

**European Guidance Note on the
Safe handling of Raw Hides and Skins
throughout the whole value chain
in the Community.**

Prepared by

GME, COTANCE, UECEBV, Collagen Industry

April 2006

CONTENTS

Foreword

1. General introduction
 - 1.1. Types of hides and skins
 - 1.2. Plants where hides and skins are obtained in the Community
 - 1.3. Extra EU imports of hides and skins
 - 1.4. The EU Hides and Skins value chain
2. Aim of the guidance
 - 2.1. Scope & Coverage
 - 2.2. Guidance structure
 - 2.3. Handling procedures
 - 2.4. Disposal routes
3. Guidance Notes
 - 3.1. Guidance Note on the handling of bovine hides originating in EU slaughterhouses
 - Annex 1**
Slaughterhouses – detailed description of the applied processes
 - Annex 2**
Hide traders and Tanneries - detailed description of the applied processes
 - Annex 3**
Gelatine and Collagen manufacturers - detailed description of the applied processes
 - 3.2. Other Guidance Notes (may be developed if necessary)

Foreword

Hides and Skins originate as an agricultural product and finds multiple applications in industry. The most important outlet of this value chain is of course leather manufacture, but the nature of hides and skins allows also a useful application in the food and feed sector.

Hides and skins are valuable natural renewable resources at the crossroad of agriculture and industry subject to a wide variety of regulatory requirements. These have to be met by business sector's and operators in traditional value chains that have evolved over the time but which are still composed by a large majority of small and medium sized companies.

This Guidance agreed by the most representative organisations involved in the value chain is submitted for endorsement to EU authorities so as to harmonise handling practices where relevant in the Community.

1. GENERAL INTRODUCTION

1.1. Types of hides and skins

Hides and Skins are the dermal envelopes of animals. They are by-products of the meat industry and are obtained after flaying through the separation of the dermal tissue from the carcass.

- *Hides* are the dermal envelopes of bigger ruminants such as cattle, elks, buffaloes, camels or horses, while
- *Skins* are those pertaining to smaller animal species such as pigs, sheep, goats, rabbits or hares or younger animals like calves, but also fur animals and certain reptiles such as snakes, lizards or crocodiles.

The trade distinguishes between both categories according to the thickness of the dermis.

The thickness of the hide is of relevance for certain products of the leather industry, such as the vegetable tanned leather for footwear soles requiring a higher mass of collagen for the strength of the material.

The thickness of bovine hides or similar allows splitting the material in three layers (splits) of which the outer layer containing the grain structure is the most valuable one for high quality leather production (grain split). The second layer is generally uniform and may serve to produce a coated leather with an artificial grain structure or a different finishing (split for leather production). As this layer is very rich in collagen as well, parts which are not suitable for tanning can be used as high quality raw material for gelatine and collagen production (hide splits). The third layer may already present large wholes due to the uneven structure of the hide. Leather making of such a split material is not cost efficient enough. Other valorisation routes of this otherwise valuable material have been developed, including the animal feed chain.

Hides and skins may carry remains of the connecting tissue that need to be removed as fleshings. Fleshings may find valorisation routes in technical applications (tallow, glue, fertilisers, biogas).

The skins of smaller animals generally do not allow spitting due to the much lower mass of collagen material. The exception is the production of Chamois leather with sheepskins where the fine grain split is used to produce *skivers* (bookbinding leather) and the lower grain serves for the production of the traditional piece of oil tanned Chamois.

Hides and skins are covered by hair or wool that may be removed during early processing unless the article requires their presence (double face leather or wool-on sheepskins or rabbitskins, or furskins). The hair or wool is either dissolved and eliminated or saved and recovered. It is a valuable bio-fertiliser or soil improver authorised for organic farming in the EU.

Hides and skins are generally trimmed to the traditional leather shape by cutting away from the edges those parts that are irregular or redundant for leather production. This operation may occur at various processing stages.

Contrary to bovine hides and pigskins, the remains of skins of smaller animals that do not serve for tanning have currently no outlet in the human food chain. They are eventually valorised in technical products.

1.2. Plants where hides and skins are obtained in the Community

Flaying is the operation where the hide or skin is taken off the animal liberating the carcass for further handling.

It is performed under veterinary control in authorised plants when the carcass of the farmed animal is destined for further use in the food or feed chain.

When this operation is performed by rendering plants or on a farm, the hides or skins as well as the carcass can only be destined for technical uses or final disposal.

Flaying can also be performed by other authorised persons such as hunters at a small scale.

Hides and skins obtained in the EU are produced by professionals organised in plants registered and authorised for this function by the competent authorities.

1.3. Extra EU imports of hides and skins

Hides and skins are not always available in sufficient quantity and quality for the European tanneries. Therefore imported hides or skins complete the demand in the EU for these raw materials. This demand is driven by the EU tanning industry.

Imported raw hides and skins are accompanied by a sanitary documentation harmonised at EU level setting the sanitary status of the consignment, keeping them separated and determining thus the valorisation potential in the food, feed or technical value chains.

1.4. The EU Hides and Skins value chain

Production

Hides and skins are carried by the animals during their life. They have no separate identity from the originating animal until they are obtained through flaying.

Before slaughter, hides and skins belong to the owner of the animal, generally a breeder, or to wildlife authorities setting the rules for their commercial use.

Farmed animals are given away for slaughter or culling by specialised plants (slaughterhouses for healthy animals fit for human consumption, rendering plants for animals killed to eradicate an epizootic disease, fallen stock, etc.).

Wild animals are hunted and processed by professionals according to hunting regulations in force in the EU.

If an animal is found dead either on the farm (fallen stock) or in nature, such an animal can only be handled by rendering plants.

Hides and skins placed on the market in the EU are thus obtained by

- Commercial plants:
 - servicing the food and feed chain: slaughterhouses
 - servicing technical value chains: rendering plants
- Professionals
 - Importers
 - Others: servicing food, feed and technical value chains, e.g. hunters

Transport

Hides and skins are transported by professionals competent for the transport of these materials contracted for this purpose by the seller or the buyer in the supply chain.

Storage

Hides and skins and all parts thereof are collected and stored in collection centres, in slaughterhouses or in tanneries authorised as collection centres until dispatch for further processing.

Processing

Raw hides and skins or their parts are further processed

- in tanneries (e.g. leather production)
- in food businesses (e.g. gelatine or collagen production)
- in feed plants (e.g. pet food production)
- in technical plants (e.g. production of tallow, glue, fertilisers, etc...)
- in disposal centres (e.g. incineration plants, biogas plants, etc...)

End use of processed hides and skins

From cradle to grave, hides and skins are valorised according to the principles of

- waste minimisation
- best allocation of resources

The resource hide or skin and all their constituent parts are allocated to a valorisation route according to the sanitary status of the material. The definitive sanitary status of a hide or skin is given by the competent authorities in EU Member States delivering the results of the meat inspection carried out on the animal before and after slaughter. The decision of the competent authority covers all parts of the slaughtered animal, including the hides and skins.

Hides and skins can be deemed:

- Fit for human consumption
- Unfit for human consumption

According to their sanitary status, hides or skins can be channelled into different valorisation routes.

Fit bovine hides or pigskins and their parts are eligible to be processed into the human food chain apart of keeping intact all other possible technical valorisation routes, such as leather processing. They require for that purpose the appropriate documentation certifying that the material can enter the human food chain.

Unfit hides or skins and their parts are precluded to enter the human food chain for precautionary reasons, but they can be valorised in technical valorisation routes. These materials are identified with a commercial document that bans their use in the human food chain.

2. AIM OF THE GUIDANCE

2.1. Scope & Coverage

The aim of this Guidance is to provide the hide and skin value chain with peer reviewed handling procedures for their safe handling.

Its scope comprises the whole value chain of raw hides and skins, from their origin until their transformation in end products or their disposal ensuring where relevant and appropriate traceability, notably for those materials eligible for entering the human food chain in the form of gelatine and collagen.

The Guidance covers all parts of hides or skins, notably their off cuts (cuttings, trimmings, splittings, shavings) following the principle that all parts exclusively remain in the status of the starting material it comes from.

The Guidance sets up the procedures for safe handling of hides and skins throughout the whole value chain in the Community. The procedures clearly set out the rules that have to be observed so that the Community legal order is complied with.

The Guidance develops self-regulation there where EU legislation fails to address specific circumstances or needs additional clarification.

Risk management procedures for tracing, retrieving and separating with certainty certain materials that are misclassified are opportunely addressed in the specific Guidance Note.

2.2. Guidance structure

The Guidance has been structured so as to allow the eventual development of safe handling procedures for all possible hides or skins in specific Guidance Notes.

