AIP 60 YEARS 1963-2023

INTRODUCTION TO PACKAGING SPECIFICATIONS

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INTRODUCTION TO PACKAGING SPECIFICATIONS

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QUIZ

True or False

1. A specification is defined as 'a document giving a description of material, machinery, equipment, process or product in terms of its required properties or performance'.
2. One needs to understand and know the nature of the product which is to be packed, its properties before drawing up any type of specification.
3. To create a specification, would we need to know fragility, chemical and biological properties.
4. For biscuit packaging would we need to know fragility factor, abrasiveness, and moisture sensitivity.
5. Meat is normally packed in environments operating at 6°c.
6. Specifications should be clear and free of any assumptions.
7. The specification plays a vital role in the product development process.
8. A specification is required to ensure that the chosen supplier provides what is specified.
9. Specifications are to be provided by the those purchasing the packaging materials.
10. A specification becomes the legal documents.

ABOUT THE PACKAGING EXPERT

Prof Pierre Pienaar MSc, FAIP, CPP
Education Director - Australian Institute of Packaging (AIP)
President - World Packaging Organisation (WPO)

Pierre Pienaar's interest in packaging started in 1984 after having studied pharmacy. Soon after joining a large pharmaceutical company, Pierre became concerned about a number of packaging-related issues in the pharmaceutical world. This combined field has taken him to the far corners of the world, always involving one or other aspects of research in packaging. Pierre has attended international congresses and conferences where he has delivered and continues to present papers and continues to judge national and international packaging competitions. He continues to write articles for numerous packaging magazines around the world.

Pierre has a Master of Science Degree (Packaging Engineering/Technology) from Brunel University, UK. He also has a Master of Manufacturing and Production Degree from University of Hertfordshire, UK. He is a registered Certified Packaging Professional in over 60 countries.

He has been National President of the South African Institute of Packaging (IPSA), an honorary life member of (IPSA), a Fellow of the Australian Institute of Packaging (AIP), Professional member of the Australian Food, Industry and Science Technology as well as the Refrigerated Warehouse and Transport Association of Australia.

He is a packaging engineer in his own global packaging consulting business, PackTech Solutions Pty Ltd and has extensive experience in the pharmaceutical and food and beverage packaging industries with over 35 years of experience in the field of packaging science and engineering as well as its related subject matter. He is the current National Education Director, Past President of the AIP and past Vice President of the World Packaging Organisation (WPO), responsible for global packaging education.

He has lectured in the technology and science of packaging at various universities and institutions around the world for the past thirty years. He currently lectures the Masters students in Food Innovation and Packaging at University of Melbourne (Australia), as well as: Bond University (Australia), University of Newcastle (Australia), University of New South Wales (Australia), Monash University (Australia), Queensland University of Technology (Australia), University of Southern Queensland (Australia). Beijing Institute of Graphic Communication (China), Sichuan University (China), Jiangnan University (China), Tra Vinh University (Vietnam), Gadjah Mada University (Indonesia), Rochester Institute of Technology (USA) and Wien University of Applied Sciences (Austria).

He is regularly called to be an expert witness in court cases, due to his extensive experience in packaging science, packaging engineering and the technology thereof.

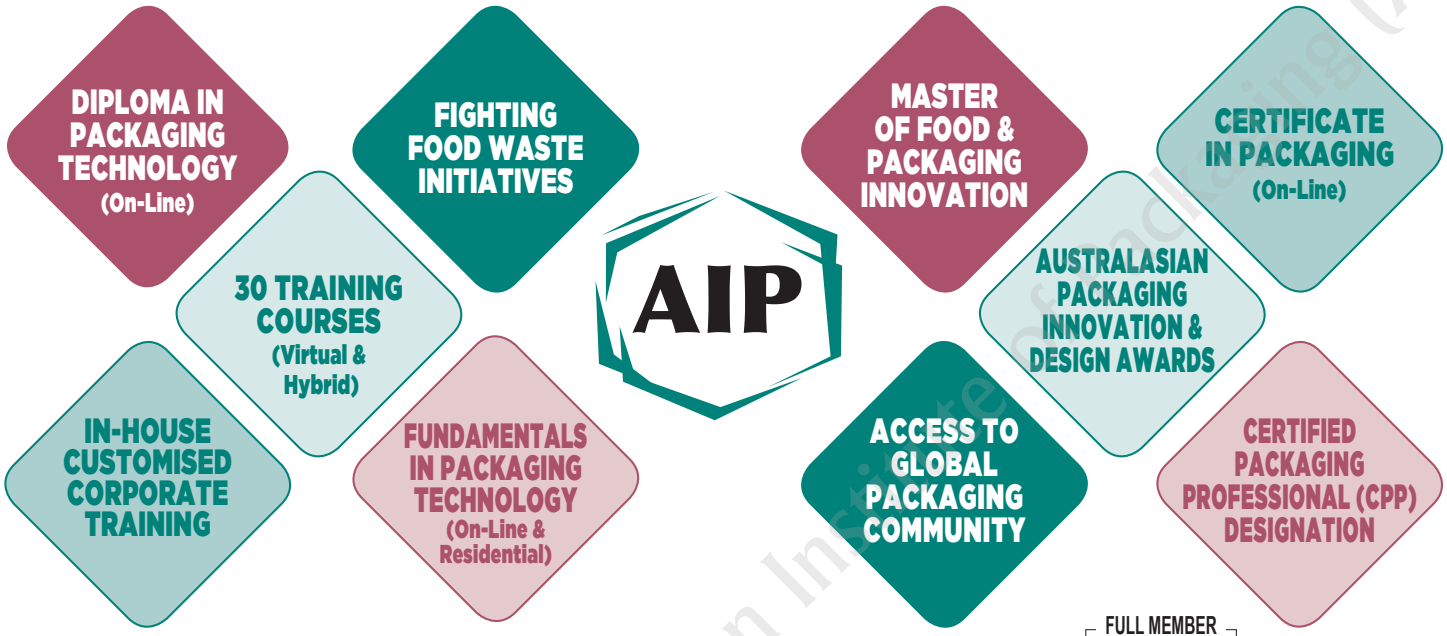
Inducted into the International Packaging & Processing Hall of Fame in 2022. He holds a professorship in Packaging Science and is the current President of the World Packaging Organisation (WPO).

*CPP points are used to maintain your Certified Packaging Professional (CPP) Designation.

INTRODUCTION TO PACKAGING SPECIFICATIONS

AIP: PEAK PROFESSIONAL BODY FOR PACKAGING EDUCATION & TRAINING IN AUSTRALASIA

HELPING SHAPE THE CAREERS OF EVERYONE WHO WORKS IN AND AROUND PACKAGING



MEMBER: AIPIA Active & Intelligent Packaging Industry Association; APF The Asian Packaging Federation; FRIENDS OF CHAMPIONS 12.3; initiative SAVE FOOD Solutions for a world aware of its resources

FULL MEMBER: WPO WORLD PACKAGING ORGANISATION

SUPPORTING SIGNATORY: AUSTRALIAN FOOD PACT

CORE PARTICIPANT: FIGHT FOOD WASTE CRC

FOUNDING PARTNER: STOP FOOD WASTE AUSTRALIA

SUPPORTER: ANZPAC PLASTICS PACT SUPPORTER

AUSTRALIAN INSTITUTE OF PACKAGING (AIP)

Having been around for 60 years the Australian Institute of Packaging (AIP) is the peak professional body for packaging education and training in Australasia. The Institute has helped to shape the careers of generations of packaging professionals – from packaging technologists to international packaging business leaders along with a host of people in associated disciplines including sales and marketing, production and quality, sustainability and environment, procurement and purchasing, design agencies and graphic designers.

The AIP is the only professional body that is designed to provide internationally accredited and recognised packaging degrees and courses for the Australasian market and have designed a detailed Certified Professional Development program for anyone working in the packaging industry.

AIP Educational Offerings

AIP educational offerings include the Diploma in Packaging Technology, the Certificate in Packaging, the Master in Food & Packaging Innovation, Certified Packaging Professional (CPP) Designation, Fundamentals of Packaging Technology course, training courses, conferences, technical forums, site visits, Influential Women's Mentoring program, internship program and more. The AIP covers Australia, New Zealand and parts of Asia.

Chapter 1: Introduction

Packaging is a vital component of the total operation of consumer goods manufacturing, distribution and retailing organisation, and of most industrial goods manufacturers. Its role rises above its function to impede degradation and to minimise waste.

A specification is defined as ***'a document giving a description of material, machinery, equipment, process, or product in terms of its required properties or performance. Where quantitative limits are stated, they are either in terms of limits or in terms of standards with permitted tolerances'***.

The packaging specification defines all the necessary packing levels for a product in order, for example, to put away or transport the product. For a product, a packaging specification mainly describes in which quantities you can pack the product into which packaging materials in which sequence.

Packaging specifications are the backbone of your products' packaging system, yet not all companies internalise ownership of their specifications.

Packaging specifications are the backbone of your product's packaging system. They are the key communication tool to communicate our designs, requirements, and graphics to our packaging suppliers. Yet not all companies internalise ownership of their packaging specifications, leaving a gap in your process on the path to quality.

Packaging components will vary depending on material type and will often include a detailed drawing layout for production, a die line for graphics and written directions to ensure conformance to ISO or TGA requirements.

Because the vast world of packaging touches all industries, packaging specifications will cover a similar wide range of materials and packaging types including corrugated fibreboard, paperboard, flexible films, bottles, closures, labels, pallets, and stretch film to name a few. When you consider the various tiers of primary, secondary and tertiary packaging within your value chain, the list will be quite expansive.

However, not all companies are as advanced in identifying the value within packaging or especially owning those packaging specifications. In many instances, drawings and specifications are written and controlled by the packaging material suppliers. And while these suppliers also need their own specs to produce these materials, it leaves little control or ownership for the brand user.

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Chapter 2: Reasons for Specifications

Compiling and owning all your packaging drawings, die lines, and specifications may be a long-term strategic activity, depending on the number of product SKUs and packaging components within your operations. But once you gather all this information there can be significant benefits for your organisation, such as:

1. **Speed to react:** When the time comes for change – to improve operational efficiency, address a quality concern, to implement sustainability programs, or execute a strategic sourcing initiative – having access to your specs can save days on the front end of your change management process. Easy access to digitised drawings and specs within your internal system enables fact-based collaboration to address any changes or modifications.
2. **Competitive sourcing:** When a single packaging vendor controls your design specifications it provides limited opportunities to shop other vendors for reduced costs, better service levels or improved quality. Pulling together bid packets without having your own digitised specifications can then be an arduous task requiring significant time and resources to compile these documents.
3. **Geographic flexibility/flexible operations:** Having the ability to shift sources of supply or move manufacturing operations to different geographic locations allows for a lower rate of risk within your supply chain. Whether your company is looking to move manufacturing from China to Vietnam or from California to South Carolina, owning your digital packaging specifications can enable seamless transitions when these supply chain shifts are needed.
4. **Improved communications:** Many companies operate with a centralised corporate packaging engineering team which support satellite plant manufacturing and production. Owning packaging specs within your systems can allow for fast and effective communication and collaboration with remote sites and cross-functional teams.
5. **Version control:** Following any new product launch, it's common that packaging is optimised to maximise the product's profitability. To achieve results, both designs and materials are often incrementally revised – changes to the primary, secondary, or tertiary packaging, or to all levels. Maintaining ownership of your packaging drawings and specifications allows for improved control managing these revisions along the way.

There can be great strategic value to internalising and owning your packaging material specifications. Creating digitised specifications and owning these documents within your system is a foundational task on the road to establishing good quality outcomes.

SPECRIGHT

Technical specification characteristics

Details the technical and physical aspects of the goods and services, such as dimensions, design specifics, physical properties.

Technical specifications are used when functional and performance characteristics are insufficient to define the requirement. Diagrams and dimensions can be used in a specification as technical characteristics or to provide guidance to suppliers.

Chapter 3: Specification Management System

It must be said that deciding which Specification Management System are right for your company can be confusing. To help narrow the playing field and find your right-fit solution, here is a list of 6 things to consider before you choose a specification management system.

1) Flexibility

An important feature of any specification management system is the amount of flexibility it allows. This includes, but is not limited to:

1. A security model that supports control over who within your company can do what to which content (Common specs v. SKUs v. BOMs v. Drawings).
2. Providing different, configurable form types for different types of specifications.
3. Offering the ability to store and manage related content – drawings, references, etc.

These capabilities allow your company to take control of your packaging content and make the most out of a spec management system. If you are limited to one type of form for creating specifications or are unable to store drawings and/or references, you are greatly limited in terms of what happens with your data and how your employees are able to manage it. When looking for a spec management system, make sure it has these flexible capabilities.

2) Ease of Use

In addition to flexibility, it is necessary to investigate a system's ease of use. If the software you choose is too confusing for the average user, your company will lose out on a lot of its important functionality. Will your employees need a computer science degree just to understand how to create specifications? Will you need to ask the vendor when you want to make even simple changes? Do you need the vendor to query your data to mine it out for analysis? If the answer to any of these questions is yes, the system may not be the right fit for your business.

You want a spec management system that works for you and your employees and makes your business processes easier, not one that is going to add confusion and make simple tasks less efficient. Be sure to do your research and make sure your chosen software has an ease of use that fits with your company.

Chapter 3: Specification Management System

3) Controlled Access to Appropriate Specifications

A good specification management system should have configurable security settings that will dictate which users are able to access certain specifications. Security is important, and you do not want anyone within or outside of your company having the ability to view and edit any spec on record without the proper permissions. So, when searching for a software it is important to check if systems allow you to closely monitor and choose who can access content, participate in workflows, and who will receive emails when specs go effective.

4) Integration Capabilities

Sometimes using only, a packaging spec software does not offer all of the capabilities your company needs to be as efficient as possible. In this case, it is important to have a system that can integrate with other programs.

For example, Enterprise Resource Planning (ERP) is a software that many companies layer on top of their specification management programs to add greater functionality. ERP helps businesses manage operations, and when integrated with packaging management software, the two can make internal collaboration easier and improve project management. Such integration enables the collection of organisation-wide information and data. It allows for less manual entry by packaging engineers, procurement and distributors and lets the system of record control various inputs (i.e., SKUs, GTINs, etc) and automatically share and tie the information to the other business critical system.

Before choosing a specification management system, it is important to remember that your company may need a software that can integrate with other important programs at some point in the future. This can allow your company to increase its efficiency and continue improving your packaging capabilities.

5) Document Control Capabilities

The integration of document control with packaging management is crucial. To remain compliant with industry standards and to keep packaging operations tightly organised, document control ties together the components of packaging specifications and processes and keeps track of all data needed to perform packaging correctly.

Chapter 3: Specification Management System

Even further, choosing a specification management system with version control capabilities within the document control integration will greatly improve business processes. Version control is a method of tracking changes to documents and files so that you always know which version is current. And in case you want to review changes or need to restore a previous version, it also enables you to maintain old copies of your documents. Supervising products and communicating with suppliers results in the creation of a lot of documents. By using specification management software with version control, you can efficiently track and control changes to these documents directly within your software.

When you have multiple revisions and no streamlined way to control versions, the risk of working from the wrong file is very likely. But with version control, when important specs are being passed and edited by various suppliers and co-workers, no one will need to worry if the information they are looking at is up to date. And, you will be able to track and manage the changes made to each document, ensure that content cannot be accessed by unauthorised users, get notified if there are pending updates that are awaiting approval, view the most current content and know who reviewed/approved it and when, and respond to external audits with history reports. For these reasons, document and version control is an integral part of packaging specification management.

6) Data Migration

The last capability you should look at when choosing a packaging specification management system is how your legacy data will be migrated into your new software. You need to put your trust in a vendor that you know has the experience and expertise to quickly and efficiently transfer your important information without making mistakes or requiring months to finish the process.

The data migration you choose should have the ability to do the following:

1. Identify optimum routing workflows.
2. Handle metadata when coming from a paper-based or network share data management process.
3. Link related documents.
4. Use picklists to organise data (as opposed to text-based user entries), default numbering schemes, and other ways to control data inputs.
5. Consult about read-only fields, read-only form pages, custom reports, use of masters and templates, security to control who can do what to the various datasets, etc.

With these capabilities, the transfer process will be a somewhat easier, and one will have no reason to worry about wasting time or losing important company data.

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Chapter 4: Collecting the Data

Packaging specs may be spread across different departments/sites along the supply chain, and any data that packaging technologists do have access to is generally managed using documents, legacy databases, spreadsheets, and shared drives. A manual specification management process can cause errors and rework for employees, inconsistent processes across different sites, and costly delays in production. It can also have a major impact on highly regulated companies who must comply with government regulations, possibly resulting in legal ramifications, sanctions and fines.

The specification document can range from a simple statement of basic requirements to a very detailed document which is highly prescriptive. In operational terms the development or a detailed and prescriptive specification has much to commend. They existence and formulation of a comprehensive document provides a reference point for several users who need to reaffirm to specifications. There will be a few operational areas which will have a vested interest in specification(s). Primarily the purchasing department will be a major user of specifications whilst the legal department may require only sighting the final document for its approval. The specification may form part of a formal contract in which case it becomes a legal document and as such needs to be carefully prepared in terms of detail. As we shall see the import to the writing of specifications is likely to involve many people in the initial stage.

We need to define the role of packaging. The primary requirements of packaging fall into two major categories firstly to contain, protect and transport secondly to inform, sell and promote. We must always strive to attain sustainable packaging. To fulfil all these requirements, we need to be able to draw on a wide range of knowledge. This will involve an understanding of the properties of various packaging materials, the nature of design, the use of colour and print and their associated technologies, the erection, filling and closing operations associated with the pack. Those systems involved in transporting the packed goods from the packaging line through the warehouse and distribution centres and finally to the consumer.

In addition to collecting the data we need also to set a timetable for the preparation of specifications and to identify those key stages where we need to contact outside organisations and must have adequate information on which to proceed.

As a means of collecting the information we can do so with the aid of a check list which is available, see Appendix 1. This may seem daunting at first but is comprehensive in its scope and identifies those contributors to the specification process and the information they will be expected to provide.

