

Guide to good manufacturing and hygiene practices for metal packaging in contact with food



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Preface

This guidance document has been produced by the membership of EMPAC¹ and SEFA². Its aim is to provide guidance on the maintenance of good manufacturing practices and good hygiene practices in the manufacture of metal cans, ends, closures, and metal drums, where the end-use is for contact with foodstuffs.

This guide was developed to reflect the strong commitment of the European metal packaging industry to comply with food contact and consumer safety requirements. The use of this guide is voluntary but strongly recommended.

This guide has been compiled under the auspices of the Food Contact Commission of EMPAC.



¹ European Metal Packaging – The association of the manufacturers of light metal packaging in Europe

² European Association of Steel Drum manufacturers

Overview of EMPAC – Its mission and activities

EMPAC is the successor to SEFEL³ the secretariat formerly representing the manufacturers of light metal packaging in Europe. SEFEL operated between the years of 1959 and 2006. EMPAC takes a significantly different approach to the former SEFEL in that it has added a measure of 'vertical integration' into its structure by having as 'partners' upstream elements of the supply chain, such as the suppliers of packaging steel. Through this vertically integrated approach, which will evolve further with time, EMPAC's presence and visibility is enhanced.

EMPAC is the umbrella association representing the manufacture of rigid metal packaging across Europe, and has a substructure of national associations, contact details for which can be found via the EMPAC website (www.empac.eu). It provides guidance to its members in areas such as food safety, environment and standardisation. Much day-to-day work is carried out at national level, but the key issues are addressed through 'Technical Commissions', the Food Contact Commission responsible for this document being one of the key ones. Others address issues such as standardisation, metal substrate developments, environmental matters and transport of dangerous goods.

EMPAC promotes rigid metal packaging as a 'smart and sustainable' choice, especially for fillers of foods and beverages, and retailers, because it:

- prevents product spoilage, is abuse resistant and ensures that products remain fit for use over a long shelf life.
- maintains safe, nutritious and wholesome food.
- is economical through highly efficient manufacturing and filling processes.
- is produced from viable sources of primary and recycled materials.
- is infinitely recyclable without loss of quality.
- has an excellent record in resource minimisation through reducing the amount of material used consistent with meeting the requirements of manufacture, storage, distribution and marketing (saving energy and reducing CO₂ emission).

These represent a direct technical translation of the six sustainability messages that form the basis of EMPAC's overall strategic activity. It is the mission of the Food Contact Commission (FCC) to maintain in the mind of customers and consumers alike the safety record and credibility of our packaging products. It strives to achieve this in a proactive and well informed way. Food safety and integrity is an ever growing important issue for regulators and the whole supply chain through to the final consumer in all parts of the world. It is, therefore, an essential part of our sustainable development strategy and the guarantee for our industry's continuous and balanced development.

In its turn, EMPAC FCC belongs to the multi-association Light Metal Packaging Joint Industry Group (JIG), with international representation from chemical suppliers through to food fillers. As such a unified body, JIG brings together the knowledge and expertise of the entire value chain allowing an efficient 'single voice' response to food contact issues.

³ Secrétariat Européen des Fabricants d'Emballages Métalliques Légers

Overview of SEFA – Its mission and activities

SEFA (www.sefa.be), the European Association of Steel Drum Manufacturers was founded in 1953. Drum manufacturers range from large international organisations to small independent specialist manufacturers in Europe, Africa and the Middle East. Manufacturers of steel for drums, as well as of machinery and equipment, serve as supplier members. The association represents and promotes the interests of companies involved in the production of new steel drums and pails with a capacity ranging from 30 to 240 litres. Through several statutory bodies, SEFA offers its members opportunities to meet and exchange information and views on technical, standardisation, regulatory, promotional, environmental and general issues of common interest. In particular, the association defends members' views to governments and to European as well as international bodies. Above all, in doing so, SEFA aims to promote the use of large metal packaging and to secure a basis for a prospering industry.

Acknowledgements

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The input of the national Empac metal packaging trade associations, and their members, is recognised with a special thanks to:

AME – Asociación Metalgráfica Española, Spain
ANFIMA – Associazione Nazionale fra i Fabbricanti di Imballaggi Metallici ed Affini, Italy
MEG – Metalemballagegruppen, Denmark
MPMA – Metal Packaging Manufacturers Association, UK
Sekasel – Hellenic Association of Steel Packaging Manufacturers, Greece
SNFBM – Syndicat National des Fabricants de Boîtes, Emballages et Bouchages Métalliques, France
SVHM – Schweizerischer Verband der Hersteller von Metallverpackungen, Switzerland
VBI – Vereniging van Blikverwerkende Industrie, Netherlands
VMV – Verband Metallverpackungen, Germany

Citations for assistance on content are also acknowledged from the following supply chain associations:

APEAL – Association of European Producers of Steel for Packaging, Brussels
CEPE – European Council of the Paints, Printing Inks and Artists' Colours Industries, Brussels
EAA – European Aluminium Association, Brussels
CIAA – Confederation of the Food & Drink Industries of the European Union, Brussels
ILSI – International Life Sciences Institute, Brussels

The citation of EN 15593 "Packaging - Management of hygiene in the production of packaging for foodstuffs - Requirements" is acknowledged.

1 Purpose and scope

1.1 Introduction

1.2 Scope

1.3 Light metal packaging and drums – the European market

1.1 Introduction

Manufacturers of metal packaging and closures intended to come into contact with food intended for humans or animals are obliged to supply fit-for-use products ensuring consumers' health protection. This guide recommends in detail the necessary good hygiene and manufacturing practices to meet this requirement. Elsewhere in this guide also are details of the European, national and USA regulations and standards that the metal packaging industry will need to comply with to fulfil its obligation.

In part, this is the sector's response to Commission Regulation (EC) No. 2023/2006, in conjunction with Regulation (EC) No. 1935/2004 (hereinafter referred to as the Framework Regulation) on materials and articles intended to come into contact with food, obliging manufacturers of food contact materials and articles to apply good manufacturing practices.

The guide covers all the manufacturing process stages from coil cutting to the shipping of ready-for-use empty cans, drums, ends and various other components.

We must stress that this guide should not be considered as a set of regulations in itself, therefore it remains essential to study and refer to the applicable official texts in the markets where the filled containers are sold. The cornerstone of this guide is, however, the European market and its regulatory basis.

1.2 Scope

Where the words 'food' or 'foodstuffs' are used in a generic way, their meaning is the totality of all food and beverages, both of which, in general, are subject to the same regulatory forces and constraints. However, for the purposes of market shape, analysis and trends, the two are often quoted separately. Although the primary objective of the guideline is to ensure the proper conditions for human food metal packaging manufacture, the same principles should also apply in practice to the manufacture of metal packaging for animal foods.

Included in the scope of this document are:

- Cans and ends for foodstuffs
- Pails and drums where used for foodstuffs
- Metal caps, lids and crowns for bottles and jars for foodstuffs

Not currently included are:

- Aluminium monobloc aerosols
- Collapsible aluminium tubes
- Aluminium or steel beer kegs
- Semi-rigid aluminium trays

1.3 Light metal packaging and drums – the European market

In 2006 the European metal packaging manufacturing industry (EU 15) was characterised by:

- An annual turnover of approximately 9 billion Euros
- Utilisation of 4,200,000 tonnes of steel
- Utilisation of 410,000 tonnes of aluminium
- Production of approximately 110 billion packaging units,
- employment of a workforce over 50,000 persons

With the expansion of the EU, these figures will continue to increase.

The food industry is by far the major market for metal packaging, taking an estimated 85% by weight of the European metal packaging industry's output.

The spectrum of the metal packaging market for food contact can be described by:

- Processed foods:
 - Human foods – Vegetables, fruit, fish, meat, ready-made meals, baby food, cream desserts, custard, puddings, milk products, pickles.
 - Petfood – primarily for dogs and cats (not treated in all countries' regulations as for human food, but the industry in general applies the same high standards to both).
- Beverages:
 - Non processed: carbonated and non-carbonated soft drinks, fruit syrups, dietetic drinks, wines, other alcoholic beverages, water
 - Processed: Fruit juices, beers etc, tea, coffee.
- Non processed food:
 - Dry: Sweets, confectionery, savouries, biscuits, milk powder, infant formula, tea, coffee, other powdered beverages.
 - Wet: salad/cooking oils, butter oil, preserves.

2 **Due diligence**

2.1 **Introduction**

2.2 **Suitability for purpose**

2.3 **Process control through hazard analysis**

2.4 **Traceability**

2.1 Introduction

The Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food requires that such materials and articles, including food packaging, are manufactured in compliance with good manufacturing practice. The application of good manufacturing practice should ensure that such materials and articles do not transfer their constituents to food in quantities which could;

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

In 2006, the European Commission further emphasised the importance of having Good Manufacturing Practice regimes in place via Commission Regulation (EC) No. 2023/2006 on “good manufacturing practice for materials and articles intended to come into contact with food.”

It is considered that the utilisation of appropriate manufacturing processes and hazard analysis and control systems, under the umbrella of a management systems such as ISO 9000 and ISO 22000 (see later), should satisfy the requirements of Good Manufacturing Practice laid out in this Regulation. However, the adherence to an industry Good Manufacturing and Hygiene Practice recommendation, as in this case produced by EMPAC for the guidance of the manufacturers of light metal packaging and drums, provides a further insurance against contamination of food by the packaging itself and against loss of packaging integrity.

2.2 Suitability for purpose

Part of due diligence is to ensure by dialogue, more preferably by a formally recorded approach, that there is an understanding between the packaging supplier and his customer on the performance capability of the packaging on the one hand and the product and its conditions of use on the other. The packaging supplier therefore must be fully aware of the product type and nature, filling conditions, storage conditions and timescale, etc, before a contract to supply is made. On the other hand, the filler is primarily responsible for informing the packaging supplier of any changes to product or their conditions of use. This should be an integral part of the quality assurance process. Whilst it is the responsibility of the packaging manufacturer to ensure that the packaging is suitable for the declared purpose, it remains the responsibility of the filler to ensure ultimate suitability of the filled package for market.

2.3 Process control through hazard analysis

It is recommended that individual Critical Control Points are identified by local risk assessment for each process. A Critical Control Point (CCP) is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. We can define a CCP as a key step at which control must be applied to prevent or minimise issues relating to packaging integrity and food contact. Some typical potential hazards that should be considered when identifying CCPs are given for the different generic processes in chapter 6. These are however only for guidance and it should not be assumed that the lists are exhaustive. Different plants, processes and materials may be expected to have different CCPs.

2.4 Traceability

A further part of due diligence is to ensure proper traceability along the supply chain. Article 17 of Framework Regulation (EC) No. 1935/2004 calls for “the traceability of materials and articles (intended for use in contact with food) shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.” The light metal packaging industry has contributed towards an initiative by many packaging converter sectors to develop and publish general traceability principles to adhere to, with each sector adding in detail how this is accomplished.

This document – “Industrial guidelines for traceability of materials and articles in contact with foods” of 30th May 2006 – is available for public view on the European Commission’s Joint Research Centre website at:

http://crl-fcm.jrc.it/index.php?option=com_docman&task=cat_view&gid=41&Itemid=57

The detail specific to metal packaging is at Annex 2 Part 2.

3 Description of bought-in materials

3.1 **Introduction**

3.2 **Steel**

3.3 **Aluminium**

3.4 **Organic coatings**

3.5 **Polymer coated metal**

3.6 **Foil laminates**

3.7 **End sealant and closure gasket compounds and wads**

3.8 **Process lubricants**

3.9 **Secondary packaging**

3.1 Introduction

There are several different types of products which are bought in by the metal packaging manufacturer to be converted into a metal packaging article. It is not within the scope of this document to cover the control of the manufacturing processes for these materials, but it is an essential part of the overall process that these materials as delivered to the converter are suitable for purpose and within an agreed specification. Good manufacturing practices, preferably based on sector guidelines, should be applied by all the parts of the supply chain. Actions and factors which control this aspect could be any or a combination of:

- the supplier operates to his own sector's written Good Manufacturing Practice guideline
- the supplier provides a batch test certificate in advance of delivery
- the supplier provides a certificate of conformity against relevant regulatory requirements or standards
- the supplier complies with auditable manufacturing and hygiene control procedures which is periodically checked by customer audit

Principle material types in this category are hereafter described in brief detail, with an indication of their role in the overall package. In Appendix 10.1, European or other international standards which relate to a material's fitness for purpose, particularly food contact purpose, are listed. These primarily relate to the metal substrate. Reference is given elsewhere in this guideline to any existing Good Manufacturing Practices guidelines issued by upstream suppliers or their organisations (refer to Annex 10.3).

3.2 Steel

Steel is used as a substrate with various forms of surface passivation and/or other forms of surface treatment that both protect the steel from corrosive environments and preserve the long-term performance of the packaging over its shelf life. This latter requirement often also requires the adjunct of an organic coating. It is often externally printed.

Steel substrate is made of mild, low carbon steel, with various elements added to obtain the required performances. Depending on the rolling process, steel can be single reduced or doubled reduced: the latter gives higher mechanical properties and so the possibility to decrease the thickness of the metal.

There are three types of surface treatment which gives three types of steel based products, sometimes called 'tinmill products'. These are:

- Tinplate (tin coated steel) which has applied electrolytically on both sides of the steel base a layer of tin of weight between 1.0 and 15.1 g/m² which acts as a protector of the steel surface. A further passivation of the surface is normally carried out.
- Electrolytically chromium coated steel (ECCS), also known as 'Tin Free Steel' or 'TFS' where the initial protection of the steel is obtained by depositing a chromium/chromium oxide layer electrolytically on the steel surface.
- Black plate is the steel base without surface treatment.

An organic coating is often applied to tinplate internally and sometimes externally, and always to both sides on ECCS and Black plate.