The first Guidance Note concerns the safe handling of hides of healthy bovine animals obtained in EU slaughterhouses of which certain parts constitute a valuable raw material for the production of gelatine or collagen for human consumption. This is a mature value chain in the Community and all representative organisations have agreed a harmonised framework of practical handling procedures ensuring compliance with Community rules and principles.

Other Guidance Notes concerning different value chains may be added to this structure if so required by public or private stakeholders provided they are agreed by the corresponding value chain partners.

Disposal routes distinct or complementary to those specifically indicated in the corresponding Guidance Note can also be added as appropriate and agreeable by the corresponding value chain partners.

All changes made to the Guidance must be communicated with and approved by the relevant European authorities (DG Sanco, Member States, etc.)

2.3. Handling procedures

The Guidance establishes the principle of separation between streams of fit and unfit hides or skins. The specific Guidance Notes provide reasonable and applicable handling procedures taking into account local circumstances and practices approved at national level in development as well.

3. GUIDANCE NOTES

3.1. Guidance Note on the handling of bovine hides originating in EU slaughterhouses

3.1.1. General Remarks

See Annex 1 slaughterhouses Diagram 2.

Bovine hides are of high economic importance for all industries involved in the further processing of this material. The bovine hides obtained from healthy animals provide an excellent raw material for different applications in both the leather industry and the food industry. The upper part of the hides (dermis) grain layer is used by the leather industry. The middle part of the derm, the hide split, is the collagen rich layer of the hides, of which the central part ("croupon") can also be used for further processing in the leather industry, and the lower part and the edges are a valuable raw material for the production of gelatine, collagen (e.g. sausage casings) and some technical uses.

Hides are obtained as a first step after slaughtering of healthy animals. From the slaughterhouses the fresh hides are transported as quickly as possible to the collection centres and/or the tanneries with an own collection centre. Once segregated into fit and unfit materials, the hides can be dispatched for further processing to tanneries. After dehairing and fleshing at the tanneries, the cleaned hide pieces may be cut off and the remaining hides are split into two (or more) layers, the upper layer (grain split for leather production) and the lower layer (hide splits). This initial separation is made before tanning the hides in order to maximise their valorisation following the principle of the best allocation of resources. The hide pieces and hide splits not destined for leather production are finally transported to the gelatine and collagen production plants.

3.1.2. Background legislation

The Guidance Note is based on European legislation covering issues related to the separation and processing of bovine hides:

- Regulation (EC) No 1774/2002 for materials not intended for human consumption, especially defined by Article 6 (1) (b) and (c)and
- Regulation (EC) 853/2004, Annex III, SECTION XIV and XV for materials intended for human consumption.

The guidance supports the intra-community implementation of the requirements for the safe separation, storage and transport of hides from cattle slaughtered under veterinary control for human consumption.

3.1.3. Stakeholders involved

The major trade associations and industries involved in the value chain of hides are:

- **UECBV** (European livestock and meat trading union),
- **UENCPB** (Union Européenne des Négociants en Cuirs et Peaux Brutes),
- **COTANCE** (Confederation of National Associations of Tanners and Dressers of the European Community),
- **GME** (Gelatine Manufacturers of Europe) and
- **Collagen Manufacturers of Europe**

3.1.4. Aim & Scope of the Guidance Note

The Guidance Note focuses only on bovine hides obtained in regular slaughtering.

It shall be recalled that gelatine and collagen for human consumption may be obtained exclusively from hides of animals found fit for human consumption.

The following Guidance Note describes the procedure of hide handling within a single Member State.

The Guidance Note complements current legislation with self-regulation by the value chain partners where EU legislation fails to address specific circumstances or needs additional clarification. This is the case where slaughterhouses are not prepared for separating in-house fit and unfit hides and perform this operation in a decentralised collection centre of their choice within the coverage of the official control of their Member State.

This guidance also defines

- the conditions for the identification of hides,
- the necessary documentation for final release of the hides as originating from animals found fit for human consumption, and
- the separation of hides of animals found fit or unfit for human consumption on the level of collection centres and/or tanneries acting as a collection centre,

as such ensuring a full traceability.

The procedures described in this Guidance Note may also be approved by the competent authority of the Member State releasing a special authorisation to operators.

The aim of the guidance is to ensure the availability of safe and high quality raw materials for the value chain of bovine hides, and more precisely to consolidate the bovine hide pieces and splits as an animal by-product intended for the production of gelatine and collagen for human consumption.

The guidance establishes – by means of cross-industry, uniform operating instructions – the highest possible standard of safety measures in order to exclude errors in performance or judgement. This reliably excludes that materials that are not duly separated reach a processing stage of food businesses . To reach this ambitious aim, it is important for all participants in the supply chain to comply with basic production conditions. These are described in this Guidance Note as well.

3.1.5. Provisions governing imports of raw materials for gelatine and collagen production

Section 1 a) of **Annex 3** to the Guidance deals with existing rules for the import of raw materials for gelatine and collagen manufacture. Import of raw materials for the production of gelatine for human consumption is only possible when accompanied by a Health Certificate according to Regulation 2074/2005 ANNEX VI, appendix II and III part B. This certificate has to be signed by an official veterinary who confirms that the raw materials comply with the requirements of Regulation (EC) 853/2004, Annex III, SECTION XIV and XV.

Additionally existing legal provisions ([Decision 94/723/EC](#) and [97/168/EC](#)) apply to the import and transit of fresh hides, so that there is no need for further regulation by this Guidance Note.

3.1.6. Provisions governing fallen stock and their hides

Hides and skins from fallen stock according to Regulation (EC) No 1774/2002, Article 6 (1) (k) are invariably unfit for human consumption and pet food. They were obtained in rendering plants and not in slaughterhouses and are classified without any further differentiation in the category “*exclusively for technical use*”.

As these materials always arrive totally separated, further sorting in the collection centres is not necessary.

In this context, the following must be assured:

Hides and skins from fallen stock

- are obtained exclusively in rendering plants.
- originate from animals that were emergency slaughtered or died a natural death.
- originate from animals that displayed no clinical symptoms of a disease communicable via the hides or skins to humans or animals.
- are sent to collection centres (hide traders) who treat and store them separately from hides for gelatine or collagen purposes. The batches must be marked clearly.
- are traded as category 3 hides and are accompanied by documents according to Regulation (EC) No 1774/2002.

3.1.7. Status of the different installations involved in the supply chain of raw materials for gelatine and collagen production

Not all sectors involved are directly concerned by food hygiene requirements (Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004). Nevertheless hide pieces and splits are an essential and valuable raw material for the production of gelatine and collagen. Being channelled into the food chain, the premises handling bovine hides fall under the scope of certain provisions of the food hygiene regulation, and the raw materials used need at least to comply with basic food hygiene requirements.

Collection centres and tanneries are not regarded as food premises. Both are technical plants and as such do not have to comply with the full load of food hygiene requirements. Nevertheless, due to the fact that the hide splits are used as a raw material for food, collection centres and the tanneries do already meet basic food hygiene requirements.

3.1.8. Other raw materials used for the gelatine and collagen production for human consumption

Beside bovine hides, other raw materials like pigskins, porcine, poultry and bovine bones as well fish skins can be used for the production of gelatine/collagen.

These raw materials originate in a supply chain involving different stakeholders than the ones underwriting the present Guidance Note and are therefore not dealt with here.

The regulatory requirements and systems in place for these raw materials are, however, in place and sufficiently clear. There is no need to include them in this Guidance Note.

3.1.9. Procedures

The following procedures have been agreed by the value chain partners:

In addition to the legal requirements described in the annexes of this Guidance Note, the following requirements applying notably for the supply of raw materials for the production of gelatine and collagen for human consumption have to be met:

a) Identification requirements and traceability

- Each hide must wear an individual identification mark corresponding to each animal, preferable with a ring, or with any other marking system remaining attached to the hides during manipulation and being used only once. The identification must be feasible and allow identifying the source individual animal with certainty.
- All precautions must be taken to ease the retrieval of the hide of the possible BSE positive animal, keep them separate as a lot until the results of the post mortem inspections including the BSE rapid test are available (keeping all the information concerning the slaughterhouse of origin, the date of slaughtering, the date of reception of the hide).
- The transport of the concerned lots of hides must be documented upon dispatch from the slaughterhouse and upon reception at the storage place.

b) Requirements for hide handling

Both the slaughterhouses wishing to release the hides before the results of the post mortem inspections including the BSE rapid tests, and the collection centres receiving these hides, have their premises within a single Member State. They must be registered by the competent authorities of that Member State and have a clear description of the traceability and identification system in place. This includes the measures put in place to retrace the hides in case of positive results.

The slaughterhouses should be able to provide the addresses of the collection centres located within the same Member State, where the hides are stored and handled after shipment and until the results of the test are available. The hides may not transit through more than one establishment nor may they be transported to another Member State, and the handling is limited to preservation (e.g. salting), storing and eventual trimming. No further processing is allowed. The lots must be kept together and separate until final release.