Product requirements

The introduction of a new product is frequently the initiative of Marketing particularly in the FCMG sector. They may initiate a program to fill a market segment or to copy a competitor or to branch into a new line of activity. Is it a consumer product or is it for general commercial sale? If it is in the FCMG category it is likely to require substantial graphics as the pack will be a 'selling vehicle' and there will be a need to consider practical factors such as ease of opening convenience and storage. Whichever of these options it is a requirement to have some concept of the potential market, it will be necessary to give some indication of volume as this will influence every stage thereafter. We need to keep in mind that predicting volumes are not easy and even the most careful predictions can be wrong. A complete 'flop' or a runaway success can create serious problems.

The next requirement is then to identify the products characteristics in terms of what needs to be protected and contained. Secondly, is this a pack from which several dispensations will be made or is it merely a vehicle for conveying the product to the consumer who then discards the packaging material.

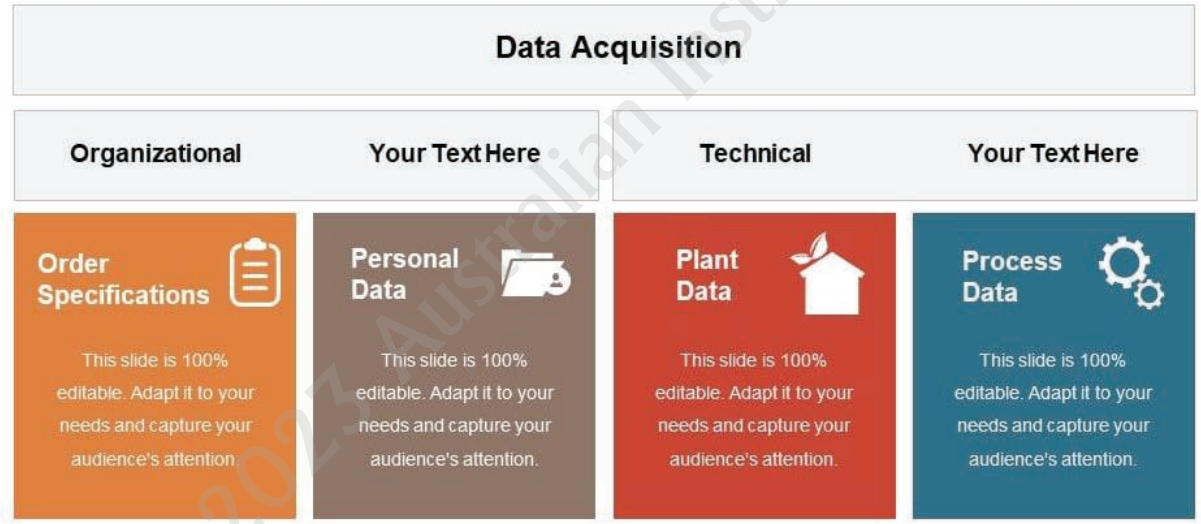
Chapter 4: Collecting the Data

In the case of food some 65% of all packaging is used for this product sector. Pharmaceuticals and OTC Over the Counter products (OTC), toothpaste, cosmetics etc- not requiring a prescription) follow as the next largest group. Both food and pharmaceuticals also make some of the severest demands on packaging in terms of protection and their sensitivity to environmental conditions. However, in the case of food the issue of overpackaging can be a key factor and evoke criticism. Packaging grapes for example in a specifically designed blister pack may ensure product protection but when the pack is empty may be seen as a waste of material.

An important factor to bear in mind from the conceptual stage onwards is the relevance and application of the Trade Practices Act which prohibits conduct which is likely to mislead the public.

In particular the risk of misleading the purchaser as to
i) quantity or volume of product
ii) labelling requirements and iii) product claims

The issue of free space in terms of the amount of product and the space it requires careful consideration in pack design. In the case of foods for example the pack should not contain specifically created voids with the intent of conveying a greater volume of product than is the case.



Product information

First however we need to understand and know the nature of the product which is to be packed, its properties and any influence they may have on the packaging requirements.

It is essential to establish the characteristics such as its physical state, its fragility, chemical and biological properties. Alternatively in the case of packaging a piece of equipment we will need to know its shape, weight, dimensions fragility etc. We also need to know whether it is temperature-sensitive or affected by light or humidity. We need as much information as possible about the product and its properties to establish the packaging requirements.

In the case of food, we need to know the product life and its deterioration characteristics. In other words what are trying to guard against? In the case of pharmaceuticals, the hygroscopic nature of some tablets can be demanding in terms of protection from moisture. Add to these the need for child resistance and tamper evidence and the pack becomes more complex not merely in terms of the design process but obtaining the necessary clearance from such bodies as the Therapeutic Goods Authority.

Chapter 4: Collecting the Data

If we look closer at two food products which are demanding in packaging terms, biscuits and meat pose challenges. In the case of biscuits, they are fragile, subject to abrasion hence we need a good moisture barrier, and we need physical protection to prevent the biscuits breaking through attrition. Added to which these same characteristics requires care in the packaging process. Meat on the other hand is moist and produces an unfortunate exudate i.e., blood, which must be absorbed or hidden in some way in the primary pack. In the packaging process the non-uniform shape must be taken into account. Meat is normally packed in environments operating at 6°c which complicates the operation and then requires transport and storage at low temperature to maintain its limited shelf life. It can be a vehicle for bacterial contamination and hygiene at all stages is a pre-eminent requirement at all stages. In both examples the demands on packaging materials is considerable bearing in mind that cost is also a key factor. Consumers may complain about what they consider is overpackaging without fully realising the conditions a product must face in reaching the consumer.

Electrical equipment such as domestic irons or vacuum cleaners present different problems. They may be robust, but they will still require protection for transportation but with the pattern of self-service they require elaborate high quality graphics. In addition, information may need to be in several languages involving a range of fonts.

Product considerations

The question of the packaging line is extremely important and not infrequently this doesn't get considered until discussions are well advanced. It is important therefore that this requirement receives the earliest consideration particularly if the delivery of new machinery is likely to be involved. If a completely new line is envisaged, then not only does the question of delivery time arise but also the question of space, plant disruption, staff training, etc.

If this is not the case and it is planned to use existing machinery, with or without some minor changes then the question must be addressed as to the available production time for a new product. If an existing line is to be utilised, then it is important that the proposed packaging material is assessed at an early stage on the existing line. Even quite minor changes can cause problems such as a reduction in the weight of packaging material or variations in surface characteristics. This in turn can result in pressures on the supplier to make corresponding adjustments.

Secondary and tertiary packs

Having determined the basic degree of protection we can then progress from the primary pack through to the secondary pack and tertiary packs. As we progress through each stage so the various interested parties can start to pick up on their involvement. The marketing/sales figures hopefully will have provided some idea of the capacity which will be required and in the early stages the Purchasing Dept. can start to identify potential suppliers.

Engineering and production can formulate their requirements in terms of the machinery required etc. If it is a non-standard pack, for example a fancy glass bottle the development time is likely to be longer than for say a basic carton. This will require more involvement from the designers particularly where a pack with some unique characteristics are envisaged. Hence in the preparation of specifications we need to proceed in a disciplined fashion and to take account of all the inputs which need to be made and to have an idea of the time frames for each stage. Inevitably problems will arise, and back tracking will be necessary. It is not unusual to arrive at an advanced stage only to find a change of plans and a need to return to the drawing board or abandonment of the proposal.

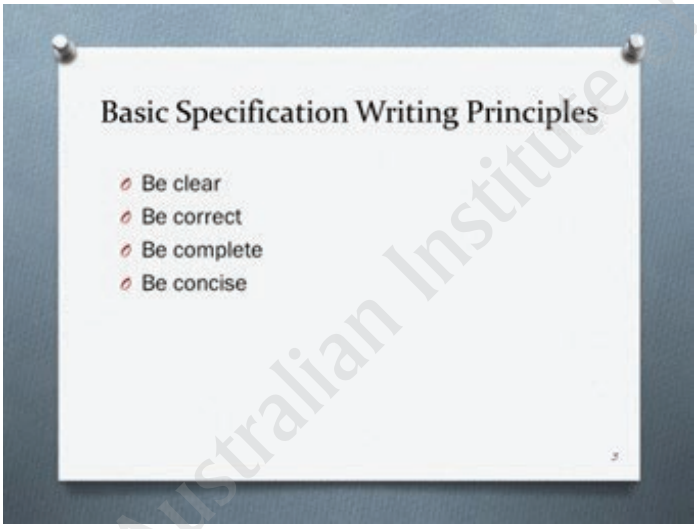
Chapter 5: Drafting the Specifications

The packaging specification is one of the very critical aspects of any organisation. The ultimate purpose of a specification is an agreement document between the purchaser and supplier.

A specification is represented as a list of tests, references to standard procedures (for e.g., AS, ASTM & ISO), and appropriate tolerance measures, including numerical limits, series, or other standards for the tests described. It sets the requirements to which a new packaging material should conform to be considered acceptable for its intended use.

'Conformance to specifications' indicates that the packaging material specification will meet the listed acceptance criteria when tested according to the documented standard procedures.

Specifications are significant quality standards proposed and maintained by the manufacturer and approved by regulatory authorities as approval provisions.



Formalising the incoming packaging material specification:

- Communicates the exact needs to the supplier
- Provides the supplier with a basis for judging production
- Provides one's staff with a basis for accepting packaging and components
- Allows for supplier bids on a fair and identical basis
- Serves as the contractual benchmark when there is dispute
- Serves as the benchmark for packaging improvement

Writing a specification requires understanding of what performance factors are critical, be that for machine packing or hand packing. Great care is to be taken to establish the correct tolerance level for critical performance. Too broad a tolerance can cause machine problems or aesthetic issues. By establishing unreasonably tight tolerances may limit the number of potential suppliers and increase costs.

A complete specification is not usually one single document, but rather a group of documents, describing all the materials, components, and manufacturing steps that will result in the required product. A good specification is one drawn up in collaboration with the supplier. The supplier must have production facilities that can produce the product within the tolerance range required by the buyer.

Chapter 5: Drafting the Specifications

The packaging material specification must be divided into three categories:

Step 1 A general overview of packaging material for tracing

Step 2 Physical Measurement and other tests (destructive and non-destructive test)

Step 3 Packing Instruction for logistic (packing for transport from supplier side)

A packaging specification is usually documented under the following layout headings:

General Overview

- Standard title (bottle, cap, laminate, etc.)
- Specification reference number and date have written.
- Previous edition/specification ref. No.
- General description of the item.
- Materials of construction—types, grade, colour, etc.

Physical Measurement and other tests (destructive and non-destructive tests):

- Construction, the process by which constructed; size/weight/capacity, with tolerances (maybe under a drawing reference).
- Drawing ref., date, details of dimensions and tolerances.
- Decoration, a component of print, decoration method, colour target(s), artwork reference, etc.
- Performance tests (concerning test method, number, etc.).

Transport Instructions of packaging material from the supplier side:

- How to be delivered and identified.
- Signatures of approval: supplier/purchaser.

Packaging specification template

This is a general overview of the packaging material's content, but the central part of the packaging specification is measurement parameters.

The measurement parameters started from visual appearance and then needed to specify the available measuring such as length, width, and diameter values. After next, it needs to set the value of functionality tests such as sealing and torque testing. Then, add performance tests such as transport worthiness tests (Drop, Vibration, and Stack load test). And then needs to add aesthetical tests such as artwork and Pantone colour of the packaging material.

The tentative idea to address any packaging material to analyse – start from the basics: such as visual, dimensional analysis, aesthetical appearance, functional test, performance test, safety, and security features, and artwork.

Writing the specification:

- Use simple, clear language without jargon (to minimise misinterpretation).
- Define terms, symbols, and acronyms (include a 'Glossary of Terms').
- Be concise.
- Do not explain the same requirement in more than one section.
- Define each aspect of the requirement in one or two paragraphs where possible.
- Adopt a user-friendly format.
- Number the sections and paragraphs.
- Seek feedback from someone unfamiliar with the requirement.
- Discuss the draft and refine it.

Chapter 5: Drafting the Specifications

Corporate policy standards and specifications are those documents that govern the entire specification process. They will identify:

- A consistent corporate specification format.
- Who is responsible for writing specifications.
- How the specifications are written.
- How specifications are issued, who gets copies and where are they kept.
- How a specification is revised and how a specification is withdrawn.
- Implementation.
- Courses of action when events occur that are outside of the specification.

Information required on the specification

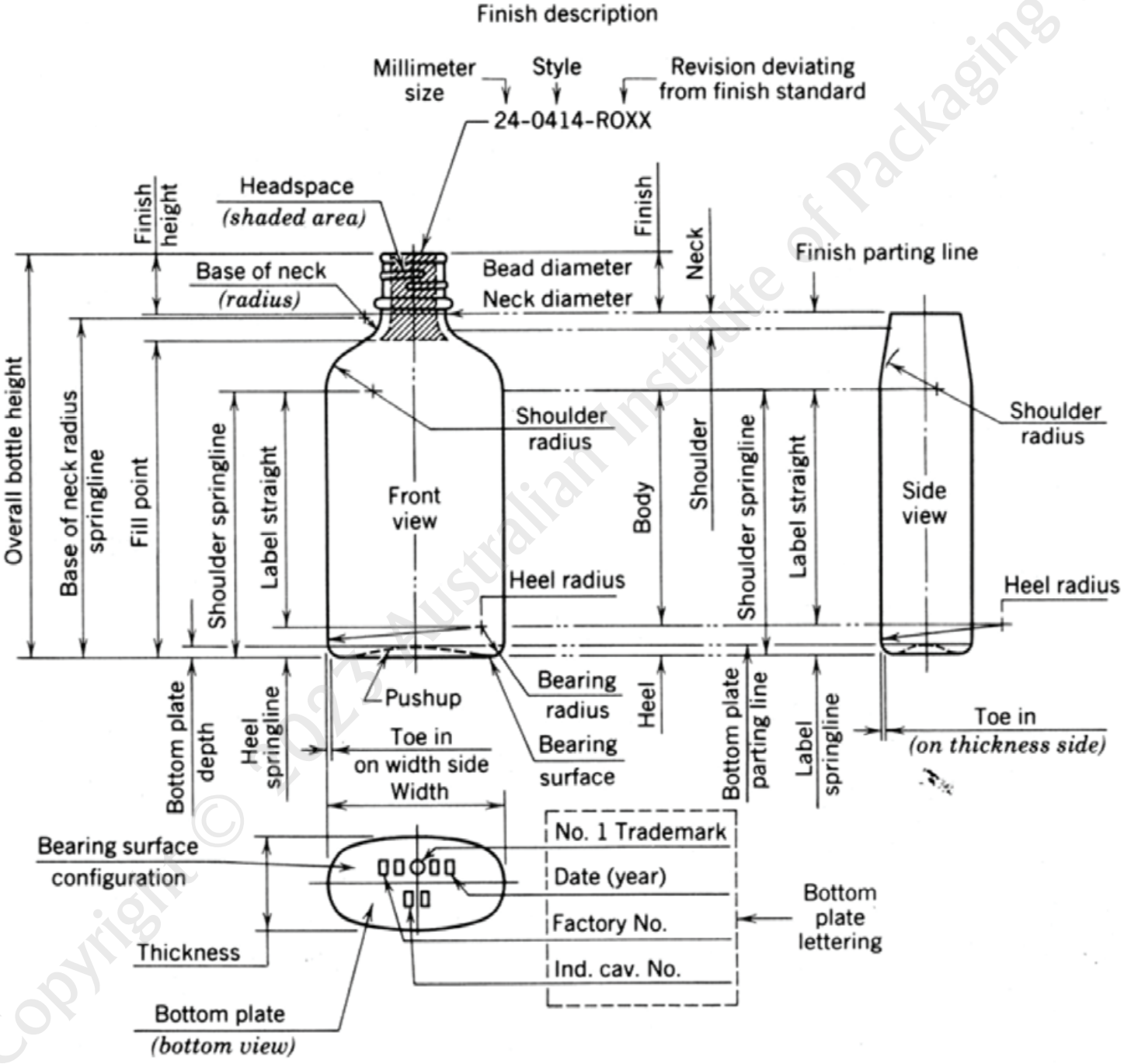
All specifications require some basic information, such as:

Company Name & Address

Item description	This needs to be a clear and concise statement as to the designation.
Unique Code/Ref Number	The code or reference number may be derived internally or may refer to a stock item in a suppliers range.
Supplier	Name and address Tel No. Email. Contact Dept/person.
Description	The description will define the container is i.e. jar, bottle and its shape, round, square, and intended use e.g sauce bottle, face cream jar etc. The closure will be defined, e.g roll-on, twist cap, vacuum cap, press on-twist off, lug closure, crown closure etc. In addition, the composition of the closure, metal or plastic should be stated. The inclusion of a liner and if so, its composition and sealing to the rim of the bottle or jar etc. Any tamper evident or security device such as a shrink seal or wrap. In the case of pharmaceutical products, a child resistant closure may be necessary etc.
Material:	This must state the type of glass, lightweight, colour etc. and the surface coatings (hot and cold end treatments) etc. The addition of colourants such as amber or green glass is achieved by the use of metallic oxides In the pharmaceutical area there are essentially three basic types of glass:- Type I or neutral glass Type II surface treated Type III soda or alkaline glass The type of glass is important as the medication can be affected by a shift in pH.
Decoration:	The decoration or printing should be described including embossing, in-mould treatments, acid etching, silk screen etc. The decoration will require artwork accompanied by proof references signed off with the approval date. Colour values can be expressed in PANTONE® together with a colour target.

