INDUSTRIAL GUIDELINES ON TRACEABILITY OF MATERIALS AND ARTICLES FOR FOOD CONTACT

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I. OBJECTIVE

The objective of this paper is to provide guidelines to the industry on how to implement traceability in order to fulfil the requirements set down in Article 17 of the Framework Regulation (Regulation (EC) No 1935/2004) on materials and articles in contact with food.

"Article 17

Traceability

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information."

In several parts of these guidelines, traceability tools are proposed which go beyond what is the strict legal requirement of the above article 17, or which extend the application of such traceability tools in the current industrial practice. Any requirement in excess of what is required for legal compliance should be conisdered as a target.

This document is a living document and will be updated periodically (e.g. by the addition of additional sector specific guidelines)

II. SCOPE

The Framework Regulation covers any type of food contact material or article, regardless of its composition. This Code therefore aims to cover a very wide scope of materials and articles. Any material or article not explicitly covered in these guidelines should be aligned with the most appropriate material listed and treated in a similar manner.

For complex non-packaging multi-material products such as household appliances it could happen that these guidelines are too general.

II.1 Materials

The scope of this paper is determined by article 1 of the Framework Regulation (EC) No 1935/2004, and examples of food contact materials are given in Annex I of this Regulation:

- Active and intelligent materials and articles
- Adhesives
- Ceramics
- Cork
- Rubbers
- Glass
- Ion-exchange resins
- Metals and alloys
- Paper and board
- Plastics
- Printing inks
- Regenerated cellulose
- Silicones
- Textile
- Varnishes and coatings
- Waxes
- Wood

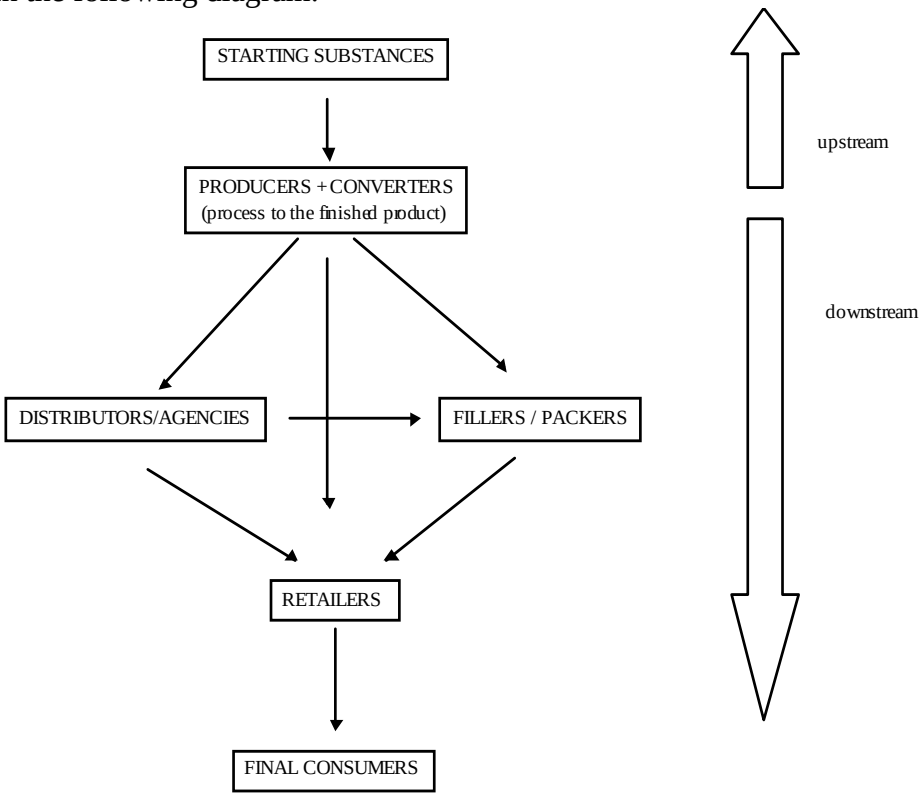
This list was used as a reference for contacting representative trade associations within the supply chain who take responsibility for each material group.
The trade associations, who have worked together on this document, are listed in Annex 1.
Industry guidelines concerning traceability of materials and articles, which served as the basis for this document, are described in Annex 2.

II.2 Applications

The scope of this document is specified as food-contact materials and articles, when first placed on the market at the retail stage, and also, where appropriate, to those starting materials used for the manufacture of the said food-contact materials and articles.

III. STAKEHOLDERS WITHIN THE FOOD CONTACT MATERIALS AND ARTICLES SUPPLY CHAIN

The stakeholders involved along the supply chain of food-contact materials and articles are represented in the following diagram:



Using the above diagram, it is possible to identify a point where the food contact material or article is manufactured, i.e. the converters and producers. At this point there is a separate identity, “upstream” and “downstream”. Converters transform materials, which have been produced by “upstream” suppliers, into finished articles or semi-finished goods. Producers manufacture articles directly from starting materials, using processes involving chemical, as well as physical change

The scheme illustrated above assumes that the whole chain is within the European Community. However, in some cases, part of the chain can be outside the Community; therefore another stakeholder must be included in the scheme, namely the Importer. Imports may take place at different levels, such as:

- Import of starting materials by the converters and producers;
- Import of empty packaging by distributors or fillers;
- Import of food contact articles by distributors or retailers;
- Import of filled food contact materials and articles by distributors or retailers.

IV. DEFINITIONS

Among the numerous definitions of traceability, the following was selected:

"The ability to trace back the history of a food contact material or article from the retail stage to the point of its manufacture, identifying all appropriate information."[1]

There are two levels of traceability, i.e.:

Level 1: within the operation of each stakeholder

This level covers the systems that each stakeholder has in place to link his products to the raw materials used to produce them.

Level 2: between different stakeholders

This level is concerned with the transmission of information along the chain. It should be possible from any point downstream, and in particular from the retailing point to go back up the chain to understand by whom the material or article has been manufactured.

This also implies that, in the opposite direction, the material or article can be traced from any point up the chain down to the retailing point.

Both levels must function to achieve full traceability.

V. TRACEABILITY BACK TO WHERE?

The traceability chain ends at the retailer and the starting point for traceability of a food contact material or article, is placed at the point at which it, or its components/ingredients are first placed on the market with the intention of being "for food contact use".

In the case of materials or articles, or their components/ingredients which have been imported from outside the European Community, traceability shall extend back to the importer responsible for placing them on the EU market for an intended food-contact application.

VI. LEVEL 1: TRACEABILITY WITHIN A STAKEHOLDER'S OPERATION

VI.1 The role of Quality Systems

Traceability has become an integral requirement of modern quality management systems. According to the ISO 9000 management standard, companies that have adopted this system are required to prepare and maintain documented procedures aimed at identifying the product, from the purchase of starting materials through the production process, and shipment. All procedures for the identification of production batches and single products must be appropriately documented (e.g. in writing or through computer archiving).

ISO 9000 is not the only system requiring industry to establish procedures for traceability; other systems, such as good manufacturing practice, in place in many industries, have the same requirements.

All these systems have the aim of ensuring a constant quality of products during manufacture.

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[1] definition based on:
*Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28/01/2002 laying down the general principles and requirements of food law, OJ L31/1
*European Commission Proposal of regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products derived from GMOs, adopted 25/07/2001, 2001/0180(COD)
*Codex Alimentarius Commission ; 2-7/07/2001+ Comments European Commission on this matter

VI.2 The industrial practice

The business operator ensures that the incoming starting materials are supplied with information given by the relevant supplier. This information is either printed on the starting materials' containers, or reported on labels, bar codes, or in accompanying documentation.

Information must be provided which enables the identification of:

1. Name of supplier and type (grade) of starting material;
2. Location of production, date, batch number and/or shift of manufacture and/or order number;
3. When appropriate (for example in the case of plastics) documents certifying the legislation with which they are complying;
4. Documents of analysis that, depending on their nature, report the key attributes against the agreed specifications.

The downstream user often carries out further analyses in order to confirm the suitability of the starting materials for their intended use. Also, according to ISO 9000 procedures, downstream users can carry out audits to ensure that the upstream supplier's process is under control, and therefore the relevant technical attributes of the starting materials are constantly maintained.

The above considerations ensure that all measures are taken to identify defects before they can cause an effect on the finished product(s)

VI.3 Need for quality systems

Some companies involved in the food contact materials and articles distribution chain, especially small and medium size enterprises, may not have the critical mass for being accredited through a certified quality system. Nevertheless, they should establish an equivalent quality system internally. Whatever procedure is adopted, it is essential that every manufacturer of a food contact material or article maintains a documented quality system aimed at identifying and preventing the production of defective products and, in the case of delayed defects detection, allowing minimal product recall.

VI.4 Requirements for shipped materials and articles

Food contact-materials or articles, and/or their container, and/or the accompanying documentation shall always report all appropriate information, e.g. the manufacturer's name, a reference relative to the location and date of production.

The upstream producer ensures that essential production information is transferred to customers. Essential production information is:

a) Producer name and address;
b) Article number/product name;
c) Production date and identification of the product.

Several tools such as alpha-numeric descriptions, bar codes, labels, the documentation that accompanies shipped goods, or even electronic tags that are capable of carrying the above information can be used, the use of these tools is dependant on the further use of the material and their cost. Some examples are reported below:

a) Usual means of identification for food and beverage metal cans are labelling, bar-coding and sometimes inkjet coding. These are applied either to individual cans or to batches and are dependant on feasibility and the needs of the product;
b) A label can be used as an appropriate information conveying tool for transport packaging containing rigid packaging such as plastic trays, glass containers, PET pre-forms etc. The same result can be achieved by reporting the information on freight documentation.

c) In the case of articles sold to the consumer without being in contact with food, such as plastic cutlery, glass jars or paper baking forms, the information can be printed or labelled on the article itself or its sales packaging, or reported in freight documents.
d) In the case of reels of films or paper that will be further processed before being used, the information can be printed on to a label fixed to the wrapping or fixed to the core, printed on the conveying tool, or printed on the freight documentation.

It must be pointed out that it is not important how the information is conveyed to the next organisation in the distribution chain, but it is of fundamental importance that the information is complete, unambiguous and is maintained along the chain.

Individual industry guidelines are outlined in detail in annex 2.

VII. LEVEL 2 - TRACEABILITY ALONG THE SUPPLY CHAIN

Traceability is achieved only if each single part of the chain complies with the rules of identification enabling it to go back to its upstream supplier(s). In other words, the information that accompanies materials and articles when they leave the manufacturing company must be maintained by each downstream user in the supply chain.

In the ideal supply chain, e.g. a chain composed entirely by ISO 9000 certified companies, traceability will be always guaranteed, as every single step of the chain will have been documented, In practice different identification rules may apply for upstream and downstream users .

Not all distribution chains are composed entirely of certified companies, and one basic concept must be introduced that forms a fundamental part of a traceability system. Upstream suppliers supplying a company operating under a certified quality system shall strictly guarantee traceability of their products. It is essential that companies operating under a certified quality system control their suppliers and ensure that the supplied products are appropriately identified.

The food contact materials and articles chain consists of three applications which must be treated differently when discussing traceability. These are, firstly, materials and articles already in contact with food; the second category is materials and articles manufactured for food use intended to be brought into contact with food. Finally, a third category is composed of material & articles that can reasonably be expected to be brought in contact with food or to transfer their constituents to food under foreseeable conditions of use.

VII.1 Materials & articles already in contact with food

Materials and articles already in contact with food are commonly called “packaging”. For ease of reading, this term will be used in the section below.
Filling represents the boundary to the downstream end of traceability of packaging materials.
When the packaging is filled with food, its information overlaps the information required of the food itself, which is guaranteed through the following:

- “Best-before” date (mandatory for all foodstuffs);
- Date of packaging and/or lot number.

It is required that fillers maintain records of specific information for the packaging material that has been used for each foodstuff, and that the link between the two information flows is not interrupted.

The objective of establishing a mandatory system for traceability primarily focuses on obligatory record-keeping of the packaging information for each lot of food packed and sold.

It is not important how the link between food and the material used for its packaging is maintained by each body in the chain, whether it consists of, for instance, document filing or electronic archiving, as long as an unequivocal and unambiguous link is demonstrated. For example, companies may choose to archive the material's shipment documentation with its reference lot number, or to store in a spreadsheet the material's reference codes versus time, if the process is continuous.

Thus, the traceability of food packaging materials will be ensured and additional marking of the material or article itself will be not be required.

VII.2. Materials & Articles intended to be brought into contact with food

These are materials and articles in a stage of their production and marketing prior to the stage at which they are brought into contact with food. Alternatively they are materials and articles sold in the retail stage with the intention of being brought into contact with food. For this reason their identification system can not overlap with the food identification system. In these cases, it is necessary that the information (e.g. manufacturer's name, date and place of production, code, etc…) be maintained down to the retail stage.
The tools employed for the identification of food contact materials can be used for food contact articles, i.e., alpha numeric descriptions or bar codes, reported on labels, directly printed or provided in appropriate documentation.

VII.3. Material & Articles that can reasonably be expected to be brought in contact with food or to transfer their constituents to food under foreseeable conditions of use

In relation to traceability information and its flow in the supply chain this section is not a separate category of food contact materials and articles. The point at which the material or article is identified as coming into contact with food, or the fact that this contact can be indirect indicates that the starting points of the traceability chain can be different. However the end point is still the retailer. At this point the material is either in contact with food or not. Thus dependant on the case either of the previous two paragraphs apply.

VIII. STRUCTURE OF THESE INDUSTRY GUIDELINES

The guidelines are divided in material groups as defined in annex I of the Framework Regulation and are available in appendix II to this document.

Each material specific guideline has the following structure:

1) Scope
2) General information
3) Traceability information and "propagation"
4) Recall
5) Others

IX. CONCLUSIONS

As a general principle, the food market does not accept food contact materials and articles of uncertain origin. The quality of food contact materials and articles is not only a legal requirement, but is increasingly becoming a competitive advantage. It is in the industry's own interest to maintain a high level of control over its production and this can be achieved only through a suitable traceability system.

ANNEX I:

ASSOCIATIONS WHICH PARTICIPATED IN THIS WORK

1. List (in alphabetical order)

- **APEAL**, Association of European Producers of Steel for Packaging
- **BLIC,** European Association of the Rubber Industry
- **CEFIC FCA,** European Council of Chemistry, Food contact Additives
- **CEI-Bois,** European Confederation of Woodworking Industries
- **CEPE,** European Council of Paint, Printing Inks and Artists' Colors Industry
- **CEPI,** Confederation of European Paper Industries
- **CITPA,** International Confederation of Paper and Board Converters in Europe
- **CIPCEL,** Comité International de la Pellicule Cellulosique
- **CPIV,** Standing Committee of the European Glass Industries
- **EAA,** European Aluminium Association
- **ETS,** European Tissue Symposium
- **EuPC,** European Plastics Converters Association
- **FPE,** Flexible Packaging Europe
- **FEFCO/ProBox,** European Federation of Corrugated Board Manufacturers
- **FEVE,** European Container Glass Federation
- ***PlasticsEurope*,** Association of Plastics manufacturers in Europe
- **SEFEL,** European Secretariat of Manufacturers of Light Metal Packaging

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TRACEABILITY APPLIED TO

GLASS PACKAGING CONTAINERS (BOTTLES AND JARS)

(Practical Guidelines)

I. SCOPE

This industry guideline describes the traceability of glass packaging containers (bottles and jars). It is emphasized that this guideline applies to the traceability of reusable glass packaging containers only on their first delivery from a glassworks.

II. GENERAL INFORMATION

II.1 Associations taken as part of the glass packaging container & bottle group

FEVE European Container Glass Federation

II.2 General information and limitations

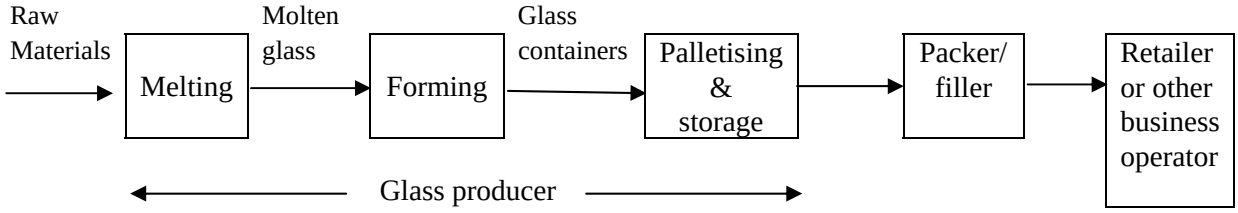
In the vast majority of situations, producers of glass packaging containers are able to assure a high degree of traceability of their products.

There are some practical limitations: these can arise in particular with regard to the tracing of raw materials or when added-value services are provided by operators external to the glass container industry (as described below). However, since the properties of glass (in particular its virtual inertness) are such that food contact issues are extremely rare, these limitations on traceability need to be balanced against the very low risk of problems arising.

The traceability of *materials used for the production* of glass packaging containers cannot be precisely defined by this guideline, for two reasons.

Firstly, raw materials must be stored in large quantities before they are used, so that a definite identification of the individual deliveries or suppliers (if there is more than one supplier for the same raw material) is not possible from information relating to the glass containers produced. This is especially true for the recycled cullet that is, depending on the glass colour and the production site, often the main raw material in the glass melt.

Secondly, glass melting furnaces are continuously operated facilities in which raw materials are introduced on one side, while molten glass is removed on the other side and formed into a product after a thermo-chemical melting process has taken place. This process, in which partial mixing occurs, is another factor inhibiting a definite traceability of the starting materials used to make particular glass containers.



Beside the question of raw materials, should the information on the pallet labels that serve the purpose of traceability be lost, then traceability would be confined to information that can be gathered only from the glass container itself (see point 3). This could happen if the glass packaging containers were later externally depalletised, e.g. for passing through an added-value process, and then received a different pallet label from another operator.

III. INFORMATION ON TRACEABILITY AND "PROPAGATION"

In practice, three identification methods are applied to ensure traceability of glass containers:

III.1 Pallet labels

Pallet labelling is essential for the traceability of glass containers. Should any defects be detected in the most critical stage, which is the filling of the glass containers, a detailed traceability is only ensured with the help of pallet labels. Information on pallets applies to fillers, intermediaries (e.g. decorators) etc. The labels themselves are usually disposed of at the customer's premises, at the latest when filling the containers, and are no longer available at the retailer or consumer stages.

Pallet labels usually indicate at least the date of manufacture, line of manufacture, shift, pallet number and article number. In some cases a batch number is attached that allows retrieval of the date of manufacture from an internal database.

Pallet labels can also reveal information on the number of containers per pallet, glass colour etc. Some may have bar codes that relate to the glass manufacturer or customer codes.

The customer is able to use the pallet information in his production data acquisition to ensure traceability back to the original manufacturer.

III.2 Engraving marks

Engraving marks serve as a source of information throughout the complete supply chain "from manufacturer to end user". Company engraving symbols enable consumers' traceability back to the original manufacturer.

Engraved mould numbers are an essential characteristic of traceability already during the manufacturing process. In this way it is possible to check glass containers one by one when passing through automatic inspection devices and to reject individual containers as necessary.

Engraving marks that can deliver information on date of manufacture, runtime of moulds etc. by means of coding systems are within the manufacturer's discretion and not mandatory. These marks cannot be applied limitlessly, especially to single trip glass containers, without diminishing the functional qualities (the strength) of the container. Moreover, it may not be practicable to apply them to non-round containers.

III.3 External marks

Where specifically requested by a customer, it is also possible to equip a production line with a means of applying external marks. They are much less commonly used than pallet labels and engraving marks; they complement, and in no way obviate, the need for pallet label information.

These marks are mostly applied by ink jets, laser or U.V.

The marks contain information on the exact date of manufacture (date, time) in optical character or encoded.

This information can always be traced back to the filler or intermediary (e .g. decorator). It is, however, only of limited value to the end user, due to technical particularities of the marks.

IV. RECALL

In general, containers that satisfy all quality-relevant criteria faultlessly are delivered to the customers.

Nevertheless, should any defects be detected on delivered products during intermediate processing (e. g. decorating) or filling or when being traded, the size of the defective production has to be limited according to the traceability characteristics defined in point 3.

TRACEABILITY APPLIED TO METAL PACKAGING FOR FOOD & DRINKS (Practical Guidelines)

INTRODUCTION

- A document prepared by the "Traceability & Food Contact Materials Industry Liaison Committee" was submitted to the EU Commission in 2002. As a result, Member States requested that Industry produce a practical guideline document in order to illustrate, with examples, some of the current industrial practices used to ensure traceability.

- In order to understand the full picture regarding traceability applied to Packaged Food, it is recommended that the Reader of these guidelines reads the document prepared for the commission in 2002.

I. SCOPE

- The present guide describes how traceability is currently applied to Metal Packaging for Food & Drinks.
- It is the objective of this document to provide a guidance for the Industry in order to allow it to adopt systems capable of fulfilling the requirements of Article 17 in Framework Regulation 1935/2004/EC which deal with traceability of materials and articles for food contact.
- The present document describes Traceability along the manufacturing process, starting from upstream raw materials (incoming materials) downstream to supply of metal packaging products (finished articles) to customers.
- For information, examples of practices used by the producers of raw materials is also supplied..

II. GENERAL INFORMATION

II.1 Associations taken as part of the metal packaging group

The following associations represent suppliers of raw materials used for food contact paint/lacquers:

- Plastics*Europe*
- EPRA - European Phenolic Resins Association

The following associations represent incoming materials used for metal packaging:

- APEAL – Association of European Producers of Steel for Packaging
- EAA – European Aluminium Association
- CEPE – Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art (European Confederation of Paints, Printing Inks and Artists Colours Manufacturers)
- Rubber – No European Association identified ; information provided by an individual company

The following associations represent metal packaging manufacturers:

- EAA – European Aluminium Association (e.g. trays)
- FPE – Flexible Packaging Europe, - covered in the Plastic Appendix Guide- (e.g. aluminium foil lids and laminates).
- SEFEL – European Secretariat of Manufacturers of Light Metal Packaging (e.g. cans, closures, aerosols, etc.)

II.2 Methodology

In order to provide a consistent approach to consolidate the work prepared by the different associations, the following structure was used by each association:

1) Flow chart
The chart consists of a short overview of the major steps related to traceability for that specific industry. The chart provided by each association is illustrated in chapter III.

2) Scope and Tools
This document consists of the key Traceability steps and the related tools used to cover these steps. This document provided by each association is available in Chapter III. Below is an example of the document structure:

Metal Packaging	Traceability Scope	Traceability Tools
e.g. Beverage 2 piece cans	*Metal coil reception*	*Description of tools (1)**
	Raw material to production line	….
	….	…

** this number refers to the example*

3) Examples

Examples provided by each association are available in the appendix section of this document. The purpose of the examples is to illustrate the existing tools used in the production environment and through the Supply Chain. These examples are not to be considered as either a standard to be reached or as the reference for that industry. The examples have been taken across all of the industries represented by the associations contributing to this document.

II.3 Existing System and Key Traceability concepts

II.3.1 Existing System

The overall metal packaging industry value chain is based on several industries providing their products in parallel or at consecutive levels downstream to the metal packaging producers (see flowchart under III.2.1). In the consecutive level structure the products of one level of industry are raw materials to the next level downstream.
In this scenario, the expression 'raw material' indicates different products.
All levels of the metal packaging supply chain have to be able to trace their incoming raw materials and outgoing products.
The existing traceability system allows for timely alert, and this in turn provides for the option of appropriate recall steps to be undertaken as necessary.

II.3.2 Key Concepts

Requirements for sustaining and further improving traceability are seen as follows:

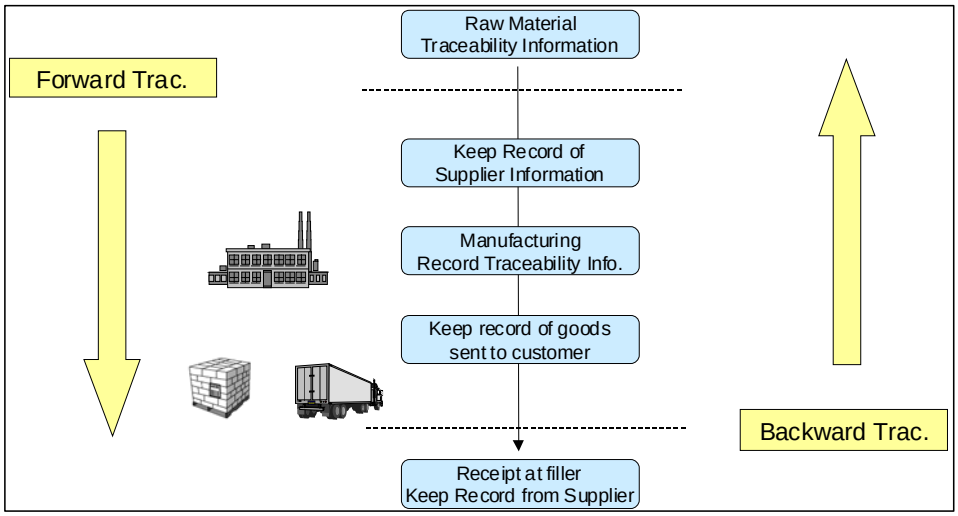
- Traceability must be ensured at all stages – incoming goods, manufacturing and despatch.
- Joint responsibilities among partners to share information.
- Goods must be adequately labelled and identified to facilitate their traceability.

II.3.3 Example

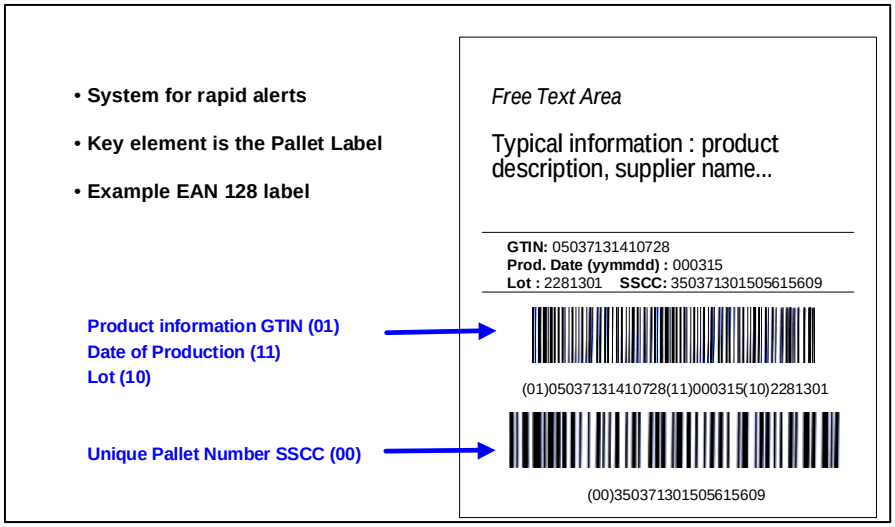
Example of traceability requirements typical for metal food packaging

- Food packaging suppliers provide information to fillers such as:
  - Supplier name
  - Product number and name
  - Date of production
  - Traceability number
- Fillers must keep records of food packaging supplier information.
- Partners must ensure that upstream and downstream Traceability exist (see graph below).
  - Upstream means that it is possible to trace back to the source of the incident
  - Downstream means that it is possible to trace down the Supply Chain
- The same concept applies between the packaging manufacturer and its own suppliers.

Example of Upstream and Downstream Traceability Concepts



Example of standard pallet label for cans and closures manufacturers, which is a key element to communicate the relevant information



III. TRACEABILITY INFORMATION AND PROPAGATION

A flow chart and traceability "scope/tools" information is presented in the following pages, with each of the finished articles and incoming materials listed below.