Independently of the results of the post mortem inspections and the BSE rapid tests, the slaughterhouses and collection centres and/or tanneries acting as a collection centre will perform on a regular basis audits to verify the compliance to the above mentioned measures which should include also traceability tests performed by professional staff.

The professional staff is responsible for the individual identification of all hides. The omission of an identification of a hide of one animal may have as a consequence

that the identification of the other hides of the same lot is no longer valid. Further details on slaughtering practices and hide handling at the slaughterhouses can be found in **Annex 1**.

c) Procedures for the expedition of hides

A document containing the following information must accompany the hides during transport, within one single Member State, from the slaughterhouse to the collection centre, if released before the post-mortem inspection results including the rapid BSE test:

- the individual identification number of each hide
- mentioning “bovine hides submitted to post mortem inspections and BSE rapid tests but transported before test results are available”
- indicating the place of final destination

This document, signed by the local veterinary services of the slaughterhouse, is the visa and also mentions that “the hides may not be released and must remain under supervision at the collection centre, until the notification of release is established by the veterinary services of the slaughterhouse”. The document also contains the registration number of the slaughterhouse, is dated and also numbered in case several shipments from the same slaughterhouse take place the same day.

Upon reception at the collection centre, the lots of hides are kept under consignment. They may only be released to tanneries upon reception of the information from the veterinary services of the slaughterhouse of origin.

The information must contain the lot reference (slaughterhouse/registration number, date of expedition, document number) and mention that all tested animals obtained a negative result of the BSE rapid test. The release of a lot may not take place as long as the results of one single animal is not yet finalized.

In case of a positive result, the veterinary services of the slaughterhouse inform the competent authority of the region where the hides are stored. The necessary separation of hides by hides fit or unfit for consumption and the further separate treatment of both streams is described in detail especially in **Annexes 1 and 2**, and made quite clear in diagrams.

In separate deliveries only batches of hides that can be clearly distinguished into hides fit or unfit for consumption by means of the accompanying trade documents and marks on the hides reach the tanneries. Next come separate and controlled processing, production, storage and dispatch of by-products according to **Annex 2** to the guidance.

d) Final provisions

A written procedure, approved by the competent authorities, should be in place which clearly describes the traceability and management systems in case an animal did not obtain a negative BSE result and the hide from that animal must be retrieved in a collection centre. In the event of an error the only option is to sort out the concerned materials and to channel them into safe disposal or processing, separated from fit materials. The hide of a BSE positive animal must be incinerated directly or after processing in specialized rendering plants. However, if for one or

the other reason, the hide from a positive animal cannot be traced back with certainty, the whole lot will have to be incinerated.

Hides of animals declared unfit for human consumption, shall be separated from hides of animals found fit for human consumption on the level of collection centres and/or tanneries acting as a collection centre.

Collection centres and tanneries completely separate the streams of fit and unfit hides and ensure that only hide pieces and hide splits from animals declared fit for human consumption are delivered to gelatine and collagen for human consumption production facilities.

All shipments to these facilities (tanneries, gelatine and collagen plants) have to be accompanied by a Commercial Document complying with the model provided in Regulation 853/2004 appendix to ANNEX III. Additionally, it must be confirmed that all raw materials have been derived from animals found fit for human consumption. The gelatine and collagen manufacturers can only accept and process raw materials which are accompanied by such a document and the additional confirmation.

They have to audit their suppliers on a regular basis in order to verify compliance with the requirements laid down in this Guidance and the relevant European legislation.

The competent authorities make regular controls in the gelatine and collagen production plants in order to verify compliance with these requirements as well. Further details of gelatine and collagen manufacturing can be found in **Annex 3**.

3.1.10. CONCLUSIONS

In order to safeguard the supply of raw materials for gelatine and collagen production and in order to ensure all food safety aspects, the stakeholders involved committed themselves to prepare this European Guidance Note on how to handle bovine hides, which would emphasize the current practice and harmonize the procedures within the industries concerned.

The Guidance Note described above explains the procedures agreed by the value chain partners for ensuring the separation of streams of fit and unfit hides, including the transport, within one single Member State, of fresh hides derived from healthy cattle and slaughtered in EC approved slaughterhouses prior to the availability of the results of the post mortem inspections and the BSE tests.

This procedure guarantees safety of the whole value chain of fresh hide handling as does current European legislation. It ensures that fresh hides under official control are fully traceable until the hides are finally released as derived from animals found fit for human consumption and can be separated from hides not in compliance with this requirement.

As only the hides and hide pieces from animals declared fit for human consumption can be supplied for the production of gelatine and collagen for human consumption, this guidance further ensures the supply of these industries with high quality and safe raw materials.

Slaughterhouses

Detailed description of the applied processes

When skinning the carcasses in the slaughterhouses, cattle hides are marked with an unmistakable individual identification mark (hide number) where required. Subsequently, skinned hides are placed into collection containers. These collection containers are picked up by hide dealers in short intervals. Hides in transport containers are marked clearly. When the hides are not preserved in the slaughterhouse, hides are transported exclusively to a collection centre and known to the veterinary inspection services, where they are immediately preserved by way of chilling or salting. **See Diagram 3.**

Hides from animals subject to BSE testing and before the results are available may only be transported within the same Member State from the slaughterhouse to a collection centre. Upon approval of the competent authorities a tannery can also act as a collection centre.

The official veterinarian competent for the slaughterhouse sends by fax a letter of referral each to the official veterinarian competent for the collection center and to the collection center itself.

The letter of referral should contain the following items of information:

- Number of hides of the day of slaughter
- Unfit hides
- Temporarily confiscated hides'
- "BSE test" hides

including slaughter and hide numbers of all hides in this batch.

Based on this letter of referral, hides are separated and preserved in the collection centre.

As soon as the results for 'temporarily confiscated' and 'BSE test' hides are available, the official veterinarian competent for the slaughterhouse sends the relevant releases to the collection centres and to the veterinary office competent for the collection centres. Only when all supplied hides are 'released' – i.e. only when each individual hide can be classified as fit, unfit or SRM - the hides can be distributed/sold in lots with a 'commercial document for gelatine/collagen producers' or a 'commercial document for non-human consumption'.

In the clear majority of slaughterhouses it is, for constructional and economic reasons, difficult or possible only at indescribable expense and effort to sort out and remove from collecting containers the hides from cattle found unfit. By contrast, this is easy at collection centres, because – prior to preservation – the hides need to be dealt with individually and separated for weighing, assessment, sorting for sale and documentation.

Where cattle undergo BSE testing, usually results are available only in the morning of the day following slaughter. Consequently, a final assessment can be made only with considerable delay. However, to prevent spoiling and value-reducing damage due to putrefaction, hides must be transported as soon as possible for treatment and preservation to a specialized operation of the collection centres. After only 6 to 8 hours, bacterial and enzymatic activities can cause irreversible damage to the hide collagen which no longer enables the manufacture of high-quality leather. Where a bacteriological examination is necessary, even 4 to 5 days pass up to the final assessment.

In terms of consumer protection, it is not of primary importance whether sorting takes place at the slaughterhouse or, at a later stage, at the collection centres; the important point is that sorting is performed in due form and that this is inspected regularly by the competent veterinary services. Consequently, the careful and well-documented sorting out of hides from unfit animals at the collection centres, based on the prescribed markings, is an indispensable part of the safety chain in gelatine and collagen production.

Deviating from the provisions of Annex III, Chapter XIV of Regulation (EC) No 853/2004, cattle hides from slaughterhouses can be supplied to collection centres, without differentiating between hides from fit or unfit animals, only on the following conditions:

1. Collection centres ('hide dealers') registered with competent authorities according to Regulation (EC) No 853/2004 are subject - just like the tannery it supplies - to the control of the official veterinarian competent for the operating site.
2. Cattle hides must be marked, at slaughter, with an unmistakable hide number (individual identification number).
3. The distribution of cattle hides to collection centres takes place by means of a letter of referral issued by the slaughterhouse and countersigned by the official veterinarian competent for the slaughterhouse; the letter of referral states the individual identification numbers of the cattle hides as well as appertaining slaughter numbers and, additionally, the assessment of the respective cattle under official meat inspection regulations: 'fit', 'unfit', 'temporarily confiscated', and 'BSE test'.

Where the assessment under official meat inspection regulations is not yet finalized at the time of dispatch from the slaughterhouse (temporarily confiscated, BSE test), the hides remain within the same Member State and under the supervision of the veterinary authorities. As soon as results from pending examinations become available, the collection centres receive from the official veterinary service for the slaughterhouse the final assessment in form of a release.

4. The collection centre may distribute to tanneries cattle hides fit for the production of edible gelatine only if the relevant declaration of fitness by the official veterinary services for the slaughterhouse has been issued in writing. Cattle hides found 'unfit' must be sorted out immediately and separated from the hides intended to serve as raw material for the production of food grade gelatine or collagen. Hides from animals with a positive outcome of BSE testing are recalled, dyed and destroyed.

