ABP and immediately removed from the food area.
6. Unprocessed cattle masks intended for human consumption are offal. As offal, the masks should be stored at no more than 3°C. The finished product is an edible co-product that should also be stored and refrigerated at no more than 3°C (or frozen) including during transport and despatch to another food premises.
7. Only cattle masks that have been harvested at the slaughterhouse may be processed at that slaughterhouse. Unprocessed masks cannot be taken to another slaughterhouse for cleaning/processing (i.e. scalding and/or depilating), neither can they be brought in from another slaughterhouse or other premises – even if these other premises are in the same ownership or are very close to the slaughterhouse of harvesting. It is not permissible for the cattle masks to be stored at an off-site cold/chill store until the slaughterhouse is ready to process them.
8. Whilst masks can be produced from cattle of any age, **heads** of cattle 8 months old or younger if destined for further handling for human consumption must be either skinned or scalded and depilated; this must be undertaken before they leave the establishment of slaughter. The scalding and depilation of heads of cattle over 8 months is not permitted.

Processing cattle masks

9. Bovine heads intended for human consumption must be completely skinned, except for the muzzle and lips (paragraph 8, Chapter IV, Section I, Annex III of Regulation (EC) No. 853/2004, refers).

10. In the case of calves, if the heads are not skinned, they must be scalded and depilated before leaving the premises of harvesting (paragraph 18, Chapter IV, Section I, Annex III of Regulation (EC) No. 853/2004).

11. Normal practice at most slaughterhouses in the UK is to remove the head from the carcase before skinning the head in preparation for post-mortem inspection; alternatively, the head can be left attached to the carcase until after the skin has been completely removed (where using a hide puller to remove skin from carcase and head) then removing the head for inspection. The mask is then removed from the rest of the hide.

12. If an invasive system of stunning was used, an area of approximately 5-10cm radius around the bolt hole should be removed to mitigate the risk of cross contamination from leakage of brain tissue and/or CNS fluid. This is better achieved if done before scalding and depilation.

13. Cattle masks should be processed in a separate part of the premises and not in the same area in which slaughter takes place. During and after processing there should be clear separation to avoid the risk of cross contamination of the processed mask from other processed or unprocessed masks/foods, the slaughter hall and other parts of the premises or actions undertaken in or around the premises. After processing, cattle masks should be visibly clean and

the skin should be free of hairs, extraneous detritus and other contamination.

14. The processing of cattle masks must form part of the food business operator's HACCP system and must take into account potential hazards, including the potential for cross contamination with other material or ABPs and contamination with SRM. At all times, before and after processing, masks must be stored and despatched at no more than 3oC.

15. Food grade caustic soda (sodium hydroxide) may be used as a processing aid[1] to help in the removal of the hair of the masks. It should be thoroughly rinsed off afterwards and its use must be included in the HACCP plan for the processing operation. The food hygiene legislation does not permit burning/singeing the hair from the head skin of any animal other than for small amounts of hair that have not been removed by the scalding operation.

SRM controls

16. There is no legal requirement to plug the bolt hole where the invasive system of stunning is used or the foramen magnum, when part of the head is intended for human consumption except when head meat is harvested offline (i.e. without removing the bovine head from the hook) or when the head is transferred to a registered cutting plant to be processed, in which case, it is required to plug the bolt hole.

17. However, to achieve best practice, sealing the bolt hole with an impermeable and durable stopper would help to reduce the risk of cross contamination resulting from the leakage of brain tissue and CNS fluid. Additional precautions include to avoid the harvesting of any head meat where the eyes are damaged and to handle the mask carefully for avoiding accidental contamination from the foramen magnum dripping during the harvesting and handling.

18. To reduce the risk of contamination with SRM from around the captive bolt hole a piece between 5 and 10cms in diameter around the hole should be removed. The exact size should be decided on a case-by-case basis, in consultation with the relevant veterinary staff at the plant and considering the way the carcases and heads are handled in those premises and the method of collection of the head skin. This practice should be built into the operating procedure for removing the mask. There is no legal requirement to sample masks for CNS contamination when they are harvested in the slaughterhall line without removing the bovine heads from the hook or directly from the pulled hide.