III.1 Traceability for finished articles

- Beverage cans & ends
- Food cans & ends
- Metal closures
- Aerosols cans

III.2 Traceability applied to incoming materials (examples)

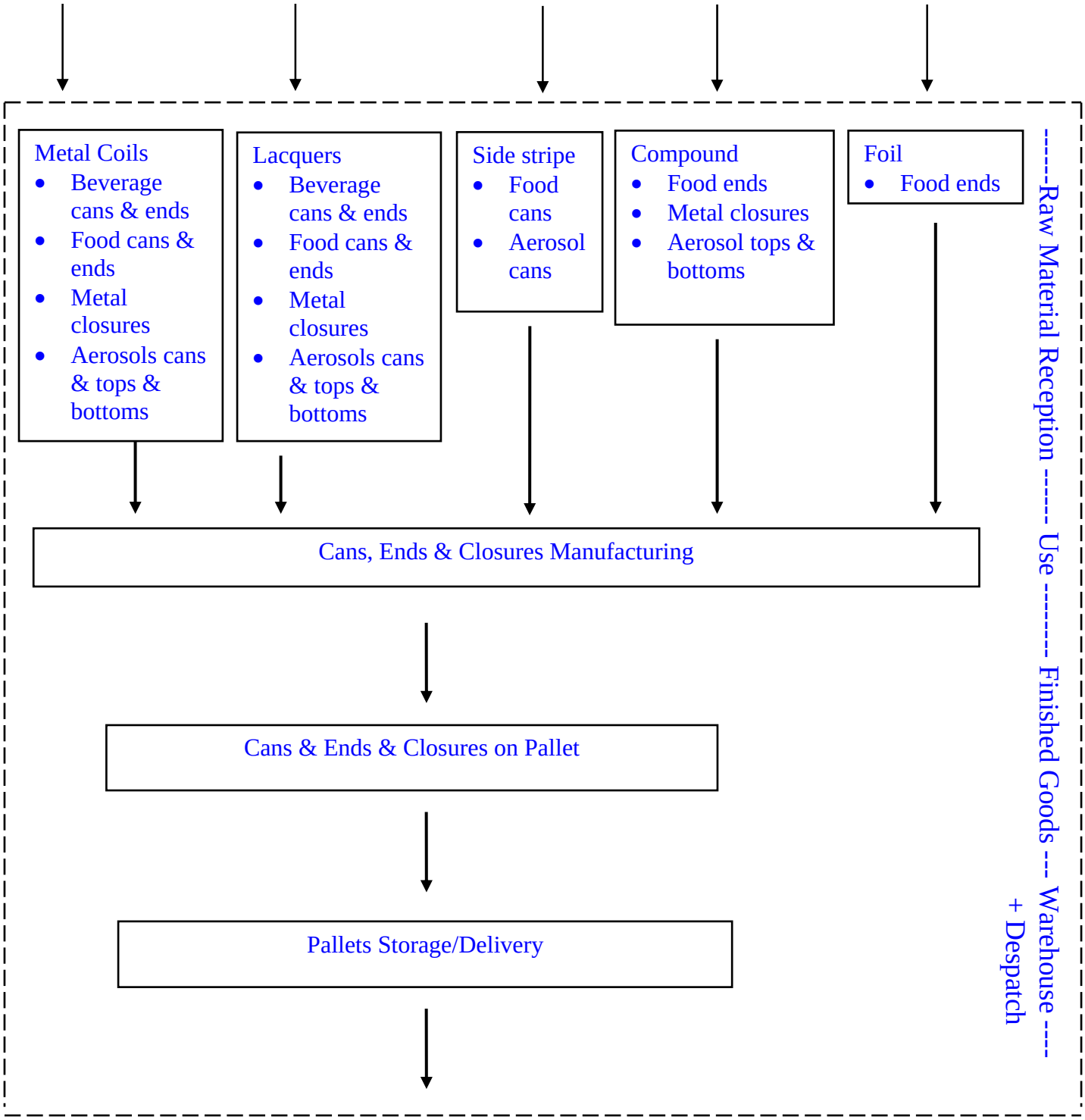
III.2.1 Steel for packaging – APEAL
III.2.2 Aluminium for packaging – EAA
III. 2.3 Lacquers for Packaging – CEPE
III.2.3.1 Examples of Raw Materials for coating manufacturers
- Plastics*Europe*/ERC
- EPRA

III.2.4 Compound for packaging – Rubber Association

III.1 Traceability for finished articles

Flow Chart

From Suppliers



To CIAA (To Food and Drink Industry)

Scope & Tools

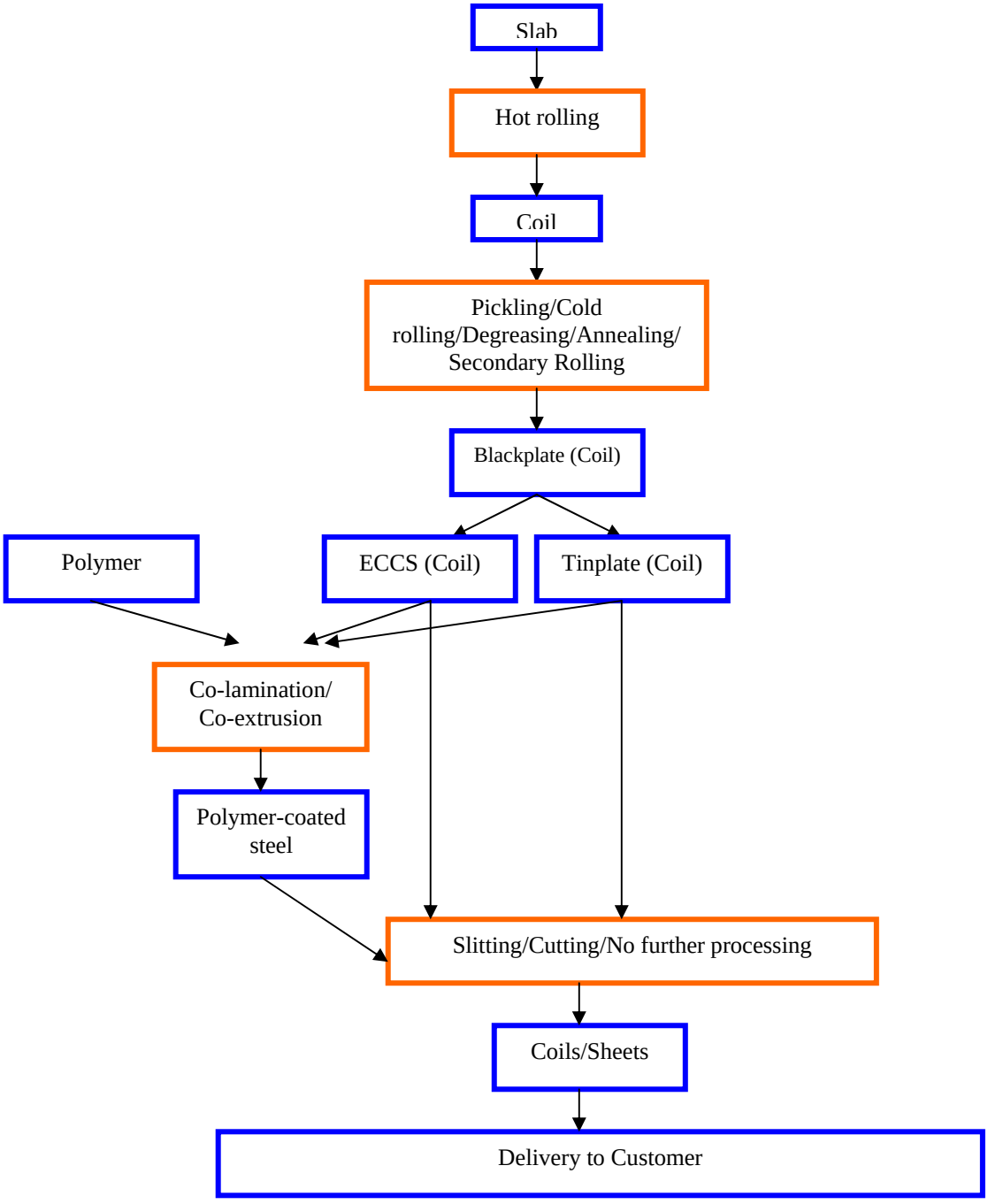
Traceability Scope	Traceability Tools
Raw Materials reception	
Metal Coil reception	Supplier provides coil label. Label contains supplier identification, coil serial number and date of production. (see examples SEFEL 1 n°1 & SEFEL 2 n°2). At reception the coil label is kept on the coil
Lacquer & Side stripe reception	Supplier provides document, which contains supplier identification and lot number (see example SEFEL 1 n°2).
Compound reception	Supplier provides document, which contains supplier identification and lot number (see examples SEFEL 3 n°2 & SEFEL 4 n°2).
Foil reception	Supplier provides coil label. Label contains supplier identification, mother coil serial number and date of production. At reception the coil label is kept on the coil.
Issue Raw Materials & Components to production line	
Coil is moved onto the line	"Manual" Scenario Coil label is kept with the date, time and line number Or Keep track of coil serial number issued to production (see example SEFEL 1 n°3). "Automated" Scenario Coil label barcode (serial number) is scanned and recorded into the system.
New container of lacquer, side stripe or compound is	"Manual" Scenario Lot number is recorded with date & time on

	used	production log book (see examples SEFEL 1 n°4 & SEFEL 3 n°3 and n°4 & SEFEL 4 n°5). “Automated” Scenario Lot number is recorded into system and associated to production order.
	New component pallet is used (end pallet and stillage of lacquered plates)	“Manual” Scenario Pallet label is kept with the date, time and line number. “Automated” Scenario Label barcode (serial number) is scanned and recorded into the system (see example SEFEL 2 n°5).
	Finished Goods Production Cans, Ends and closures are stored on a pallet (on a unit pack)	“Manual” Scenario A label is applied to the pallet. It contains manufacturer identification, date, lot and unique pallet reference. “Automated” Scenario A barcode label (EAN) is applied to the pallet. It contains a unique pallet number: Serial Shipping Container Code (SSCC). This number is linked in the system to further information (lot, date, time, etc.) (see examples SEFEL 2 n°6 & SEFEL 4 n°6).
	Warehouse Management & Despatch	“Manual” Scenario When goods are sent to a customer , a manual record of the goods sent is kept. “Automated” Scenario When goods are loaded the system keeps record of the pallet number and the load reference (linked to customer order) (see examples SEFEL 2 n°7 & SEFEL 4 n°7).

III.2.1 Steel for packaging – APEAL

Flow chart

Simplified production flow of steel for packaging



Scope & Tools

What is steel for packaging?
The European standards EN10202 and EN10205 specify requirements for steel for packaging products. Steel for packaging consist of single and double reduced low carbon mild steel electrolytically coated with either tin (tinplate) or chromium/chromium oxide (ECCS/TFS).

Traceability of steel for packaging – an overview
From a few hundred tonnes of molten steel (+1600°C), steel slabs are produced which are further processed into coils or cut into sheets and, in most instances, delivered directly to the can manufacturing industry[1].

Depending on steel makers, the identification system of coils may change but, at each step of the production process, there is always a unique coil ID number which enables its traceability. Slide #12 is an example of a typical coil label (Mill #3) mentioning the ID coil number and other relevant information.

Examples of traceability of steel used for packaging by APEAL members are shown in Annex:

1) Mill #1
A detailed example of traceability of steel for packaging from the caster to warehouse in Mill #1 is described in Annex. (see slides #2 to #7).

2) Mill #2
Based on the coil label used in the example of beverage can traceability (Mill #2), upstream & downstream traceability between a steel maker and a can manufacturer is illustrated in Annex (see slides #8 to #11).

a) **Continuous casting**: After the converter, liquid steel is loaded in a casting ladle and a unique cast number is automatically allocated to that load. At that stage, the chemistry of the steel is determined.

b) **The slab caster**: Steel slabs are produced from the cast load in slab casters which run in parallel. Each slab automatically receives a unique slab number which is made up of the associated cast number and an additional code (a string number and a serial number). Therefore, the slabs will be uniquely identified by their slab numbers. The slab is automatically marked with a spraying robot (see slide #11).

c) **The hot strip mill**: at the hot strip mill, each slab is reduced in thickness and at the end of the hot roll process, a hot rolled coil is produced with a unique coil number. It is normally a 1 to 1 relation with the slab. A label is manually fixed to the hot strip coil.

d) **The pickling line**: before cold rolling, the hot rolled coil has to pass through a pickling process. After the pickling line, each hot rolled coil will be attributed a unique number on a one-to-one basis. A label with barcode is fixed to the pickled coil before cold-rolling. In general, the coil number after pickling will remain unchanged until delivery to the can manufacturing industry.

Generic description of the next production steps and traceability (see slides #5 to #7 for more details)

The subsequent production process can be described as follows: after pickling, the coil is cold rolled to almost final gauging. The cold-rolled strip is cleaned (degreased) and sent to the

[1] *See schematic production of steel for packaging (simplified) on the previous page "Flow Chart"*

annealing process (batch or continuous) which will restore its mechanical properties. After annealing, the coil goes through the secondary rolling where its mechanical properties and geometry are fine-tuned.

The coil is then electrolytically coated with a layer of tin (tinplate) or chromium (ECCS/TFS). The supplier of tin ingots provides documents which contain supplier identification and lot number, certification of purity. The lot is analysed in order to check conformance with the declared composition.

After plating, the ECCS coil is lacquered either in the steel mill (rarely) or by another company (the general rule). The lacquer supplier provides written information including supplier identification, lot number and product information. Lacquers are generally delivered in drums.

Delivery of steel for packaging to can makers as coils and plates
Coils can be slit (adaptation of coil width) or cut into plates and bundled before being delivered to customers. Traceability is ensured by adding a serial number to the slit coil or bundle. A label accompanies the delivery (see slide #7).

Polymer-coated steels (film lamination or extrusion)
Tinplate or ECCS/TFS can be additionally coated with a polymer. The polymer is often delivered in big bags with indication of lot number, manufacturing date, identification of supplier and nature of the polymer (see slide #13 & 14). Traceability is ensured by internal documentation.

The illustrated examples can be extrapolated *mutatis mutandis* to all APEAL members.

III.2.2 Aluminium for packaging – EAA

Flow chart, Scope & Tools

Traceability of Aluminium Packaging
Basic operation: Casting and Rolling

Primary Material and Products	Traceability Scope	Traceability Tool
Melting oven / Casting aluminium ↓ Ingots		Ingot: • Batch number (no.), bar code, alloying constituents, etc. • Reference no. with bar code for identification of cast and all subsequent aluminium coils. • Alloy composition registered - cast analysis on request.
Aluminium coils, about 3-7 mm thickness	Warm rolling and cold rolling	Coils: • Coil no., batch no., bar code, etc. • Reference no. with bar code for identification of cast, and all subsequent aluminium coils. • Computer based reference to cast.
Aluminium coils, about 0.4-0.7 mm thickness	Rolling	Coils: • Coil no., batch no., bar code, etc. • Computer based reference to input material and cast. (1)
Aluminium coils, about 0.006-0.3 mm thickness	Rolling	Coils: • Product no., article no., coil no (batch no)/bar code, etc. • Computer based reference to input material in the rolling program.
I) Bare aluminium trays, II) Beverage can lid stock, rigid containers and semi-rigid containers		

Traceability Aluminium Packaging:
I) Bare aluminium trays

Primary Material and Products	Traceability Scope	Traceability Tool
Aluminium coils, +/-40-300µm thickness		Coils: • Product no, article no, coil no (batch no)/bar code, etc. • Computer based reference to input coil
Lubricant	Lubricating and slitting	Lubricant: • Recipe: batch no, article no, etc.; - lubricant components in recipe: article no, batch no, product name, etc. • *Computer based or manual reference to raw material.*
Aluminium coils, lubricated		Coils: • Product no, article no, coil no (batch no) with bar code, etc. • Computer based reference to input material.
Aluminium trays in packed units	Stamping and forming	Tray units: • Product no, batch no, bar code, etc. • Computer based reference to input material
Packed units on palettes	Packing	Palettes: • Product no, batch no, bar code, etc. • Computer based reference to input material (2)
Trade		

Traceability Aluminium Packaging:
II) Lidstock for beverage cans and rigid or semi-rigid containers

Primary Material and Products	Traceability Scope	Traceability Tool
Aluminium coils, +/- 40-300µm thickness ↓ Pretreatment (optional) ↓ Aluminium coils, pretreated (optional, partly inline) ↓ Lacquer, adhesive, and/or plastic film ↓ Lacquered and/or laminated aluminium coils ↓ lubricant (optional) ↓ Coils packed in units on palettes ↓ Can maker	Aluminium pretreatment Lacquering and/or laminating (post) Lubricating (optional) and slidding and Packing (see I)	Coils: • Supplier, batch no supplier (coil no), article no, etc. • Converter identification: batch no, article no, etc. • Computer based reference to input material Pretreatment chemicals: • No significance for food contact. • Traceability for weekly production possible. Coils: • Batch no (coil no), article no, etc. • Computer based reference to input material Lacquer/adhesive: • Supplier: product name, article no, batch no • Recipe: article no, batch no • Computer based or manual reference to raw material Plastic film: • Supplier, product name, article no, batch no, • Computer based or manual reference: input material to coil Coils: • Batch no (coil no), article no, etc. • Computer based reference to input material Lubricant: • Recipe: batch no, article no, etc.; - lubricant components in recipe: article no, batch no, product name, etc. • *Computer based or manual reference to raw material.* Palette: • Batch no (coil no), article no, etc, batch no palette • Computer based reference to input material (2)

Traceability Aluminium Packaging:
III) Casting and Rolling for Foil

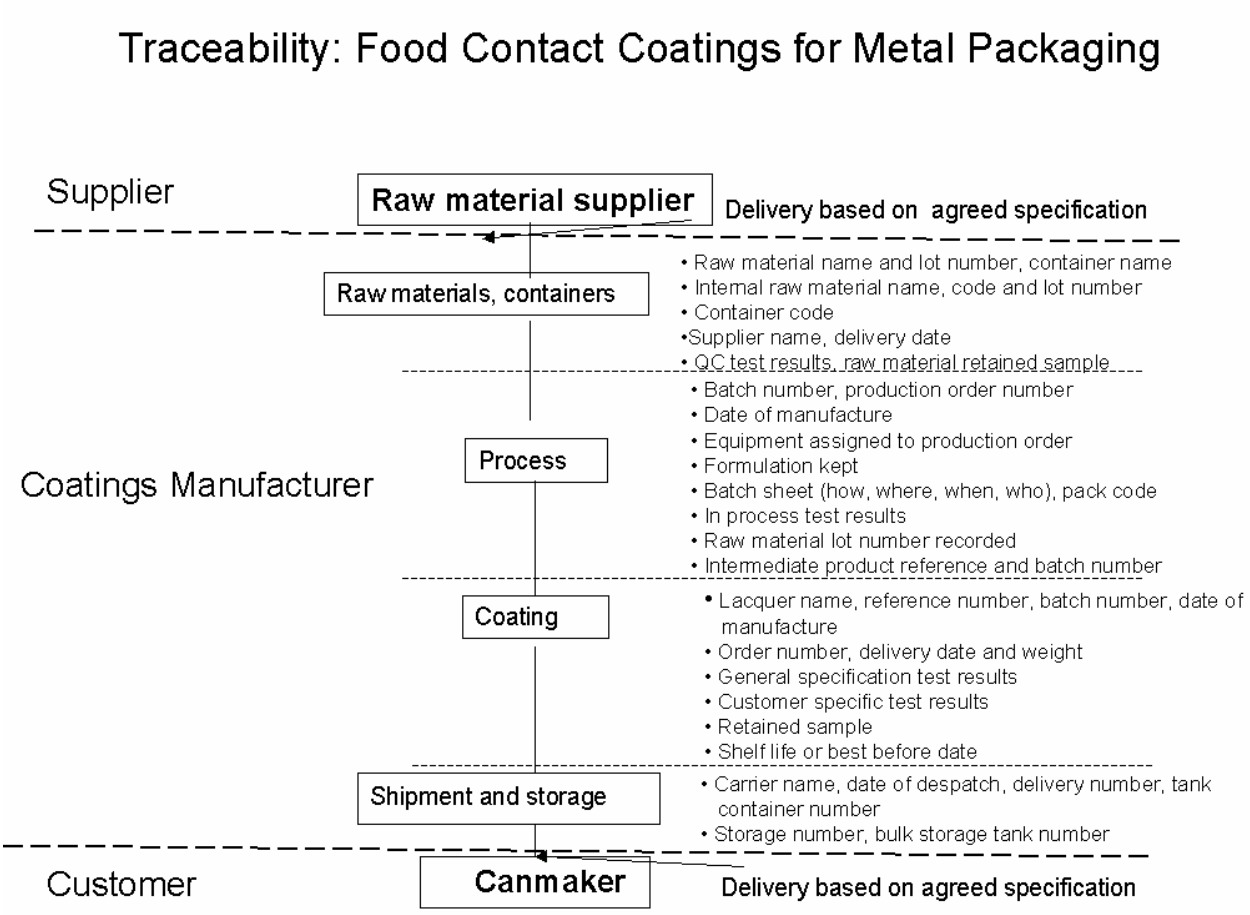
Primary Material and Products	Traceability Scope	Traceability Tool
Casting/ Melting Furnace		Aluminium raw material: ingot or aluminium scrap – sorting and identification according to alloy composition
Discontinuous Casting (DC) Continuous Casting (CC)	Aluminium Raw Material	Slab: batch number and/ or reference number
Slab rolling		
Foil stock 3 to 7 mm	CC and DC foil stock	Coil identification number, alloy composition, possibility of all subsequent coils (for both CC and DC foil stock)
Rolling	Rolling	
Foil stock 0.4 to 0.7 mm		
rolling		
Foil stock 0.006 to 0.2 mm	Foil	Coil identification number, batch number, possibility of identification of all subsequent coils
Flexible Packaging Household Foil		

Traceability Aluminium Packaging: Key Aspects

- The traceability process consists of a customer order no with the identification of batch nos. of the materials that are used/produced in the process..
- The Quality Management System ensures the identification of the input aluminium coil and the output aluminium coil by process with a coil number and a bar code reference.
- Lubricating, coating and polymeric materials are correlated with a production order and the individual coil numbers, either manually or by a computer system. During a change of these materials all reference numbers are recorded.
- Traceability is a key feature in the quality management system and is audited on a regular basis by internal and external auditors.

III. 2.3 Lacquers for Packaging – CEPE

Flow Chart



Scope & Tools

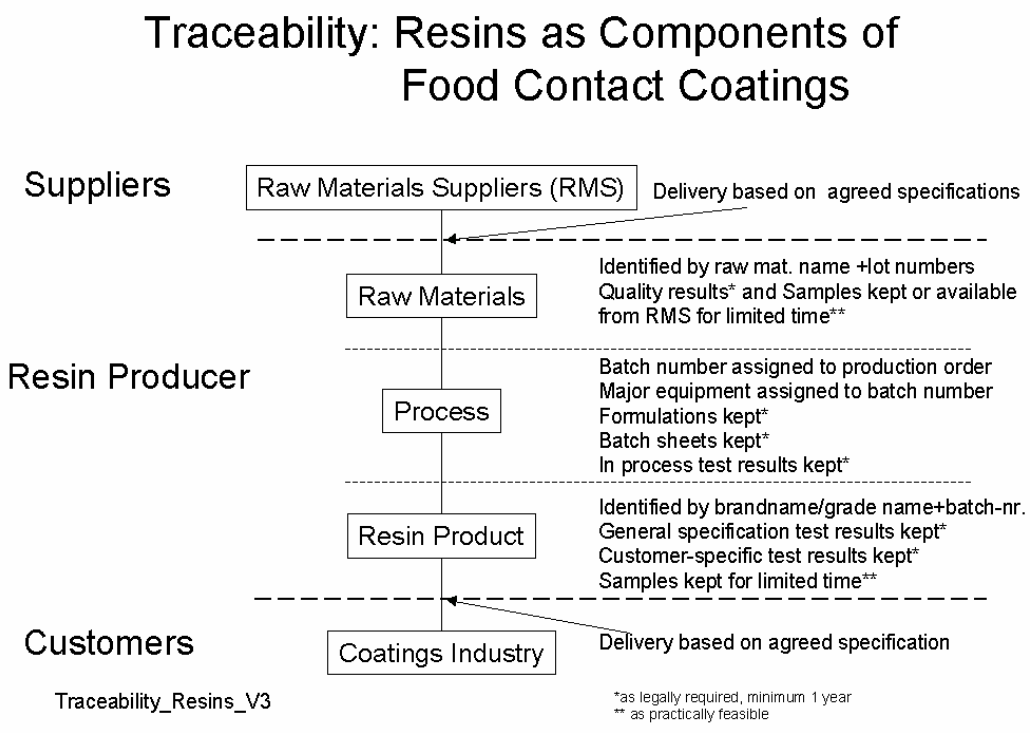
Primary Material	Traceability Scope	Traceability Tool
Coatings	Raw materials	Delivery based on agreed specification Raw material name (1) Raw material lot number (1) Supplier name Delivery date (2) Internal raw material name (2) Internal raw material code (2) Internal raw material lot number (2) Raw material QC results kept or available from raw material supplier Raw material samples kept for appropriate time or available from raw material supplier Concession requests for raw material deliveries concerned
	Containers	Delivery based on agreed specification Container name Supplier name Delivery date Container code
	Process	Batch number Production order number Date of manufacture Equipment assigned to production order Formulation retained Batch sheets retained with process details (How? Where? When? Who?) Pack code In process test results retained Raw material lot number recorded Intermediate product reference and batch number recorded
	Finished product	Lacquer name (3)(4)(5) Lacquer reference number (3)(4)(5) Lacquer batch number (3)(4)

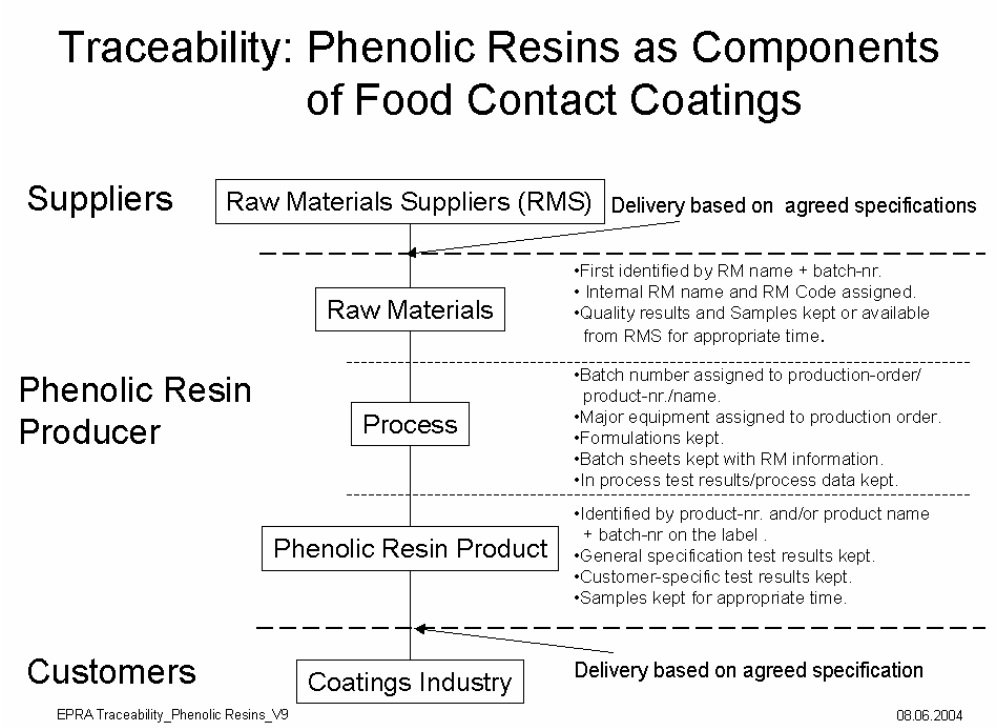
		General specification test results Customer specific test results Retained samples kept for appropriate time Shelf life or best before date quoted (3) Barcode (5)
	Storage	Storage location number Bulk storage tank number
	Shipment	Carrier name Date of despatch Delivery number Tank container number
	Customer order file	Lacquer name Lacquer reference number Lacquer batch number Date of manufacture Delivery date Delivery weight Order number Customer bulk storage tank number
	Supportive documentation	Hard copies Computer based files (individual log on passwords)

III.2.3.1 Examples of Raw Materials for coating manufacturers

- Plastics Europe/ERC
- EPRA

Flow Charts





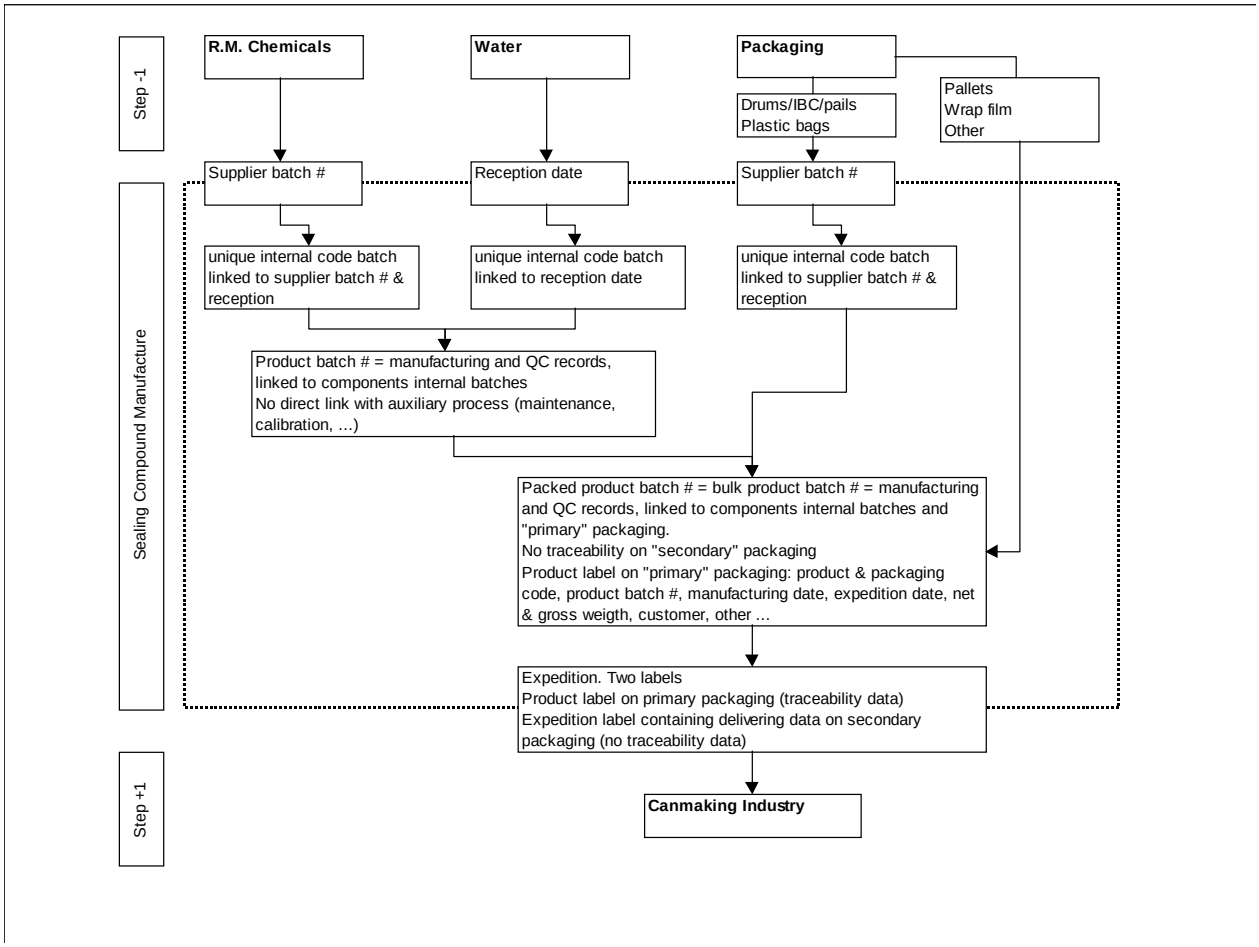
Scope & Tools

Primary Material	**Traceability Scope**	**Traceability Tools**
Phenolic Resins (completed by EPRA)	Raw material identification	- First identification by RM name + batch-no. - Assignment of internal RM name and RM Code. - Quality results and Samples retained or available from RMS for appropriate time.
	Formulation & Process	- Batch number assigned to production-order/ product-no./-name. - Major equipment assigned to production order. - Formulations retained. - Batch sheets retained with RM information. - In process test results/ process control data retained.
	Finished resin product identification	- Identified by product-no. and/or product name + batch-no. on the label. - General specification test results retained. - Customer-specific test results retained. - Samples retained for appropriate time.