All forms of packaging steels as delivered have a thin layer of oil, of a grade suitable for the intended use, on both sides.

Steel products are delivered in coil or sheet form. Organic coating and printing are done on the coil or sheet before forming or for Drawn and Wall Ironed (DWI) 2-piece cans and Drums after forming.

Steel may be used to make all the types of packaging described in this guide.

The URL for the GMP document of APEAL, the European organisation representing the manufacturers of steel for packaging, is given in Annex 10.3.

3.3 Aluminium

Aluminium is used as a substrate, generally with an organic coating on both sides. This is necessary to facilitate the forming of the metal and/or to protect the metal against corrosion during the shelf life of the can or can end. It is often externally printed.

Aluminium substrates are alloys. There are two major families of alloys depending on the main alloying element: magnesium or manganese. The rolling process is driven to obtain the required mechanical properties. It is for instance possible to obtain harder metal and thereby allowing reduced thickness.

There is a surface treatment to increase adhesion of organic coatings.

Aluminium products are delivered in coil or sheet form. Organic coating and printing are done on the coil or sheet before forming or for DWI 2-piece cans after forming.

Aluminium may be used for 2-piece Drawn and Redrawn (DRD) and DWI cans, ends and bottle closures.

The URL for the GMP of the European Aluminium Association (EAA) is given in Annex 10.3.

3.4 Organic coatings

This is the generic term for any internal lacquers, external coatings, inks and varnishes applied to the metal surface either for protective or decorative purposes. There are several different types of coatings giving a range of technologies and properties to suit requirements for appearance and internal and external protection over the expected shelf life of the filled package.

Depending on requirements, the inside of the metal packaging may be uncoated or coated with single or multiple coating layers. The external may be decorated optionally with basecoat, inks and varnish, or left plain to receive finally a paper label at the filler. On 3-piece welded food cans, the welded overlap area is generally organically coated, both internally and externally, with a protective 'sidestripe'.

Over time, substances from coatings may migrate into the foodstuffs. Legislative requirements for food contact both within Europe and globally place restrictions on the composition of, and migration from, direct food contact coatings and this is dealt with in detail in Chapter 8. Potential migrants could include starting substances, impurities and reaction products formed within the organic coating, as well as "indirect" contaminants on the food contact surface originating for example from external coatings or process lubricants, all of which need to be considered in assessing the food contact hazards (see 5.2).

The number of different food types packed in contact with metal packaging is extensive, therefore the number of potential product / coating interactions is similarly large. It is the triumvirate of coating supplier, packaging converter and food packer in collaboration that selects a suitable specification of container and its coating through technical expertise and an appropriate level of testing. However it is the filler, through his own knowledge of the conditions that the coated package needs to withstand during filling, in-package processing then through to the final consumption of the product, who retains the ultimate responsibility for a specific package's suitability for purpose.

The URLs for the GMPs of CEPE, representing the European manufacturers of coatings, and that of their sub-group EuPIA representing the manufacturers of printing inks, are given in Annex 10.3.

3.5 Polymer coated metal

For polymer coated metal, the surface protection is in the form of pre-manufactured polymeric material bonded to the metal surface either by direct heat lamination or extrusion or by an adhesive layer. This can be done both for tinmill products and for aluminium and would normally be carried out by an outside supplier and supplied 'ready-for-use' as a protected substrate for further metal forming into such as 2-piece DRD cans, can ends and aerosol cones and domes. One or both sides can be polymer coated.

3.6 Foil laminates

Broadly these are multilayer flexible structures, the inner of these being capable of adhering to the (coated or uncoated) metal substrate under suitable conditions. Their main use is as a diaphragm closure, with easy opening (peelable) capability, applied across the opening end of a metal container. They may be used in conjunction with a 'snap on' overcap to provide reclosability.

The URL for the joint GMP of Flexible Packaging Europe (FPE) and CITPA, representing respectively European manufacturers of flexible packaging and paperboard, are given in Annex 10.3.

3.7 End sealant and closure gasket compounds and wads

3.7(a) Can end sealant

Can ends for beverages and processed foods almost always make use of a rubber based sealant (sometimes called "compound") in the curl of the end which is buried within the seam when the end is seamed onto the can. The function of this "can end sealant" is to ensure a hermetic seal under thermal processing of the can and to reduce the likelihood of seam leakage due to abuse of the can during handling, storage and distribution. The can end sealant is usually a water or solvent based dispersion of generally synthetic rubber/latex with fillers and other additives to enhance performance. The sealant is applied into the curl of the end, and either allowed to dry (solvent based) or dried in a hot air oven (water based). When correctly applied, the area of the sealant exposed to

the can contents is extremely small, but the material does need to be considered as a potential food contact component. Can end sealants are generally bought in ready formulated and are usually optimised for particular applications. It is therefore important that the correct sealant is used for particular applications.

3.7(b) Closure gasket compounds and wads

Metal closures come in a wide variety of forms but the majority are either "vacuum" closures for heat processed foods (PT for babyfood and Twist for most other food types) or beverage closures (Roll on Pilfer Proof or ROPP and Crowns). They all share the same basic components and processes, incorporating a drawn metal shell with internal protective coatings, external protective/decorative coatings and a sealing gasket. The performance of the sealing gasket is critical to the safety and effectiveness of the closure.

The metal substrate is covered by the entries for tinmill products (3.2) and aluminium (3.3). The coatings are covered by (3.4). The coating/decorating processes may either be carried out in-house by the closure manufacturer or be bought in ready coated/decorated.

The gasket compounds used for vacuum closures are generally plastisols of plasticised PVC these may either be compounded by the closure manufacturer, or be bought in ready mixed. The plastisols are viscous liquids which are applied either as a circumferential bead (PT and most Twist), or a coating over the whole panel of the closure (some Twist). In the case of PT closures, a heated metal punch is then inserted to mould the compound into the correct profile as well as partially gelling the compound. All PT and Twist closures then undergo a short stoving operation for gelation and (for foamed gaskets) foaming. It is very important that the correct formulation of gasket compound is selected for the intended application as different food types and food processing methods may require different gasket compound formulations to give satisfactory pack performance and migration control.

Seals for beverage closures may use wet plastisols, similar to those used in vacuum closures, or compression moulded dry granulate plasticised PVC or Polyolefinic compounds. The wet plastisols may be bought in or made in-house, but the compression moulded materials are always bought in. Where plasticised PVC is used, it

is important to consider the formulation particularly with regards to plasticisers. ROPP closures for spirits/liquors generally use foamed polyolefin wadding which will be bought in. In some cases thermoplastic non-return fitments are also incorporated into spirits/liquor closures to prevent illicit refilling.

3.8 Process lubricants

Under ever evolving food contact legislation, particularly in Europe, the food contact suitability of process lubricants which might remain as small residues on the final food contact surface needs to be established with suppliers and the residual levels on the food contact surface monitored to ensure the safety and compliance of the finished article.

Wash chemicals would generally be used in all Draw & Wall Ironed (DWI) 2-piece can manufacture and some other 2-piece cans where the use of significant levels of metal forming lubricant or coolant requires a washing process, both to minimise the risk of food contamination and for DWI cans, to ensure good wettability and coverage of the internal protective coating which is applied after the metal forming operations.

Process lubricants are used in a wide range of metal forming applications in the light metal packaging industry. Depending on where in the manufacturing process the metal forming operation takes place, the lubricant could be applied to the unprotected metal surface or to the finished food contact surface. If the lubricant is applied before the final internal protective coating, it still needs to be considered as a food contact material because the final coating may not be a functional barrier, or residual lubricant may lead to dewetting of the final coating and therefore exposure of the lubricant to food. Additionally, process lubricants applied to the external surface of light metal packaging need to be considered as food contact materials unless it can be conclusively demonstrated that cross contamination of the food contact surface via tooling (e.g. necking, and beading) or set off (e.g. with easy open end tab lube) does not occur.

Process lubricants are generally bought in, or in the case of coil coated materials they may be applied by the coil coater. Issues to consider in the choice of lubricants include the status of any hydrocarbon components with respect to the specifications developed by the EU Food Safety Authority (EFSA) and its predecessor the Scientific Committee on Food (SCF), ethnic status (e.g. against Kosher and Halal requirements), the allergenicity and TSE status of triglycerides and other animal derivatives and the potential use of products derived from genetically modified sources.

Whilst FDA regulations are not directly applicable in Europe, 21 CFR 178.3910 may provide guidance on suitable materials.

3.9 Secondary packaging

In the context of this section, secondary packaging, whether virgin or re-used, refers to the packaging used by this sector for the protection, storage and transport of its products. Typical secondary packaging includes wooden components (pallets, etc.), paper and board (layer pads, cartons, end bags), plastic (pallets, layer pads, bags). It is not expected that there would be any direct contact between secondary packaging and foodstuffs, however there have been instances in the past where the food contact surface of metal packaging has been contaminated (chemical and microbiological) by constituents from secondary packaging through vapour phase transfer or transfer of particulates. The risk of contamination is increased by the widespread re-use of wooden and board secondary packaging such as pallets, top frames, layer pads and cartons. GMP therefore applies to the specification and sourcing of virgin secondary packaging and also to the sourcing and sorting of re-used secondary packaging. In addition to managing the risk of contamination of metal packaging articles, secondary packaging should be specified and sourced to comply with Packaging and Packaging Waste regulations.

The use of the term 'secondary packaging' in this document indicates the common understanding within the metal packaging sector of what this is. It may not exactly represent what is understood as secondary packaging in other parts of the supply chain.

More detail of potential control measures for secondary packaging can be found at Annex 10.2.

3.9 (a) Wooden components - pallets and top frames

New pallets and top frames should be free from visible contamination or damage, and be specified to be compliant with those requirements given at Annex 10.2.

3.9 (b) Paper & board components - layer pads, end bags, interleaving, cartons

Materials should be specified as being suitable for use in contact with food packaging under the anticipated conditions of use and not compromise the compliance of the metal packaging articles with EU Regulation (EC) No. 1935/2004 with respect to consumer safety or food quality/acceptability. More detailed requirements are given at Annex 10.2.

3.9 (c) Plastic components – pallets, layer pads, bags, end wrap, pallet wrap

Materials should be specified as being suitable for use in contact with food packaging under the anticipated conditions of use and not compromise the compliance of the metal packaging articles with EU Regulation (EC) No. 1935/2004 with respect to consumer safety or food quality/acceptability. This may most readily be demonstrated by using plastics materials that comply with EU Directive 2002/72/EC and amendments (on plastics food contact materials and articles) taking account of any restrictions associated with constituents of the plastic. If compliance with Directive 2002/72/EC can not be shown then a detailed risk assessment should be undertaken of the likelihood and severity of contamination of the metal packaging articles from the plastic secondary packaging. Recycled content should not be accepted unless it has either been processed in compliance with EU Regulation (EC) No. 282/2008 or been subjected to an appropriate risk assessment.

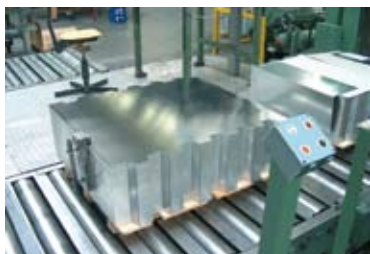
The URL for the GMP document of PlasticsEurope, the umbrella association for national plastics federations in Europe, is given in Annex 10.3.

3.9 (d) Re-used secondary packaging

Re-use of secondary packaging must be very closely controlled as it presents a significant risk of contamination of the metal packaging articles. Wood, cardboard, paper and plastic will all absorb substances from the environment and from previous usage that could present a contamination risk through contact or vapour phase transfer. In the case of plastic secondary packaging, risks can be reduced through a washing/drying procedure after a specified number of cycles or after a set period of time. It is recommended that only new layer pads be used for high sensitivity non processed products such as dry infant formula.