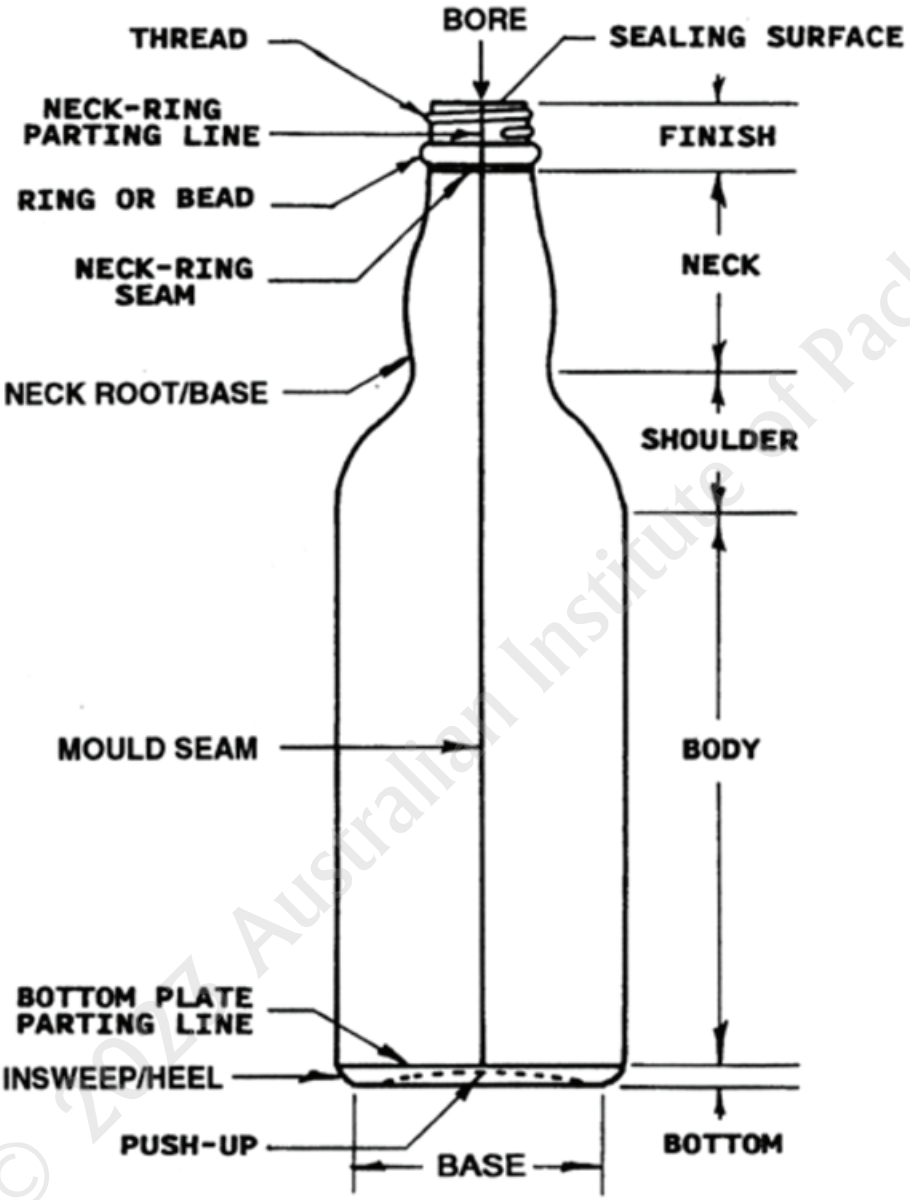
Chapter 5: Drafting the Specifications

Drawing: A drawing is essential and should be correctly annotated and be signed by an authorised person.



This is a detailed overview which identifies all of the measurements associated with a glass bottle. A simpler version is given on the next page.

Chapter 5: Drafting the Specifications



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Chapter 5: Drafting the Specifications

Dimensions: It is critical that the drawing carry detailed dimensions and tolerances; key amongst these are body diameter and height, capacity and headspace.

Body and Height Dimensions ensure to include allowed tolerances (max and min).

Body/Diameter Tolerances D (mm) up to and including	T_D (mm) ±	**Height Tolerances** H (mm) up to and including	T_H (mm) ±
25.0	0.8	25	0.7
36.5	0.9	50	0.8
50.0	1.1	75	0.9
62.5	1.2	100	1.0
75.0	1.4	125	1.1
87.5	1.5	150	1.2
100.00	1.7	175	1.3
112.5	1.8	200	1.4
125.0	2.0	225	1.5
137.5	2.1	250	1.6
150.0	2.3	275	1.7
		300	1.8

HEADSPACE Nominal capacity (mls)	Maximum design headspace (mls)
100	10
125	10
200	15
250	15
330	15
250	20
375	20
500	20
750	30
1000	35
1500	50

The headspace specified allows for temperature rises of up to 50°c from 5°c. The increased headspace for pasteurised products, where temperature rises of up to 80°c may be experienced should be kept as small as possible and should not exceed 1.66 times the appropriate values listed above. Bottles for carbonated soft drinks and carbonated water bottles are required to be designed to more restricted values than those shown above.

In addition to the dimensions listed above and following , neck diameter, thread wall diameter, transfer bead neck, neck height, and neck bore diameters including tolerances are essential. The thread style and finish together with minimum wall thickness should be stated.

It is important that the specification details and requirements are sufficiently detailed, clear and unambiguous at every stage. They should verified and signed by persons with the delegated authority to do so on behalf of both the supplier and the customer.

Chapter 5: Drafting the Specifications

Benefits to Packaging Technologist

Packaging Technologists are forced to examine a problem by drafting a technical spec before going straight into packaging material code, overlooking some aspects of the solution.

Time-wasting is reduced, especially when integrated. Specifications should never run short. Instead, they should be in excess. The scalability of managing teams is simple since the process is already drawn, and new developers understand the technical requirements without pressure. The entire group can work on a large project without confusion and any problems.

It offers developers a specifically defined contingency plan, so you don't end up with the 'failing to plan planning to fail' poster child. The chances of failure are reduced since the supplier would know the specifications and work within the plan.

What factors should be considered when drawing up packaging specifications?

Here are five factors to consider when designing packaging:

1) What Should the Graphics and Imagery Look Like?

2) What is the Product's Typical Supply Chain Journey?

3) What Material Will the Packaging Be Made Of?

4) How Sustainable is the Packaging?

5) How Much Does the Packaging Cost?

There is probably no other area of packaging that has been less understood than cost. Although many organisations calculate the cost of the package material itself as the total cost, the true cost is the total cost of the entire packaging system involved. A simple replacement of one component of a packaging material for a less expensive one may not be a true reduction and vice versa. The question to be asked is, 'How will the change affect the entire packaging system, and ultimately increase (or decrease) sales and/or profits?

Vetting Specifications

It is useful to have the specification vetted by someone other than the author.

The person vetting the specification should check that the specification:

- Is easy to read.
- Is easy to understand.
- Is clear
- Is consistent with specifications for similar or the same goods and/or services
- Has a logical structure
- Contains only essential information

Steps in the process

Step 1: Identify the Need

Step 2: Collaboration and Information Gathering

Step 3: Writing the Specification

Step 4: Approving the Specification

Step 5: Issuing the specification

Chapter 6: Types of Specifications

The meaning of the term 'specification' varies depending on how it is used.

Functional specifications

These are specifications that define the function, duty or role of the goods or services. It nominates what the goods or services are broadly required to do. Functional specifications define the task or desired result by focusing on what is to be achieved rather than how it is to be done. They do not describe the method of achieving the intended result. This enables suppliers to provide solutions to defined problems. For example, a specification for 'an accessible device capable of conveying children from their school to their homes' does not limit responses to bus operators alone.

Performance specifications

These are specifications that define the purpose of the goods or services in terms of how effectively it will perform, that is, in capability or performance terms. Performance is a logical extension of function. Performance specifications define the task or desired result by focussing on what is to be achieved. They do not describe the method of achieving the desired result. This enables suppliers to provide solutions to defined problems. For example, a specification could be written: 'An accessible device is required to convey at least 30 children every afternoon of the school week from their school in a safe manner to their homes within a radius of the school of 15 kilometres. The device shall be capable of achieving this within 1 hour. The device shall be capable of maintaining a comfortable environment for the children at an average temperature of 22 degrees Celsius in all types of weather. The device should allow equitable access by all children'. Such a specification does not limit offers to one type of transportation or one type of user.

Technical specifications

These are specifications that define the technical and physical characteristics and/or measurements of a product, such as physical aspects (for example, dimensions, colour, surface finish), design details, material properties, energy requirements, processes, maintenance requirements and operational requirements. They are used when functional and performance characteristics are insufficient to define the requirement.

Chapter 6: Types of Specifications

Project Specification

This describes a design and performance requirements for a particular project. It might contain requirements for how a product should be used.

Master Specification

This is a template that can be used to create a Project Specification. It may contain requirements for several products to help the select the one or ones best suited for a particular project.

Guide Specification

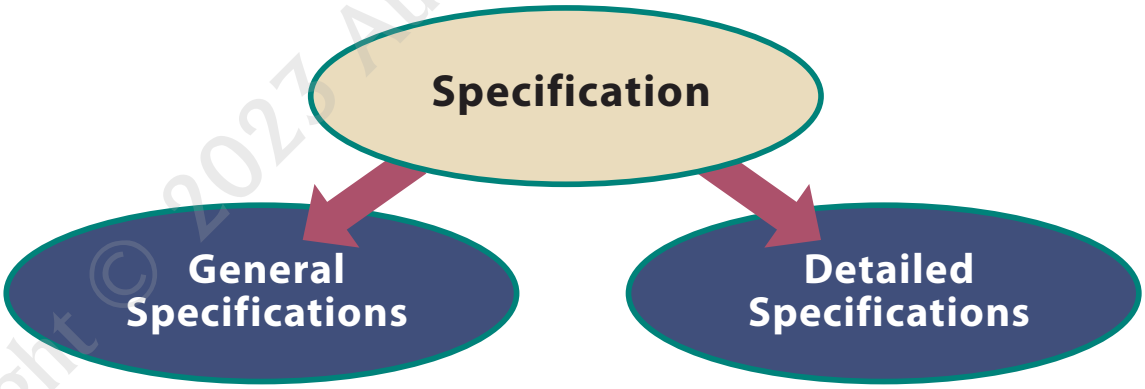
This is a type of master specification that is published by a product manufacturer to help write a project specification that is based on the manufacturer's products.

Product Specification

This describes a manufacturer's product and its performance without always considering a particular application. A manufacturer publishes this information as part of its sales literature. In the case of a material, it is well defined.

In the case of a packaging specification, it defines all the necessary packing levels for a product in order, for example, to put away or transport the product. For a product, a packaging specification mainly describes in which quantities you can pack the product into which packaging materials in which sequence.

The packaging specification can be used to monitor packaging being received and help to manage any issues and disputes that may arise. It is also important to update the packaging specification with any changes to the packaging material.



What is a specification

In a procurement context, a specification can be defined as a statement of needs. It defines what the procurer wants to buy and, consequently, what the supplier is required to provide. Specifications can be simple or complex depending on the need. The success of the procurement activity relies on the specification being a true and accurate statement of the buyer's requirements. Apart from being a means of identifying the goods or services required, a specification will form part of any future contract that might result from offers received. The specification forms part of an 'Invitation to Offer' document. Other elements in the invitation document include the 'Conditions of Offer', the 'Conditions of Arrangement/Supply/Contract' and response schedules.

Chapter 6: Types of Specifications

A good specification should:

- State the requirement clearly, concisely and logically in functional and performance terms unless specific technical requirements are needed for goods, state what the item will be used for .
- Contain enough information for those that offer to decide and cost the goods or services they will offer and at what level of quality.
- Permit offered goods or services to be evaluated against defined criteria by examination, trial, test or documentation.
- State the criteria for acceptance of goods or services by examination, trial, test or documentation.
- Provide equal opportunity for all potential suppliers to offer goods or services which satisfies the needs of the user, including goods or services incorporating alternative solutions.
- Form the fundamental basis of the contract between buyer and seller not over-specify requirements.
- Not contain features that directly or indirectly discriminate against people with disability, but allows optimal access and inclusion.
- Not contain features that directly or indirectly discriminate against Australian and New Zealand suppliers.

All three types (functional, performance, technical) may be combined to form the one specification. While Government generally encourages the use of performance and functional specifications rather than technical specifications, certain requirements may not be adequately defined in these terms alone. Technical characteristics may be needed to define some requirements more clearly.

Specification examples

This gives an example of a known product or service which would be appropriate and allows for alternatives by including the words 'or equivalent' or 'or similar'. It may be necessary to specify items when the equipment is genuinely necessary and does not reflect a bias towards particular items or suppliers. The reasons for specifying the nominated items should be given. Try to specify at least two acceptable products to avoid suggestions of bias and to select from the widest possible range of solutions.

Samples

For some products it may be necessary to supply an actual example of the item required by the buyer department to the supplier. Suppliers must produce goods that are identical in all respects to the sample. Samples should only be used in appropriate circumstances with a complementary specification. Instances where samples may be used to specify requirements include clothing, footwear, Government badges, etc.

Chapter 6: Types of Specifications

Drawings

Drawings can be used in a specification as technical characteristics or to provide guidance to offerors. Examples include site drawings, custom-made furniture for fit outs, system drawings and schematics. Drawings in specifications involve risk. Requesting a supplier to produce an item to a drawing or set of plans is like nominating a brand name: the manufacturer is largely absolved of responsibility if the item does not work (providing, of course, that the item is built to the drawing of plan). There are contractual clauses to cover this eventuality, but the use of drawings as a specification generally requires the buyer to bear most of the risk of things going wrong.

In addition, seeking offers on the basis of drawings provides little opportunity for offerors to offer new or alternative solutions to the requirement. However, if research on the requirement shows that a drawing is the best way to define the need, it should be used.

Whenever a drawing is used as part of a specification, check to see if ownership of the copyright should reside with the department/agency. If in doubt seek both technical and legal advice. Australian Standards for drawings exist and these should be consulted when preparing and revising drawings.

Evaluation criteria

Whatever methods are used to define the goods or services, there must be criteria to evaluate compliance of offers with the specification, legislative requirements or associated standards. Such evaluation criteria should be developed at the same time as developing the specification. They may be combined with other criteria, for example, price, accessibility, delivery, warranty, to give an overall assessment of the value for money represented by each offer. On the other hand, compliance may be a 'pass' or 'fail' to meet the mandatory requirements. Value for money may then be assessed on other variables.

Who is involved in developing the specification?

Users of the procured goods or services should be involved in defining their requirements together with appropriate project officers, technical officers (for example, information technology or medical staff) and procurement officers.

Step 1: Planning and analysis

The foundation of a good specification is in the planning and analyses which are undertaken before writing begins. Key people who can help such as procurement staff, technical officers, project officers and managers, disability representatives and end users need to be involved. Planning and analysis will provide a better understanding of the requirement(s) and may reveal alternative solutions.

Planning and analysis are particularly important when developing complex requirements. These may take some time to define, perhaps even years in the case of major equipment. The accuracy and detail of the definition is likely to improve as information is gathered and assimilated.

Define the requirement(s) and then approach industry to see what is available to meet the department's/agency's needs. If industry is approached too early in the development process, there is the risk of deciding the solution to the problem before the requirement(s) is fully defined.

Chapter 6: Types of Specifications

In some cases potential solutions may be discovered and explored which may allow refinement of needs.

Think in terms of the performance required or the functions to be performed. In other cases, however, solutions may not be readily available or there could be the danger in stating a solution up front that may restrict offers of alternative solutions. In this situation, a full explanation of the issue or problem is needed.

Breaking down the requirement(s) in terms of function and performance will better define the need.

Defining the requirement(s) in terms of the lowest level functions or sub components should also help to discover conflicts and inconsistencies within the requirement(s). Alternative solutions, too, may be revealed in the process.

Value analysis could be used to highlight and explore possible solutions. It is a complex cost analysis technique that requires expertise for its successful use. In simple terms, value analysis looks for the optimum way of using materials, designs, equipment etc. to meet a (functional) requirement while providing savings over the life of the equipment or at the initial purchase stage. The technique is particularly useful in identifying potential, innovative solutions.

Step 2: Consultation and information gathering

Developing specifications requires consultation and can be perceived as an evolutionary process involving close and continuous liaison between the end-user, technical officers, project officers/managers, procurement officers and the specification writer.

Breaking down the requirement(s) in terms of function and performance will better define the need.

Valuable information and advice relating to the requirement can be obtained by discussing it with procurement officers, technical officers and other users of similar goods or services within the department/agency. Procurement officers should be involved from the start of the process (that is, the information gathering and design stages).

Other sources of information include:

- Other departments or agencies (including federal and local governments).
- Industry - either industry associations or particular companies (ensure that industry does not assume pre-offer negotiations).
- Educational institutions, for example, universities and TAFE Institutes.
- Standards Australia.
- Industry Capability Network Queensland which can assist in identifying and evaluating appropriate.
- Local industry capabilities
- Disability representatives on category council industry reference groups.
- Other users of the goods or services.

These organisations may help to refine the requirement and also suggest potential solutions.

Chapter 6: Types of Specifications

Step 3: Writing the specification

Some writing tips:

- Use simple, clear language without jargon (to minimise misinterpretation)
- Define terms, symbols and acronyms (include a 'Glossary of Terms')
- Be concise
- Do not explain the same requirement in more than one section
- Define each aspect of the requirement in one or two paragraphs where possible
- Adopt a user-friendly format
- Number the sections and paragraphs
- Seek feedback from someone unfamiliar with the requirement
- Discuss the draft and refine it.

There are no fixed rules on formats and structures because each specification reflects a different requirement or need. A specification should list the functional, performance and technical characteristics separately.

Refine the structure before writing by discussing with colleagues and procurement officers. Include tables, sketches, diagrams, or statistical matter if these help to make the specification clearer. Be careful that these types of information do not limit the options for offerors to provide alternative solutions.

Step 4: Vetting the specification and obtaining approvals

After writing the specification, ask a colleague who is unfamiliar with the requirement to critique it from a potential supplier's view.

Try to identify improvements by considering:

- Readability
- Simplicity of meaning
- Clarity
- Logic

Seek approval from the appropriate financial or procurement delegates in the department/agency after vetting the specification but before issuing it.

Step 5: Issuing the specification

The specification should be included as part of the 'Invitation to Offer' document.

Step 6: Managing amendments to the specification

Should a need arise to amend the specification during the 'Invitation to Offer' process, the amendment should be authorised by the project manager. The amended specification should be noted in the project files and all offerors or potential offerors must be given a reasonable opportunity to offer to the new specification.

Step 7: Revising and storing the specification

The specification should be reviewed at the end of the procurement activity to ensure that it effectively defined the goods or services that were actually bought. If areas for improvement are identified, revise the specification with the benefit of hindsight.