Approval

19. Harvesting and processing cattle masks does not require a separate approval, but this activity should be recorded as part of the operations undertaken at a slaughterhouse when consideration of approval is sought or when a food business operator starts this process.

20. Processed (i.e. scalded, depilated and cleaned) cattle masks for human consumption are considered to be an edible co-product and should leave the slaughterhouse with the appropriate commercial documentation and bearing the ID mark of the slaughterhouse.

Traceability

21. Article 18 of Regulation (EC) No. 178/2002 requires food business operators to be able to identify the person or persons from whom they have received food (including food producing animals) for human consumption and to whom they have supplied food for human consumption.

22. To achieve this, food business operators must have in place systems and procedures that allow for the full traceability of food, including food-producing animals, entering their premises. This traceability must be maintained throughout all stages of production, processing and

distribution. This information must be made available to the competent authorities on demand.

Compulsory Beef Labelling Scheme

23. Cattle masks fall outside the scope of the Compulsory Beef Labelling Scheme.

[1] ‘processing aid’ is defined in Regulation (EC) No 1333/2008, as meaning any substance which:

i. is not consumed as a food by itself.

ii. is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

iii. may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product.

Annex 2 Model documentation to accompany raw material destined for the production of collagen / gelatine

Number of the commercial document:…….

I. Identification of raw material Nature of the raw material:……

Animal species:……

Type of packaging:……

Number of packages:……

Net weight (Kg):……

II. Origin of raw material Type, name, address and approval/registration/special authorisation number of the establishment of origin:

……

Name and address of the consignor[1]……

III. Destination of raw material Type, name, address and approval/registration/special authorisation number of the production establishment of destination:

……

Name and address of the consignee[2] :……

IV. Means of transport:……

Done at:……On……

(Signature of the operator of the establishment of origin or its representatives)

1 Only if different from the establishment of origin.

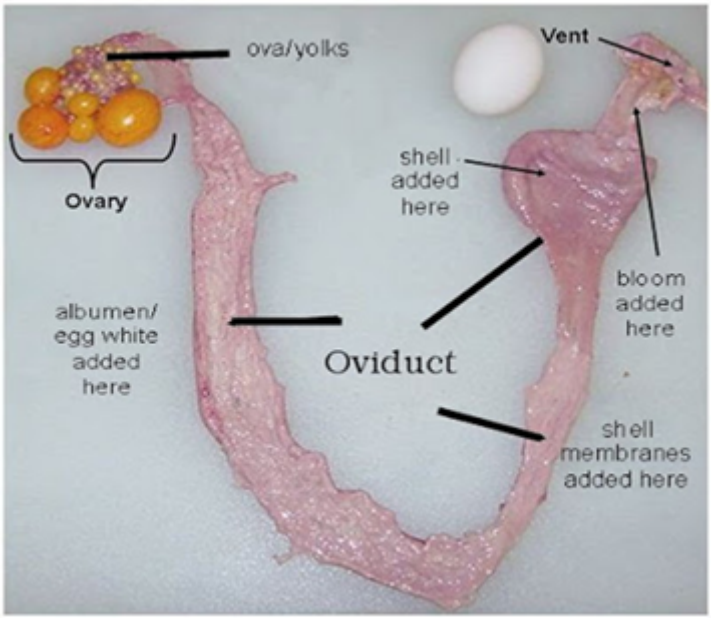
2 Only if different from the establishment of destination.

Annex 3 Q&A Harvesting of eggs at poultry slaughterhouses for human consumption

Q1. What are the Issues?

OVs have observed FBOs harvesting and selling “eggs” at various stages of their development for human consumption, when “spent hens” are consigned to slaughter. This includes:

- fully formed eggs laid naturally following their consignment from a production site to a poultry slaughterhouse and during lairaging and hang on,
- what appear to be fully formed eggs “pulled” from dead birds after killing and prior to evisceration,
- what appears to be fully formed eggs with cracked shells found either in the lairage or on the evisceration line,
- nearly fully formed eggs that are harvested from the evisceration line,
- immature ova / yolks, harvested from the dead bird after PMI for sale to the Jewish community, for what are described as “traditional products”.