RM = Raw Material
RMS= Raw Material Supplier 08.06.2003

III.2.4 Compound for packaging – Rubber Association

Flow Chart



Scope & Tools

PRIMARY MATERIAL	TRACEABILITY SCOPE	TRACEABILITY TOOLS
Water Based Sealing Compounds	**Raw Material Identification**	
	Chemicals	Assign to internal batch linked to supplier batch & reception date (1)
	Primary packaging (pails/drums/ibc, plastic bags)	Labelling according to internal name and batch
		Purchasing & QC records (internal and supplier) and RM sample kept for appropriate time
	Water	Assign of internal batch linked to reception date
	Secondary packaging (pallets, wrap film, ...)	Labelling according to internal name
		Purchasing records kept for appropriate time
	Manufacturing Process	
	Bulk Product	Product batch = production order
		Formulation based on internal RM name
		Manufacturing records contains components (RM or intermediate products) internal name + batches & quantities, major equipment, processing indications, workers, PRD date and time, in process QC and PRD comments
		(2) (3)
		Manufacturing records, QC records & Formulation kept
	Packed Product	Packed product batch = bulk product batch = production order (4)
		Packed order includes bulk product

		batch & primary packed batch Packed product code = product name + primary packaging type
	Finish Product Identification	Product label, on primary packaging, contains (5) • product batch (=packed, bulk and production order) • product name (product + primary packaging) • end manufacture and expiry date • gross and net weight • customer • notes (upon request) • safety information (when needed) Expedition label, on secondary packaging, contains delivering information Delivery note includes product batch and also some information about secondary packaging Delivery docs and product label retained

RM: raw material; PRD: production; QC: quality control

IV. RECALL

If a problem arises at the retail level, and a decision is made to recall the products, the following procedures would usually be used.

- The packaged food product sold on the shelf provides the following information:

  - Product code and product owner (typically the EAN 13 barcode)
  - Best Before Date
  - A number used for traceability (lot number, filling time, etc.)

- With this information the retailer identifies the Food Packer and provides him with the above information and description of the defects.

If the defects identified by the Food Packer, the Distributor, or others, relate to the metal packaging. The Food Packer, the Distributor, or others would provide the Metal Packaging Manufacturer(s) with the traceability information that was displayed on labels or documentation which accompanied the metal packaging goods.

- The Metal Packaging Manufacturer will use that information to identify at which steps the defect arose. The failure could be due to either:

  1) A defect in the production process
  2) or a problem with incoming raw materials

  In case 2) the Metal Packaging Manufacturer will contact his own supplier(s) in a similar manner as the one described above.

- Once the source of the problem has been identified (upstream traceability exercise finished) the Metal Packaging Manufacturer analyses the situation and can begin the downstream traceability exercise. Internal records are used to identify all products that could possibly contain the same defect.

- The Metal Packaging Manufacturer will then communicate back to his customers, the lot number(s) and / or unit packs (pallet) number(s) to be blocked and / or recalled.

- The Food Packer will use that information to continue the downstream traceability exercise to the retailer and final point of sale.

NB: In case of serious incident the complete process both upstream and downstream can be accelerated by taking preventive measures and impounding larger quantities of goods that have similar attributes (i.e. date of production, lot number(s), etc.

V. OTHERS

This paper does not cover traceability aspects related to Importers and Traders.
It is also recognised that not all possible raw materials for food contact paint/lacquers are covered by this paper due to a lack of contributions by their respective associations.
In this case however, similar traceability concepts apply, and it is the responsibility of the company placing the goods on the marketplace to ensure that Traceability links are ensured.

The paper also does not cover materials such as unit packs (pallets), layer pads, etc. which are used to carry metal packaging products. However it is important to mention that these products are subject to strict specification defined in most cases jointly by the metal packaging manufacturer and food packers.

APPENDIX

This section contains the examples for each Association.

SEFEL Beverage cans

SEFEL Food cans & ends

SEFEL Metal closures

SEFEL Aerosols cans

APEAL

EAA

CEPE

Plastic Europe / ERC

EPRA

Compound for packaging

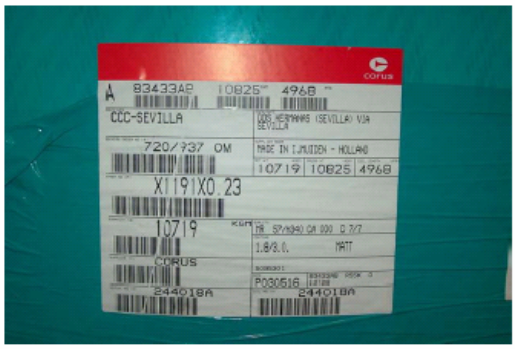
SEFEL 1. Beverage Cans

Reception of Raw Material : Metal Coil (1)

Keep Supplier Label

Traceability Key :

Coil Serial Number



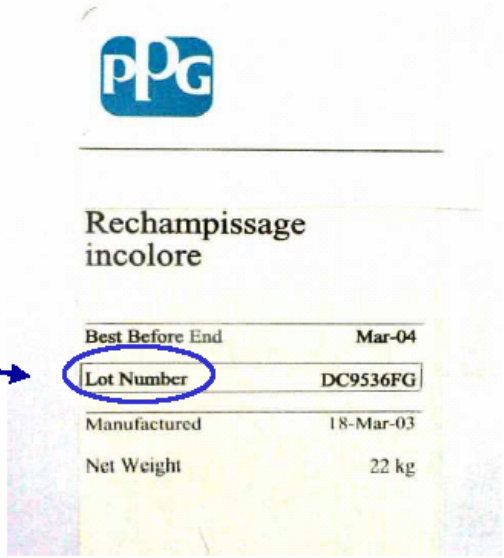
SEFEL 1. Beverage Cans

Reception of Raw Material : Lacquer (2)

Keep Supplier Document

Traceability Key :

Lot number



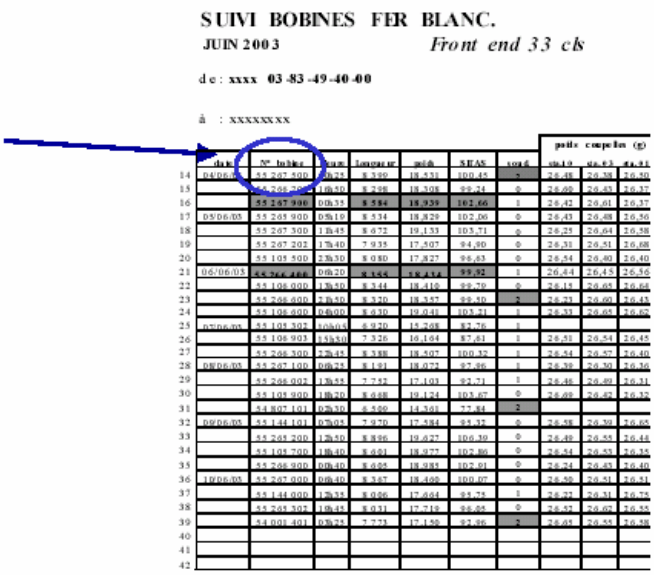
SEFEL 1. Beverage Cans

Issue to Production : Coil (3)

Keep Track of Coil Serial Number issued to production

Analyse quality & performance of coil

Feedback to Metal supplier



SUIVI BOBINES FER BLANC.
JUIN 2003 *Front end 33 cls*

de : xxxx 03-83-49-40-00

à : xxxxxxxx

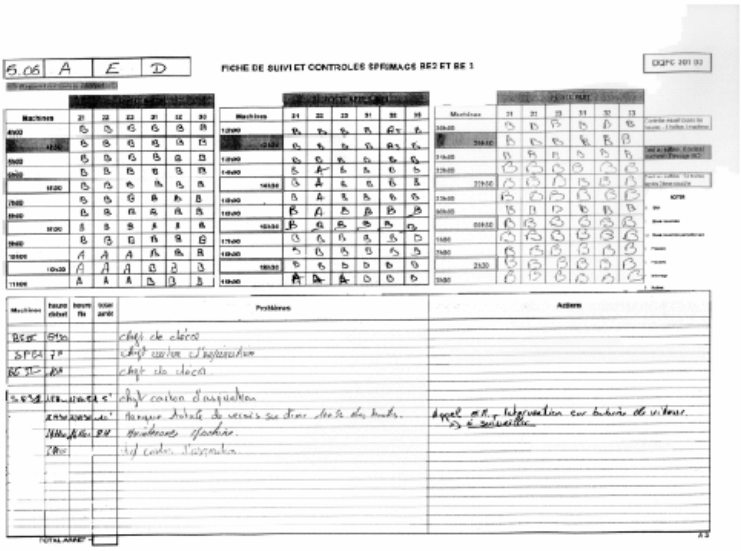
	date	N° bobine	heure	longueur	poids	STEAS	tonné	poids capelin (g)		
14	04/06/03	55 207 500	00h25	8 390	18 531	100,45	2	26,48	26,38	26,40
15		55 206 200	11h50	8 298	18 308	99,24	0	26,60	26,43	26,37
16		55 207 900	00h35	8 584	18 939	102,66	1	26,42	26,01	26,37
17	05/06/03	55 205 900	05h10	8 534	18,820	102,06	0	26,43	26,48	26,56
18		55 207 300	11h45	8 672	19,133	103,71	0	26,25	26,04	26,58
19		55 207 202	17h40	7 935	17,507	94,90	0	26,31	26,51	26,68
20		55 105 500	23h30	8 080	17,827	96,63	0	26,54	26,40	26,40
21	06/06/03	55 206 400	06h20	8 355	18 434	99,92	1	26,44	26,45	26,36
22		55 106 000	13h50	8 344	18,410	99,79	0	26,15	26,05	26,66
23		55 206 000	23h50	8 320	18,357	99,50	2	26,23	26,00	26,45
24		55 106 000	04h00	8 630	19,040	103,21	1	26,33	26,05	26,65
25	07/06/03	55 105 302	10h04	6 920	15,268	82,76	1			
26		55 106 903	15h30	7 326	16,164	87,61	1	26,51	26,54	26,45
27		55 206 300	23h45	8 388	18,507	100,32	1	26,54	26,57	26,40
28	08/06/03	55 207 100	06h25	8 191	18,072	97,96	1	26,39	26,39	26,36
29		55 206 002	13h55	7 752	17,103	92,71	1	26,46	26,49	26,31
30		55 105 900	19h20	8 688	19,124	103,67	0	26,69	26,62	26,32
31		54 807 101	02h30	6 500	14,307	77,84	2			
32	09/06/03	55 144 101	07h05	7 970	17,584	95,32	0	26,58	26,59	26,65
33		55 205 200	12h50	8 896	19,627	106,39	0	26,49	26,55	26,44
34		55 105 700	18h40	8 691	18,977	102,80	0	26,54	26,53	26,35
35		55 206 900	00h40	8 695	18,985	102,91	0	26,24	26,43	26,40
36	10/06/03	55 207 000	06h40	8 587	18,408	100,07	0	26,50	26,51	26,31
37		55 144 000	12h35	8 006	17,664	95,75	1	26,22	26,31	26,75
38		55 205 302	19h45	8 031	17,719	96,05	0	26,52	26,62	26,55
39		54 001 401	03h25	7 773	17,150	92,96	2	26,65	26,55	26,58
40										
41										
42										

SEFEL 1. Beverage Cans

Issue to Production : Lacquer (4)

Keep Track of Lot number issued to production

Example of lacquer line report



5.06 A E D

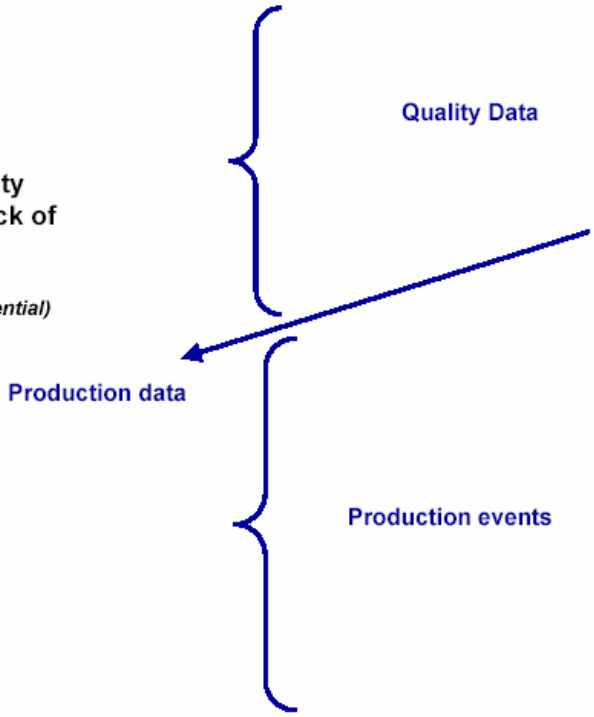
FICHE DE SUIVI ET CONTROLES SPRIMAGE RED ET BE 1

SEFEL 1. Beverage Cans

Continuous Production Process (5)

Production & Quality reports to keep track of events

(data not shown - confidential)



SEFEL 1. Beverage Cans

Finished Goods Production (6)

Apply Pallet label

Traceability Key :

Unique pallet number
Lot
Date of production

SEFEL 1. Beverage Cans

Warehouse Management & Despatch (7)

Keep track of movements

Despatch by FIFO

Traceability Key :

Pallet / Lot number
Load Reference
Customer Order

SEFEL 2. Food Cans & Ends

Reception of Raw Material : Tinplate Coil (1)

Double labelling :

- input data = Supplier label
- output data = Crown label

SEFEL 2. Food Cans & Ends

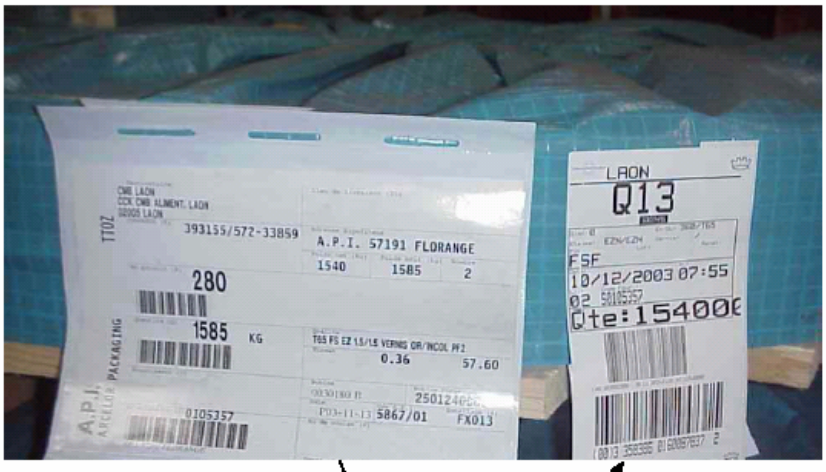
Reception of Raw Material : Tinplate Coil (2)

Key data : Coil Serial Number
+ specifications (dim., tin, weight)

Software stores data and generates an unique pallet number

SEFEL 2. Food Cans & Ends

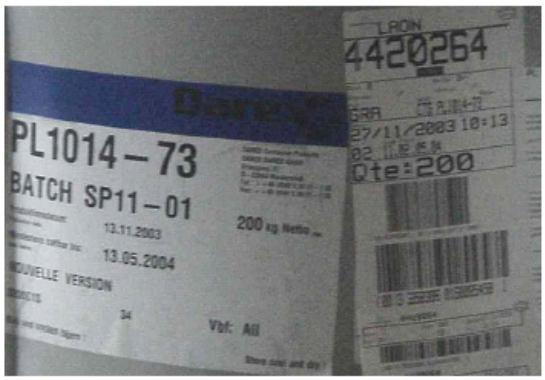
Reception of Raw Material : Tab Metal Coil (3)



Same system : from supplier data to unique label

SEFEL 2. Food Cans & Ends

Reception of Raw Material : Compound & Lacquer (4)



Always the double labelling

Same system : from supplier data to unique n° label

SEFEL 2. Food Cans & Ends

Process Production : Common Steps (5)

Complete the production data (product n°; date; quantity; line n°)

Track the labels of components used

The software generates a label for each pallet produced

SEFEL 2. Food Cans & Ends

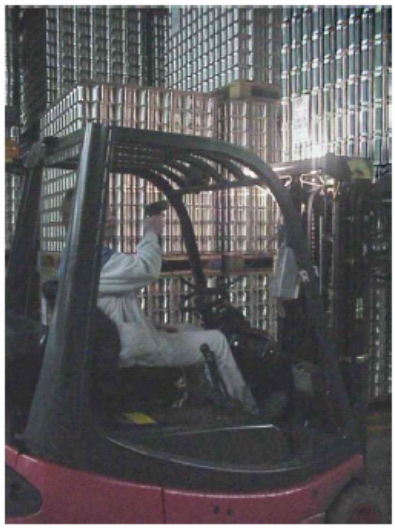
Process Production : End & Can making (6)

Each pallet has its unique label

Note : the bare-code is a sufficient key to get all traceability data

SEFEL 2. Food Cans & Ends

Warehouse and Delivery (7)



Keep track of pallet labels => by Sales order, check the correct reference to be loaded and store the pallets n° delivered to the Customer

SEFEL 3. Metal Closures

Reception of Raw Material : Metal Sheets (1)

Keep Supplier Label

Traceability Key :

Stillage Serial Number

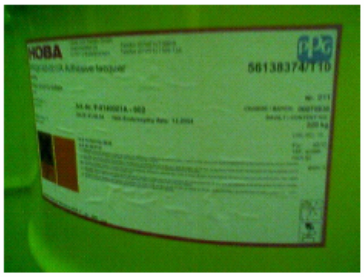
SEFEL 3. Metal Closures

Reception of Raw Material : Compound (2)

Keep Supplier Document

Traceability Key :

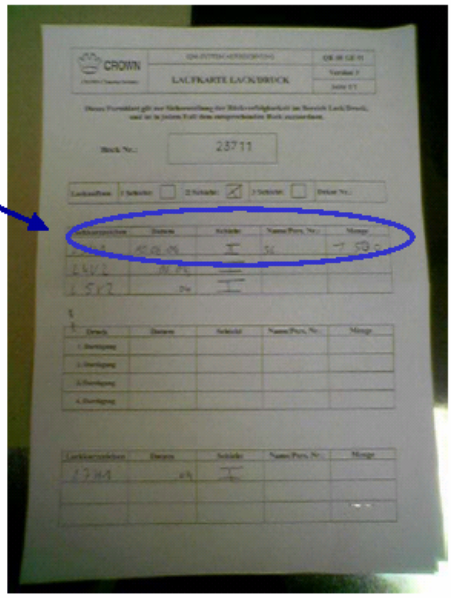
Lot number, drum number, ...



SEFEL 3. Metal Closures

Issue to Production : Lacquer (3)

Keep Track of Lot Number issued to production

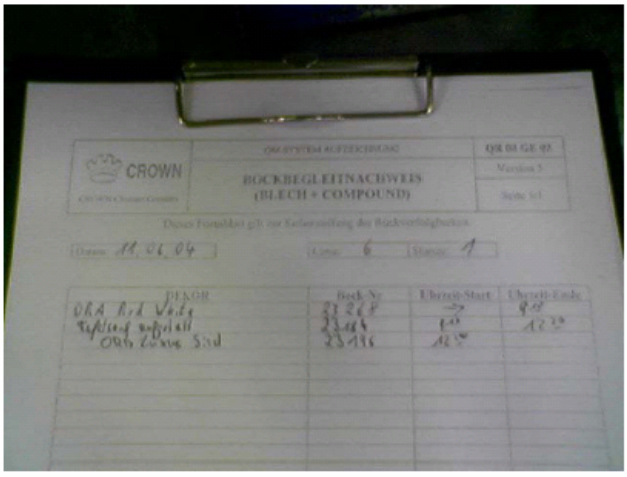


SEFEL 3. Metal Closures

Issue to Production : Compound (4)

Keep Track of Lot number issued to production

Example of log sheet line report



SEFEL 3. Metal Closures

Production Process (5)

Production & Quality reports to keep track of events

SEFEL 3. Metal Closures

Finished Goods Production (6)

Apply information on individual cartons

Product description
Production order
Date and time
...

Apply Pallet label

Traceability Key :

Unique pallet number
Lot
Date of production

SEFEL 4. Aerosols Cans

Reception of Raw Material : Metal Coil (1)

Keep Supplier Label

Traceability Key :

Coil Serial Number

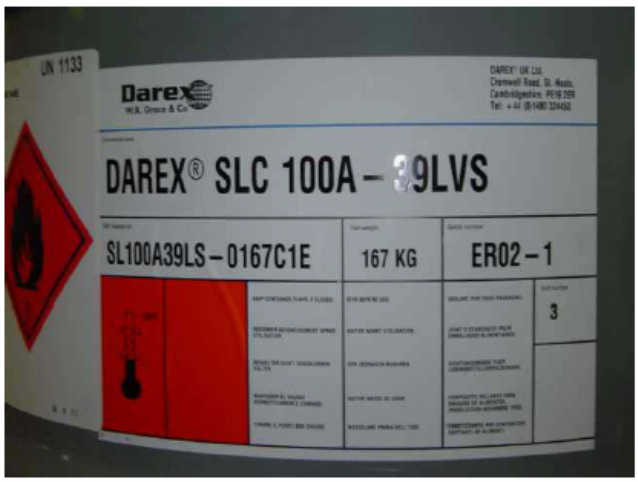
SEFEL 4. Aerosols Cans

Reception of Raw Material : Compound (2)

Keep Supplier Document

Traceability Key :

Lot number, drum numbers, ...



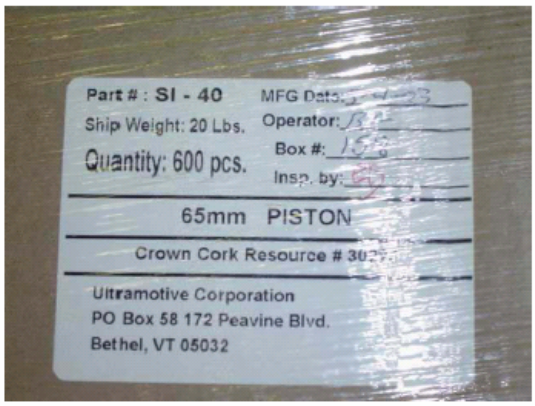
SEFEL 4. Aerosols Cans

Reception of Raw Material : Piston (3)

Keep Supplier Document

Traceability Key :

Box numbers, date of production, ...

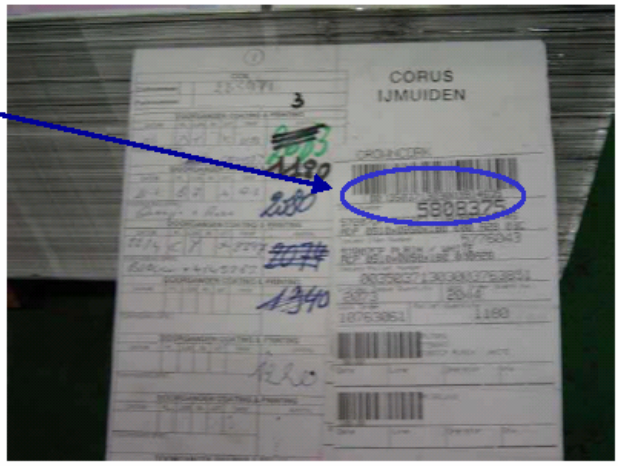


SEFEL 4. Aerosols Cans

Issue to Production : Printed Plate (4)

Keep Track of stillage of plate unique number (SSCC) issued to production

Keep track of each passes

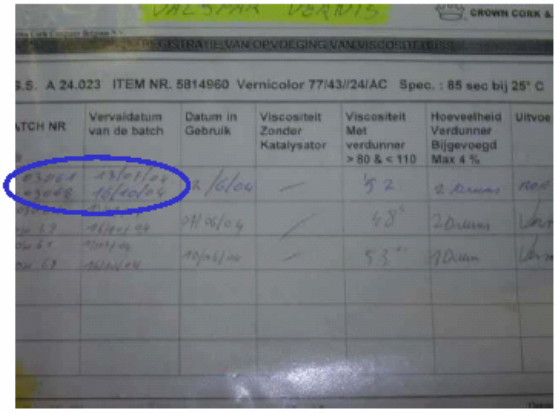


SEFEL 4. Aerosols Cans

Issue to Production : Side stripe lacquer (5)

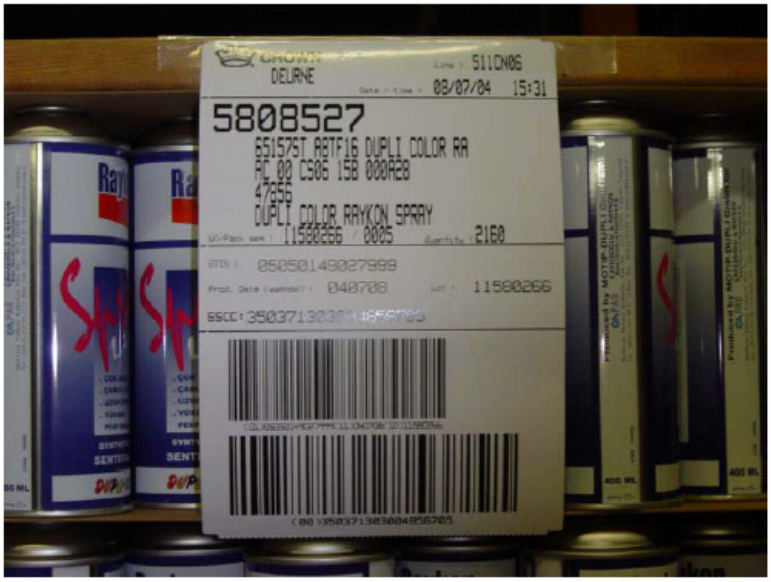
Keep Track of supplier batch number when issued to production

Example of log sheet report



SEFEL 4. Aerosols Cans

Finished Goods Production (6)



Apply Pallet label - Traceability Key :
Unique pallet number (SSCC) - Lot - Date of production

SEFEL 4. Aerosols Cans

Warehouse Management & Despatch (7)

Keep track of movements

Traceability Key :

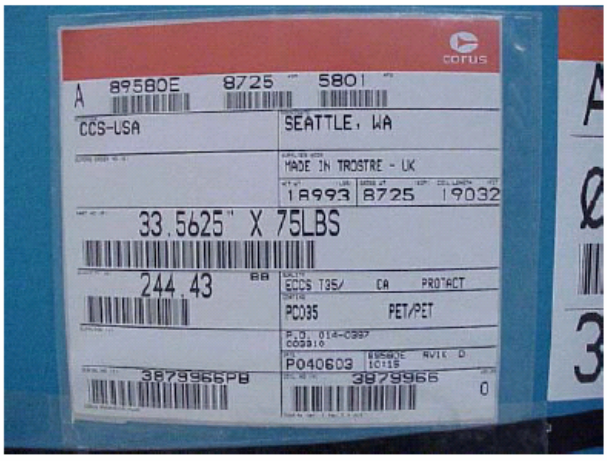
Pallet / Lot number
Load Reference
Customer Order

APEAL

Example of coil labels

APEAL

Label of Polymer-coated steel



EAA

Coil etiquette after rolling to a thickness of 0.650mm

EAA

Palette etiquette of a palette unit

CEPE

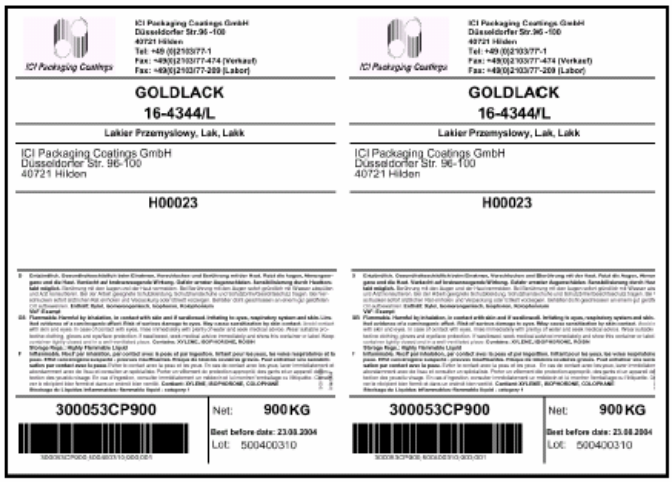
Raw Material Name and Lot Number (1)

CEPE

Internal Raw Material Name, Code & Delivery Date (2)

CEPE

Lacquer Label (3)

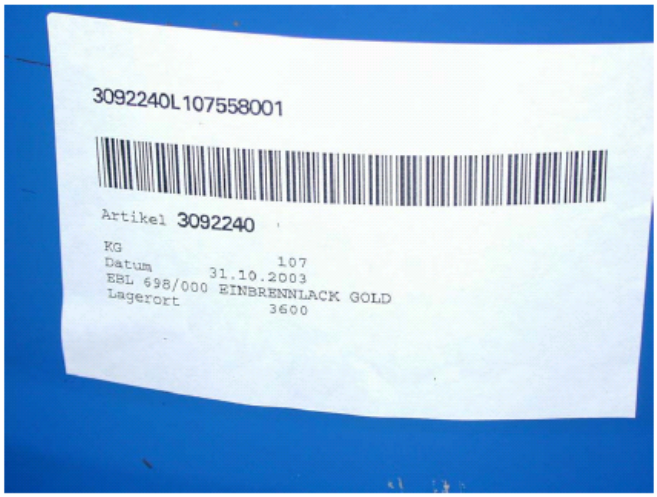


CEPE

Lacquer Catalyst Identification Supplier (4)

CEPE

Lacquer Identification Barcode (5)



Rubber Compounds

Raw Material Reception (1)

ALTANA Coatings · Sealants

MANUAL DE CONTROL DE PRODUCTO/PROCESO

ALMACÉN

Internal raw material batch

PARTE DE ENTRADA — NÚMERO: 4987

PROVEEDOR: Supplier — FABRICANTE: Manufacturer

ALBARAN Nº: 25112999 — PEDIDO Nº: CN/728 — FECHA DE PEDIDO:

	ALMACEN			LABORATORIO		COMPRAS
PRODUCTO / ARTÍCULO	LOTE	CANTIDAD	ESTADO	CONTROL	BOLETÍN	IMPORTE
raw material name	19093E06	22.425 KG.				

