contents

5 Chapter 5

Animal By-Products

Introduction

1. This Guide is written for operators of meat plants to help them understand the legislative requirements on the handling of animal by-products and edible co-products. It is without prejudice to the TSE legislation. This document is particularly relevant to operators of slaughterhouses sending animal by-products and edible co-products to other premises for further processing.

2. Although the difference between **edible products** ("meat") and **animal by-products** is generally well understood, the status of **edible co-products** has sometimes been misunderstood by operators and enforcers alike. The differences between these three categories of products are illustrated in the table below.

Edible products ("meat")	**Edible Co-products**	**Animal By-products**		
Examples	**Examples**	**Examples**		
		Category 3	**Category 2**	**Category 1**
• Wholesale and retail meat • Carcase material used for meat recovery (eg 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.	• Parts of animals slaughtered and found fit, but not intended, for human consumption.	• Dead on arrival • Post mortem failures • Soiled or contain medicine residues	• TSE positives • SRMs
>>>>>>>>>>>> one way only >>>>>>>>>>>>>>>>				

Edible Products

3. The most obvious products of animals are **edible products** ("meat") which are intended for human consumption (eg carcasses, offal, etc). Rules for the production of this are explained in the Meat Industry Guide (see paragraph 8).

Animal By-Products

4. Parts of an animal which are *not intended for human consumption* are animal by-products. These can include parts of animals which are perfectly fit for human consumption but which are not *intended* for human consumption, such as heads, feet and some offal. Once these have become animal by-products, they cannot later return to the human food chain. Rules on the handling of animal by-products (which are mainly set out in Regulation (EC) No. 1069/2009, Regulation (EC) No. 142/2011- the Implementing Regulation - and the Animal By-Products (Identification) Regulations 1995 (as amended)) are explained in Chapter 5 of this Guide. As this guide is aimed at operators of meat plants, it does not cover the rules applying to animals that die on farm or other products of animal origin – eg dairy, eggs or fishery products.

Edible Co-Products

5. There are also some parts of animals that are unsuitable for human consumption when they are produced at the slaughterhouse, but which can later be processed for use in human food. Examples of these would be hides and skins later processed into gelatine and collagen, sheep intestines processed into sausage casings, and omental fat processed into lard.

6. The raw materials for these products have often been called “by-products” at the slaughterhouse, leading to the mistaken belief that these can be handled like animal by-products (above). For the purpose of this Guide, and to avoid this confusion, we call these edible co-products. The rules on the handling of these in meat plants are explained in Chapters 1 to 4 of this Guide.

Layout of the guide

7. The requirements for these products have not always been well understood, and the Guide attempts to explain these in a way that is helpful for operators. In particular, each chapter is colour coded and much of the Guide is split into three columns, each giving different information as follows:

   - the left column sets out the **legal requirements,** usually by reproducing the actual words of the relevant Regulation;
   - the middle column is a **guide to compliance** with those legal requirements, and sets out to explain in Plain English what operators have to do to comply with the legislation, and
   - the right column contains **recommendations for best practice** which would go beyond the minimum legal requirements. **These are not obligations and take up by operators is optional.**

Hygiene Legislation

8. This Guide should be read alongside the *Guide to Food Hygiene and Other Regulations for the UK Meat Industry* (or “Meat Industry Guide”) which explains the legislation that applies to the hygienic production of meat more generally. These are Regulation (EC) No. 852/2004, which sets out the hygiene requirements for food production generally and Regulation (EC) No. 853/2004, which sets out the specific hygiene requirements for production of products of animal origin. In addition, Regulation (EC) No. 854/2004 sets out the official control requirements for products of animal origin for enforcement authorities.

Interpretation

9. .This Guide sets out the Food Standards Agency’s best understanding of the legislative requirements. Every effort will be made to keep it up-to-date in line with changes to the legislation or amendments to its interpretation but if you have any queries please contact Rosalind Glover at Rosalind.glover@foodstandards.gsi.gov.uk or ring her on 020 7276 8320.

Chapter 1

Rendered Animal Fat and Greaves

WHY ARE HYGIENE REQUIREMENTS IMPORTANT FOR THE PRODUCTION OF RENDERED ANIMAL FAT AND GREAVES?

The production of rendered animal fat and greaves must be carried out so that physical, chemical and microbiological contamination is prevented. Micro-organisms that cause food poisoning (e.g. salmonella, campylobacter and *E.coli*) can be present in healthy animals from which the raw materials for rendered animal fats and greaves are derived, thus posing a risk to the consumer.

USE OF THE TERM "RENDERING"

Food business operators should be aware that the use of the term "rendering" in this chapter and in the relevant provisions of Regulation (EC) No. 853/2004 is a term reserved exclusively to indicate the processing of edible fat for human consumption. It should not be confused with rendering of/for animal by-products purposes.

The term is also used and can be confused with the processing of animal by-products into meat and bone meal and tallow. In this guidance it should be interpreted as the process of extracting fat for human consumption from meat by melting (heat treatment).

PREMISES		
Approval of premises		
Legal requirements	**Guide to Compliance**	**Recommendations for best practice**
Establishments that collect or process raw material for the production of rendered animal fat 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. *(Regulation (EC) 853/2004, Article 4.2)*	Establishments collecting or processing (fat and greaves) intended for human consumption must be approved by the relevant competent authority. For premises that are co-located with a slaughterhouse, cutting plant or game handling establishment this will be the Food Standards Agency. In all other cases it will be the local food authority. Establishments needing approval would therefore include, for example: • plants processing the raw material into rendered animal fats and greaves for human consumption ("melting plants"); and • plants collecting or storing raw material and requiring temperature-controlled storage. However establishments that only carry out transport and/or ambient temperature storage of raw materials (fat and greaves) are exempt from approval. Such establishments must nevertheless be registered as food establishments under Regulation (EC) No. 852/2004. **Further information –** Please refer to Part One, Chapter 7, Approval of Fresh Meat Establishment, of the Meat Industry Guide.	

Design and layout - general		
Legal requirements	**Guide to Compliance**	**Recommendations for best practice**
The layout, design, construction, siting and size of food premises are to permit good food hygiene practices, including protection against contamination. *(EC 852/2004, Annex II Chapter I, General requirements: para 2(c))*	**Further information –** Please refer to Part Two, Chapter 1, Design & Facilities of the Meat Industry Guide at: http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	

Design and layout – specific		
Legal requirements	**Guide to Compliance**	**Recommendations for best practice**
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. Each processing establishment /melting plant must have: • refrigeration facilities; • a dispatch room, unless the establishment dispatches rendered animal fat only in tankers; and • if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings. 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. *(EC 853/2004, Annex III, Section XII, Chapters I and II)*	All premises must have refrigeration facilities capable of storing raw material at no more than 7 °C, unless: • alternative arrangements are made to ensure that the raw material is stored and transported at no more than 7°C, or • arrangements are made to ensure that the raw material is rendered by midday the day after it was obtained. Raw material must therefore be stored and transported at an internal temperature of 7°C or less unless it is rendered by midday the day after it was obtained. At the melting plant, if the rendered animal fat is mixed with other foodstuffs or seasonings the equipment for doing so must be such as to prevent contamination.	Rooms that are used for chilling should be designed to chill the product as rapidly and as hygienically as possible. Equipment designed to promote rapid and thorough chilling, such as racks, shallow trays, etc., should be available. In areas or rooms of the establishment where raw material is handled or stored, the operator should have appropriate equipment to control and monitor the temperature on a regular basis.

Separation in the slaughterhouse		
Legal requirements	**Guide to Compliance**	**Recommendations for best practice**
To avoid contaminating meat, slaughterhouses (including game handling establishments) must: • have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis; • ensure separation in space or time of evisceration and further dressing, handling clean guts and tripe, packaging offal and dispatching meat; • have lockable facilities for the refrigerated storage of meat declared unfit for human consumption; • have a special area or place for storing manure or digestive tract content if stored in the slaughterhouse. *(EC 853/2004, Annex III, Section I, Chapter II, 2(b)(c), 5, 8)*	It is the plant operator's responsibility to ensure that all dressing procedures are conducted in a hygienic manner so that meat/ material for human consumption is not contaminated. This includes providing for separation of the different dressing activities and separation between edible co-products and inedible by-products. Food business operators should look at the entire operation to determine locations and/or activities that can be separated to minimise the potential for contamination. Rooms for emptying and cleaning stomachs and intestines can be where animal fat for rendering is obtained. These are probably the dirtiest rooms in the plant and must be properly isolated from operations on fresh meat carried out in the rest of the premises. Wherever separation in time is permitted, the processing area and equipment must be cleaned by washing, and disinfected before reuse. Containers used to hold material or meat unfit for human consumption must be specifically identifiable and be equipped with a lock, to prevent malicious or accidental contamination of meat for human consumption. Where fat is harvested during dressing of the carcass, FBOs should consider whether this fat is for human consumption or for animal feed and should be handled accordingly, eliminating risks of cross-contamination, as necessary.	Best practice would be to ensure that separate rooms are provided for: (a) evisceration; (b) separating the raw material from fresh meat and animal by-products; (c) storing it; (d) packaging it; and (e) dispatching it. This reduces the risk of contamination.

HYGIENE		
Post-mortem inspection		
Legal requirements	**Guide to Compliance**	**Recommendations for best practice**
Until *post-mortem* inspection is completed, parts of a slaughtered animal subject to such inspection must remain identifiable as belonging to a given carcass and must not come into contact with any other carcase, offal or viscera, including those that have already undergone post-mortem inspection. *(EC 853/2004, Annex III, Section I, Chapter IV, 13)* After *post-mortem* inspection: • parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment; • meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption *(EC 853/2004, Annex III, Section I, Chapter IV, 16(b) and (c))* If the offal of several animals is collected in the same container before completion of *post-mortem* inspection, the entire contents must be declared unfit for human consumption if the carcass of one or more of the animals concerned has been declared unfit for human consumption. *(EC 853/2004, Annex III, Section I, Chapter IV, 15)*	If the raw materials (fat and greaves) are separated from the carcass before completion of the *post-mortem* inspection, the operator must establish: • a system to ensure the separate *post-mortem* inspection of those raw materials (fat and greaves), and • a system to ensure that if a carcass is separately declared unfit, the raw materials (fat and greaves) from that carcass are also declared unfit and disposed of accordingly. When it is impossible to identify the raw material from a particular carcass declared unfit, the entire batch of raw materials (fat and greaves) which might have been derived from that carcass must be declared unfit. Where the raw material (fat and greaves) is for human consumption (following further processing) it should be labelled as such and kept separate from any material that is not for human consumption – ie it is ABP. All raw material (fat and greaves) must be kept in clean containers; with separate containers for food for human consumption, and for ABPs.	Best practice would be to ensure that the raw material remains identifiable with the carcase/offal until the *post-mortem* inspection is complete. This would eliminate the need for an entire batch of raw materials (fat and greaves) to be declared unfit when a carcass is declared unfit.

Hygiene in the slaughterhouse		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
Measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning. *(EC 853/2004, Annex III, Section I, Chapter IV, 7(c))*	The operator is responsible for maintaining, at all times, the proper separation of meat fit for human consumption and animal by-products. This includes the separation of raw materials (fat and greaves) intended for human consumption and those not intended for human consumption (which are animal by-products – see "animal by-products" section below). Such animal by-products should be stored in an entirely separate part of the slaughterhouse, so that they could neither be confused with food material, contaminate it nor be substituted for it. The operator is also responsible for providing plant facilities, equipment and staff for the collection, hygienic handling and disposal of inedible by-products. **Further information**: please refer to the section "Separation from animal by-products" below and to Chapter 5, Animal by-products, of this guide and to Chapter 1, Design and Facilities (Section D), Part Two of the Meat Industry Guide. Link to the Meat Industry Guide: http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	During evisceration care must be taken to prevent the contamination of the carcass by faecal matter and gut contents in particular. Accidental opening of stomachs and tripes can lead to contamination spreading to internal and external surfaces of the carcass. To avoid cross contamination, plant staff empting stomachs and intestines should wash their hands and clean and disinfect their work clothing and equipment before entering the clean sector of the slaughterhouse. Best practice would be to ensure that 'gut-room' staff are not permitted to enter any other processing room. This further reduces the risk of contamination. Containers/liners/trays of raw material, fat and greaves should be covered or otherwise closable. When liners are used as containers they should be disposable, of a suitable strength/ durability and should be sealed. This also further reduces the risk of contamination.

Raw materials (fat and greaves)		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
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; • come from establishments registered or approved under Regulation (EC) No.852/2004 or Regulation (EC) No. 853/2004. *(EC 853/2004, Annex III, Section XII, Chapter II, 1(a)(b)(c))*	See section "*"Post-mortem* inspection", above, on how to ensure that the raw material comes from animals which have passed *ante-mortem* and *post-mortem* inspection. Fat trimmings/tissues harvested from carcasses prior to *post-mortem* inspection cannot be used unless they too have passed a separate *post-mortem* inspection (see section *"Post-mortem* inspection" above). Any visual contamination (e.g. faecal) on the fat which cannot be removed by washing should, wherever possible, be removed by, for example, trimming. At the melting plant, incoming raw materials (fat and greaves) should be inspected upon receipt to ensure that they are suitable for processing and as free as is reasonably possible from blood and impurities, including faecal contamination.	Best practice would be to ensure that fat is as free from blood and impurities as is practically possible including faecal contamination when it is collected at the slaughterhouse. The hygienic collection of clean fatty tissues from carcasses fit for human consumption should be carried out as speedily as possible. After collection they should be refrigerated immediately, unless they are rendered by midday the day after they were obtained. A plant employee should be responsible for examining the raw material prior to further handling i.e. chilling and packing. At the melting plant, best practice would be to ensure that raw materials (fat and greaves) are received and inspected in a separate area from the processing area.

Treatment (Processing Plant)		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
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 the legislation (and reproduced at Annex I of this Chapter, for ease of reference). *(EC 853/2004, Annex III Section XII, Chapter II, paras 2 and 4)*	The table in point 4 of Chapter II (see Annex 1) sets out maximum levels of insoluble impurities, peroxide and FFA in the rendered fat. It also requires odour, taste and colour in the rendered fat to be normal. Rendered animal fat for refining may, provided it meets the standards in the table, be refined to improve its physic-chemical quality in the same rendering plant or elsewhere.	The operator should carry out regular checks to ensure that the standards in the table in point 4 of Chapter II of Regulation (EC) No. 853/2004 are being met and maintained.

Temperature Controls		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
Raw material for the production of rendered animal fats and greaves (unless the fat is rendered within 12 hours after the day it was obtained) must be transported and stored at an internal temperature no greater than 7°C. 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. *(EC 853/2004, Annex III, Section XII, Chapter II, paras 1(d) and 5)*	Raw material must be stored and transported at an internal temperature of 7°C or less unless it is rendered by midday the day after it was obtained. The design of refrigeration facilities must ensure the maintenance of an appropriate temperature throughout the product. It must also ensure the hygienic storage and/or transport of the product. There is no temperature requirement for the transport or storage of animal fat once it has been rendered at the processing/melting plant.	Best practice would be to ensure that the raw material is stored and transported at no more than 7°C, even if it is to be rendered by midday the day after it was obtained. Once greaves have been produced at the processing/melting plant, best practice would be to freeze them at a temperature no higher than –18°C.

Identification Marking		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
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 at which they were handled and prepared. *(EC 853/2004, Article 5)*	In most cases, the raw material will bear the identification mark of the slaughterhouse or other meat plant at which it was obtained, and the final product will bear the identification mark of the processing/melting plant. **Further information -** please refer to Chapter 13, Traceability of Food (Identification and Health Marking), Part Two of the Meat Industry Guide. Link to the Meat Industry Guide: http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	

Traceability		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Food business operators must, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin. *(EC 178/2002, Article 18 EC 853/2004, Annex II, Section I, A4)*	The requirement applies a "one step back one step forward" approach. Each operator in the supply chain must have in place a system enabling him/her to identify the immediate supplier(s) and immediate customer(s) of his/her products. .	A documentary control system will provide a clear paper trail for tracing and tracking consignments of stomachs, bladders and intestines to their destination. The information should include date, description of consignment, consignor's/ sender's details including address and approval number, haulier's and consignee's/ receiver's details including address and approval number. A model Document Control System can be found at Annex 2.