5. Collection centres keep the letters of referrals and the official declarations of release together with the commercial documents and prove, in this manner, at any time for inspection by the official veterinary services that exclusively hides from cattle found fit for human consumption and accompanied by a commercial document are dispatched to tanneries and/or gelatine/collagen manufacturers.
6. The slaughterhouses, collection centres and/or tanneries acting as a collection centre must deliver hides from cattle found unfit, due to positive BSE results, against receipt to the rendering facility for category 1 by-products competent for the given geographical area. The receipt is to be placed in the files and kept.
7. Slaughterhouses, collection centres and tanneries carry out internal audits on a regular basis in order to verify compliance with the requirements of this Guidance.

See next page how hides and skins are obtained in typical slaughterhouse.

Diagram 1: In a typical slaughterhouse, hides and skins are obtained as follows:

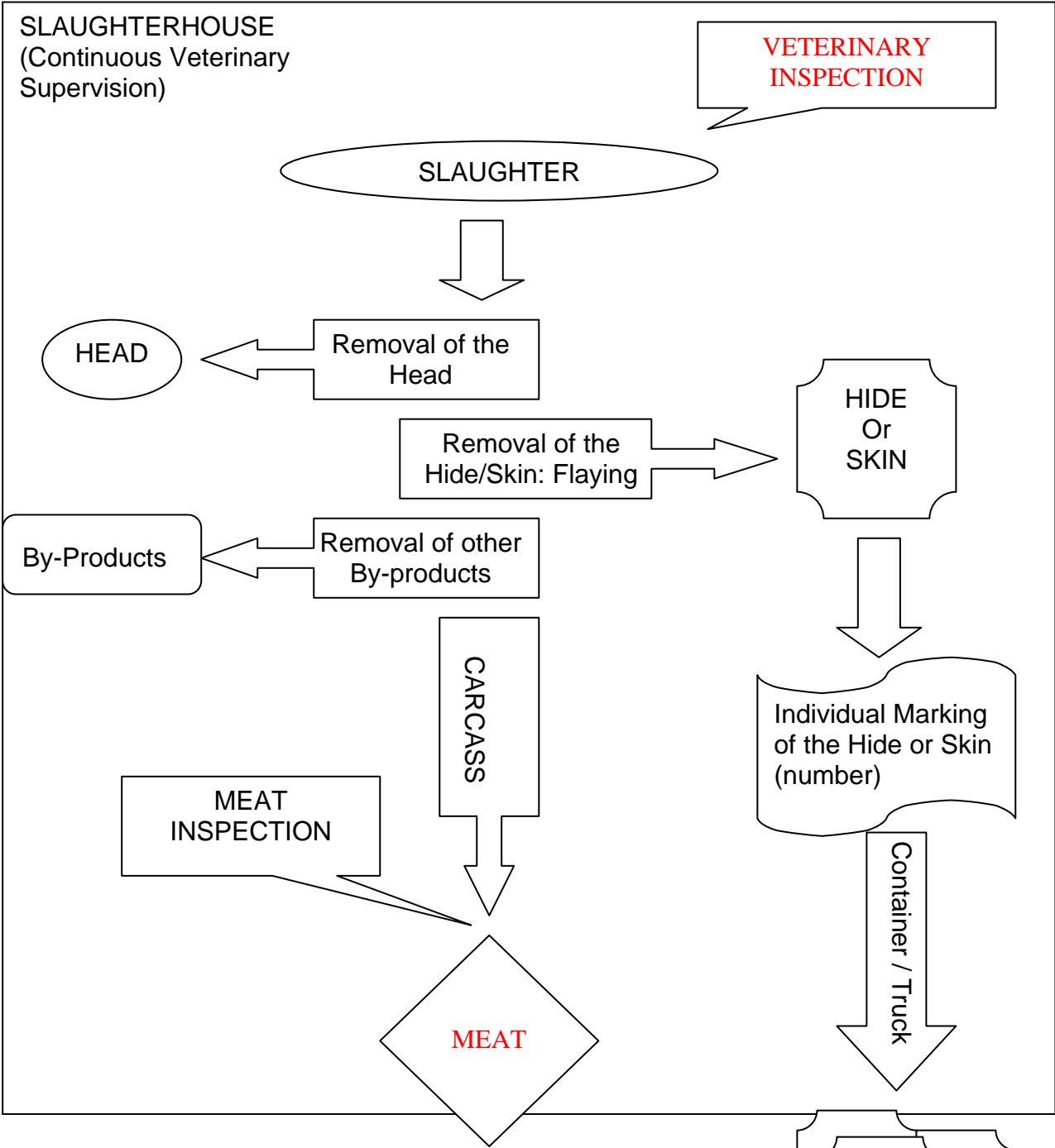


Diagram 2:

Release after BSE and Post Mortem inspection results (different commercial documents)