When the review of the specification has been completed and if it relates to goods or services that are likely to be procured frequently, keep it on file. Before each procurement, review the specification to ensure that it reflects your department's/agency's needs at that time. Alternatively, institute a program to review specifications on a regular basis.

Chapter 7: Specification Outlines

What information is included in a specification? After agreement about what information will be included in the specification and an appropriate structure, it must be formatted into a usable specification.

There is a range of information that can be included in a specification. Including particular topics will depend on the nature of the goods or services being specified.

Structure	Content
Header	The name of the packaging specification, the user who created it and it status.
Contents	The name of the product to be packed or the number of another packaging specifications.
Level	The level associated with the packaging specification. A packaging specification an have one or more levels.
Element Group	The element group associated with the packaging specification. A packaging specification can have one or more element group. An element group can have one or more elements. Element groups can be re-used.
Element	A packaging material and/or a work step.

The list is not exhaustive and there may be other topics that are needed.

1. Title
2. Table of Contents
3. Introduction
4. Scope
5. Background information or history of the required goods and services
6. List of terms, symbols and acronyms (glossary)
7. List of relevant documents
8. External approvals
9. Security aspects
10. Environmental and ergonomic limitations
11. Detailed requirements
12. Whole-of-life support
13. Marking of supplies
14. Preservation and packaging
15. Quality requirements
16. Testing

Chapter 7: Specification Outlines

1. Title

Use a simple description of the specified goods or services for the title. The title should be as broad as possible to allow alternative solutions to be offered. To achieve this, particular materials (for example, steel or timber) or energy sources (e.g. electricity) or other restrictions should not be included in the title unless they are essential.

Use broad, open titles to describe the basic function (for example, 'Materials Handling Equipment' or 'Waste Management') where more than one type of solution may be available. Where a range of goods or services are required, the title should encompass the generic nature of those goods or services.

2. Table of contents

A table of contents needs to be considered particularly for longer and more complex specifications.

3. Introduction

An introduction sets the scene for the specification by describing the required goods or services in the larger context of the department/agency. A well written introduction will increase potential suppliers' interest in the invitation and help them to understand the department's needs. Detailed requirements should not be included in the introduction. The decision to use an introduction will be influenced by such factors as:

- The expected level of public awareness about the department/section.
- The complexity of the required goods or services.
- The novelty or innovativeness of the required goods or services or their intended use.
- The need to describe the required goods and services in a larger context.

4. Scope

The scope is a general statement or summary about the required goods or services. Complex specifications are more likely to benefit from a scope section than simple ones. However, even for simple specifications a scope may represent an effective way to highlight the main aspects of the requirement.

Consider writing the scope as a stand-alone statement of the requirement. This will permit procurement officers to use the scope in offer and contract documents as well as in advertisements seeking offers. The scope should include a brief description of the requirement and the application, purpose or function of the goods or services required.

5. Background information or history of the required goods and services

Goods or services that are complex may be better understood by potential offerors if their history is explained. Giving offerors information about how and why the requirement arose can help them decide their best solution.

Background information includes:

- The origin of the need for the required goods or services.
- The current need for the goods or services.
- An outline of the research which has been undertaken into the goods or services.
- What options (if any) have been considered.
- What options have been dismissed and why.
- A description of the current system, equipment and methods which will be replaced by the goods or services being defined or solutions being sought.
- How this requirement is related to earlier purchases and perceived future requirements.
- The implications for the user resulting from implementing the selected solution.

Chapter 7: Specification Outlines

6. List of terms, symbols and acronyms (glossary)

- Use acronyms and symbols sparingly.
- Do not assume that such words and phrases will be understood or interpreted correctly by offerors (if in doubt, research the market to find the commonly used terms).
- Use a glossary to define abbreviations, acronyms, technical terms or symbols if there is a need to use them.
- Jargon should not be used (unless it is a well-accepted industry standard).
- Use accepted definitions or standards to explain acronyms and symbols.
- Place the glossary where it best assists reading and understanding the specification.

7. List of relevant documents

Provide a list of all documents referred to in the specification rather than including the actual documents or extracts. Documents that are readily available commercially, or which offerors can reasonably be expected to already hold, do not need to be provided. However, unusual or hard to find documents should be provided to offerors. But be prepared to provide a copy of any relevant document if an offeror makes the request.

Documents most commonly referred to include other specifications, Standards, reference publications, Codes of Practice, Acts of Parliament and Government directions and regulations. Nominate the part(s) of the specification to which each document applies.

Determining which documents to reference should be part of the analysis of the requirement. List only primary documents (that is, those documents actually referred to in the specification). Secondary documents should not be listed as they are automatically invoked by implication.

Standards

Standards are the most frequently nominated documents. These are generally produced by Standards Australia, the International Organization for Standardization, professional organisations, individual companies, industry organisations, and commonwealth and state departments/agencies.

Only list Standards relevant to the required goods and services. Similarly, where Standards are mandatory for a particular good or service, ensure that they are included. Because Standards are revised from time to time, nominate the current version to be used. Inappropriate Standards, or those which are too stringent, will not guarantee the integrity of the goods or services and may contribute to a higher cost. Requirements for off-the-shelf items in particular offer little opportunity to invoke Standards other than those generally used by industry (e.g. electrical safety standards).

Precedence of documents

Nominating documents raises the possibility of inconsistency between the specification and the other documents or between the other documents. To help minimise this possibility, relevant documents should be given an order of precedence.

The specification should be given importance in this order and then all other documents from the most specific to the most general, making the latter the least important. Acts of Parliament or Government directions or regulations that affect the required goods or services, of course, take precedence over the specification.

8. External approvals

A contractor may need approval from a relevant authority to perform certain work under the contract. For example, to make an electrical connection, close roads or access properties for survey work. It is normally the contractor's responsibility to make arrangements for obtaining any approvals or certifications necessary for the completion of the task in accordance with the laws of Australia, Queensland and any bylaw, ordinance etc. that may be applicable.

Chapter 7: Specification Outlines

9. Security aspects

Define the required security measures the offeror may need to consider. A purchase may require security measures to:

- Protect the community's interest.
- Safeguard personal information.
- Provide confidentiality of commercial information.
- Safeguard expensive equipment.

Where security considerations apply, they should be listed but only to the extent that they affect the definition of the requirement. General security aspects of the procurement, along with procedures for managing security, should be given in the offer and contract documents. Consult relevant departmental officers if there is uncertainty about security considerations.

10. Environmental and ergonomic limitations

The physical environment in which the goods or services will operate, or be located, may have an impact on their design or performance.

These limitations and constraints should be stated in the specification.

Limitations may include:

- Operating and storage conditions (e.g. maximum and minimum temperatures, noise, pressure, humidity, atmosphere, altitude, shock, vibration, radiation, terrain, dust, chemicals, electrical interference).
- The physical space available for installing equipment.
- The effects on the environment of using the equipment or providing the service.
- The need for interchangeability or compatibility with existing equipment, systems, etc. – the nature of, and reason for, this must be stated to give offerors the opportunity to adapt products accordingly • availability of energy and other services.
- Intended users of the product and their ergonomic requirements (e.g. suitability for use by people who use wheelchairs or have other access needs).
- Personnel safety aspects.
- Provisions needed for unskilled people or people with disability (e.g. the need for signs/labels in various languages).
- Servicing or maintenance requirements or limitations.

11. Detailed requirements

This section in the specification describes the requirement in detail. The amount of detail provided should reflect the complexity of the requirement. Allow for alternative solutions when defining the requirement.

- Detailed requirements are usually best described as:
- Functional characteristics
- Performance characteristics
- Technical characteristics.

Combining performance and functional characteristics provides the opportunity for suppliers to offer solutions tailored to the requirement based on their product and service range. Alternative solutions should be assessed against the evaluation criteria, including an assessment of any desirable features offered as part of each solution.

Other aspects If parts of the required goods or services are not easily defined in terms of function, performance or technical characteristics, these should be defined separately. For example:

- Site preparation
- Installation
- Drawings
- Training
- Maintenance services
- Reports and other documentation (e.g. equipment handbooks, software, computer file listings)

Chapter 7: Specification Outlines

12. Whole-of-life support

If requirements for equipment include their maintenance, modification or upgrade during use (e.g. mainframe computer systems, air conditioning plants and scientific devices) the specification should address reliability, availability and maintainability in order to minimise whole-of-life costs of the equipment. This information should be included whether the equipment is to be maintained or operated by the supplier or by the department/agency.

Analysis of reliability, availability and maintainability can be a complex and difficult area requiring expert technical skills and knowledge. Use of value analysis can help optimise reliability, availability and maintainability requirements during requirement analysis and equipment design. Consider possible upgrades and avenues for upgrading equipment and software. Define what additional or enhanced capability is, or may be, required. Include in the request for offers the timeframe for implementing the upgrade and information required to evaluate the offers received.

- Operating and storage conditions (e.g. maximum and minimum temperatures, noise, pressure, humidity, atmosphere, altitude, shock, vibration, radiation, terrain, dust, chemicals, electrical interference).
- The physical space available for installing equipment.
- The effects on the environment of using the equipment or providing the service.

13. Marking of supplies

Goods purchased by the government can be marked to:

- **Denote government ownership:** Departments/agencies need to decide what identification markings, if appropriate, should be applied to goods purchased.
- **Identify the item:** Many off-the-shelf products are marked with the name of the manufacturer and the model number. Specify if more (or less) is required but changing the standard, commercially produced item will probably be expensive.
- **Provide warnings or other cautionary information:** Warnings and cautionary information will be required where there is potential for injury to operators, maintainers or bystanders. Sometimes such warnings are a legal requirement. Check what needs to be done in each case.
- **Address consignments:** Be clear about the address to which the package or consignment is to be delivered.
- **Note special precautions:** Any special storage, operating, handling or packaging needs should be identified (e.g. 'Store below 45 degrees Celsius' and 'This way up').

14. Preservation and packaging

Items may need to be preserved and/or packaged before delivery. Preservation is protecting an item from damage or degradation during shipment and storage (e.g. by dipping it in wax or infusing it with a chemical preservative). Packaging is the provision of an outer wrap to protect an item (for example, a foam-lined box).

The level and type of preservation and packaging required depends on the item, type of transportation, its use and the responsibilities of the contractor. Contracts for supply and installation of equipment need not nominate any preservation or packaging requirements, as these are the responsibility and risk of the contractor. The risk associated with goods in transit should be dealt with in the contract for supply.

Off-the-shelf commercial standards may be adequate. Nominating higher standards may delay delivery and increase costs. Use preservation and packaging standards wherever possible or define requirements in functional and performance terms (e.g. 'Packaging suitable for transport by (mode) to the site of installation' or 'Preservation to ensure no corrosion in a commercial-type warehouse storage'). Dangerous goods need special care. Refer to the Australian Code for the Transport of Dangerous Goods by Road and Rail, International Air Transport Association (IATA) regulations and other similar codes of practice.

Chapter 7: Specification Outlines

15. Quality requirements

For purchasing purposes, quality can be broadly defined as fitness for purpose. It is the totality of an item's characteristics which make it suitable to satisfy a department's/agency's needs. Quality can cover attributes such as reliability, performance, standard of workmanship, accessibility inclusions, conformance of design and economic and perceived value.

Including quality requirements into a specification is one of the methods of managing the risks associated with the goods and services required by a department/agency. The aim is to remove, transfer or minimise these risks before the goods or services are acquired. The seriousness of these risks depends on the likelihood and consequences of something going wrong with either the acquired goods or services or with the procurement.

16. Testing

Goods are tested to ensure that they meet the requirements of the specification. If standards or other documents have been specified, they may list tests to assess certain aspects of the item (e.g. electrical safety).

These tests will have to be performed by the contractor to satisfy those documents. In the specification or 'Invitation to Offer' documents be clear about who is responsible for testing. Other tests may need to be specified. These should cover all aspects of the requirement and be designed to prove that the product offered is suitable for its intended purpose. Specifying the tests includes nominating the criteria for passing or failing those tests as well as the implications of failing. Criteria for passing the tests as a package (as opposed to passing each test) should also be stated.

The supplier may develop and conduct tests for some requirements. The right to approve the contractor's testing plans should be specified before they are implemented.

Testing may be conducted through an independent organisation instead of the supplier. National Association of Testing Authorities (NATA) may be used for technical tests in purchasing. For more information refer to the NATA website at www.nata.com.au.

Get proof of all test results from the supplier. Accordingly, nominate pro forma or test certificates to be completed by the contractor or other testing organisation.

Information which should not be included in specifications

Excluding unnecessary information is as important to preparing an effective specification as including relevant information. These decisions can be difficult to make so consult with procurement officers to resolve uncertainties about what information belongs in the specification and what information belongs in the other 'Invitation to Offer' documents.

NOTES

Chapter 8: Material Types

Each packaging material – paper, glass, metal and plastics – and each form of packaging within these segments, continuously struggles for its share of this enormous market. But because the total is growing slowly, the industry has come to resemble a zero game where one material's gain is another's loss. This accelerating competition between the different materials has forced a greater emphasis on new technology, new packaging systems and new distribution systems, and these developments are increasingly occurring on a worldwide basis.

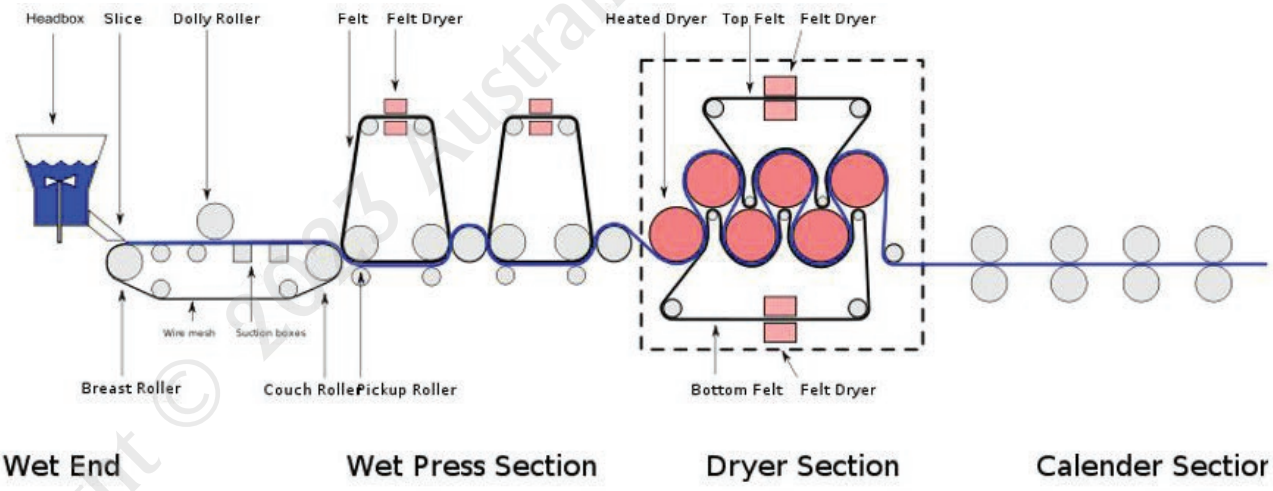
PAPER AND BOARD

Modifications of natural pulp

Many grades of printing papers contain sizing and/or filling materials such as starch or resin sizes or clay fillers to modify the absorbency, hardness, smoothness, printability, durability, weight and handling characteristics of the paper. Therefore, there is wide variety of starch-sized, resin-sized, clay filled and titanium-filled papers.

Paper is made from both unbleached and bleached fibres, depending on whether strength and economy are more important than pure white appearance. Coloured papers are also made by adding dyes to the pulp slurry in the stock preparation section prior to entering the paper machine. Coloured papers made in this fashion are termed beater-dyed and must be ordered in large quantities due to the expense involved in paper machine changeovers.

To impart increased smoothness and density to the sheet, paper is calendered, i.e. passed through varying numbers of nips between smoothing rollers under pressure.



Paper and paperboard specifications

Paper is made in many different weights and thicknesses and in a wide variety of densities and surface finishes. Thick papers are usually referred to as paperboard. There is no definite point where paper becomes paperboard. The terminology usually depends on such factors as density, composition and end use.

Paper is referred to in grams per metre. Paperboards are usually classified by thickness or calliper, rather than by basis mass. This is expressed in micrometres (microns). One micron (um) = 0.001mm.

Unbleached kraft, or coarse brown paper, is the most economical and strongest packaging paper. It is used for wrapping paper, paper bags and general packaging purposes. Unbleached kraft can be laminated, coated and impregnated with various protective materials such as plastics and waxes.

Chapter 8: Material Types

Coated paper

Many different coatings are applied to paper surfaces. Some are applied mainly to enhance the appearance of the paper and to improve the printing surface, others are used to provide functional qualities such as water-resistance, grease resistance and heat – sealability.

Mineral fillers

Coating comprising mainly clay or other mineral fillers with starch binders provides smoother and more even printing surfaces without slowing the drying rate of inks and used for magazines and high gloss labels. Binders usually enhance printability but can decrease the absorbency of the paper surface so that ink trapping and drying problems are increased.

There are two general classifications of boxes and cartons: 1. folding boxes or carton, 2. corrugated and solid fibre shipping boxes. The British Standards Institution defines a carton as a package which is: 1. made from paper board of thickness between 300 and 1000um, 2. delivered by the manufacturer to the user either in the flat form or in a collapsed form for erection.

Manufacture of cartons

The manufacturing stages are: 1. Printing, 2. Cutting and creasing, 3 Stripping and 4. Folding/gluing.

Printing

All major printing processes can be used for cartons. Lithography has been the preferred method for many years, but in the last 10 years due to vast improvements in flexography, more and more cartons are using this method. When a design is to be printed on cartons, the layout of the cutting and creasing forme is used as a template for the plate making layout.

Cutting and creasing

The prime objectives of creasing board are: 1. to define the shape of the carton panels, 2 allow the blank to fold without distortion.

Laser die cutting

Here all dimensions for cutting the forme are fed into a computer which drives a laser cutting device. The laser beam cuts channels into the plywood base and cutting and creasing rules are inserted into the channels in a similar way to jig cut dies. The advantages of laser die cutting are its accuracy and speed of cutting. Costs of installing a laser die cutting system can only be justified for a large turnover of carton work.