ANIMAL BY-PRODUCTS		
Separation of raw material for human consumption from animal by-products		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
For the purposes of the Animal by-products (ABPs) legislation, ABPs are defined as: entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen. *(EC 1069/2009, Article 3.1)* The legislation requires that at all stages there must be a clear separation between material for human consumption and ABPs. *(Implementing Regulation (EC) No. 142/2011, Annex IV, Chapter I, Section 1)* ABPs must be handled and disposed of according to Regulation (EC) No. 1069/2009. *(EC 1069/2009: Article 12 (Cat 1); Article 13 (Cat 2); Article 14 (Cat 3))*	Animal fat (e.g. from the omentum) is normally disposed of as ABP immediately after *post-mortem* inspection. However, when it is intended for human consumption, it is important that they are handled not as ABPs, but in line with the requirements of the food hygiene legislation. The important point is the **intention** of the material since products become ABPs as soon as the operator decides that they are no longer intended for human consumption. Once the operator has decided that he does not intend or no longer intends raw materials (fat and greaves) to go for human consumption, they become ABPs and stay that way. As ABPs they cannot revert to being a food-stuff. The operator is obliged to dispose of ABPs appropriately (e.g. by consignment to a registered/ approved ABP premises). In practical terms, this would involve re-labelling the material as ABP when it is dispatched. The operator is responsible for supervising and maintaining, at all times, the proper separation of material intended for human consumption from that which is ABP. This includes the separation of animal fat and greaves for human consumption and those not intended for human consumption (ie ABPs). Such ABPs should be stored in an entirely separate part of the slaughterhouse, so that they can neither be confused with food material, contaminate it or be substituted for it.	See section “separation in the slaughterhouse” above, for best practice on hygienic handling and separation of ABPs from material intended for human consumption.

Labelling		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
The legislation requires that ABPs must be labelled as such and be conveyed directly to the legitimate plant of destination. *Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter II)*	Material becomes ABP when it is not or is no longer **intended** for human consumption (see "separation from animal by-products" section above). If an operator labels material as animal by-products, that is clear evidence of their intention. Material/food to go into the human food chain must not be labelled as ABP. If it is, these products will be treated as ABPs and will not be able to go back into the food chain.	Strict separation of ABPs from material intended for human consumption reduces the risk of the latter being mis-labelled as ABP or of ABP inadvertently being transferred to the human food chain. See also the 'Best practice' column in the above section on 'Separation in the slaughterhouse'.

Storage of food material in ABP processing plants		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
ABP plants must not engage in activities other than those in connection with which they are registered or approved. ABP plants must also be adequately separated from food premises. *(EC 1069/2009, Article 26 and EC 142/2011, Annex IV, Chapter I, Section I)*	Although not desirable, it is possible for raw materials (fat and greaves) intended for human consumption (i.e. food material) to be consigned to a site on which an ABP plant is situated, before it is consigned to a processing/ manufacturing premises, but strict conditions apply at the ABP plant. These include: • the ABP plant and the food plant must be clearly and demonstrably separate; • food material cannot under any circumstances be taken into the ABP plant; • the ABP plant must be approved or registered under Regulation (EC) No. 1069/2009; • the food plant must be registered under Regulation (EC) No. 852/2004 or approved under Regulation (EC) No. 853/2004	Best practice would be to transport raw materials (fat and greaves) intended for human consumption direct from the slaughterhouse to the melting/processing plant, without passing through sites that contain ABP plants. This greatly reduces the risk of cross-contamination and of ABPs being diverted into the food chain. If, however raw materials (fat and greaves) intended for human consumption are held in a food premises which shares a site with an ABP plant, a number of additional precautions could be taken to reduce the risk of diversion or cross-contamination. For

	(see section “approval of premises” above). To be demonstrably separate, the food plant and the ABP plant that share the same site must have separate boundaries and separate entrances, with no common air space. This is to ensure that under no circumstance does food enter the ABP plant nor ABPs enter the food plant.	example, containers should be of a different colour or type so as to distinguish those used for food from those used for ABPs. There should also be no interchange of personnel between the food plant and the ABP plant, nor any interchange of equipment. There should also be separate staff changing facilities.

Documentation requirements		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
The legislation requires operators to ensure that ABPs are accompanied during transport by a commercial document or a health certificate, as necessary. *Regulation (EC) No. 1069/2009, Article 21)* ***See also the section on Traceability, above.***	See the Chapter on “Documentation Requirements” in Chapter 5 of this Guide.	See the Chapter on “Documentation Requirements” in Chapter 5 of this Guide.

Transport of ABPs and food		
Legal requirements	**Guide to compliance**	**Recommendation for best practice**
Operators consigning, transporting or receiving ABPs shall keep a record of consignments and related commercial documents or health certificates. *(EC 1069/2009, Article 22 (traceability)* Where conveyances and/or containers are used for transporting anything in addition to food material, there must where necessary be effective separation of products. *(EC 852/2004, Annex II, Chapter IV)* ABPs must be collected and transported in sealed new packaging or covered leak-proof, lidded and correctly labelled containers or vehicles. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 1)* During transport, ABPs must be maintained at an appropriate temperature to avoid any risk to animal or public health. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 2)*	The requirement applies a "one step back one step forward" approach. Each operator in the supply chain must have in place a system enabling him/her to identify the immediate supplier(s) and immediate customer(s) of his/her products. If food material and ABPs are transported together, each container or liner used for ABPs must be of sufficient size and strength to safely hold its contents without spillage or leakage, throughout the transport process. There must be effective separation between the ABPs and the food material. Any vehicles or item of equipment that comes into contact with ABPs must be cleaned, by washing, and disinfected after each daily use. Containers must be kept clean and disinfected. Containers used for food material must be clearly identified and only used for the designated purpose. If food becomes mixed with ABPs then it must all be treated as ABPs. ABPs must be consigned only to permitted approved destinations. **Further information**: please refer to Chapter 5, Animal by-products, of this Guide.	A documentary control system will provide a clear, paper trail for tracing and tracking consignments of rendered animal fat to their destination. The information should include date, description of consignment, consignor's/ sender's details including address and approval number, haulier's and consignee's/receiver's details including address and approval number. A 4-part model Movement Document for Edible Fat can be found at Annex 2 of this chapter. Raw materials (fat and greaves) should be transported from the point of production to the processing/ melting plant as quickly as practicable. Best practice would be to ensure that food material and ABPs are not collected or transported in the same container or vehicle. This greatly reduces the risk of substitution or contamination. If, nevertheless, food material and ABPs are collected or transported together, an additional precaution would be to ensure that containers or liners are of a colour or type that distinguishes those for ABP use from those for food material.

WHAT ARE THE OFFICIAL CONTROL REQUIREMENTS?

Establishments that handle or process raw materials (fat and greaves) for the production of rendered animal fats and greaves intended for human consumption will be subject to the official control requirements of Regulation (EC) No. 854/2004. All establishments will therefore be subject to audit and inspection by the competent enforcement authority (which is the Food Standards Agency, Operations Division, York, in slaughterhouses, cutting plants and game handling establishments, and local food authorities elsewhere). The audits and inspections will contain the following elements:

- Audits of good hygiene practice and HACCP based procedures *(EC 854/2004, Article 4(3))*
- Checks that the operators' procedures guarantee, to the extent possible, that meat does not show evidence of faecal or other contamination *(EC 854/2004, Annex I, Section I, Chapter I)*
- Visual *post-mortem* inspection of the gastro-intestinal tract,etc *(EC 854/2004, Annex I, Section IV, Chapter IB, paragraph 6, Chapter II, paragraph 6, Chapter IV B, Paragraph 1(f))*
- Checks on compliance with the requirements of Regulation (EC) No. 1069/2009 and the accompanying Implementing Regulation (*EC 854/2004, Article 4, paragraph 2(c)).*

ANNEX 1

Rendered animal fat, depending on type, must meet the following standards:

	Ruminants			Porcine animals			Other animal fat	
	Edible tallow		Tallow for refining	Edible fat		Lard & other fat for refining	Edible	For refining
	Premier jus (1)	Other		Lard(2)	Other			
FFA (m/m % oleic acid) maximum	0,75	1,25	3,0	0,75	1,25	2,0	1,25	3,0
Peroxide maximum	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg
Total insoluble impurities	Maximum 0,15 %			Maximum 0,5%				
Odour, taste, colour	Normal							

(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.

(2) Rendered animal fat obtained from the adipose tissues of porcine animals.

ANNEX 2

Model, 4-Part, Movement Document for Edible Fat

Part 1: for completion by Consignor/Sender (To accompany the consignment to its final destination and to be retained by the Receiver for 2 years from date of receipt)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**
Date	
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:
Address of Consignor/Sender:	
Description of the Material	Quantity/Weight of Material
Name of Haulage/Transport Company:	
Name of intended Consignee/Receiver:	
Address of intended Consignee/Receiver:	
Signed for Consignor/Sender:	Name :
	(Print)

Section 2 (to be completed by Haulier)	
Date Collected:	Time :
Signed for Haulier:	Name
(Driver)	(Print)

Section 3 (to be completed by the Consignee/Receiver)

Name of Consignee/Receiver:

Address of Consignee/Receiver:

I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.

Material Description	Quantity/ Weight	Approval/Registration No. of Consignee/receiver	Site	Signature & Date Received

Date Received:	Time :
Signed for Consignee/Receiver:	Name:
	(Print)

Model, 4-Part, Movement Document for Edible Fat

Part 2: to be returned to the Consignor/Sender by Consignee/Receiver (Consigner/Sender to match and keep with retained part 4 for 2 years)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**
Date	
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:
Address of Consignor/Sender:	
Description of the Material	Quantity/Weight of Material
Name of Haulage/Transport Company:	
Name of intended Consignee/Receiver:	
Address of intended Consignee/Receiver:	
Signed for Consignor/Sender:	Name :
	(Print)

Section 2 (to be completed by Haulier)	
Date Collected:	Time :
Signed for Haulier:	Name
(Driver)	(Print)

Section 3 (to be completed by the Consignee/Receiver)

Name of Consignee/Receiver:

Address of Consignee/Receiver:

I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.

Material Description	Quantity/ Weight	Approval/Registration No. of Consignee/receiver	Site	Signature & Date Received

Date Received:	Time :
Signed for Consignee/Receiver:	Name:
	(Print)

Model, 4-Part, Movement Document for Edible Fat

Part 3: for retention by Haulier (To be retained by haulier for 2 years from date of delivery)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**
Date	
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:
Address of Consignor/Sender:	
Description of the Material	Quantity/Weight of Material
Name of Haulage/Transport Company:	
Name of intended Consignee/Receiver:	
Address of intended Consignee/Receiver:	
Signed for Consignor/Sender:	Name :
	(Print)

Section 2 (to be completed by Haulier)	
Date Collected:	Time :
Signed for Haulier:	Name
(Driver)	(Print)

Section 3 (to be completed by the Consignee/Receiver)

Name of Consignee/Receiver:

Address of Consignee/Receiver:

I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.

Material Description	Quantity/ Weight	Approval/Registration No. of Consignee/receiver	Site	Signature & Date Received

Date Received:	Time :
Signed for Consignee/Receiver:	Name:
	(Print)

Model, 4-Part, Movement Document For Edible Fat

Part 4: to be retained by the Consignor/Sender (To be retained for 2 years from date of dispatch)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**
Date	
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:
Address of Consignor/Sender:	
Description of the Material	Quantity/Weight of Material
Name of Haulage/Transport Company:	
Name of intended Consignee/Receiver:	
Address of intended Consignee/Receiver:	
Signed for Consignor/Sender:	Name :
	(Print)

Section 2 (to be completed by Haulier)	
Date Collected:	Time :
Signed for Haulier:	Name
(Driver)	(Print)

Section 3 (to be completed by the Consignee/Receiver)				
Name of Consignee/Receiver:				
Address of Consignee/Receiver:				
I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.				
Material Description	Quantity/ Weight	Approval/Registration No. of Consignee/receiver	Site	Signature & Date Received
Date Received:		Time :		
Signed for Consignee/Receiver:		Name:		
		(Print)		

Chapter 2

Treated stomachs, Bladders and Intestines

WHY ARE HYGIENE REQUIREMENTS IMPORTANT IN THE PRODUCTION OF TREATED STOMACHS, BLADDERS AND INTESTINES?

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 when stomachs, bladders and intestines are treated for human consumption, in order to prevent these pathogens passing into the human food chain.

PREMISES		
Approval of premises		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Establishments that handle or treat stomachs, bladders and intestines must be approved by the competent authority. Approval will not be required if the establishment carries out only: • transport operations, or • storage of products not requiring temperature-controlled storage conditions. *(EC 853/2004, Article 4.2)*	Establishments handling stomachs, bladders and intestines intended for human consumption must be approved by the relevant competent authority. For establishments co-located with slaughterhouses, game handling establishments or cutting plants this will be the Food Standards Agency; in all other cases it will be the local food authority. Establishments needing approval would therefore include, for example: • plants manufacturing sausage casings ("manufacturing plants"); and • plants storing stomachs, bladders and intestines requiring temperature-controlled storage. However, establishments that only carry out transport and/or ambient temperature storage of stomachs, bladders and intestines that have already been heated, dried or salted are exempt from approval. Such establishments must nevertheless be registered as food establishments under Regulation (EC) No. 852/2004. **Further information** – please refer to Part One, Chapter 7, Approval of fresh meat establishments, Part One of the Meat Industry Guide.	

Design and layout		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The layout, design, construction, siting and size of food premises are to permit good food hygiene practices, including protection against contamination. *(EC 852/2004, Annex II, Chapter I: General requirements: paragraph 2(c))*	**Further information** – please refer to Chapter 1, Design & Facilities, Part Two of the Meat Industry Guide at: http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	
Separation in the Slaughterhouse		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
To avoid contaminating meat, slaughterhouses (inc game handling establishments) must: • have a separate room for emptying and cleaning the stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis; • ensure separation in space or time for evisceration and further dressing, handling clean guts and tripe, packaging of offal and dispatching meat; • have lockable facilities for the refrigerated storage of meat declared unfit for human consumption; • have a special area or place for storing manure or digestive tract content if stored in the slaughterhouse. *(EC 853/2004, Annex III, Section I, Chapter II, 2(b)(c), 5, 8)*	It is the plant operator's responsibility to ensure that all dressing procedures are conducted in a hygienic manner so that meat for human consumption is not contaminated. This includes providing for separation of the different dressing activities and separation between edible co-products and inedible by-products. Food business operators should look at the entire operation to determine locations and/or activities that can be separated to minimise the potential for cross-contamination. Rooms for emptying and cleaning stomachs and intestines are probably the dirtiest rooms in the plant and must be properly isolated from operations on fresh meat carried out in the rest of the premises. Wherever separation in time is permitted, the processing area and equipment must be cleaned by washing and disinfected before reuse. Containers used to hold meat or material unfit for human consumption must be specifically identifiable and be equipped with a lock, to prevent malicious or accidental contamination of meat for human consumption.	Best practice would be to ensure that separate rooms or areas are provided for: (a) cleaning the raw material, (b) treating it, (c) storing it after treatment, and (d) dispatching it. This reduces the risk of contamination.