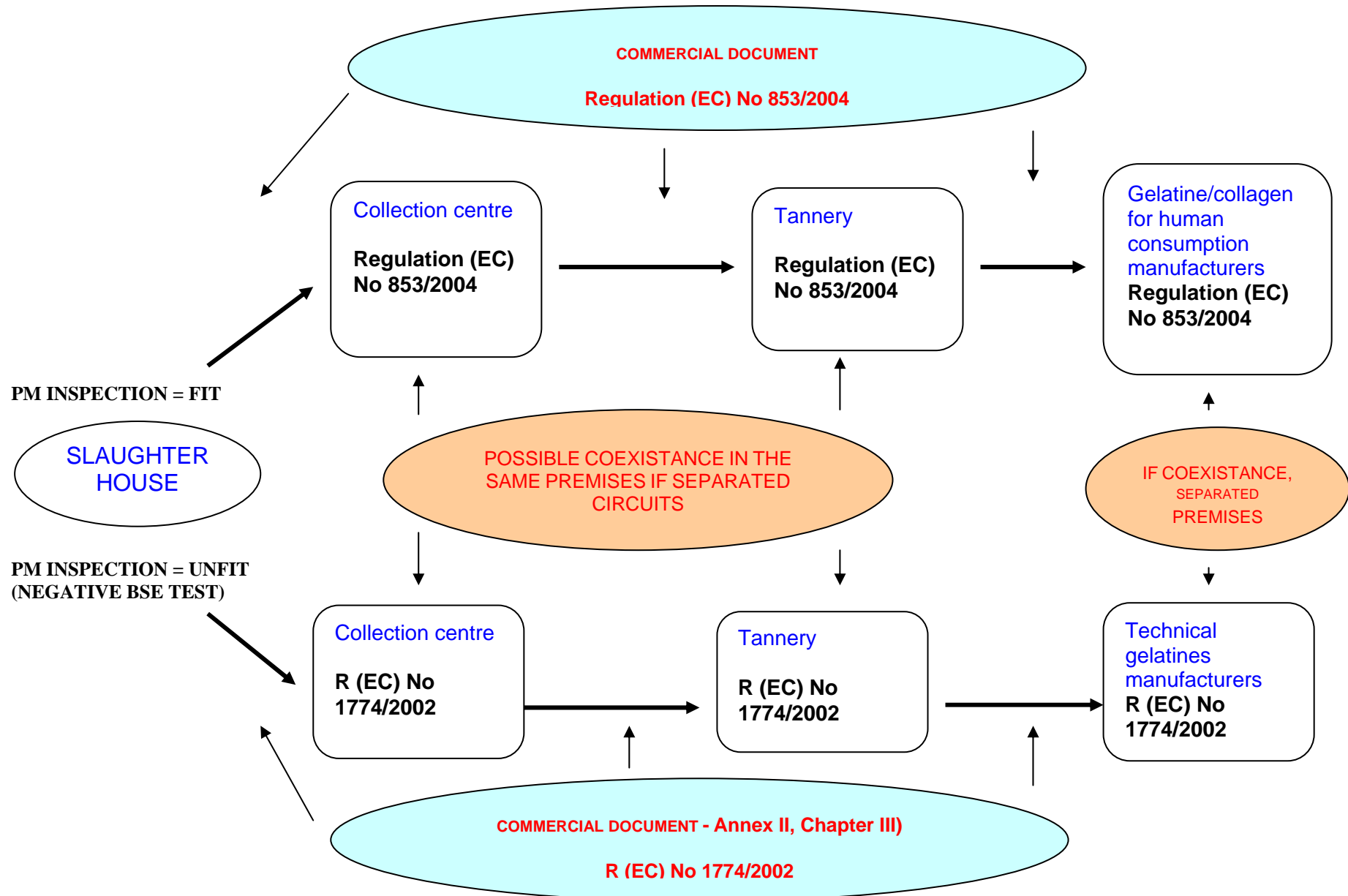
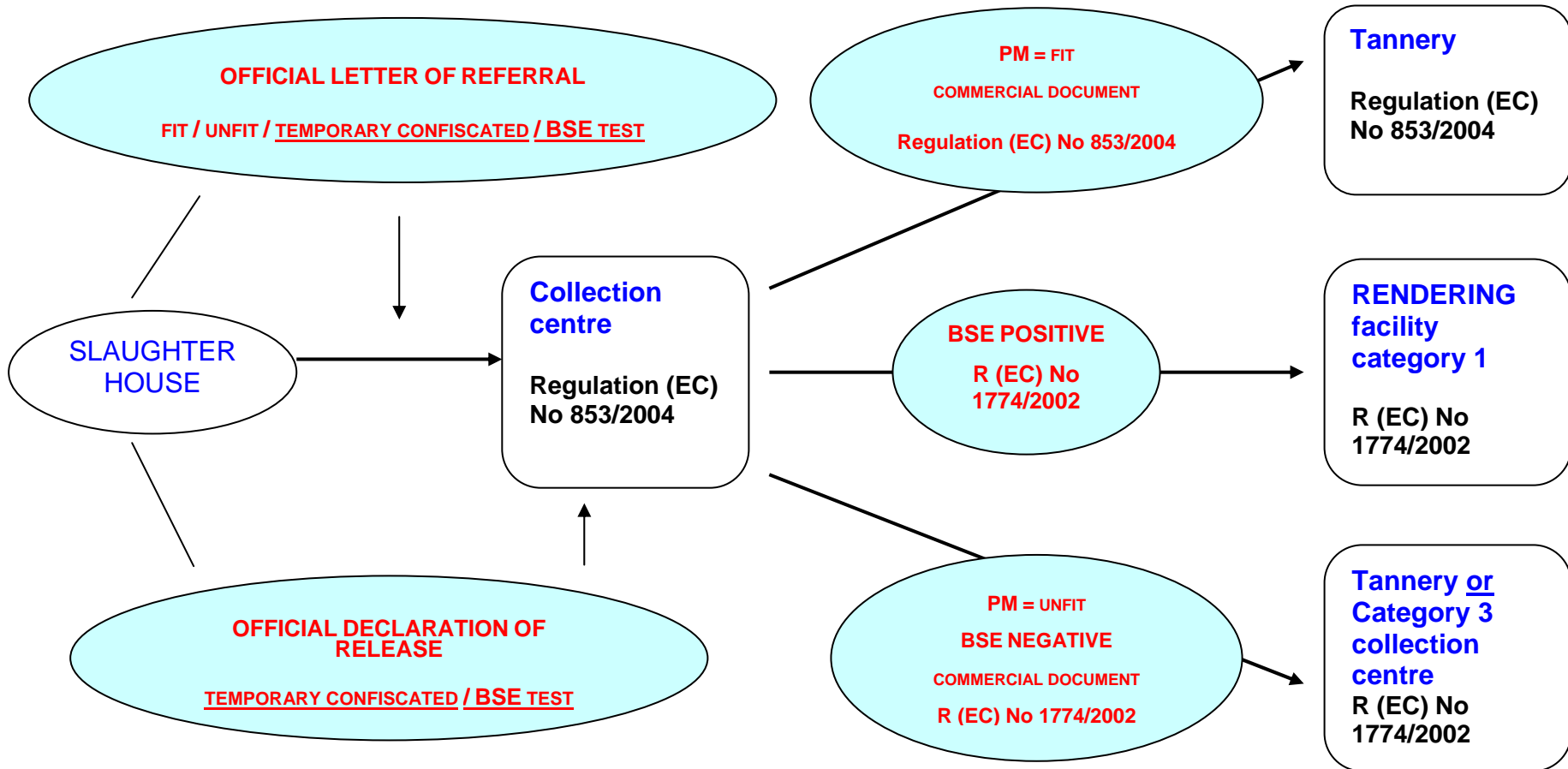


Diagram 3:

Release without BSE and Post Mortem inspection results (different commercial documents + LETTER OF REFERRAL)



Hide traders and tanneries

Detailed description of the applied processes

1. INTRODUCTION

The objective of this document is to provide a comprehensive overview of the processes established by the hide traders and tanneries. This document focus on sanitary and health aspects associated with the valorisation of hides and skins of which certain parts enter the human food chain in the form of gelatine and collagen destined for human consumption.

It is important to understand that hides and skins freshly obtained from animals slaughtered for human consumption are particularly vulnerable to enzymatic and bacteriological deterioration. Scientific studies indicate that deterioration and decay of hides and skins can start as soon as six hours after their separation from the carcass. It is known that this could lead to irreversible damage to the outer surface layer of the hide or skin and therefore could render the material useless for its further processing to quality leather. Yet, leather production through tanning is the most important value adding process that justifies the recovery of these animal by-products diverting them from waste streams.

It is thus of utmost importance to dispose of hides and skins as quickly as possible when they are obtained in order not to impair their full economic potential. Preservation of this valuable but delicate raw material is done through immediate cooling and/or salting, and rapid transportation to collection centres and tanneries in order to preserve their quality.

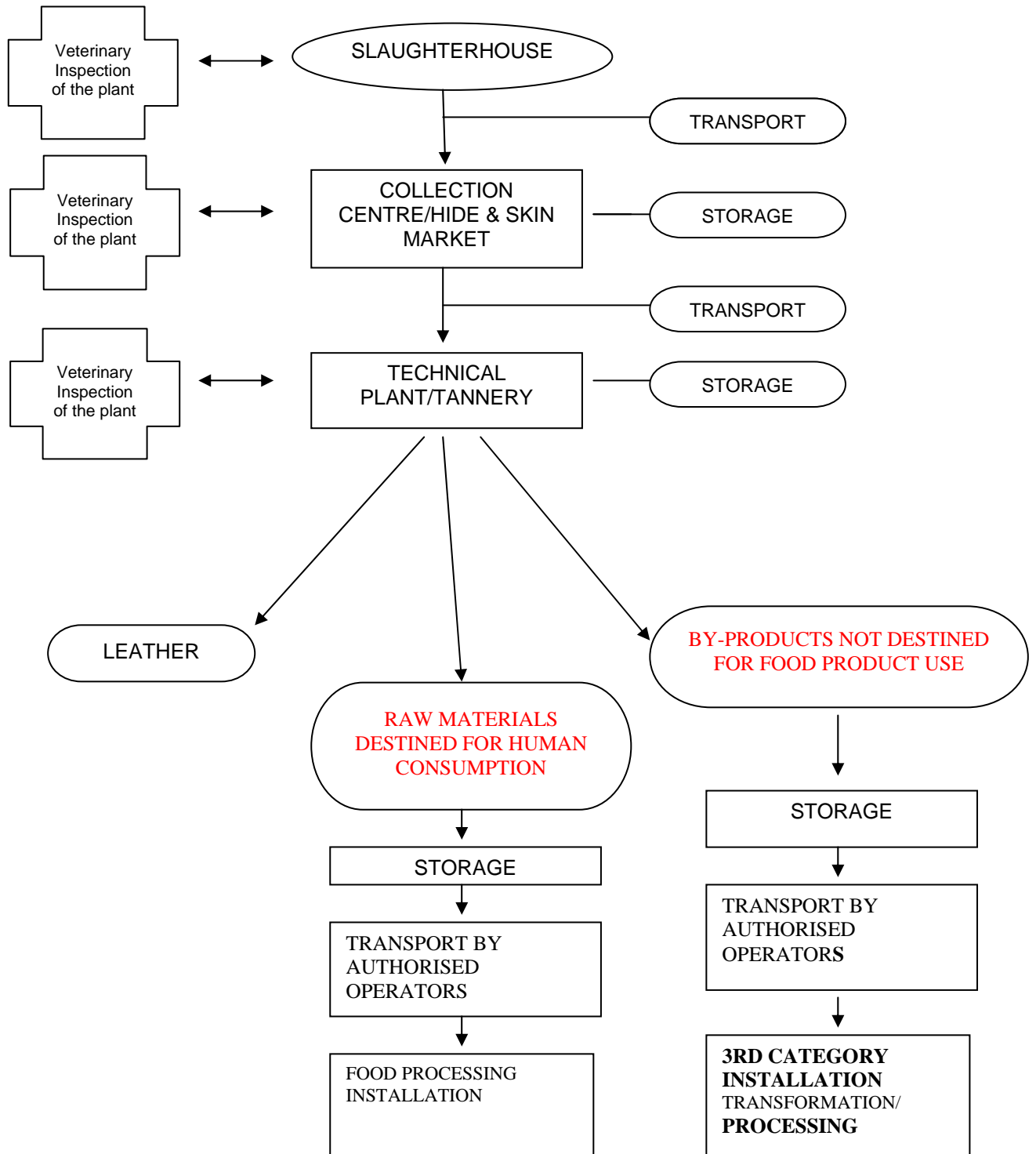
2. OBJECT AND SCOPE OF APPLICATION

The object of the Guidance Note is to describe good handling practices for the various operators with responsibilities in the management and handling of hides and skins and its by-products in order to safeguard high quality supply of raw materials destined for the production of gelatine or collagen intended for human consumption.