Q2. What is the legal definition of an “egg”?

“Eggs” are defined in:

Regulation (EC) 853/2004, Annex I, Point 5.1 “eggs in shell — other than broken, incubated or cooked eggs — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.

Regulation (EC) 589/2008, Article 1(k) ‘eggs’ means eggs in shell — other than broken, incubated or cooked eggs — that are produced by hens of the species Gallus gallus and are fit for direct human consumption or for the preparation of egg products;

Q3. Can shell eggs that have been naturally laid and found; in transport crates following transport from a production site to a slaughterhouse, or in the hang on section of the lairage prior to the bird being killed, be marketed and sold for human consumption, either:

- **as Class A / B eggs,**
- **sold at a local public market,**
- **door to door, or**
- **at the factory gate.**

No. Whilst fully formed eggs in shell, laid naturally prior to the death of the bird, comply with the definition of “eggs” in both the egg marketing and food hygiene legislation, the eggs were not laid:

- whilst at a “production site” [defined in Regulation (EC) 589/2008, Article 1(p) as an “establishment keeping laying hens, registered in accordance with Commission Directive

2002/4/EC"], and subsequently

- sent to a "packing centre" [defined in Regulation (EC) 589/2008, Article 1(q) to mean a packing centre within the meaning of Regulation (EC) No 853/2004 that is authorised according to Article 5(2) of this Regulation and where eggs are graded by quality and weight. Regulation (EC) 853, Annex I, Point 5.4 defines a packing centre as an establishment where eggs are graded by quality and weight], or
- to a "collector" [defined in Regulation (EC) 589/2008, Article 1(c) as an establishment registered in accordance with Article 6 of Regulation (EC) No 852/2004 to collect eggs from a producer for delivery to a "packing centre", to a market selling exclusively to wholesalers whose undertakings are "approved" as packing centres, or to the food or non-food industry], which the slaughterhouses does not do.

To be sold to retail or catering establishments or sold at markets direct to consumers, shell eggs have to comply with the "Class A" definition of fresh eggs under the marketing requirements and be weighed, graded or supplied with the appropriate marketing information from a packing centre.

To be sold as "Class B" eggs, they must only be delivered to the food industry or to the non-food industry, but only if they bear a label with the dispatching packing centre details, packing centre code and marked with "Class B" or "B" and display a packing date.

The FBO of the slaughterhouse could not be "registered" under Article 6 of Regulation (EC) 852/2004 as a "collection centre", as collectors by definition transport ungraded eggs from registered producers to packing centres, the food industry or non-food industry, which they do not!

Slaughterhouses do not satisfy the relevant definitions of "a registered production site" or "a packing centre" and therefore FBOs cannot sell eggs direct to the final consumer in a retail transaction, to the food industry, from the "farm gate" or "door to door" and could not comply with the labelling and traceability requirements required in the marketing legislation.

Even though FBOs can be exempt from the requirements of the EU Hygiene Regulation (EC) where there is a "direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer", this does not exempt them from the EU marketing regulations and the slaughterhouse FBO is not a producer of eggs as a primary product or a production site as defined above [Regulation (EC) 852/2004, Article 1(2)(d) and Regulation (EC) 853/2004, Article 1(3)(c)].

Q4. Can an FBO give ungraded shell eggs away to plant staff for free?

No. Giving or selling eggs to plant staff will fall under the definition of "marketing" [Regulation (EC) 589/2008, Article 1(n) means holding eggs for the purpose of sale, including offering for sale, storage, packing, labelling, delivery, or any other form of transfer, whether free of charge or not] and would be unlawful under the egg marketing legislation.

Member States may exempt FBOs from the requirements of Regulation (EU) 1308/2013, where eggs are sold directly to the final consumer by the producer:

(a) on the production site, or

(b) in a local public market or by door-to-door selling in the region of production of the Member State concerned (Regulation (EU) 1308/2013, Annex VII, Part VI, Point I. 2).

Slaughterhouse FBOs are not "producers" and cannot take advantage of this exemption.

Eggs sold by "producers" to final consumers at local public markets in the region of production of the Member State, must still be marked with quality and weight grading stating either - Class A or

"fresh" or Class B. Member States may exempt producers from this requirement who have no more than 50 laying hens, provided that the name and address of the “producer” is indicated at the point of sale.