Stripping

Cutting and creasing results in a sheet of carton shapes, lightly held by bridges, and containing unwanted board which is removed by stripping. Automatic stripping is possible but a great deal is still by hand.

Folder/gluer

Cartons are supplied by the manufacturer in a collapsed state, with a glued side-seam and two principal folds already made. Folding gluing is done at high speed and adhesives must have a high tack. Crease quality is important otherwise poorly formed cartons cause deformation of the blanks.

Styles of Cartons

Many different types of cartons exist. The entire range stems from either a tube or a tray. A tube consists of a sheet of board folded over and glued at the edges to form a tube, the ends of which can sealed or locked in a variety of ways. A tray is a sheet of board with all four sides folded at right angles to the main sheet, and locked or adhered together at the corners.

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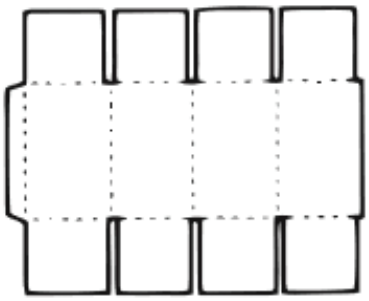
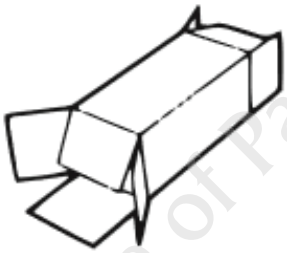
TUBE STYLE CARTONS

Glue-end carton

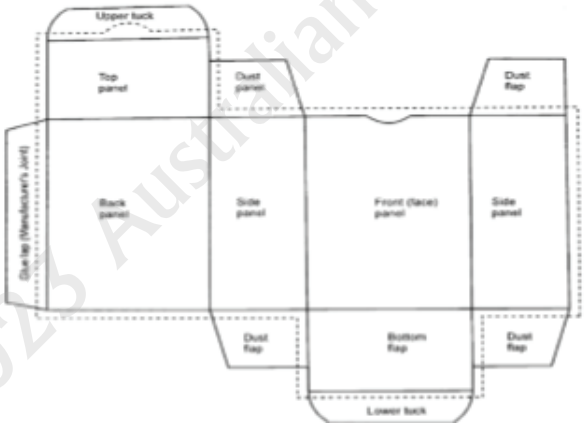
This is the most common carton style. These are produced from a single blank and delivered in the form of a collapsed rectangular tube with four flaps at each end for sealing. Suited for high speed automatic filling.





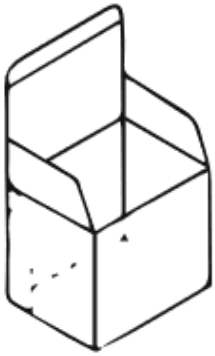
Tuck-end carton

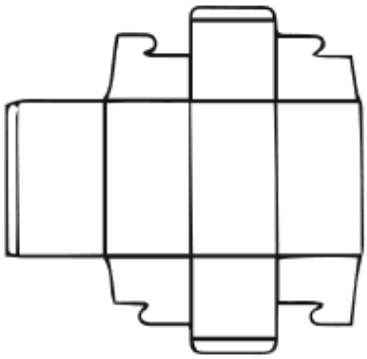
Used where reclosure is a feature of use or where customer inspection of the contents may occur. One of the four flaps of the glue end style is omitted and on the opposite flap an extension is provided which tucks into the body of the carton.



Lock-end carton

Heavier articles often require a safer re-closure than the tuck-end and a lock-end style is appropriate where a tongue engages with slits. Numerous patented styles of carton have been developed incorporating this locking feature.





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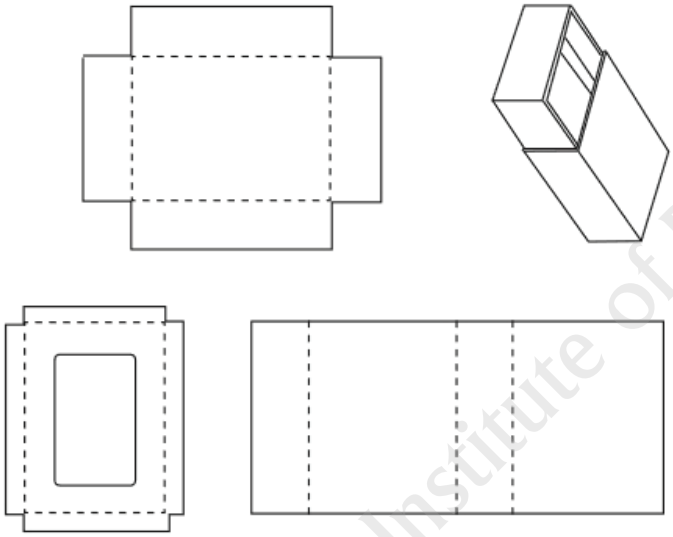
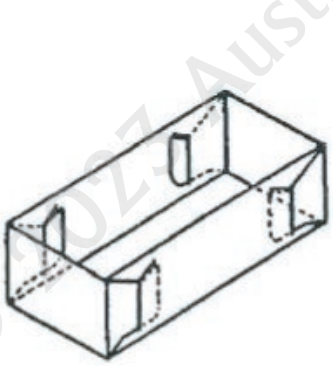
Shell and slide carton

This is an outer tube with a tray-like slide with tuck ends. Commonly used for match boxes, where frequent dispensing of the contents is required

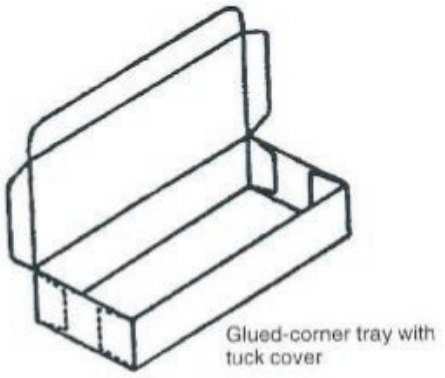


Tray style cartons

They have an unbroken bottom with sides folded at right angles, secured by spot gluing, locking or stitching to complete the tray. Trays may be one piece with lids, have a separate lid over wrapped with transparent film, etc.



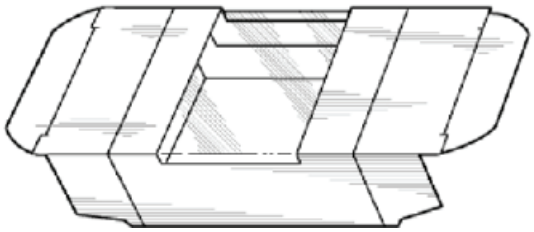
Lock-corner tray



Glued-corner tray with tuck cover

Window carton

Cartons are made with cut-outs or windows. Modern display trends, where customers are encouraged to buy by seeing or feeling the contents, have particularly helped to develop these cartons.



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Main Paperboard grades

- Paperboard used to make folding cartons usually consist of several layers.
- Chipboard – 100% recycled fibre and lowest cost type of paperboard.
- Lined Chipboard – has a white face liner to improve appearance.
- Bending Chipboard – 100% recycled fibre with enough high quality fibre to allow scoring/folding.
- Single White-Lined Paperboard – top liner is 100% new pulp.
- Double White-Lined Paperboard – both liners are 100% new pulp.
- Clay Coated Paperboard – SWL or DWL board that has been clay coated for brightness/printing.

Carton design for strength

The most important aspect of paperboard in the design of folding cartons and boxes is stiffness. Stiffness depends on the thickness of paperboard and on the fibre, quality used to make it. Stiffness decreases with increase in the proportion of recycled fibres. Therefore, if the board has a high recycled (wastepaper) content, greater thickness is needed to provide the same stiffness as one containing virgin fibres.

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CORRUGATED BOARD

Corrugated fibreboard is a structure consisting of arches and columns. In the horizontal plane, the fluting medium forms a continuous series of upright and inverted arches. In the vertical plane the fluting medium forms a continuous series of columns.

What is corrugated board?

It is a composite structure made up of at least one corrugated layer and at least one flat layer. The corrugated (or fluted) layers are generally called corrugated medium or fluting. The flat layers are called 'liners'.

The performance requirements of a corrugated fibreboard box range from concern for its appearance and advertising appeal, to requirements for mechanical strength and ability to protect the packaged commodity. The mechanical strength properties are stacking strength and containment or resistance to rough handling (vibration and shock).

Classification

1. Board made from one layer of fluting and one liner called 'single faced corrugated board.
2. Board made from one layer of fluting sandwiched between two liners, called 'single wall' or 'double lined' corrugated board.
3. 3. Board made from two layers of fluting sandwiched between three liners, called 'twin cushion' or 'double wall' corrugated board. Different flutes may be combined in double wall board.
4. Three layers of fluting sandwiched between four liners, called 'triple wall' or 'triple flute'.
5. Duo Arch board is single wall board in which two thicknesses of corrugated medium are formed and adhered together.

The resulting structure has two major properties:

Rigidity – resistance to bending in the direction parallel to the flutes

Cushioning – resistance provided by the fluted structure when pressure is applied at right angles to the flute arches.

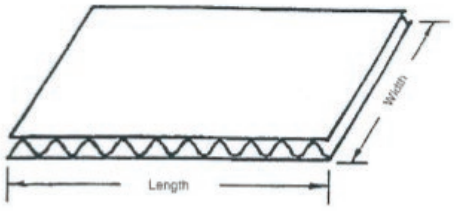
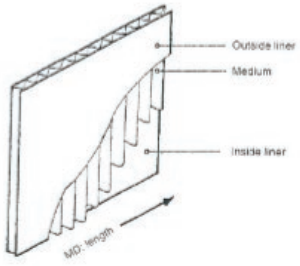


Figure 1:

In the vertical plane the fluting medium forms a continuous series of columns.



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The basic structure consists of a sheet of paper (fluting medium) which has been fluted to form a continuous series of arches. The structure can be faced with a sheet of paper (liner) on one or both sides.

Corrugated board is made up of at least:

- One corrugated or fluted layer
- One flat layer and
- One flat layer or liner

Classification of corrugated board

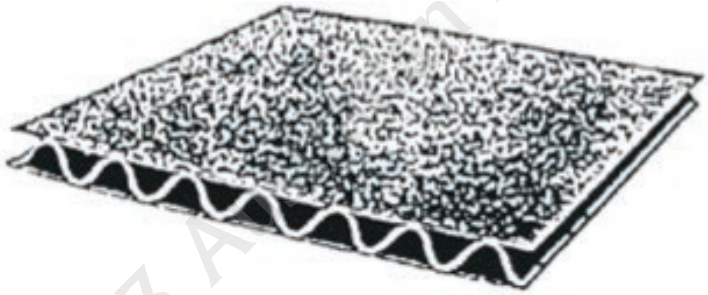
Single faced kraft

This consists of one layer of fluting and one layer of liner and is used for:

- Padding inside boxes
- Partitions • Wrapping uneven object

Single wall board

• Single wall board consists of one layer of fluting and two layers of liners



Double wall board

• Double wall board consists of two layers of fluting and three layers of liners • Note that different profiles of flute may be combined

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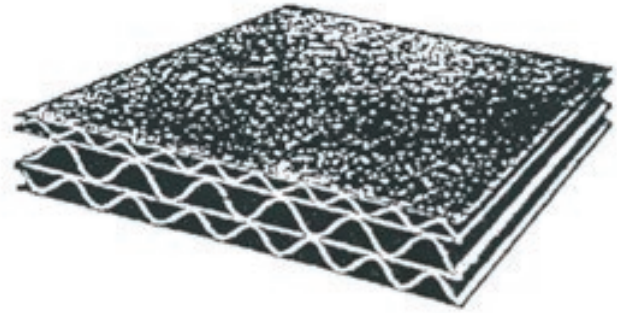
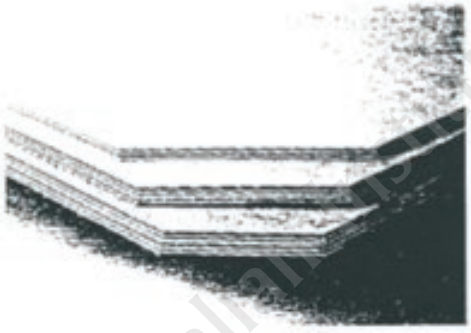
Quadruple board

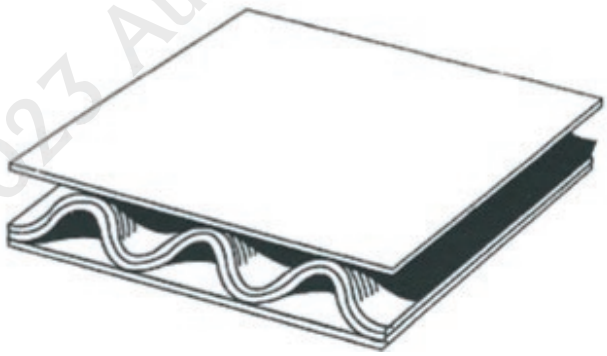
Quadruple board consists of two double wall boards hand-laminated together.



Laminated board



Duplex board



Liners

Liners are:

- Chosen for structural strength.
- Chosen for decorative purposes.
- Can be laminated.
- Can have after-treatments.

Types of finishes

Kraft: various grammages are available.

White liner: bleached on brown kraft gives clear white finish.

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Profiles of flute

Flute configurations in corrugated board.

Flute	Average flute height (mm) caliper	Average number of flutes/meter	Medium take-up factor draw
A	4.7	110	1.54
B	3.61	129	1.45
C	2.46	154	1.33
D	1.14	278	1.26
E	0.76	420	1.23
F	0.58	503	1.19
G	0.45	558	1.12

The main problems arising from board manufacture

Warp This may affect:

- Size of box
- Quality of printing
- Production output
- Erection of boxes in auto erector

Causes of warp

- Uneven moisture in liners used
- Uneven grammage in liners used
- Uneven application of glue
- Uneven temperature

Delamination

This when the liners and fluting come apart.

- Ineffective starch bonding
- Variance in temperature during manufacture

Soft board This is caused by:

- Excess moisture.
- Too much starch
- Poor flute formation

Shyliner

This when the liner does not reach the edge of the board and therefore the fluting is exposed.

Washboarding

This occurs when the liner instead of being taut and therefore flat tends to form ridges and valleys, partially following the contours of the flutes, making good printing impossible. It is caused by excessive glue.

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MULTIWALL PAPER BAG

During the early 1950's the sack industry developed the pasted valve sack. The ends of the tube were closed by gluing, and this type of sack is now universally used for the packing of cement, sugar lime, rice, salt, flour based products, and many other powdered and granular products.

Materials used in paper sacks

- Paper
- Laminations/coatings
- Free film
- Adhesives
- Inks

Paper

Main types of paper used are:

- Natural kraft
- Wet strength kraft
- Low stretch crepe kraft
- Extensible kraft
- Fully bleached kraft
- Clay coated kraft
- Silicon coated kraft
- Foil laminated kraft

Laminations/Coatings

Laminations or coatings can be incorporated into paper sacks giving added protection against ingress of moisture, retention of moisture, free acid in the product, odour barrier or additional strength.

A laminate of paper/polyethylene paper is normally used as an outer ply for strength and scuff resistance but can also be positioned as an inner ply as protection against products with sharp abrasive qualities. A laminate ply incorporating aluminium foil provides excellent barrier protection e.g. odours, and is usually positioned as an inner ply with the foil facing towards the product.

The most commonly used barrier ply is polyethylene coated Kraft.

FREE FILM LDPE and HDPE, thickness of 30 – 100um provide protection against moisture, moisture vapour, and certain types of fats, and are incorporated in sacks for milk powders, feed supplements, some chemicals and pharmaceuticals.

Adhesives

- Starch, which is derived from maize or tapioca
- Latex/PVA, has a high solid content
- Hot melt, 100% solid materials based on thermoplastic polymers, used extensively in pinch-bottom sacks and where foil laminate plies are used

Chapter 8: Material Types

Inks

- Water based, widely used in flexographic printing. They rely on penetration for drying. Advantage is lower costs and safer to use.
- Solvent based, most common solvent is alcohol, other solvents are added to control the flow during the printing process.

Types of Paper Sacks

- Open mouth sewn
- Open mouth pasted bottom
- Open mouth pinched bottom.
- Pasted valve
- Pasted sleeve valve
- Sewn valve
- Sewn sleeve valve

PLASTIC MATERIALS

Not new on the scene but of the newest of the major packaging materials, are the basic plastics. They have become major packaging materials alongside paper, paperboard, metal, and glass. Although plastics were originally employed primarily for consumer packages in the form of films, pouches, semi-rigid and rigid bottles, and jars, they are finding increasing use in secondary and tertiary packaging to assist distribution. Films are used to bond or unitise pallet loads. Semirigid plastics are the base materials used for larger size containers and drums for replacing the more traditional spiral-wound paperboard and steel. Plastic materials are derived chemically from petrochemicals, primarily oil and natural gas with a few being derived from coal.

Plastic materials compete with traditional packaging such as glass, aluminium, steel, and paperboard while having inherent values that permit them to be packaging materials unto themselves. These properties include elasticity, memory and squeezability as well as natural permeability properties[3].

In packaging it focuses on the following: Injection moulding –crates, tubs, small and large containers (PE, PA, PS, ABS, PP, PVC) Blow moulding – bottles and drums from 50ml perfume containers to large 200 litre industrial drums (HDPE, PVC, PC, PP, PP, HDPE, PVC, PET, EVOH, PA)

Vacuum / Thermoforming – tubs, containers, chocolate, yogurt containers (PE and perspex). Rotational moulding – drums and containers using (PE, PC, PA, acetals and PVC). Casting – statues, toys, car parts, birdbaths (PC, ABS, PP, PE, PA, HDPE, LLDPE, PVC).

The list of thermoplastics used today is endless and it is not surprising that this period is sometimes referred to as 'The plastic age'.

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MATERIALS

Cellophane

Cellophane is not essentially a plastic material since it is derived from cellulosic raw materials. It is produced from clean wood pulps that are purified and dissolved with solvents to produce a viscose material that is pumped out of a slot die into a sulfide bath to form a film. Regenerated cellulose means that the fibre form of the cellulose is transformed into a transparent film. Plasticisers may be incorporated into the film to extend its useful life..