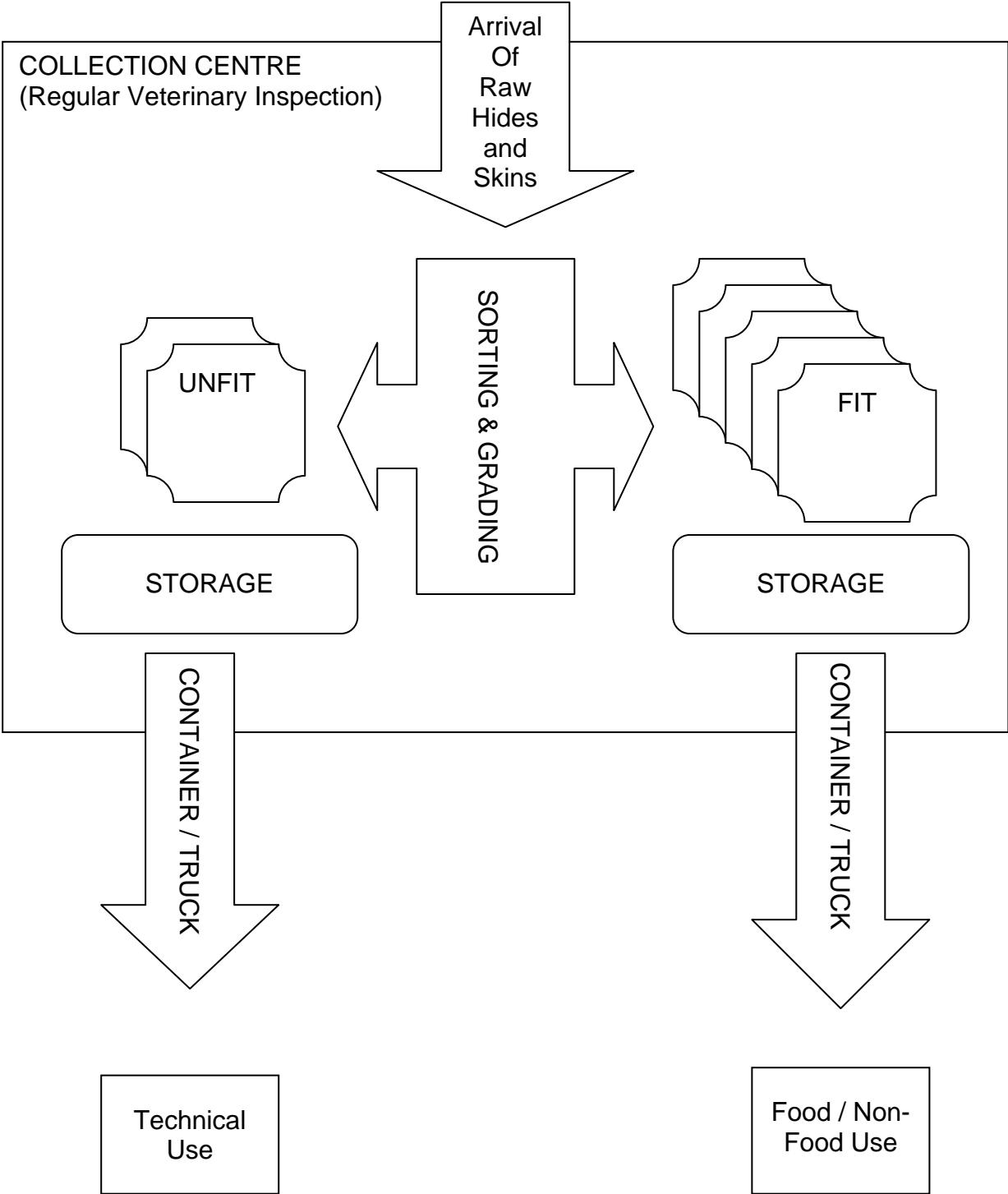
The Guidance Note provides also a clear and transparent system for sound veterinary control and supervision with the aim of fulfilling the legal objectives for consumer protection.

3 PROCESS ANALYSIS

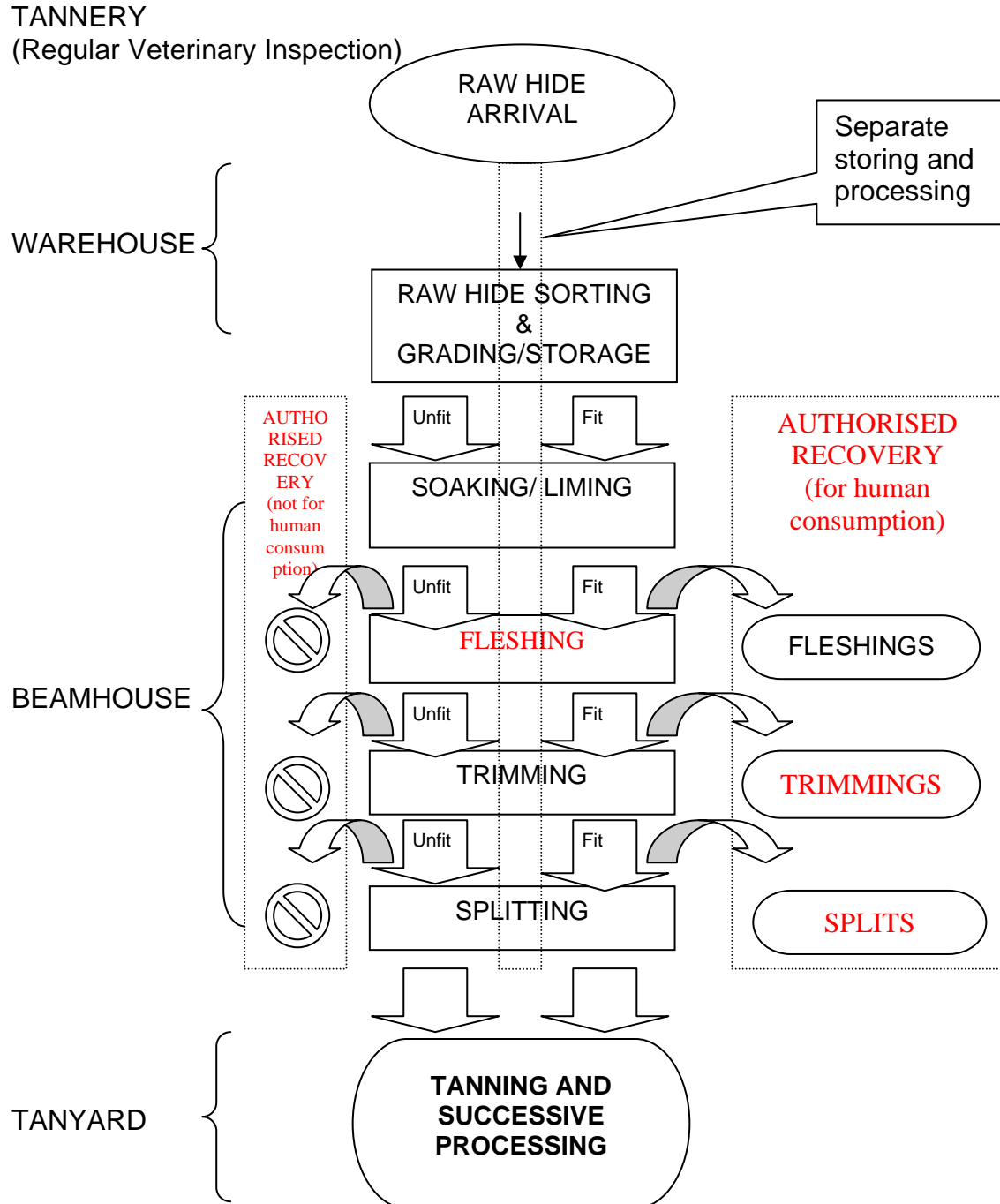
The following flow diagram summarises the various operators and their corresponding competent authorities involved in the supply chain of hides and skins.



In a typical collection centre, hides and skins are processed as follows:



In a typical tannery, the preliminary production stages are as follows:



4 GENERAL PROCESSING REQUIREMENTS

(A) *Raw materials to be used for the production of gelatine and/or collagen destined for human consumption*

In compliance with Regulation (EC) No 853/2004, hides obtained from farmed animals, and slaughtered (in authorised slaughterhouses) and found fit for human consumption following ante and post mortem inspection (performed by an official veterinarian) can be recovered as raw materials for the production of gelatine and/or collagen for human consumption.

