

# **Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings**

**STRICTLY CONFIDENTIAL**

## **Author**

CIPCEL (Comité International de la Pellicule Cellulosique) is a non-profit-making Association for producers of regenerated cellulose film and latterly also non-edible cellulose casings. It has member companies in Belgium, France, Germany, Japan, Spain and the United Kingdom. The headquarters of the Association is in Paris, France.

The objectives of the Association are:

- to improve and develop the use of the products manufactured;
- to study and to provide solutions to problems of common interest; and
- to maintain relations with all relevant private and public, national and international, organisations including governments.

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## FOREWORD

Pure cellulose casings<sup>1</sup> were first produced commercially in 1925 to complement the use of natural gut in the rapidly expanding meat industry. The manufacture of such casings was based on the discovery of cellulose dissolution by Cross, Bevan and Beadle in 1892.

Developments in production methods spurred the demand for casings of larger diameters and greater strength, in addition to more exacting size requirements. This led to the introduction in 1935 of reinforced fibrous casings (RFC) for products such as Bologna and Pepperoni.

For more than 80 years, cellulose casings (pure cellulose casings and reinforced fibrous casings) have increasingly replaced the use of natural gut, particularly in high-volume outlets, for example, hot dogs. Moreover, further developments in highly mechanised processing methods have led to the manufacture of casings of increasingly larger diameters for products such as Mortadella.

From the outset, the fact that cellulose is regarded as a natural product and can be almost completely regenerated from the viscose solution has been advantageous both to regenerated cellulose film manufacturers and to cellulose casing manufacturers.

CIPCEL (Comité International de la Pellicule Cellulosique) was founded in 1949 and is registered in Paris, France. Initially, CIPCEL represented solely the interests of regenerated cellulose film manufacturers before the introduction of other polymeric films—such as cast or oriented polypropylene—which have supplanted, to a large extent, the use of regenerated cellulose films in many of its traditional applications. This has resulted in the rationalisation of European regenerated cellulose film producers.

CIPCEL, together with CIRFS (Comité International de la Rayonne et des Fibres Synthétiques), actively promotes the interests of the viscose products industry in terms of both consumer protection and environmental concerns.

Since the Cellulose Casing Manufacturers' Working Group (CCMWG) joined CIPCEL in 1993, the film and casing industry has collaborated on a range of projects that form the foundations of this *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings*.

**CIPCEL Cellulose Casing Manufacturer's Working Group (CCMWG)<sup>2</sup>  
January 2019<sup>3</sup>**

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<sup>1</sup> See Glossary for definitions of casings.

<sup>2</sup> Member companies of the Comité International de la Pellicule Cellulosique (International Committee for Cellulose Films) and their representatives which form the CIPCEL Cellulose Casing Manufacturers' Working Group (CCMWG).

<sup>3</sup> The contents of this *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings* are based on information available until the end of 2018. Documentation published more recently should also be considered.

## INTRODUCTION

At one time, the cellulose casing industry used to be regarded as a niche business of the giants of the chemical industry where anti-trust rules dictated that the main manufacturers should work in isolation from one another. This changed somewhat with the introduction in the 1980s of harmonised European Union legislation for specific types of food contact materials, of which European Commission Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs was the first.<sup>4</sup>

The CCMWG held its inaugural meeting in 1988 in Paris, France. The following year, the Group produced a document comprising a list of all the chemicals, including those used by its member companies as well as those perceived to be of potential interest, for the manufacture of cellulose casings. The document was presented to the European Commission (Health & Consumer Protection Directorate-General, subsequently renamed Directorate-General for Health and Food Safety) which instructed the Group to produce a shorter list comprising the main chemicals required for the manufacture of cellulose casings.

The CCMWG became associate members of CIPCEL in March 1993 and full members in 1998. During this time, the European Commission advised the Group to use the existing Directive for regenerated cellulose films and the evolving Directive for plastics as a basis for producing a “bridge document”, which the European Commission could then review with the aim of preparing a specific Directive for cellulose casings.

This *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings* is based upon the manufacturing practices followed in the European Union since the early 1990s. The aim of this *Guide* is to inform about the substances and manufacturing methods used in the production of cellulose casings. In addition, information is provided on how the casing industry has sought to address the increasingly stringent legal requirements from both suppliers and customers in the food processing sector.

Finally, it should be noted that the *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings* has been submitted to the Directorate-General for Health and Food Safety of the European Commission.

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<sup>4</sup> Specific information regarding regenerated cellulose film intended to come into contact with foodstuffs is contained in Appendix 4.

## SCOPE

This *Guide* applies to non-edible cellulose casings (pure cellulose casings and reinforced fibrous casings). These casings are formed from regenerated cellulose<sup>5</sup> obtained from the viscose process and are used mainly in processing and manufacturing a variety of food products, predominantly in sausage production.

**This *Guide* does not apply to the following:**

- **natural gut casings obtained from, for example, the intestines of sheep and pigs;**
- **collagen casings, edible or non-edible, produced from reconstituted collagen derived from, for example, the hides of cattle;**
- **plastic casings produced using a variety of polymeric starting materials, typically comprising one layer or more of polyethylene, polyamide, polyester or the like, and usually not incorporating polymers such as cellulose principally derived from plant origin; and**
- **regenerated cellulose films or sheets.<sup>6</sup>**

There have been three main principles for the manufacture of cellulose casings that the CCMWG has adhered to.