OBSERVACIONES: Supplier raw material batch

CONFORMIDAD CON ESPECIFICACIONES: ACEPTADO — RECHAZADO — REPROCESAR

ALMACEN — CONTROL CALIDAD — COMPRAS

NÚMERO BULTOS: 20 PALETS — FECHA: 25.11 — FIRMA:

FECHA 25.11.03 — FIRMA:

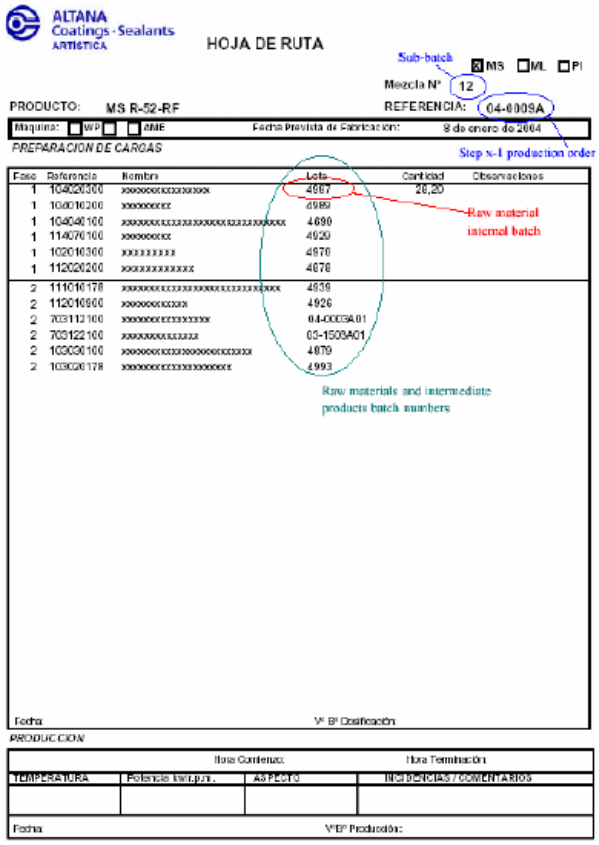
CONFORME RESPECTO A PEDIDO: Nº FACTURA: T130 6069 — FECHA FACTURA: 26-11-03 — FIRMA:

reception date

CIRCUITO:
MP : ALMACÉN → COMPRA
PT devuelto : ALMACÉN → CALIDAD → COMERCIAL (Copia)

Rubber Compounds

Production step x-1 (2)



ALTANA Coatings · Sealants ARTISTICA

HOJA DE RUTA

Sub-batch ☒ MS ☐ ML ☐ PI

Mezcla Nº 12

PRODUCTO: MS R-52-RF

REFERENCIA: 04-0009A

Máquina: ☐ WP ☐ ☐ AME Fecha Prevista de Fabricación: 8 de enero de 2004

Step x-1 production order

PREPARACION DE CARGAS

Fase	Referencia	Nombre	Lote	Cantidad	Observaciones
1	104020300	xxxxxxxxxxxxxxx	4987	26,20	
1	106010200	xxxxxxxxx	4989		
1	104040100	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	4990		
1	114070100	xxxxxxxxx	4920		
1	102010300	xxxxxxxxx	4970		
1	112020200	xxxxxxxxxxxx	4978		
2	111010178	xxxxxxxxxxxxxxxxxxxxxxxxxxxx	4939		
2	112010900	xxxxxxxxxxx	4926		
2	703112100	xxxxxxxxxxxxxxx	04-0009A01		
2	703122100	xxxxxxxxxxxxx	03-1508A01		
2	103030100	xxxxxxxxxxxxxxxxxxxxxx	4979		
2	103020178	xxxxxxxxxxxxxxxxxx	4993		

Raw material internal batch

Raw materials and intermediate products batch numbers

Fecha: Vº Bº Dosificación:

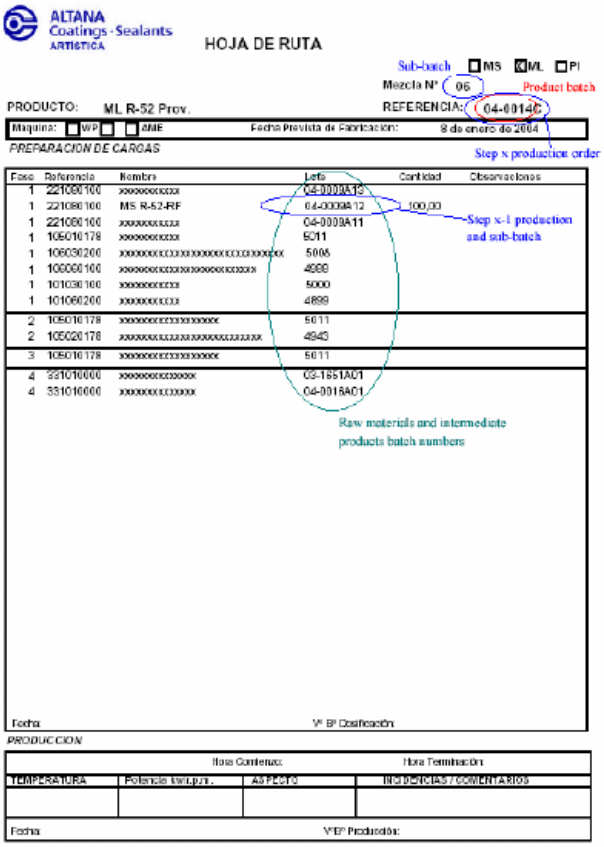
PRODUCCION

Hora Comienzo:			Hora Terminación:
TEMPERATURA	Potencia kw/p.n.	ASPECTO	INCIDENCIAS / COMENTARIOS

Fecha: Vº Bº Producción:

Rubber Compounds

Production step x (3)



ALTANA Coatings · Sealants ARTISTICA

HOJA DE RUTA

Sub-batch ☐ MS ☒ ML ☐ PI

Mezcla Nº 06

Product batch

PRODUCTO: ML R-52 Prov.

REFERENCIA: 04-0014C

Máquina: ☐ WP ☐ ☐ AME Fecha Prevista de Fabricación: 8 de enero de 2004

Step x production order

PREPARACION DE CARGAS

Fase	Referencia	Nombre	Lote	Cantidad	Observaciones
1	221080100	xxxxxxxxxxx	04-0009A13		
1	221080100	MS R-52-RF	04-0009A12	100,00	
1	221080100	xxxxxxxxxxx	04-0009A11		
1	105010178	xxxxxxxxxxx	5011		
1	106030200	xxxxxxxxxxxxxxxxxxxxxxxxxxxx	5005		
1	106060100	xxxxxxxxxxxxxxxxxxxxxxxxxx	4999		
1	101030100	xxxxxxxxxxx	5000		
1	101060200	xxxxxxxxxxx	4999		
2	105010178	xxxxxxxxxxxxxxxxx	5011		
2	105020178	xxxxxxxxxxxxxxxxxxxxxxx	4943		
3	105010178	xxxxxxxxxxxxxxxxx	5011		
4	331010000	xxxxxxxxxxxxx	03-1551A01		
4	331010000	xxxxxxxxxxxxx	04-0016A01		

Step x-1 production and sub-batch

Raw materials and intermediate products batch numbers

Fecha: Vº Bº Dosificación:

PRODUCCION

Hora Comienzo:			Hora Terminación:
TEMPERATURA	Potencia kw/p.n.	ASPECTO	INCIDENCIAS / COMENTARIOS

Fecha: Vº Bº Producción:

Rubber Compounds

Packaging order (4)

ALTANA Coatings · Sealants ARTÍSTICA

HOJA DE RUTA DE PRODUCTO TERMINADO

Packaging order

PRODUCTO: R-52-CC/50 (R200TD-BE) REFERENCIA: 04-0014G

Cuba Nº: Agitador: Mezcla Nº 01

Fecha Prevista de Fabricación: 12 de enero de 2004 Equipo Impulsor:

Operario: Hora comienzo: Hora Terminación:

Product batch

Fase	Referencia	Nombre	Lote	Cantidad	Observaciones
1	4521001100	R-52-CC/50	04-0014 G01	2.510,00	Bulk product
1	108121300	Bidón Rojo 200 TD 17	5001	1,00	Packaging components
1	108121300	Bidón Rojo 200 TD 17	5021	9,00	
1	108302000	Bolsa Ecobody 675x1000-150mis L	4956	10,00	
1	108302100	Tapa plástica bidón 200L (Ref. 0011	4021	10,00	

Packaging components batches

Fecha: Nº Dosificación:

AJUSTES

COMPUESTO	CANTIDAD	REFERENCIA	OPERARIO	TENS. SUP.	SÓLIDOS	VISCOSIDAD	FECHA

FILTRACIÓN / ENVASADO

OPERARIOS: Hora comienzo: Hora Terminación:

Color Inicio	Tipo Inicio	Tara Inicio	Peso Inicio	Nº de Bidones	Bolsa Saturada	Pala

Rubber Compounds

Product Label (5)

ALTANA Coatings · Sealants ARTÍSTICA

Sealing Compound

Packaging type

PRODUCT : R-52-CC/50 (R200TD-BE)

BATCH Nº: 04-0014G01 **DATE:** 12/01/2004

Manufacturing step

NET: 251,00 KG **GROSS:** 268,00 KG

Product batch number = production order

USE BEST BEFORE: July, 2004

CUSTOMER: :

TRACEABILITY APPLIED TO THE PAPER AND BOARD FOOD PACKAGING CHAIN (Practical Guidelines)

INTRODUCTION

This document gives guidelines for product traceability within the paper and board food packaging chain[1].

I. SCOPE

These guidelines cover paper and board and their converted products from the paper mill downstream to the packer-filler stage. In accordance with EU Regulation 1935/2004, manufacturers of materials, articles, substances and products covered by this Regulation are required to implement traceability and product recall measures.

Thus, these guidelines are principally to demonstrate traceability and recall down the paper and board supply chain. Papermaking raw materials and certain additives used in subsequent processes are not materials and articles within the meaning of this Regulation. However, it may be necessary for the authorities or the manufacturer concerned to establish links to such materials to determine commercial or legal liability and details are included to facilitate how this might work in practice.

These guidelines do not cover tissue products (see part 7).

II. GENERAL INFORMATION

II.1. Food Uses of Paper and Board and its Converted Products

Although sold as "intended to come into contact with food" the physical properties of paper and board, as it leaves the paper mill, prevent any application as a food packaging material until it has been converted in some way. Examples of the food applications for converted products include bags for confectionery, pizza boxes, bread wrap, chocolate interleaving, frozen food containers, vegetable boxes, sugar bags, beverage cartons and food service boards.

II.2 Overview of the Flow Line

The processing chain for paper and board food packaging is extremely complex. There are literally thousands of different ways in which paper may be processed before use. Examples of these processes include: slitting reels to smaller reels, cutting to sheets, calendaring, laminating to metal and plastic, corrugating operations, die cutting, printing, varnishing, gluing, box and carton making, packaging and labelling. As well as the processes themselves, there is a considerable overlap of the operations performed in different types of converting plants. For instance, both paper mills and separate companies will perform coating operations and some corrugating plants will produce only unprinted flat blanks whilst others will produce complete boxes and trays.

It is, thus, impossible to produce guidelines covering all aspects of the production and converting process. These guidelines explain best practice and the main principles are shown in Diagram 1. These principles will apply to any specific process, irrespective of the particular material flow and the type of plant in which it is performed.

[1] Information provided, on behalf of their respective members, by the Confederation of European Paper Industries (CEPI) and The International Confederation of Paper and Board Converters in Europe (CITPA).

II.3. Examples of Packaging Processes and Products

To illustrate the details of traceability, four typical packaging products have been selected (cartons for liquid food, corrugated boxes, paper for hot filtration and folding box board cartons) and the operation of traceability during their manufacture is shown in Diagrams 3 to 6. In addition, equivalent information for the papermaking process (which precedes all of the above operations) is shown in Diagram 2. A Glossary of Terms is given in Table 1.

II.4. Special Consideration of Bulk Raw Materials

A feature of many operations, in the paper and board packaging chain, is the use of bulk additives such as sizing agents during paper and board manufacture, starch during corrugated board production and clay for coating operations. The principles of traceability for these materials will differ from those applicable during batch operations. In both cases, the manufacturer and batch number will be known from identifications and accompanying documentation. Batches of bulk materials will be used, on a continuous basis, from silos or other storage devices and the link from these to the treated or finished product may be less precise. However, because all batch process additions are recoded in a timed log, it is possible to relate the times at which the batch of additive concerned was introduced to the process and was thus at a significant concentration. From the timed log of the process concerned, these data can be related to the identification of the paper and board products. The achievement of higher precision is not technologically feasible in a continuous, industrial process.

III. Recall

One of the main purposes of the traceability requirements within Regulation 1935/2004 is to enable recall of defective product. Throughout all the stages of all the processes described in these guidelines, it can be seen that extensive documentation is in place both within operations and between organisations in the packaging chain. In particular, there is a clause in the Regulation which states:

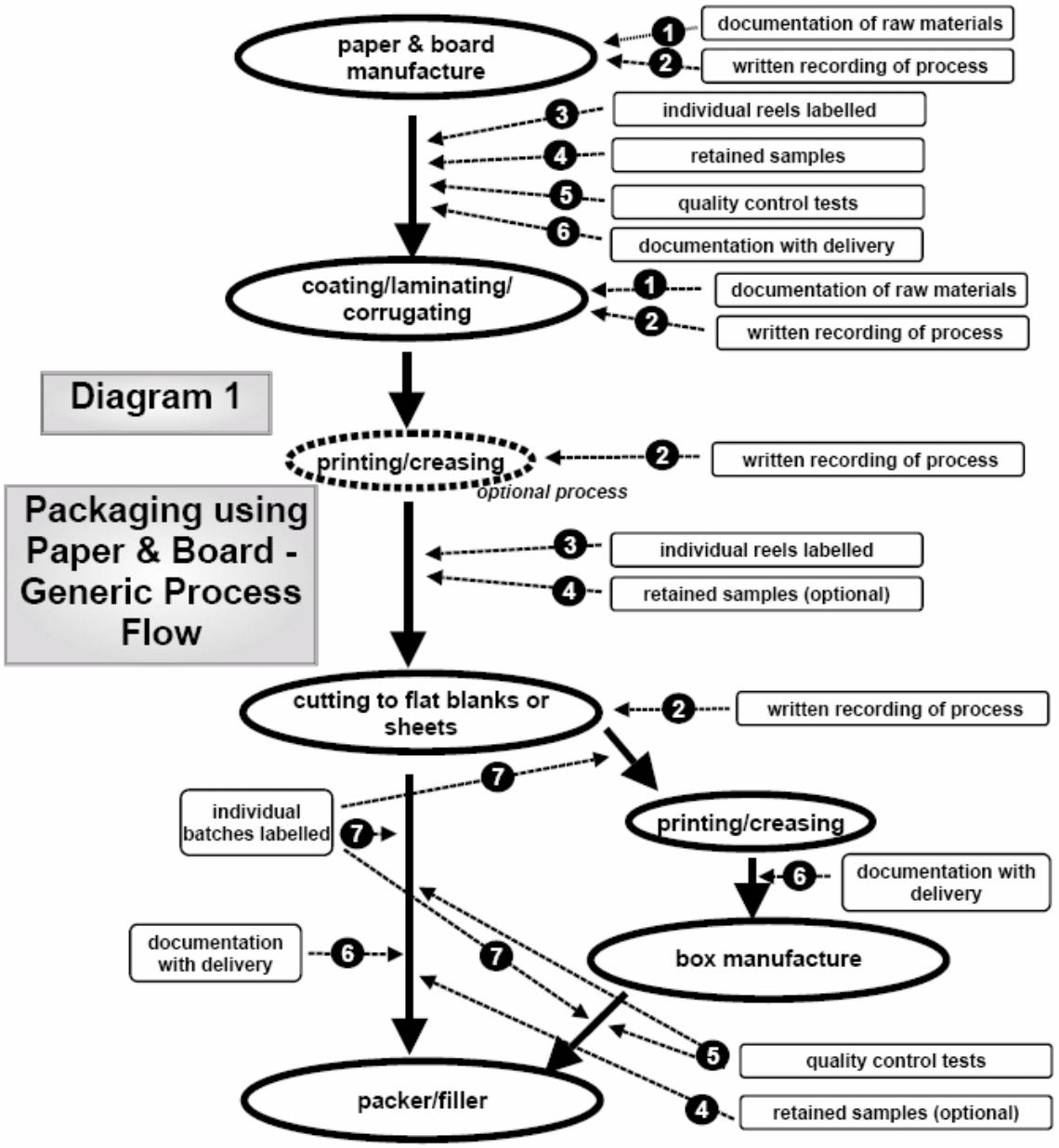
Business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied.

This requirement is fulfilled from the paper mill downstream to the final packaging product either in the form of identification on the product itself or contained in the accompanying documentation.

It can be seen, in the diagrams, that large reels produced in a paper mill are subdivided many times to produce the final paper and board packaging products. Because of extensive record keeping within all the processes of the paper packaging chain, both upstream and downstream product traceability and the identification of the source of any problem will be assured. The batch numbers and suppliers of all starting materials are recorded and internal records relate these to the packaging product itself. Thus, using downstream traceability, the identification of an affected product or starting material sent to other locations and customers is possible. This will define rapidly the full extent of any affected material in the market place or still in production thus enabling full recall of any defective product

.Table 1
Glossary of Terms

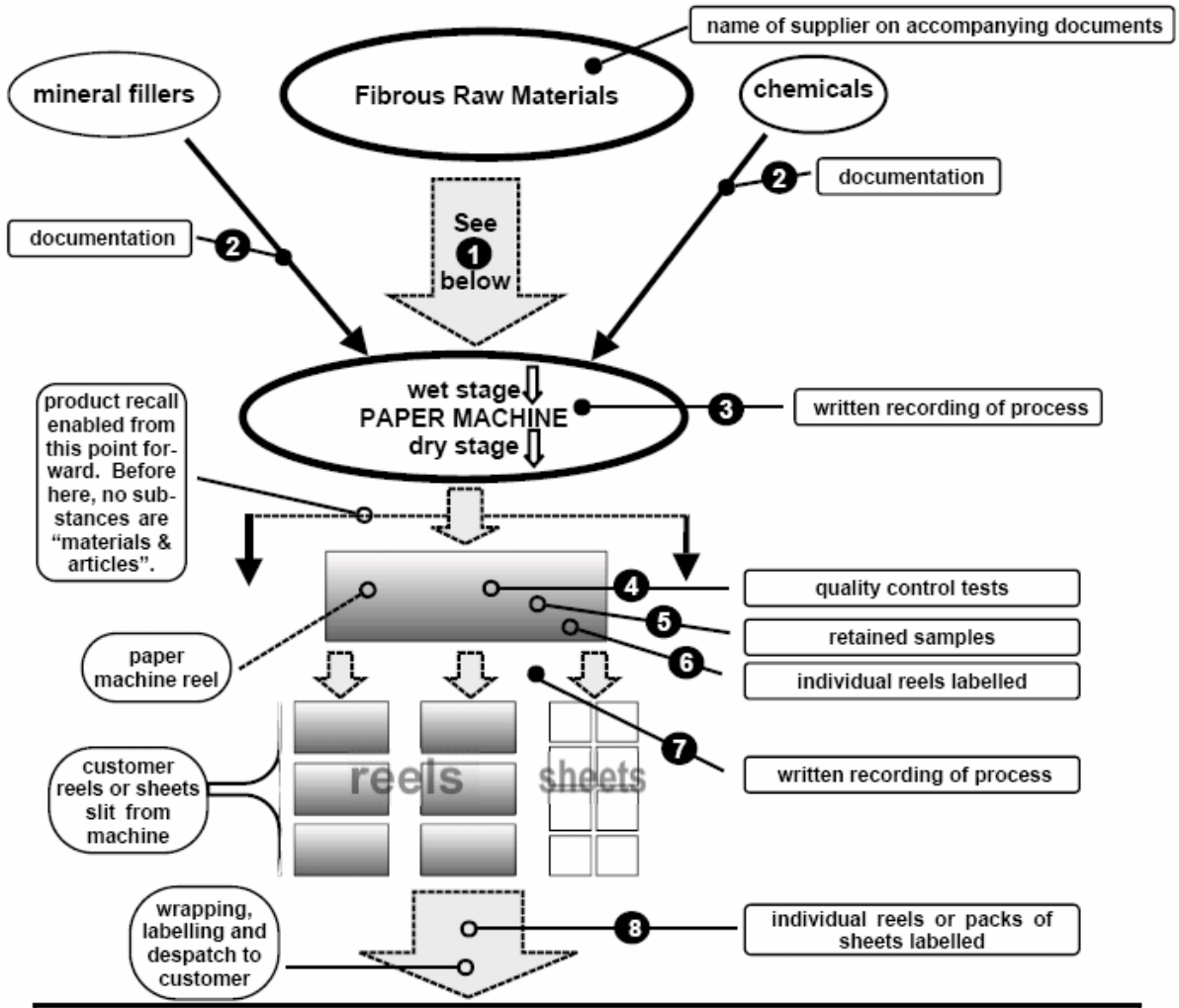
blank	a shaped, flat piece of paper or board for use in a subsequent process e.g. folding/gluing into a frozen food box or milk carton
calendaring	passing a web of paper between metal or fibre rollers in order to produce a more smooth or glossy appearance
coating	a process of applying to the surface of paper or board one or more layers of a liquid suspension of pigment or other material in a fluid form. The purpose is to improve printability or other properties such as grease or water resistance
converting	any operation, applied after the normal paper or board manufacturing process, which changes the physical shape or appearance of paper and board e.g. slitting, cutting into sheets, bag and box manufacture, printing, etc.
creasing	the process of making an indentation in board materials in order to produce a line along which it may be folded. This enables the folding of a blank to produce a shaped package
die cutting	cutting or stamping a sheet or web of paper or board with a shaped knife to produce a special shape or blank
extruder	equipment used to produce a layer of plastic prior to laminating
laminating	the fixing of a ready-formed layer of plastic, paper, metal, etc. to paper or board normally using an adhesive
palletising	placing paper and board packaging products on to a pallet and then wrapping and labelling the whole unit
sizing agent	a liquid material applied to paper or board and used to improve its resistance to the penetration and spread of aqueous liquids, for example printing inks
slitting	the passing of a moving web of paper or board from a reel though knives resulting in the production of a number of reels of smaller width and/or diameter
web	a continuous length of paper or board travelling along a paper machine or through converting equipment



Details of Traceability Tools	
1	All raw materials have a batch number which is recorded at the time of use.
2	A detailed, timed, running log is kept which records all relevant production activities and relates identification of incoming reels and/or raw material batches to final product identification and/or customer job number.
3	All reels are marked with a unique number and may also carry order numbers and batch numbers. Bar coding identification systems, e.g. CEPI Unit Identifier, FEFCO Bar Code standard, are widely used.
4	Samples are taken from reels or batches and retained for a period appropriate to the packaging life-cycle..
5	Quality control tests are performed. Records will show time of production as well as testing results.
6	Detailed documentation will accompany all deliveries. At a minimum, supplier name, customer name, customer order number, reel/batch number is included.
7	All batches/pallets are marked with a unique number, customer name and supplier name.