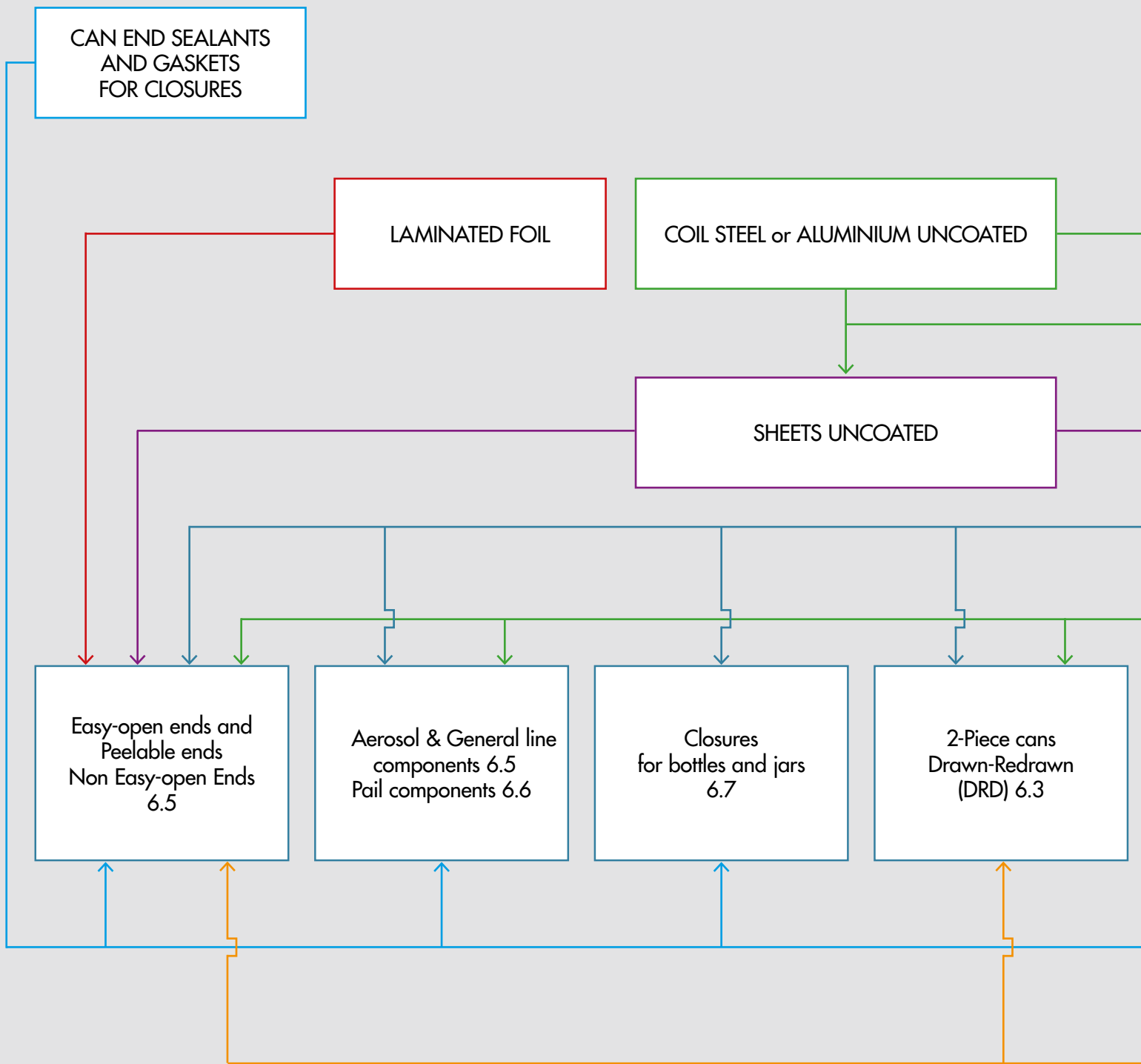
A system should be in place to ensure:

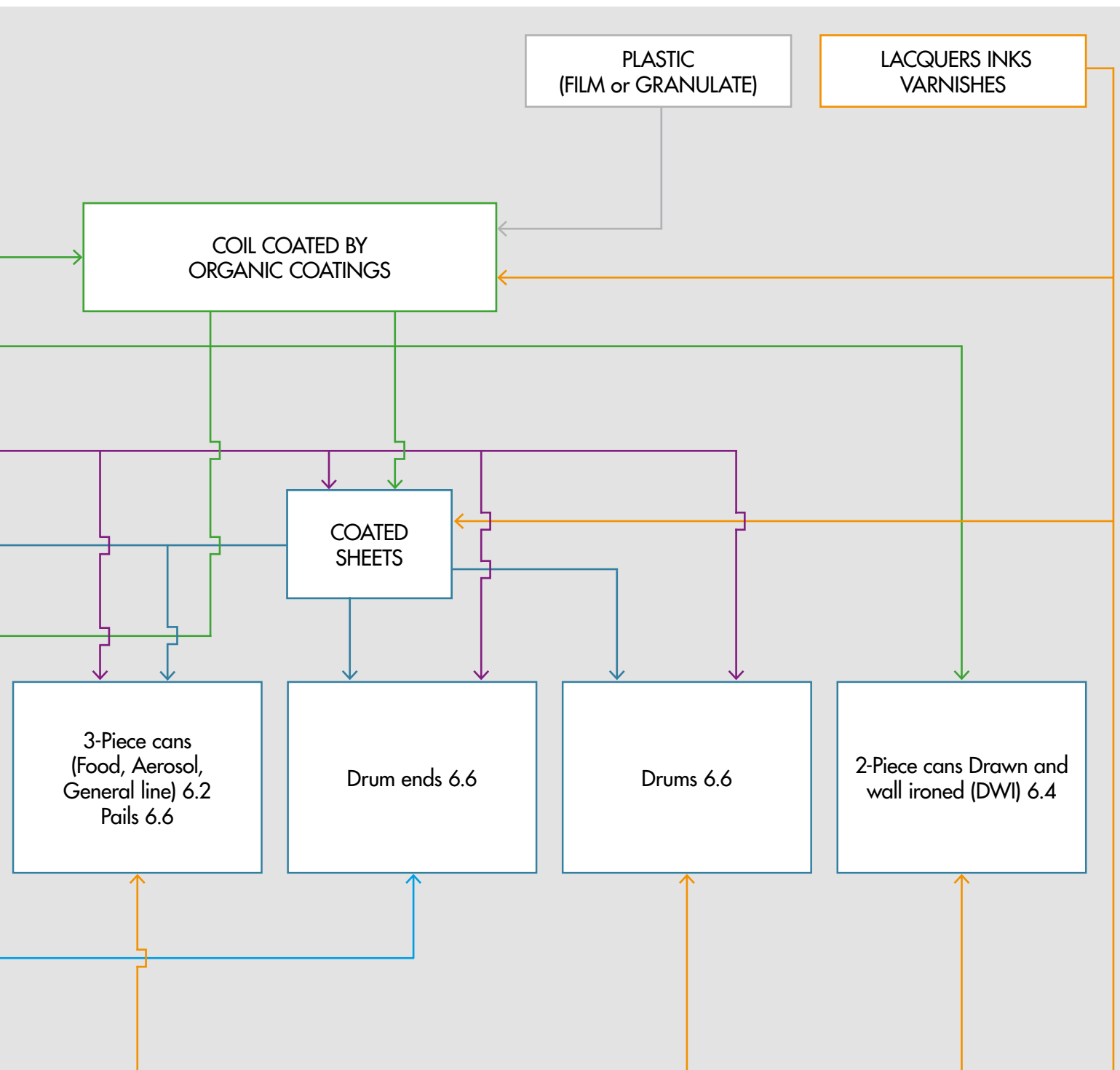
- that only secondary packaging originally specified and sourced for use with food packaging is used
- that only fully traceable sources are used
- that returned secondary packaging undergoes thorough inspection and sorting to exclude damaged, abraded, marked or visibly contaminated material
- that the moisture content of re-used wood, paper and board secondary packaging be maintained at the limits specified for new materials
- that sources that handle potentially allergenic materials (e.g. nuts etc) are excluded.





4 **Manufacturing process schematic**





5 Hazards to be considered

5.1 **Introduction**

5.2 **Food contact hazards**

5.3 **Hygiene hazards**

5.4 **Package integrity hazards**

5.1 Introduction

This GMP document is primarily intended as a guide for manufacturers of light metal packaging and drums for foodstuffs towards ensuring that their products are safe and fit for purpose for the intended application. Potential contaminants of the food contact surface could either be related to the materials used in the manufacture of the article, or related to the environment of the manufacturing process. Potential contaminants related to the materials used to manufacture the article are covered under the requirements of EU "Framework" Regulation No. 1935/2004 whereas contaminants (chemical or microbiological) related to the environment of the manufacturing process can be considered to be controlled by ensuring a hygienic manufacturing environment. Whilst there is overlap between the two sources of potential contaminants, it is considered appropriate to cover them separately in this document, both for convenience and as a consequence of the scope of Framework Regulation 1935/2004.

A further consideration regarding potential hazards is that the manufacturing process, the materials used or the manufacturing environment could directly or indirectly compromise the integrity of the final packaging article. This can be an important consideration for consumer safety as one of the key attributes of metal packaging is that long term, safe ambient storage of the finished packaged product is made possible by the ability of metal packaging to provide a completely sealed package, impervious to microbiological, chemical or environmental ingress. A degradation of this seal (i.e. a loss of package integrity) may compromise the long term ambient safety of the foodstuff.

5.2 Food contact hazards

Hazards related to the materials used in the manufacture of the articles can generally be described as "Food Contact" hazards and these are principally covered by the Regulation No. 1935/2004. The hazards can be categorised as:

- Authorised constituents of the food contact material or aids to manufacture such as metal forming lubricants passing into the foodstuff at levels exceeding the authorised levels.
- Unauthorised constituents of the food contact material or aids to manufacture such as metal forming lubricants passing into the foodstuff.
- Reaction/degradation products of constituents of the food contact material or aids to manufacture passing into the foodstuff.
- Constituents or reaction products of non food contact materials used to manufacture the article which contaminate the food contact material via set-off, vapour phase transfer or through migration, and then pass into the foodstuff.

Consideration must be given to the control of allergens amongst the materials used in the packaging and in the manufacturing process. Examples could include:

- Natural rubber latex
- Nut derivatives/oils
- Specific metals (e.g. nickel)

5.3 Hygiene hazards

Hazards related to the hygiene can generally be described as physical, chemical or microbiological hazards coming from manufacturing environment. These hazards are principally covered by the Good Hygiene Practices given in Chapter 7 sub-part 2.

The following list of hazards will help manufacturers to identify those hazards which relate to their own products.

- a) Physical hazards - These are foreign bodies, generally of an inert nature, which are solid and of sufficient size to be capable of injuring the consumer if bitten or swallowed. Their presence could cause dental damage, choking or internal injury. Examples are glass, brittle plastic, wood or metal fragment, screw, paper clip, piece of stone or ceramic, etc.
- b) Other foreign bodies: These are those foreign bodies which do not present a direct physical hazard, but which must also be controlled as they would represent unacceptable contamination of the food, and in the case of non-processed foods could represent a microbiological hazard (e.g. insects, pest faeces, elastic band, hair, paper/board dust, etc).
- c) Chemical hazards (this list is not exhaustive):
- | | |
|----------------------------|-----------------|
| Cleaning product | Machine grease |
| Water treatment product | Machine oil |
| Hydrocarbons (exhaust gas) | Solvent |
| Pesticides | Penetrating oil |
| Paint | etc... |
- d) Microbiological hazards:
- Pathogenic micro-organisms
 - Spoiling micro-organisms

The major preventative measures against microbiological hazards are related to the control of packaging integrity (see section 5.4) and pack hygiene (see section 7.2).

The subsequent filler processes (e.g. sterilisation and pasteurisation) and product specification (e.g. pH, stability) should be taken into account when assessing microbiological risk.

For certain high sensitivity non-processed products such as powdered infant formula, microbial contamination must be carefully controlled and monitored. For this product category further specific control measures have been established. These are highlighted in the hygiene measures tables of Chapter 7.2.2 by being included in bold italic type plus an [MC] annotation depicting 'microbiological control'.

5.4 Package integrity hazards

For food products which rely on the physical integrity of the package to maintain microbiological stability, the potential for loss of packaging integrity needs to be considered.

Package integrity may be compromised in a number of ways:

- Directly, through faulty manufacturing causing potential weaknesses in the packaging
- Indirectly through the use of incorrect materials with lower resistance to attack by the foodstuff or external environment leading to integrity failure
- Indirectly through physical damage during the manufacturing process causing a reduction in the protection against attack by the foodstuff or external environment leading to integrity failure
- Indirectly through a reduction of package performance due to failures in the manufacturing process causing a reduction in the protection against attack by the foodstuff or external environment leading to integrity failure
- Indirectly through contamination causing a reduction in the resistance to attack by the foodstuff or external environment leading to integrity failure

6 **Guide for hazard analysis and critical control point identification**

6.1 **Sheet coating and printing**

6.2 **3-piece can manufacture**

6.3 **Drawn/redrawn (DRD) 2-piece can body manufacture**

6.4 **Drawn & Wall Ironed (DWI) 2-piece can body manufacture**

6.5 **End and stamped component manufacture and conversion**

6.6 **Drums, pails and their end components manufacture**

6.7 **Closures manufacture**

6.8 **Secondary packaging, warehousing and transport**

Introduction

There follow, on the basis of flow diagrams, the different processes involved in the manufacture, storage and transport of light metal packaging and drums. Each is annotated with the different hazard categories (reference Chapter 5) and their potential causes, excluding the hygiene hazards which are covered in detail in Chapter 7.

In each case there will be hazards which are more critical in a specific factory location than others. For this reason, this guide deliberately avoids highlighting critical hazards (critical control points) as they may not be critical in all cases. Alternatively, highlighting hazards could mislead users of this guide into giving non-highlighted hazards less attention than they need in their specific cases. It is therefore essential that both the critical and less critical hazards are identified locally by risk assessment.