Polyethylene (PE)

The general name polyethylene includes materials HDPE, LDPE, LLDPE and VLDPE. All of these materials have the same 'ethylene' or -CH2-CH2- repeating unit but are different because of the methods by which they are manufactured. Depending on the process, the temperatures and the pressures utilised, the polymer chains are either linear or branched. These differences are reflected in the density and crystallinity of the polymer.

HDPE – High Density Polyethylene
MDPE – Medium Density Polyethylene
LDPE – Low Density Polyethylene
LLDPE – Linear Low Density Polyethylene
VLDPE – Very Low Density Polyethylene

HDPE density range is 0.941 – 0.969g/cm^3 has linear chains which will pack well together resulting in a high crystallinity. This high crystallinity produces a hard tough material.

APPLICATIONS Vest type carrier bags where the plastic strength allows thin material or where good MVTR is required.

MDPE, the properties of MDPE materials are intermediate between low a high density polyethylene.

LDPE density range is 0.920 – 0.940g/cm^3 has a structure with many branches which are long chains, resulting in poor complex packing and low crystallinity. It is easy to process.

APPLICATIONS Shrink film, fertiliser sacks and commodity packaging bags where clarity, strength and good moisture vapour transmission rates (MVTR) is required.

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LLDPE density range is 0.910 – 0.925g/cm^3 has a structure with few short chain branches which sufficiently interrupt the packing to produce a low crystallinity. It has good strength and elongation properties but is difficult to process.

APPLICATIONS Bags where clarity, strength and good MVTR are required but not for shrink film.

VLDPE constitutes a new family of polyethylenes with the introduction of new metallocene catalyst systems. Its role in packaging is small.

APPLICATIONS Bags where drapability of the polymer lends 'image' to the product as in the garment industry.

Polyproplene(PP) Polypropylene is a linear hydrocarbon polymer. Expressed as CnH2n , it is a polyolefin or saturated polymer. It is much harder to bite than PE. It has a high crystalline structure. It is semi-rigid, translucent, has good chemical resistance, is tough with good fatigue and good heat resistance and has integral hinge property.

Production of polypropylene takes place by a solution or gas phase process in which the propylene monomer is subjected to heat and pressure in the presence of a catalyst system. Polymerisation is achieved at relatively low temperature and low pressure and the product yielded is translucent, but readily coloured. Differences in catalyst and production conditions can be used to alter the properties of the plastic.

PP does not present stress-cracking problems and offers excellent electrical and chemical resistance at higher temperatures. While the properties of PP are similar to those of Polyethylene, there are specific differences. These include a lower density, higher softening point (PP doesn't melt below 160°C. Polyethylene, a more common plastic, will anneal at around 100°C) and has higher rigidity and hardness. Additives are applied to all commercially-produced polypropylene resins to protect the polymer during processing and to enhance end-use performance.

APPLICATIONS Polypropylene is one of the most versatile polymers available with applications both as a plastic and as a fibre in most of the plastics end-use markets. Yoghurt tubs, strapping tapes and super clarity presentation bags (replacing cellulose film).

Polyethylene Terephthalate (PET)

INTRODUCTION

Engineering polyesters are engineering thermoplastics based on PBT (Polybutylene terephthalate) and PET (Polyethylene terephthalate).

Polyester resins combine excellent mechanical, electrical and thermal properties with very good chemical resistance and dimensional stability. Polyesters also offer low moisture absorption and have good flow properties.

PROPERTIES

PBT, PET and PBT blends are engineering plastics with excellent processing characteristics and high strength and rigidity for a broad range of applications. Properties in which they differentiate themselves from other engineering plastics are:

Chapter 8: Material Types

- Extreme low water absorption, in particular comparison to Nylon (Polyamides).
- Exceptional dimensional stability, due to the low water absorption.
- Excellent electrical properties.
- Excellent resistance to chemical attack and high environmental stress crack resistance.
- Very good heat and heat ageing resistance.
- Very low creep, even at elevated temperatures.
- Very good colour stability.
- Excellent wear properties.

Polyvinyl Chloride (PVC)

INTRODUCTION

Polyvinyl chloride (PVC) is a thermoplastic material used in a wide variety of applications and products.

The essential raw materials for PVC are derived from salt and oil. The electrolysis of salt water produces chlorine which is combined with ethylene obtained from oil to form vinyl chloride monomer (VCM). Molecules of VCM are polymerised to form PVC resin to which appropriate additives are incorporated to make a customised PVC compound.

PROPERTIES

PVC's major benefit is its compatibility with many different kinds of additives, making it a highly versatile polymer. PVC can be plasticised to make it flexible for use in flooring and medical products. Rigid PVC, also known as PVC-U (The U stands for 'unplasticised') is used extensively in building applications such as window frames.

Its compatibility with additives allows for the possible addition of flame retardants although PVC is intrinsically fire retardant because of the presence of chlorine in the polymer matrix.

PVC has excellent electrical insulation properties making it ideal for cabling applications. Its good impact strength and weatherproof attributes make it ideal for construction products. PVC can be clear or coloured, rigid or flexible.

Polyvinylidene Chloride (PVDC)

INTRODUCTION

Polyvinylidene chloride (PVDC) is a thermoplastic material developed by DOW in the 1930's. It is available in a copolymer form with PVC and as an emulsion that can be applied to the surfaces of cellophane. The well-known trade name of PVDC is SARAN®.

PVDC is used for barrier packaging of red meats. Barrier packages permit vacuum packaging of the red meat and thus extend the refrigerated shelf life. Also used in the packaging of a wide variety of processed meats, cheeses and starch-based snack foods. In the 1980s it was the major high-barrier plastic material used in the world.

PROPERTIES

PVDC's major benefit is that it has exceptional properties of high water-vapour, gas and grease resistance. The major disadvantages include high cost to achieve the required barrier properties.

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Polystyrene (PS)

Polystyrene is an amorphous polymer, based on the repeating unit:
-C6H5-CH2--CH2-, which is derived from styrene.

PROPERTIES

Polystyrenes are characterised by excellent clarity and rigidity but are very brittle. Their impact strength, however, can be improved by orientation techniques. They are resistant to aqueous solutions but have poor resistance to solvents and essential oils. Barrier properties are generally mediocre. Polystyrenes are moderately priced and can be easily processed by various techniques. Typical applications include a wide variety of clear and opaque rigid containers where high impact strength is not required.

Polyamide (PA)

INTRODUCTION

The common name is 'Nylon' (brand name of DuPont's family of synthetic polyamides). These polyamides, named so because the group -CONH- is the amide group, have a tendency to absorb moisture once converted. For this reason moulded components are often soaked in water before use in order to reach their proper finished dimensions.

PROPERTIES

Nylons are outstandingly tough with high melting points, resistance to a wide range of solvents and aqueous solutions, good barrier properties to many organic materials but with high moisture permeability.

Polycarbonate (PC)

Polycarbonates are so named because they are polymers having functional groups linked together by carbonate groups (-O-(C=O)-O-) in a long molecular chain.

PROPERTIES

Polycarbonate are easily worked, moulded, and thermoformed. They are a clear plastic, widely used in the modern chemical industry. Their interesting features (temperature resistance, impact resistance and optical properties) position them between commodity plastics and engineering plastics. Typically used in shatterproof windows and lightweight eyeglass lenses.

Acrylonitrile Butadiene Styrene (ABS)

ABS ter-polymers are tough, rigid, and resistant to aqueous solutions of chemicals, to aliphatic hydrocarbons and most oils. Available mainly in opaque form but some transparent grades are available. ABS is an ideal material wherever superlative surface quality; colour fastness and lustre are required. ABS offers rigidity, hardness, and heat resistance.

Typically used in margarine tubs, automotive dashboards, office equipment and telephone casings.

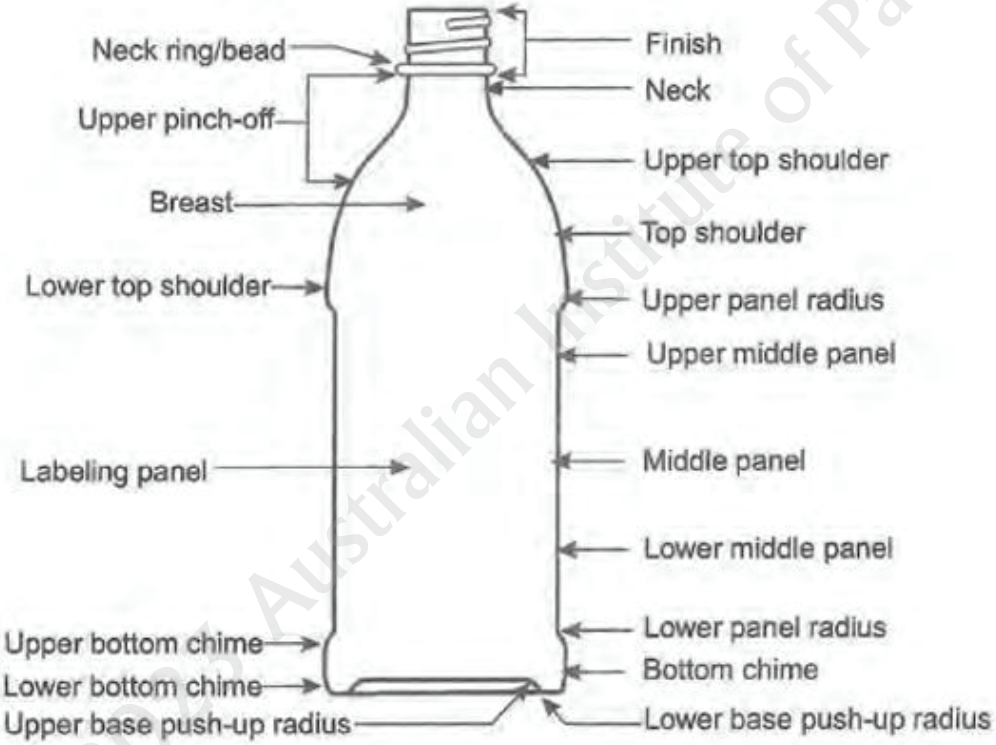
Chapter 8: Material Types

Ethyl-Vinyl-Alcohol (EVOH)

Ethyl - vinyl – alcohol is an ethylene copolymer composed of repeating units of ethylene and vinyl alcohol, produced by hydrolysing an ethylene-vinyl acetate copolymer.

PROPERTIES

Ethyl - vinyl – alcohol has good strength but high permeability to water. Thus, its use was originally limited to being a water-soluble film, and packages fabricated from EVOH required external water vapour barrier packaging. More recently with copolymerisation of polyvinyl alcohol with ethylene led to very good oxygen and water vapour barriers.



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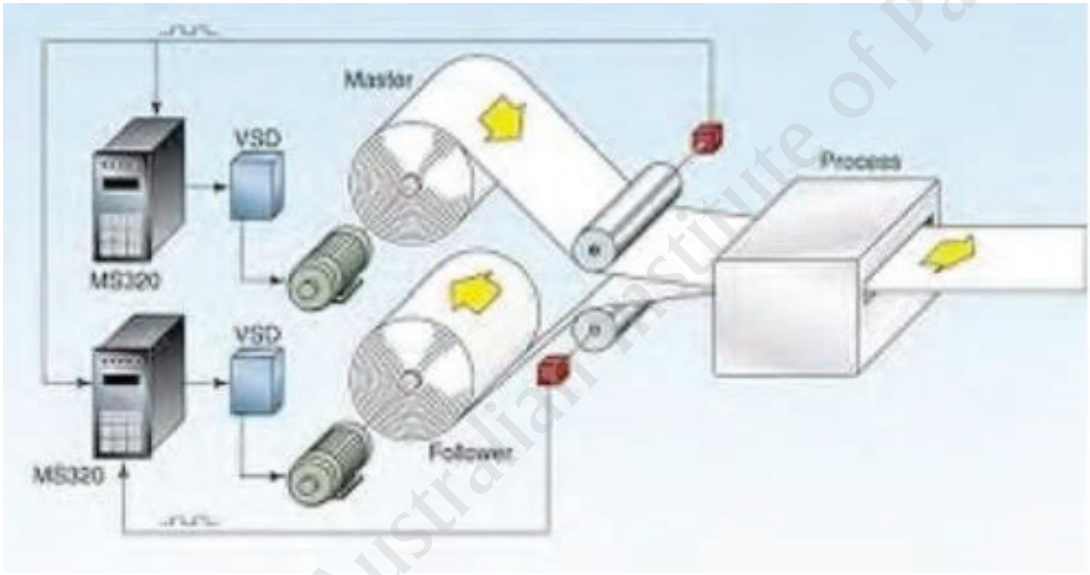
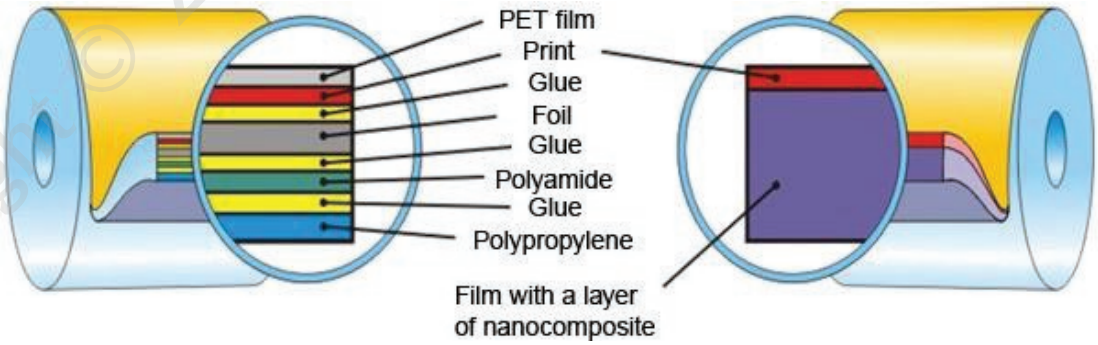
FLEXIBLE PACKAGING MATERIALS

This is the most complex and versatile sector of the packaging mix. It varies from simple monoweb films to multiple films and coextrusions. Flexibles utilise a wide variety of materials, a broad range of processes for manufacturing, producing films and laminates all of very different properties and applications. From simple LLDPE stretch film used in palletising to various laminates required for packaging foods and pharmaceuticals. Today we find ourselves in a time where renewable based materials are emerging, with properties and end of life opportunities, different from traditional polymers and films.



Common materials are paper, aluminium foil, various polymers, e.g. LDPE, LLDPE, HDPE, OPP, cPP, polyamide, PET and PVC. They can be a singular material of these or a combination of them, called laminates.



LAMINATION

This is the technology of adhering one web of film to another. This process is used to produce the required barrier properties, strength, or even to produce an adhesive layer in a package. There are various methods of film lamination in use today and the method used depends on the result required.

Chapter 8: Material Types

These are:

- **Hot melt lamination**

  The low cost advantage can adhere many different substrates with numerous laminates in minutes, allowing immediate fabrication

- **Extrusion lamination**

  Extrusion lamination is the process of applying a coating of molten polymer onto a support substrate, and then almost simultaneously bringing a second substrate into contact with the polymer. The combined structure is then compressed via a chill roller that freezes the molten polymer and sets the laminate structure

- **Adhesive lamination**

  Adhesive lamination of films is done via a dry bond lamination method, where an adhesive is applied to the substrate; the solvents are then dried off via heat and air flow, and then is subsequently laminated to a second substrate under pressure using a heated nip roller

- **Wax lamination**

  This is an economical method of joining a paper or tissue support to aluminium foil

- **Co-extrusion**

  When co-extrusion dies combine the outputs of two or more extruders so that the curtain of material exiting is actually several materials fused together

Choosing a laminate or a flexible packaging film

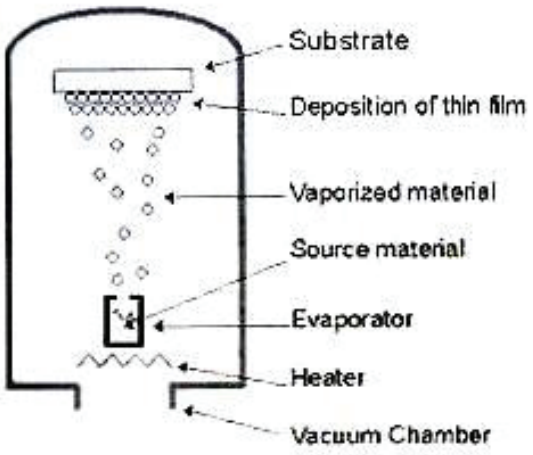
- Chemical aspects
- Physical aspects
- Production requirements

METALLISATION Metallised films are often confused with aluminium foil, due to their appearance, but that is where it ends. Metallisation is done to:

- To improve oxygen barriers
- To improve appearance

Metallisation process

In vacuum metallisation very pure aluminium wire of 99.99% purity is heated by electricity in a vacuum chamber. Under these conditions the wire turns into aluminium vapour which condenses on the surface of the moving web of film. In these metallised films, spherical molecules of aluminium are condensed on the surface of the carrier film and held there by surface tension only. The layer is so thin that the mass of aluminium deposited on a square metre of carrier film cannot be detected on a four decimal place analytical balance (about 25um).



Uses of metallised film

Often used in low optical density variants for decorative laminates and in high optical densities to improve the gas barriers significantly, e.g. oxygen barrier of PET and BOPP films.

PRINTING Flexible packaging is normally printed in continuous rolls on a reel-to-reel printer. The main methods of printing flexible films are rotogravure or flexographic. After printing and if required, lamination, the parent or mill reel is slit down on a slitting machine to the customer's required widths.

Chapter 8: Material Types

Some examples of laminations

Pharmaceutical PVC/PE/PVDC; PVC/PVDC, PVC/PE/PCTFE (Polychlorotrifluoro ethylene or PCTFE) OPA/aluminium/PVC.

Margarine 7um aluminium foil/20g/m^2/LDPE/41g/m^2 greaseproof. This laminate is made by the extrusion method and then surface printed after lamination.