Collection centres and tanneries that intend to trade Category 3 raw and limed hides and skins whose by-products will be further processed for human consumption must

- ✓ be recognised and registered by competent veterinary authorities (authorisation),
- ✓ set up a traceability system capable to guarantee the correct sanitary management of the hides and skins in question,
- ✓ satisfy a series of sanitary requirements, and
- ✓ ensure compliance with specific documentary obligations (commercial documents, health certificates only for origin third countries, loading/unloading register).
- ✓ Audit their suppliers on a regular basis in order to verify compliance with the requirements of this Guidance.

The raw hides must also remain under official control in the same Member State until the BSE rapid test results are available. Moreover, these raw materials must be treated according to the prescribed hygiene practice when obtained during slaughter and flaying and during transport, storage, and handling (refer to Regulation (EC) No 853/2004 as well as Regulation (EC) No. 1774/2002).

The certificate demonstrating that the raw material is authorised for human consumption must accompany the animal by-product when dispatched to tanneries and up to the arrival at the Food Business operator's premises.

In collection centres and tanneries acting as a collection centre the following requirements must be applied:

1. They must have storage rooms which are easy to clean and disinfect.
2. 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,
3. If raw materials not in conformity to this part or not yet separated into fit and unfit raw materials are processed and/or stored in these premises, the streams must be segregated throughout storage and processing.

All authorised collection centres and tanneries will be subject to regular control by competent authorities. Tanneries receiving direct supply of temporarily confiscated hides and hides from animals subject to BSE testing before the results are available, must be approved as collection centres.

(b) By-products not destined for human consumption

All hides and skins that do not satisfy the requirements according to Regulation (EC) No 853/2004 are classified as animal by-products according to Regulation (EC) No. 1774/2002 and may not be used for human consumption. None of their constituent parts may enter the human food chain.

5. SPECIFIC PROCESSING REQUIREMENTS

(a) Raw materials destined for the production of gelatine and/or collagen for human consumption

In cases where hide and skin by-products are used as raw materials for the production of gelatine and/or collagen for human consumption, the following specific requirements must be observed:

AT THE COLLECTION CENTRE

- ✓ Rapid collection of the individually marked hides and skins from the slaughterhouse;
- ✓ Control of documents accompanying the hides and skins, communication with the veterinary service of the slaughterhouses regarding final release of hides as fit or unfit for human consumption;
- ✓ Rapid weighting;
- ✓ Separate fit and unfit materials as well as those being submitted to a provisional embargo and final veterinary clearance;
- ✓ Separate handling and storage according to the category of the hides and skins;
- ✓ Dispatch of hides and skins unfit for human consumption with a health certificate according to Chapter 5 (B) of Annex X of Regulation (EC) No. 1774/2002;
- ✓ Dispatch of hides and skins fit for human consumption with a health certificate according to Regulation (EC) No 853/2004;
- ✓ Dispatch of hides and skins only to approved tanneries;
- ✓ Ensure that hides and skins are cleared by sanitary authorities and separated in fit and unfit categories before dispatch to the tanneries;

AT THE TANNERY

Stage 1: reception and storage of raw hides upon arrival

- ✓ Keep fit and unfit materials separate throughout storage and processing
- ✓ Control all documents on delivery (trade/ commercial documents, health certificates);
- ✓ Control all hides/skins visually.

Stage 2: soaking & liming

- ✓ Separate processing of batches of fit/unfit materials;

Stage 3-5: fleshing / trimming / splitting

- ✓ Clean all equipment and machinery with care;
- ✓ Ensure that all by-products are collected in suitable containers constructed from materials that can be washed and disinfected.

Stage 6: hide and skin by-product storage

- ✓ Storage must be performed using closed containers to prevent any external contamination;
- ✓ In the case of non-limed raw materials, storage time must occur in due time to prevent deterioration and decay unless stored cooled or refrigerated.

(b) *By-products not destined for human consumption*

In cases where hides and skins by-products are used as raw materials not destined for human consumption the following regulations must be observed for each critical stage.

AT THE COLLECTION CENTRE

- ✓ Control all documents on delivery (trade/commercial documents, health certificates);
- ✓ Separate storage and handling of fit/unfit materials;

AT THE TANNERY

Stage 1: reception and storage of incoming raw hides and skins

- ✓ Control all documents on delivery (trade/commercial documents, health certificates);
- ✓ Control all hides visually;
- ✓ Ensure that no by-product of these hides be mixed-up with material that is fit for human consumption.

Stage 2-4: fleshing / trimming / splitting

- ✓ Clean all equipment and machinery with care;
- ✓ Ensure that all by-products are collected in suitable containers constructed from materials that can be washed and disinfected.

Stage 5: by-product storage

- ✓ Ensure that these by-products are stored separate and no by-products can be mixed up with material that is fit for human consumption;
- ✓ In the case of non-limed raw materials, storage time must not exceed 48 hours to prevent deterioration and decay.

Gelatine and collagen manufacturers

Detailed description of the applied processes

Definitions

Hide gelatine means gelatine (gelling or non-gelling) for human consumption intended for edible and pharmaceutical applications and obtained exclusively from hides and skins of farmed animals.

Collagen means collagen for human consumption intended for edible and pharmaceutical applications and obtained exclusively from hides and skins from farmed animals.

1. SHORT DESCRIPTION OF THE CURRENT PRACTICES IN THE GELATINE / COLLAGEN PLANT

a) The Origin of raw material

The European Commission has implemented strict requirements with respect to the employment of hide splits for the production of gelatine and collagen for human consumption. Commission Regulation (EC) No 853/2004 require that hides and skins must originate from healthy animals, slaughtered in a slaughterhouse, and the meat found fit for human consumption following ante and post mortem inspection.

As already described, the slaughtering practice in Europe avoids any risk of cross-contamination of the hides with Specified Risk Materials (SRM) due to the official slaughtering technique which requires to remove the skins before sawing the carcasses.

All hide splits supplied to gelatine and collagen production must be accompanied by a Commercial Document according to Commission Regulation (EC) No 853/2004, certifying the origin of the hide splits. Additionally, it must be confirmed that all raw materials have been derived from animals found fit for human consumption.

This has also to be certified for hides and skins imported into the EU from third countries by an official Health Certificate according to Commission 2074/2005 ANNEX VI, appendix II and III part B.

Suitable raw materials for the production of hide gelatine and collagen can be obtained by the slaughtering of farmed animals like bulls, cows, calves and heifers.

The supply chain includes the following sources:

- ***Slaughterhouses***

The first source of hides are slaughterhouses which supply whole skins, usually destined to tanneries, and hide trimmings which, for technical reasons of slaughtering, are cut off before further processing of the whole hides and usually not used for tanning.

The structure of the whole hides and trimmings is similar, and includes the whole epidermis with hair on the outer layer and parts of tissue of the subcutis (fleshing) on the inner layer. Hide trimmings have to be stored chilled until further processing. As a matter of fact the presence of hair and fleshing causes a more extensive processing of trimmings and a lower yield of gelatine during extraction. However, trimmings are generally suitable for gelatine and collagen production and can, therefore, be regarded as a high quality and economically necessary raw material.

- ***Raw skins dealers, stock houses and import-export agencies***

The second source of hide trimmings is distribution companies of salted raw hides which sell the trimmings because they are not interested in the subsequent tanning process.

These trimmings include also the whole epidermis with external hair and parts of fleshing in the inner layer, but different to the trimmings arriving from slaughterhouses, they are salted and therefore can be stored without refrigeration.

- ***Tanneries***

The third source of trimmings and hide splits are the tanneries. After dehairing and before splitting the hides, the tanneries remove side sections of the hides due to technical reasons. The resulting trimmings can be used without extensive pretreatment as a high quality raw material for gelatine and collagen production.

After splitting, the resulting hide splits (inner collagen rich layer of the hides) are separated and transported to the gelatine and collagen production plants for further processing by the gelatine/collagen manufacturers, whereas the grain splits are further processed into leather. This ensures that no tanned material enters the gelatine and collagen raw material supply chain.

- ***Collectors of hide splits***

Collecting companies, selecting and transport companies can be included in the supply chain of hide splits and trimmings. The collectors get these materials from different tanneries and usually select the products according to quality specifications for further processing either in the gelatine manufacturing plants, or in the collagen production facilities.

b) Reception of raw material (hide splits)

In Europe, raw materials are exclusively purchased from suppliers approved and registered by the competent local authorities or from slaughterhouses approved by the European Community. Additionally, the arrival of raw material from EU suppliers may according to local requirements be signalled to the competent Health Authorities with 24 working hours notice in order to allow, if necessary, the inspections before processing.