Q5. Can an FBO harvest fully formed eggs for their own personal consumption?

Yes. The domestic preparation, handling or storage of food for private domestic consumption is exempt from the scope of Regulations (EC) 853/2004, Article 1(3)(c) / Regulation (EC) 178/2002, Article 1(3) and would fall outside the definition of marketing under Regulation (EC) 589/2008, Article 1(n).

Q6. Can eggs recovered from the lairage or from transport crates prior to the birds death that are cracked, be sold to the food industry as eggs, or for the manufacture of “egg products” or “liquid eggs”?

No. The use of eggs with cracked shells is only permitted for use as a raw material, if they have been consigned directly from a “production” site or “packing centre” to an approved establishment for the manufacturer of liquid eggs or to a processing establishment where they must be broken as soon as possible [Regulation (EC) 853/2004, Annex III, Section X, Chapter II, Part II, point 1].

Q7. Can “eggs” retrieved from a dead bird on the processing line during evisceration or pulled from a dead bird prior to evisceration, which have not been physically laid naturally by the bird prior to its death and the shells of which are not fully developed, be sold for human consumption?

Raw materials used for the manufacture of egg products must come from eggs, the shells of which are fully developed and which must have been supplied from the establishment of “production” or from a “packing centre”.

Eggs that have not been laid prior to the animal’s death, cannot be “eggs” by definition, but would fall under the definition of “offal” in Regulation (EC) 853/2004, Annex I, Point 1.11 and 1.12:

- Offal - fresh meat, other than that of the carcase, including viscera and blood,
- Viscera - includes organs of the thoracic, abdominal and pelvic cavities as well as the trachea and oesophagus and in birds the crop.

As offal, the “egg” could be harvested as an edible co-product, ID marked and sold for human consumption, however, there does not appear to be a market for such a product and FBOs are consigning such products as Category 3 ABP.

Q8. Is it lawful for FBOs to harvest for human consumption the ova / yolk (in the early stages of its development before the point at which the albumen / shell membrane is added) to be used in soups for the Jewish and other communities?

Yes, the unformed proto eggs or ova would fall under the definition of “offal” in Regulation (EC) 853/2004 (see above). However, harvesting such products should only be done after the completion of a successful ante and post-mortem inspection at which there are no grounds to declare the carcase / offal unfit for human consumption.

Whilst an argument had been raised that a flexibility could be applied under the Hygiene Regulations for the harvesting of such proto eggs as a traditional method or product demanded by the Jewish and other communities as an ingredient for traditional soups etc. this is not the case, given that the harvesting of offal is a legally permissible activity, provided that a hazard analysis has been undertaken, risks are being managed, the product is treated hygienically,

appropriately chilled to 3°C, ID marked and labelled correctly as a food product, with appropriate allergen labelling.

Q9. How are proto eggs currently being harvested?

When harvesting yolks for the kosher Market ova have been:

- collected carefully from the oviduct at the evisceration point after PMI, to ensure correlation to rejections is possible,
- repeatedly salted, soaked and washed before wrapping, ID marking and refrigeration or freezing,
- sold to the final consumer directly from the plant or to kosher shops that sell to the final consumer without modification to the product, variation in the ID marking or packaging used by the slaughterhouse,
- sold without the appropriate labelling required when selling direct to the final consumer or to mass caterers under Regulation (EU) 1169/2011, namely:
    - durability marking, Article 24 and Annex X,
    - instructions for use, Article 27,
    - storage conditions or conditions for use, Article 25,
    - labelling for certain substances or products causing allergies or intolerances, Article 21 and Annex II.

Q10. Can this harvesting method mitigate against potential pathogens and the risk that the unprotected egg yolk can become contaminated during extraction and further handling?

