

**Traceability APPIED 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.

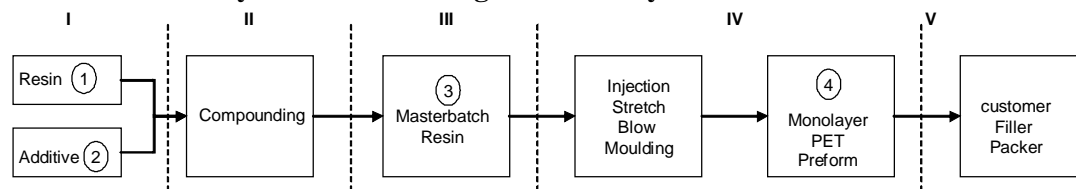
There are also cases where finished products are sold directly to consumers eg multiple use containers for food storage in the fridge and stretchable cling films.

.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

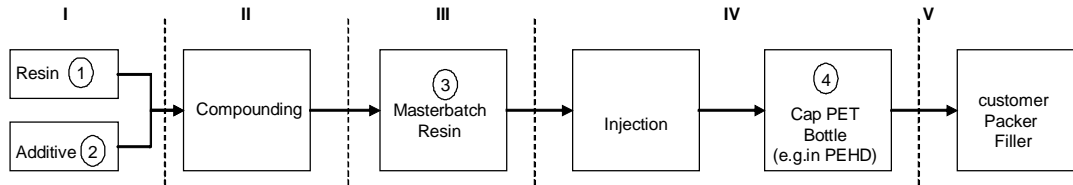
II.3.1 Case study 1: Manufacturing of a monolayer PET bottle



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:



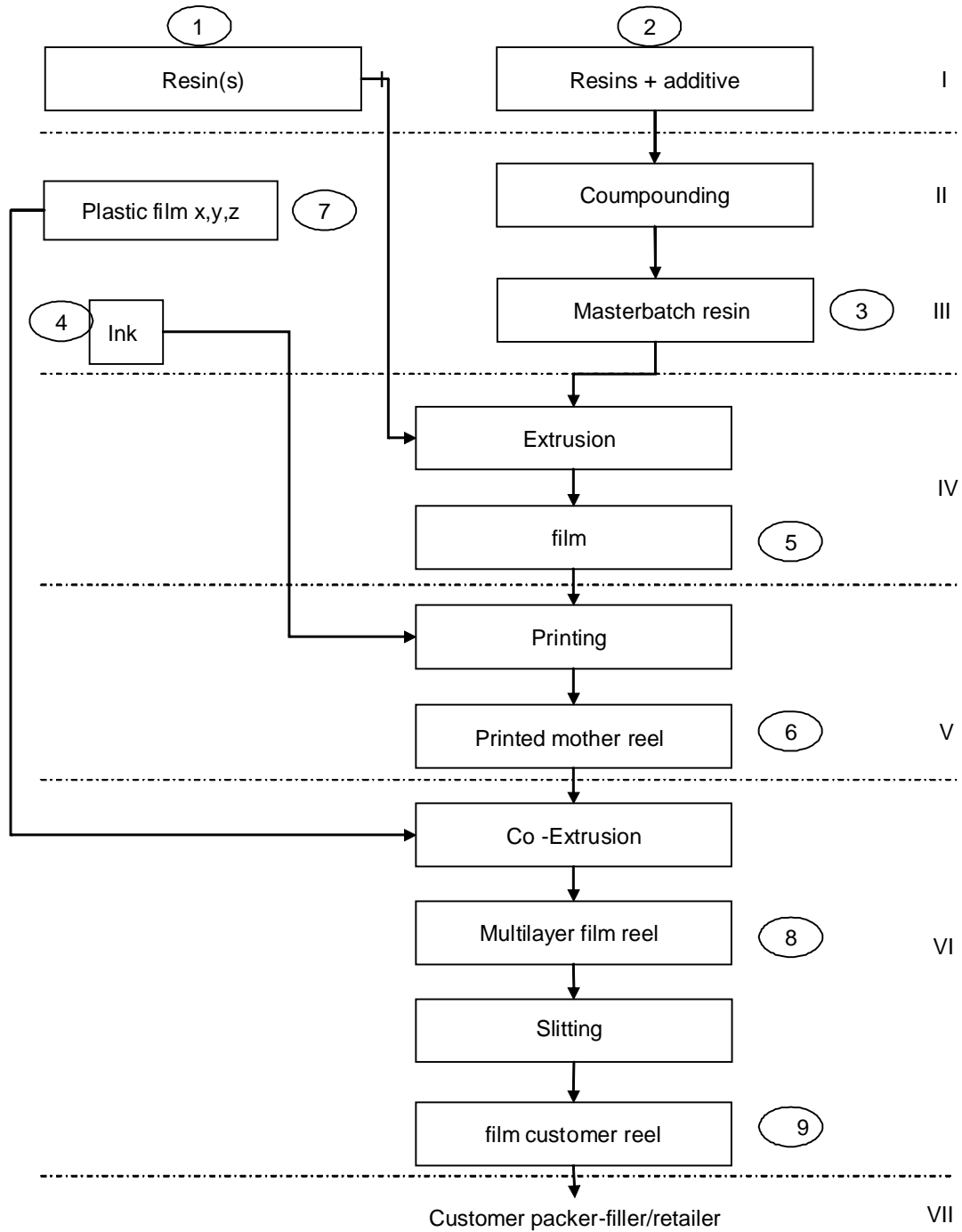
The cap is manufactured using a similar process as that used to manufacture preforms. However the raw materials and additives used are different.