- The first principle was to observe, as far as possible, the global migration limit of all substances from food contact materials into food as outlined in the Plastics Directive (Commission Directive 2002/72/EC of 6<sup>th</sup> August 2002) (OJ L 220 of 15.8.2002 p.18), and latterly the Plastics Regulation (Commission Regulation (EU) No 10/2011 of 14<sup>th</sup> January 2011) (OJ L 12 of 15.1.2011 p.1).
- The second principle was to review all the chemicals used. In cases where chemicals did not appear in the national lists of the participating members' countries, it was necessary to seek other listings.
- The third principle was the traceability of materials and articles intended to come into contact with food.

These three main principles provide the foundations to this *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings*.

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<sup>5</sup> Regenerated cellulose is a generic term and applies, in general, to cellulose made soluble as sodium cellulose xanthate before reconstitution using the viscose process. The term can apply equally to cellulose reconstituted from other solvents such as cellulose-NMMO (N-methylmorpholine N-oxide) dope and/or from other chemical derivatives such as alkaline cellulose carbamate.

<sup>6</sup> *Op. cit.*, footnote 4.

## CHAPTER 1

# HISTORY OF THE CIPCEL CELLULOSE CASING MANUFACTURERS' WORKING GROUP

The Cellulose Casing Manufacturers' Working Group (CCMWG) was formed in June 1988. During the following year, a document containing a list of the chemicals used by the participating companies to manufacture cellulose casings was produced and submitted to the European Commission.

In March 1993, the CCMWG became associate members of CIPCEL. The first meeting between the CCMWG and CIPCEL took place in November 1993 in Brussels.

Through contacts between the CCMWG and the European Commission, it became very clear that the preparation of a specific Directive for cellulose casings would be a long-term issue.

The European Commission requested that the list should be founded upon necessity. Wherever deficiencies occurred, in terms of insufficient toxicity data etc and/or the use of chemicals not already having been accepted for food contact use within the individual lists of Member States, either approval should be sought by the CCMWG or the use of such substances should be discontinued.

Since the CCMWG also had responsibility for other issues in addition to food contact legislation, members also cooperated with respect to matters regarding occupational health and the environment. Regarding environmental protection, for example, reassuring the consumer through various official channels became an increasingly important issue for the CCMWG.

The principles set out in the scope of this *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings* have, in effect, been adhered to since the mid-1990s. This *Guide* represents the views and interests of the cellulose casing industry with regard to food contact issues and occupational health and environmental concerns. Furthermore, the *Guide* aims to keep abreast of the changing requirements of the European Union as well as important developments in other areas.





## CHAPTER 2

### RAW MATERIALS

The raw materials used to manufacture regenerated cellulose casings are cellulose pulp, humectants and water. Reinforced fibrous casings also require a suitable cellulose paper substrate, most commonly provided by abaca or Manila hemp, while coated versions also require an inside or outside polymer coating.

Cellulose pulp is obtained from wood chips, normally acquired from renewable and sustainable forests, by chemical separation of lignin, hemicelluloses and wood resins. This is a very demanding process chemically, as many of the short-chain celluloses are not suitable for pulp intended for use as a raw material for casing and viscose fibre manufacture. High alpha cellulose wood pulp (i.e. long-chain celluloses) is used for cellulose casings. All casing suppliers convert this pulp into a viscose solution.

Regarding humectants, the industry uses a variety of products of which glycerol is the most common. Some substance classes, like for example phthalates, are not used by the cellulose casing industry.

The paper substrate used in reinforced fibrous casings is similar to that used in teabags. Paper suppliers assure cellulose casing suppliers that the paper conforms to the requirements of the relevant food contact legislation.

Reinforced fibrous casings can be coated with polymers to create a barrier against the transmission of moisture and oxygen. These resins can be applied on the outside or on the inside of the cellulose substrate depending upon the final packaging requirements.

Colourants and printing inks are widely used on cellulose food packaging materials. Migration of the pigments (which are virtually insoluble) is precluded by the correct choice of raw materials, by embedding into the cellulose matrix and by printing on the non-food contact side of the casing. Transferable colours (as a function of the final meat colour) are used only if these additives are approved by the appropriate authorities responsible for food contact legislation.

Depending upon the final application, regenerated cellulose casings undergo additional processing including compressing, shirring, slitting, sewing, cutting and tying to make them fit for use. In addition, coating, peeling and release agents are introduced to make casings adhere to, or peel off from, the food surface.

Flavourings, food colours and other food ingredients can be applied to the inner surface of the casings. They are transferred to processed foodstuffs to add specific properties to the finished food.



## CHAPTER 3

# MANUFACTURING PROCESSES

The business operator ensures that manufacturing operations are carried out in accordance with Articles 4-7 inclusive of European Commission Regulation (EC) No 2023/2006 of 22<sup>nd</sup> December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384 of 29.12.2006 p.75). It is applicable from 1<sup>st</sup> August 2006.<sup>7</sup>

### **Viscose preparation**

The starting material for the viscose manufacturing process is a high-purity cellulose wood pulp. The alpha cellulose pulp sheets are steeped in an aqueous solution of sodium hydroxide to produce sodium cellulose. Once this alkali cellulose is formed, the following process is the shredding of the cellulose into small crumbs facilitating further alkali cellulose ageing, followed by conversion to viscose by xanthation. After filtration, deaeration and ripening, the cellulose transforms into viscose. The entire process of making viscose is time consuming, lasting up to three days.

### **Spinning, washing and drying**

Spinning of the viscose is accomplished by extruding the solution through a die, followed by coagulation (dewatering) and regeneration of the cellulose. For coloured casings, pigments are usually added into the viscose supply line to the die prior to extrusion. Once the cellulose has been washed in order to remove residues, the casings are passed through a humectant bath followed by drying. Finally, the casings are wound onto reels, wrapped and dispatched.

### **Converting**

Converting refers to actions required to customise the roll stock for its intended application and includes cutting, tying, drilling, shirring and printing. Converters may be either subsidiaries or completely independent from the casing manufacturer.