Guide to diagrams

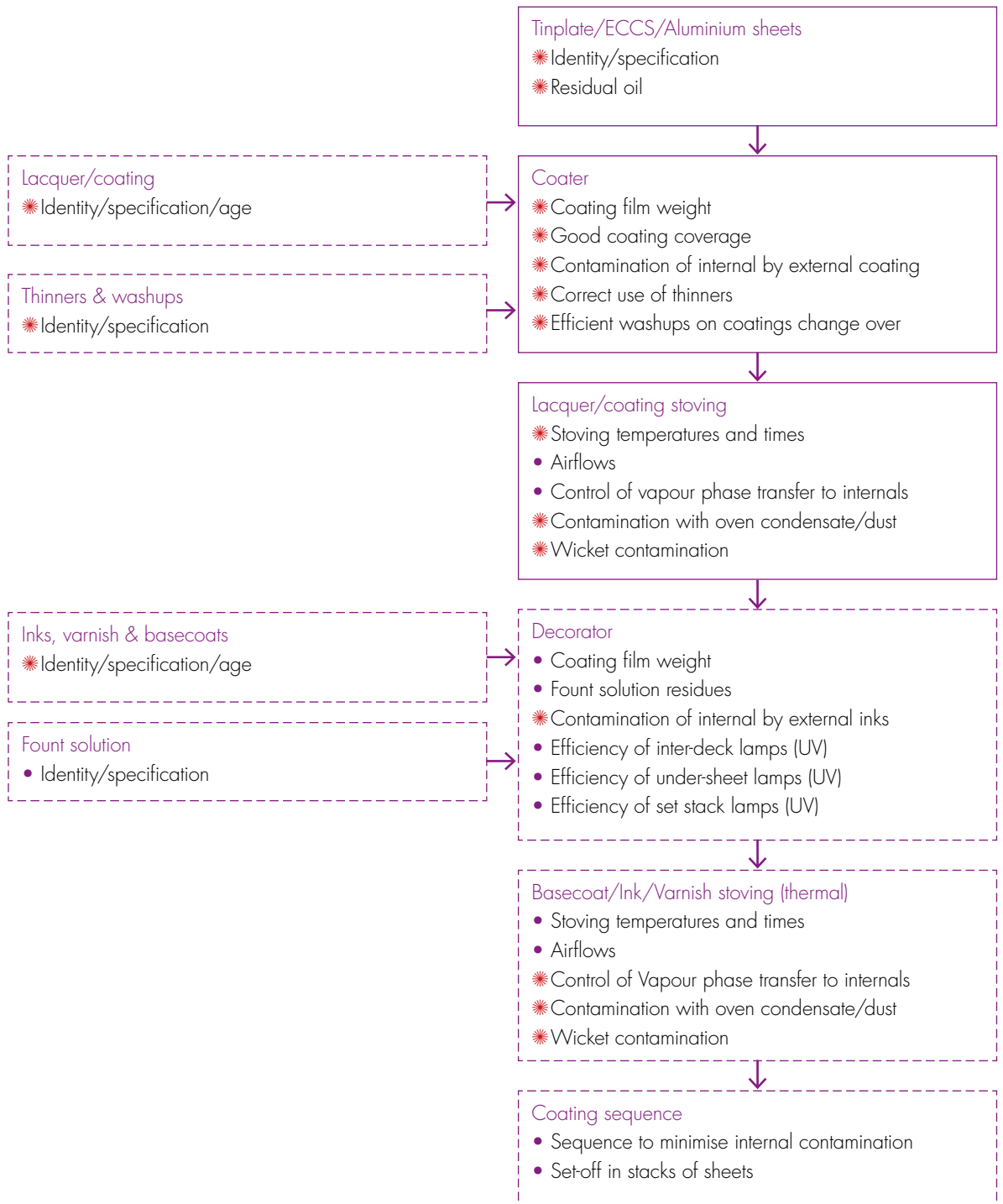
Principle Process (solid outline)

Optional or alternative process (broken outline)

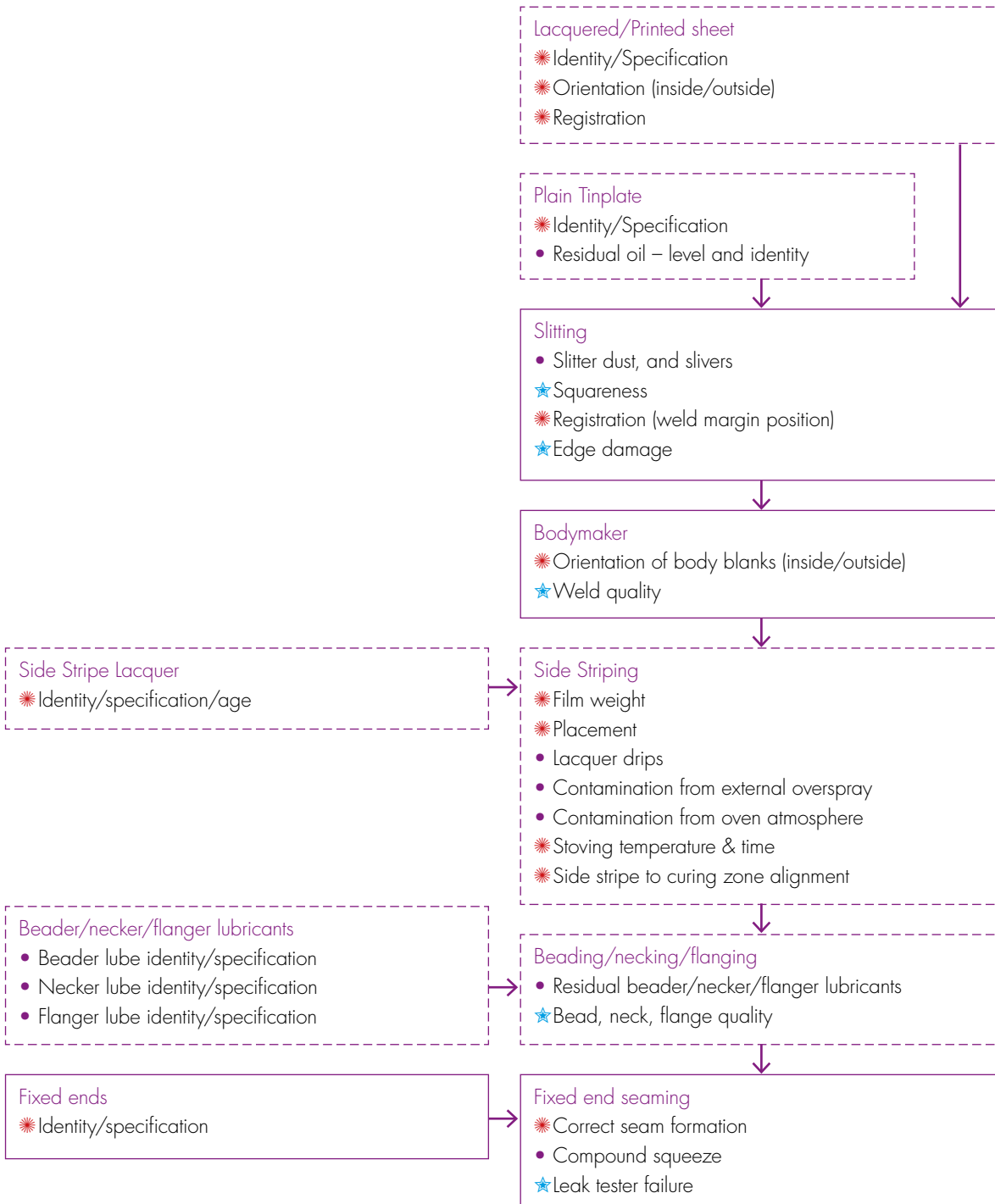
For each process flow diagram the following hazard identifications apply

- Food Contact hazard
- ★ Integrity hazard
- ✱ Food Contact and integrity hazards