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.

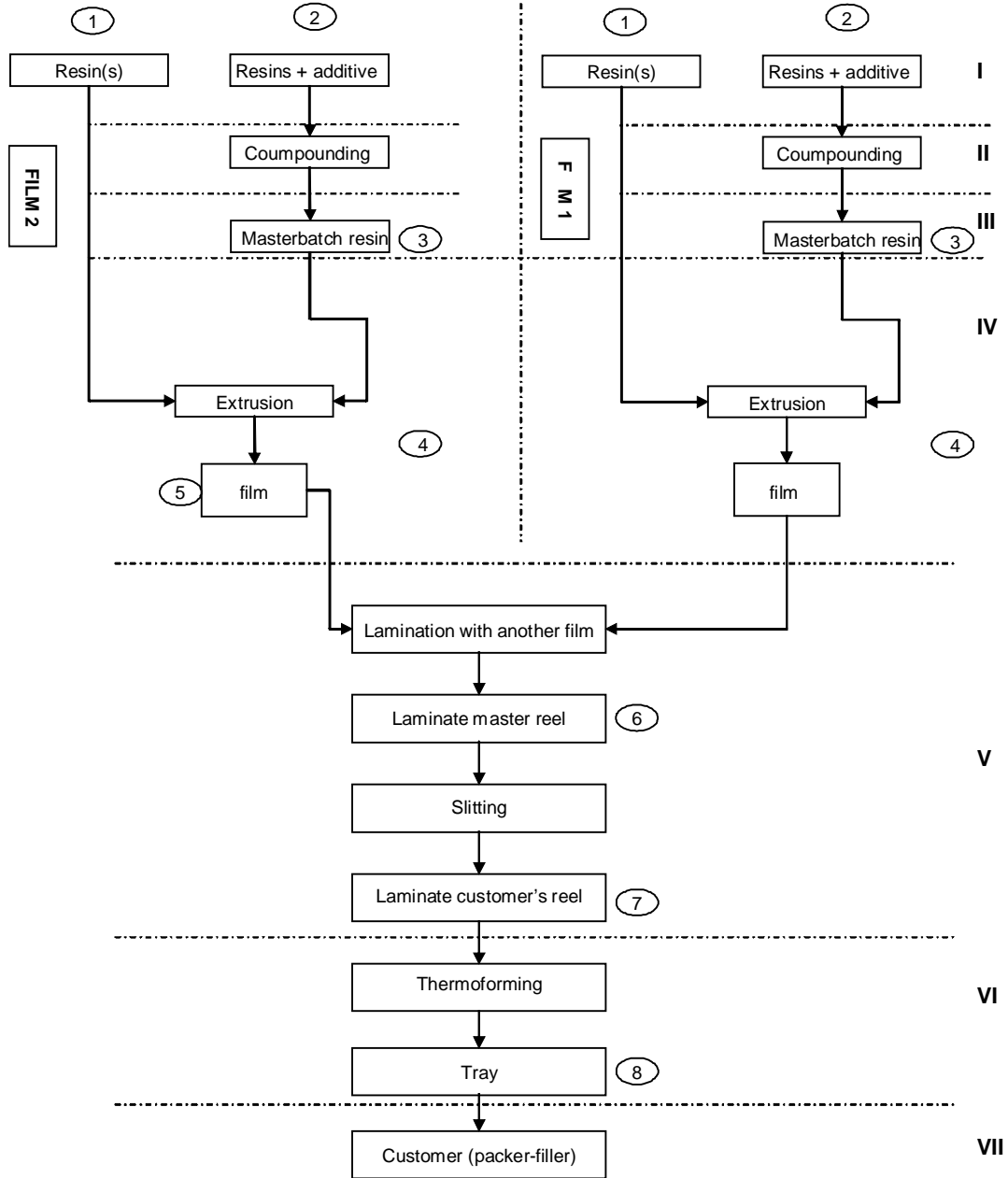
Making of co-extruded multilayer film reel