HYGIENE		
Post-mortem Inspection		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Until *post-mortem* inspection is completed, parts of a slaughtered animal subject to such inspection must remain identifiable as belonging to a given carcass and must not come into contact with any other carcase, offal or viscera, including those that have already undergone post-mortem inspection. *(EC 853/2004, Annex III, Section I, Chapter IV, 13)* After *post-mortem* inspection: • parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment; • meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption. *(EC 853/2004, Annex III, Section I, Chapter IV, 16(b)(c))* If the offal of several animals is collected in the same container before completion of *post-mortem* inspection, the entire contents must be declared unfit for human consumption if the carcass of one or more of the animals concerned has been declared unfit for human consumption. *(EC 853/2004, Annex III, Section I, Chapter IV, 15)*	If the stomachs, bladders and intestines are separated from the carcass before completion of the *post-mortem* inspection, the operator must establish: • a system to ensure the separate *post-mortem* inspection of those stomachs, bladders and intestines, and • a system to ensure that if a carcass is separately declared unfit, the stomachs, bladders and intestines from that carcass are also declared unfit and disposed of accordingly. When it is impossible to identify the specific stomachs, bladders and intestines from a particular carcass declared unfit, the entire batch of stomachs, bladders and intestines that might include those derived from that carcass must be declared unfit for human consumption.	Best practice would be to ensure that stomachs, bladders and intestines remain identifiable with the carcass/offal until the *post-mortem* inspection is complete. This would eliminate the need for an entire batch of stomachs, bladders and intestines to be declared unfit when a carcass is declared unfit.

Hygiene in the Slaughterhouse		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning. *(EC 853/2004, Annex III, Section I, Chapter IV, 7(c)*	The operator is responsible for maintaining, at all times, the proper separation of meat fit for human consumption and animal by-products. This includes the separation of stomachs, bladders and intestines intended for human consumption and those not intended for human consumption (which are animal by-products – see "animal by-products" section below). Such animal by-products should be stored in an entirely separate part of the slaughterhouse, so that they could neither be confused with food material, contaminate it nor be substituted for it. The operator is also responsible for providing plant facilities, equipment and staff for the collection, hygienic handling and disposal of inedible by-products. **Further information –** please refer to the section: "Separation from animal by-products" below and to Chapter 5 Animal By-Products of this Guide and to Chapter 1, Design and Facilities (Section D), Part Two of the Meat Industry Guide. Link to the Meat Industry Guide: http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	Care must be taken during evisceration to prevent the contamination of the carcass by faecal matter and gut contents in particular. Accidental opening of stomachs and tripes can lead to contamination spreading to internal and external surfaces of the carcass. Where plant staff empty stomachs and intestines they should wash their hands and clean and disinfect their work clothing and equipment before entering the clean sector of the slaughterhouse to avoid cross contamination. However best practice would be to ensure that staff employed in the gut room are not permitted to enter any other processing room. This further reduces the risk of contamination. Containers/liners/trays of both raw and treated material should be covered or otherwise closable. When liners are used as containers they should be disposable, of a suitable strength/durability and should be sealed. This also further reduces the risk of cross-contamination.

Cleaning in the Slaughterhouse		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
When destined for further handling: • stomachs must be scalded or cleaned • intestines must be emptied and cleaned *(EC 853/2004, Annex III, Section I, Chapter IV, 18(a)(b))*	Stomachs and intestines intended for human consumption must be thoroughly cleaned and washed in the slaughterhouse i.e. manure stripped. Manure stripping must be done in such a way that prevents the contamination of already clean material. As a result of the cleaning and washing, the stomachs and intestines must be visually clean. They must be as free as is practically possible of visible faecal contamination.	

Temperature Controls		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Treated stomachs, bladders and intestines that cannot be kept at ambient temperature must be stored chilled until their dispatch, using facilities intended for that purpose. If they have been neither salted nor dried, they must be kept at a temperature of not more than +3°C. *(EC 853/2004, Annex III, Section XIII, 2 and Annex III, Section I, Chapter VII, 1 (a)).*	The requirement to chill to +3°C or lower applies to *treated* material that has been neither salted nor dried. This must be stored at +3°C or lower under hygienic conditions and be kept at that temperature before dispatch in refrigerated transport. The requirement to chill to +3°C or lower also applies to the untreated raw material (i.e. material that has been manure stripped but not salted, heated or dried) that leaves the slaughterhouse.	Best practice would be to chill the raw material as soon as it is recovered/harvested on a chilling curve that ensures a continuous decrease in temperature to +3°C.

Treatment (Processing)		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Animal intestines, bladders and stomachs may be placed on the market only if: a) they come from animals slaughtered in a slaughterhouse, which following *ante-mortem* and *post-mortem* inspection have been judged fit for human consumption b) they are salted, heated or dried, and c) after the treatment referred to in (b), effective measures are taken to prevent re-contamination. *(EC 853/2004, Annex III, Section XIII, 1, (a), (b), (c)),*	See section "Separation requirements in the slaughterhouse", above on how to ensure that the raw material comes from animals which have passed *ante - mortem* and *post-mortem* inspection. Once the raw material has been cleaned (manure stripped) in the slaughterhouse, it must then be either salted or heated or dried, or a combination of these. This treatment (i.e. salting, heating or drying) may take place either in the slaughterhouse or in a separate processing plant to which the raw material has been transported. If it takes place in the slaughterhouse, it must be in a room approved for the purpose and separated in space or time from the room used for cleaning the raw material. See also the section "Separation of animal by-products" in Chapter 5 of this Guide, on how to ensure hygienic handling and separation from material which could lead to contamination.	Treatment by salting should be thorough, since salting contributes to the destruction of pathogens. If treatment takes place in the slaughterhouse, best practice would be to ensure that the room approved for treatment is clearly separated from the room used for cleaning the raw material, and is used only for this purpose. See sections "separation requirements in the slaughterhouse" and "separation from animal by-products" for best practice on the hygienic handling and separation of material.

Identification Marking		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Both raw material (i.e. the *untreated* stomachs, bladders and intestines) and the final product (i.e. the *treated* stomachs, bladders and intestines) must bear an identification mark showing the approval number of the establishment that handled them and/or that prepared them. *(EC 853/2004, Article 5)*	In most cases, the raw material will bear the identification mark of the slaughterhouse where it was obtained, and the final product will bear the identification mark of the manufacturing plant where it was treated. **Further information –** please refer to Chapter 13, Traceability of Food (Identification and Health Marking), Part Two of the Meat Industry Guide. http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	

Traceability		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Food business operators must, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin. *(EC 178/2002, Article 18 EC 853/2004, Annex II, Section I, A4)*	The requirement applies a "one step back one step forward" approach. Each operator in the supply chain must have in place a system enabling him/her to identify the immediate supplier(s) and immediate customer(s) of his/her products. .	A documentary control system will provide a clear paper trail for tracing and tracking consignments of stomachs, bladders and intestines to their destination. The information should include date, description of consignment, consignor's/ sender's details including address and approval number, haulier's and consignee's/ receiver's details including address and approval number. A model Document Control System can be found at Annex 2 of Chapter 1 ("Rendered Animal Fat and Greaves")

ANIMAL BY-PRODUCTS		
Separation of raw material for human consumption from animal by-products		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
For the purposes of the Animal by-products (ABPs) legislation ABPs are defined as: entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen. *(EC 1069/2009, Article 3.1)* The legislation requires that at all stages there must be a clear separation between material for human consumption and ABPs. *(Implementing Regulation (EC) No. 142/2011, Annex IV, Chapter I, Section 1)* ABPs must be handled and disposed of according to Regulation (EC) 1069/2009. *(EC 1069/2009:* *Article 12 (Cat 1);* *Article 13 (Cat 2);* *Article 14 (Cat 3))*	Stomachs, bladders and intestines may be disposed of as ABPs immediately after *post-mortem* inspection or cutting. However when intended for human consumption, it is important this material is not handled as ABPs, but are handled in line with the requirements of the food hygiene legislation. The important point is the **intention,** since products become ABPs as soon as the operator decides that they are no longer intended for human consumption. Once the operator has decided that he does not intend or no longer intends raw materials to go for human consumption, they become ABPs and stay that way. The ABPs cannot then revert to being a foodstuff. The operator is obliged to dispose of them appropriately (e.g. by consignment to an approved ABP premises). In practical terms, this would involve re-labelling the product as ABP when it is dispatched. The operator is responsible for supervising and maintaining, at all times, the proper separation of material intended for human consumption and that which is ABP. This includes the separation of stomachs, bladders and intestines intended for human consumption and those not intended for human consumption (ie ABPs). Such ABPs should be stored in an entirely separate part of the slaughterhouse, so that they could neither be confused with food material, contaminate it nor be substituted for it.	See section “separation requirements in the slaughterhouse”, above, for best practice on hygienic handling and separation of ABPs from material intended for human consumption.

Labelling		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The legislation requires that ABPs must be labelled as such and be conveyed directly to the legitimate plant of destination. *(EC 1069/2009, Article 22 (traceability) and the Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter II)*	Materials become ABPs when they are not or are no longer **intended** for human consumption (see section "separation from animal by-products" above). If an operator labels material as ABPs, that is clear evidence of their intention. Material/food to go into the food chain must not be labelled as ABP. If it is, these products will be treated as ABPs for enforcement purposes and will not be able to go back into the food chain.	Strict separation of ABPs from material intended for human consumption reduces the risk of the latter being mis-labelled as ABP or of ABP inadvertently being transferred to the human food chain. See also the 'Best Practice' column in the above section of on 'Separation in the slaughterhouse'.

Storage of food material in animal by-products processing plants		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
ABP plants must not engage in activities other than those in connection with the ABPs for which they are registered or approved. ABP plants must be adequately separated from food premises. *(EC 1069/2009, Article 26 and EC 142/2011, Annex IV, Chapter I, Section I)*	Although not desirable, it is possible for stomachs, bladders and intestines intended for human consumption (i.e. food material) to be consigned to a site on which an ABP plant is situated, before it is consigned to a processing/ manufacturing premises, but strict conditions apply at the ABP plant. These include: • the ABP plant and the food plant must be clearly and demonstrably separate; • food material cannot under any circumstances be taken into the ABP plant; • the ABP plant must be approved or registered under Regulation (EC) 1069/2009; • the food plant must be registered under Regulation (EC) 852/2004 or approved under Regulation (EC) 853/2004 (see section "approval of premises", above). To be demonstrably separate, the food plant and the ABP plant sharing	Best practice would be to transport stomachs, bladders and intestines intended for human consumption direct from the slaughterhouse to the processing/manufacturing plant, without passing through sites that contain ABP plants. This greatly reduces the risk of cross-contamination and of ABPs being diverted into the food chain. If, however stomachs, bladders and intestines intended for human consumption are held in a food premises which is on the same site as an ABP plant, a number of additional precautions could be taken to reduce the risk of diversion or cross-contamination. For example, containers should be of a different colour or type so as to distinguish those used for food from those used for ABPs. There should also be no

	the same site must have separate boundaries and separate entrances with no common air space. This is to ensure that under no circumstances does food enter the ABP plant nor ABPs enter the food plant.	interchange of personnel between the food plant and the ABP plant, nor any interchange of equipment. There should be separate staff changing facilities.

Transport of animal by-products and food		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Food business operators must, in accordance with Article 18 of Regulation (EC) No. 178/2002, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin, including ABPs. *(EC 853/2004, Annex II, Section I, A4)* Where conveyances and/or containers are used for transporting anything in addition to food material, there is, where necessary, to be effective separation of products. *(EC 852/2004, Annex II Chapter IV)* ABPs must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles that have been correctly labelled. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 1)* During transport, ABPs must be maintained at an appropriate temperature to avoid any risk to animal or public health. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 2)*	The requirement applies a "one step back one step forward" approach. Each operator in the supply chain must have in place a system enabling him/her to identify the immediate supplier(s) and immediate customer(s) of his/her products. If food material and ABPs are transported together there must be effective separation between the two. In addition, each container used for ABPs must be of sufficient size and strength to safely hold its contents, without spillage or leakage, during transportation. Any vehicle or item of equipment that comes into contact with ABPs must be cleaned by washing and disinfected after each use. Containers must be kept clean and disinfected. Containers used for food material must be clearly identified and only used for the designated purpose. If food becomes mixed with ABPs then it all has to be treated as ABP. ABPs must be consigned only to permitted approved uses and destinations. **Further information**: please refer to Chapter 5 (Animal By-Products) of this Guide.	A documentary control system will provide a clear, paper trail for tracing and tracking consignments of rendered animal fat to their destination. Best practice would be to ensure that food material and ABPs are not collected or transported in the same container or vehicle. This greatly reduces the risk of substitution or contamination. If, nevertheless, food material and ABPs are collected or transported together, an additional precaution would be to ensure that containers are of a colour or type that distinguishes those for ABPs from those for food material. Stomachs, bladders and intestines should be transported from the slaughterhouse to the processing/manufacturing plant as quickly as practicable after harvesting.

Documentation Requirements		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The legislation requires operators to ensure that ABPs are accompanied during transport by a commercial document or a health certificate, as necessary. *Regulation (EC) No. 1069/2009, Article 21)*	See the Chapter on "Documentation Requirements" in Chapter 5 of this Guide.	See the Chapter on "Documentation Requirements" in Chapter 5 of this Guide.

WHAT ARE THE OFFICIAL CONTROL REQUIREMENTS?

Establishments that handle stomachs, bladders and intestines intended for human consumption will be subject to the official control requirements of Regulation (EC) No. 854/2004. All establishments will therefore be subject to audit and inspection by the competent enforcement authority (which is the Food Standards Agency, Operations Group, York in slaughterhouses, cutting plants and game handling establishments, and local food authorities elsewhere). The audits and inspections will contain the following elements:

- Audits of good hygiene practice and HACCP based procedures *(EC 854/2004, Article 4(3))*
- Checks that the operators' procedures guarantee to the extent possible that meat/raw material does show evidence of faecal or other contamination *(EC 854/2004, Annex I, Section I, Chapter I)*
- Visual *post-mortem* inspection of the gastro-intestinal tract *(EC 854/2004, Annex I, Section IV, Chapter IB, paragraph 6, Chapter II, paragraph 6, Chapter IV B, Paragraph 1(f))*
- Checks on compliance with the requirements of Regulation (EC) No. 1069/2009 *(EC 854/2004, Article 4(c)).*

Chapter 3

Gelatine

WHY ARE HYGIENE REQUIREMENTS IMPORTANT FOR THE PRODUCTION OF GELATINE?

Careful sourcing of raw material and hygienic processing to remove any physical, chemical, biological and other hazard are essential factors for producing safe gelatine. The raw materials used in gelatine production must come only from animals inspected and passed fit for human consumption.

PREMISES		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Approval of premises	**Approval of premises**	**Approval of premises**
Establishments that handle or process raw material for the production of gelatine must be approved by the competent authority. Approval will not be required if the premises carries out only: • transport operations, or • storage of products not requiring temperature-controlled storage conditions. *(EC 853/2004, Article 4.2)* Authorisation from the Competent Authority is also required for tanneries and collection centres supplying raw materials. *(EC 853/2004, Annex III, Section XIV, Chapter I, 5; and EC 852/2004, Article 1.2(d)))* Raw materials for the production of gelatine intended for food use must come from registered, approved or authorised establishments. *(EC 853/2004, Annex III, Section XIV, Chapter I, 4 & EC 178/2002, Article 18)*	Establishments handling or processing raw materials intended for the production of gelatine for human consumption must be approved. This must be by the Food Standards Agency (in the case of establishments co-located with slaughterhouses, game handling establishments or cutting plants) or by the local food authority (in all other cases). Establishments needing approval would therefore include, for example: • plants processing the raw material into gelatine ("gelatine plants"); • collection centres or tanneries collecting raw material to send to the gelatine plant (unless they are authorised); and • plants collecting or storing raw material and requiring temperature controlled storage. The competent authority will check the approved (and authorised) establishments regularly and suspend approval (authorisation) – or a process - immediately if the conditions under which it was granted are no longer fulfilled. All raw materials for the production of gelatine, and the gelatine itself, must come from identifiable sources.	