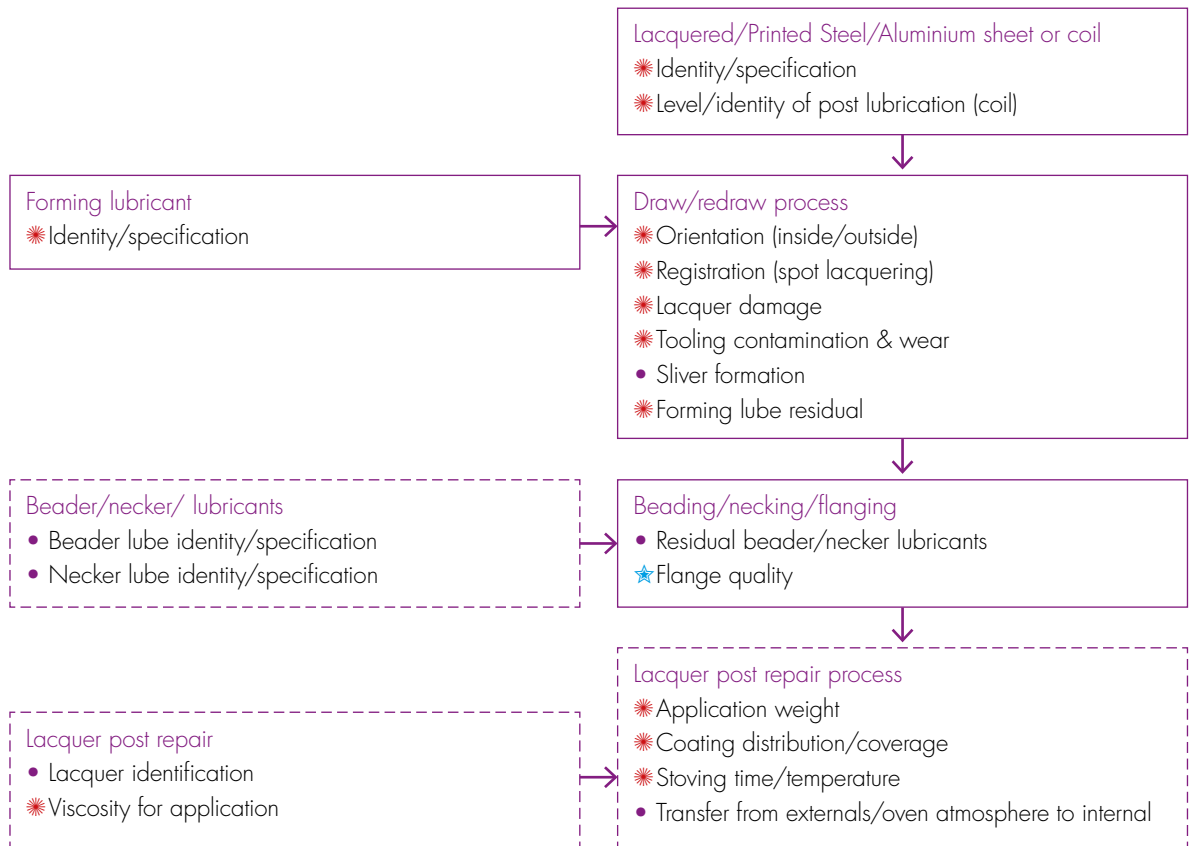
6.1 Sheet coating & printing



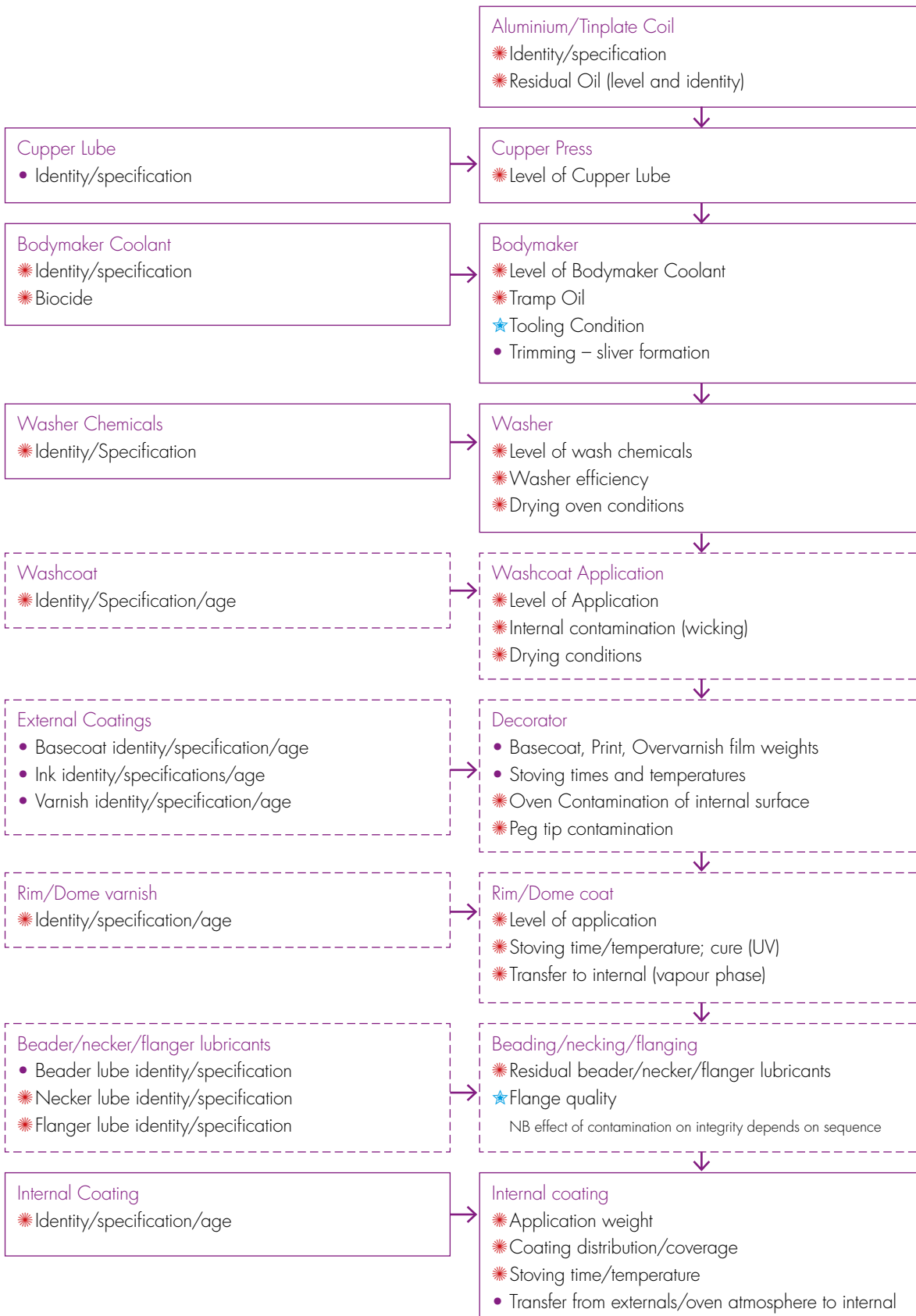
6.2 3-piece can manufacture



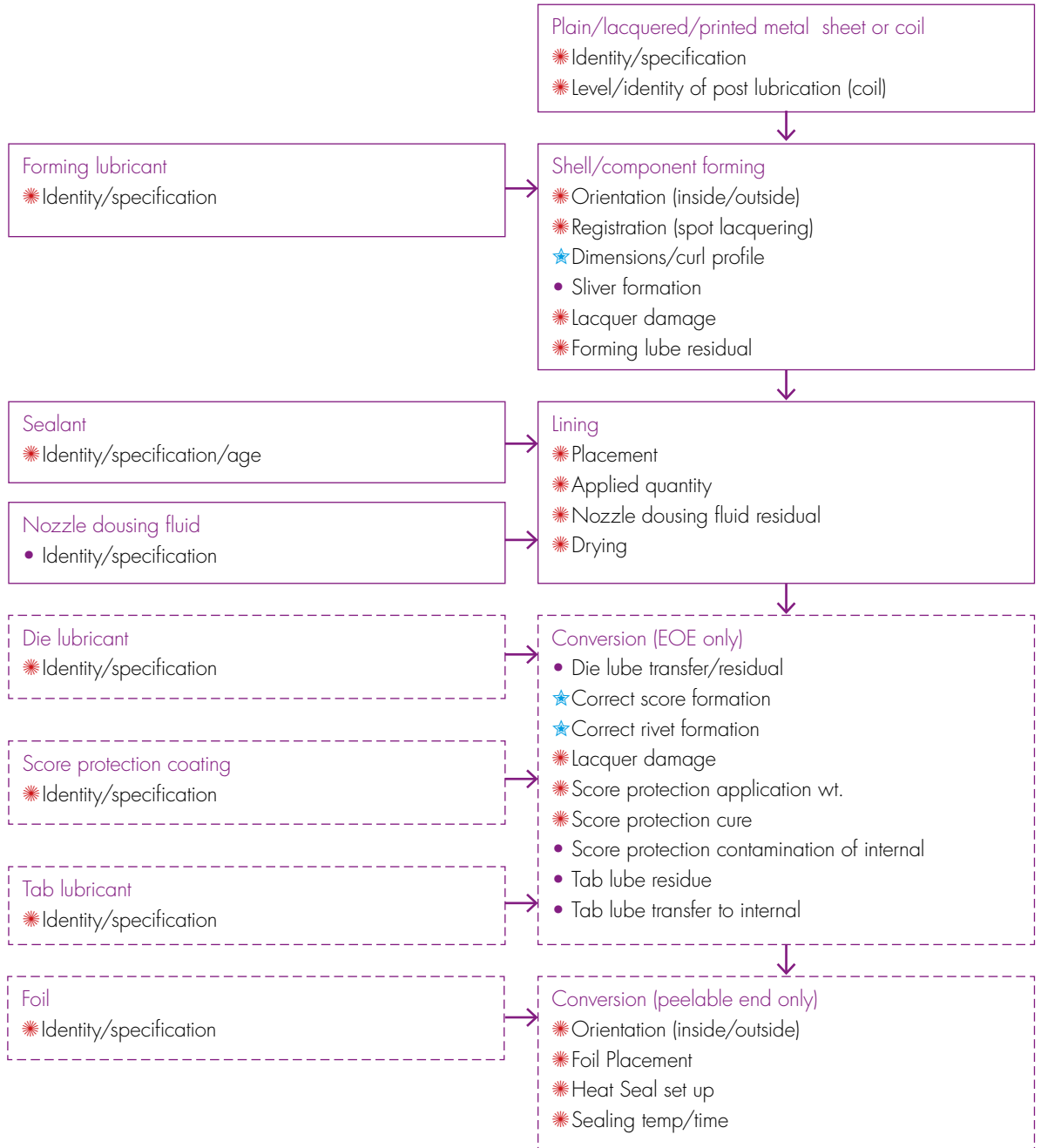
6.3 Drawn / Redrawn (DRD) 2-piece can body manufacture



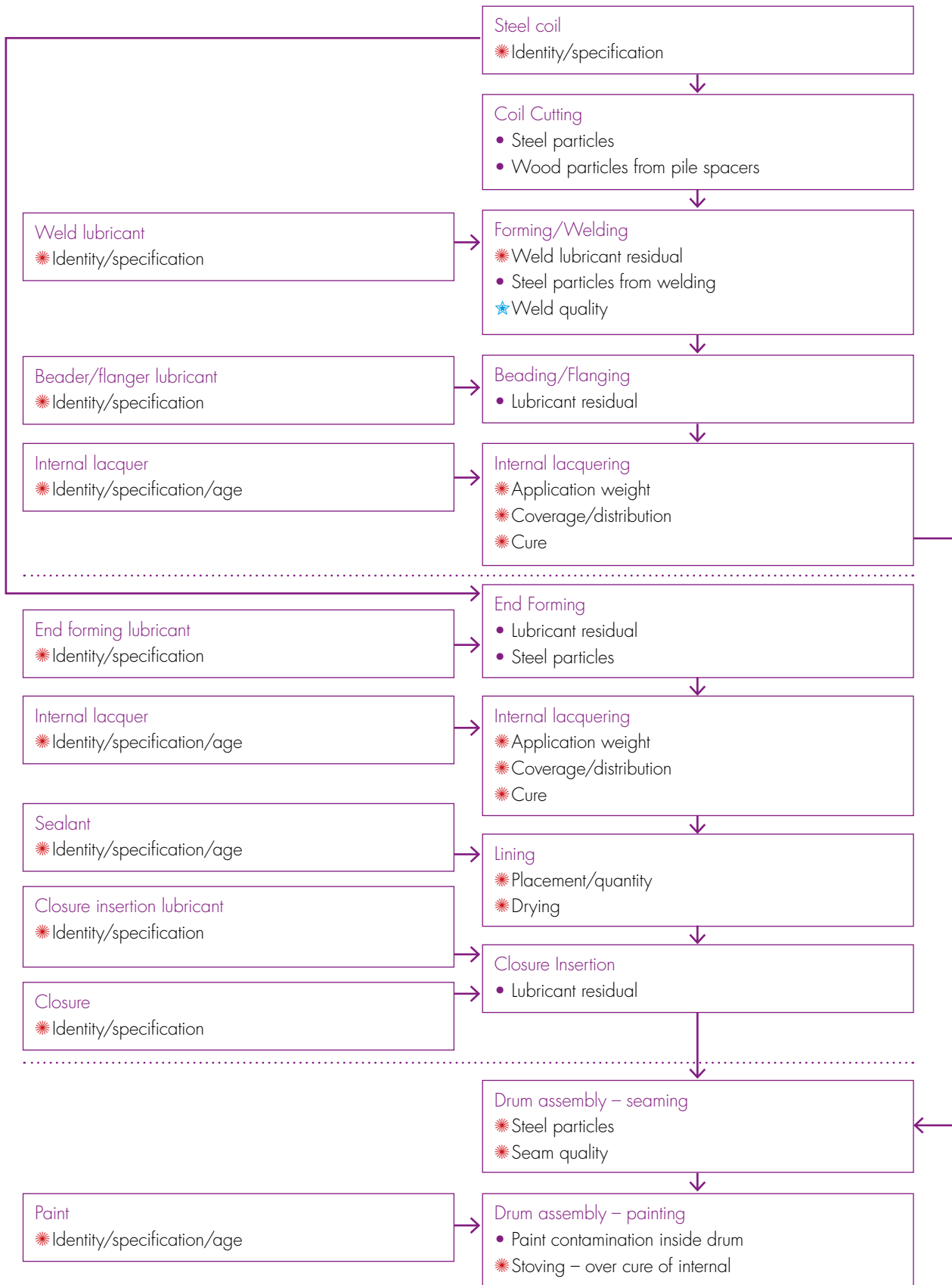
6.4 Drawn and wall-ironed (DWI) 2-piece can body manufacture



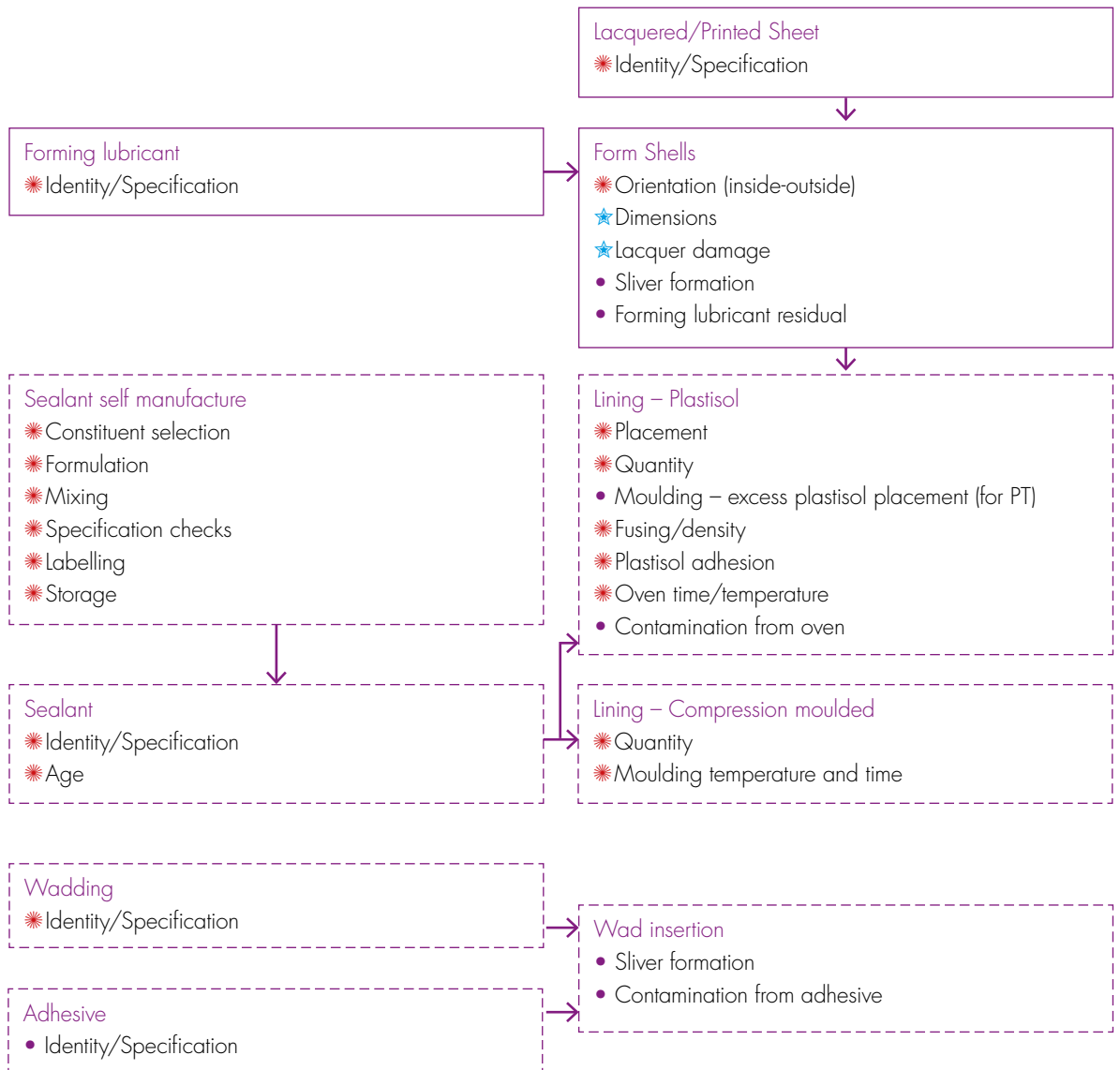
6.5 End and stamped component manufacture and conversion



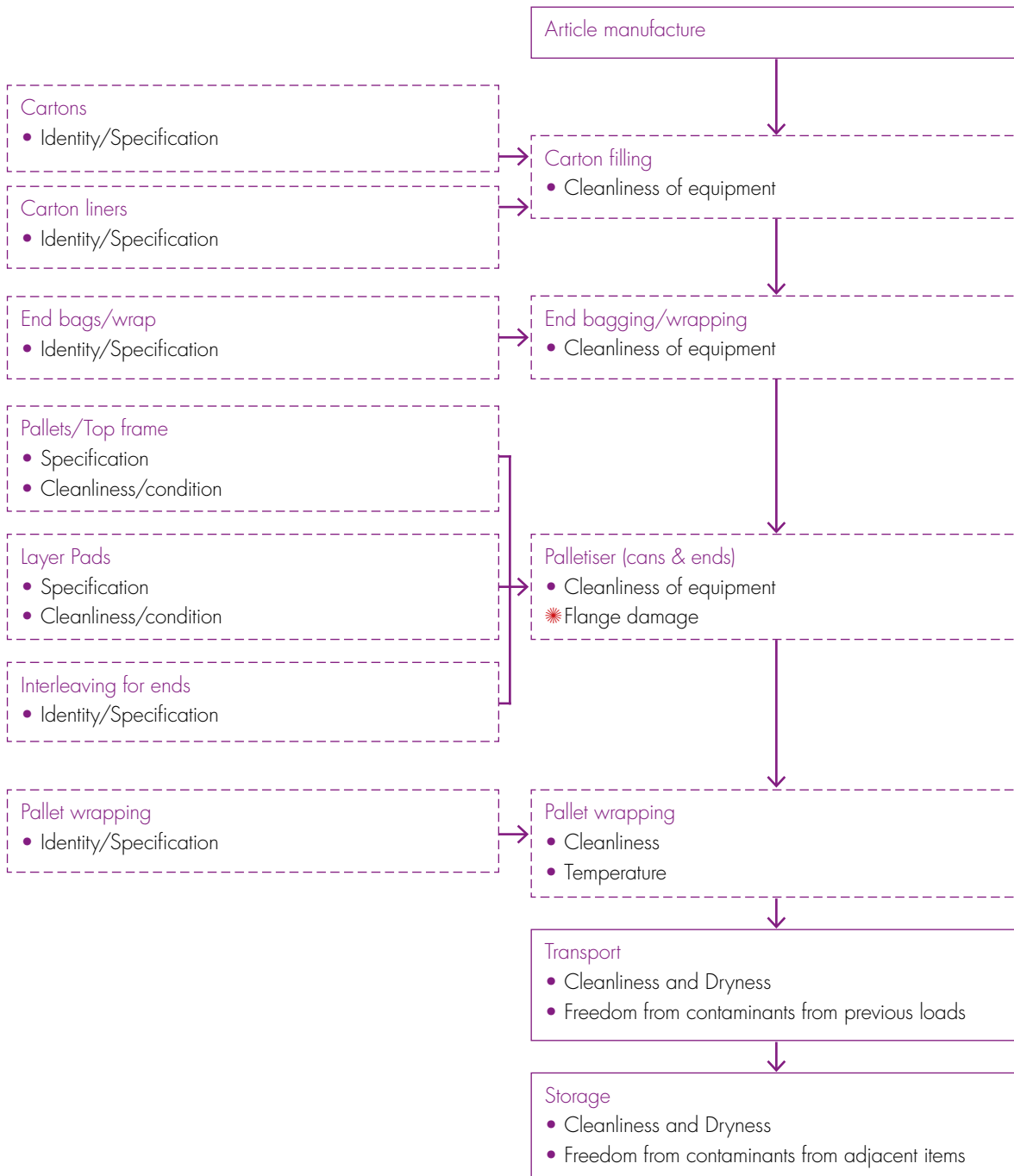
6.6 Drum, pail and their end component manufacture



6.7 Closure manufacture



6.8 Secondary packaging, warehousing and transport



7 **Good manufacturing practices**

7.1 **Food contact**

7.2 **Hygiene**

7.1 Food contact

This sub-chapter relates to compliance with the Framework Regulation (EC) No. 1935/2004. With regard to the control of food contact hazards from metal packaging, good manufacturing practice can be expected to include the following requirements.