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

Production of thermoformed trays for food packaging from laminated film

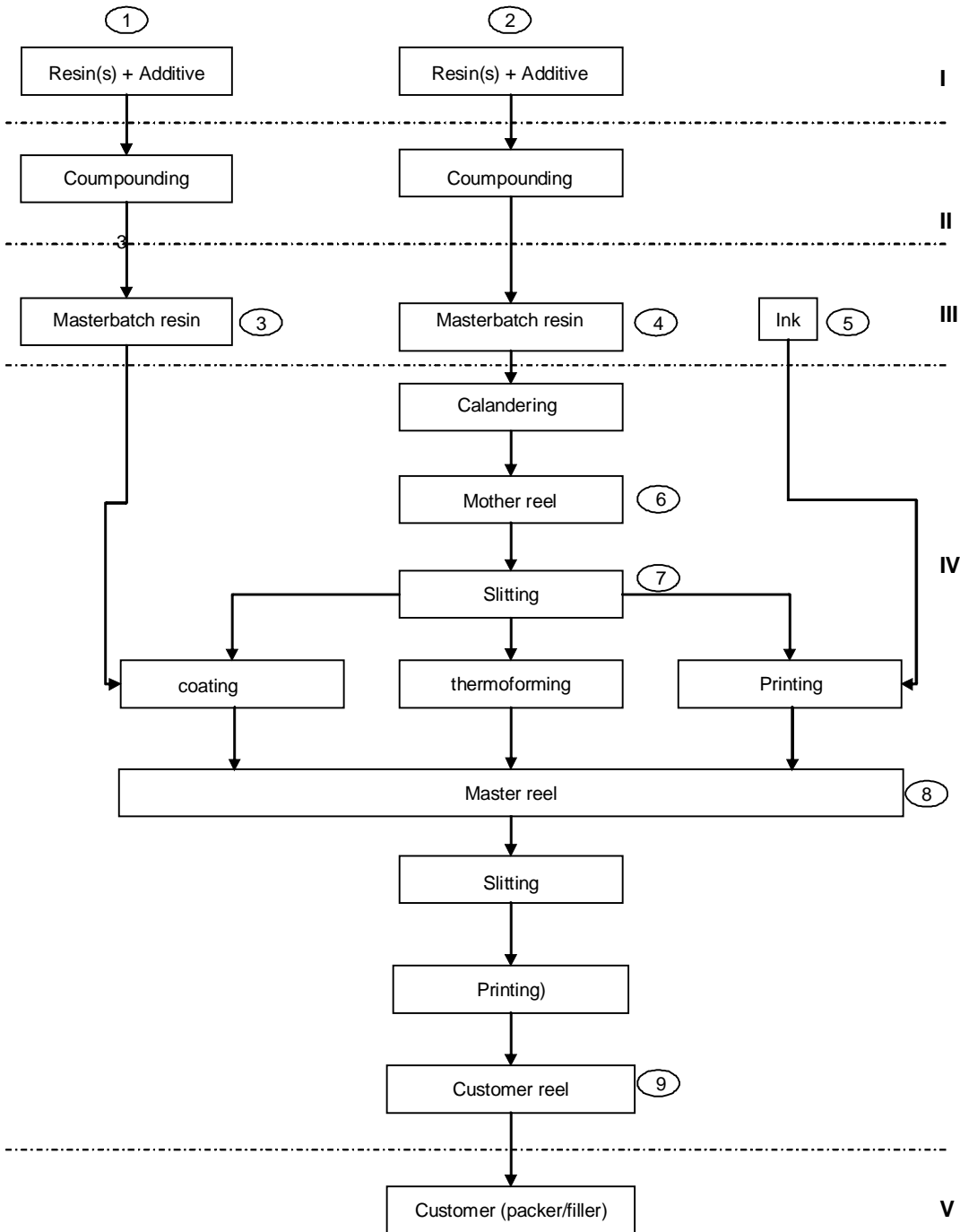
A film laminated with another film, slit and thermoformed into a tray. At consumer unit level, food is packaged and another film product is used to provide a lid.