Design and layout	Design and layout	Design and layout
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The layout, design, construction, siting and size of food premises are to permit good food hygiene practices, including protection against contamination. *(EC 852/2004, Annex II, Chapter I: General requirements for food premises: point 2(c))*	**Further information –** Please refer to the Meat Industry Guide, Part Two, Chapter 1 (Design & Facilities) at: *http://www.food.gov.uk/foodindustry/meat/guidehygienemeat*	

Design and layout for collection centres and tanneries	Design and layout for collection centres and tanneries	Design and layout for collection centres and tanneries
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Collection centres and tanneries supplying raw materials for use in the manufacture of gelatine intended for human consumption must have: • storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities; • the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials. • If non-compliant raw material is also stored and/or processed in these premises, it must be segregated from raw material for the production of gelatine for food throughout the period of receipt, storage, processing and dispatch. *(EC 853/2004, Annex III, Section XIV, Chapter I: 5(a), (b) and (c))*	The design and layout of collection centres and tanneries must facilitate the safe and hygienic collection and storage of all raw materials for food use. For example, hides for food use must be kept separate, at all times, from hides that are not for food use ie they are animal by-products. Where hides and skins to be used in food for human consumption are 'split' in machines that are also used to 'split' hides and skins not going for human food use, the machines must be thoroughly cleaned between such batches of processing.	Best practice would be to ensure the absolute separation of facilities within the collection centre or tannery for the handling of material for food and non-food use. Failing that, separate rooms could be provided for the storage of hides for food use and for non-food use. The rooms should be constructed of cleanable and durable materials with adequate ventilation to remove odours from the room. When this is not possible, the design, use and layout of the room should provide for absolute segregation of the material for food and non-food use so that there is no possibility of contact between the two e.g. during receipt and dispatch.

HYGIENE		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Post mortem inspection	**Post mortem inspection**	**Post mortem inspection**
Until post-mortem inspection is complete, parts of slaughtered animals subject to such inspection must remain identifiable as belonging to a specific carcase. It must not come into contact with any other carcase, offal or viscera that has under-gone post-mortem inspection. If the blood or other offal (see note below) (including hides and skins) of several animals is collected in the same container before completion of *post-mortem* inspection, the entire contents of that container must be declared unfit for human consumption if one or more carcasses of the animals concerned has been declared unfit for human consumption. *(EC 853/2004, Annex III, Section I, Chapter IV, 13 & 15)* *<u>Note</u>: Offal is defined as meaning "fresh meat other than that of the carcase, including viscera and blood.* *(EC 853/2004 Annex I,1.11)*	If the raw materials (e.g. hides) are separated from the carcass before completion of the *post-mortem* inspection, the operator must establish a system to ensure that if a carcass is separately declared unfit, the raw materials from that carcass are also declared unfit. If it is impossible to identify the hide or other raw material from a particular carcass declared unfit, the entire batch of hides or other raw materials which might have been derived from that carcass must be declared unfit.	A careful system to ensure that the carcasses and their offals and hides are in one-to-one correlation until *post-mortem* inspection is completed would eliminate the need for an entire batch of hides or other raw materials to be declared unfit. A system of smaller lots/batches might also be a consideration.

Raw Materials for the production of gelatine		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The following raw materials, may be used to manufacture gelatine for human consumption: • 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 guide). *(EC 853/2004, Annex III, Section XIV, Chapter I, 1)* Raw materials must derive from animals which have been slaughtered in a slaughter-house and whose carcases have been found fit for human consumption following *ante-mortem* and *post-mortem* inspection or, in the case of hides and skins from wild game, (and fish skin and bone) from animals found fit for human consumption. *(EC 853/2004, Annex III, Section XIV, Chapter I, 3)* The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed. *(EC 853/2004, Annex III, Section XIV, Chapter I, 2)* Tanning means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminum salts, ferric salts, silicic salts, aldehydes & quinones, or other synthetic hardening agents. *(EC 853/2004, Annex III, Section XIV, 2)*	Raw material used in the manufacturing of gelatine for human consumption must be derived from animals that have been slaughtered in approved slaughterhouses and whose carcases have been found fit for human consumption following *ante-* and *post-mortem* inspection. See section *"post-mortem* inspection" above on how this should be achieved. Ruminant hides and skins for the production of gelatine for human consumption must derive from carcases found fit for human consumption following *ante-* and *post-mortem* inspection, including a negative result from the BSE test where this is required by Community legislation. All incoming raw materials should be inspected upon receipt at the gelatine plant to ensure that they are suitable for processing. It is reasonable to expect that hides may contain some hair and other foreign matter. Raw materials should be received in an area separate from the processing area. When hides and skins are not intended for the production of food gelatine, then they become animal by-products and Regulation (EC) No. 1069/2009 applies to them. They must be handled and stored separately from hides and skins destined from the production of food gelatine – see section "separation of raw material for human consumption from animal by-products" below. Tanned hides and skins are prohibited for use in gelatine production for human consumption. They must therefore be stored and processed separately from hides and skins that are intended to be used for the production of food gelatine.	

Treatment		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**

The production process for gelatine must ensure that:
• all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4% and pH < 1,5) over a period of at least two days. This treatment is followed by either:
  • an alkaline treatment of saturated lime solution (pH>12,5) for a period of at least 20 days with a heat treatment step of 138°C minimum during at least 4 seconds; or
  • an acid treatment (pH<3,5) during 10 hours minimum with a heat treatment step of 138°C minimum during at least 4 seconds; or
  • a heat-and-pressure process for at least 20 minutes with saturated steam of 133°C at more than 3 bars; or
  • any approved equivalent process.
• Other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine
	Gelatine that is not for human consumption may be produced on the same site and in the same establishment as gelatine which is for human consumption. However, if this is undertaken, the gelatine that is not for human consumption must conform to exactly the same requirements as those for the gelatine which is for human consumption.	

must be extracted by heating one or more times in succession, followed by purification by means of filtration and heat treatment. A food business operator may produce and store both gelatine intended for human consumption and gelatine 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 intended for human consumption. *(EC 853/2004, Annex III, Section XIV, Chapter III, 2)* Food business operators must ensure that gelatine complies with the residue limits set out in Chapter IV of Annex III, Section XIV of Regulation (EC) No. 853/2004.	Plant operators should carry out regular checks to ensure that the residue limits are being complied with (see Annex 1 to this chapter).	

Temperature Controls		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Raw material for the production of gelatine for human consumption must be transported and stored chilled 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. *(EC 853/2004, Annex III, Section XIV, Chapter II, 2)*	The design and use of refrigeration facilities must ensure the maintenance of an appropriate temperature throughout the product. It must also ensure the hygienic storage and/or transport of the product.	Depending on how the hides and skins are presented (for example whether or not they are salted), best practice would be to ensure that the raw material is stored and transported chilled or frozen even if it is to be processed at the gelatine plant within 24 hours of departure from the slaughterhouse.

Identification Marking		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
When delivered to a collection centre or tannery, the raw material used in the manufacture of gelatine must, instead of an identification mark, be accompanied by a document containing the information set out in the Appendix of Annex III of Regulation (EC) No. 853/2004 (reproduced in Annex 2 to this chapter). *(EC 853/2004, Annex III, Section XIV, Chapter II, 1)* Collection centres and tanneries that supply raw material to a gelatine processing establishment must ensure that the raw materials are accompanied by a document containing the information set out in the Appendix of Annex III of Regulation (EC) No. 853/2004. (See Annex 2 to this chapter.) *(EC 853/2004, Annex III, Section XIV, Chapter II, 1)* Each production batch of gelatine for human consumption must bear an identification mark. The mark must be oval in shape and include the appropriate abbreviation as specified in Annex II of Regulation (EC) No. 853/2004. *(EC 853/2004, Article 5.1)*	Raw materials must be accompanied by the document in the Appendix from the time they leave the slaughterhouse until they arrive at the gelatine plant, irrespective of whether they go through a collection centre, tannery or ABP plant. Once produced, the gelatine must bear an identification mark bearing the approval number of that gelatine plant. The document in the Appendix of Annex III of Regulation (EC) No. 853/2004 (see Annex 2 to this chapter) must contain the approval number of the slaughterhouse or establishment where the raw materials originated. **Further information –** please refer to Chapter 13, Traceability of Food (Identification and Health Marking), Part Two, of the Meat Industry Guide at: http://www.food.gov.uk/multimedia/pdfs/migparttwonov10.pdf#page=384	

Labelling		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Wrapping and packaging containing gelatine must bear the words “gelatine fit for human consumption” and must indicate the date of minimum durability. *(EC 853/2004, Annex III, Section XIV, Chapter V)*		

ANIMAL BY-PRODUCTS		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Separation of raw materials for human consumption from animal by-products	**Separation of raw materials for human consumption from animal by-products**	**Separation of raw materials for human consumption from animal by-products**
For the purposes of the Animal by-products (ABPs) legislation ABPs are defined as: entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen. *(EC 1069/2009, Article 3.1)* The legislation requires that at all stages there must be a clear separation between material for human consumption and ABPs. *(Implementing Regulation (EC) No. 142/2011, Annex IV, Chapter I, Section 1)* ABPs must be handled and disposed of according to Regulation (EC) No. 1069/2009. *(EC 1069/2009: Article 12 (Cat 1); Article 13 (Cat 2); and Article 14 (Cat 3))*	Hides, skins and bones are normally disposed of as ABPs immediately after *post-mortem* inspection or cutting. However when intended for human consumption, it is important that this material is not handled as ABPs, but are handled in line with the requirements of the food hygiene legislation. The important point is the **intention,** since products become ABPs as soon as the operator decides that they are no longer intended for human consumption. Once the operator has decided that he does not intend, or no longer intends, raw materials to go for human consumption, they become ABPs and must stay that way. The ABPs cannot then revert to being a foodstuff. The operator is obliged to dispose of ABPs appropriately (e.g. by consignment to an approved ABP premises). In practical terms this would involve re-labelling the material as ABP when it is dispatched. The operator is responsible for maintaining, at all times, the proper separation of material intended for human consumption and that which is ABP. This includes the separation of hides and skins intended for human consumption and those not intended for human consumption (which are ABPs). Such ABPs should be stored in an entirely separate part of the slaughterhouse, so that they could neither be confused with food material, contaminate it nor be substituted for it.	

Legal Requirements	Guide to Compliance	Recommendations on Best Practice
Labelling	**Labelling**	**Labelling**
The legislation requires that ABPs must be labelled as such and be conveyed directly to the legitimate plant of destination. *(EC 1069/2009, Article 22 (traceability) and the Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter II)*	Materials become ABPs when they are not, or are no longer **intended,** for human consumption (see section "separation of raw material for human consumption from animal by-products" above). If an operator labels material as ABP, that is clear evidence of their intention. Material/Food to go into the food chain must not be labelled as ABP. If it is, these products will be treated as ABPs for enforcement purposes and will not be able to go back into the food chain.	Strict separation of ABPs from material intended for human consumption reduces the risk of the latter being mis-labelled as ABP or of ABP inadvertently being transferred to the human food chain.

Legal Requirements	Guide to Compliance	Recommendations on Best Practice
Storage of food material in ABP plants	**Storage of food material in ABP plants**	**Storage of food material in ABP plants**
ABP plants must not engage in activities other than those in connection with the ABPs for which they are registered or approved. *(EC 1069/2009, Articles 23 & 24)* ABP plants must be adequately separated from food premises. *(EC 1069/2009, Article 26 and EC 142/2011, Annex IV, Chapter I, Section 1)*	Although not desirable, it is possible for raw material intended for human consumption (i.e. food material) to be consigned to a site on which an ABP plant is situated, before being consigned to the gelatine plant, but strict conditions apply at the ABP plant. These include: • the ABP plant and the food plant must be clearly and demonstrably separate; • food material cannot under any circumstances be taken into the ABP plant; • the ABP plant must be approved or registered under Regulation (EC) No. 1069/2009. • the food plant must be registered under Regulation (EC) 852/2004 or approved under Regulation (EC) 853/2004 (see "approval of premises", above). To be demonstrably separate, food plants and ABP plants sharing the same site must have separate boundaries and separate entrances with no common air space. This is to ensure that under no circumstance does food enter the ABP plant nor ABPs enter the food plant.	Best practice would be to transport raw material intended for human consumption direct from the slaughterhouse to the gelatine plant, without passing through sites that contain ABP plants. This greatly reduces the risk of cross contamination and of ABPs being diverted into the food chain. If, however, raw material intended for human consumption is held in a food premises which is on the same site as an ABP plant, a number of additional precautions could be taken to reduce the risk of cross contamination or diversion. For example, food containers should be of a colour or type to distinguish them from ABP containers. There should also be no interchange of personnel between the food plant and the ABP plant, nor any interchange of equipment.

Legal Requirements	Guide to Compliance	Recommendations on Best Practice
Transport of ABPs and food	**Transport of ABPs and food**	**Transport of ABPs and food**
Where conveyances and/or containers are used for transporting anything in addition to food material, there is, where necessary, to be effective separation of products. *(EC 852/2004, Annex II, Chapter IV)* ABPs must be collected and transported in sealed new packaging or covered leak-proof, containers or vehicles. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 1)* During transport, ABPs must be maintained at an appropriate temperature to avoid any risk to animal or public health. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 2)*	If food material and ABPs are transported together there must be effective separation between the two. In addition, each container used for ABPs must be of sufficient size and strength to safely hold its contents, without spillage or leakage, during transportation. Any vehicle or item of equipment that comes into contact with ABPs must be cleaned, by washing, and disinfected after each use. Containers must also be kept clean and disinfected. Containers used for food material must be clearly identified and only used for the designated purpose. If food becomes mixed with ABPs then it all has to be treated as ABP. *ABPs must* be consigned only to permitted approved destinations. **Further information** – please refer to Chapter 5 (Animal By-Products) of this guide.	Best practice would be to ensure that food material and ABPs are not collected or transported in the same container or vehicle. This greatly reduces the risk of substitution or contamination. If, nevertheless, food material and ABPs are collected or transported together, an additional precaution would be to ensure that containers are of a colour or type that distinguishes those for ABPs from those for food material. Raw material should be transported from the slaughterhouse to the gelatine plant as quickly as practicable.

WHAT ARE THE OFFICIAL CONTROL REQUIREMENTS?

With the exception of collection centres and tanneries that fall to AHVLA for supervision and enforcement, establishments that handle raw materials for the production of gelatine intended for human consumption will be subject to the official control requirements of Regulation (EC) No. 854/2004. All establishments will therefore be subject to audit and inspection by the competent enforcement authority (which is the Food Standards Agency, Operations Group, York in slaughterhouses, cutting plants and game handling establishments, and local food authorities elsewhere). The audits and inspections will contain the following elements:

- Audits of good hygiene practice and HACCP based procedures *(EC 854/2004, Article 4(3))*
- Checks that the operators' procedures guarantee to the extent possible that meat does not bear faecal or other contamination *(EC 854/2004, Annex I, Section I, Chapter I)*
- *Post-mortem* inspection of the carcase *(EC 854/2004, Annex I, Section IV, Chapter IB, paragraph 6, Chapter II, paragraph 6, Chapter IV B, Paragraph 1(f))*

Checks on compliance with the requirements of Regulation (EC) No. 1069/2009 *(EC 854/2004, Article 4(c)).*

ANNEX 1

REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that gelatine complies with the residue limits set out in the following table.

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

ANNEX 2

MODEL DOCUMENTATION TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF 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.

Chapter 4
Collagen

WHY ARE HYGIENE REQUIREMENTS IMPORTANT FOR THE PRODUCTION OF COLLAGEN?

Careful sourcing of raw material and hygienic processing to remove any physical, chemical, bacteriological and other hazards are essential factors for producing safe collagen. The raw materials used in collagen production must come only from animals inspected and passed fit for human consumption.