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<sup>7</sup> An amendment, Commission Regulation (EC) No 282/2008 (OJ L 86 of 28.3.2008 p.9) on recycled plastic materials intended to come into contact with foods and amending Regulation (EC) No 2023/2006 is not applicable to this *Guide*.



## CHAPTER 4

### STORAGE

Casing manufacturers wrap and pack cellulose casings. The stages are:

- warehousing at the point of manufacture;
- road, rail or air freight transportation;
- re-warehousing at the converter's premises;
- printing operations; and
- re-packaging as cut or shirred goods, whether pre-moisturised or dry.

As cellulose casings are susceptible to damage during transportation, they are best stored as reels inside containers (either of a cardboard construction or re-usable boxes). The containers are stacked on pallets when necessary.

Stretch film and/or steel bands are used to secure the cardboard containers to the pallets. Plastic film or bags inside the containers are used to prevent moisture loss during transportation, which can be of long duration, when the containers may be exposed to a wide range of temperatures and humidity.



## CHAPTER 5

### TYPES OF CASING

The main types of casing include:

- pure cellulose casings;
- reinforced fibrous casings; and
- coated reinforced fibrous casings.

In addition, other important types of casing are pre-smoked casings and netted casings.

Cellulose casings are manufactured via the viscose process. These casings have been produced by Viskase since the 1920s and, although company names have changed, by Kalle, Walsroder Casings and ViskoTeepak since the 1930s, and by Viscofan since the 1970s.

#### **Pure cellulose casings**

Small cellulose casings of up to 40 millimetres in diameter represent the largest segment of the market for products such as Frankfurters and similar skinless sausages. Medium to large cellulose casings are manufactured for a diverse range of products and offer larger diameter sizes. Pure cellulose casings are available in coloured (solid and stripe) and printed varieties.

#### **Reinforced fibrous casings**

Reinforced fibrous cellulose casings represent the second largest segment of the market. These casings incorporate a fibrous paper substrate impregnated by the viscose solution to produce a composite structure.

The diameters of reinforced fibrous cellulose casings are usually in the range of 30 to 250 millimetres. These casings provide size stability to the user due to their superior tensile strength in both longitudinal and transversal directions. Furthermore, the casings are readily adaptable to high-speed stuffing and processing operations used in the most modern automated sausage and meat processing plants. As most fibrous casings have to be soaked before usage, so-called ready-to-use or pre-soaked fibrous casings are also available. Fibrous casings are available in coloured and printed versions. Depending upon the meat cling or meat release requirements, fibrous casings can be used for cooked and smoked sausages, hams, and dried and semi-dried sausages.

**Coated reinforced fibrous casings**

Reinforced fibrous casings can be coated on their inner or outer surface. These casings provide an excellent barrier to the transmission of oxygen and moisture vapours. Coated casings are available in coloured and printed types. Coated casings prevent weight loss during processing and storage and improve the shelf life of the product. Typical applications include scalded sausage, cooked sausage, liver sausage and all kinds of poultry rolls.

**Other types of casing**

Pre-smoked casings are reinforced fibrous casings impregnated with liquid smoke. Other flavouring treatments are also possible depending on the time and investment necessary.

For netted casings, a net is attached to the outside surface of the reinforced fibrous casing thereby creating an “olde-worlde” charm effect.



## CHAPTER 6

### APPLICATIONS

The main applications are:

- dry and semi-dry;
- cooked;
- ham; and
- cheese.

#### **Dry and semi-dry**

The dry and semi-dry process is characterised by the meat emulsion being processed enzymatically, typically in the pH range 4 to 7, either using starter cultures which may be prepared from a previous product or via inoculation with “fresh cultures” for each new batch of sausage.

#### **Cooked**

Cooked sausages are heated at elevated temperatures in a steam oven. Time, temperature and pressure are monitored. Temperature probes are placed in the product in order to monitor the cooking temperature up to a maximum of about 85°C, depending on the constituents of the meat emulsion used.

#### **Ham**

Ham includes turkey and chicken in addition to traditional pork products. Indeed, this category covers all whole meat products, including beef, which may be cooked but may also be dry cured, cold smoked etc.

Manufacturers of meat products, as well as those of processed cheese, have their own specific requirements for the casing manufacturer. Some requirements include pH control, expansiveness, easy-peel or meat-cling properties.

#### **Cheese**

Cheese casings are used for processed cheeses. The cheese is prepared separately and subsequently added to the casing (unlike sausages which are prepared in the casing). For the stuffing process, the cheese is in a molten form at a temperature of between 90 and 100°C, while the casing either has an easy-peel finish or is untreated.

It is important to note that the processing temperatures for cheese are substantially higher than those for sausage meat and, therefore, the composition and mechanical attributes of cheese casings may need to be modified.

## CHAPTER 7

# LEGISLATIVE FRAMEWORK

### Introduction

At the time of the formation of the CCMWG in June 1988, each of the companies represented was subject to national legislation operating in their countries of manufacture and subject to legislation operating in the countries of sale.

Not all countries had their own specific requirements. Some countries used the conformance recommendations of other countries, for example, the Food and Drug Administration (FDA) of the United States of America. Others deferred to the more comprehensive Bundesinstitut für Risikobewertung (BfR) recommendations of Germany to address any issues not covered specifically in their own legislation.

Conformance testing is centred on the laws and/or the recommendations of the country of origin plus those of the FDA of the United States of America and those of any other countries with specific requirements. In addition, each manufacturer is subject to legislation governing the sale of cellulose casings in their customers' countries.