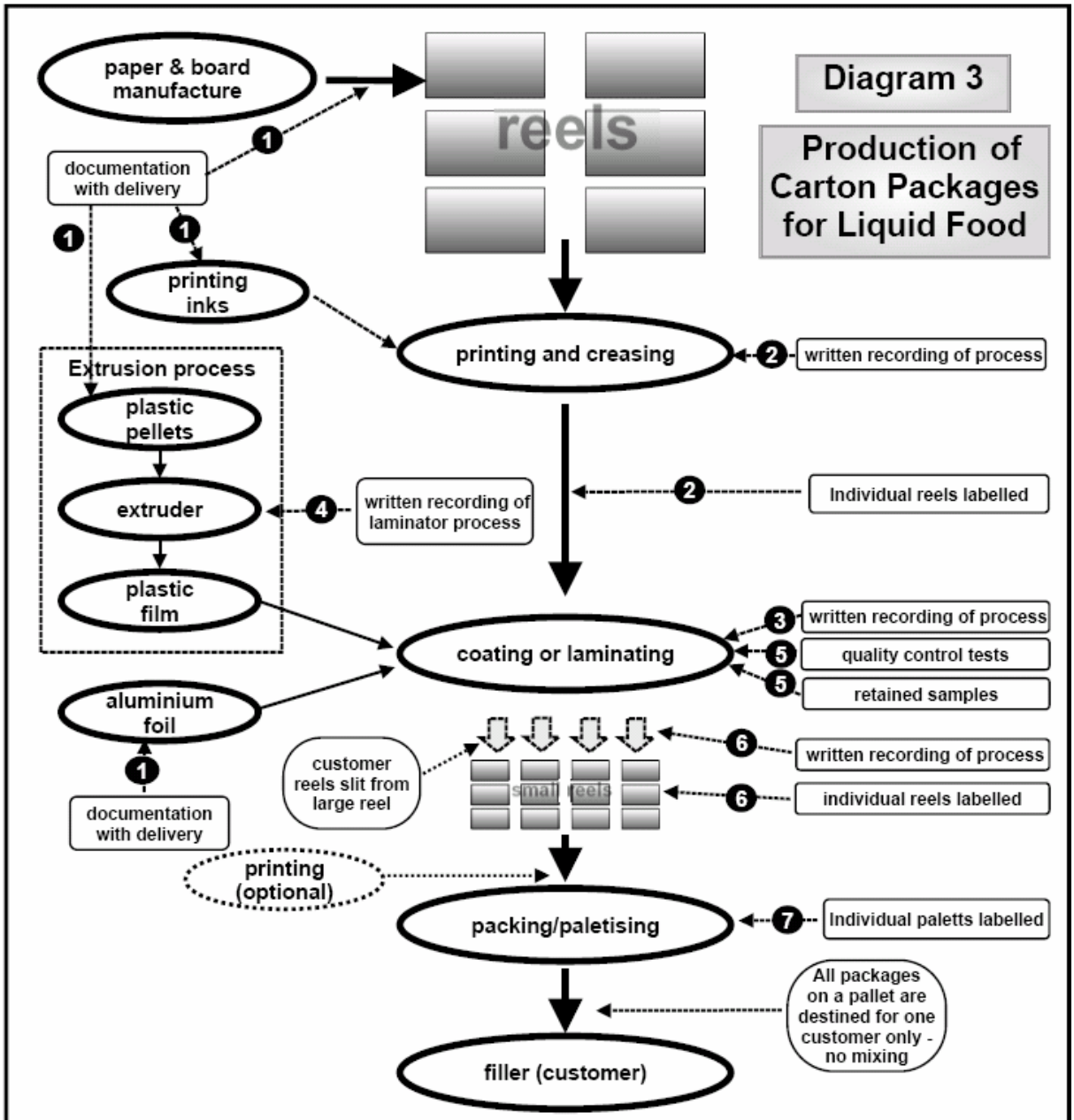
Diagram 2

Paper & Board Manufacture - Flow Diagram

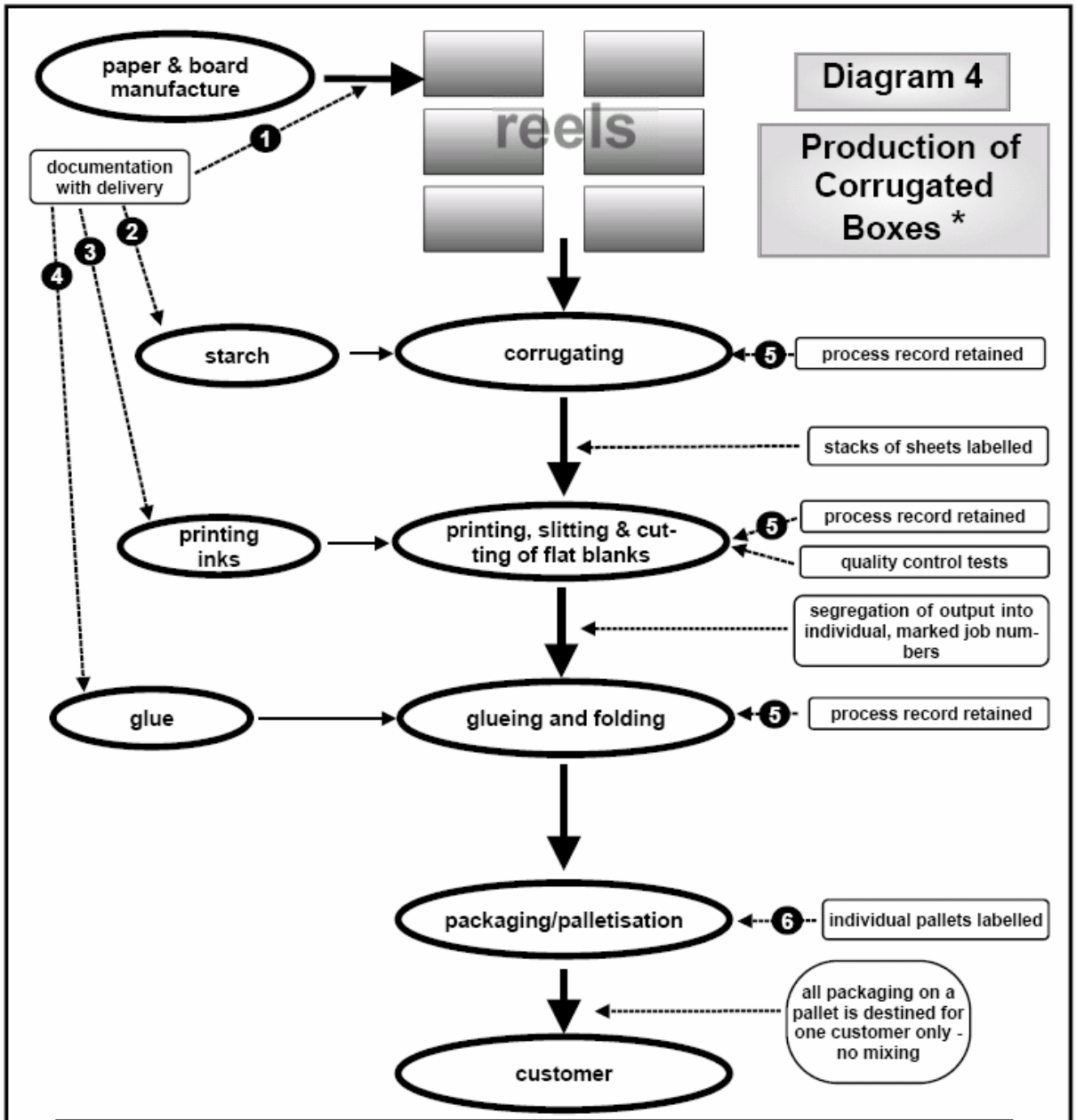


Details of Traceability Tools

1	Woodpulp comes either from adjacent pulp mill or from pulp agent/importer. Recovered paper is purchased according to industry guidelines for "Responsible Sourcing" which uses the "approved supplier" principle and covers, amongst other items, sorting, hygiene, transport, inspections and control of prohibited grades.
2	All batches of auxiliary raw materials are labelled with supplier name and batch number and accompanied by documentation stating, additionally, paper manufacturer's order number and date of supply.
3	A detailed, timed log is kept which records all relevant production activities and relates time of production to batch numbers of raw materials and final product reel numbers.
4	Quality control tests are performed. Records will show time of production as well as testing results.
5	Samples are taken from each paper machine reel and retained for a period appropriate to the packaging life-cycle. Examination of samples will enable identification and isolation of defective material and that produced immediately before and after it.
6	All paper machine reels are sequentially numbered, thus linking raw materials to customer orders.
7	Paper machine reels are slit into smaller reels. A timed log is kept which records machine reel number and defines from where, inside it, the slit reel originates and allocates a unique number to the latter.
8	All reels are marked and/or labelled with a unique number and supplier name. They may also carry order numbers and batch numbers. Bar code systems are normally used also. Documents accompany the order giving numbers and weights and/or lengths of reels, supplier and customer name.

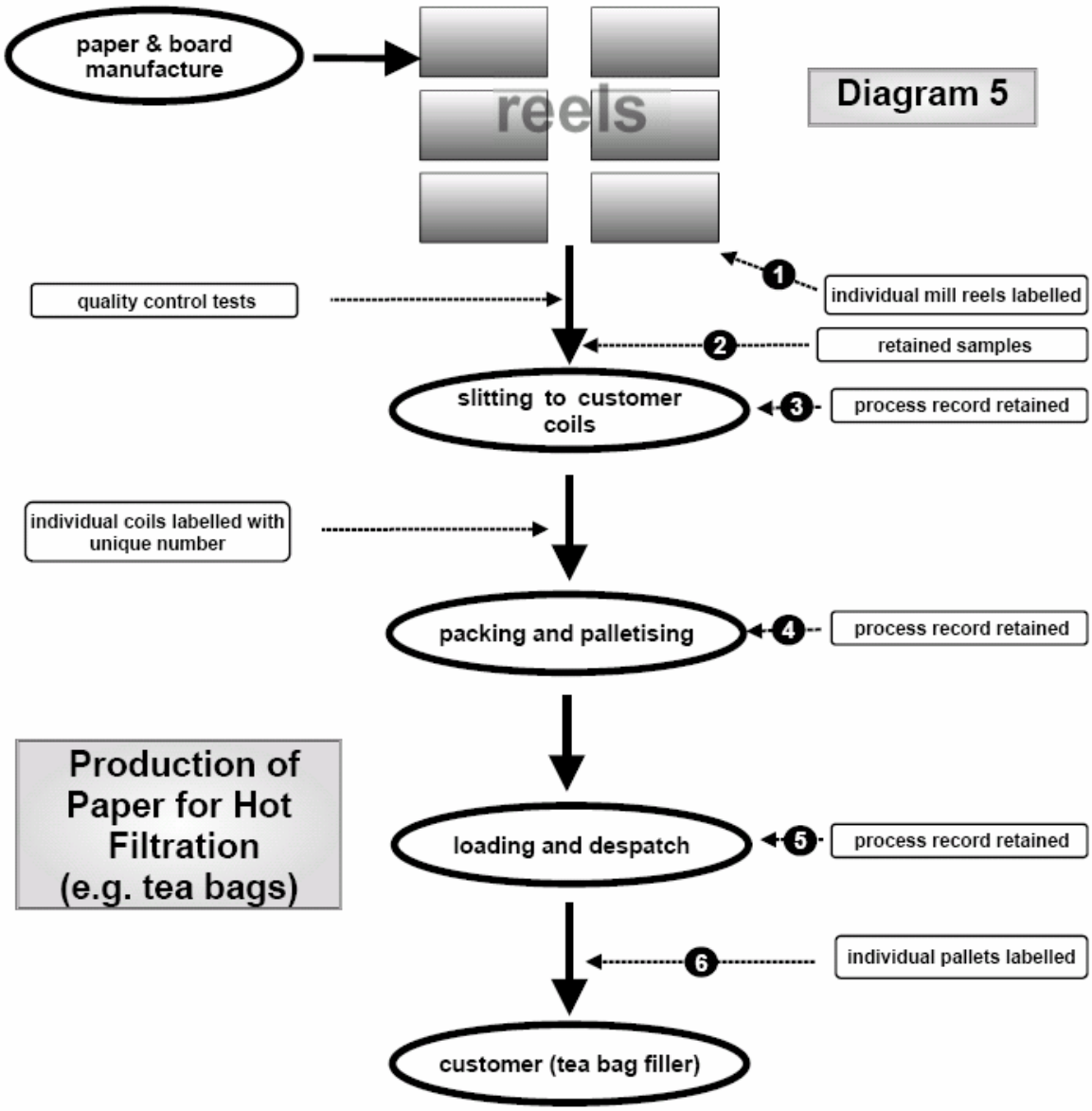


Details of Traceability Tools	
1	All raw materials are identified with manufacturer's name and, respectively, paper and aluminium reel numbers, ink and plastic pellet batch numbers.
2	A detailed, timed, running log is kept which records all relevant production activities and relates identification of incoming reels and printing ink batches to printed reels.
3	A timed, written log is kept to relate coated/laminated reels to incoming board reel numbers, plastic laminate and aluminium batches. The type and supplier of raw materials, within one order, are the same.
4	Supplier & batch number of plastic pellets for each layer recorded in timed log to relate to laminator activity.
5	Quality control tests are performed and the samples and results are retained for a period appropriate to the packaging life-cycle.. Records will show the time of production as well as testing results.
6	A timed, written log of slitting operations is kept which connects incoming (large) and outgoing (small) reels. Advanced labelling system covers unique output reel number, order no., date, supplier and customer.
7	All pallets carry a label with a unique number, customer order no., supplier, reel numbers, date, etc.

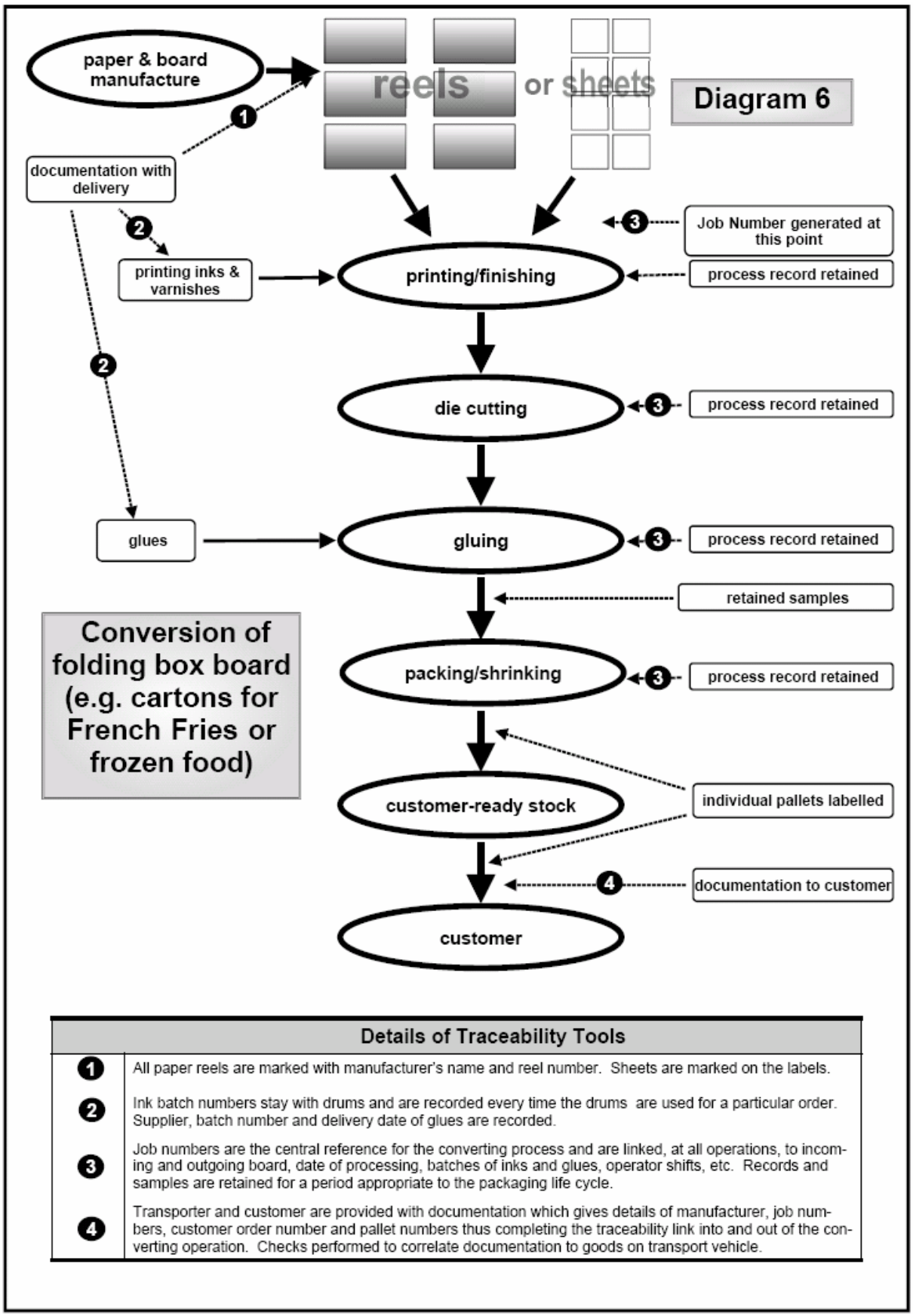


Details of Traceability Tools	
1	All paper reels are marked with manufacturer's name and reel number
2	Starch is delivered by tanker. Supplier, batch number and delivery date are recorded. See text for explanation of traceability where bulk raw materials are used. More details are given also in the reference below *.
3	Inks are delivered in approx. 200 litre drums marked with supplier and batch number. Batch numbers stay with drums and are recorded every time the drums are used for a particular order.
4	Glues are normally delivered by intermediate bulk container. Supplier, batch number and delivery date are recorded.
5	Timed log is kept which relates outgoing customer orders (job numbers) to all production variables and incoming raw material batches. Records are kept according to the lifetime of the product.
6	Pallet is labelled with details of product, job number, customer and date of manufacturer. Information is duplicated on an accompanying customer delivery note.

* *The information provided on this page is also available as descriptive text on the website* **www.fefco.org** *which additionally provides links to supporting documents.*



Details of Traceability Tools	
1	All reels individually identified according to normal papermaking traceability standards.
2	Samples from all incoming reels taken and retained for a period appropriate to the packaging lifetime.
3	Incoming reels are slit into coils. A timed log is kept, often computer-generated, which records incoming reel number and defines from where, inside it, the final coil originates and allocates a unique number to the latter. All operations in accordance with pre-defined customer configuration and packaging specification.
4	Record made which establishes link between factory order, customer order, incoming reel number and the outgoing cartons or drums containing the coils.
5	Customer documents generated at this stage showing customer order, factory order, coil information and transportation details. Checks performed to correlate documentation to goods on vehicle.
6	Pallet is labelled with details of product, factory order, customer and date of manufacturer. Information is duplicated on the accompanying customer delivery note.



Details of Traceability Tools	
1	All paper reels are marked with manufacturer's name and reel number. Sheets are marked on the labels.
2	Ink batch numbers stay with drums and are recorded every time the drums are used for a particular order. Supplier, batch number and delivery date of glues are recorded.
3	Job numbers are the central reference for the converting process and are linked, at all operations, to incoming and outgoing board, date of processing, batches of inks and glues, operator shifts, etc. Records and samples are retained for a period appropriate to the packaging life cycle.
4	Transporter and customer are provided with documentation which gives details of manufacturer, job numbers, customer order number and pallet numbers thus completing the traceability link into and out of the converting operation. Checks performed to correlate documentation to goods on transport vehicle.

Traceability APPLIED in the plastics chain (Practical Guidelines)

I. SCOPE

This annex describes how traceability can be implemented in the production of Food Contact Materials and Articles consisting of plastics or of multilayers consisting primarily of plastics. The objective of this paper is to provide guidance for Industry in order to allow them to adopt systems capable of fulfilling the requirements of Article 17 of Regulation (EC) No 1935/2004 (Framework Regulation), dealing with traceability of materials and articles for food contact.

The present paper covers the production chain beginning from the selection of starting substances downstream to shipment of such materials and articles to direct customers.

It does not include the operations performed to bring the material into contact with foodstuffs (packing/filling) once the finished plastic products have left the manufacturing plant.

It is intended that other guidelines will address traceability at the packer/filler or retailer stage.

Finished plastic products for contact with food cover a wide range of applications.

The major application in terms of volume (especially if considering surface area) is food packaging. However all materials and articles such as plastic crates, pallets, containers, kitchenware, etc. are covered in this practical guide

This guide will describe traceability downstream, for different manufacturing processes and excludes the food packer/filler or retailer stage.

II. GENERAL INFORMATION

II.1 Associations taken as part of the plastics group

The following associations cover the incoming materials used for plastics material:

CEFIC-FCA European Chemical Industry Council – Food Contact Additives
PlasticsEurope Association of Plastics manufacturers in Europe

The following associations cover the converters of those materials:

EuPC European Plastics Converters Confederation
FPE Flexible Packaging Europe

II.2 Overview

Food contact materials and articles made of plastics are subjected to strict legislation as far as their suitability for food contact is concerned; in addition, converters have generally implemented quality assurance and hygiene programs that make the occurrence of contaminated or defective products very unlikely. Existing tools that enable identification and traceability are a further reassurance for customers and consumers alike.

Raw materials used for the production of plastic food contact materials and articles are:

- Resins, almost always purchased as pellets and then submitted to various processing steps such as extrusion, blow-moulding, injection moulding etc.
- Additives, added in-line as such or in solutions during the production of the material or articles, or used off-line to produce a compound masterbatch that is further processed for the manufacturing of the material or articles,
- plastic films or sheets, purchased as reels and then either coated and/or printed and/or laminated to another substrate,
- Primers, inks, varnishes and coatings, used in the printing process,
- Adhesives and tie-layer resins used to laminate or bond together various layers,
- Where appropriate, non-plastic substrates such as paper, aluminium foil, RCF, etc.

Traceability in the area of plastic food contact materials and articles is very complex and

resides, primarily in the recording of all of the elements that allow the identification of raw materials and how these are transformed in a production process. For each product, traceability should allow identification of the raw materials that have been used in its production (supplier name, date of receipt, batch identification, optional quality data); and each step which these substances underwent in the production process. These production processes can be of varied nature (extrusion, blow moulding, injection, printing, coating, lamination,), and are used independently, or combined in order to produce a wide range of products.

Traceability during the manufacture of finished products can be straightforward (e.g. blow moulding of a monolayer PET bottle preform) or very complex (e.g. production of a plastic bag from a printed co-extruded film).

The case studies that follow give examples of typical production processes and describe the processes which ensure traceability.

Steps after converting
The finished products, as derived from the production, are sold to:
a food producing company, who will use them to pack the food and distribute it via a retailing chain;
a distributor, who will sell the product to a food producing company;
a retailer, using the products to pack food in the backstore and sell it direct to consumers.
In the three cases mentioned above the finished products will be in contact with food ready for use by the consumer.

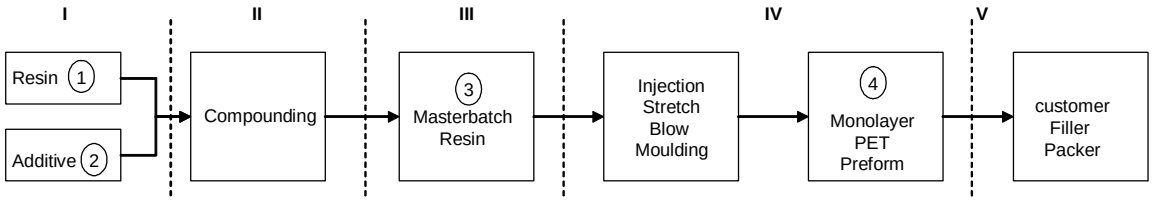
There are also cases where finished products are sold directly to consumers eg multiple use containers for food storage in the fridge and stretchable cling films.

.II.3 Case studies

Key to the graphs

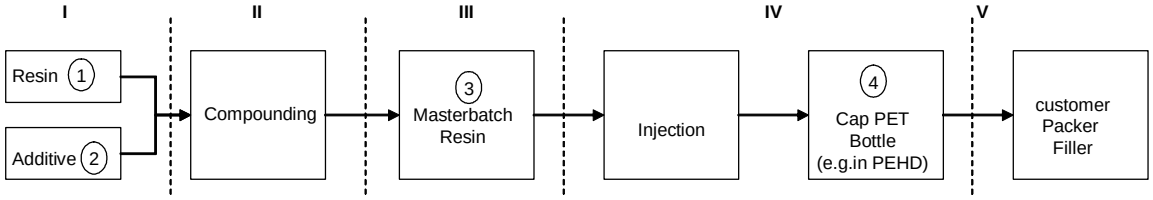
- Roman numerals (I, II, III…) represent the different levels of the production chain
- Arab numbers (1,2,3…) represent a material or article in the production chain

II.3.1 Case study 1: Manufacturing of a monolayer PET bottle



Making of the bottle preform:
The raw materials which consist of PET resin, additives and pigments are compounded. A compounder can be located at the converters plant or be an independent company. Preforms are injected and sold either directly to a packer-filler, a subcontracting converter or via a distributor for small businesses.

Making of the cap:

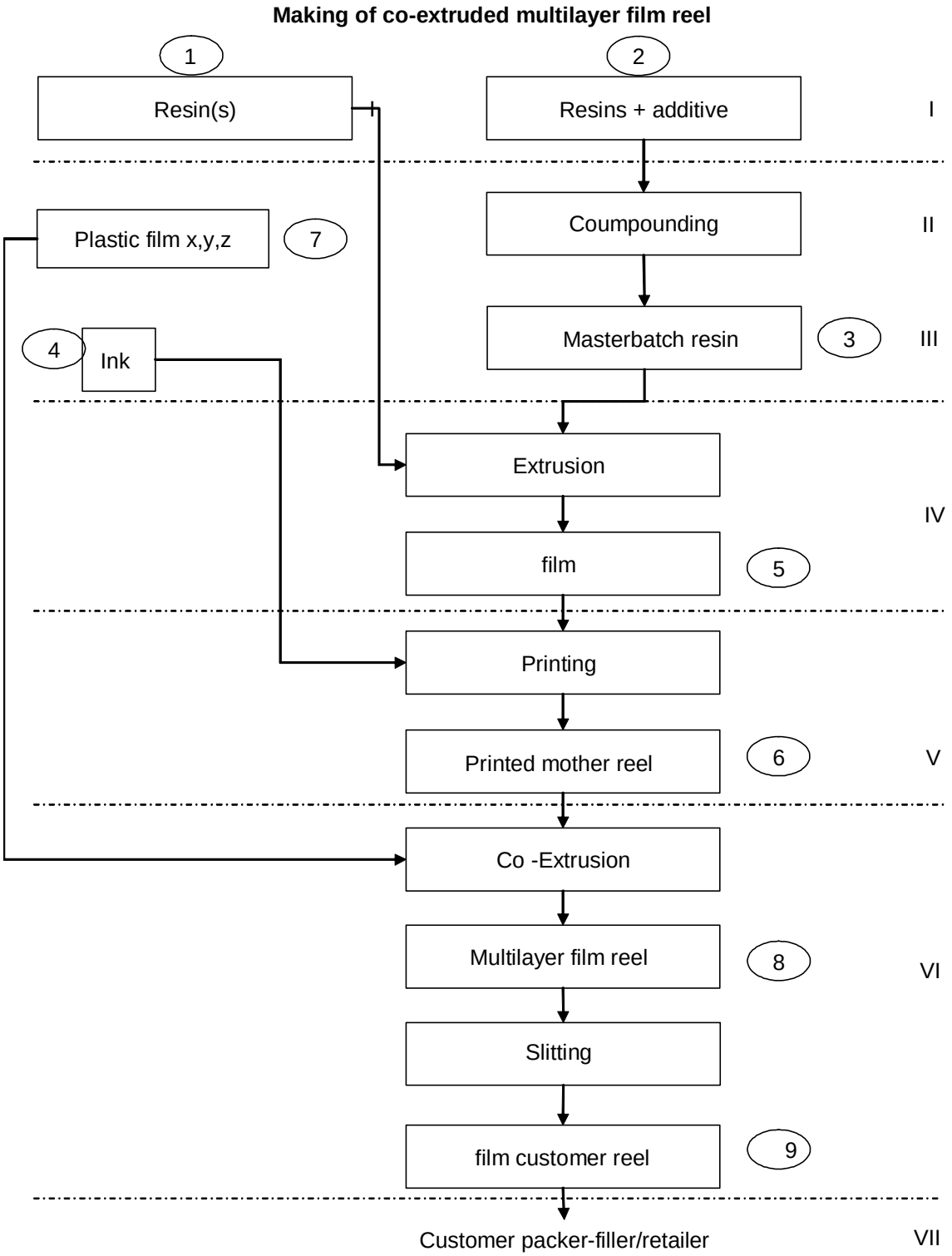


The cap is manufactured using a similar process as that used to manufacture preforms. However the raw materials and additives used are different.

II.3.2 Case study 2: production of film based plastics products

In the production of a plastic film the initial step is either extrusion or calendering. These processes can involve a pure resin and additives or a pure resin and a masterbatch of resins and additives. The following example has been simplified as typically there are a number of resins, and additives with several different suppliers.

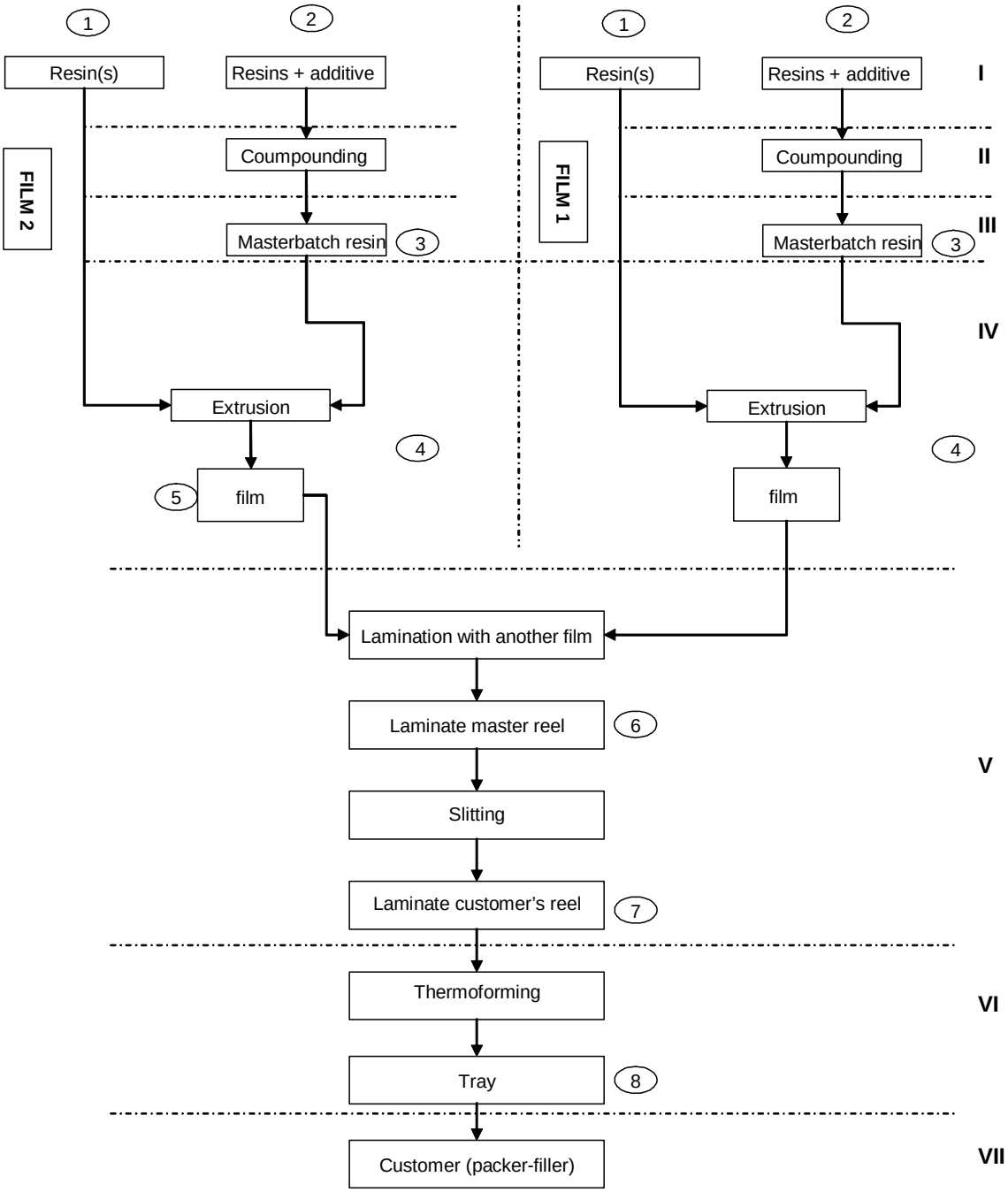
The film may be printed and then folded, sealed and cut into bags.