PREMISES		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Approval of premises	**Approval of premises**	**Approval of premises**
Establishments that handle or process raw material for the production of collagen must be approved by the competent authority. Approval will not be required if the premises carries out only: • transport operations, or • storage of products not requiring temperature-controlled storage conditions. *(EC 853/2004, Article 4.2)* Authorisation from the Competent Authority is also required for tanneries and collection centres supplying raw materials. *(EC 853/2004, Annex III, Section XV, Chapter I, 5)* Raw materials for the production of collagen intended for use in food must come from registered, approved or authorised establishments. *(EC 853/2004, Annex III, Section XV, Chapter I, 4)*	Establishments handling or processing raw materials intended for the production of collagen for human consumption must be approved. This must be by the Food Standards Agency (in the case of establishments co-located with slaughterhouses, game handling establishments or cutting plants) or by the local food authority (in all other cases). Establishments needing approval would therefore include, for example: • plants processing the raw material into collagen ("collagen plants"); • collection centres or tanneries collecting raw material to send to the collagen plant (unless they are authorised); and • plants collecting or storing raw material and requiring temperature controlled storage. The competent authority will check the approved (and authorised) establishments regularly and suspend approval (authorisation) – or a process - immediately if the conditions under which it was granted are no longer fulfilled. All raw materials for the production of collagen, and the collagen itself, must come from identifiable sources.	

Design and layout	Design and layout	Design and layout
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The layout, design, construction, siting and size of food premises are to permit good food hygiene practices, including protection against contamination. *(EC 852/2004, Annex II, Chapter I: General requirements: point 2(c))*	**Further information** – Please refer to the Meat Industry Guide, Part Two, Chapter 1 (Design & Facilities) at: http://www.food.gov.uk/foodindustry/meat/guidehygienemeat	

Design and layout for collection centres and tanneries	Design and layout for collection centres and tanneries	Design and layout for collection centres and tanneries
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Collection centres and tanneries supplying raw materials for use in the manufacture of collagen intended for human consumption must have: • storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities; • the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials. • If non-compliant raw material is also stored and/or processed in these premises, it must be segregated from raw material for the production of collagen for food throughout the period of receipt, storage, processing and dispatch. *(EC 853/2004, Annex III, Section XV, Chapter I: 5(a), (b) and (c))*	The design and layout of collection centres and tanneries must facilitate the safe and hygienic collection and storage of all raw materials for food use. For example, hides for food use must be kept separate, at all times, from hides that are not for food use ie they are animal by-products. Where hides and skins to be used in food for human consumption are 'split' in machines that are also used to 'split' hides and skins not going for human food use, the machines must be thoroughly cleaned between such batches of processing.	Best practice would be to ensure the absolute separation of facilities within the collection centre or tannery for the handling of material for food and non-food use. Failing that, separate rooms could be provided for the storage of hides for food use and for non-food use. The rooms should be constructed of cleanable and durable materials with adequate ventilation to remove odours from the room. When this is not possible, the design and layout of the room should provide for absolute segregation of the material for food and non-food use so that there is no possibility of contact between the two e.g. during receipt and dispatch.

HYGIENE		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Post mortem inspection	**Post mortem inspection**	**Post mortem inspection**
Until post-mortem inspection is complete, parts of slaughtered animals subject to such inspection must remain identifiable as belonging to a specific carcase. It must not come into contact with any other carcase, offal or viscera that has under-gone post-mortem inspection If the blood or other offal (see note below) (including hides and skins) of several animals is collected in the same container before completion of *post-mortem* inspection, the entire contents of that container must be declared unfit for human consumption if one or more carcasses of the animals concerned has been declared unfit for human consumption. *(EC 853/2004, Annex III, Section I, Chapter IV, 13 & 15)* *<u>Note</u>: Offal is defined as meaning "fresh meat other than that of the carcase, including viscera and blood.* *(EC 853/2004 Annex I,1.11)*	If the raw materials (e.g. hides) are separated from the carcass before completion of the *post-mortem* inspection, the operator must establish a system to ensure that if a carcass is separately declared unfit, the raw materials from that carcass are also declared unfit. When it is impossible to identify the hide or other raw material from a particular carcass declared unfit, the entire batch of hides or other raw materials which might have been derived from that carcass must be declared unfit.	A careful system to ensure that the carcasses and their offals and hides are in one-to-one correlation until *post-mortem* inspection is completed would eliminate the need for an entire batch of hides or other raw materials to be declared unfit. A system of smaller lots/batches might also be a consideration.

Raw Materials for the production of collagen		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The following raw materials, may be used in the manufacture of collagen: • 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. *(EC 853/2004, Annex III, Section XV, Chapter I, 1)* Raw materials must derive from animals which have been slaughtered in a slaughter-house and whose carcases have been found fit for human consumption following *ante-mortem* and *post-mortem* inspection or, in the case of hides and skins from wild game (and fish skin and bone), found fit for human consumption. *(EC 853/2004, Annex III, Section XV, Chapter I, 3)* The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed. *(EC 853/2004, Annex III, Section XV, Chapter I, 2)* Tanning means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminum salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents. *(EC 853/2004, Annex III, Section XV, 2)*	Raw material used in the manufacturing of collagen for human consumption must be derived from animals that have been slaughtered in approved slaugh-terhouses and whose carcases have been found fit for human consumption following *ante-* and *post-mortem* inspection. See section *"post-mortem* inspection" above on how this should be achieved. Ruminant hides and skins for the production of collagen for human consumption must derive from carcases found fit for human consumption following *ante-* and *post-mortem* inspection, including a negative result from the BSE test where this is required by Community legislation. All incoming raw materials should be inspected upon receipt at the collagen plant to ensure that they are suitable for processing. It is reasonable to expect that hides may contain some hair and other foreign matter. Raw materials should be received in an area separate from the processing area. When hides and skins are not intended for the production of food collagen, then they become animal by-products and Regulation (EC) No. 1069/2009 applies to them. They must be handled and stored separately from hides and skins destined from the production of food collagen – see section "separation of raw material for human consumption from animal by-products" below. Tanned hides and skins are prohibited for use in collagen production for human consumption. They must therefore be stored and processed separately from hides and skins that are intended to be used for the production of food collagen.	

Treatment		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
The production process for collagen must ensure that: • all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4% and pH < 1,5) over a period of at least two days. This treatment must be followed by pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion, or by any approved equivalent process; • other raw material must be subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process; the extrusion step may not be carried out when manufacturing low molecular collagen from raw materials of non-ruminant origin. After having been subjected to the process referred to above, collagen may undergo a drying process.	Collagen that is not for human consumption may be produced on the same site and in the same establishment as collagen which is for human consumption. However, if this is undertaken, the collagen that is not for human consumption must conform to exactly the same public health requirements as those for the collagen which is for human consumption.	

If a food business operator manufacturing collagen complies with the requirements applying to collagen intended for human consumption in respect of all the collagen that he produces, he may produce and store collagen not intended for human consumption in the same establishment. *(EC 853/2004, Annex III, Section XV, Chapter III, 1, 2, 3)* Food business operators must ensure that collagen complies with the residue limits set out in Chapter IV, Section XV, Annex III, of Regulation (EC) No. 853/2004.	Plant operators should carry out regular checks to ensure that the residue limits are being complied with (see Annex I to this Chapter).	

Temperature Controls		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Raw material for the production of collagen for human consumption must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. 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. *(EC 853/2004, Annex III, Section XV, Chapter II, 2)*	The design and use of refrigeration facilities must ensure the maintenance of an appropriate temperature throughout the product. It must also ensure the hygienic storage and/or transport of the product.	Depending on how the hides and skins are presented (for example whether or not they are salted), best practice would be to ensure that the raw material is stored and transported chilled or frozen even if it is to be processed at the collagen plant within 24 hours of departure from the slaughterhouse.

Identification Marking		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
When delivered to a collection centre or tannery, the raw material used in the manufacture of collagen must, instead of an identification mark, be accompanied by a document containing the information set out in the Appendix of Annex III of Regulation (EC) 853/2004 (reproduced in Annex 2 to this chapter). *(EC 853/2004, Annex III, Section XV, Chapter II, 1)* Collection centres and tanneries that supply raw material to a collagen processing establishment must ensure that the raw materials are accompanied by a document containing the information set out in the Appendix of Annex III of Regulation (EC) 853/2004. (See Annex 2 to this chapter.) *(EC 853/2004, Annex III, Section XV, Chapter II, 1)* Each production batch of collagen for human consumption must bear an identification mark. The mark must be oval in shape and include the appropriate abbreviation as specified in Annex II of Regulation (EC) No. 853/2004. *(EC 853/2004, Article 5.1)*	Raw materials must be accompanied by the document in the Appendix from the time they leave the slaughterhouse until they arrive at the collagen plant, irrespective of whether they go through a collection centre, tannery or ABP plant. Once produced, the collagen must bear an identification mark bearing the approval number of that collagen plant. The document in the Appendix of Annex III of Regulation (EC) No. 853/2004 (see Annex 2 to this chapter) must contain the approval number of the slaughterhouse or establishment where the raw materials originated. **Further information –** please refer to Chapter 13, Traceability of Food (Identification and Health Marking), Part Two, of the Meat Industry Guide at: http://www.food.gov.uk/multimedia/pdfs/migparttwonov10.pdf#page=384	

Labelling		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Wrapping and packaging containing collagen must bear the words “collagen fit for human consumption” and indicate the date of preparation. *(EC 853/2004, Annex III, Section XV, Chapter V)*		

ANIMAL BY-PRODUCTS		
Legal Requirements	**Guide to Compliance**	**Recommendations on Best Practice**
Separation of raw materials for human consumption from animal by-products	**Separation of raw materials for human consumption from animal by-products**	**Separation of raw materials for human consumption from animal by-products**
For the purposes of the Animal by-products (ABPs) legislation ABPs are defined as: entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen. *(EC 1069/2009, Article 3.1)* The legislation requires that at all stages there must be a clear separation between material for human consumption and ABPs. *(Implementing Regulation (EC) No. 142/2011, Annex IV, Chapter I, Section I)* ABPs must be handled and disposed of according to Regulation (EC) No. 1069/2009. *(EC 1069/2009: Article 12 (Cat 1); Article 13 (Cat 2); and Article 14 (Cat 3))*	Hides, skins and bones are normally disposed of as ABPs immediately after *post-mortem* inspection or cutting. However when intended for human consumption, it is important that this material is not handled as ABPs, but are handled in line with the requirements of the food hygiene legislation. The important point is the **intention,** since products become ABPs as soon as the operator decides that they are no longer intended for human consumption. Once the operator has decided that he does not intend or, no longer intends, raw materials to go for human consumption, they become ABPs and must stay that way. The ABPs cannot then revert to being a foodstuff. The operator is obliged to dispose of ABPs appropriately (e.g. by consignment to an approved ABP premises). In practical terms this would involve re-labelling the material as ABP when it is dispatched. The operator is responsible for maintaining, at all times, the proper separation of material intended for human consumption and that which is ABPs. This includes the separation of hides and skins intended for human consumption and those not intended for human consumption (which are ABPs). Such ABPs should be stored in an entirely separate part of the slaughterhouse, so that they could neither be confused with food material, contaminate it nor be substituted for it.	.

Labelling	Labelling	Labelling
The legislation requires that ABPs must be labelled as such and be conveyed directly to the legitimate plant of destination. *(EC 1069/2009, Article 22 (traceability) and Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter II)*	Materials become ABPs when they are not, or are no longer **intended,** for human consumption (see section "separation of raw material for human consumption from animal by-products", above). If an operator labels material as ABP, that is clear evidence of their intention. Material/Food to go into the food chain must not be labelled as ABPs. If it is, these products will be treated as ABPs for enforcement purposes and will not be able to go back into the food chain.	Strict separation of ABPs from material intended for human consumption reduces the risk of the latter being mis-labelled as ABP or of ABP inadvertently being transferred to the human food chain.

Storage of food material in ABP plants	Storage of food material in ABP plants	Storage of food material in ABP plants
ABP plants must <u>not</u> engage in activities other than those in connection with the ABPs for which they are registered or approved. *(EC 1069/2009, Articles 23 & 24)* ABP plants must be adequately separated from food premises. *(EC 1069/2009, Article 26 and EC 142/2011, Annex IV, Chapter I, Section 1)*	Although not desirable, it is possible for raw material intended for human consumption (i.e. food material) to be consigned to a site on which an ABP plant is situated, before being consigned to the collagen plant, but strict conditions apply at the ABP plant. These include: • the ABP plant and the food plant must be clearly and demonstrably separate; • food material cannot under any circumstances be taken into the ABP plant; • the ABP plant must be approved or registered under Regulation (EC) No. 1069/2009. • the food plant must be registered under Regulation (EC) 852/2004 or approved under Regulation (EC) 853/2004 (see section "approval of premises", above). To be demonstrably separate, food plants and ABP plants sharing the same site must have separate boundaries and separate entrances with no common air space. This is to ensure that under no circumstance does food enter the ABP plant nor ABPs enter the food plant.	Best practice would be to transport raw material intended for human consumption direct from the slaughterhouse to the collagen plant, without passing through sites that contain ABP plants. This greatly reduces the risk of cross contamination and of ABPs being diverted into the food chain. If, however, raw material intended for human consumption is held in a food premises which is on the same site as an ABP plant, a number of additional precautions could be taken to reduce the risk of cross contamination or diversion. For example, food containers should be of a colour or type to distinguish them from ABP containers. There should also be no interchange of personnel between the food plant and the ABP plant, nor any interchange of equipment.

Transport of ABPs and food	Transport of ABPs and food	Transport of ABPs and food
Where conveyances and/or containers are used for transporting anything in addition to food material, there is, where necessary, to be effective separation of products. *(EC 852/2004, Annex II, Chapter IV)* ABPs must be collected and transported in sealed new packaging or covered leak-proof, containers or vehicles. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 1)* During transport, ABPs must be maintained at an appropriate temperature to avoid any risk to animal or public health. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 2)*	If food material and ABPs are transported together there must be effective separation between the two. In addition, each container used for ABPs must be of sufficient size and strength to safely hold its contents, without spillage or leakage, during transportation. Any vehicle or item of equipment that comes into contact with ABPs must be cleaned, by washing, and disinfected after each use. Containers must also be kept clean and disinfected. Containers used for food material must be clearly identified and only used for the designated purpose. If food becomes mixed with ABPs then it all has to be treated as ABP. *ABPs must* be consigned only to permitted approved destinations. **Further information** – please refer to Chapter 5 (Animal By-Products) of this guide.	Best practice would be to ensure that food material and ABPs are not collected or transported in the same container or vehicle. This greatly reduces the risk of substitution or contamination. If, nevertheless, food material and ABPs are collected or transported together, an additional precaution would be to ensure that containers are of a colour or type that distinguishes those for ABPs from those for food material. Raw material should be transported from the slaughterhouse to the collagen plant as quickly as practicable.

WHAT ARE THE OFFICIAL CONTROL REQUIREMENTS?

With the exception of collection centres and tanneries that fall to AHVLA for supervision and enforcement, establishments that handle raw materials for the production of collagen intended for human consumption will be subject to the official control requirements of Regulation (EC) No. 854/2004. All establishments will therefore be subject to audit and inspection by the competent enforcement authority (which is the Food Standards Agency, Operations Group, York in slaughterhouses, cutting plants and game handling establishments, and local food authorities elsewhere). The audits and inspections will contain the following elements:

- Audits of good hygiene practice and HACCP based procedures *(EC 854/2004, Article 4(3))*
- Checks that the operators' procedures guarantee to the extent possible that meat does not bear faecal or other contamination *(EC 854/2004, Annex I, Section I, Chapter I)*
- *Post-mortem* inspection of the carcase *(EC 854/2004, Annex I, Section IV, Chapter IB, paragraph 6, Chapter II, paragraph 6, Chapter IV B, Paragraph 1(f))*

Checks on compliance with the requirements of Regulation (EC) No. 1069/2009 *(EC 854/2004, Article 4(c)).*

ANNEX 1

REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that collagen complies with the residue limits set out in the following table:

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

ANNEX 2

MODEL DOCUMENTATION TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF COLLAGEN

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.