### Legislation in the European Union

#### Regulatory information

The European Union adopted a “Framework Regulation” on materials and articles intended to come into contact with food. It is applicable in all Member States. Article 3 of this Regulation (EC) No 1935/2004 of the European Parliament and of the Council (OJ L 338 of 13.11.2004 p.4) establishes the general requirements that food contact materials must be manufactured in compliance with good manufacturing practice so that they do not transfer their constituents to food in quantities which could endanger human health or bring about an unacceptable change in the composition of food or bring about a deterioration in the organoleptic characteristics thereof. Thus, in the absence of any specific European Union criteria for regenerated cellulose casings, the criteria of Regulation (EC) No 1935/2004 are applicable. Suppliers ensure that they use in the casings only substances that are demonstrated to be safe for their intended use: by referencing positive lists for casing components from European Union food contact Directives; by providing testing under laboratory conditions; by mathematical calculations; by dietary exposure; by diffusion; by toxicological analyses; and by providing supplier certificates. Even if all cellulose casing components are legally permitted, all substances used in the casings must also be shown not to migrate from the casings at levels that could adulterate the food.

The principle of mutual recognition is extremely useful for manufacturers of food contact materials, as it is an area which is only partially harmonised at European Union level and where many types of materials are still not subject to harmonised European Union law.

The principle of mutual recognition should, in theory, allow companies to sell freely in all national markets of the European Union. However, it is the responsibility of the manufacturer of the finished packaged food to ensure that all relevant regulatory or legislative requirements and specifications applicable to the packaged food product are met.

### **Current European Union regulatory status for cellulose casings**

The basic raw materials, additives and coating substances used in regenerated cellulose casings have suitable listings (details are provided in Appendix 3) demonstrating their suitability and safety for use as intended. Components which are not listed can be used if the suitability of their intended use is supported by internationally recognised scientific principles.

In the absence of a harmonised regulation of colourants for food contact materials in the European Union, materials containing colourants are covered by the Framework Regulation. As a result, cellulose casing suppliers ensure that the colourants used do not pose a public health or safety issue by ensuring that the colourants are sufficiently integrated into the cellulose matrix to preclude any visible migration of the colourants into the food and by ensuring that all colourants used in the manufacture of cellulose casings meet the necessary purity criteria.

Printing inks, together with their constituent pigments, are not yet subject to specific harmonised European Union legislation, although they are noted in Annex I of Regulation (EC) No 1935/2004 as well as in Commission Regulation (EC) No 2023/2006 (OJ L 384 of 29.12.2006 p.75) on good manufacturing practice. The requirements are fulfilled as cellulose casings are printed exclusively on the outer surface as a flattened tube prior to being stuffed, the inner surface being the food contact surface with no contact with the outer printed surface. Printing inks used by cellulose casing manufacturers are formulated for use on the non-food contact surface of food packaging and articles intended to come into contact with food in accordance with the EuPIA<sup>8</sup> “*Exclusion Policy for Printing Inks and Related Products*” and with the CEPE<sup>9</sup> “*Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials*”.

Cellulose products also comply with the norm for heavy metals of a maximum of 100 ppm for the total amount of lead, mercury, cadmium and chromium (VI).

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<sup>8</sup> European Printing Ink Association, <http://www.eupia.org>.

<sup>9</sup> The European Council of the Paint, Printing Ink and Artists’ Colours Industry, <http://www.cepe.org>.

## Legislation in the United States of America

### Regulatory information

A substance that meets the Food and Drug Administration (FDA) definition of a “food additive” contained in the Federal Food, Drug and Cosmetic Act (FFDCA) is considered “safe” if it is used in accordance with an applicable food additives regulation, a Threshold of Regulation exemption letter or an effective Food Contact Notification (FCN). A food additive is any substance whereby its intended use results, or may reasonably be expected to result, directly or indirectly in it becoming a component of any food. Exemptions from the FFDCA food additives requirements include substances that are “generally recognised as safe” (GRAS) or are the subject of a sanction or approval issued prior to the enactment of the Food Additives Amendment of 1958. If a substance is not reasonably expected to become a component of food under the intended conditions of use, it is not a food additive by definition and may be used without prior sanction by the FDA.

Substances used for food contact applications must be of a purity suitable for their intended use. Any material that is not of suitable purity is unacceptable for use in contact with food, even if the material has a suitable regulatory status.

Certificates obtained from laboratories provide a useful basis for supporting a GRAS or a “no migration/no food additive” position, performed under the conditions as described in the appropriate FDA regulations.

### Current United States of America regulatory status for cellulose casings

Regenerated cellulose is manufactured in compliance with the FDA’s indirect food additives regulation for Polymers under Cellophane (Title 21 CFR Section 177.1200). Cellophane is explicitly cleared for use in cellulose food packaging applications. In addition, substances used as components of paper and paperboard in contact with aqueous and fatty foods in the FDA’s indirect food additives regulation and previously sanctioned food ingredients are considered safe for use in regenerated cellulose products, as the base component of these materials (cellophane and regenerated cellulose) stems from a common source material.

Colourants used only to impart colour to the package have an appropriate FDA status by way of an explicit clearance in the FDA’s colourants for polymers regulation, a listing in the FDA’s Threshold of Regulation exemption inventory, the subject of an applicable FCN clearance or cleared by an appropriate exemption, for example, a GRAS or a “no migration/no food additive” position.

Substances that are not intended to have a technical effect in or on food are known as *indirect food additives* (this being in addition to general principles such as GRAS and the prior sanction exemption), while substances used to have a technical effect in the food are known as *direct food additives*.

## **Legislation in Mercosur, including Brazil and Argentina**

In August 2002, Mercosur (Argentina, Brazil, Paraguay, Uruguay and Venezuela) introduced legislation on cellulose casings based upon German BfR recommendations. The difference between the BfR recommendations and the Mercosur legislation is that the latter is legally binding.