The film is printed and then slit into co-extruded multilayer film reel.

Production of thermoformed trays for food packaging from laminated film

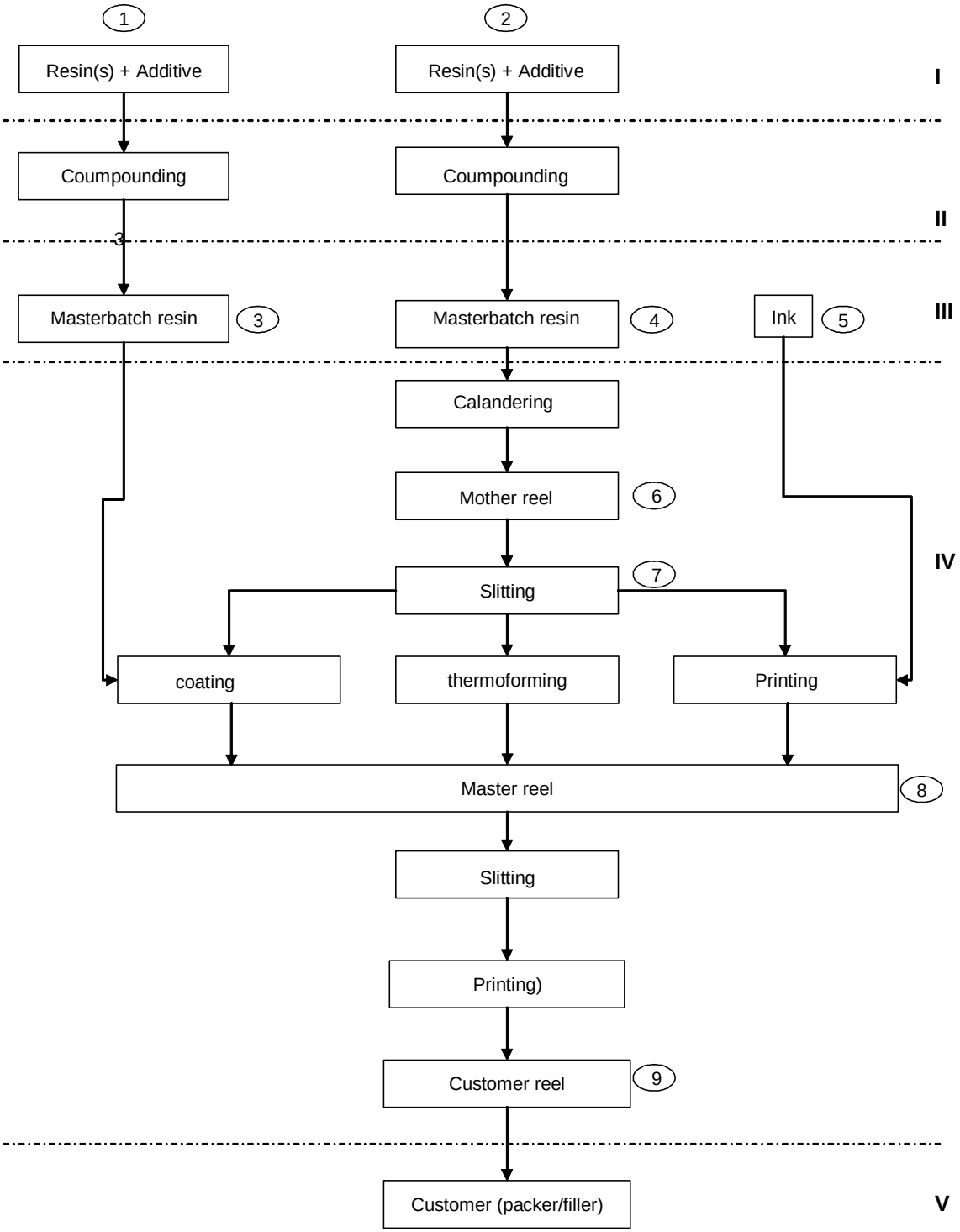
A film laminated with another film, slit and thermoformed into a tray. At consumer unit level, food is packaged and another film product is used to provide a lid.



Thermoforming can either be done by a converter or directly by the packerfiller

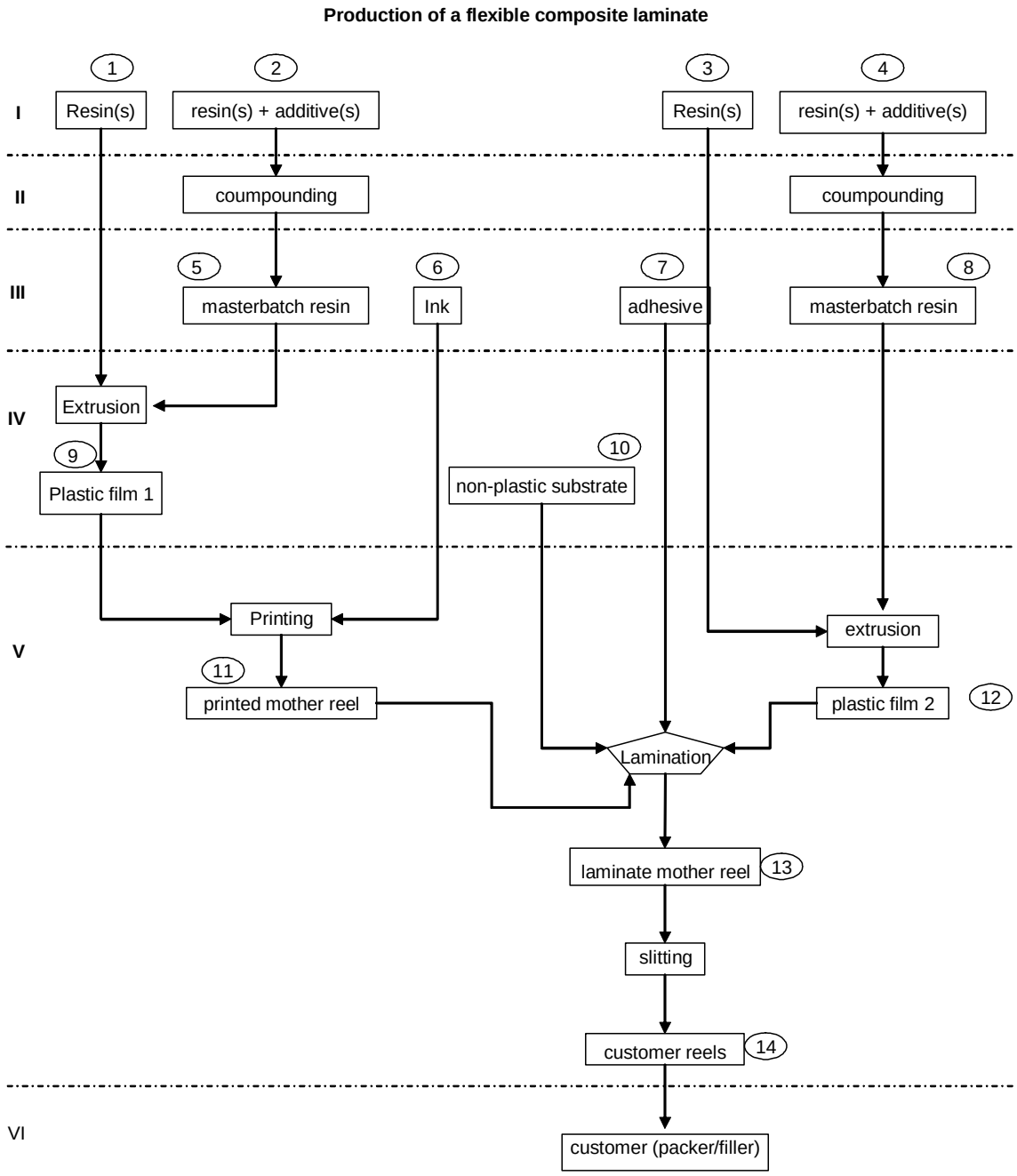
Film production by calendering

This kind of processing is mainly used for PVC processing. The film is calendered into a mother reel, which is slit. The slit film can then be converted into various products. It can be coated, thermoformed or printed. The reel obtained can then be slit again and printed.



II.3.3 Case study 3:

For a description of this flowchart, see paragraph III.2.3



III. TRACEABILITY INFORMATION

III.1 Incoming information

Converters must ensure that incoming raw materials are accompanied by information when delivered by each supplier. Raw materials are delivered either in transport packaging (e.g. bags or cardboard containers), or in bulk (filled into a silo or tank). Depending on the delivery method, the information can reside on labels (with text and/or barcodes), on the transport packaging or in freight documents. The information needed for the purpose of traceability is:

Name of supplier, type and grade of raw material

Batch number and/or production date

Labels or freight documents specify the identity of the raw material and its lot number. Such information should also identify the plant where the raw material has been produced, and its production date.

The converter should establish procedures for transferring the information given by the raw material supplier into internal records.

III.2 Internal information

Converters must establish records associated with each individual step which raw materials undergo to enable full traceability from their own production, upstream, to the supplier of raw materials,. These records should provide:

- the lot number of raw materials used in the production
- the date in which each single step of the production had been carried out
- plant and manufacturing line identification
- other info when necessary, e.g. related to Quality Control
- optionally a more detailed timing such as the production shift

Using the production records above will enable each intermediate (semi finished) product to be identified so that any possible action upon that product can be traced.

The information recorded may differ depending on the type of product and method of manufacture.

Traceability records should be kept by the plastic converters in appropriate archives for a time consistent with either the lifetime of the products or in accordance with warranty and legal requirements.

In all of these situations, traceability can be guaranteed with the help of suitable identification codes on the finished products, e.g. by documents and/or barcodes and/or certificates and/or labeling, with a back up in the administration of the converters.

III.2.1 Case study 1 -injection of a monolayer PET bottle preform

All of the information on raw materials for compounding should be recorded in step I (arrival of materials) (see III.1). In compounding (step II), the consumption of raw material is recorded from each production run. A batch code will be allocated to each batch of compound produced (most often a barcode), the quantities produced will then be packed. This first step should be treated as a separate operational unit.

The compound is then injection molded into a PET preform (step III) and a new identification (ID) code is attributed to each batch of preform produced (enabling quick reference to the production run). During internal production monitoring, the ID code of the compound used is recorded and linked to the ID code of the batch of preforms actually produced.

The same sequence applies to the production of PET bottle caps.

III.2.2 Case study 2 - production of film based products

Making of a co-extruded multilayer film reel

Info has to be transmitted through 8 steps involving up to five different companies

The raw materials used are numbered 1, 2 3, 4 and 7 and are obtained from suppliers on levels I, III and IV. Materials nos 5,6, and 8 are intermediate products made in-house by the converter. Material 9 is the finished product, and is delivered to the customer on level VII, usually a packer/filler.

III.2.2.2 Tray for food packaging

In the schematic representation, arrows indicate the flow of materials. Traceability requires that these flows of material be accompanied by a flow of information. These flows lead to the penultimate level, indicating the raw materials directly purchased by the converter, and one flow leads the finished product out towards the customers. For each flow we will describe the common practices and requirements to achieve traceability:

1. Plastic film 1 is purchased from a film converter; this material is delivered in the form of mother reels packed on pallets. It is common that both the reels and the transport packaging are labeled with information including the grade of material and the batch.

Converters shall record the required information to ensure traceability, but may translate this information into their internal documentation system (e.g. as a unique bar code). Whenever possible, converters shall ensure a traceability system for this material which goes to smaller units of a given batch, i.e. down to the level of the pallet or the individual mother reel..

2. Plastic film 2 is produced in-house by the converter, from resins and masterbatches (purchased elsewhere). Resins used in large volumes are usually supplied into silos; for these the special provisions for bulk storage (see below) shall apply. For resins and masterbatches supplied in bags or octabins full traceability shall be obtained from the information given on the labels or accompanying documents.

   Partly used left-over mother reels of extruded film shall be treated as under 1. A special case is that of “edge-trim”, which is the sides of the extruded film being cut off to achieve a better winding on the mother reel. When this edge trim is shredded and immediately fed back into the extrusion process, there is no issue about traceability. However the shredded edge-trim may also be collected and stored for future use. In this case the converter shall assign a new batch number to this shredded material, and record which batches of materials have contributed to this newly defined batch.

3. Inks and adhesives (as well as coatings) are commonly purchased in a liquid form, and depending on the case are delivered in drums or tanks. For materials delivered in drums, the information provided on the labels or accompanying documents shall be recorded, and full traceability is assured. For liquid materials delivered into large volume tanks, the traceability requirements for bulk storage (see below) shall apply.

4. The finished product is most often shipped in the form of reels, several reels being placed on a pallet, and possibly many pallets making up a batch (production run). Converters shall ensure that adequate information is given to the customer to allow traceability down to the sub-units of the product batch, either down to pallet level, or preferably down to reel level. This can be achieved by placing a label on the reel or in its core (or both).

   Where the packaging material is supplied to the customer under the form of bags or sheets, these are usually packaged in smaller portions (boxes) allowing for adequate labeling on the boxes.

As far as the production processes are concerned – extrusion, laminating, printing, coating

(not used in the example given), slitting – the converter shall record adequate information to ensure that the production history is known for the finished product, including any separate production processes performed in parallel on different portions of the finished product shipment.

III.2.2.3 Production by calendering

Information has to be transmitted through nine steps involving up to seven different companies.

The raw materials used are numbered 1 through 5, and are obtained from suppliers on levels I and III. Materials nos 6 and 8 are intermediate products made in-house by the converter. Material 9 is the finished product, and is delivered to the customer on level VII, usually a packer/filler.

III.2.3 Case study number 3: Production of a flexible composite laminate (submitted by FPE).

This description of the "traceability flow" for the manufacturing of a typical composite flexible packaging material is written from the viewpoint of a flexible packaging converter – level V in the schematic.

The raw materials used are numbered 1 through 10, and are obtained from suppliers on levels I, III and IV. Materials nos. 11, 12 and 13 are intermediate products made in-house by the converter. Material 14 is the finished product, and is delivered to the customer on level VI, usually a packer/filler.

Traceability is required whenever a material undergoes a change in composition or physical shape, and follows the "one step up / one step down" principle outlined in the Framework Regulation. The purpose of this is to provide a traceability link between the product delivered to the customer and the raw materials used to make that product as well as its production history, and vice versa.

In the schematic representation, arrows indicate the flow of materials. Traceability requires that these flows of material be accompanied by a flow of information. Six flows lead into level V, indicating the raw materials directly purchased by the converter, and one flow leads the finished product out towards the customers. For each flow we will describe the common practices and requirements to achieve traceability:

1. Plastic film 1 (material no. 9) is purchased from a film converter; this material is delivered in the form of mother reels placed on pallets. It is common that both the reels and the transport packaging are labelled with information including the grade of material and the batch.

Converters shall record the required information to ensure traceability, but may translate this information into their internal documentation system (e.g. as a unique bar code). Whenever possible, converters shall ensure a traceability system for this material which goes to smaller units of a given batch, i.e. down to the level of the pallet or the individual mother reel.

Production returns of left-over mother reels (partly used) shall be adequately labelled so that traceability is not lost when these materials are used in another production run.

2. Plastic film 2 (material no. 12) is produced in-house by the flexible packaging converter, from resins (material no. 3) and masterbatches (material no. 8) purchased elsewhere. Resins used in large volumes are usually supplied into silos; for these the special provisions for bulk storage (see below) shall apply. For resins and masterbatches supplied in bags or octabins full traceability shall be achieved from the information given on the labels or accompanying documents.

Partly used left-over mother reels of extruded film shall be treated as under 1, i.e. their existing grade/batch information is maintained, or alternatively they are assigned a newly defined batch identifier. A special case is that of “edge-trim”, which is the sides of extruded film being cut off to achieve a better winding on the mother reel. When this edge trim is shredded and immediately fed back into the extrusion process, there is no issue about traceability. However the shredded edge-trim may also be collected and stored for future use. In this case the converter shall assign a new batch number to this shredded material, and record which batches of materials have contributed to this newly defined batch.

3. For non-plastic substrates such as paper or aluminium foil, the traceability practices and requirements are identical to those of plastic film as given under 1.3. Inks and adhesives (as well as coatings) are commonly purchased in a liquid form, and depending on the case are delivered in drums or tanks. For materials delivered in drums, the information provided on the labels or accompanying documents shall be recorded, and full traceability is assured. For liquid materials delivered into large volume tanks, the traceability requirements for bulk storage (see below) shall apply. For liquid materials prepared in-house by the converter (not uncommon for inks, and even rather common for coatings), adequate information from the raw materials and the production history shall be recorded for the traceability.
4. The finished product is most often shipped under the form of reels, several reels being placed on a pallet, and possibly many pallets making up a batch (production run). Converters shall ensure that adequate information is given to the customer to allow traceability down to the sub-units of the product batch, either down to pallet level, or preferably down to reel level. It is common practice to place a label on the reel or in its core (or both).

   In the less common case where the flexible packaging material is supplied to the customer under the form of pre-made bags or pre-cut sheets, these are usually packaged in smaller portions (boxes) allowing for adequate labelling on the boxes and/or the pallets.

As far as the production processes are concerned – extrusion, laminating, printing, coating (not used in the example given), slitting – the converter shall record adequate information to ensure that the production history is known for the finished product, including any separate production processes performed in parallel on different portions of the finished product shipment.

III.2.4 Special cases:

III.2.4.1 Dry product in bulk storage

Resins and other starting substances can be stored in silos. Bulk storage implies the mix of several batches of raw material. At that point, it is no longer possible to refer to one batch number but reference is made to a series of batch numbers.

The information that shall be recorded in case of bulk storage is the following:

- the date in which a given raw material batch is stored in the silo
- the quantity of material introduced into the silo on that date
- the grade and batch number of the raw material
- reference to the silo's number and consumed quantity is kept in the production records

By using this information it will be possible to determine when an additive or resin was stored in a silo, from which silo these raw materials have been used and for which production run.

Over time, depending on the material (solid or liquid), on the size and shape of the silo/tank 100% of a given batch can reasonably be expected to be consumed.

III.2.4.2 Liquid products in bulk storage (drums and containers or tanks)

Liquid raw materials such as adhesives, inks and coatings, etc. are commonly delivered to the packaging manufacturer in drums which are adequately identified to allow full traceability between the batch of raw material and the finished products in which they were used. However, the following special cases have to be recognized:

First, when a container of any such liquid raw material is only partly used for a given manufacturing run, and the rest is used later in another production, a system needs to be in place to maintain the original traceability of the liquid raw material into the next production run. With such system in place, full traceability can still be ensured.

Second, when several partly-used units of liquid raw materials are collected into one container for further use, ful traceability would require that the collected liquid be assigned a new traceability identifier, and that the traceability information clarifies from which batches or raw materials this new batch was constituted. If this is no feasible for technological or logistical reasons, at least the source of the various incoming batches should be clarified. Liquid raw materials from different suppliers should preferably not be mixed.

Third, when large volume containers are used which are refilled before completely empty, the situation is the same as described above for bulk storage of resins in silos, and the information recorded has to be the same.

III.2.4.3 Use of in-plant production scrap

In-plant production scrap which is immediately re-introduced into the manufacturing process, does not constitute a separate material and therefore does not need to be considered in separate traceability information. It is therefore excluded from this special case. Other production scrap, which is collected before being re-used in another manufacturing run, shall be stored in a separate container that will be assigned a reference number. If different batches of production scrap are collected and re-processed together, the traceability information shall clarify from which sources the materials originate.

In some cases, production scrap from various origins (finished and semi finished articles (e.g. different reels), end of production run, production defects, off cuts, edge trimming, transition of formulation) are shredded and stored in a silo of "fluff". This fluff is then regranulated and stored in a silo of regranulate and used as a new raw material in production. The process can be discontinuous: the silo of fluff is first fully filled and then regranulated. In this case a batch number can be allocated to the waste in the silo of fluff to be regranulated. The

process can also be continuous: waste is shredded into fluff and fluff immediately regranulated. In this case the mean time to completely fill a silo of regranulate produced from fluff obtained from production scrap should be estimated. This "average filling time" together with an accurate material accounting of the use of the regranulate will then be used in case of recall if it appears that a defect is originating in the regranulate used.

III.3 Outgoing information

The converter shall ensure that essential information given in the daily production records is transferred into outgoing information that follows the products when they are sold. Such information could consist of a label on the outside of the container (e.g. for rigid products or for plastic bags shipped in cardboard boxes) or on the pallet or wrapping film of flexible film rolls. The information can be also provided on the documents that accompany the products when they are sold. Essential information is:

- Name and address of the manufacturer of the finished product (i.e. the converter);
- Commercial name of the product;
- Numbers or codes for identification of the place and date of production (e.g. line of production, shift of production etc.), or any identifier which can be traced by the manufacturer to this same information in his internal records.
- Batch number or production's reference number

Such information, retained by the customers of the plastic materials and articles manufacturing industry, allows the identification of all the elements necessary for tracing back products, therefore establishing a suitable system for both product recall, whenever needed.

The system, maintained along the whole chain, ensures full traceability of plastic materials and article for food contact use.

From an administrative point of view, this entails that the converter keeps a record of all the customers to whom a specific batch or part of a batch from a given production run has been sold, as well as a record on materials used in the different steps of internal production processes (with ID number).

IV. RECALL

Following the process described in chapter III, the plastic products sent to distributors, packerfillers, retailers or others are adequately identified.

Should a problem occur at the retail level, and it is needed to recall the products, one can proceed up the chain and identify the material or process that caused the problem, this will allow the identification and removal from the market of all products that may have the same problem.

The process would be:

The retailer identifies his supplier.

The supplier (filler, distributor, converter, or other) determines whether the failure is due to a defect in his internal process or a defective raw material. In case of doubt, both options are investigated further.

If appropriate, the supplier contacts his own raw material supplier, and they can contact their suppliers, and so on.

Depending on where the origin of the problem has been identified, each affected stakeholder contacts his customer(s) with information on which products are potentially defective.

Each customer takes appropriate measures such as a recall or other corrective actions.

Note: depending on the number of steps and the layout of the supply chain, which covers many different possibilities, the procedures to be followed will vary. Plastics converters together with their suppliers and customers in the chain should set-up procedures to be used when an emergency arises.

Keeping a list of the persons responsible for traceability and recall issues at suppliers and customer level is strongly advised. This information should be linked with the orders and sales documentation.

TRACEABILITY APPLIED IN THE REGENERATED CELLULOSE FILM (CELLOPHANE) SECTOR (Practical Guidelines)

I. SCOPE

This document describes the traceability procedures in place within the cellophane manufacturing industry.

It refers to the primary manufacture of plain and coated cellophane, but not the possible subsequent operations performed by conversion industry customers e.g. printing and laminating.

II. GENERAL INFORMATION

Cellophane is a natural product derived from wood pulp. Trees from managed plantations provide the raw material from which wood pulp is obtained. A pure grade of dissolving pulp is supplied to the cellophane industry in the form of compressed wood pulp sheets or reels.

The cellophane manufacturing process starts with bales or reels of wood pulp being agitated with caustic soda solution and a catalyst to form slurry. The slurry is fed through a press where it is compressed to produce alkali cellulose crumb. The alkali cellulose is reacted with carbon disulphide under vacuum to make sodium cellulose xanthate. This is then mixed with a weak caustic soda solution to produce viscose.

The cellulose in the viscose is regenerated by extruding the liquid viscose through a jet into a bath of dilute sulphuric acid to form a sheet of film. This is known as the casting operation. The film then passes though a series of wash baths, which treat the film and remove all impurities. Carbon disulphide is recovered during part of this process. Along its path through the casting machine the film is treated with softeners to make the film more flexible, and anchoring agents to provide a chemical bond between the film and subsequent application of a coating.

At the end of the casting machine the dried base cellulose film is wound up into “mill rolls” and given a unique number, which then stays with that film through all further operations. These “mill roll” numbers are the main identity of all cellophane. All production records can be related to the “mill roll” numbers and samples of daily production are kept for reference. These records include (a) up-stream data of pulp and other chemical use, (b) results of quality control tests, (c) time and date of manufacture and (d) down-stream details of any coating application and conversion to smaller reels and sheets.

In the context of traceability, it is the down-stream area which is most important as it is only here that the product first becomes recognisable as being for food contact use and thus available for recall in the event of an incident. The “mill rolls” can be coated with a PVdC, nitrocellulose or other coating to give the final film properties of heat sealability, moisture permeability etc. The coatings are applied from solvent or aqueous dispersions. The coated and uncoated film “mill rolls” are then transferred to slitting equipment where “slit reels” of smaller diameter and widths are produced.

III. TRACEABILITY INFORMATION AND PROPAGATION

III.1 Up-stream Information

Up-stream traceability is important for internal purposes for monitoring what raw materials are used during the production of cellophane. All manufacturers of cellophane that have implemented the ISO9001 (or equivalent) quality management systems maintain details of all raw materials that are used in the production of the “mill rolls”. All raw materials are purchased against agreed specifications, preferably from suppliers who employ accredited quality management systems.

Therefore the raw materials used can be traced to “mill rolls”, either directly (where batches of raw materials are used e.g. wood pulp) or by reference to a time period (where raw materials are delivered in bulk and continuous feed is operated e.g. softeners). This process will facilitate the identification of “mill rolls” (in addition to those notified by a customer) if considered defective due to faulty raw materials.

III.2 Internal Information

Within the cellophane production environment, departmental logs record the time of manufacture of the “mill rolls”, related processing conditions and quality control information. Other logs record the details of raw materials used and the details of any in-process testing. All rolls of cellophane being processed internally are labelled with the “mill roll” numbers. These logs are either in paper or electronic format and are stored for various lengths of time as defined in departmental ISO9001 procedures.

Information stored against the customer’s order number identifies all “slit reels” supplied to that order. Labels attached to the outside of the reels carry such information as the type of film, “slit reel” number, customer order number, date and shift of production etc.

III.3 Downstream Information

The primary purposes of traceability within the cellophane industry are (a) internal control of quality, (b) the ability to trace back to identify possible corrective action following internal or external complaints and non conformances and (c) the facilitation of product recall.

Traceability is especially important when a product is placed on the market as suitable for contact with food. In the case of cellophane, the product will almost always be supplied to the customer as “slit reels”. Several “slit reels” would make up a customer order. All “slit reels” of cellophane are labelled with identification numbers, which can be directly traced back to the parent “mill roll”.

Therefore, the requirements for full traceability are in place. A customer, next along the food packaging chain, will receive “slit reels” labelled with these identification numbers.

IV. RECALL

If notified of a defect, the cellophane manufacturer can directly trace back to the “mill roll” and to all other possibly affected “slit reels” from the same “mill roll”. Most manufacturers, who have implemented ISO9001 (or similar) quality management systems, would have implemented procedures in their system for tracking and recall of product.

TRACEABILITY APPLIED FOR FOOD CONTACT MATERIALS IN THE RUBBER INDUSTRY

Foreword:

This document was submitted by BLIC, the European Association of the Rubber Industry.

This annex is based on a Good Manufacturing Practice (GMP) document for the rubber industry. Whilst it is not in the same format as the other materials guidelines, traceability is covered by these GMP provisions and more specifically the following sections :
"2.5, 2.6, 2.8, 2.9 and 2.10 for minimum traceability requirements and sections 4.5, 4.65, 4.7,4.8,4.1.and 4.11 for extensive traceability requirements"

GOOD MANUFACTURING PRACTICE
FOR RUBBER PRODUCTS
INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

I. GENERAL REQUIREMENTS

I.1 Introduction

This document (Guideline) is intended to provide guidance for Good Manufacturing Practice (GMP) for the manufacture of rubber products intended to come into contact with foodstuffs. It is also intended to help ensure that Rubber Products intended to come into contact with foodstuffs meet requirements of quality and purity.
In this Guideline "manufacturing" is defined as including all operations from receipt of materials, production, packaging, repackaging, labelling/relabelling, quality control, storage downstream to the distribution of Rubber Products.

Good Manufacturing Practice (GMP) rules are primarily directed at diminishing the risks, inherent in any rubber production that cannot be reasonably prevented through the testing of final products. In most cases, it is left to the manufacturer to determine the best methods to attain quality objectives.

The Guideline as a whole does not cover safety aspects for personnel engaged in manufacture or protection of the environment. These controls are the responsibility of the manufacturer and are governed by national laws.

Good Manufacturing Practice (GMP) is concerned with both Production and Quality Control (QC) and the basic requirements are:

1. Manufacturing processes are clearly defined and controlled.
2. Manufacturing processes are controlled and any changes to the process are evaluated. Changes that have an impact on the quality of the rubber product are where appropriate validated.
3. Instructions and procedures are written in clear and unambiguous language;
4. Records are made, manually or by instruments, during manufacturing processes which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the rubber product was as expected.
5. Records of manufacturing processes include distribution which will enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form;
6. The distribution of the rubber products minimises any risk to their quality;

To ensure compliance with the Good Manufacturing Practice (GMP) this guideline requires the manufacturer to be aware of current industry practice and any innovations that may be applied to different types of rubber products. This guidline does not prescribe in detail how a manufacturer should develop and produce a specific rubber product .

The content of this guideline should not be accepted as the only interpretation of the Good Manufacturing Practice (GMP) nor does it intend to cover every conceivable case. Alternative means of compliance with this Guideline can be considered provided there is appropriate scientific justification.