7.1.1 Information Flow

It is essential that there is an efficient and clear route of information flow between metal packaging manufacture and both customer and supplier so that at each interface, both parties know what their product will be used for, how the products should be used, and the expected performance of the product. The documentation will include a Declaration of Compliance from supplier to customer at each interface, including the metal packaging manufacturer to the filler. This relationship forms an important element of due diligence.

7.1.2 Selection of Materials

- Suppliers must be reputable and be subject to an approval and monitoring procedure as required by quality systems
- Materials should be selected and specified as being suitable for the particular application for which they will be used
- Materials should be accompanied by recommended conditions of use for the intended process/application
- Materials must be accompanied by adequate Declarations of Compliance for the specified application and market

7.1.3 Manufacturing Processes

- Procedures should be in place to ensure that only the specified materials are used for the appropriate application, and that only the authorised materials are used for thinning, line wash-up etc⁴
- Process conditions must be maintained within prescribed limits in accordance with the supplier's recommended conditions of use to avoid for example:
 - incorrect coating weights
 - undercure or overcure of coatings
 - excess process lubricant application
 - compound (can end sealant) squeeze
 - contamination of the food contact surface with external coatings/inks etc].
- Coating sequencing and production sequencing should be optimised to minimise contamination of the food contact surface through:
 - vapour phase transfer or offset onto the food contact surface from external materials
 - contamination of the food contact surface during coating/stoving due to previous jobs run on the line
- General care should be taken during the production process to avoid a contaminated or unauthorised food contact surface – e.g.:
 - avoidance of environmental contamination
 - control of the use of lubricants, cleaning materials, pest control substances etc in the vicinity of production
 - misidentification of internal/external plate surface

7.1.4 Post-manufacturing handling

Contamination of the food contact surface during palletisation, storage and distribution must be avoided through:

- Correct selection and specification of packaging for our products (layer pads, bags, cartons, pallets, shrink wrap) with particular care with regard to wood/board treatment chemicals and to where materials are being re-used
- Procedures should be in place to ensure that storage and transport does not lead to contamination of the food contact surface though e.g.:
 - storage adjacent to inappropriate products/materials
 - transport of mixed loads with inappropriate products/materials
 - contaminated shipping containers.

⁴ The sector has available a Good Practices Protocol guideline specifically covering this issue

7.2 Hygiene

7.2.1 Foreword

Aware of its role in the “farm to fork” chain, and therefore in the final destination of its products coming into contact with all types of foodstuffs, the metal packaging industry has particularly focused on good hygiene and cleanliness practices for its products for many decades.

Enshrined in a strong corporate policy of “suitability for use in contact with food” or “food safety”, these good practices have been, and continue to be considered by the metal packaging industry as fundamentally necessary to maintain a hygienic environment to produce safe packaging.

The Good Hygiene Practices listed in the following sub chapter are based on standard EN 15593 “Packaging – Management of hygiene in the production of packaging for foodstuffs – Requirements”. Numbering in the left hand column duplicates that within EN 15593. The corresponding measures in the right hand column represent the guidance in each category provided by EMPAC specific to metal packaging manufacturing processes. As is the case with EN 15593, hazard analysis and risk assessment shall be applied to determine the applicability of each of the practices listed in Section 7.2.2.

This set of Good Hygiene Practices associated with other existing GMPs in the supply chain can be considered as a sector standard when establishing Prerequisite Programmes (PRPs) as required by ISO 22000: “Food safety management systems – Requirements for any organisation in the food chain” in managing food safety”.

In section 5.3 d) it was stated that microbial contamination needed to be carefully controlled with certain high sensitivity non-processed products such as powdered infant formula. For this product category further specific control measures have been established, and these additional hygiene measures are highlighted in the following tables by being in bold italic type with an additional [MC] annotation depicting ‘microbiological control’. *It is to be emphasised that these additional measures apply only in certain special cases, to be identified in collaboration with the food manufacturer / filler. They do not apply for the large majority of packed products.*



7.2.2 List of general measures intended to prevent physical, chemical and microbiological contamination risks

EN15593
Reference

Measures

6 Sources of contamination

6.1 Physical contaminants

6.1.1 Glass and brittle material policy in place:

- Brittle material risk eliminated over areas where product can be contaminated (e.g. brittle material must be eliminated over finished product conveyors and palletisers or line must be covered),
- A written procedure available describing the measures to be taken when glass breakage is detected (e.g. line stoppage, product isolation),
- Broken brittle materials replaced as quickly as possible,
- All brittle items on a register and checked on a regular basis,
- Containers made of glass or breakable material are prohibited from storage & production premises.

6.1.2 Light sources protected.

- All lights over finished product process & finished product storage areas.

6.1.3 Cleaning schedule needed for production and storage floor.

6.1.4 No use of loose fastenings (e.g. drawing pins and staples):

- Use banned in areas where product can be contaminated (e.g. packaging & sorting area...),

6.1.5 - Sharps policy defined,

- No use of snap-off blades in production and storage area,
- No sharp objects or loose tools left in areas where product can be contaminated (e.g. packaging & sorting area) if not fixed.

6.1.6 Development of an incident management procedure so that, whenever an incident occurs, the process of cleaning up or the maintenance shall be carried out under the control of a 'designated' person. Any contaminated product that cannot be effectively cleaned shall be discarded.

6.1.7 No non intended use of products.

6.1.8 Cleaning schedule for building, facilities and equipment:

- Cobwebs to be removed
- Dust, flaking paint and damaged insulation to be removed (or repaired) wherever there is a direct risk of product contamination.

6.2 Chemical contaminants

6.2.1 Chemicals controlled to prevent contamination:

- Cleaning processes used to clean mechanical parts in contact with packaging shall be safe (e.g. Food grade products or products without residue after evaporation),
- Use of food grade machinery lubricant (compliant with relevant national regulation) wherever there is a risk of incidental contamination. US FDA 21 CFR 179.3570 can be used for guidance,
- Handling equipment used in the factory to be electrically or LPG powered,
- Food safety requirements be defined for packaging material (pallets/layer pads/carton/plastic bag/ Top frame/Drum, Containers...).

6.2.2 Cleaning agents to be:

- Suitably identified (labelling or another way),
- Stored in designated area,
- Cleaning products used to clean equipment to be odour free,
- Cleaning products used to wash hands to be odour free.

6.2.3 Surface lubricants applied on metal packaging to be food grade (compliant with relevant national legislation)

- See section 3.8 for more details.

6.2.4 Machinery lubricant to be risk managed by maintenance (no leakage that could contaminate the product) –

- See also section 6.2.1 of this table. US FDA 21 CFR 178.3570 may provide useful guidance.

6.2.5 Compressed air blown on product should be suitably filtered.

EN15593
Reference

Measures

6.3 Biological contaminants

- 6.3.1 Control measures in place to prevent contamination from pests:
- Rodent & flying insect control program in place with monitoring and maintenance included,
 - Crawling insect control program in place. The implementation of a few traps used for monitoring is suitable,
 - For birds, a basic monitoring is suitable (intrusion will be avoided if factory is closed – See also section 6.3.3 of this table).
- 6.3.2 Effective pest control in place.
- 6.3.3 Doors kept closed and in good condition (use of rapid door wherever needed).
- 6.3.4 Incoming material inspected prior to unloading (cleanliness, contamination).
Product and truck (cleanliness, leakage, odour) inspected prior to loading.
- 6.3.5 See section 6.3.1 of this table.
- 6.3.6 Use of competent contracted company or internal expert.
- 6.3.7 Pest Control programme in place - not in any position to itself cause contamination:
- Electrical insectocuter sited so that dead insects cannot fall onto products, components or packaging (keep at least 4m distance),
 - For flying insects a sticky trap is preferred,
 - For rodent bait boxes, use rigid & fixed boxes and do not use granulates.
- 6.3.8 In the event of pest infestation, immediate action shall be taken (See also section 6.1.6 of this table).
- 6.3.9 Microbiological tests on products (at least one per year and per process) [MC].

6.4 Storage and distribution

- 6.4.1 Raw materials, packaging materials and products protected against contamination during transport, storage and delivery.
Suitable ventilation for production and storage area.
- 6.4.2 Same as section 6.4.1 of this table.
- 6.4.3 Packaging material (e.g. pallets/layer pads/top frames/etc.) contaminant free before use. Re-used returned packaging 100% inspected before use.
- Carton layer pads moisture content checked prior to use. [MC].
- 6.4.4 Same as section 6.3.4 of this table.
- 6.4.5 Warehouses controlled to prevent cross-contamination.
- 6.4.6 Same hygiene rules applied for subcontracted warehouses.

6.5 Cleaning

- 6.5.1 Cleaning carried out in accordance with scheduled plans.
- 6.5.2 Cleaning operations carried out regularly and in an effective way.
- 6.5.3 Segregated storage of cleaning equipment.
- 6.5.4 Cleaning equipment used for toilets is segregated from production and storage area.
- 6.5.5 Work station tidy and checked regularly.
- 6.5.6 If cleaning activities are outsourced, the appointed company to use an agreed and documented procedure.

6.6 Maintenance

- 6.6.1 Good maintenance practices are documented and include the following items:
- Contamination risk management on process. No residue of oil/grease left in areas which could contaminate the product,
 - Excess grease is cleaned off,
 - During corrective maintenance, product on line is protected (whenever line cannot be emptied) against contamination,
 - Cleaning of the line after corrective & preventive maintenance,
 - Signing off the process "OK for manufacturing" prior to start the manufacturing.

EN15593
Reference

Measures

- 6.6.2 See section 6.6.1 of this table.
6.6.3 Maintenance personnel follow the factory hygiene rules. See section 8 of this table.

6.7 Scrap and waste handling

- 6.7.1 Containers for waste and for scrap emptied at appropriate frequencies and kept in an adequate condition of cleanliness.
6.7.2 Production scrap intended for recovery and/or reuse segregated and protected against contamination.
6.7.3 Bins and container used for food waste provided with lids, identified and kept away from production and storage area.

7 Factory requirements

7.1 External areas

- 7.1.1 All external areas belonging to the company and close to the premises tidy and in good condition. Personnel and truck access ways asphalted or tarred (not necessary if trucks don't need to drive inside for loading).
7.1.2 A clean and unobstructed area provided along the external walls of buildings used for production and storage.
7.1.3 Wherever external transportation of finished products or raw material cannot be avoided it must be managed such as to avoid any contamination.
7.1.4 All the external openings for auxiliary devices and equipment suitably protected.
7.1.5 Finished products and components not stored outside.
7.1.6 External drainage systems constructed to prevent the access of pests (properly trapped).
7.1.7 Factory periphery closed to prevent the access of non-authorised persons or animals such as dogs.

7.2 Buildings

- 7.2.1 Construction and layout permit adequate maintenance and cleaning.
Wherever there is a direct risk of product contamination:
- No flaking paint,
- No damage (insulation/etc.).
7.2.2 In production and storage area an appropriate gap along the wall provided (enough to allow one person to pass for cleaning).
7.2.3 Effective protection against pests – no gaps under doors, pipes well sealed, no hole in walls, etc.
7.2.4 Waste disposal - See sections 6.7.x of this table.
7.2.5 Surface of walls, partitions and floor permit appropriate cleaning. See section 6.5 of this table.
7.2.6 To minimize the accumulation of dust and to prevent the possibility of condensation contaminating the product, ceilings and overhead fixtures should allow access for cleaning.
7.2.7 Windows, sills and doors are properly fitted, cleanable and well maintained.
7.2.8 Other construction such as stairs, steps, platforms, etc. maintained and cleanable.
7.2.9 Adequate lighting provided in all areas. See also section 6.1.2. of this table.
7.2.10 Raw material and finished products not stored close to potential source of contamination (e.g. chemicals, mechanical parts...)
7.2.11 Windows in production and storage areas intended to be opened to be screened.