## **Legislation in Japan**

Japanese food packaging legislation is based upon the Food Sanitation Act (Act No 233, 24<sup>th</sup> December 1947). Chapter 3 “Apparatus and Containers and Packaging” is concerned with regenerated casings.

The safety of the food, food additives, apparatus and containers and packaging is voluntarily implemented through the practice of self-regulation in addition to undertaking other necessary measures regarding food intended for sale according to Chapter 1, Article 3.

Apparatus and containers and packaging which contain or are covered with toxic substances or substances injurious to human health shall not be sold, nor be produced or imported for the purpose of marketing, nor be used in business, according to Chapter 3, Article 16.

Japan’s Ministry of Health, Labour and Welfare (MHLW) is revising the Food Sanitation Law in 2018 by replacing the existing “negative list” system with a “positive list” system for regulating food-contact materials. The aim is to reduce the risk of hazardous substances migrating into foods through food-contacting materials by putting restrictions on substances made from synthetic resin.

The new “positive list” system will be consistent with the standards of other countries’ rules for the purpose of effectively coping with increased imports of food items. It is likely that an implementation phase of several years will be introduced in order to promote a smooth transition to the new system.

## CHAPTER 8

### REQUIREMENTS OF TESTING

It is the responsibility of the manufacturer of the finished packaged food to ensure that all relevant regulatory or legislative limitations and specifications applicable to the packaged food are met.

CIPCEL members guarantee that the delivered cellulose casings:

- conform with the regulations in place for food contact materials as described in Chapter 7 of this *Guide*;
- consist of raw materials that are demonstrated to be safe for their intended use with reference to positive lists contained in the European Union food contact Directives; and
- are tested under laboratory conditions and/or evaluated through mathematical calculations.

As an example, reinforced fibrous casings incorporating a fibrous paper substrate have been cleared by BfR Recommendation XXXVI/1 “Koch-und Heissfilterpapiere und Filterschichten”.

Laboratory tests are performed by accredited laboratories in accordance with the specific requirements of migration testing (notably time and temperature) for cellulose casings. It is well known, for example, that one-sided testing for cellulose casing is practically impossible due to the permeability of the cellulose substrate. Furthermore, the impact of food grade humectants should be taken into account, by subtracting it from the total value, when performing total migration testing for aqueous food products.





## CHAPTER 9

### TRACEABILITY

According to the Framework Regulation cited previously, the traceability of materials and articles intended to come into contact with food should be ensured at all stages of manufacture in order to facilitate control, for example, the recall of defective products, the provision of consumer information and the attribution of responsibility. Manufacturers should have in place systems and procedures in order to be able to identify the businesses from which, and to which, are supplied materials or articles covered by the Regulation, and information should be made available to the relevant authorities on demand. Furthermore, the materials and articles placed on the market in the European Union should be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

Since 26<sup>th</sup> October 2006, full traceability has become a requirement of cellulose casing manufacturers, as indeed of all businesses involved in the supply of food contact materials to the European food industry. “*Industrial Guidelines on Traceability of Materials and Articles for Food Contact*” refers to the materials detailed in the Framework Regulation.

For pure cellulose casings, traceability is achieved by means of packaging identification of the smallest packaging unit. For reinforced fibrous casings, traceability of the smallest useable unit is similarly achieved by means of an individual traceability code system.



## CHAPTER 10

### CONTROLS

The Framework Regulation on food contact articles requires that materials and articles manufactured according to good manufacturing practice must not transfer their constituents to food in quantities which:

- endanger human health;
- cause an unacceptable change in the composition of the food; or
- bring about deterioration in the organoleptic characteristics.

These requirements for the finished product have implications not only for the purity and specifications of the raw materials and production aids used in the production of cellulose casings, but also for the operational practices utilised at each stage of manufacture.

In a modern cellulose casing manufacturing plant, control programmes are implemented and consist of adequate testing procedures to ensure that all risks and sources are monitored and controlled.



## CHAPTER 11

### QUALITY SYSTEMS

Quality management systems are available to the industry to provide a guarantee to the customer and consumer that all steps are taken to ensure products are made to the highest manufacturing standards under quality assurance procedures together with the correct documentation. Once certificated, the quality systems adopted and introduced remain viable through external auditing and regular updating by the quality standards authorities. The most comprehensive systems embrace all aspects pertaining to well-run organisations and include production/manufacturing, sales and marketing, and research and development.

The International Organisation for Standardisation (ISO)<sup>10</sup> is the certification system most commonly utilised by the cellulose casing industry. This quality certification system covers the development, production and marketing of all types of casing.

Regarding food safety management systems, the latest standard for any organisation in the food chain is the European Standard ISO 22000:2018 *Food safety management systems—Requirements for any organization in the food chain*. This standard specifies the requirements for a food safety management system to ensure food safety throughout the entire food chain from raw materials to final consumption. The key elements include:

- interactive communication;
- system management;
- prerequisite programmes; and
- Hazard Analysis and Critical Control Point (HACCP) principles.

This international standard integrates the concept of HACCP and application steps as described by the Codex Alimentarius Commission. By means of auditable requirements, it combines the concept of HACCP with relevant programmes. It must be stressed that cellulose casings need not necessarily comply with this standard. Indeed, it is still unknown whether any food contact materials must comply. At present, therefore, it can only be stressed that, in the absence of a regulation specific to cellulose casings, all manufacturers must pursue a comprehensive hygiene policy.

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<sup>10</sup> The International Organisation for Standardisation (ISO) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing international standards is normally carried out through ISO technical committees. Each member interested in a subject, for which a technical committee has been established, has the right to be represented on that committee. International organisations, both governmental and non-governmental, in liaison with the ISO also take part in this work. The ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardisation.