5

Chapter 5
Animal-by-products

Chapter 5

Contents 5

Chapter 5
Animal By-Products

WHAT ARE ANIMAL BY-PRODUCTS? Animal by-products (ABPs) are defined in Article 3 of Regulation 1069/2009 as "entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are **not intended for human consumption**". The **intention** is the important point since all products of animal origin would be considered to be ABPs if they were not intended for human consumption. Animal products therefore, become ABPs because they are either unfit and/or unsafe, or the food business operator decides that they will not be used for human consumption. As soon as operators generate ABPs they must be identified and dealt with in accordance with the ABPR. The ABPs cannot then revert to being a foodstuff, and they must be kept out of the food chain. EC and national legislation establish strict health rules so that they are properly identified, handled, stored, transported, processed, used or disposed of.

WHICH LEGISLATION APPLIES TO ANIMAL BY-PRODUCTS (ABPs)?

Regulation (EC) No. 1069/2009 (APBR) lays down the health rules for the:

- collection, transport, storage, handling, processing and use or disposal of ABPs; and
- placing on the market and, in certain cases, the import, export and transit of ABPs and products derived from them.

Regulation (EC) No. 142/2011 (the Implementing Regulation), which lays down implementing measures for the public and animal health rules for animal by-products and derived products laid down in Regulation (EC) No. 1069/2010

The Animal By-Products (Enforcement) (England) Regulations 2011 (APBR 2011) provide for the administration and enforcement of Regulation (EC) No. 1069/2009 and Regulation (EC) No. 142/2011 in England. Similar controls and legislation apply in Scotland, Wales and Northern Ireland.

The Animal By-Products (Identification) Regulations 1995, as amended (ABPI) made under the Food Safety Act, lay down rules for:

- the staining of most Category 2 and some Category 1 (non-SRM) ABPs in *approved* premises;
- the storage and labelling during storage of ABPs in *approved* premises; and
- restricting the movement of ABPs that require staining.

Similar arrangements apply in Scotland, Wales and Northern Ireland.

Regulations (EC) Nos. 852/2004, 853/2004, 854/2004 (the food hygiene Regulations), seek to ensure the hygiene of foodstuffs at all stages of the production process and require ABPs to be kept separate from food material at all times by:

- appropriate labelling; and
- storage in separate lockable facilities until the material is removed from the premises.

Regulation (EC) No. 999/2001 (the Community TSE Regulation) as amended**,** which contains a requirement for SRM to be stained in accordance with EU ABP Regulations.

The Transmissible Spongiform Encephalopathies (England) Regulations 2010, which contains requirements for:

- staining Specified Risk Material (SRM); and
- storage conditions prior to consignment.

Similar arrangements apply in Scotland, Wales and Northern Ireland.

HOW ARE ANIMAL BY-PRODUCTS CATEGORISED?

Regulation (EC) No. 1069/2009 (ABPR) divides animal by-products into three categories, depending on their potential risk to human and animal health or to the environment. These categories are:

- Category 1 - which includes SRM (the highest risk);
- Category 2 (high risk); and
- Category 3 (low risk).

If any material comes into contact with an animal by-product material from a higher risk category it is treated as the higher risk category, for example Category 3 material coming into contact with Category 1 material is then treated as Category 1 material; Category 3 material coming into contact with Category 2 material is to be treated as Category 2 material.

The ABPR allows the mixing of SRM and other animal by-products, but all material automatically becomes Category 1 SRM and is stained blue. It is transported and disposed of as Category 1 SRM.

There is more information on the ABP categories and their handling requirements (including on staining, storing, labelling, disposal and transport) in the following pages.

CATEGORY 1

The table below lists Category 1 animal by-products. These pose the highest risk to human and animal health and include SRM. Examples of Category 1 animal by-products are also given but this list is intended for guidance only and is not exhaustive *(Article 8 of Regulation (EC) No. 1069/2009).*

Definition of Category 1 (Article 8 of Regulation (EC) No. 1069/2009)

- Entire bodies and all body parts, including hides and skins, of the following animals:
  - animals suspected of being infected by a TSE in accordance with Regulation (EC) No. 999/2001 or in which the presence of a TSE has been officially confirmed (Article 8(a)(i));
  - animals killed in the context of TSE eradication measures (Article 8(a)(ii));
  - wild animals when suspected of being infected with disease communicable to humans or animals (Article 8(a)(v)).
- Specified risk material (Article 8(b)(i)).
- Entire bodies or parts of dead animals containing specified risk material at the time of disposal (Article 8(b)(ii)).
- Animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC (Article 8(c)).
- Animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation (Article 8(d)).
- Animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27, from:
  - establishments or plants processing Category 1 material; or
  - other establishments or plants where specified risk material is being removed (Article 8(e)).
- Mixtures of Category 1 material with either Category 2 material or Category 3 material or both (Article 8(g)).

Examples of Category 1 ABP material

- Material tested positive for TSE.
- Bodies of wild game animals affected by disease communicable to humans or animals, for example Foot and Mouth Disease or tuberculosis.
- SRM.
- Any animal material that comes into contact with SRM after it has been removed from the carcase.
- All parts (including hides/skins and blood) of TSE-sampled carcases disposed of prior to test results being obtained.
- Whole bodies of cattle, sheep, goats, water buffalo and bison either rejected at *ante-mortem* inspection, or found dead on arrival, or found dead in the lairage (unless SRM has been removed at the point of disposal).
- Products suspected of containing EC-prohibited non-medicinal treatments or illegal substances e.g. elevated dioxin or heavy metal contaminants (but does NOT include products containing residues of permitted veterinary drugs[1]).

[1] products derived from animals to which substances prohibited under Directive 96/22/EC have been administered and products of animal origin containing residues of environmental contaminants and other substances listed in Group B (3) of Annex I to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (3), if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation

CATEGORY 2

The table below lists Category 2 animal by-products. These pose a high risk to human or animal health. Any material that does not fall into Category 1 or 3 must be treated as Category 2 material. Examples of Category 2 animal by-products are also given but this list is intended for guidance only and is not exhaustive *(Article 9 of Regulation (EC) No. 1069/2009).*

Definition of Category 2 (Article 9 of Regulation (EC) No. 1069/2009)

- Manure, non-mineralised guano and digestive tract content (Article 9(a)).
- Animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27 (Article 9(b)):
  - from establishments or plants processing Category 2 material (Article 9(b)(i)); or
  - from slaughterhouses other than those covered by Article 8(e) (Article 9(b)(ii));
- Animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of Directive 96/23/EC (Article 9(c));
- Products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products (Article 9(d));
- Products of animal origin, other than Category 1 material, that are (Article 9(e)):
  - imported or introduced from a third country and fail to comply with Community veterinary legislation for their import or introduction into the Community except where Community legislation allows their import or introduction subject to specific restrictions or their return to the third country (Article 9(e(i))); or
  - dispatched to another Member State and fail to comply with requirements laid down or authorised by Community legislation except where they are returned with the authorisation of the competent authority of the Member State of origin (Article 9(e)(ii));
- Animals and parts of animals, other than those referred to in Article 8 or Article 10 (Article 9(f)),
  - that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes (Article 9(f)(i));
  - foetuses (Article 9(f)(ii));
  - oocytes, embryos and semen which are not destined for breeding purposes (Article 9(f)(iii)); and
  - dead-in-shell poultry(Article 9(f)(iv));
- Mixtures of Category 2 material with Category 3 material (Article 9(g));
- Animal by-products other than Category 1 material or Category 3 material (Article 9(h)).

Examples of Category 2 material

- Any carcase, part of a carcase or offal which comes from an animal or bird that was not presented for *ante-mortem* inspection, or not presented with necessary food chain information.
- Carcases or parts of carcases rejected at or following *post-mortem* that contain pathological lesions indicating disease communicable to human or animal, for example, some parasitic diseases: C. bovis, Hydatid cysts, generalised conditions: septicaemia(eg salmonellosis) or pyaemia; local conditions: septic lungs, joints; specific conditions/diseases: tuberculosis, etc.

- Whole bodies of pigs or poultry either rejected at *ante-mortem* inspection, found dead on arrival or found dead in the lairage.
- Any meat found to contain residues, in excess of permitted levels of, for example, antibacterial substances (antibiotics), anthelmintics, etc.
- Blood from any animal that has not passed *ante-mortem* inspection (and therefore has not been slaughtered for human consumption.

CATEGORY 3

The table below lists Category 3 animal by-products. Examples of Category 3 animal by-products are also given but this list is intended for guidance only and is not exhaustive *(Article 10 of Regulation (EC) No.1069/2009)*.

Definition of Category 3 (Article 10 of Regulation (EC) No. 1069/2009)

- Carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons (Article 10(a)).
- Carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Community legislation (Article 10 (b)):
  - carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Community legislation, but which did not show any signs of disease communicable to humans or animals (Article 10(b)(i));
  - heads of poultry (Article 10(b)(ii));
  - hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of (Article 10(b)(iii)):
    - animals, other than ruminants requiring TSE testing, and
    - ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No. 999/2001;
  - pig bristles (Article 10(b)(iv));
  - feathers (Article 10(b)(v));
- Animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regulation (EC) No. 853/2004, which did not show any signs of disease communicable to humans or animals (Article 10(c).
- Blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation (Article 10(d)):
  - animals other than ruminants requiring TSE testing (Article 10(d)(i)); and
  - ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No. 999/2001 (Article 10(d)(ii)).
- Animal by-products arising from the production of products intended for human consumption, including degreased bones, greaves and centrifuge or separator sludge from milk processing (Article 10(e)).

- Products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise (Article 10(f)).
- Blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show any signs of disease communicable through that product to humans or animals (Article 10(h)).
- The following material originating from animals which did not show any signs of disease communicable through that material to humans or animals (Article 10(k)):
  - the following originating from terrestrial animals(Article 10(k)(ii)):
    - hatchery by-products,
    - eggs,
    - egg by-products, including egg shells,
  - day-old chicks killed for commercial reasons (Article 10(k)(iii));
- Animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) (Article 10(m));
- Hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point (b) of this Article (Article 10(n));
- Adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an *ante-mortem* inspection in accordance with Community legislation (Article 10(o));
- Catering waste other than as referred to in Article 8(f) (Article 10(p)).

Examples of Category 3 material

- Carcases or parts of carcases that have passed *ante-* and *post-mortem* inspection but, for commercial or other reasons, are not intended for human consumption, for example: incised pig lungs, pig spleens, stomachs and intestines from mammals or ratites empty of digestive material (except bovine intestines, and ovine and caprine ileum which are Category 1), poultry necks, poultry intestines (note: the intestinal tracts of poultry do not have to be empty to be considered as Category 3 material), testicles, pig rind, bones from a cutting plant.
- Parts of a carcase or offal that are not permitted by the Hygiene Regulations to be used for human consumption but which nevertheless show no sign of disease communicable to humans or animals, for example, livers with fluke lesions, liver milk spot lesions, muellerius lung lesions, melanosis, meat trimmed from the sticking point, and meat trimmed because of old healed lesions.
- Trimmed fat or waste carcase meat not intended for human consumption.
- Lymph nodes and nervous tissue removed during cutting of fat from bovine animals.
- Meat rejected by the producer because it no longer meets specification.
- Poultry heads and feet that have passed *a post-mortem* inspection on the line attached to the carcase.
- Poultry heads and feet separated from the carcase prior to *post-mortem* inspection but which have passed *ante-mortem* inspection.
- Meat that falls on the floor and which is rejected as unfit for human consumption for that reason. (Meat that falls on the floor can be retrieved for human consumption from a visibly clean floor if suitable procedures are in place to control risk.)

- Hides, skins, hooves/feet, horns, pig bristles and feathers derived from animals other than ruminants requiring TSE testing or with a negative result that have passed *ante-mortem* inspection, and do not show any clinical sign of disease communicable through that product to humans or animals.
- Any carcase, part of a carcase or offal certified as not being produced, stored or transported in accordance with the hygiene regulations which consequently cannot be sold for human consumption, for example, traceable meat with no health/identification mark; meat stored or found over temperature (unless it is Category 1 or Category 2 material).
- Decomposed or spoiled meat in line with Article 14 (d) of Regulation (EC) No. 1069/2009.

CATEGORIES: SEPARATION OF ANIMAL BY-PRODUCTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
The different categories of ABPs must be kept separate from each other at all times, to avoid cross-contamination. They must also be kept separate from food for human consumption. *Regulation (EC) No. 1069/2009, Article 26* *Implementing Regulation (EC) No. 142/2011, Annex IV, Chapter I, Section I, para 1(a), and Sections 3 and 4*	It is important that each category of ABP is kept separate in order to avoid contamination and down-grading. This requirement applies in all meat plants and in ABPs plants. ABPs are categorised according to the degree of risk they present. Category 1 material is the highest risk and includes SRM and generally goes for destruction. Category 3 material is low risk and goes for a wider variety of uses, including the manufacture of petfood. When a lower risk category of ABPs is mixed or cross-contaminated with a higher risk category the ABPs in question must be treated as the higher risk category. Separation among the different categories of ABPs must be guaranteed at all times. As a minimum, this applies to the following: • Reception bay; • Pre-processing operations • Processing operations; • Use of mobile equipment; • Personnel movements; • Maintenance procedures; • Post-processing procedures; • Storage and dispatch of processed products.	Best practice in the prevention of cross-contamination would be for each category of by-products and the associated implements, cleaning tools and vessels to be uniquely colour-coded. Separate storage rooms should be used for each stream of material. To ensure that their routine work does not result in different categories of ABPs contaminating each other, staff should change their clothes, footwear and utensils when working in different parts of the premises.

SEPARATION OF ANIMAL BY-PRODUCTS FROM FOOD MATERIAL		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
In all cases, ABPs must be kept separate from meat that is fit for human consumption. Meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption. *(Regulation (EC) No. 853/2004, Annex III, Section I, Chapter IV, 16 and Section II, Chapter IV, 7)* To avoid contaminating material for human consumption food premises must keep unfit meat and non-edible products in separate lockable facilities from fit meat. *(Regulation (EC) No. 853/2004, Annex III, Section I, Chapter II, 5 and Section II, Chapter II, 5)* *See also the section on Separation of Animal By-Products plants from Food Premises (below).*	Operators are responsible for ensuring that meat that has been declared or judged as unfit for human consumption, or is otherwise not intended for human consumption, is not mixed with, substituted for, or in any way contaminates meat for human consumption. Particular care and attention must be paid to determine locations or activities that, during the slaughter and further dressing of the carcase, can be separated to minimise the potential for contamination. Meat condemned or judged as unfit for human consumption and inedible materials must be placed without delay into clearly identified containers and stored in an entirely separate part of the food plant. *See also the section of this Guide on the 'Storage, transport, identification and labelling requirements for ABPs'.* Rooms, equipment and utensils for use with inedible or condemned materials must be reserved for that purpose and not used for edible products. Whenever separation in time is permitted, the processing area and equipment must be thoroughly cleaned and disinfected before reuse.	To ensure proper separation, best practice would be for each individual by-product stream and the associated implements to be uniquely colour coded. It is recommended that ABPs not held in a separate dedicated room are removed from the premises daily.