EN15593
Reference

Measures

7.3 Equipment

- 7.3.1 All parts of equipment coming into contact with the products maintained and cleaned. (see also sections 6.2.1 & 6.5 of this table).
- 7.3.2 Handling equipment such as forklift shall be well maintained and kept clean.
- 7.3.3 Equipment shall be installed in order to allow adequate cleaning of the surrounding area.
- 7.3.4 All equipment made of a material suitable for the intended use:
- 7.3.5
- Fixtures, piping and ducts not to cause condensation or leakage to fall onto the product,
 - Product conveyors covered wherever needed (e.g. if the ceiling is in bad condition),
 - Fasteners (e.g. screws, bolts, pins) which may fall into the manufactured products to be captive, or guards must be fitted to avoid contamination risks (Nylock nuts recommended).
- 7.3.6 "Temporary engineering" (use of adhesive tape, carton parts, etc.) only to be used in an emergency. Temporary engineering logged and scheduled for early permanent repair.

7.4 Facilities

- 7.4.1 Facilities should be maintainable.
- 7.4.2 Wherever water comes into contact with packaging (e.g. use of water bath tester) then potable water to be used. Tank to be emptied and cleaned at appropriate intervals.
Cans to be scrapped after contact with water [MC].
- 7.4.3 Designated areas provided for storing cleaning equipment, utensils and work tools.
- 7.4.4 Adequate facilities for dressing, hand washing and hygienic drying to be available:
- 7.4.5
- Hand washing encouraged by provision of adequate advisory signs - at least on toilet doors,
- 7.4.6
- Sufficient toilet facilities provided,
 - Toilets not to open directly into production and storage areas,
 - Toilets appropriately ventilated,
 - Toilets equipped with hand washing facilities,
 - Toilets utilise non-scented liquid soap,
 - Single-use towels, roller towels or hot air blow dryers recommended,
 - Lidded bins provided.
- 7.4.7 Hand washing or disinfecting facilities located close to social areas
- 7.4.8 Designated area provided for eating and drinking (other than water). If smoking is allowed, a designated area for smoking isolated from production and storage areas to be provided.
- 7.4.9 A suitable place provided to store all food and drinks (not stored in lockers).
Food kept in sealed containers.
- 7.4.10 Facilities provided for the storage of work clothes and personal belongings.
2-compartment lockers provided to segregate works clothes & personal clothing.
- 7.4.11 Adequate means of natural or mechanical ventilation provided in all production and storage area to prevent excessive build up of condensation and odours.
- 7.4.12 Mechanical systems not to contaminate products, raw materials or packaging.
Mechanical systems designed so that they can be cleaned.
- 7.4.13 Packaging used for raw materials and auxiliary packaging products (e.g. wooden & plastic pallets used for raw material or finished products..) not to be used for other purposes.
Provision of non standard, coloured, or specific storage unit for other purposes.

EN15593
Reference

Measures

8 Personnel

8.1 Access points and specific routes

- 8.1.1 All entrances to the site to be specified and controlled by the Organisation. Includes access points and routes to all production and storage areas.
- 8.1.2 The entry of unauthorised persons to the premises to be prevented (see also section 7.1.7 of this table).
- 8.1.3 Product handling:
- Avoid touching finished product food contact surfaces,
 - Touching finished product food contact surfaces forbidden [MC],
 - Hands to be clean,
 - Antiseptic hand cleaner/lotion to be used [MC],
 - Product to be scrapped if handling rules not respected,
 - All personnel both internal and external including contractors to wash or disinfect their hands whenever necessary and before entering into production or storage areas [MC].

8.2 Work clothes

- 8.2.1 The Organisation to specify work clothes to be worn in the production and storage areas:
- Clothing available in sufficient quantity to allow personnel to wear clean working clothes every day,
 - Work clothing not to be worn outside the site,
 - Work shoes not to be worn outside the site.
- 8.2.2 Work clothes to be suitably designed to prevent loose items contaminating the product. Shall have no external pockets above the belt, no sewn buttons, press-studs required and sewn label only.
- 8.2.3 At workstations where people work directly over products (sorting area, packaging station...) adequate covering of scalp hair shall be in place.
Include protection of beard and moustache.
- 8.2.4 Work clothes shall be regularly cleaned or replaced.
Suitable guidance shall be provided and monitored when a self-care system is in place.

8.3 Personal belongings

- 8.3.1 The organisation to have a policy to avoid personal belongings being taken in production or storage area.
See also section 7.4.10 of this table.
- 8.3.2 Jewellery, wristwatches and visible piercing not to be worn in production and storage areas.
- 8.3.3 All personnel both internal and external including contractors not to use false nails or nail varnish when working at workstations where products are touched by operators' hands (e.g. sorting area, packaging station, etc).

8.4 Toilets and lockers

- 8.4.1 All sanitary facilities in the production and storage areas to be kept clean. See also section 6.5.
- 8.4.2 After using toilets, hands to be washed. See also section 7.4.6 & 8.1.3 of this table.
- 8.4.3 See section 7.4.10 of this table.
- 8.4.4 Lockers to be kept clean. Nothing to be placed on top of lockers or on the floor.
- 8.4.5 When entering from outside, locker rooms to be accessible without crossing production and storage areas.

EN15593

Measures

Reference

8.5 Eating, drinking and use of tobacco and medicines

- 8.5.1 All food, drinks and medicines to be stored in designated areas where there is no risk of product contamination. See also sections 6.7.3 and 7.4.9 of this table.
- 8.5.2 Eating (including consuming confectionery, chewing gum or chewing tobacco), drinking other than water (no glass bottles) and smoking only allowed in designated areas. See also section 7.4.8.
- 8.5.3 All such areas to be kept clean. See also section 6.5.
- 8.5.4 Smoking area: See section 7.4.8. Adequate containers for smokers waste to be provided.
- 8.5.5 Personnel to wash or disinfect their hands after eating, drinking (with exception of drinking water) and smoking. See also sections 7.4.4, 7.4.5, 7.4.7 and 8.1.3 of this table.

8.6 Injuries and diseases

- 8.6.1 Personnel to follow documented guidelines for injuries and diseases to prevent product contamination:
- Treat injuries (visible skin lesion: cuts, boils, etc.),
 - Treat diseases [persons suffering from the diseases mentioned in the CODEX: Ref. CAC / RCP 1-1969, Rev 4 (2003)]. Affected personnel to report to the company's medical services [MC],
 - Personnel to be informed about the risk due to sneezing and blowing of nose close to products.
- 8.6.2 All injuries including minor cuts treated immediately to avoid any contamination.
- 8.6.3 Dressings changed at appropriate intervals. Self-adhesive plasters not to contaminate the product - they shall be differentiated from the product by colour (blue recommended).

8.7 Visitors

- 8.7.1 Hygiene rules defined for visitors.
Protective clothes worn by visitors prior to entering into production or storage area.
- 8.7.2 Visitors informed about hygiene rules to apply to production and storage area and/or accompanied.
- 8.7.3 See section 8.7.1 of this table.



8 Food contact regulations

8.1 **Introduction**

8.2 **Harmonised European regulations**

8.3 **National regulations in the EU**

8.4 **USA regulations**

8.1 Introduction

Although, increasingly, metal packaging for foodstuffs and foods packed in metal are traded globally, there remains no global food contact legislative approach. The two major regulatory systems for control of materials and articles for use in contact with food are those of the EU and US (FDA), although detailed harmonised EU legislation for coated and uncoated metal packaging is still awaited. Food contact legislation is continually developing. Therefore, the information in this chapter may only remain current for a short time, and should be seen as the position as of 2008, after which this should only be used as a guide. To obtain more information regarding the current regulatory position of metal packaging, particularly as it relates to individual Member States, the appropriate European or national member state trade association (e.g. EMPAC for light metal packaging), or appropriate consultant organisations should be consulted.

8.2 Harmonised European regulations

Within the EU, materials and articles intended for use in contact with food are partly regulated at the EU level through harmonised Regulations and Directives, and partly at the member state level through their own legislation and recommendations. Wherever harmonised EU legislation exists, EU member states cannot maintain their own independent measures except in cases of specific derogation based on demonstrable risk to inhabitants of that member state. As EU harmonised legislation continues to develop, the importance of individual national member state measures will decrease.

The core of EU legislation on food contact materials and articles is the "Framework" Regulation (EC) No. 1935/2004 which sets out in Article 3 the fundamental requirement that substances should not pass into the food at levels that may be harmful to health; or that may adversely alter the composition of the food; or that may lead to a deterioration in its organoleptic qualities. Furthermore, this regulation lays out intended means of detailed regulation of materials and articles by material type.

Harmonised EU regulations specific to coatings have not yet been developed. However, the Framework Regulation

applies to all packaging materials as does the "GMP" Regulation (EC) No. 2023/2006 together with substance specific measures such as the "Epoxy" Regulation (EC) No 1895/2005, and the Vinyl Chloride Monomer (VCM) Directive 78/142/EEC.

Compliance with these measures is essential, and whilst it is clear what needs to be achieved for compliance with the substance specific measures, the Framework Regulation, and in particular the key Article 3 gives no guidance on how compliance may be demonstrated. In the absence of harmonised legislation, EU national member state regulations, where they exist, may be used to help to demonstrate compliance with the Framework Regulation. US FDA CFR21 175.300 (polymeric and resinous coatings) also remains an essential point of reference.

The Dutch Verpakkingen- en Gebruiksartikelenbesluit (Hoofdstuk X) is the most comprehensive of the member state measures and has a positive list of permitted starting substances that may also be used in other EU member states as a means of demonstrating compliance with the Framework Regulation. Other EU member states with legislation covering at least some aspects of coated metal FCM include France, Belgium and Greece.

In addition to national member state legislation, reference to the Council of Europe Resolution on Surface Coatings AP (2004) 1, together with published opinions of the Scientific Committee on Food/European Food Safety Authority (SCF/EFSA) and EU legislation not directly applicable to coatings (such as Directive 2002/72/EC on plastics food contact materials and articles) may be used in demonstrating compliance.

In the case of thermoplastic polymer coated metal, the thermoplastic layer would generally be expected to be fully compliant with the provisions of 2002/72/EC. However the more generally used thermoset coatings are more complex and can not generally be formulated using only substances authorised in 2002/72/EC.

As can be seen, there is currently no clear path to compliance for coated metal foodstuff packaging in the EU, and it is hoped that harmonised EU legislation in this area will be developed soon. In the absence of such harmonised legislation, the European Coatings manufacturing industry (represented by CEPE) has coordinated the compilation, by the coated packaging

industry chain, of a Coatings Code of Practice⁵. This document which has been developed from the CoE Resolution AP (2004)¹, incorporating the style and spirit of the “Plastics” Directive 2002/72/EC, is intended as a guide to demonstrating compliance with article 3 of the Framework Regulation. Discussion continues with Member States and the European Commission to encourage acceptance of the Coatings Code of Practice as the prime route to demonstrating compliance with the Framework Regulations.

In summary:

- the following EU measures must be complied with:
 - The “Framework” Regulation (EC) No. 1935/2004
 - The “Epoxy” Regulation (EC) No. 1895/2005
 - The “Vinyl Chloride” Directive 78/142/EEC and associated test Directives
 - The “GMP” Regulation (EC) No. 2023/2007
 - The “Transitional” Regulation (EC) No. 372/2007 for closure sealing gaskets only – as amended by Regulation (EC) No. 597/2008
 - The “Plastics” Directive 2002/72/EC and amendments (particularly 2004/1/EC and 2007/19/EC) for closure sealing gaskets only
- The following measures⁶ and non EU-regulatory documents are useful references in demonstrating compliance
 - CEPE Coatings Code of Practice (as referred previously)
 - EuPIA guidelines on printing inks applied to the non-food contact surface of food packaging materials and articles⁷
 - Council of Europe Resolution on coatings AP(2004)¹ Edition 2⁸
 - Council of Europe Resolution on Aids to Polymerisation AP(92)²
 - Council of Europe Policy Statement on Metals and Alloys 13/02/2002⁹
 - EU “Plastics” Directive 2002/72/EC and amendments (except for closure gaskets for which compliance is mandatory)
 - US FDA 21CFR 175.300 (Polymeric and Resinous Coatings)
 - US FDA 21CFR 177.1210 (Closures with sealing gaskets for food containers)
 - US FDA 21CFR 178.3910 (Surface Lubricants)
 - Standards for packaging steel and aluminium as indicated in Annex 10.1 to this document.

8.3 National regulations in the EU

The different member states within the EU have a wide range of approaches to the regulation of food contact materials and articles. As EU harmonised legislation evolves, it will replace member state legislation, but until that process is complete (and there is no certainty when that will be achieved for coated metal packaging), it is recommended that the various national metal packaging trade associations be consulted regarding the individual member state legislation in force.

8.4 USA Regulations

US legislation of food contact materials and articles is managed by the Food & Drugs Administration (FDA) under the Code of Federal Regulations (CFR) Title 21 parts 170-199 in which, potential migrants are considered as indirect food additives. These regulations have developed over many years and have a wider scope than the EU legislation. Under FDA, all types of food contact materials and articles are covered including coatings. Historically, the FDA regulations have been considered the most important global reference point for demonstrating the compliance and safety of packaging. With the evolution of EU legislation on food contact materials and articles, the relevance of FDA compliance in the EU is decreasing, but for materials such as coatings which are still not covered by harmonised detailed EU legislation, compliance with FDA remains an important element in the overall management of safety and compliance. Additionally, FDA compliance remains important globally.

For coated metal packaging, the most important sections of 21CFR are:

- US FDA 21CFR 175.300 (Polymeric and Resinous Coatings) – this also covers can end sealants (xxxii)
- US FDA 21CFR 177.1210 (Closures with sealing gaskets for food containers)
- US FDA 21CFR 178.3910 (Surface Lubricants)

⁵ http://www.cepe.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=100087&eas:dat_im=05043D

⁶ Most recent versions available in all EU languages from Eurolex: <http://europa.eu.int/eurllex/en/index.html>

⁷ EuPIA guidelines - http://www.cepe.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=100087&eas:dat_im=050485

⁸ http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/COE%27s%20policy%20statements%20food%20contact.asp#TopOfPage

⁹ http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/TECH%20DOC%20GUIDELINES%20METALS%20AND%20ALLOYS.pdf



9 **Conclusion**

This GM&HP document is the practical result of a voluntary and proactive initiative launched by the European metal packaging manufacturers of EMPAC shortly after publication in the French Official Journals, in 2006, of a similar work carried out at national level by the French metal packaging association, SNFBM .