Other programmes are in operation to assist the management of the cellulose casing industry. Responsible Care, for example, is an international initiative of the chemical industry concerning the environment, health and safety. Originally launched in Canada in 1985, the initiative has spread to over 50 countries worldwide.

Also regarding safety management, Occupational Health and Safety Assessment Series (OHSAS) is an internationally applied British Standard for occupational health and safety management systems, developed to assist in the reduction and prevention of accidents and the deterioration of equipment over time.

Note should also be taken of the International Food Standard (IFS) which was set up by the Hauptverband des Deutschen Einzelhandels (HDE), the German trade association of food distributors, with the aim of developing a common audit standard. It has been designed as a uniform tool to ensure food safety and to monitor the quality level of producers of branded retail food products.

Finally, the British Retail Consortium (BRC) has developed a standard aimed at suppliers of food products sold under distributors' brands. This national standard is similar to the International Food Standard.

## CHAPTER 12

### CONCLUSIONS

This *Guide to Good Manufacturing Practice for Non-Edible Cellulose Casings* applies to non-edible cellulose casings which are formed by regenerating cellulose from the viscose process.

The packaging material, usually known as “casings”, is used in the manufacturing and processing of a variety of food products but mainly for sausage production. The *Guide*, prepared by CIPCEL, is based upon manufacturing practices followed in the European Union since the early 1990s and offers a unique insight into manufacturing methods and substances used in the production of pure and reinforced cellulose casings.

Detailed information has been provided on the response of the cellulose casing industry to the increasingly stringent requirements of both suppliers and customers in the food processing sector.

Unlike plastic materials and regenerated cellulose film, the European authorities have not, as yet, harmonised the regulation of cellulose casings used as a food contact material. There is currently no European Union Directive specifically addressing cellulose casings. As with all materials used in contact with food, cellulose casings are covered by the European Union Framework Regulation for food contact materials, i.e. they must be manufactured in accordance with good manufacturing practices and they must not endanger human health.

Finally, this *Guide* accurately represents the views and interests of the cellulose casing industry with regard to food contact legislation. The industry is proactive with respect to the changing requirements of the European Union as well as developments in other food contact issues. While not legally binding, the *Guide* is a unique tool for the industry to show its commitment and responsibility towards its customers within a continuously changing environment.





## APPENDIX 1

### GLOSSARY

<b>Artificial casings</b>	Artificial casings are produced from various materials including cellulose and collagen.
<b>Collagen casings</b>	Collagen casings are made by stripping the natural collagen from animal hides, such as those of cattle, and dissolving it in a suitable solvent. Subsequently, the collagen is reconstituted and sold in both edible and non-edible forms.
<b>Natural casings</b>	Natural casings are produced from the intestines of animals, usually sheep and pigs.
<b>Pure cellulose casings</b>	Cellulose casings originally comprised pure cellulose from viscose and, as such, were considered to be man-made in the sense of taking a natural polymer, i.e. cellulose, and regenerating it following dissolution. These casings are non-edible.
<b>Reinforced fibrous casings</b>	Reinforced fibrous cellulose casings are formed using the same chemical process as pure cellulose casings. These casings include, in addition to pure cellulose from viscose, a paper substrate generally produced from abaca or Manila hemp fibres, or a nonwoven fabric. They offer good dimensional stability for high-speed manufacturing and packaging operations. These casings are non-edible.
<b>Synthetic casings</b>	Plastics are to be considered as synthetic casings. They are normally made from several layers of polymeric materials. Some of the more common man-made polymers include polyamide, polyethylene, polypropylene, polyester, polyvinylidene chloride and polyvinyl chloride. These casings are non-edible.

## **APPENDIX 2**

### **THE MEMBERS OF THE CIPCEL CELLULOSE CASING MANUFACTURERS' WORKING GROUP WHO CONTRIBUTED TO THE GUIDE**

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Mr Richard Armstrong

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Mr Benoît Clerc  
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Viscofan S.A.

Dr Carlos Longo, CIPCEL past Chairman and President

ViskoTeepak N.V., formerly Visko Oy and Teepak NV, and now a wholly owned subsidiary of Eriksson Capital Ab

Mr Jan Maas  
Mr Eric Verschueren, CIPCEL past Chairman and President

The *Guide* was edited by Ms Fiona Butterworth.

## APPENDIX 3

### REGULATORY INFORMATION

#### Regulatory Information of the European Union

The foremost piece of European Union legislation is Regulation (EC) No 1935/2004<sup>11</sup> of the European Parliament and of the Council of 27<sup>th</sup> October 2004 on materials and articles intended to come into contact with food, which repeals Directives 80/590/EEC and 89/109/EEC and is otherwise known as the “Framework Regulation”. The purpose of the Regulation is to ensure the effective functioning of the internal market of the European Union for materials and articles intended to come into contact with food, whilst securing a high level of protection of human health and the interests of consumers. It sets out the general requirements that all food contact materials must be manufactured in accordance with good manufacturing practices, that they are safe and that they do not change the properties of the food in unacceptable ways. Separate rules are set out in Commission Regulation (EC) No 2023/2006/EC<sup>12</sup> of 22<sup>nd</sup> December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The principle of mutual recognition allows for the legal importation and sale in a Member State of products that are legally marketed in another Member State even if the products do not comply with specific regulatory requirements of the country of import, unless authorities of the country of import can demonstrate that the products raise legitimate concerns. This principle is meant to fill in the gaps of non-harmonised law between the Member States of the European Union.