SEPARATION OF ANIMAL BY-PRODUCTS PLANTS FROM FOOD PREMISES		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
ABP plants must be adequately separated from food premises. In addition they must not engage in activities other than those permitted for the Category of ABPs for which they are registered or approved. *(Regulation (EC) No. 1069/2009, Article 26 and Implementing Regulation (EC) No. 142/2011, Annex IX, Chapter II)* ABP processing plants (for processing by pressure sterilisation or in accordance with the processing methods referred to in Article 15(1)(b) of Regulation (EC) No. 1069/2009) must not be on the same site as a slaughterhouse unless in a completely separate building. *(Regulation (EC) No. 1069/2009, Article 26 and Implementing Regulation (EC) No. 142/2011 Annex IV, Chapter I, Section I – for processing and certain other plants and establishments)* Note: ABPs plants may also be premises where ABPs are temporarily stored prior to dispatch to another ABP premises. Cutting, sorting, freezing etc can also take place at a processing plant.	To avoid cross-contamination, the processing plant must be physically separated from the slaughterhouse or other establishments that have been registered or approved under Regulations (EC) Nos. 8522004 and 853/2004 (respectively). This means that there must be: • separate buildings with separate entrances and exits; • separate reception bays; and • separate equipment and utensils. Although not desirable, it is possible for raw material of animal origin which is intended for the manufacture of products for human consumption ("food material") to be consigned to a site on which an ABP plant is situated before being consigned to the manufacturing premises but strict conditions apply. These include: • the food plant and the ABP plant must be adequately and demonstrably separate; • food material cannot under any circumstances be taken into the ABP plant; • the food plant must be registered under Regulation (EC) No. 852/2004 or approved under Regulation (EC) No. 853/2004. To be demonstrably separate, food plants and ABP plants sharing the same site must have separate boundaries and separate entrances. This is to ensure that under no circumstances does food enter the ABP plant nor ABPs enter the food plant and become cross-contaminated.	The food premises (including slaughterhouse) and the ABP premises would have separate air space. Best practice would be to transport raw materials intended for human consumption direct from the slaughterhouse to the manufacturing plant, without passing through sites that contain ABP plants. This greatly reduces the risk of ABPs being diverted into the food chain. If, however, raw material intended for human consumption is held in a food premises which shares a site with an ABP plant, a number of additional precautions could be taken to reduce the risk of diversion or contamination. For example, containers should be of a colour or type that distinguishes those for ABPs from those used for food material. There would also be no interchange of personnel between the food plant and the ABP plant, nor any interchange of equipment. Separate staff would operate in each part of the premises. However, where this is not possible, persons working in the unclean sector must not enter the clean sector without changing their working clothes and footwear or without cleaning and disinfecting the latter. Equipment and utensils must not be taken from the unclean sector into the clean sector unless first thoroughly cleaned and disinfected.

REGISTRATION/APPROVAL REQUIREMENTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
Premises producing, processing, handling or storing meat for sale for human consumption must be either registered or approved by the competent authority, under Regulations (EC) Nos. 852 and 853/2004 respectively. *(Regulation (EC) No. 852/2004, Article 6; and Regulation (EC) No. 853/2004, Article 4)*	The Food Standards Agency (FSA) is the competent authority for issuing approvals for slaughterhouses, cutting plants and game handling establishments. In all other cases registration or approval is by the local food authority	
All premises that receive, handle or process ABPs must be registered or approved under the ABPR by the competent authority. *(Regulation (EC) No. 1069/2009 Articles 23 and 24)*	To be registered or approved, plants must meet the requirements of the ABPR aimed at preventing the risk of spreading transmissible disease. Some of the hygiene requirements relate to: • layout and construction of the plant; • staff hygiene facilities; • protection against pests; • washing the site to a hygienic standard; • washing containers and vehicles to a hygienic standard; and • disposal of waste water. Registration and approval is issued by Animal Health (AH) (an Agency of Defra) or the devolved agriculture departments, as appropriate. Establishments that have been registered or approved by Regulations (EC) Nos. 852 and 853/2004 do not need to be registered or approved by the ABPR. Compliance with the ABPR in approved ABP premises is enforced by AH Officers of the AH/VLA (Animal Health and Veterinary Laboratory Agency) and Trading Standards Officers (TSOs) of the local authorities. Approval is suspended if the requirements of the ABPR are no longer being met.	

STAINING REQUIREMENTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
The TSE Regulations require that all SRM is stained blue immediately after removal. These Regulations also include a requirement to stain any product consisting of or incorporating any material derived from a bovine animal born or reared in the UK before August 1996. *(Regulation (EC) No. 999/2001, Annex V (as amended); (Transmissible Spongiform Encephalopathies (England) Regulation 2010, Schedule 7)*	Category 1 SRM can be mixed with other material at source but the mixture must be treated as Category 1 material and all must be stained blue. The specific stain is Patent Blue V (E 131) with a concentration of 0.5% weight/volume. Category 1 material which is <u>not</u> SRM and has <u>not</u> been in contact with SRM must be stained with Black PN or Brilliant Black BN and transported and disposed of as Category 1 material.	Stain should be applied layer by layer as the containers are filled.
The ABPI requires the occupier of slaughterhouses, cutting plants, cold stores, game handling-establishments and animal by-products premises to stain most Category 2 material and Category 1 material which is not SRM, **without undue delay.** *(ABPI, Regulations 6 & 7)* "Animal by-products premises" means premises, other than a cold store, cutting plant, slaughterhouse or game-handling establishment, from which animal by-products are dispatched to other premises. *(ABPI, Regulation 2(1))* <u>Staining exemptions:</u> • blood • feathers, bones, skins, hides, hooves, wool, horns and hair (even if mixed with Category 2 material) • entire body of a dead animal, except poultry carcases • animal by-products removed for OV examination. • animal by-products used for scientific purposes • animal by-products which	Category 2 material, <u>with the exception of gut contents and green offal</u> must be stained with a solution of Black PN or Brilliant Black BN. Category 2 material must be stained **without undue delay** and that means not allowing large amounts of material to accumulate to such an extent that it would be difficult to apply the stain evenly as required by the ABPI. Every surface of the material should be evenly covered with the solution which shall be of sufficient strength to provide a dark colouring so that the by-products cannot be illegally salvaged and diverted into the food chain. All pieces of red meat Category 2 material weighing more than 25kg and all poultry by-products comprising the entire poultry carcase (whether or not de-feathered or eviscerated) must have the solution applied after the surface has been opened by multiple and deep incisions. **Category 3 does not require staining unless it is mixed with a higher risk category (ie Category 1 or 2), in which case it must be treated as the higher risk category and stained accordingly**.	Stain should be applied layer by layer as the containers are filled.

are immediately moved through a sealed and leak-proof pipe which connects the meat plant or ABP plants to an approved rendering plant or incineration plant • manure and digestive tract contents • any green offal (unless it is being disposed of as SRM (e.g. bovine intestine), or animal by-products that are placed in a container the contents of which consist mainly of green offal. Only small quantities of other products may be mixed with the green offal. *(ABPI, Regulations 5 & 6(4)); (Transmissible Spongiform Encephalopathies (England) Regulation 2010, Schedule 7)* Where there has been: • a permanent or temporary closure of the approved premises; • a breakdown of the machinery installed there; or • a trade dispute, the ABPs may be moved, unstained, from the approved premises to other premises for incineration or rendering providing the movement is under the control of authorised officers of the FSA or of the Local Authority Environmental Health Department (EHD) or Trading Standards Department (TSD). *(ABPI, Regulation 10(2) ABPI)*	The exception for ABPs immediately moved through a sealed and leak-proof pipe applies to premises which have the rendering or incineration facilities located in the same premises in which the animal by-products are produced, or in a separate but contiguous premises. Bird carcases, when placed in the container with green offal, must be in such a state that the stain seeps into the flesh, i.e. by slashing. In this case the whole content of the container must be treated as Category 2 by-product. The list of circumstances in regulation 10(2) of the ABPI is not exhaustive; other exceptional circumstances may arise. In these cases operators must discuss each case with the authorised officers of the FSA, EHD or TSD who will determine whether exceptional circumstances apply.	

STORAGE, TRANSPORT, IDENTIFICATION AND LABELLING REQUIREMENTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
Animal by-products must be collected, identified and transported without undue delay. *(Regulation (EC) 1069/2009, Article 4.4(a))* *'non-edible by-products ….. are to be removed from rooms where food is present as quickly as possible……',* *(Regulation (EC) No. 852/2004, Annex II, Chapter VI, para 1)*	Material that is fit for human consumption and that is to go into the human food chain must not be labelled as ABP. If it is it may not go back into the human food chain and it will be treated as ABPs for enforcement purposes. Products of animal origin become ABPs when they are no longer intended for human consumption. If operators label material as ABPs, this is clear evidence of their intention.	
Storage of ABPs In all premises, animal by-products must <u>not</u> be stored in the same room as any product which is intended for human consumption unless it is placed in a suitable, sufficient and lockable receptacle with closely fitting covers that is only used for holding meat rejected as unfit for human consumption and is clearly marked to that effect. *(ABPI, Regulation 6, 2(a)(ii))* *(Regulation (EC) 853/2004, Section I, Chapter II, para 5 and Annex III, Section II, Chapter II, para 5)*	Storage facilities must be secure, soundly constructed or fully enclosed and proofed against birds and pests. Storage of ABPs must be in a lockable room if the quantity of ABPs is large enough to necessitate this. Receptacles or containers for the storage of ABPs must be leak-proof, with a lid and made of non-corrodible material.	
Labelling during storage, collection and transport For the storage of ABPs in meat plants the operator must label the containers in accordance with the ABPR **<u>or</u>** with the ABPI, as appropriate. During collection and transport from the meat plant, ABPs **must** be identified and labelled in accordance with the ABPR or the ABPI, as appropriate. *(Transmissible Spongiform*	For the storage and transport of ABPs in meat plants the operator must label the containers in accordance with either the ABPR **or** the ABPI, as appropriate. Both references have been given in this guidance. However, where ABPs are exported to another Member State the require-ments of the ABPR must be followed – not the ABPI.	Strict separation of the different categories of ABPs and strict separation of ABPs from material intended for human consumption reduces the risk of cross-contamination, accidental misplacement or mis-labelling material.

Encephalopathies (England) Regulation 2010, Schedule 7, para 17; and Implementing Regulation (EC) No. 142/2011 Annex VIII Chapters I and II; or ABPI, Regulation 9(3)). During storage, collection and transport the label attached to the container of ABPs must indicate the category of the material and must be marked as follows: 1. <u>if Category 1 containing SRM</u> • **"containing Specified Risk Material"** *(TSE (England) Regulation 2010, schedule 7, para 17),* <u>2. Other Category 1 material, Category 2 material or Category 3 material</u>: Either: (i) As required by paragraph 2, Chapter II, Annex VIII of the Implementing Regulation; <u>or</u> (ii) **"not intended for human consumption"** in letters at least 2 cm high. *(ABPI, Regulation 9(3)).*		Best Practice would be to have the full text written out, eg "Category 1 material – for disposal only". However, providing the labelling remains clear, then this may be shortened to, for instance: "Cat 1 material – for disposal only".
Transport of ABPs ABPs must be collected and transported in sealed new packaging or in covered leak-proof containers or vehicles. Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products must be maintained in a clean condition. In particular, unless they are dedicated to the carriage of particular ABPs in a way which avoids cross-contamination, vehicles and containers must be: (a) clean and dry before use; and	Trailers or containers must be washed to a hygienic standard each time they are emptied. Clean means visibly clean. If trailers or containers are not cleaned before they come on-site, operators must designate an area of the premises for cleaning vehicles, containers and receptacles used for transporting ABPs, on a suitably drained hard-standing. Operators must have adequate water supplies and equipment e.g. brushes, hoses, power-washers, for cleaning.	Ensure that all transport trailers or containers are adequately cleaned before they come on site. When justified by volumes, and to avoid contamination, best practice would be that each stream of material is transported in different vehicles. It is still necessary to transport all ABPs in leak proof and covered containers.

(b) cleaned, washed and/or disinfected after each use to the extent necessary to avoid cross-contamination. Reusable containers must be dedicated to the carriage of a particular ABP or derived product to the extent necessary to avoid cross-contamination. *(Regulation (EC) No. 1069/2009, Annex VIII, Section I)* During transport a label attached to the packaging, container or vehicle must clearly indicate the Category of the ABPs and be marked as required. *(Implementing Regulation (EC) No.142/2011, Annex VIII, Chapter II, paragraph 2*)	ABPs must be consigned only to the permitted approved destinations. If ABPs and food material are transported in the same vehicle the containers used for ABPs must be of sufficient size and strength to safely hold their contents without spillage or leakage, throughout the whole loading, transport and unloading process. Effective separation between ABPs and food material must be guaranteed at all times. If food becomes mixed with ABP then it has all to be treated as ABP. Containers/liners used for food material must be clearly identified and only used for the designated purpose.	
If ABPs and food material are transported in the same conveyance/on the same vehicle they must be kept separate and identifiable during transport. *(Regulation (EC) No. 852/2004 Annex II, Chapter VI)*	Where conveyances and/or containers are used for transporting anything in addition to food material, there must where necessary be effective separation of products.	Best practice would be to ensure that food material and ABPs are not transported in the same vehicle at the same time. This greatly reduces the risk of cross contamination and downgrading of material.

TEMPERATURE REQUIREMENTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
Temperature requirements The transport of animal by-products for the production of feed material or pet food must take place at an appropriate temperature. In the case of ABPs from meat and meat products which have been destined for purposes other than human consumption, at a maximum temperature of 7°C. Unprocessed Category 3 material destined for the production of feed material or pet food must be stored and transported chilled, frozen or ensiled, unless it is processed within 24 hours after collection or after the end of storage in chilled or frozen form, if the subsequent transport takes place in means of transport in which the storage temperature is maintained. The design of vehicles used for refrigerated transport must ensure that an appropriate temperature is maintained throughout the transport. There should also be provision for the temperature to be monitored during the journey. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter I, Section 2)*	Feed material must be transported under satisfactory hygiene conditions and at the temperature required for that material by the feed hygiene legislation.	

DOCUMENTATION REQUIREMENTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
Operators shall ensure that animal by-products are accompanied during transport by a **commercial document** or, when required by the legislation, a health certificate. *(Regulation (EC) No. 1069/2009, Article 21.2)*	It is not mandatory to use the model Commercial Document given in Annex VIII of the Implementing Regulation providing the information required by that document is included in any alternative document.	Best practice would be to use the **recommended model commercial document** in Chapter III, Annex VIII of the Implementing Regulation.
(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter III) The commercial document must specify at least: • the date on which the material was taken from the premises (ie the date of consignment); • the place of origin of the material, from where the material is dispatched (ie the name and address of the consignor/sender); • the name and address of the carrier of the material (ie name and address of haulage/ transport company); • the quantity of such ABPs, in volume, weight or number of packages; • a description of the ABPs including: the identification of the material – ie which Category ABP; the animal species and specific reference to the applicable point in Article 10 for Category 3 material and products derived from them which are destined for feeding; and, if applicable, the ear-tag number of the animal; • the name and address of the receiver and, if applicable, its approval or registration number (either under the ABP Regulations, the food hygiene Regulations or Regulation No. 183/2005); • if appropriate the approval or	Food business operators do not have to use the Commercial Document specified in the Implementing Regulation; any format may be used providing it contains the relevant information. The "quantity of material" should generally be the weight, or an estimation of the weight, of ABPs collected. However, in some cases it may be more appropriate to measure the quantity by volume, eg blood, or the number of containers (with an estimated weight). If the receiver is an approved ABP plant the details of that premises should be recorded, not those of the final destination, ie the place where the ABP end up would need to be recorded on the commercial document. A fresh commercial document would need to be	An acceptable example of a model Commercial Document is included as an Annex to this Chapter of the Edible Co-products Guide.

registration number of the establishment or place of origin and issued under either the ABP Regulations, the food hygiene Regulations or Regulation No. 183/2005, as applicable, and the nature of the methods of treatment; • the colour of the signature of the responsible person shall be different to that of the printing; and • the document reference number (ie the consignment number) and the local reference number shall only be issued once for the same consignment. *(Regulation (EC) 1069/2009, Article 21.3 and the Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter III, para 6)*	issued when the place of destination changes. Commercial documents must be produced in at least triplicate (one original and two copies). The original must accompany the consignment to its final destination and the receiver must retain it. The producer must retain one of the copies at the premises where the ABPs were generated (at the time of dispatch, not retrospectively), and the carrier must retain the other.	Best practice would be to produce four copies of the commercial document and for Part 2 to be returned to the original sender/consignor of the ABP for linking with the copy retained by the sender/ consignor.
Records of the above documentation must be kept for a minimum of two years. *(Implementing Regulation (EC) No. 142/2011, Annex VIII, Chapter III, para 5)*	Documents shall be retained by all those involved in transporting and processing ABPs, therefore records of usage of these materials are required as well. Records must be kept of any animal by-products (except manure) destroyed or used on the premises. This requirement is only likely to apply to meat plants that use on-site incinerators and rendering plants. In these cases, the operator shall record the quantity and description of the animal by-products, and the method and date of disposal or use.	