Soup

45g/m^2 Bleached kraft/ 12g/m^2 LLDPE/7um aluminium foil/adhesive/28g/m^2/LDPE Coated side of bleached kraft is printed first before lamination. The LDPE is solvent (drybond) laminated on the second pass.

Milk powders

12um PET/adhesive/7um aluminium foil/adhesive/30um Na ionomer Both passes through the laminator in this case use the dry bond process and the PET is reverse printed prior to lamination.

Snacks

20um BOPP/adhesive/20um metallised BOPP The 20um BOPP is first reverse printed.

PACKAGING PROPERTIES

Definitions of Main Properties The main packaging properties that you will come across discussed in reference to flexibles are:

1. **Sealing properties**
   How well and how fast a plastic film fuse together between jaws under the influence of sealing temperature and sealing pressure.

2. **Hot-tack strength**
   The force required to separate two fused plastic materials while still hot (above their melting point). Low hot-tack strength => product weight/gas flushing can open the warm seal.

3. **Tensile strength and Elongation**
   Tensile strength is the force required to break a plastic film when pulled. Elongation is the elongation of the plastic film in percentages when breaking.

4. **Puncture resistance**
   The maximum force that a 'needle' requires to perforate a plastic film.

5. **Flex-crack resistance**
   Number of cracks/holes/leaks in a plastic film after 400 flexes.

6. **Tear strength**
   The force required to continue tearing a plastic film after the tearing process has commenced.

7. **Rigidity**
   A measurement describing how rigid a material is and feels.

Chapter 8: Material Types

8. Coefficient of friction (COF)
The slide resistance of a plastic film. Well-defined levels are required for different packaging machines.

9. Oxygen and Water vapour permeability
The quantity of oxygen (O^2) and water vapour (H^2O), which permeates through a plastic film.

10. Stretching and shrinkage stability
The ability of a plastic film to resist stretching when pulled and shrinking when exposed to heat.

11. Electrostatic Build-up
Electrostatic charge is the sudden flow of electricity between two electrically charged objects caused by contact. A build-up of static electricity can be caused by electrostatic induction.

GLASS PACKAGING

Glass bottles are one of the oldest forms of packaging dating back 2500 years. Glass containers can be re-used many times and recycled indefinitely. The four main ingredients in glass are silica sand, soda ash, calcite or dolomite and feldspar. Generally, most glass produced contains a substantial proportion of recycled glass. There are significant environmental and economic benefits from recycling glass, it is therefore important to recycle glass correctly to avoid contamination.

These days, plastic and aluminium are the most popular forms of packaging for food. In fact, plastic food packaging has exploded in popularity since plastic debuted. As a result of plastic's soaring popularity, glass isn't used nearly as much. After all, glass shatters; it can be dangerous when it gets chipped or cracked. Many companies find plastics to be much more convenient, and consumers tend to agree. Despite all of that, glass is still used for several different products.

Types of glass

The quality of glass is expressed in terms of its resistance to acid and alkali attack.

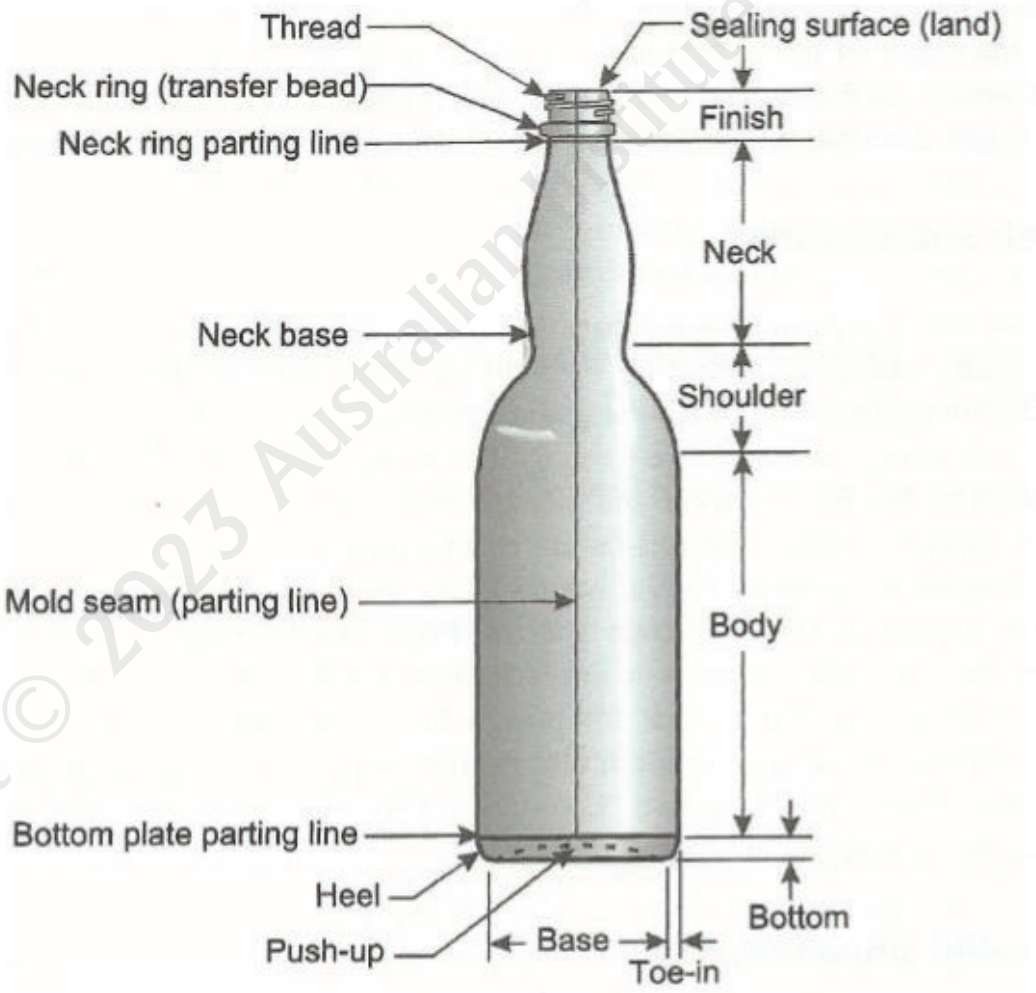
- Type III: all soda lime glass.
- Type II : same as type III but coated with Sulphur inside the bottle.
- Type I: Borosilicate Glass. Hard, more expensive. Predominantly used for pharmaceuticals.

Design of glass containers – Terminology

- Finish – section through which the bottle is filled and where the closure is applied.
- Screw Finish – see 'root' and 'crest of thread'.
- Bore – is the aperture in the finish, is the first 1mm or 2mm at most.
- Choke – is that part of the entry down through the finish and neck of the bottle where the tightest constriction will occur.
- Sealing Surface – the surface to which the closure seals and must be blemish free.
- Guide Ring Match – is a faint but visible horizontal seam immediately below the sealing surface.

Chapter 8: Material Types

- Transfer Bead – is a protruding circumferential bead below the finish, used to transfer the bottle during forming operations.
- Neck Ring Match – is a visible circumferential seam.
- Neck – is the narrow upper part of the bottle.
- Shoulder – the portion that flows outwards from the neck to the body.
- Body – the part of the bottle containing the major part of the contents.
- Toe-in – is the radius which brings the body into the reduced diameter.
- Heel – is the final, small radius between the toe-in and the standing surface.
- Push-up bottom – is a concave form at the bottom of the bottle contained within the standing circumference.
- Mould Seam – is a faintly visible line running vertically down the bottle.



SURFACE TREATMENT

When a metal oxide film is deposited on the surface of the glass at a temperature of about 600°C, it fills and heals the numerous micro-flaws and micro-cracks with the oxide coating imparting greater surface hardness and improved scratch resistance.

Chapter 8: Material Types

Glass bottle defects

- Birdswing
- Black specks
- Stones
- Seeds
- Blisters
- Brush marks
- Hair line
- Spike

Advantages of glass

- Chemical inertness
- Optical clarity
- Rigidity
- Internal pressure resistance
- Heat resistance
- Reusability and recycling
- Cost
- Bloom

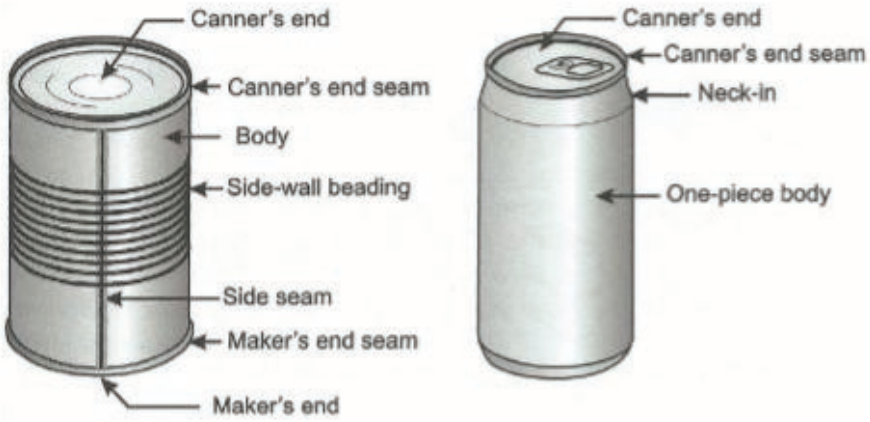
Disadvantages of glass

- Fragility
- Mass
- Cost

METAL PACKAGING

INTRODUCTION

Metal containers are well established and the ubiquitous can whether in tin plate or aluminium continues to be a reliable container. Available in a range of formats they can be neatly divided into those designed for hermetic sealing and heat processed for foods or for the containment of aerated beverages and those as basic containers. In the latter case these can range from utilitarian containers for paint, oil etc. to decorative boxes for sweets or biscuits. Metal containers are also used as pressure vessels which are self-dispensing as in the case of aerosols. Shapes and sizes of metal containers are extensive and the original food can has evolved into a variety of shapes. In terms of the environment metal containers are recyclable and in the case of aluminium it is cheaper to recover aluminium from recycling than from the native material.



Chapter 8: Material Types

Heavy Metal Based Packaging

During the early part of 1900's, the problem arose on how to transport petroleum products in reasonable quantities and the steel drum became the tool to solve this problem.

The basic raw materials are:

- Cold Rolled Steel
- Tinplate
- Galvanised Steel
- Stainless Steel

Cold Rolled Steel is easily workable, better priced than hot rolled steel, used in a wide range of products and easily treatable.

Tinplate has fast replaced cold rolled steel in the manufacture of small capacity drums and pails mainly in the 20 to 25 litre range. This is mainly because of its enhanced resistance to rusting.

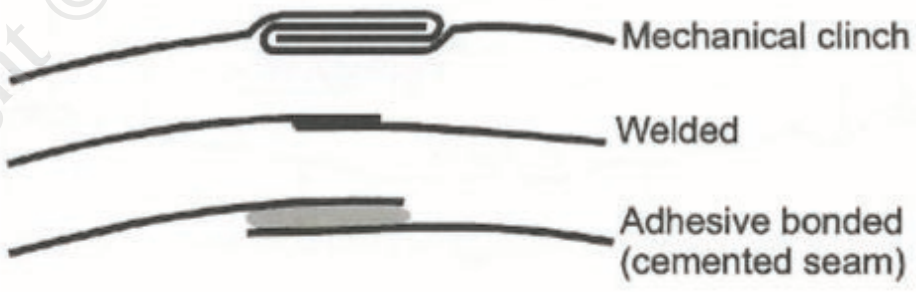
Galvanised steel is mainly used in the production of 100 to 200 litre capacity drums but losing popularity due to the cost factor.

Stainless steel is a high-cost material and is only used when packing a highly concentrated chemical which would attack both ordinary steel and any internal paint coated surface.

Seaming compounds

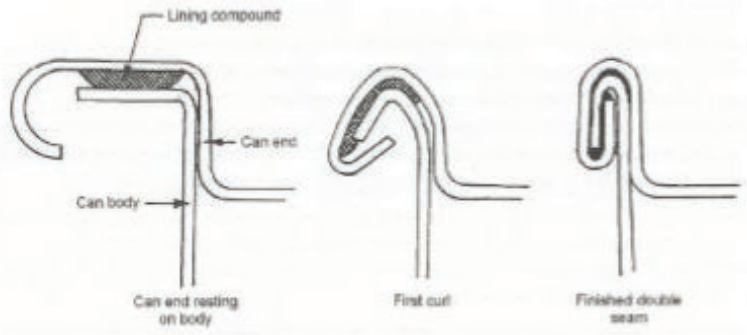
- Seaming compounds must be elastic and remain so for unlimited time, otherwise it would become brittle and crack in the seam causing leakage.
- Seaming compounds are also to be chemically resistant to the contents of the drum.
- They are rubber based and stored at temperatures of 10 – 3500 C.
- Purpose is to fill the voids.

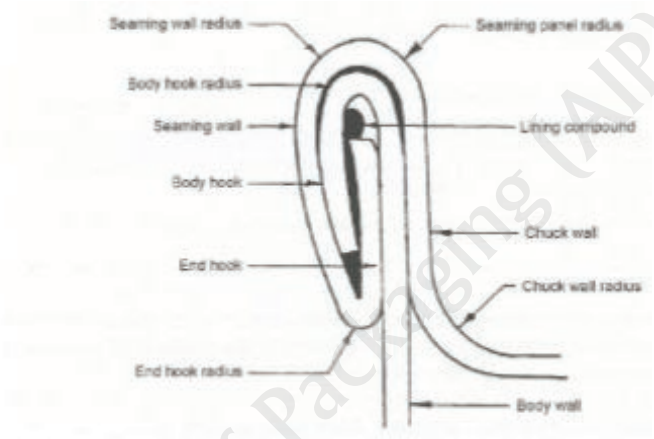
Joining



Resistance welding – is a method which uses the heat generated by an electric current when this current flows through a resistance.

Chapter 8: Material Types



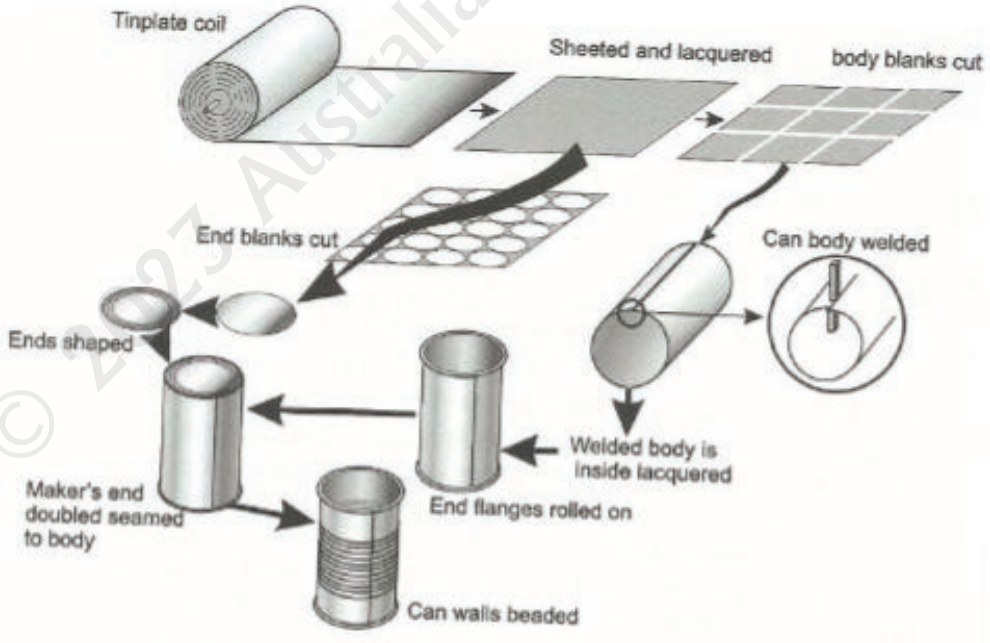


Seaming – is where the drum end is permanently fixed to the drum body. This is achieved through a metal folding process by means of rotating the drum body and assembled end whilst two independent cam-operated rams fitted with seaming rollers, seam the end body flanges together.

Light Metal Based Packaging

Metal packaging forms a major component of the industry.

For example, cans have been around since 1810. Canning was discovered as a method of preserving food. Metals employed for this type of packaging are often combined or alloyed state with another metal to enhance strength, ductility, or corrosion resistance.



The primary metals namely, steel, tin, chromium, and aluminium are mainly used for food packaging in the following forms: Black Plate - is uncoated mild steel, has limited use as it is very susceptible to rusting and corrosion. Tinplated Steel – is black plate with a thin coating of tin on each side and is widely used for packaging. Tin Free Steel - is black plate with a thin coating of chromium and chromium oxide on each side (surface). Aluminium – is made from the ore bauxite which contains 40% - 60% of aluminium oxide (Al2O3). The aluminium oxide is separated from the other impurities in a long process to give alumina, a white powder. The alumina is dissolved in molten cryolite at high temperature (10000 C) and by means of an electric current is split into oxygen and aluminium.

Chapter 8: Material Types

Properties of Tin Free Steel

Darker in colour than tinplate.

Advantages
- Cheaper than tinplate
- Coatings and varnishes adhere well.

Disadvantages
- Cannot be soldered
- Less resistant to corrosion than tinplate.

Properties of Aluminium

Advantages
- Very light, reduced transport costs
- Soft and ductile
- Shiny and attractive
- When alloyed with various metals the strength of aluminium is greatly increased
- Does not rust

Disadvantages
- Cannot be soldered or welded easily
- Can be expensive

NOTES

Chapter 9: Sampling Plans

A sampling plan is a detailed outline of which measurements will be taken at what times, on which material, in what manner, and by whom. Sampling plans should be designed in such a way that the resulting data will contain a representative sample of the parameters of interest and allow for all questions to be answered.

A sampling plan allows an auditor or a researcher to study a group (e.g., a batch of products, a segment of the population) by observing only a part of that group, and to reach conclusions with a pre-defined level of certainty.

The different types sampling plans

- Random sampling, where all units/parts have the same likelihood of being selected for inspection.
- Statistical sampling (The most popular plan was developed by the US Department of Defence, and was formalised in standards MIL-STD 105E, 2859-1, and ANSI Z1.4.)