The basic raw materials used to manufacture regenerated cellulose casings are cellulose pulp, while reinforced fibrous casings also require a cellulose paper substrate. The former complies with Commission Directive 2007/42/EC<sup>13</sup> of 29<sup>th</sup> June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, while the latter complies with BfR Recommendation XLIV<sup>14</sup> “Kunstdärme” and BfR Recommendation XXXVI/1 “Koch-und Heissfilterpapiere und Filterschichten”<sup>15</sup>.

Additives and coating substances used in regenerated cellulose casings have suitable listings demonstrating their suitability and safety for use as intended under:

- the list of approved monomers and starting substances of the Plastics Directive of the European Commission 2002/72/EC subsumed under Commission Regulation (EU) No 10/2011 of 14<sup>th</sup> January 2011 on plastic materials and articles intended

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<sup>11</sup> OJ L 338 of 13.11.2004 p.4.

<sup>12</sup> OJ L 384 of 29.12.2006 p.75.

<sup>13</sup> OJ L 172 of 30.6.2007 p.71.

<sup>14</sup> [https://bfr.ble.de/kse/faces/DBEmpfehlung\\_en.jsp](https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp) NB: this is an unofficial translation and only the German version is binding.

<sup>15</sup> *Op. cit.*, footnote 15.

- to come into contact with food and its amendments<sup>16</sup> and/or the list of approved additives of the same directive; and/or
- European Commission Directive 2007/42/EC<sup>17</sup> of 29<sup>th</sup> June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs; and/or
  - German BfR Recommendation XLIV<sup>18</sup>(“Artificial Sausage Casings”); and/or
  - the US Food and Drug Administration’s food additives regulation in Title 21 of the Code of Federal Regulations (CFR) Parts 170-199<sup>19</sup> on food contact materials; and/or
  - the European Community Synoptic Document<sup>20</sup> “Provisional list of monomers and additives notified to European Commission as substances which may be used in the manufacture of plastics or coatings intended to come into contact with foodstuffs”; and/or
  - authorised food additives under the European Parliament and Council Directive 95/2/EC of 20<sup>th</sup> February 1995 and its amendments<sup>21</sup>; and/or
  - other relevant European and Member State legislation, i.e. Paper and Board<sup>22</sup>.

Smoke flavourings<sup>23</sup> comply with Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16<sup>th</sup> December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods. Moreover, the solution is subject to an application for the evaluation and authorisation of primary products and/or derived smoke flavourings intended for use in or on foods.

All colourants used in the manufacture of cellulose casings meet the necessary purity criteria as listed under:

- the specifications of the Council of Europe Resolution AP (89) 1<sup>24</sup> on the use of colourants in plastic materials coming into contact with food; and/or
- German BfR Recommendation IX (“Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände”<sup>25</sup>); and/or
- the French positive list of colourants for food contact plastics, Circulaire No 176 of 2<sup>nd</sup> December 1959, which is revised continually and provides a positive list of

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<sup>16</sup> OJ L 220 of 15.8.2002 p.18; OJ L 39 of 13.2.2003 p.2; OJ L 12 of 15.1.2011 p.1.

<sup>17</sup> *Op. cit.*, footnote 14.

<sup>18</sup> *Op. cit.*, footnote 15.

<sup>19</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

<sup>20</sup> [http://www.contactalimentaire.com/fileadmin/ImageFichier\\_Archive/contact\\_alimentaire/Fichiers\\_Documents/Avis\\_de\\_AESA/synoptic\\_doc\\_en\\_-\\_version\\_June\\_2005.pdf](http://www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Avis_de_AESA/synoptic_doc_en_-_version_June_2005.pdf)

<sup>21</sup> OJ L 61 of 18.3.1995 p.1; OJ L 86 of 28.3.1997 p.4; OJ L 295 of 4.11.1998 p.18; OJ L 55 of 24.2.2001 p.59; and OJ L 24 of 29.1.2004 p.58.

<sup>22</sup> <http://www.cepi.org/system/files/public/documents/publications/foodcontact/2012/Industry%20guideline-updated2012final.pdf>

<sup>23</sup> OJ L 354 of 31.12.2008 p.34. The suppliers of smoke flavourings made a submission for the authorisation of Smoke Primary products. Article 20, concerning transitional measures, of Regulation 2065/2003/EC (OJ L 309 of 26.11.2003 p.1), lays down that only primary products for which a valid application was submitted before 16<sup>th</sup> June 2005 can continue to be placed on the market thereafter.

<sup>24</sup> <https://rm.coe.int/16804f8648>

<sup>25</sup> *Op. cit.*, footnote 15.

pigments and colourants for plastic materials and packaging, including purity criteria.

The specific requirement of no colour release, according to the above listings, can be tested by visual determination of the colour release for which a German BfR method BII IX<sup>26</sup> can be used.

Whilst printing inks, together with their constituent pigments, are not subject to specific harmonised European legislation, they are noted in Annex I of Council Regulation (EC) No 1935/2004 and are also referred to in Commission Regulation (EC) No 2023/2006 on good manufacturing practice. Specifically, Commission Regulation (EC) No 2023/2006 gives detailed rules on good manufacturing practice in relation to processes involving the application of printing inks to the non-food contact side of materials or articles. These rules, applicable to regenerated cellulose casings, include the following.

- Printing inks applied to the non-food contact surface of materials and articles must be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food contact surface, either through the substrate or by set-off in the stack or reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Council Regulation (EC) No 1935/2004.
- Printed materials and articles must be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food contact surface.
- The printed surfaces must not come into direct contact with food.

These requirements are fulfilled since cellulose casings are printed exclusively on the outer surface as a flattened tube prior to being stuffed, the inner surface being the food contact surface with no contact with the outer printed surface.