In addition to this Guideline, further guidance in specific areas is provided as Part II b of this document.

I.2 Scope and field of application

Good Manufacturing Practice (GMP), is applied to the manufacture of Rubber Products intended to come into contact with foodstuffs and defines Minimum Requirements for Normal Utensils (see Part Ia) and Extensive Requirements for Specific Applications such as multi -use rubber products (see Part Ib)

Good Manufacturing Practice (GMP), will represent existing industrial practices used to achieve production of materials and articles, for direct use which is intended to come into contact with foodstuffs eg, gaskets, pipes, conveyer belts etc.
A very specific application of multi-use rubber articles that falls into food contact regulations are baby teats:.

The basic raw material for Rubber Products is natural or synthetic rubber. This is masticated, to accelerate the reticulation process, and to modify and improve the properties of the finished product. Increasingly complex chemical additives (catalysts, antioxidants, etc.) are added and mixed to obtain a finished rubber compound that, with vulcanization (a chemical reaction that bonds together molecules) is transformed into a material suitable for the manufacture of finished products.

The type of the rubber used and additives used determine the physical, chemical and thermal characteristics of the product.
Rubber products have much in common, for example:

- They are all elastic i.e. they resume their original form after being subjected to deformation.
- They all undergo, an ageing process determined by exposure to ozone, oxygen, light, heat, humidity and/or radiation.
- Their practical use is determined by the interaction of the rubber and the products for which they are used.

Examples of single use and multi use rubber articles are given in annex 1.

I.3 Other Management Systems

This guideline do not include requirements that are specific to other management systems such as environmental, occupational health and safety, or financial management.

Although some companies, especially small and medium size enterprises, that are involved in the production of food contact rubber products, may not have the critical mass for being accredited through a certified Quality System, they always establish an equivalent system.

Manufacturers not having ISO 9000 or similar management systems in place would have to design their process to comply with GMP..

Whatever procedure is adopted, it is essential that every manufacturer of a food contact rubber products maintains a documented internal system aimed at identifying and preventing the production of defective products and, in the case of delayed defects detection, easy product recall.

This guideline enables an organisation to align, adapt or integrate its existing Quality System (QS) with related Quality Management System (QMS) requirements.

Companies working to ISO 9000 Standards are required to prepare and maintain documented procedures (e.g. in writing or through computer archiving) from the purchase of starting materials downstream through the whole production process to shipment.

Producers working to ISO 9000 and/or QMS and /or QC and/or QA comply with a large majority of GMP. The overlap between proposed GMP and other standards and systems

should be clearly understood. Based on this each manufacturer (and inspector) should be able to identify which part of GMP is in place and which other standards need to be established.

All these systems are designed to maintain constant quality of products.

I.4 Quality Management System (QMS)

The Good Manufacturing Practice (GMP) guideline is slightly more extensive than ISO 9000 because it includes extensive coverage of labelling, complaint handling and is important to the development of the industry.

Good Manufacturing Practice (GMP) is integrated with Quality Assurance (QA) and ensures that rubber products are consistently produced and controlled to quality standards appropriate to their intended use as required by a marketing specification.

The concepts of GMP, Quality Assurance(QA), and Quality Control (QC) are interrelated aspects of Quality Management System (QMS).

It should be emphasised that the Quality Management System (QMS) requirements specified in this guideline are complementary to the technical requirements of products and can be used by both internal and external parties. If required certification bodies can use this guideline to assess the organisation’s ability to meet customer and regulatory requirements. The adoption of a Quality Management System (QMS) should be a strategic decision of the organisation.

The Good Manufacturing Practice (GMP) guidelines require that domestic or foreign manufacturers have a quality system for the design, manufacturing processes, packaging, labelling, storage, installation, and servicing of finished rubber products intended for commercial distribution in the market and do not place consumers at risk due to inadequate safety and/or quality.

This assurance is demonsrated through change control proceedures, day-to-day observance of operations, and by periodic audits of the quality system. This quality objective is the responsibility of management and requires the participation and commitment of personnel in many different departments and at all levels within the establishment, and by its suppliers.

To achieve the objective there should be a comprehensively designed and correctly implemented Quality Assurance (QA) system incorporating Good Manufacturing Practice (GMP) and thus Quality Control (QC). It should be fully documented and its effectiveness monitored. All parts of the Quality Assurance (QA) systems should be adequately resourced with qualified personnel in suitable premises and provided with monitoring equipment.

The system will remain dynamic with continuous feedback from monitoring by system audits and management review This will drive both corrective and preventive action. Sufficient personnel with necessary education, background, and experience should be available to ensure that quality system activities are properly and adequately performed.

I.5 Quality Assurance

"Quality Assurance" (QA) is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that rubber products are of the quality required for their intended use.

Quality Assurance (QA) should be a totally integrated systems approach, to satisfy the safety and performance needs of a specific manufacturer, product, and end user-market.

A suitable Quality Assurance (QA) system will execute a Quality Assurance (QA) program by following documented written policies and specifications in order to achieve stated objectives and should ensure that:

1. Rubber products are designed and developed in a way that takes into account the Good Manufacturing Practice (GMP) guidelines;
2. Managerial responsibilities are clearly specified;
3. Systems, facilities and procedures are adequate;
4. Production and control operations are clearly specified and Good Manufacturing Practice (GMP) is adopted;
5. Arrangements are made for the supply and use of the correct raw and packaging materials;
6. Control on intermediates, in-process monitoring and validation activities are carried out;
7. The finished product is processed, packaged/labelled, verified and tested according to defined procedures;
8. Rubber products are not sold or supplied before the Quality Control (QC) department has indicated that each batch has been produced and controlled in accordance with the specific requirements and any other regulations relevant to the production, control and release of rubber products;
9. Satisfactory arrangements exist to ensure that the rubber products are stored, distributed and subsequently handled so that (where appropriate) quality is maintained throughout their shelf life;
10. There is a procedure for self-inspection and/or quality audit which regularly appraises the effectiveness and applicability of the Quality Assurance (QA) system.

In all cases, quality should be considered at the earliest stages in every significant area that has an effect on the quality, safety, and effectiveness of the rubber products.

These areas include product development, design verification and validation, component and/or supplier selection, documentation, development of labelling, design transfer, process development and validation, pilot production, routine manufacturing, test/inspection, device history record evaluation, distribution, service, and complaints.

Complaints and, of course, favorable comments constitute customer feedback that may result in improvements in the products , labeling, packaging or quality system.

I.6. Quality Control (QC)

Quality Control (QC) is that part of Good Manufacturing Practice (GMP) which is concerned with sampling, specifications, testing, documentation and release procedures. This ensures that materials are not released for use or rubber products released for sale or supply, until their quality has been deemed to be satisfactory.

The basic requirements of Quality Control (QC) are that:

1. Adequate facilities, trained personnel and approved procedures are available for sampling, inspecting and testing of raw materials, packaging materials, intermediate bulk and finished products, and where appropriate for monitoring environmental conditions for Good Manufacturing Practice (GMP) purposes;
2. Samples of raw materials, packaging materials and intermediate, bulk and finished products are taken according to procedures approved by the Quality Control (QC) department;
3. Test methods are validated;
4. Records are made which demonstrate that all the required sampling, inspecting and testing procedures were actually carried out and any deviation is recorded and investigated;

5. Records are made of the results of inspection and that testing of materials, intermediate, bulk, and finished products is formally assessed against specification;
6. Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures;
7. No batch of rubber product is released for sale or supply prior to approval by the Quality Control (QC) department,;
8. Reference samples of raw materials and rubber products are retained to permit future examination of the rubber product. The rubber product is retained in its final pack unless exceptionally large packs are produced.

I.7 Term and definitions

In general the terms and definitions given in ISO 9000 series apply. However they may have different meanings in the rubber industry as they do not define terms intended for particular rubber products.

I.7.1 General

Acceptance criteria
The product specifications and the acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject a lot or batch

Airlock
An enclosed space with two or more doors, which is interposed between two or more rooms, e.g., of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for and used by either people or goods.

Authorized person
A person responsible for the release of batches of finished product for sale. In certain countries the batch documentation and/or and the batch test results for a finished product must be signed by an authorized person from the production department before the batch is released for use or sale.

Batch (or lot)
A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form an homogeneous batch.

Batch number (or lot number)
A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc

.

Batch numbering system

Standard operating procedure describing the details of the batch numbering.

Batch records
All documents associated with the manufacture of a batch of bulk or finished product. They provide a history of each batch of product and information pertinent to the quality of the final product.

Bulk product
Any product that has completed all processing stages up to, but not including, final packaging.

Calibration
The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding values of a reference standard. Limits for acceptance of the results of measuring should be established.

Change control
Written procedure describing the action to be taken if a change is proposed that may affect the quality or support system operation. This procedure includes facilities, materials, equipment, processes used in manufacture and the packaging and testing of rubber products.

Certificate of Analysis
A document relating specifically to the test results of a representative sample drawn from the batch.

Clean area
An area with defined environmental control of particulate and/or microbial contamination and constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants.

Complaint
Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a rubber product after it is released for distribution.

Consignment (or delivery)
The quantity of starting material, or of a rubber product, made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

Critical process
A process that may cause variation in the quality of the rubber product.

Cross-contamination
Contamination of a starting material, intermediate product, or finished product with another starting material or production product.

Finished product
A product that has undergone all stages of production, including packaging in its final container and labelling.

Foods

All solid, liquid, animal, vegetable or mineral comestibles either as they are, or after being processed, transformed or mixed and including chewable preparations (e.g. chewing gum) or similar items that can be ingested by man.

Food contact materials
Materials and articles that are intended to come into contact with foods.

In-process control
Checks performed during the production process to monitor and control the process or environment to ensure that the product conforms to its specifications..

Intermediate product
Partly processed material that must undergo further manufacturing steps before it becomes a bulk product.

Lot failure
A lot or batch which has been rejected having failed to meet in-process or final product release specifications.

Manufacture
All process operations from purchase of raw materials and products, through to shipment of finished products..

Manufacturer
A company that carries out at least one step of a manufacturing process.

Marketing authorization (product licence, registration certificate)
A legal document issued by a competent regulatory authority that establishes the detailed composition and formulation of a product. This may include the pharmacopoeial or other recognized specifications of the ingredients of the final product, and could include details of packaging, labelling, and (if required) shelf-life.

Master formula
A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

Master record
Compilation of records containing the procedures and specifications for a finished rubber product.

Non conforming Material
Any material that does not meet manufacturer’s specification or applicable good manufacturing practice.

Nonconformity
Failure to meet a specified requirement.

Packaging
All operations, including labelling, that a bulk product has to undergo in order to become a finished product.

Packaging material
Any material, including printed material, employed in the packaging of a rubber product, excluding any secondary packaging used for transportation or shipment.
Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Positive list
A list of the substances the use of which is authorized to the exclusion of all others.

Process validation
Establishing by objective evidence that a process consistently produces a result or product meeting predetermined specifications.

Processing instructions
Procedures required to produce a finished product including the in-process controls.

Production
All operations involved in the preparation of a rubber product, from receipt of materials, downstream through processing and packaging, to the finished product.

Representative Sample
A number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample is representative of the material being sampled.

Rubber Product
A finished or semi-finished item designed for a specific use and manufactured from rubber or rubber latex by compounding and/or moulding, extrusion, spreading, dipping or other means of fabrication.

NOTE: A rubber product may be made almost entirely of rubber, as for example a medical glove, or it may contain components and reinforcements other than rubber, as for example in a rubber-coated fabric, a tyre, a steel laminated bridge bearing and a rubber hose fitted with a metallic coupling. Rubber products are usually made by the rubber industry. *(ISO 1382:1996 amend.)*

Quarantine
Raw or packaging materials, intermediates, or bulk or finished products physically isolated or separated by other effective means while a decision is awaited on their release, rejection, or reprocessing.

Reconciliation
A comparison, making allowance for normal variation between the amount of product or materials theoretically produced or used and the amount actually produced or used.

Reprocessing
The reworking of all or part of a batch of product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.

Returned product
Finished product sent back to the manufacturer.

Shelf life / expiration dating period
Where appropriate, the time interval during which a raw material or rubber product is expected to remain within the approved specification provided that it is stored under the conditions defined on the label in the recommended containers and closure.

Specification
A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

Standard operating procedure (SOP)
An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation,

maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

Starting material (Raw material)
Any substance of a defined quality used in the production of a rubber product, but excluding packaging materials.

System
A regulated pattern of interconnected activities and techniques that form an organised whole.

Validation
The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

I.7.2 Types of rubber

Elastomer
A non-cross-linked but cross-linkable (vulcanisable) long chain visco elastic polymer with high molecular weight. and elastic properties at room temperature.
At higher temperature and/or under the influence of deforming forces, thermoplastic elastomers exhibit increasing viscous flow, and can be moulded under suitable conditions.

Latex
A colloidal aqueous dispersion of polymeric natural or synthetic rubber particles.

Natural rubber
cis 1,4- polyisoprene obtained from the botanical source Hevea brasiliensis

Rubber (in articles)
Family of polymeric materials which are flexible and elastic. Rubber can be substantially deformed under stress, but recovers quickly to near its original shape when the stress is removed.

Rubber is usually made from a mixture of materials (solid or liquid), and in most articles the base polymer is cross linked by either chemical or physical links. *(ISO 1382:1996 amend.)*

Rubber (raw material)
Natural or synthetic elastic polymer (elastomer) which forms the basis of the compound used in many rubber articles, examples include natural rubber and styrene butadiene rubber. *(ISO 1382:1996 amend.)*

Synthetic rubber
Rubber produced by polymerizing one or more monomers

Thermoplastic rubber

Polymeric mixture or blend of polymers that do not require vulcanization or crosslinking during processing yet have, at normal or low temperatures, (60 - 70°F) elastic properties .

Thermoplastic elastomer
Common commercial term for thermoplastic rubber**.**

Vulcanized rubber
Product of the vulcanization of a compound**.** *(ISO 1382:1996 amend.)*

I.7.3 Compounding ingredients - processes

Accelerators
Chemicals which are added to rubbers to accelerate the rate of vulcanisation. Rubber without accelerators takes twenty or thirty times longer to cure.

Activators
Compounding ingredient used in small proportions to increase the effectiveness of an accelerator.

Additives
A substance compounded into a resin to enhance certain characteristics such as plasticizers (for flexibility), light stabilizers, flame retardants, etc.

Antidegradant
Compounding ingredient used to retard deterioration by ageing

NOTE: Antidegradant is a generic term for certain additives such as antioxidants, antiozonants, waxes and other protective materials

Antioxidant
Compounding ingredient used to retard deterioration caused by oxidation.

Antioxozonant
Compounding ingredient used to retard deterioration caused by ozone

Coagulation
A chemical reaction in which polyvalent ions neutralize the repulsive charges surrounding colloidal particles. The clumping together of solids to make them settle out of solution faster. Coagulation of solids is brought about with the use of certain chemicals, such as lime, alum or polymers.

Compound
Intimate mixture of an **elastomer or elastomers or other polymer forming materials** with all the ingredients necessary for the finished product. *(ISO 1382:1996 amend.)*

Compounding ingredient
Substance added to a rubber or rubber latex to form a mix. The ingredient can be a natural or synthetic raw material which can be of organic or inorganic origin. The ingredient is used with the rubbers to form a compound.

Crosslink
Chemical bond or atom (s) joining two rubber chains or two parts of the same rubber chain as a result of vulcanization.

Crosslinking(the act of)
Insertion of crosslinks between or within rubber chains to give a network structure.

Elasticity
The rapid recovery of a material to its approximate shape and dimensions after substantial deformation by a force and subsequent release of that force. *(ISO 1382:1996 amend.)*

Retarder
Compounding ingredient used to reduce the tendency of a rubber compound to vulcanize prematurely

Softener
Compounding ingredient used in small proportions to reduce the stiffness of a rubber mix or the hardness of the vulcanizate

Vulcanization
Process **(usually involving heat)** in which a **compoun**d, through a change in its chemical structure (for example, crosslinking), is converted to a condition in which the elastic properties are conferred or re-established or improved or extended over a greater range of temperatures. In some cases, the process is carried to a point where the substance becomes rigid *(ISO 1382:1996 amend.)*

Vulcanizing agent
Compounding ingredient that produces crosslinking in rubber**.**

II. MINIMUM REQUIREMENTS

II.1 Scope and field of application

Good Manufacturing Practice (GMP) for rubber products are guidelines that describe the MINIMUM REQUIREMENTS for methods, equipment, and controls required for producing rubber products intended for commercial distribution in the market as required by the marketing specification.

The MINIMUM REQUIREMENTS are applied to (as Category II and III) rubber products intended to come into contact with foodstuffs.

Articles belonging to Category II, if applied as intended, have conditions of contact with food which may cause significant migration of its constituents. The products should comply with a restricted positive list. Migration should be measured at worst case representative conditions in food or food simulants. Migration values should conform with the restrictions specified.

Articles belonging to the Category III, by definition have very limited contact with food. As a consequence migration will be very limited and of no significance. Limited contact is the consequence of time, temperature, surface area or recurrent use. A selection of substances from the more extensive positive list can be taken for the manufacture of the products. In addition the migration will be very limited and therefore no migration experiments are required. Carcinogenic substances may be excluded from this rule.

II.2 Requirements

Good Manufacturing Practice (GMP) guidelines / Quality Management Systems (QMS) provide detailed guidance in the following areas that are in the following paragraphs:

II.2.1 General Provisions
II.2.2 Organization and Personnel
II.2.3 Buildings and Equipments
II.2.4 Control of components and Rubber Materials
II.2.5 Production and Process Controls
II.2.6 Packaging, Labelling, Handling and Distribution
II.2.7 Laboratory Controls
II.2.8 Records and Reports
II.2.9 Returned and Salvaged Rubber Products

II.2.1 General provision

Good Manufacturing Practice (GMP) guidelines for rubber products represent a system for ensuring that products are consistently produced and controlled according to quality standards.
The guidline is designed to minimize the risks involved in any rubber products production that cannot be eliminated through testing the final product.
The Good Manufacturing Practice (GMP) guideline covers all aspects of production; from starting materials, premises and equipment to the training and personal hygiene of staff.

Detailed, written procedures are essential for each process that could affect the quality of the finished product. There should be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process every time a product is made.

Good quality must be built in during the manufacturing process; it cannot be tested into the product afterwards. Good Manufacturing Practice (GMP) guidelines are designed to ensure that mistakes do not occur and to prevent errors that cannot be eliminated through the Quality Control (QC) of the finished product.

Making poor quality products does not save money. In the long run, it is more expensive finding mistakes after they have been made than preventing them in the first place Implementation of Good Manufacturing Practice (GMP) is an investment in good quality Rubber Products. Making and distributing poor quality Rubber Products leads to loss of credibility for everyone: both public and private health care and the manufacturer.

Basic elements of Good Manufacturing Practice (GMP) include:

- Availability of production manuals and instructions;
- Compliance with specified quality requirements for raw materials;
- Appropriate storage and handling
- The application of processes to avoid or remove contamination;
- Specifications for end-product testing;
- Equipment and facilities being properly designed, maintained, and cleaned;
- Standard Operating Procedures (SOPs) be written and approved;
- An independent Quality unit (like Quality Control)

II.2.2 Organisation and Personnel

People are the most important element in any operation, because without the proper personnel with the right attitude and the right training, it is almost impossible to fabricate, package/label, test or store good quality rubber products.
It is essential that qualified personnel are employed to supervise the fabrication of rubber products. The operations involved in the fabrication of rubber products are highly technical and require constant vigilance, attention to details, and a high degree of competence on the part of employees. Inadequate training of personnel, or the absence of an appreciation of the importance of production control, often accounts for the failure of a product to meet the required standards.

II.2.3 Buildings and Equipment

Manufacturing sites should be designed and constructed to permit cleanliness, tidiness and prevent contamination. Regular maintenance is required to prevent deterioration of premises. The ultimate objective of all endeavours is product quality.

II.2.4 Equipment

The fabrication of rubber products of consistent quality requires that equipment performs in accordance with its intended use. Equipment used in the manufacturing process, packing, or holding of a rubber product must be of appropriate design, adequate size, and suitably located to facilitate operations and for its cleaning and maintenance.
Equipment arranged in an orderly manner permits cleaning of adjacent areas and does not interfere with other processing operations. It also minimizes circulation of personnel and optimizes flow of material.
Balances and other measuring equipment of an appropriate range and precision should be available for production and control operations and should be calibrated on a scheduled basis.

Control-laboratory equipment and instruments should be suitable for the testing procedures undertaken.

Production equipment should not present any hazard to the products. The parts of the production equipment that come into contact with the product should not be reactive, additive, or absorptive to an extent that would affect the quality of the product.

II.2.5 Control of components and Rubber Materials

The main objective of a rubber plant is to produce finished products from a combination of different materials

Rubber components, containers and finished products shall at all times be handled and stored in a manner which will prevent contamination.

All materials and finished products should be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation cleaning and inspection.

Particular attention should be given to maintaining batch identity of raw materials, components, semi-finished products, finished products all along the storage and production operations. An adequate traceability system must be well established and effective in use in the plant.

In recent years, the application of validation techniques to increase the level of Quality Assurance (QA) has been emphasized. This has extended to suppliers and is most usually referred to as vendor certification. Vendor certification is a system that assures that a supplier's product is produced under controlled conditions, resulting in consistent quality conformance.

Validation is based on the principle of defect prevention, rather than defect detection and it significantly reduces the need for customer inspection.

Vendor certification is a supplier-customer partnership and can only be successful with the involvement and agreement of both partners. Several key steps are involved in the certification process.

II.2.6 Production and Process Controls

All manufacturing processes are clearly defined, systematically reviewed in light of experience, and shown to be capable of consistently manufacturing rubber products of the required quality that comply with their established specifications.

In-process controls are mostly performed within the production area. They should not carry any risk to the quality of the product.

Contamination of a starting material or of a product by another material or product has to be avoided. This risk of accidental cross-contamination arises from the uncontrolled release of dust, gases, vapours, sprays, or organisms from materials and products in process, from residues on equipment, from intruding insects, and from operators' clothing, skin, etc.

The significance of this risk varies with the type of contaminant and of the product being contaminated. Measures to prevent cross-contamination and their effectiveness should be checked periodically according to standard operating procedures.(i.e. cleaning procedures)

Before any processing operation is started, steps should be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels, or documents not required for the current operation. Any necessary in-process controls and environmental controls should be carried out and recorded.
Any significant deviation from the expected yield should be recorded and investigated.
Measuring, weighing, recording, and control equipment and instruments should be serviced and calibrated at pre-specified intervals and records maintained.

II.2.7 Packaging, Labelling, Handling and Distribution

Where appropriate, procedures designed to assure that correct labels, labelling and packaging materials are used for rubber products are written
Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to a product do not occur during handling. When the quality of a product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

II.2.8 Laboratory controls

Quality Control (QC) is part of Good Manufacturing Practice (GMP) and is concerned with sampling, specifications, and testing. It covers organization, documentation, and release procedures. This ensures that necessary and relevant tests are carried out and that raw and packaging materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality Control (QC) is not confined to laboratory operations but should b involve all activities and decisions concerning the quality of the product.

II.2.9 Records and reports

Good documentation is an essential part of the Quality Assurance (QA) system and, as such, should be related to all aspects of Good Manufacturing Practice (GMP) .

Its aims are to define the specifications for all materials and components methods of manufacture and control, to ensure that all personnel concerned with manufacture know what to do and when to do it, to ensure that authorized persons have all the information necessary to decide whether or not to release a batch of a rubber for sale, and to provide an audit trail that will permit investigation of the history of any suspected defective batch. The design and use of documents depend upon the manufacturer.

Documents should be designed, prepared, reviewed, and distributed with care, should comply with the relevant parts of the manufacturing process and should be approved, signed, and dated by appropriate authorized persons. No document should be changed without authorization.

Documents should have unambiguous contents: the title, nature, and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check.

Reproduced documents should be clear and legible. The reproduction of working documents from master documents should not allow any error to be introduced through the reproduction process.

When a document has been revised, a system should exist to prevent inadvertent use of the superseded version.

Records and associated standard operating procedures should be retained for at least one year after distribution of the batch or ,where appropriate, for at least one year after the expiry date of the finished product.

Written procedures describing the handling of all written and oral complaints regarding a rubber product shall be established and followed. Such procedures shall include provisions for review by the Quality Assurance (QA) unit, of any complaint involving the possible failure of a rubber product to meet any of its specifications and, for such rubber products, a determination as to the need for an investigation.

Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse rubber experience which is required to be reported

II.2.10 Returned rubber products

Returned rubber products shall be identified as such and held. If the conditions under which returned rubber products have been held, stored, or shipped before or during their return, or if the condition of the rubber product, its container, carton, or labelling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality, or purity of the rubber product, the returned rubber product shall be destroyed unless examination, testing, or other investigations prove the rubber product meets appropriate standards of safety, identity, mechanical requirements, quality, or purity.

ANNEX 1

Some examples of single and multi use rubber articles in contact with foodstuffs where marking is possible, impossible/difficult.

Single use:

- Rubber rings for binding vegetables and chicken: No brand name, marking impossible
- Seal for glass bottle : marking impossible/difficult
- Rubber gloves: Marking possible.
- Bottle teats sold direct to hospitals as single use items: Brand name and product identification codes on label or on the packaging or on invoice.

Multiple use:

- Large rubber seals in pressure cookers: Via brand name and type and production codes on part.
- Small rubber seals in pressure cookers, espresso machines etc.: No marking possible, via OEM or identification code on spare part packaging or invoice.
- Rubber seals in drinking bottles and thermos bottles: No marking possible, via OEM or identification code on spare part packaging
- Rubber seals in household supplies: Via production lot code and type code of the device of OEM, spare parts via identification no. on packaging or invoice.
- Bottle teats: Producer or importer printed on article and packaging.
- Glass jar for marmalade and bottles for beverages with adherent rubber seal: printed on the metal cap does not belong to the area of rubber industry.
- Rubber gloves : Marking possible
- Gasket for glass containers : marking impossible/difficult

III. EXTENSIVE REQUIREMENTS

III.1. Scope and Field of Application

The EXTENSIVE REQUIREMENTS are applied to SPECIFIC APPLICATIONS (as Category I) of RUBBER PRODUCTS intended to come into contact with foodstuffs.

Articles belonging to the Category I, if applied as intended, are used in connection with the consumption of food, or, if used as intended, are being or can be expected to be mouthed: the more specific application is represented by child care articles intended for feeding babies, the most important of which are feeding teats. (Babies and very young children are vulnerable consumers due to the relative large food consumption per kg body weight. Therefore the substances allowed for the manufacture of rubber products intended for contact with baby food is very restrictive) Feeding teats are defined as items with the shape of a truncated cone or similar shapes, used as substitutes for the mother's nipple. These products are pierced at their narrowest end in order to allow ingestion of liquids and/or food.

These articles for baby, are regulated by Directive 93/11/EEC concerning the release of N-Nitrosamines and N-Nitrostable substances and EN 12868 concerning Methods for determining the release of N-Nitrosamines and N-Nitrostable substances from elastomer or rubber teats and soothers. Other properties will be governed by an EN standard currently under development.

III.2. Introduction

The EXTENSIVE REQUIREMENTS of Good Manufacturing Practice (GMP) is concerned both with Production and Quality Assurance (QA) and their basic requirements are:

1. Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
2. Manufacturing processes are controlled and any change to the process is evaluated. Changes that have an impact on the quality of the rubber product are where appropriate validated.
3. All necessary key elements for Good Manufacturing Practice (GMP) are provided including:
   - qualified and trained personnel
   - adequate premises and space
   - suitable equipment and services
   - correct materials, containers and labels
   - approved procedures and instructions
   - suitable storage and transport;
4. Instructions and procedures are written in clear and unambiguous language;
5. Operators are trained to carry out documented procedures;
6.- Records are made, manually or by instruments, during manufacturing processes which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the rubber product was as expected. Deviations are investigated and documented;
7. Records of manufacturing processes including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form;
8. The distribution of the rubber products minimizes any risk of their quality;
9. A system is available to recall any batch of rubber product, from sale or supply;
10. Complaints about commercialised rubber products are examined, the causes of quality defects investigated and appropriate measures are taken in respect of the defective rubber products and to prevent re-occurrence.

III.3. Normative reference

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, Quality Management systems — Fundamentals and vocabulary.

III.4. Requirements

Good Manufacturing Practice (GMP) guidelines / Quality Management Systems(QMS) provide detailed guidance for the sections below.:

III.4.1 General Provisions
III.4.2 Organization and Personnel
III.4.3 Buildings and Facilities
III.4.4 Equipment
III.4.5 Control of components and Rubber Materials
III.4.6 Production and Process Controls
III.4.7 Packaging and Labeling
III.4.8 Holding and Distribution
III.4.9 Laboratory Controls
III.4.10 Records and Reports
III.4.11 Returned and Salvaged Rubber Products

III.4.1 General Provisions

Good Manufacturing Practice (GMP) guidelines for rubber products represent a system for ensuring that products are consistently produced and controlled according to quality standards.
They are designed to minimize the risks involved in any rubber product production that cannot be eliminated through testing that final product.

Good Manufacturing Practice (GMP) guidelines cover all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff.

Detailed, written procedures are essential for each process that could affect the quality of the finished product.

There should be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process every time a product is made.