By providing such a new tool which helps to control both the primary materials and the manufacturing processes from the combination of food contact, hygiene and pack integrity perspectives, our industry continues to demonstrate its seriousness and commitment to produce safe metal packaging for use with foodstuffs.

Furthermore, it also gives timely guidelines which fit the requirements of Commission Regulation (EC) No. 2023/2006 on GMP which came into force on 1st August 2008.

It is nevertheless worth highlighting that this GM&HP document only reflects the practices put into place by just one element of the business chain, namely the metal packaging manufacturing industry. Encouragement is therefore strongly made to have both upstream and downstream stakeholders also to fulfil the needs in order to ensure that food contact and hygiene requirements are under control during all stages of the production and delivery of the final product used by the consumer.

Appropriate revisions will be made to this document when required.

10 Annexes

10.1 **Material standards - Metal substrates**

10.1.1 Introduction

10.1.2 Tinmill products

10.1.3 Aluminium

10.2 **Control measures for secondary packaging**

10.2.1 Wooden components

10.2.2 Paper and board components

10.3 **Supporting sector GMPs**

10.4 **Glossary of terms**

10.5 **Useful URLs**

10.1 Material standards - Metal substrate

10.1.1 Introduction

There is a fundamental difference between regulations and standards. The former places a compulsion on the manufacturer to comply in all respects with the text, whilst the latter, although normative in character, is advisory rather than compulsory. However, adherence to a standard can be an important element in maintaining good manufacturing practices, and may be particularly useful if a dispute arises with a control authority or within the supply chain, as the adherence to agreed norms can give a due diligence defence. Supply of a product to the requirements of a standard will often be part of the business level supply contract anyway.

10.1.2 Tinmill products

EN 10202 – “Cold reduced tinmill products – Electrolytic tinplate and electrolytic chromium/chromium oxide coated steel” – This standard covers specification, mechanical properties, tolerances, impurity limitations and delivery quality and is applicable to supply for both food and non-food applications.

EN 10205 – “Cold reduced blackplate in coil form for the production of tinplate or electrolytic chromium/chromium oxide coated steel” – Blackplate (which is the base steel with a light oiling protection), can be used as a substrate in its own right for application of protective organic coatings then container manufacture. This is limited to the drum sector.

EN 10333/10334/10335 – “Steel for packaging – flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption – Non-coated steel – [Substrate]” – In respective order these are separate standards (with common aspects for the base steel) for tinplate, blackplate and ECCS. These cover the chemical composition of the base steel and purity criteria for additional coatings such as the tincoating.

10.1.3 Aluminium

EN 602 – “Aluminium and aluminium alloys – Wrought products – Chemical composition of semi-finished products used to manufacture items designed to come into contact with foodstuffs”

EN 541 – Aluminium and aluminium alloys – Rolled products for cans, closures and lids – Specification

EN 573-1 – “Aluminium and aluminium alloys – Chemical composition and form of wrought products – Part 1 : numerical designation system”

EN 573-3 – “Aluminium and aluminium alloys – Chemical composition and form of wrought products - Part 3 : chemical composition”

EN 14287 – “Aluminium and aluminium alloys – Specific requirements on the chemical composition of products intended to be used for the manufacture of packaging and packaging components”

EN 14392 – “Aluminium and aluminium alloys – Special requirements for anodized products for use in contact with food.”

10.2 Control measures for secondary packaging

10.2.1 Wooden components

- Drying:
 - Moisture Content should not exceed 18% for wooden secondary packaging.
- Anti-blueing treatment requirements:
 - Anti-blueing chemicals may be used in the initial stages of wood manufacture at the sawmill to prevent internal mould growth.
 - Use of kiln-drying is preferable to the use of chemicals.
 - Whenever used, anti-blueing chemical treatment must comply with Directive 98/8/EC on biocidal materials.
 - These biocidal materials must be registered as wood preservatives. NB, this doesn't mean that they are authorised for use in contact with foods & drinks.
 - The safety of these materials in this application must be assessed.

- Other chemical treatments of wooden components:
 - Chemical treatments are not allowed except for anti-blueing purpose (see above).
 - Painting is not allowed (except for marking on the side).
 - ISPM15 compliance: where specified, heat treatment must be used instead of the chemical treatment (e.g. with methyl bromide).

10.2.2 Paper and board components

- In order to assure the microbiological stability of paper and board secondary packaging, moisture content should be maintained below 9%.
- Fibrous constituents – Use of recycled fibres from recovered paper is allowed subject to thorough cleaning and de-inking, and subject to an exclusion list of recovered paper sources. As a minimum, the exclusion list can be expected to include:
 - Recovered paper from hospitals, etc.
 - Recovered paper which has been mixed with garbage
 - Recovered paper from old archives
 - Recovered paper from painting industry
 - Hygiene papers
 - Packaging used for chemicals
 - Carbon free copy paper (NCR)
 - Thermal paper
- Non Fibrous constituents: All raw materials must appear on at least one positive list such as FDA 21 CFR 176.180 (Dry contact) or German standard BGVV – XXXVI. “Paper and board for food contact”.
- Good Hygiene and Manufacturing Practices: GHP and GMP must be implemented by the supplier according to the International Good Manufacturing Practices Standard for Corrugated and Solid Board.

For further guidance, reference can be made as necessary to the CEPI (paper & board) and FEFCO (corrugated board) Good Manufacturing Practice documents for which the URLs are given in Annex 10.3.

10.3 Supporting sector GMPs

APEAL (Packaging steel)

www.apeal.org/emc.asp?pagelid=303

CEPE (Coatings)

www.cepe.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=100087&eas:dat_im=05043D

CEPI (Paper / board)

www.cepi.org/Objects/1/Files/IssueSheet%20IndustryGL.pdf

EAA (Aluminium – including Foils)

www.eaa.net/en/publications/food-contact-good-manufacturing-practice/

EuPIA (Printing inks)

www.eupia.org/homepage.htm

FEFCO (Corrugated board)

www.fefco.org/index.php?id=306

FPE (Flexible laminates) + CITPA (paperboard)

www.flexpack-europe.org/upload/Documents/GMP_FPE_version_28.11.2007.pdf

Plastics Europe (plastic materials)

www.plasticseurope.org/DocShareNoFrame/docs/2/BONMDBDAAIIFDLAJPOGPBAGNB38XCLAQKH1Q7HNL8KC8E/PlasticsEurope/docs/DLS/AMH_GuidelinesGMP_updatedApr2008_151208-20081215-001-EN-v1.pdf

10.4 Glossary of terms

2-Piece can

A can where body and base are integral and a separate top end is seamed on after filling.

3-Piece can

A can comprising a double open-ended body cylinder with separate ends seamed on at both ends.

Aerosol can

A can to contain pressurised, sprayable products with special top end components and valve. Body construction may be 2-piece or 3-piece.

Beading/Beader

Change in the cross section of a can body or end, designed to reinforce strength/Machine which achieves this.

Black plate

Packaging steel with only a thin coating of oil for anti-corrosion protection. Generally only used in the manufacture of drums.

Blank

Pressed metal sheet on which subsequent processes will be carried out.

Blueing

Blue-coloured phenomenon when mould grows on improperly treated wood.

CCP

Critical control point as defined in HACCP. A CCP is a point, stage or procedure where a control measure can be applied to prevent, eliminate or reduce a hazard to an acceptable level.

Coolant

Water with additives which acts both as a lubricant during the bodymaking part of the DWI process and a means of cooling the wall ironing process.

Crown closure

Closing means for glass bottle or necked-in can from light gauge tinplate, TFS or aluminium with dentate (castellated) skirt.

Copper/Cupping

The first drawing stage of 2-piece can bodymaking process/The machine which achieves this.

Deep drawing

Process consisting in forming flat metal into a hollow shape by means of a punch and a die.

Drawing and wall ironing (DWI)/DWI can

Metal forming process by which an initially formed shallow cup is increased in height by progressive reduction of the cup diameter and thinning of the wall to produce a 2-piece can.

DRD

Draw/Redraw process whereby a two piece can body/base is formed via successive drawing operations

Drum

A medium or heavy gauge metal package, of 3-piece construction and with special closing features, with a capacity between 20 and 240 litres.

Easy-open end

Seamed-on rigid end which can be opened without using a tool by means of a ring-pull feature.

ECCS

Electrolytic chromium/chromium oxide coated steel. Same as Tin Free Steel or TFS

End

Collective term for devices serving to close, protect and secure the top and/or bottom ends of metal packaging.

FDA

US Food and Drug Administration.

Flanging/Flanger

Flaring out of a can's open end(s) to receive an end for seaming/Machine which achieves this.

HACCP

Hazard Analysis and Critical Control Points: A method consisting of collecting and evaluating information on hazards and conditions causing hazards, with the aim of identifying significant hazards (or conditions) in terms of food safety.

Hazard

The possibility of causing damage. Hazards can be biological, chemical or physical.

Film weight

The weight of an applied film in relation to a given surface area.

Lid

End (or end part) made of metal or plastic.

Lining

Application of a (elastomer) sealing compound intended to make an end seam leak proof.

Necking/neck

Forming inwards of the upper end of a can body to allow the application of a smaller diameter end/Machine which achieves this.

Pail

A medium gauge, generally tapered and nestable metal container, with a fully removable top end, of capacity in the range 5-40 litres

Pathogenic micro-organisms

Micro-organisms which may cause food poisoning or infections.

Plastisol

A gasket compound for a metal closure which is based on plasticised polyvinyl chloride.

Polymer coated metal

Metal substrate coated with a thermoplastic layer by lamination or extrusion.

PT Closure

Metal closure for glass jar of a type which is pressed on after the initial filling of product but twisted off by the consumer.

Risk

A function of the probability of the occurrence of a hazard and the severity of its outcome.

ROPP closure

'Roll-on pilfer-proof' closure for bottles, normally drawn from pre-coated aluminium.

Seaming/Seamer

The process of applying an end to a can body by specially interlocking the end with the flange of the can/Machine which achieves this.

Score/Scoring

Thinning of the metal of an easy opening end such that it tears readily when the tear tab/ring is pulled.

Shell

Simple profile metal pressing which is the first stage in the formation of various ends and closures.

Side seam

Welded or interlocked joint when a rectangular body blank for a 3-piece can is formed into a body cylinder.

Side stripe

Protection of side-seam area with an organic coating.

Sliver

Thin hair of metal, polymer or coating arising where cutting or trimming equipment is incorrectly set.

Spoiling micro-organisms

Micro-organisms which, although they are not hazardous, are likely to make food unfit for consumption.

Stoving

Support for lacquered/printed metal sheet during its passage through a drying/curing oven.

Tab/Ring-pull

Feature of an easy opening end which provides the grip for manual opening.

Thinners

Solvent used to bring organic coatings to the required viscosity for application.

TSE

Transmissible spongiform encephalopathies.

TFS

Tin Free Steel: same as Electrolytic Chromium Coated Steel.

Thermoplastic coating

A coating product in solvent, or as a powdered solid, which when applied/dried under the action heat does not undergo any further chemical reaction.

Thermoset coating

A coating product in solvent, or as a powdered solid which, when applied to a metal substrate and heated, develops its mechanical and chemical resistance properties through further chemical reaction (cross-linking).

Tinplate

Steel plate coated with a thin layer of tin.

Traceability

The ability to trace and follow a material or article through all stages of manufacturing, processing and distribution.

Tramp oil twist closure

Bodymaker gearbox lubricant which may contaminate the coolant Metal closure for glass jar which is twisted on and off via lugs in the closure engaging a thread in the jar neck finish.

Vacuum closure

Metal closure of the Twist or PT type which is applied to a filled jar whilst the product is hot and maintains the partial vacuum which is formed when the product cools.

Wicket

Support for lacquered/printed metal sheet during its passage through a drying/curing oven.

DG Sanco/Europa ec.europa.eu/health

EAA www.eaa.net
European Aluminium Association

EFSA www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm
European Food Safety Authority

EMPAC www.empac.eu
European Metal Packaging

EuPIA www.eupia.org
European Printing Ink Association

EuPC www.plasticsconverters.eu
European Plastics Converters

FDA www.fda.gov
US Food and Drug Administration

FEFCO www.fefco.org
European Association of Corrugated Board Manufacturers

FPE www.flexpack-europe.org
Flexible Packaging Europe

ISO www.iso.org
International Organisation for Standardisation

NAMPA www.metal-pack.org
North American Metal Packaging Alliance

Plastics Europe www.plasticseurope.org

SEFA www.sefa.be
European Association of Steel Drum Manufacturers

UNESDA www.unesda.org
Union of European Beverages Associations

10.5 Useful Uniform Resource Locators (URLs)

APEAL www.apeal.org
Association of European Producers of Steel for Packaging

BCME www.bcme.org
Beverage Can Makers Europe

CEN www.cen.eu/cenorm/homepage.htm
European Committee for Standardisation

CEPE www.cepe.org
European Council of the Producers and Importers of Paints, Inks and Artists' Colours

CEPI www.cepi.org
Confederation of European Paper Industries

CIAA www.ciaa.be
Confederation of the Food and Drink Industries of the EU

Codex Alimentarius

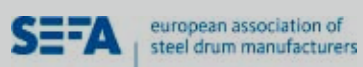
www.codexalimentarius.net/web/index_en.jsp

Council of Europe (Public Health and Social Cohesion) www.coe.int/T/E/Social_Cohesion/soc-sp/



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