Raw materials originating from Europe must be accompanied by the Commercial Document according to the models laid down in Commission Regulation (EC) No 853/2004. Raw materials, which do not comply with this requirement, are rejected and they are excluded from further processing.

Raw materials purchased from third countries have to be accompanied by an official Health Certificate according to the model laid down in Commission 2074/2005 ANNEX VI, appendix II and III part B.

The commercial document (or health certificate for third countries) serve as a documentation of traceability of raw materials and compliance with the legal requirements.

Transport is carried out exclusively in suitable and cleaned containers or other means of transportation (e.g. trucks). A specific declaration released by the suppliers/dealers proves that the containers/trucks have been cleaned before loading the raw material. If the raw material is fresh (for example trimmings from slaughterhouses), it is necessary that the beginning of the production process starts within 24 hours after their departure. If transport times are longer than 24 hours the material has to be transported and stored chilled or frozen. If raw material is salted (salted trimmings from dealers or tanneries) or treated with alkali (trimmings from tanneries or hide splits), the material can be transported without a time limit and any further particular preservation at ambient temperature.

Additionally to these legal requirements, raw materials intended for the production of gelatine and collagen have to comply with written quality specifications requested by the gelatine/collagen manufacturers which are part of the contracts with the suppliers. In Europe, the raw material suppliers are audited regularly by the gelatine/collagen manufacturers on the basis of audit plans and audit checklists.

Criteria for the inspection and acceptance of incoming raw materials are as follows:

- Proper documentation (e.g. Commercial Documents, Health Certificates)
- Identification of the material as regards animal species and part of the animal (shoulders, bellies, trimmings, hide splits etc.)
- Compliance with external aspects (size, thickness, colour, odour etc.)
- Presence of fleshing
- Presence of foreign materials
- pH control as appropriate
- Presence of liquids (e.g. water, blood etc.) in appropriate quantity
- Other requirements according to company specific specifications

Some of the above controls are to be made when the material is still on the truck in order to avoid unloading of non-conforming material, especially when deterioration of raw material is suspected. In case health requirements are not met, the material has to be rejected and either sent to destruction or returned to the supplier.

c) Handling

All raw materials must be accompanied by a Commercial Document or an equivalent document confirming both quality and traceability.

The receipt, storage and processing of raw material has to be done in dedicated production areas in order to avoid cross-contamination with foreign materials and/or other not acceptable substances (protected or closed areas). Additionally, traceability of the subsequent production batches is ensured by batch specific documentation and as far as necessary by complete separation and intermediate cleaning between different production batches.

The containers have to be easy to clean with smooth surfaces (e.g. stainless steel) and suitable for the intended purpose. The production areas have to be properly ventilated and an appropriate pest control system must be in place. All the surfaces in the production area (floors, etc.) must allow effluents (e.g. cleaning water, wastewater) to flow into a proper drainage system which carries them to the wastewater treatment.

Transportation and handling of raw materials is done by means of specific lifting instruments such as hydraulic cranes, which transport the raw materials to the skin cutting apparatus. On this production level there is an additional opportunity to once more make a visual inspection of the raw materials in order to remove foreign parts, if any would still be contained in the raw materials (maybe supported by the use of magnets, metal detectors etc.).

All the parts of the processing machines in contact with the raw materials have to have smooth surfaces and must be produced from appropriate materials (e.g. stainless steel) in order to allow a perfect cleaning and long term maintenance of the equipment.

After the cutting step, washing steps complete the first production stages of raw material pretreatment. From this stage onwards all the raw materials processed in gelatine production are conveyed by pumps in closed systems. The transportation systems are subject to regular cleaning with cleaning and sanitification agents, which have to be clearly labelled and identified in order to avoid the danger of a wrong use.

d) Documentation / Traceability

All companies involved in the supply chain of gelatine and collagen production must ensure complete traceability from the finished products back to the raw materials. For this reason gelatine/collagen manufacturers cannot accept raw material shipments without the necessary documentation (e.g. Commercial Document, Health certificate). On the basis of these documents, and additionally by means of a batch or lot identification system (batch records) implemented in the production sites from raw material receipt through the subsequent production steps to the final product, it is possible to allow, beyond any doubts, to trace back the final products to the origin of the raw materials. Compliance with these requirements is checked on a regular basis by internal audits and by official inspections of the competent authorities.

2. PRECAUTIONS IN PLACE TO COMPLY WITH THE LEGAL REQUIREMENTS

The production site has to be approved and registered by the competent national authorities, which guarantees the supervision of the production sites through controls made on a regular basis by an official veterinarian. This approval and registration is based on inspections carried out by the competent authorities in order to control compliance with the legal requirements for gelatine and collagen production sites and the hygienic conditions required by Commission Regulation (EC) No 853/2004, Annex III, Sections XIV and XV.

Every production plant has Standard Operational Procedures (SOP) in place to ensure proper handling, inspection, cleaning, monitoring and documentation of the raw material processing.

3. SHORT DESCRIPTION OF THE HIDE GELATINE MANUFACTURING PROCESS

All European gelatine manufacturers are certified according to the ISO 9000 standards and have HACCP systems in place. The gelatine manufacturing process consists of several production steps which are shortly described in the following paragraph.

The transport of raw material is usually done in bulk by trucks dedicated to this transport in order to ease the unloading into the reception tanks. During reception, the raw materials are subject to extensive inspections, which is necessary to control compliance with the quality requirements and to decide on the acceptance of the raw materials before further processing.

The raw material is then taken by mechanic devices (e.g. cranes) and fed to a cutting apparatus which reduces the size of the hides to pieces of about 20x20 cm. After cutting, the material is washed and treated with acid or alkali in order to prepare the raw materials for further processing. At the end of the pre-treatment, raw material is accurately washed, conditioned or neutralised with acid until the final pH is close to neutrality.

Only raw materials thus conditioned and pre-treated can be used for the further gelatine production steps.

This includes extraction with hot water in one or several steps of increasing temperature of approximately 50°C to 90°C, purification of the gelatine solution by filtration and ion exchange, followed by concentration, sterilization, and finally drying by conditioned hot air of the gelified “spaghetti noodles” after chilling, respectively spraydrying of the gelatine solution.

Grinding, blending and packing are carried out according to customers’ specifications as the finishing production steps (Regulation (EC) No 853/2004). The final product must be stored under dry and cool conditions.

4. SHORT DESCRIPTION OF THE COLLAGEN MANUFACTURING PROCESS

Collagen is produced by a process that ensures that the raw material is subject to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion. Collagen may then be additionally subject to a drying process (Regulation (EC) No 853/2004).

5. VETERINARY CONTROL OF THE PRODUCTION PLANTS

Gelatine and collagen production plants are subject to regularly carried out inspections by the competent health authorities, which conduct the controls mainly on the basis of the following operational procedures and management rules:

- Control of availability of accompanying documents (e.g. Commercial Documents, Health certificates) and recordkeeping for all raw materials received (records of the inspections of all incoming raw materials).
- Controls regarding the traceability of raw material.
- Control of all incoming raw materials and sampling where appropriate (optional activity).

- Supervision of the HACCP system in order to verify the correct application and revision of the system.
- Inspections of the production facilities and the social rooms (changing rooms, canteen, toilets, etc.) for the employees in order to verify appropriate availability and maintenance of equipment.
- Control of the water supply (unprocessed water, drinking and demineralised water, used for several different applications and for the production processes).

6. INSPECTIONS OF THE PRODUCTION PLANTS

The production sites may be subject to three levels of inspections:

- Regular health inspections by the competent authorities (please refer to section 6.2b)
- Supervision of experts of Member States and of the Commission
- Internal audits on the basis of written SOPs which ensure that all personnel is informed on the internal procedures in order to achieve optimal compliance with the documentation and quality requirements. Guidelines for the inspections (e.g. audit checklists) and auditing plans ensure that the inspections are carried out properly and that a final audit report will be issued. This will ensure as well that in case of non-conformities the necessary preventive and/or corrective actions will immediately be taken.

As far as the activities regarding the arrival of raw material are concerned, internal inspections are mainly addressed to check e.g. the following aspects:

- Availability of the relevant documents (e.g. Commercial Document, Health Certificate)
- Correct fulfilment of all the procedure regarding raw material receipt
- Clear identification of batches in order to avoid any risks of mix-up
- Immediate disposal of material which is not acceptable
- Cleaning documents of unloaded trucks, complete emptying of the raw material vessels (tanks or pits for incoming raw materials) and machines used for further processing of the raw materials and their cleaning
- Cleaning of floors and surfaces of the relevant production areas
- Maintenance of the relevant production areas (as far as possible closed and well ventilated areas)
- Integrity and efficiency of the pest control system (protections against insects, small animals and rodents etc.).
- Control of correct calibration of the internal instruments used for control tests.

Most of the points mentioned above are additionally covered by the requirements of the HACCP system and ISO 9000 certification.