Good quality must be built in during the manufacturing process; it cannot be tested into the product afterwards. Good Manufacturing Practice (GMP) guidelines are designed to ensure that mistakes do not occur and to prevent errors that cannot be eliminated through Quality Control (QC) of the finished product.

Making poor quality products does not save money. In the long run, it is more expensive finding mistakes after they have been made than preventing them in the first place Implementation of Good Manufacturing Practice (GMP) is an investment in good quality Rubber Products. Making and distributing poor quality Rubber Products leads to loss of credibility for everyone: both public and private health care and the manufacturer.

Basic elements of Good Manufacturing Practice (GMP) guidelines include:

- Availability of production manuals and instructions;
- Compliance with specified quality requirements for raw materials;
- Adequate premises and space;
- Appropriate storage and handling conditions;
- The application of processes to avoid or remove contamination;
- Specifications for end-product testing;
- Information to ensure traceability and to maintain production records;
- Equipment and facilities being properly designed, maintained, and cleaned;
- Standard Operating Procedures (SOPs) be written and approved;
- Appropriately qualified and trained personnel;
- An independent Quality unit (like Quality Control and/or Quality Assurance) well trained personnel and management.

III.4.2 Organization and Personnel

RATIONALE

The purpose of these requirements is that people are the most important element in any operation, because without the proper personnel with the right attitude and the right training, it is almost impossible to fabricate, package/label, test or store good quality rubber products.

It is essential that qualified personnel are employed to supervise the fabrication of rubber products. The operations involved in the fabrication of rubber products are highly technical and require constant vigilance, attention to details, and a high degree of competence on the part of employees. Inadequate training of personnel, or the absence of an appreciation of the importance of production control, often accounts for the failure of a product to meet the required standards.

The establishment and maintenance of a satisfactory Quality Assurance (QA) system and the correct manufacture and control of rubber products rely upon people. For this reason there should be sufficient qualified personnel to carry out all the tasks for which the manufacturer is responsible. Individual responsibilities should be clearly understood by the individuals concerned and recorded as written descriptions. All personnel should be aware of the principles of Good Manufacturing Practice (GMP) that affect them.

The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibilities placed on any individual should not be so extensive as to present any risk to quality.

The manufacturer should have an organization chart. All responsible staff should have their specific duties recorded in written descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with the application of Good Manufacturing Practice (GMP) guidelines.

All personnel should be aware of the principles of the GMP guidelines that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs. All personnel should be motivated to support the establishment and maintenance of high-quality standards.

Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

III.4.3 Building and Facilities

RATIONALE

This section requires that the rubber establishment should be designed and constructed in such a manner that it permits cleanliness, orderliness and prevents contamination. Regular maintenance is required to prevent deterioration of premises. The ultimate objective of all endeavours is product quality.

Any building or buildings used in the manufacturing process, packing or holding of rubber product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

Premises should be located, designed, constructed, adapted, and maintained to suit the operations and should not present any hazard to the quality of products. The layout and design should aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

Premises should be cleaned and, where appropriate, disinfected according to detailed written procedures.

Premises should be designed and equipped so as to afford maximum protection against the entry of insects or other animals.

III.4.4 Equipment

RATIONALE:

The purpose of these requirements is to prevent the contamination of rubber product by dust, and by foreign material such as rust, lubricant, and particles coming from the equipment.

Poor design and construction may result in equipment which may be difficult to clean and may require higher degrees of maintenance. Contamination problems may arise from poor maintenance, misuse of equipment, exceeding the capacity of the equipment, use of worn-out equipment, and improper modification of equipment.

Equipment arranged in an orderly manner permits cleaning of adjacent areas and does not interfere with other processing operations. It also minimizes circulation of personnel and optimizes flow of material. The fabrication of rubber products of consistent quality requires that equipment performs in accordance with its intended use.

Equipment used in the manufacturing process, packing, or holding of a rubber product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

The layout and design of equipment should aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

Fixed pipework should be clearly labelled to indicate the contents and, where applicable, the direction of flow.

Balances and other measuring equipment of an appropriate range and precision should be available for production and control operations and should be calibrated on a scheduled basis.

Control-laboratory equipment and instruments should be suited to the testing procedures undertaken.

Washing and cleaning equipment should be chosen and used so as not to be a source of contamination.

Production equipment should not present any hazard to the products. The parts of the production equipment that come into contact with the product must not be reactive, additive, or absorptive to an extent that would affect the quality of the product.

Defective equipment should, if possible, be removed from production and Quality Control (QC) areas, or at least be clearly labelled as defective.

Containers for waste is leak-proof, constructed of metal or other suitable impervious material which is easy to clean or disposable and where appropriate can be closed securely.

Equipment and utensils used for inedible materials or waste are so identified and are not used for edible products.

Log books are maintained daily and secured in a safe location

III.4.5 Control of components and Rubber Materials

RATIONALE

The testing of raw materials before their use has three objectives: confirm the identity of the raw materials, provide assurance that the quality of the rubber product in dosage form will not be altered by raw material defects and obtain assurance that the raw materials have the characteristics that will provide the desired quantity or yield in a given manufacturing process. Faults in the packaging and labelling of a rubber product continue to be a major cause of rubber product recalls.

It is of benefit that all aspects of the production and control of packaging materials are discussed between the manufacturer and the vendor. Finished product tests complement the controls employed during the manufacturing process. It is at this stage that rubber products are either accepted or rejected.

For these reasons, it is the responsibility of each manufacturer, distributor and importer to use adequate specifications and test methods that will ensure that each rubber product sold is safe and meets the standard under which it is represented.

The main objective of a rubber plant is to produce with special attention finished products from a combination of different materials.

There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing and approval or rejection of components of rubber products.

All raw materials and finished products should be quarantined immediately after receipt or processing, until they are released for use or distribution. Rubber components, containers and finished products shall at all times be handled and stored in a manner to prevent contamination.

All materials and finished products should be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation by a first-in, first-out rule.

Bagged or boxed components of rubber materials shall be stored off the floor and suitably spaced to permit cleaning and inspection.

Each container or grouping of containers for components or rubber products shall be identified with a distinctive code for each lot in each received shipment. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status.

(i.e., quarantined, approved, or rejected).

These important precautions are unlikely to completely prevent access to insects and other sources of contamination. Consequently, extermination or elimination programs are also required.

The guidelines also require status identification. This has, on occasion been interpreted as physical labelling of containers.

III.4.6 Production and Process Controls

RATIONALE

This section requires that a number of measures are taken to maintain the integrity of a rubber product from the moment the various raw materials enter the plant to the time the finished dosage form is released for sale. These measures seek to ensure that all manufacturing processes are clearly defined, systematically reviewed in light of experience, and shown to be capable of consistently manufacturing rubber products of the required quality that comply with their established specifications.

These Guidelines also require manufacturers, distributors, wholesalers and importers to maintain a programme of self-inspection. The purpose of self-inspection is to evaluate the compliance with Good Manufacturing Practice (GMP) of all aspects of production and Quality Control (QC).

The self inspection programme is designed to detect any shortcomings in the implementation of Good Manufacturing Practice (GMP) and to recommend the necessary corrective actions.

Production operations should follow clearly defined procedures with the objective of obtaining products of the requisite quality.

All handling of materials and products, such as receipt and quarantine, sampling, storage, labelling, dispensing, processing, packaging, and distribution should be done in accordance with written procedures or instructions and, where appropriate, recorded.

Any deviation from instructions or procedures should be avoided as far as possible. If deviations occur, they should be approved in writing by a designated person, with the involvement of the Quality Control (QC) department, where appropriate.

Checks on yields and reconciliation of quantities should be carried out as necessary to ensure that there are no discrepancies outside acceptable limits.

At all times during processing, all materials, bulk containers, major items of equipment and, where appropriate, the rooms used should be labelled or otherwise identified with an indication of the product or material being processed, its strength (where applicable), and the batch number. Where appropriate, this indication should also mention the stage of production.

Contamination of a starting material or of a product by another material or product has to be avoided. This risk of accidental cross-contamination arises from the uncontrolled release of dust, gases, vapours, sprays, or organisms from materials and products in process, from residues on equipment, from intruding insects, and from operators' clothing, skin, etc. The significance of this risk varies with the type of contaminant and of the product being contaminated.

Measures to prevent cross-contamination and their effectiveness should be checked periodically according to standard operating procedures.(i.e. cleaning procedures)

Any necessary in-process controls and environmental controls should be carried out and recorded.

Defective equipment should be withdrawn from use until the defect has been rectified. Production equipment should be cleaned according to detailed written procedures and stored only under clean and dry conditions.

Any significant deviation from the expected yield should be recorded and investigated.

Measuring, weighing, recording, and control equipment and instruments should be serviced and calibrated at pre-specified intervals and records maintained.

There shall be written procedures for production and process control designed to assure that the rubber products have the identity, strength, quality and purity as required in the specifications. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the Quality Assurance (QA)

These guidelines require that all equipment and lines always bear a label showing their status: clean, to be cleaned, or with the product name and lot number and where appropriate, the phase of processing.

If equipment is permanently installed and used for only one batch of product at a time, it may be acceptable to status label the complete suite.

Some recording system should be introduced to allow reference to the status data in the event of a problem. Alternative approaches include the retention and filing of status labels or the use of log books.

III.4.7 Packaging and Labelling

RATIONALE

This section requires that it is of benefit that all aspects of the production and control of packaging materials are discussed between the manufacturer and the vendor. Faults in the packaging and labelling of a rubber product continue to be a major cause of rubber product recalls.

For these reasons, it is the responsibility of each manufacturer, distributor and importer to use adequate specifications that will ensure that each packaging materials meets the standard under which it is represented. Each packaging material used in the packaging/labelling of a rubber product is covered by specifications that are approved by the person in charge of the Quality Control (QC) department or by a designated alternate meeting the adequacy of test or examination is established and documented.

Only packaging materials released by the Quality Control (QC) department are used in packaging/labelling process.

Outdated or obsolete packaging material is adequately segregated until it is disposed of.

When the programme for packaging operations is being set up, particular attention should be given to minimizing the risk of cross-contamination, mix-ups, or substitutions. Before packaging operations are begun, steps should be taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials, or documents previously used and not required for the current operation. The line clearance should be performed according to an appropriate checklist and recorded.

The name and batch number of the product being handled should be displayed at each packaging station or line.

The correct performance of any printing (for example of code numbers or (where appropriate) expiry dates) done separately or during packaging process should be checked and recorded.

On-line verification of all labels by automated electronic means can be helpful in preventing mix-ups, but checks should be made to ensure that any electronic code readers, label counters, or similar devices are operating correctly.

Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing. Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced should be investigated and satisfactorily accounted for before release.

There shall be written procedures designed to assure that correct labels, labelling, and packaging materials are used for rubber products; such written procedures shall be followed.

III.4.8 Holding and Distribution

RATIONALE

This section requires that conditions of transportation and storage are such that they prevent alterations to the potency, purity and physical characteristics of the raw material, packaging material and finish products. In order to demonstrate that these conditions have been met, standard operating procedures and records for shipping and receiving are available.

Rejected materials and products are clearly marked as such and stored separately in restricted areas or controlled by a system which will ensure that they are either returned to the vendors or, where appropriate, reprocessed or destroyed. Actions taken are recorded.

Each manufacturer shall establish and maintain procedures to ensure that errors, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent errors, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

Each manufacturer shall establish and maintain procedures that describe the methods for authorizing product or raw materials receipt and their dispatch to storage areas and stock rooms, the procedures for control and distribution of finished products to ensure that only those products approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before products are released for distribution. Where a product's fitness for use or quality deteriorates over time, the procedures shall ensure that deteriorated products beyond acceptable fitness for use are not distributed.

III.4.9 Laboratory controls

RATIONALE

Quality Control (QC) is part of Good Manufacturing Practice (GMP) and concerned with sampling, specifications, testing and with the organization, documentation, and release procedures. This ensures that necessary and relevant tests are carried out and that raw materials and packaging materials are not released for use, or products released for sale or supply, until their quality has been judged to be satisfactory. Quality Control (QC) is not confined to laboratory operations but should be involved in all activities and decisions concerning the quality of the product. Although manufacturing and Quality Control (QC) personnel share the common goal of assuring that high-quality rubber products are fabricated, their interest may sometimes conflict in the short run as decisions are made that will affect a company's output. For this reason, an objective and accountable quality control

process can be achieved most effectively by establishing an independent quality control department.

The independence of Quality Control (QC) from manufacturing is considered fundamental.

The responsibility for the approval of all raw materials, packaging materials and finished products is vested in the Quality Control (QC) department. It is very important that adequate controls are exercised by this department in order to guarantee the quality of the finished product.

To maintain this level of quality, it is also important to examine all returned rubber products and to pay special attention to reprocessed rubber products.

The establishment of any specifications, standards, sampling plans, test procedures or other laboratory control mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organisational unit and reviewed and approved by Quality Assurance (QA).

The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

Recently there bas been increased emphasis to provide more details of impurities in rubber substances. This includes both the expected impurities from the synthesis or degradation of the rubber products.

Where specifications and methods are not available, the manufacturer should develop his own based on current scientific practices.

Material and product specifications and test methods for new products are often generated by the research and development department. This is acceptable provided they are ultimately approved by Quality Assurance (QA) and Quality Control (QC) before implementation.

Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, in-process materials, labelling and rubber products comply with appropriate standards of identity, strength, quality and purity.

An appropriately identified sample that is representative of each lot in each shipment of each ingredient shall be retained. The retained sample consists of at least twice the quantity necessary for all tests required to determine whether the ingredient meets its established specifications, except for sterility testing. The retained sample shall be held for at least one year after distribution of the batch or, where appropriate , for at least one year after the expiry date of the finished product.

The rationale for retaining samples is to allow evaluation in the event of a complaint or query. Consequently, it is prudent to retain samples of all ingredients, active and inactive.

III.4.10 Records and reports

RATIONALE

Good documentation is an essential part of the Quality Assurance System and, as such, should be related to all aspects of Good Manufacturing Practice (GMP). Its aims are to define the specifications for all materials and production, packaging/labelling and control methods, to ensure that the Quality Control Department have all the information necessary to decide whether or not to release a batch of a rubber product for sale, and to provide an audit trail that will allow investigation of the history of any suspected defective batch.

Evidence that rubber products have been fabricated and packaged/labelled under prescribed conditions can be maintained only after developing adequate record systems. The information and evidence should provide assurance that imported rubber products are fabricated and packaged/labelled.

Documents should be designed, prepared, reviewed, and distributed with care, should comply with the relevant parts of the manufacturing process and should be approved, signed, and dated by appropriate authorized persons. No document should be changed without authorization.

Documents should have unambiguous contents: the title, nature, and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check. Reproduced documents should be clear and legible. The reproduction of working documents from master documents should not allow any error to be introduced through the reproduction process.

Documents should be regularly reviewed and kept updated. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version.

Records should be made or completed when any action is taken and in such a way that all significant activities concerning the manufacture of rubber products are traceable.

Records and associated standard operating procedures should be retained for at least one year after distribution of the batch or, where appropriate, for at least one year after the expiry date of the finished product.

Data may be recorded by electronic data-processing systems or by photographic or other reliable means. Master formulae and detailed standard operating procedures relating to the system in use should be available and the accuracy of the records should be checked. If documentation is handled by electronic data-processing methods, only authorized persons should be able to enter or modify data in the computer, and there should be a record of changes and deletions; access should be restricted by passwords or other means and the entry of critical data should be independently checked. Batch records electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper print-outs, or other means. It is particularly important that, during the period of retention, the data are readily available.

Procedures shall be established to assure that the responsible officials of the firm, are notified in writing of any investigations conducted under Compliant File, Returned or Salvaging Rubber Product of these guidelines, any recalls, reports of inspections or any regulatory actions relating to good manufacturing practice GMP) guidelines brought by a Competent Authority.

A prudent manufacturer will keep these records until the statute of limitations for liability to the consumer expires.

Written procedures describing the handling of all written and oral complaints regarding a rubber product shall be established and followed. Such procedures shall include provisions for review by the Quality Assurance (QA) unit, of any complaint involving the possible failure of a rubber product to meet any of its specifications and, for such rubber products, a determination as to the need for an investigation.

A written record of each complaint shall be maintained in a file designated for rubber product complaints.

The file regarding such rubber product complaints shall be maintained at the establishment where the rubber product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility.

III.4.11 Returned rubber products

RATIONALE

The purpose of a recall is to remove from the market a rubber product that represents an health risk.

Rubber products that have left the premises of a manufacturer, distributor, wholesaler and importer can be found in a variety of locations. Depending on the severity of the health risk, it may be necessary to recall a product to one level or another. Manufacturers, distributors, wholesalers and importers are expected to be able to recall to the consumer level if necessary. Additional guidance on recalls can be found in a document entitled "Product Recall Procedures".

Returned rubber products shall be identified as such and held. If the conditions under which returned rubber products have been held, stored, or shipped before or during their return, or if the condition of the rubber product, its container, carton, or labelling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality, or purity of the rubber product, the returned rubber product shall be destroyed unless examination, testing, or other investigations prove the rubber product meets appropriate standards of safety, identity, mechanical requirements, quality, or purity.

Records of returned rubber products shall be maintained and shall include the name and label of the rubber product form, lot number (or control number or batch number), reason for return, quantity returned, date of disposal, and ultimate disposal route of the returned rubber product.

If the reason for a rubber product being returned implicates associated batches, an appropriate investigation shall be conducted. Procedures for holding, testing, and reprocessing of returned rubber products shall be in writing and shall be followed.

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TRACEABILITY APPLIED TO TISSUE PAPER, KITCHEN TOWELS AND NAPKINS

I. SCOPE

This document describes procedures to ensure traceability of tissue paper kitchen towels and napkins ("kitchen towels and napkins").[1]

II. GENERAL INFORMATION

Kitchen towels and napkins have specific technical characteristics and perform specific functions that differentiate them from paper and board packaging materials and other paper products. They are multi-purpose products that have a broad cleaning and absorption function and are not primarily intended for food contact. However, sometimes they are put into contact with foodstuffs by the final users.

The limited and short-term use in food contact means that consumer exposure is very low.
In contrast with food packaging materials, kitchen towels and napkins are not primarily designed for food contact. Consumer studies have shown that the main use of tissue products is for hygiene and cleaning, and that use in contact with foodstuffs is limited. For instance, it is estimated that only 27% of buyers of kitchen towels regularly use them in contact with food and that on average less than one kitchen towel (or about 1.2 gr.) is used in food contact per day per person.[2] In addition, kitchen towels and napkins are soft and exhibit a lack of structural resistance. Once they absorb a liquid they lose their properties and cannot be reused. Consumer studies confirm that, in case of food related use, the predominant function is to absorb moisture or fat and that food contact is typically limited to a few seconds. Use over 15 minutes is rare.[3]

In addition, the manufacturing processes used are designed to reduce the amount of impurities and contaminants, and the high level of purity of the products has been confirmed.[4] Migration studies have also demonstrated the low migration profile of kitchen towels and napkins.[5]

Kitchen towels and napkins are not covered by the other provisions of the Code of Good Manufacturing Practice and this Appendix contains specific principles of traceability.

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[1] For the purposes of this Appendix, professional towels/wipes used in a food environment are also considered kitchen towels.

[2] IPSOS kitchen towel survey, November 1999. The results of this study have been further confirmed by an internal study commissioned by Procter & Gamble.

[3] IPSOS kitchen towel survey, November 1999.

[4] "Migration Studies on Tissues in Contact with Food", Council of Europe Committee of Experts on Materials Coming into Contact with Food, Ad Hoc Group on Tissue Papers, RD 6.3D/1-39#1; and "Survey on Tissue Papers in Food Contact", Jean-Yves Escabasse, November 1999.

[5] "Migration Studies on Tissues in Contact with Food", Council of Europe Committee of Experts on Materials Coming into Contact with Food, Ad Hoc Group on Tissue Papers, RD 6.3D/1-39#1; and "Test report on presence of fluorescent whitening agents in two samples", Council of Europe Committee of Experts on Materials Coming into Contact with Food, Ad Hoc Group on Tissue Papers, RD 6.3D/2-39#1.

III. TRACEABILITY PRINCIPLES

In determining relevant traceability principles, account has to be taken of consumer exposure and the production processes. The principles contained in this Appendix, together with the recommendations contained in the Council of Europe Guidelines on Paper Kitchen Towels and Napkins, contribute to achieve a high level of traceability for kitchen towels and napkins.

Traceability of finished products and raw materials enables an efficient recall procedure within a tissue mill where kitchen towels and napkins are produced and along the supply chain, and therefore further contributes to ensuring consumer safety. The information on traceability can also be made available to competent authorities if required.

a. Labelling of finished products

All finished products should be labelled so that relevant data of the production history can be traced.

b. Other procedures

It is recommended that manufacturers of kitchen towels and napkins put in place the following procedures:

(i) For each delivery of raw materials, the date of delivery and the name of the supplier should be recorded. In addition, each delivery should be inspected on receipt to verify that it complies with relevant requirements. This information shall be kept for at least three years.

(ii) Relevant documentation within the quality management system on the manufacturing site should be kept to enable identification of the finished products and raw materials that are considered to be involved in any recall of defective finished products.

(iii) Manufacturers of kitchen towels and napkins should be able to identify the packaged kitchen towels and napkins, for instance by a code. Such identification should allow a link between the product and the manufacturing site and date of production to be made. The link between the identification of the product and the customer should be recorded and communicated to the customer where appropriate.

TRACEABILITY APPLIED

IN THE WOODEN CRATE INDUSTRY

I. SCOPE

The present guide describes how traceability should be implemented in the wooden crate industry. It therefore, does not include the operations performed by fillers once the crates have left the manufacturing plant.

II. GENERAL INFORMATION

II.1. Document development

This document was developed by CEI-Bois

II.2. Wooden crates production process

Wooden crates for fruit and vegetables are made mainly of poplar. Member State regulations allow the use of other wood species like pine, beech and eucalyptus. The systemic analysis of crate production is as follows:

- Trees cropped
- Logs delivered to the factory
- De-barking
- Cutting into sections
- Peeling (or sawing) to produce laths.
- Plywood production.
- Component production: heads (width), sides (length) and bottoms.
- Component assembly

Dependant on member state regulations and the properties of the wood species wooden crate factories may or may not carry out the whole range of production processes:

- Integrated factories cover the whole range of production process.
- Component producers manufacture either heads and/or bottoms and/or sides.
- Assemblers buy components and assemble them.

Sawn slices and plywood are generally bought from sawmills and plywood producers. However, wooden crate factories (mainly in Spain, but also in South America, Chile and in Eastern Europe) may produce their own plywood and/or sawn wood.

Once the crate has been assembled, it is sent to the filler.

II.3. Industry responsibility

In considering the production processes above. This guide will describe how traceability should be implemented in each step of the wooden crate production process. Each manufacturing company will need to carry out all of the steps related to the production processes under their control.

III. TRACEABILITY INFORMATION

To build a traceability system we will consider the components of the crates as starting materials. Therefore, those components will be individually identified and the information needed to ensure traceability will be transferred to the assembling companies.

Traceability upstream is very difficult as the crate components can be built using wood from several different trees and traceability of the raw materials (Poplar or Pine) is unnecessary provided the wood from the trees is untreated (i.e. is designated for food contact applications).

Each manufacturing plant will decide how to define its production lots and how those lots are identified (number, production date, etc). In this document we will refer to that identification as "lot number"

III.1. Component manufacture

III.1.1. Plywood

a) Process description

The following steps are carried on:

- Debarking
- Cutting into sections
- Peeling into veneers of same dimensions
- Gluing and assembling in warming press
- Cutting

Poplar logs are debarked and cut into pieces of 1 meter long (approx.). Then, each piece goes to a peeling machine, producing long slices of poplar (1mm thick) which are cut into slices. The slices are transferred to a machine where they are warmed, glued and pressed to form plywood. This plywood may be cut to meet the customer's specification.

b) Incoming information

For the poplar just a copy of each delivery invoice is needed.

c) Internal information

The company producing plywood has to keep a record of the lots produced and the destination of those lots (customer to whom the lot was shipped). This information can be kept in paper or in electronic format.

d) Outgoing information

When the plywood is shipped to the customer, the freight documents will include the plywood lot numbers.

III.1.2. Heads

a) Process description

The plywood, peeled poplar or pine coming from sawmills (depending on the material used) is cut to the specifications needed to build the heads.

Corner pieces are cut to specification and stapled to the plywood, the sawn wood or the peeled poplar (depending on the material used) to form the head.

b) Incoming information

Plywood, sawn wood and peeled poplar: lot numbers

c) Internal information

c.1.- External Head Manufacturers

The company producing heads has to keep a record of:

- Lot numbers produced
- The link between head lots produced and the lot numbers of the materials used (plywood, sawn wood or peeled poplar)
- The destination of each head lot produced (customer to whom the lot was shipped).

This information can be kept in paper or in electronic format.

c.2.- In–house Head Manufacturers

In house manufacture is a continuous process and therefore there is no need to identify individual head lot numbers. However the companies will have to keep record of:

- The link between the lot numbers of the crate produced and the lot numbers of the materials used (plywood, sawn wood or peeled poplar)
- The lot numbers of each crate produced and their destination (customer to whom the lot was shipped).

This information can be kept in paper or in electronic format.

d) Outgoing information

When the heads are shipped to the customer, the freight document will include the head lot numbers.

III. 1.3. Sides

a) Process description

Plywood, sawn wood or peeled poplar (depending on the material used) is cut to specification for the sides of the crates.

b) Incoming information

- Plywood, sawn wood, peeled poplar: lot number

c) Internal information

c.1.- External Side Manufacturers

The company producing sides has to keep a record of:

- Lots produced
- The link between the lot numbers of the sides produced and the lot numbers of the materials used (plywood, sawn wood or peeled poplar)
- The lot numbers of each side produced and their destination (customer to whom the lot was shipped).

This information can be kept in paper or in electronic format.

c.2.- In–house Side Manufacturers

In house manufacture is a continuous process and therefore there is no need to identify individual side lot numbers. However the companies will have to keep record of:

- The link between the lot numbers of the crate produced and the lot numbers of the materials used (plywood, sawn wood or peeled poplar)
- The lot numbers of each crate produced and their destination (customer to whom the lot was shipped).

This information can be kept in paper or in electronic format.

d) Outgoing information

When sides are shipped to the customer, the freight document will include the side lot numbers.

III.1.4.Bottoms

a) Process description

The following steps are carried on:

- Debarking
- Cutting into sections
- Peeling
- Sliced at the needed measurements
- Pieces assembling

Poplar logs are debarked and cut into pieces. Each piece goes to a machine which peels the log, producing long slices of poplar which are cut to the bottoms specification. The bottom is then assembled.

b) Incoming information

Copy of the wood delivery invoice.

c) Internal information

The company manufacturing bottoms must keep a record of the lot numbers produced and the destination of those lots (customer to whom the lot was shipped). This information can be kept in paper or in electronic format.

d) Outgoing information

When the bottoms are shipped to the customer, the freight document will include the bottom lot numbers.

III.2. Crate assembly

a) Process description

The following steps are carried on:

- Laths printed (sides and/or heads) if requested by the customer
- Assembly of heads and sides (framing)
- Assembly of the bottom to the frame (bottoming)

b) Incoming information

- Side lot numbers if supplied externally
  - Head lot numbers if supplied externally
  - Bottom lot numbers if supplied externally
  - If any of the components have been manufactured internally then the lot numbers of the materials used (plywood, sawn wood or peeled poplar) will be required.

c) Internal information

The company producing crates must keep a record of:

- Lot numbers of crates produced
- The link between the lot numbers of the crate produced and the lot numbers of the components used (heads, sides and bottoms)

- The lot numbers of each crate produced and their destination (customer to whom the lot was shipped).

This information can be kept in paper or in electronic format.

d) Outgoing information

Traceability is maintained either by:

- Marking: The crate can be marked with the name of the Manufacturing company and the date of manufacture. For those companies with GROW license in Spain, France, Germany and Benelux, marking the license number of the manufacturer. In France, an identification number is provided by the authorities which when printed on crates identifies that manufacturer,
- or
- Documents: When the crates are shipped to the filler, the freight document will include the crate lots numbers.

IV. RECALL

Following the process described in chapter 3, the crates shipped to fillers are fully traceable..

If a problem is identified at retail level requiring the recall of crates, using upstream traceability documentation the problem component can be identified and a decision taken on problem crate withdrawal.

The process would be:

a) If there are no markings on the crate

1. The retailer identifies his supplier.
2. The supplier (filler), through his records, identifies the company that supplied the problem crates and the crate lot numbers.
3. The crate manufacturer, through his records, identifies the fillers to whom crates of the same lot were shipped.
4. If the problem comes from a component of the crate, the crate producer, through his records can identify the lot numbers of the crate components and also the crate lots produced with the damaged component’s lot.
5. The crate producer will contact the fillers that used crates that are to be taken out of the market.
6. The fillers through his records will contact the customers to whom the crates were shipped with product. They will proceed to take out of the market the problem crates.

b) If the GROW license and the production date or lot number are printed on the crate.

1. The crate manufacturer can be contacted directly.
2. The crate manufacturer, through his records, identifies the fillers to whom crates of the same lot were shipped.
3. If the problem comes from a component of the crate, the crate producer, through his records can identify the lot numbers of the crate components and also the crate lots produced with the damaged component’s lot.
4. The crate producer will contact the fillers that used crates that are to be taken out of the market.
5. The fillers through his records will contact the customers to whom the crates were shipped with product. They will proceed to take out of the market the problem crates.