Science colleagues provided the following advice:

- Concerns over the risk of salmonella, mycobacterium avium (M. avium) etc. in laying hen flocks should be evident in the FCI. UK flocks are either vaccinated or state negative results after intensive testing (e.g. every 15 weeks) as such the health risk is minimal.
- It is highly unlikely that laying hens will have had antimicrobials administered that require a withdrawal period, but this is monitored by VMD who sample regularly.
- When assessing the microbiological risk relating to pathogenic survival in partially formed eggs after a salting and cleansing procedure, risks may be mitigated where the flocks from which the eggs were laid are Salmonella (SE and ST) negative and this is reported in the FCI.
- Based on historical CCIR, the presence of M. avium in slaughtered flocks is unlikely, but that should be determined by PMI findings in every batch (i.e. - presence of tubercular nodules in intestine, liver, spleen, ovaries and bone marrow but the pulmonary lesions, which are a striking feature of tuberculosis in other species, are rarely observed in birds).
- M. avium can cause infections in people who are immunocompromised, and evidence indicates that M. avium can survive the acidic conditions in the human stomach (pH <3) and infection could occur via the gastrointestinal tract.
- The yolk should be heat treated for the appropriate time / temperature (70°C for 2 minutes or equivalent), which should destroy microbial vegetative cells. It would be advisable to have a label indicating that adequate heat treatment is necessary, in the same way other potential pathogen associated with fresh meat or offal can be eliminated or reduced to an acceptable level if cooked correctly. Yolks inserted into soup raw, may result in an insufficient heat treatment depending on the stage at which the egg is added to the soup and its temperature.
- The procedure of salting yolks before being added to the soup will not in itself mitigate against M. avium, as it is salt tolerant and research undertaken on casings, found M. avium survival in salted guts.

Q11. What is the appropriate disposal route for fully formed shell eggs laid naturally or partially formed eggs harvested from the dead animal?

If the FBO cannot legally harvest eggs for human consumption / to plant staff or to consume them personally, eggs must be disposed of as Category 3 Animal By-products (Article 10, K (ii) of Regulation (EC) 1069/2009). Failure to do so can be enforced through the service of a notice under Regulation 25 (2) of the domestic Animal By-products (Enforcement) England Regulations 2013 to require their disposal. If eggs originate from an animal rejected with a condition communicable through the egg itself to humans or animals, it would be a Category 2 ABP. In practical terms this is unlikely but would include entire carcases rejected prior to extracting the egg from the hen, and there are very few conditions communicable through eggs to human or animals linked to a full rejection.

Likewise, it is impossible to correlate the bird from which a fully formed shell egg has been derived when they are being collected in the lairage or from transport crates. This loss of correlation may have implications for eggs from birds subsequently rejected later in the process.

Definitions

Regulation (EC) 853/2004, Annex I, defines:

- ‘Eggs’ means eggs in shell, other than broken, incubated or cooked eggs — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.
- ‘Liquid egg’ means unprocessed egg contents after removal of the shell.
- ‘Cracked eggs’ means eggs with damaged shell and intact membranes.
- ‘Packing centre’ means an establishment where eggs are graded by quality and weight.
- ‘Egg products’ means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.
- ‘Offal’ means fresh meat other than that of the carcase, including viscera and blood.
- ‘Viscera’ means the organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop.

Regulation (EC) 589/2008, Article 1 defines:

- ‘Collector’ means any establishment registered in accordance with Article 6 of Regulation (EC) No 852/2004 to collect eggs from a producer for delivery to a packing centre, to a market selling exclusively to wholesalers whose undertakings are approved as packing centres, or to the food or non-food industry.
- ‘Eggs’ means eggs in shell — other than broken, incubated or cooked eggs — that are produced by hens of the species Gallus gallus and are fit for direct human consumption or for the preparation of egg products.
- ‘Broken eggs’ means eggs showing breaks of both the shell and the membranes, resulting in the exposure of their contents.
- ‘Marketing’ means holding eggs for the purpose of sale, including offering for sale, storage, packing, labelling, delivery, or any other form of transfer, whether free of charge or not.
- ‘Operator’ means a producer and any other natural or legal person involved in the marketing of eggs.
- ‘Production site’ means an establishment keeping laying hens, registered in accordance with Commission Directive 2002/4/EC (1).

Regulation (EC) 178/2002, Article 2 defines:

- ‘Primary products’ means products of primary production including products of the soil, of stock farming, of hunting and fishing.