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

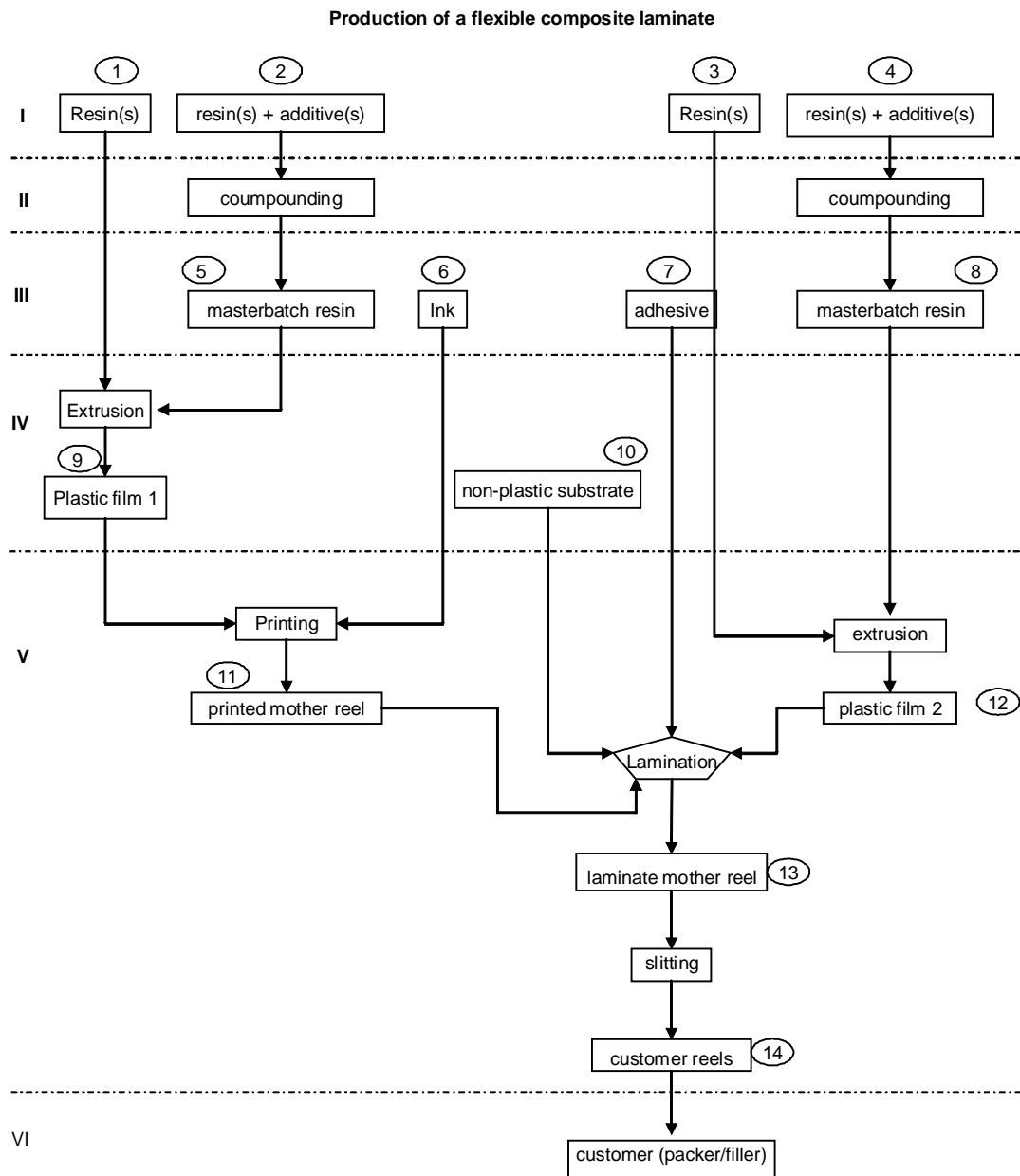
Film production by calendering

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. 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 in 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 V 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, full 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 not 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.