The steps involved in developing a sampling plan are:

- Identify the parameters to be measured, the range of possible values, and the required resolution.
- Design a sampling scheme that details how and when samples will be taken.
- Select sample sizes.
- design data storage formats.
- Assign roles and responsibilities.

An example of the process

On receipt of the Goods Receipt Note (GRN) from the Stores check the detail given on GRN and note the details of GRN in Packaging Material Sample Inward Register kept in Packing Material Testing Lab. Note down the Lot number as Analytical Reference number (A R No.) and the supplier's Lot No. (if any) shall be considered as Batch number.

Based on the number of containers listed in GRN select the number of packages to be sampled.

Enter the details of sampling containers and print out 'SAMPLED' label.

Go to the appropriate 'UNDER TEST' packaging material storage area and identify the material to be sampled from the label on the pack.

Ensure that the warehouse pastes the 'UNDER TEST' labels correctly.

Verify the number of packages as mentioned in GRN.

Check the packing condition of the material and the details mentioned on the labels.

In case of any discrepancy in above step, inform the Quality Assurance Manager and the Warehouse In-charge for corrective action.

Chapter 9: Sampling Plans

Sampling of Primary & Secondary packing materials:

Open the packages carefully and observe the material for any abnormality. In case the packing material is found in damaged condition, the same shall be informed to Manager QA.

After decision of Manger QA the material shall be further segregated or rejected.

In case of segregation the packs found in good condition shall be sampled, the remaining quantity shall be rejected. Prepare the rejection note for damaged containers / roll / packs and paste 'REJECTED' label and ensure that such containers/packs/rolls are transferred to rejected area.

Withdraw the samples randomly from different containers equal to sample size as per Table -1b.

Close the containers to be sampled with the help of BOPP Tape/ties.

Protect the samples from external contaminants like dust, water, and direct sunlight during sampling and testing operations.

Paste the 'SAMPLED' label (As per specimen given in this SOP) on the containers from which the sample is collected.

Carry out testing of the packaging material as per the laid down specifications of the respective material.

Record the dimensions observed for the required number of samples as specified in individual Physical Inspection Report.

Inspect the total number of samples of packaging materials based on Critical, Major or Minor visual defects. These defects are detailed on the format of individual Physical inspection reports.

Note down the total number of defects, which are categorised under the headings critical, major and minor.

Compare with the accept and reject numbers against the quantity of number of samples collected.

If the defect in any category is equal to or more than reject number, inform the Quality Assurance Manager for rejection of the consignment.

NOTES

Chapter 10: Packaging Testing

An extensive knowledge about the packaging material is crucial in designing of packaging material for particular products. Properties of packaging materials such as mechanical strength, gas permeability, and sealing ability determine the suitability of packaging material for intended purpose. It is therefore necessary to determine the properties of packaging material to select the suitable material for any product.

CRITICAL DIMENSION	DEFECTS	EFFECTS
Flange depth	Variation in flange depth.	Improper tucking of Aluminum skirt.
Flange diameters	Too large a diameter.	Aluminium overseal could not fit over the flange.
	Too small a diameter.	Overseal skirt would not tuck under the vial flange.
Bore diameter	Too large a bore.	Rubber plug would have a loose fit.
	Too small a bore.	The plug could not be inserted.
Vial height	The height of vial varies.	Sealing mechanism will not operate satisfactorily.
	A high vial.	May even be crusked by the filing-machine sealing mechanism.
Body diameters	Vial with too large diameter. Small diameter.	Cannot travel down the conveyor track. May not align to sealing mechanism correctly.

Testing of packaging materials generally involves determination of physical properties. But it is also important to study the chemical stability of a packaging material, particularly when it would be used for food-based applications, so as to ensure the safety of the product.

There are several standard testing protocols for packaging materials, and this chapter provides detailed information about testing methods that are in use to evaluate various properties of packaging materials.

1. Flexible packaging tests

LEAK & BURST It is important to guarantee the leak tightness of the packaging to assure that undesirable microorganisms and air (oxygen) can't affect the product and that the packaged product may not leak.

PERMEABILITY Creating an ideal atmosphere and providing the right packaging can extend the shelf life of your product. The purpose of a package is, after all, to form a barrier between the content and external factors in the environment that might affect the content. SEAL STRENGTH It is possible to determine the strength of a seal in order to determine which weight the seal can tolerate.

TENSILE STRENGTH A tensile test, or tension test, is done by pulling on a specimen, to determine how the material reacts to forces being applied in tension. As the material is being pulled, you determine the material's tensile strength and how much it will elongate. THICKNESS Measuring the thickness of all sorts of materials is very important. Not only does it determine the cost of a product, but it also has an influence on different characteristics such as strength, permeability, etc.

Chapter 10: Packaging Testing

2. Paperboard testing

TRANSPORT SIMULATION Simulating - in a controlled manner - influences products and packaging endure during transport and storage. COMPRESSION Testing how certain compressive forces have an impact on the packaging. BENDING - OPENING FORCE Simulating the resistance of materials against frequent folding and opening.

3. DROP TESTS Simulating the fall/drop of a bottle or can.

OPENING FORCE This determines the force required to open a bottle.

PRESSURE TESTS The creation of leaks and cracks in a bottle or can be due to a pressure increase.

Some methods are specific to the type of packaging material, and there are extensive number of tests available, for example:

ASTM D1653-13 (2013) Standard test methods for water vapour transmission of organic coating films. ASTM International, West Conshohocken www.astm.org

ASTM D2457-13 (2013) Standard test method for specular gloss of plastic films and solid plastics. ASTM International, West Conshohocken www.astm.org

ASTM D3078-02 (2013) Standard test method for determination of leaks in flexible packaging by bubble emission. ASTM International, West Conshohocken 2013. www.astm.org

ASTM D3418-15 (2015) Standard test method for transition temperatures and enthalpies of fusion and crystallisation of polymers by differential scanning calorimetry. ASTM International, West Conshohocken www.astm.org

ASTM D3985-05(2010) e1 (2010) Standard test method for oxygen gas transmission rate through plastic film and sheeting using a coulometric sensor. ASTM International, West Conshohocken www.astm.org

ASTM D4003-98 (2015) Standard test methods for programmable horizontal impact test for shipping containers and systems. ASTM International, West Conshohocken 2015. www.astm.org

ASTM D523-14 (2014) Standard test method for specular gloss. ASTM International, West Conshohocken www.astm.org

ASTM D5277-92 (2015) Standard test method for performing programmed horizontal impacts using an inclined impact tester. ASTM International, West Conshohocken 2015. www.astm.org

ASTM D6604-00 (2017) Standard practice for glass transition temperatures of hydrocarbon resins by differential scanning calorimetry. ASTM International, West Conshohocken 2017. www.astm.org

ASTM D6868-17 (2017) Standard specification for labelling of end items that incorporate plastics and polymers as coatings or additives with paper and other substrates designed to be aerobically composted in municipal or industrial facilities. ASTM International, West Conshohocken www.astm.org

Chapter 10: Packaging Testing

ASTM D880-92 (2015) Standard test method for impact testing for shipping containers and systems. ASTM International, West Conshohocken 2015. www.astm.org

ASTM E1356-08 (2014) Standard test method for assignment of the glass transition temperatures by differential scanning calorimetry. ASTM International, West Conshohocken 2014. www.astm.org

ASTM E2602-09 (2015) Standard test methods for the assignment of the glass transition temperature by modulated temperature differential scanning calorimetry. ASTM International, West Conshohocken 2015. www.astm.org

ASTM E398-13 (2013) Standard test method for water vapor transmission rate of sheet materials using dynamic relative humidity measurement. ASTM International, West Conshohocken www.astm.org

ASTM E96/E96M-16 (2016) Standard test methods for water vapor transmission of materials. ASTM International, West Conshohocken www.astm.org

ASTM F1249-13 (2013) Standard test method for water vapor transmission rate through plastic film and sheeting using a modulated infrared sensor. ASTM International, West Conshohocken www.astm.org

ASTM F1307-14 (2014) Standard test method for oxygen transmission rate through dry packages using a coulometric sensor. ASTM International, West Conshohocken www.astm.org

ASTM F1886/F1886M-16 (2016) Standard test method for determining integrity of seals for flexible packaging by visual inspection. ASTM International, West Conshohocken www.astm.org

NOTES

Chapter 11: Updating Specifications

The purpose of a specification is to provide a description and statement of the requirements of a product, components of a product and the capability or performance of a product.

To be effective, Packaging specifications should reflect current mandatory requirements and practices.

The following valid questions should be asked:

- What value is there in keeping updated specifications?
- How often should the specification be updated?
- Who should be updating the specifications?

The value of updating

Keeping the specification updated has many benefits, including:

By keeping a regularly updated specification document, others can easily find the products and materials that are required, benefiting you and others who use the specifications. For example:

- Improved overall performance. Without precise specifications. This rules out the use of unreliable and/or inconsistent products.
- Prevents system failures and expiry date issues.
- Better product capabilities.
- By updating your document, you include the most advanced technology, which can reduce implementation issues and minimise room for error.
- Potential cost savings. Sticking to what we know can be a comfort, but it also can cost us time. Updating specifications to include more modern commercial packaging solutions can make packaging faster, require fewer materials, and minimise additional costs from failed inspections or potential launch failures down the line.
- Maintain your company's reputation. A project that develops problems reflects poorly on your company and the associated design team. When you use trustworthy products that support projects long-term, you protect your work and build a reputation for prioritising the interest of your clients with predictable, high-quality results. And the more detailed you are, the less room there is for inconsistencies and different levels of quality.

Not every change needs to be reflected in the specification. Updating the specification is also extra work, and so it's important to ensure that extra work is adding value. If you find yourself routinely updating the specification with no person using the result, then you may need to check the need.

How often

- The guide is whenever a non-trivial decision is made, do it there and then.
- With every change made that might affect it.
- All packaging specifications should be reviewed every 2 years but never exceeding every 3 years.

Who updates

- The guide is the person making the change, assuming that he/she is qualified to making amendments to specifications.
- Remember that all completed specifications are to be reviewed by others that are qualified to do so.

Chapter 11: Updating Specifications

How to update specifications

- Trusted manufacturers can help in tightening up and fine-tuning your specifications.
- Providing product knowledge and application training in person or virtually.
- Providing accurate specification documents is a best practice.
- It helps maintain timelines, consistency, budgets and project longevity.
- It positively impacting specific product quality as well as overall company quality assurance.

NOTES

Chapter 12: Supplier Audits

Packaging specifications needs to be reviewed and updated every couple of years to stay competitive in the marketplace.

A vendor audit is a vehicle used by companies to inspect and evaluate a vendor's quality management system, as well as its practices, products, and documentation.

The need to conduct vendor audits stems from a need for quality control in an industry that needs to be regulated.

Auditing Packaging Material Vendors

Auditing Packaging Material Vendors

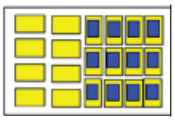
Goals

When you have completed this unit, you should be able to:

- Perform a packaging component supplier audit.
- Understand which worldwide requirements apply to packaging component suppliers.
- Use a range of information tools, including the contents of this module, in support of a packaging component supplier audit.
- Recognize compliance or non-compliance with regulations pertaining to packaging component supplier's requirements.

Definitions

Gang-printed labeling: Labeling derived from a sheet of material on which more than one item of labeling is printed. (see example below). Gang printing is considered to be an unacceptable practice for some industry since it increases the potential for label mix-up.



Packaging materials: Any material employed in the packaging of a medicinal product, excluding any other packaging used for transportation or shipment.

Packaging Component – Critical (PCC): Is any printed packaging component, primary (product contact) component or device. Furthermore any secondary packaging component critical to the microbiological integrity, stability and/or administration of the product (e.g. Aluminium pillow packs around semi permeables).

Packaging Component – Non-Critical (PCNC): Is any non-printed or secondary (non contact) packaging component or device that does not fall within the definition of a PCC.

Printed packaging components: Packaging materials that are printed and/or otherwise decorated. Examples would include cartons, labels, leaflets.

Reconciliation: A documented comparison between the amount of input materials and the output product, taking into account waste, samples and other losses inherent in the process.

https://www.gmpsop.com/sample/Audit-018-Auditing-Packaging-Material-Vendors-sample.pdf

Chapter 12: Supplier Audits

Line Clearance

Line clearance is an essential element in product mix up prevention and needs to focus on: ß Input materials on the line from the previous batch.

Samples and waste from the previous batch.

Documents on the line from the previous batch ß Verification that any electronic data is wiped from consoles etc. Clearance after maintenance activity or major interruptions as appropriate. Line clearance activities need to be documented and cover all areas, not just the machine or line:

The whole machine, including hoppers, conveyers, reject stations, etc ß The floor around the line.

Benches, cupboards, shelves around the line.

Pallets. The line clearance should be documented, signed and an independent check completed and signed before the area is released for use.

Contamination control

The facilities should be designed and laid out to appropriately reduce the risk of contamination from the environment and permit effective cleaning. Personnel gowning and hygiene practices are part of contamination control efforts that may be applicable.

The supplier should define the appropriate environmental conditions for handling and storage of the component(s) being manufactured. Guidance for minimum conditions can be found in PS 9000 Pharmaceutical Packaging Materials, as well as programs such as ISO 9001:2000 and ISO 9004:2000 for pharmaceutical packaging materials.

Validation and Qualification

Ensure the processes are adequately validated, qualified and/or demonstrated according to the quality critical parameters of the component being manufactured. This may be demonstrated in the form of capability studies.

Sampling

There should be an SOP that defines package component sampling. The components sampled should be representative of the batch and sampling should be conducted to prevent contamination from the sampling method. Any packaging materials that meet appropriate written specifications should be formally approved and released for use. Any components that fail to meet such specifications must be rejected to prevent distribution. Samples taken away from the line should not be returned to the line. They should be reconciled and placed in dedicated containers for destruction.

Documentation

The appropriate SOPs and batch records must be followed when documenting any information or data associated with a component manufacture. Other pertinent types of documentation include: · Records of how and who set up a particular machine.

Chapter 12: Supplier Audits

Key Parameters of a Packaging Component Audit

Prior to the audit:

Develop an understanding of the vendor manufacturing process specific to company requirements.

Obtain a list of company components that are manufactured at the site.

Review recent rejections, complaints and issues, of the receiving site(s) and the respective statuses.

Review any Quality Agreements and relevant registration requirements.

Review compliance status of the site by checking for service history, recalls associated with the site, recent regulatory inspections (if applicable) and outcomes.

Review previous audit reports and actions.

During the audit:

Perform a walkthrough of the manufacturing area.

Ensure the production areas are clean and tidy.

Ensure the fabric is in good condition and appropriate design for control of the process.

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Chapter 13: Abbreviations & Definitions

Some well known acronyms used in the Plastics Industry:

HDPE	High Density Polyethylene
MDPE	Medium Density Polyethylene
LDPE	Low Density Polyethylene
LLDPE	Linear Low Density Polyethylene
VLDPE	Very Low Density Polyethylene
LMDPE	Linear Medium Density Polyethylene
PVC	Polyvinyl chloride
PVdC	Polyvinylidene chloride
PP	Polypropylene
OPP	Orientated Polypropylene
BOPP	Biaxially Orientated Polypropylene
MBOPP	Metallised Biaxially Orientated Polypropylene
PA	Polyamide (Nylon)
PS	Polystyrene
PET	Polyethylene Teraphthalate
PC	Polycarbonate
EVOH	Ethyl - vinyl - alcohol
EVA	Ethyl Vinyl Acetate
ABS	Acrylonitrile butadiene styrene

Owing to the constant developments taking place, both in polymer science as well as in packaging design and technology, the list of packaging polymers will always be growing.

Chapter 13: Abbreviations & Definitions

DEFINITIONS

Packaging materials: Any material employed in the packaging of a medicinal product, excluding any other packaging used for transportation or shipment.

Packaging Component – Critical (PCC): Is any printed packaging component, primary (product contact) component or device. Furthermore any secondary packaging component critical to the microbiological integrity, stability and/or administration of the product (e.g. Aluminium pillow packs).

Packaging Component – Non-Critical (PCNC): Is any non-printed or secondary (non contact) packaging component or device that does not fall within the definition of a PCC.

Printed packaging components: Packaging materials that are printed and/or otherwise decorated. Examples would include cartons, labels, leaflets.

Reconciliation: A documented comparison between the amount of input materials and the output product, taking into account waste, samples and other losses inherent in the process.

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Chapter 15: Appendices

Appendix 1 – Check list

Packaging Material Groups	Test items
A) Primary packaging materials	
Plastic films	Dimensions, identity (e.g. IR spectrum), abrasion, appearance
Aluminium foils	Dimensions, identity (e.g. IR spectrum), texts, appearance
Composite films	Dimensions, identity (e.g. IR spectrum), texts, appearance
Tubing glass	Dimensions, light transmission, wall thickness, filling volume, hydrolytic resistance, breaking force, appearance
Blow-moulded glass	Dimensions, light transmission, wall thickness, filling volume, hydrolytic resistance, breaking force, appearance
Rubber	Dimensions, fragmentation, ash content, identity (e.g. IR spectrum), purity (chemical-analytical), appearance
Plastic injection mouldings	Dimensions, bellows elasticity, shot volume, metering accuracy, identity (e.g. IR spectrum), weld line strength, appearance
Plastic blown mouldings	Dimensions, shot volume, weight, identity (e.g. IR spectrum), tightness under overpressure, resistance to internal pressure, residual emptying, resistance to content, printing, appearance
Plastic stoppers	Dimensions, identity (e.g. IR spectrum), appearance
Desiccant capsules	Dimensions, microbial count, residual moisture, appearance
Crimp caps	Dimensions, sheet thickness, appearance
Other (e.g. tin cans, PE bags)	Dimensions, identity (e.g. IR spectrum), printing, moisture tightness, weight, filling volume, appearance
B) Secondary packaging materials	
Labels	Dimensions, material quality, code control, printing, luminescence, appearance
Package inserts	Dimensions, material quality, code control, printing, luminescence, appearance
Folding cartons	Dimensions, material quality, code control, printing, appearance
Other (e.g. desiccant pouches, banding films)	Dimensions, identity (e.g. IR spectrum), print, weight, moisture uptake, appearance

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