PERMITTED PROCESS OR DISPOSAL ROUTES FOR ANIMAL BY-PRODUCTS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**

Category 1
Category 1 material shall be:
• disposed of as waste by incineration:
  • directly without prior processing; or
  • following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
• recovered or disposed of by co-incineration, if the Category 1 material is waste:
  • directly without prior processing; or
  • following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
• in the case of Category 1 material other than material referred to in Article 8(a)(i) and (ii), disposed of by processing by pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill;
• in the case of Category 1 material referred to in Article 8(f), disposed of by burial in an authorised landfill;
• used as a fuel for combustion with or without prior processing;
• used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.
(Regulation (EC) No. 1069/2009, Article 12)
	To confirm the approval status of plants receiving by-products from approved meat plants the operator should check the AH website or contact the local AH office.
	
	SRM from TSE tested animals where a negative result has not been received must be destroyed by incineration or co-incineration.
	
	The use of SRM in plants handling ABPs or derived products for purposes outside the feed chain is no longer allowed under the ABPR (except for bovine serosa).
	
	The use of animal by-products for diagnostic, educational or research purposes or for taxidermy is covered by a general registration. Contact your local AH office for more information.	

Category 2
Category 2 material shall be:
• disposed of as waste by incineration:
  • directly without prior processing; or
  • following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
• recovered or disposed of by co-incineration, if the Category 2 material is waste:
  • directly without prior processing; or
  • following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
• disposed of in an authorised landfill, following processing by pressure sterilisation and permanent marking of the resulting material;
• used for the manufacturing of organic fertilisers or soil improvers to be placed on the market in accordance with Article 32 following processing by pressure sterilisation, when applicable, and permanent marking of the resulting material;
• composted or transformed into biogas:
  • following processing by pressure sterilisation and permanent marking of the resulting material; or
  • in the case of manure, digestive tract and its content, milk, milk-based products, colostrum, eggs and egg products which the competent authority does not consider to present a risk for the spread of any serious transmissible disease, following or without prior processing;
	Although the ABPR classifies manure and digestive tract contents as a Category 2 animal by-product, manure may still be applied untreated to any type of land.
	
	Digestive tract contents from the gut room may be applied untreated to land provided the land is not used for pasture for at least 3 weeks following application. Environmental controls must still be complied with; enforcement is by the Environment Agency (or the equivalent bodies in the devolved administrations).
	
	The use of animal by-products for diagnostic, educational or research purposes or for taxidermy is covered by an individual registration. Contact your local AH office for more information.	

• applied to land without processing, in the case of manure, digestive tract content separated from the digestive tract, milk, milk-based products and colostrum which the competent authority does not consider to present a risk for the spread of any serious transmissible disease;
• used as a fuel for combustion with or without prior processing; or
• used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.
(Regulation (EC) No. 1069/2009, Article 13)
 	
Category 3
Category 3 material shall be:
• disposed of as waste by incineration, with or without prior processing;
• recovered or disposed of by co-incineration, with or without prior processing, if the Category 3 material is waste;
• disposed of in an authorised landfill, following processing;
• processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, and used:
  • for the manufacturing of feed for farmed animals other than fur animals, to be placed on the market in accordance with Article 31, except in the case of material referred to in Article 10(n), (o) and (p);
  • for the manufacturing of feed for fur animals, to be placed on the market in accordance with Article 36;
  • for the manufacturing of pet food, to be placed on
		Note: Category 3 meat that decomposes (goes rotten) remains category 3 material unless it gets mixed with other category ABP, in which case it will take on that category.

the market in accordance with Article 35; or • for the manufacturing of organic fertilisers or soil improvers, to be placed on the market in accordance with Article 32; • used for the production of raw petfood, to be placed on the market in accordance with Article 35; • composted or transformed into biogas; • used as a fuel for combustion with or without prior processing; • used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles. *(Regulation (EC) No. 1069/2009, Article 14)* **DEROGATIONS** The legislation contains a number of derogations from the permitted disposal routes above where authorised by the competent authority. The main ones are (Note: not all these derogations will be implemented fully in GB; food business operators should speak to their competent authority for more information on whether they apply in their country):		
(b) used for research and other specific purposes in accordance with Article 17;	The use of animal by-products for diagnostic, educational or research purposes or for taxidermy is covered by an individual registration. Contact your local AH office for more information.	
(c) in the case of animal by-products referred to in Article 18, used for special feeding purposes in accordance with that Article;	Category 2 animal by-products consigned for disposal as feed for the categories of animal listed in (c) should be labelled: **'For feeding to** … [completed with the name of the species of animal intended]' instead of 'not for animal consumption'. The label should have letters at least	

	2cm high. The activities listed in (c) are covered by individual registration.	
(d) in the case of animal by-products referred to in Article 19, disposed of in accordance with that Article; (e) disposed of or used in accordance with alternative methods which have been authorised in accordance with Article 20, based on parameters which may include pressure sterilisation or other requirements of this Regulation or the implementing measures thereof;		
(g) in the case of Category 3 material and, if authorised by the competent authority, used for feeding to pet animals;	Where the competent authority has given authorisation allowing the food business operator to supply Category 3 material for supply direct to the consumer as raw material for feeding to pet animals, the food business operator must ensure that the relevant material has passed ante- and post mortem inspection and is fit for human consumption, (although not intended for human consumption). It must also have been kept separate from all other ABPs (including other Category 3 material) not intended for feeding to pet animals.	Best practice would be for Category 3 material supplied for feeding to pet animals to be kept in facilities specifically retained for such material and that are kept chilled or frozen prior to sale.
(h) in the case of animal by-products, except for Category 1 material, which arise in the course of surgical intervention on live animals or during birth of animals on farm and, if authorised by the competent authority, disposed of on that farm. *(Regulation (EC) No. 1069/2009, Article 16)*		

COLLECTION OF BLOOD		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
The ABPR requires operators to collect, identify and transport ABPs, including blood, without undue delay under conditions which prevent risks arising to public and animal health.. *(Regulation (EC) 1069/2009, Article 21.1)*	All slaughterhouses must have in place the necessary facilities to collect blood before transporting it to a registered or approved treatment plant, such as a rendering plant, biogas or composting plant. "Without undue delay" does not mean that ABPs must be disposed of immediately, but as soon as reasonably practical taking account of individual circumstances.	
Blood destined for blood products Only blood referred to in Article 10(a) and 10(b)(i) of Regulation (EC) No. 1069/2009 may be used for the production of blood products. That is: • carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons; • carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Community legislation, but which did not show any signs of disease communicable to humans or animals. *(Implementing Regulation (EC) No. 142/2011, Annex X, Chapter II, Section 2)*	If the operator wishes to collect blood for further use as a blood product, he must ensure that: • a system is in place to correlate the blood with the carcase until *post-mortem* inspection has been completed. This may be achieved by an individual or batch collection system so that a failed *post-mortem* result can be traced to a particular batch; • blood from any carcase that does not pass *post-mortem* inspection (along with any other blood it has already been mixed with) is prevented from being collected for use as a blood product and must be disposed of by other permitted means. Collection trays should be large enough to catch all the blood so as to keep the floor clean and minimise the amount of blood being washed down the drain. Blood for direct disposal can be collected in one large tank. If the operator wishes to dispose of blood from animals that have been tested for TSEs before the test results are received, it must be disposed of as Category 1 material (SRM).	Blood should, preferably, be collected daily, however for longer storage periods the use of preservatives is recommended.

Blood for pet food must derive from: • pigs and poultry which have passed *ante-mortem* inspection, or • ruminant animals which have passed both *ante-mortem* and *post-mortem* inspection. If the operator wishes to collect blood from ruminants for further use as pet food the conditions as for blood for blood products apply. *(Regulation (EC) No. 1069/2009, Article 10; and Implementing Regulation (EC) No. 142/2011, Annex X, Chapter II, Section 2)*	•	

HIDES AND SKINS		
Legal Requirements	**Operators' Compliance with Legal Requirements**	**Recommendations on Best Practice**
Hides and skins from animals that are passed fit for slaughter for human consumption following *ante-mortem* inspection, but are not destined for the human food chain, are classed as Category 3 ABPs. As with all ABPs they may only be transported to registered or approved ABP premises. *(Regulation (EC) No. 1069/2009 Article 10(a) and (b)(iii))*	Hides are subject to the same controls as other animal by-products and must be handled, stored and transported in the same way. (See above)	
However hides and skins that meet the requirements of the food hygiene legislation, have not been designated as animal by-products, and have not undergone any part of the tanning process can be used for the production of gelatine or collagen intended for use in food. *(Regulation (EC) 853/2004, Annex III, Section XIV, Chapter I, 1 and (Annex III, Section XV, Chapter I, 1)*	To ensure the safety of the raw material for the production of food grade gelatine and collagen, hides and skins must derive from animals that passed *ante* and *post-mortem* inspection as fit for human consumption. These hides and skins are not animal by-products, as they are intended for human consumption. At all times the operator must keep the streams of fit and unfit hides completely separate and ensure that only hides and skins	

	from animal declared fit for human consumption are used as raw material for the production of food grade gelatine and collagen. If the practice is for hides and skins to be separated from the carcase before completion of the *post-mortem* inspection, the operator should ensure that those hides and skins are individually identified. Alternatively, if they are not individually identified, the hides may be held in identifiable batches. The identification of hides is particularly important to guarantee their identification from animals that test positive for BSE. Those that test positive or where there is a "no test" result must be recalled, stained and destroyed according to the ABPR requirements. Collection centres and tanneries that intend to supply hides and skins as a raw material for gelatine or collagen must meet the requirements of paragraph 5, Chapter I, Section XIV or XV respectively, Annex III of Regulation (EC) No. 853/2004. **Further information –** Please refer to Chapters 3 & 4 (Gelatine and Collagen, respectively) of this guide.	Batching' hides and skins could potentially have a high economic impact, when one of the hides or skins is found to be unfit for human consumption. One way of mitigating this cost would be to mark each hide or skin with an unmistakable individual identification mark, such as a hide number, when skinning the carcase in the slaughterhouse.

WHAT ARE THE OFFICIAL CONTROL REQUIREMENTS?

Checks on compliance with the requirements of Regulation (EC) No. 1069/2009 *(Regulation (EC) No. 854/2004, Article 4(c))*

Meat plant operators must apply, continuously and properly, procedures for:

- animal by-products to be identified and separated correctly;
- animal by-products to be stained correctly;
- animal by-products to be labelled and stored correctly;
- animal by-products to be consigned from the premises to permitted approved destinations without undue delay;
- records of animal by-products consigned from the premises or disposed of on the premises to be properly kept; and
- a copy of the commercial document created at the time of the consignment to be kept.

ANNEX

Animal By-Products Commercial (Movement) Document

For ABP collected and delivered in compliance with the Animal By-Products Regulation (EC) No. 1069/2009

Part 1: for completion by Consignor/Sender (to accompany the consignment to its final destination and to be retained by the Receiver for 2 years from date of receipt)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**	
Date of consignment:		
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:	
Address of Consignor/Sender:		
Description of the Material including species (Label Wording)	Quantity/Weight/Volume of Material	Category No.
Name of Haulage/Transport Company:		
Address of Haulage/Transport Company:		
Name of intended Consignee/Receiver:		
Address of intended Consignee/Receiver:		
Approval No of intended Consignee/Receiver:		
Signed for Consignor/Sender:	Name :	
(Colour of signature to be different to that of the printing)	(Print)	

Section 2 (to be completed by Haulier)	
Date Collected:	Time:
Signed for Haulier:	Name:
(Driver)	(Print)

Section 3 (to be completed by Consignee/Receiver)				
Name of Consignee/Receiver:				
Address of Consignee/Receiver:				
I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.				
Material Description	Quantity/ Weight	Approval/Registration No. of Consignee/receiver	Site	Signature & Date Received
Date Received:		Time :		
Signed for Consignee/Receiver:		Name:		
		(Print)		

Animal By-Products Commercial (Movement) Document

For ABP collected and delivered in compliance with the Animal By-Products Regulation (EC) No. 1069/2009

Part 2: to be returned to the Consignor/Sender by Consignee/Receiver (Consignor/Sender to match and keep with retained part for 2 years)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**	
Date of consignment:		
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:	
Address of Consignor/Sender:		
Description of the Material including species (Label Wording)	Quantity/Weight/Volume of Material	Category No.
Name of Haulage/Transport Company:		
Address of Haulage/Transport Company:		
Name of intended Consignee/Receiver:		
Address of intended Consignee/Receiver:		
Approval No. of intended Consignee/Receiver:		
Signed for Consignor/Sender:	Name :	
(Colour of signature to be different to that of the printing)	(Print)	

Section 2 (to be completed by Haulier)	
Date Collected:	Time:
Signed for Haulier:	Name:
(Driver)	(Print)

Section 3 (to be completed by Consignee/Receiver)				
Name of Consignee/Receiver:				
Address of Consignee/Receiver:				
I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.				
Material Description	Quantity/ Weight	Approval/Registration No. of consignee/receiver	Site	Signature & Date Received
Date Received:	Time :			
Signed for Consignee/Receiver:	Name:			
	(Print)			

Animal By-Products Commercial (Movement) Document

For ABP collected and delivered in compliance with the Animal By-Products Regulation (EC) No. 1069/2009

Part 3: for retention by Haulier (for 2 years from date of delivery)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**	
Date of consignment:		
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:	
Address of Consignor/Sender:		
Description of the Material including species (Label Wording)	Quantity/Weight/Volume of Material	Category No.
Name of Haulage/Transport Company:		
Address of Haulage/Transport Company:		
Name of intended Consignee/Receiver:		
Address of intended Consignee/Receiver:		
Approval No. of intended Consignee/Receiver:		
Signed for Consignor/Sender:	Name :	
(Colour of signature to be different to that of the printing)	(Print)	

Section 2 (to be completed by Haulier)	
Date Collected:	Time:
Signed for Haulier:	Name:
(Driver)	(Print)

Section 3 (to be completed by Consignee/Receiver)				
Name of Consignee/Receiver:				
Address of Consignee/Receiver:				
I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.				
Material Description	Quantity/ Weight	Approval/Registration No. of consignee/receiver	Site	Signature & Date Received
Date Received:	Time :			
Signed for Consignee/Receiver:	Name:			
	(Print)			

Animal By-Products Commercial (Movement) Document

For ABP collected and delivered in compliance with the Animal By-Products Regulation (EC) No. 1069/2009

Part 4: to be retained by the Consignor/Sender (to be retained for 2 years from date of dispatch)

Section 1 (to be completed by Consignor/Sender)	**Consignment No:**	
Date of consignment:		
Name of Consignor/Sender:	Lic/App/Reg No of Consignor/Sender:	
Address of Consignor/Sender:		
Description of the Material including species (Label Wording)	Quantity/Weight/Volume of Material	Category No.
Name of Haulage/Transport Company:		
Address of Haulage/Transport Company:		
Name of intended Consignee/Receiver:		
Address of intended Consignee/Receiver:		
Approval No. of intended Consignee/Receiver:		
Signed for Consignor/Sender:	Name :	
(Colour of signature to be different to that of the printing)	(Print)	

Section 2 (to be completed by Haulier)	
Date Collected:	Time:
Signed for Haulier:	Name:
(Driver)	(Print)

Section 3 (to be completed by Consignee/Receiver)				
Name of Consignee/Receiver:				
Address of Consignee/Receiver:				
I confirm that the material identified in Section 1 above was received at the named Consignee/Receiver premises from the named haulier.				
Material Description	Quantity/ Weight	Approval/Registration No. of consignee/receiver	Site	Signature & Date Received
Date Received:		Time :		
Signed for Consignee/Receiver:		Name:		
		(Print)		