Cellulose products also comply with the norm for heavy metals of a maximum of 100 ppm for the total amount of Lead, Mercury, Cadmium and Chromium (VI) of Directive 94/62/EC<sup>27</sup>.

Finally, with respect to mineral oil hydrocarbons, note must be taken of Commission Recommendation (EU) 2017/84<sup>28</sup> of 16<sup>th</sup> January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food.

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<sup>26</sup> Kunststoffe im Lebensmittelverkehr, Franck, B II IX.

<sup>27</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:EN:HTML>

<sup>28</sup> OJ L 12 of 17.1.2017 p.95.

## **Regulatory Information of the United States of America**

The regulatory authority in the United States of America is the Food and Drug Administration (FDA). The FDA applies the “no migration” exemption principle.

If properly conducted extraction studies simulating the intended conditions of use do not yield detectable migration of a tested substance at an appropriate analytical sensitivity, the substance is not reasonably expected to become a component of the food and is not a food additive. Alternatively, if “worst case” calculations assume a 100 per cent migration of a substance to food, or other appropriate calculations demonstrate that the substance will not be detected at the appropriate sensitivity level, the same “no migration/no food additive” conclusion can be reached.

Substances deemed “generally recognised as safe” (GRAS) are excluded from the definition of a “food additive” and are exempt from pre-market clearance requirements (Code of Federal Regulations (CFR) Title 21 Parts 182, 184 and 186). The Act specifically exempts from the definition of a food additive any substance which is “prior-sanctioned”, meaning any substance sanctioned by an FDA or a United States Department of Agriculture (USDA) letter or memorandum written prior to the Food Additives Amendment of 1958, Title 21 CFR Part 181.

According to Title 21 CFR Section 170.39, the FDA can exempt a food contact material that migrates or is expected to migrate from regulation as a food additive if: its dietary concentrations are at or below 0.5 ppb; its dietary exposure to the substance is at or below 1 per cent of the acceptable daily intake; and it is not a carcinogen and does not have impurities that are potent carcinogens.

General standards of suitable purity for the intended use are given under Title 21 CFR Section 174.5. Section 176.170 concerns components of paper and paperboard in contact with aqueous and fatty foods: paragraph (c) requires certain end tests to be performed.

Title 21 CFR Section 181.30 relates to substances used in the manufacture of paper and paperboard products used in food packaging and are prior-sanctioned, while Title 21 CFR Section 178.3297 refers to colourants for polymers.

Liquid smoke solutions are explicitly listed in Title 21 CFR Section 424.21 (c) as a permitted flavouring agent for various meat and poultry products and may be used at levels that are sufficient for its purpose.

## **Regulatory Information of Japan**

Regulation of apparatus and containers and packaging is determined within “Specifications, Standards and Testing Methods for Foodstuffs, Equipment, Containers and Packaging, Toys and Detergents” (Ministry of Health and Welfare Notice No 370, 28<sup>th</sup> December 1959; final version Ministry of Health and Welfare Notice No 499, 29<sup>th</sup> November 2005) which complies with the provisions of paragraph 1 of Article 7 and with

Article 10 of the Food Sanitation Act (Act No 233, 1947). These contain general composition standards for foods, production standards and test methods. The Food Sanitation Act forbids the sale of food packaging that can be harmful to human health.

Apparatus and containers and packaging must not contain any synthetic colouring agents not listed in Table 1 of the Implementation Regulations of the Food Sanitation Act. However, this restriction does not apply in cases where the product in question is processed in such a way as to preclude the colouring agent dissolving or leaching in contact with food. Test methods for apparatus, containers and packaging as well as dissolvability are determined by an individual standard.

## **APPENDIX 4**

### **A NOTE ON REGENERATED CELLULOSE FILM**

European Commission Directive 93/10/EEC of 15<sup>th</sup> March 1993 (OJ L 93 of 17.4.1993 p.27) relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs applies to regenerated cellulose film and establishes a list of authorised substances together with restrictions on their use. The last significant amendment was European Commission Directive 2004/14/EC of 29<sup>th</sup> January 2004 (OJ L 27 of 30.1.2004 p.48). European Commission Directive 2007/42/EC of 29<sup>th</sup> June 2007 (OJ L 172 of 30.6.2007 p.71) was a codified version of the Directive.

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides. As described, the Directive applies to uncoated regenerated cellulose film, coated regenerated cellulose film with coating derived from cellulose, or coated regenerated cellulose film with coating consisting of plastics.

Regenerated cellulose is manufactured by the conversion of natural cellulose to a soluble cellulosic derivative and subsequent regeneration, typically forming either a fibre or a film. Regenerated cellulose film is a natural product usually derived from wood pulp. Trees grown in managed plantations provide the raw material in the form of compressed wood pulp or sheets (although cotton linters can be used).

The manufacturing process commences with bales or reels of wood pulp being agitated with a caustic soda solution and a catalyst to form a slurry which is fed through a press and compressed to produce alkali cellulose; thereafter, the material is reacted with carbon disulphide to produce sodium cellulose xanthate, and mixed with a caustic soda solution to produce viscose. The cellulose in the viscose is regenerated by extrusion via a bath of diluted sulphuric acid to form a sheet or a film, a process known as casting. Wash baths treat the film to remove impurities, improve flexibility and, through anchoring agents, provide a chemical bond between the film and any subsequent coating operation. The carbon disulphide is recovered.

The regenerated cellulose film is wound onto rolls which are given a unique number. All production records regarding data on wood pulp, quality control, time of manufacture and downstream operations (including coating applications) can therefore be traced.

Regenerated cellulose film is more commonly known under the trademark “Cellophane”. It is used almost entirely as a packaging material, particularly for foodstuffs.



