

**TRACEABILITY APPLIED FOR FOOD CONTACT
MATERIALS IN THE RUBBER INDUSTRY**

Foreword:

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

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

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

I. GENERAL REQUIREMENTS

I.1 Introduction

This document (Guideline) is intended to provide guidance for Good Manufacturing Practice (GMP) for the manufacture of rubber products intended to come into contact with foodstuffs. It is also intended to help ensure that Rubber Products intended to come into contact with foodstuffs meet requirements of quality and purity.

In this Guideline "manufacturing" is defined as including all operations from receipt of materials, production, packaging, repackaging, labelling/relabelling, quality control, storage downstream to the distribution of Rubber Products.

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

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

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

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

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

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

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

I.2 Scope and field of application

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

Good Manufacturing Practice (GMP), will represent existing industrial practices used to achieve production of materials and articles, for direct use which is intended to come into contact with foodstuffs eg, gaskets, pipes, conveyer belts etc.

A very specific application of multi-use rubber articles that falls into food contact regulations are baby teats:.

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

The type of the rubber used and additives used determine the physical, chemical and thermal characteristics of the product.

Rubber products have much in common, for example:

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

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

I.3 Other Management Systems

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

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

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

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

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

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

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

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

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

I.4 Quality Management System (QMS)

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

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

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

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

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

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

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

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

I.5 Quality Assurance

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

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

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

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

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

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

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

I.6. Quality Control (QC)

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

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

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

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

I.7 Term and definitions

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

I.7.1 General

Acceptance criteria

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

Airlock

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

Authorized person

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

Batch (or lot)

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

Batch number (or lot number)

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

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Batch numbering system

Standard operating procedure describing the details of the batch numbering.

Batch records

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

Bulk product

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

Calibration

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

Change control

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

Certificate of Analysis

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

Clean area

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

Complaint

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

Consignment (or delivery)

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

Critical process

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

Cross-contamination

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

Finished product

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

Foods

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

Food contact materials

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

In-process control

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

Intermediate product

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

Lot failure

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

Manufacture

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

Manufacturer

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

Marketing authorization (product licence, registration certificate)

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

Master formula

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

Master record

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

Non conforming Material

Any material that does not meet manufacturer's specification or applicable good manufacturing practice.

Nonconformity

Failure to meet a specified requirement.

Packaging

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

Packaging material

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

Positive list

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

Process validation

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

Processing instructions

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

Production

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

Representative Sample

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

Rubber Product

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

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

Quarantine

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

Reconciliation

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

Reprocessing

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

Returned product

Finished product sent back to the manufacturer.

Shelf life / expiration dating period

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

Specification

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

Standard operating procedure (SOP)

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

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

Starting material (Raw material)

Any substance of a defined quality used in the production of a rubber product, but excluding packaging materials.

System

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

Validation

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

I.7.2 Types of rubber**Elastomer**

A non-cross-linked but cross-linkable (vulcanisable) long chain visco elastic polymer with high molecular weight. and elastic properties at room temperature.

At higher temperature and/or under the influence of deforming forces, thermoplastic elastomers exhibit increasing viscous flow, and can be moulded under suitable conditions.

Latex

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

Natural rubber

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

Rubber (in articles)

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

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

Rubber (raw material)

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

Synthetic rubber

Rubber produced by polymerizing one or more monomers

Thermoplastic rubber

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

Thermoplastic elastomer

Common commercial term for thermoplastic rubber.

Vulcanized rubber

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

I.7.3 Compounding ingredients - processes**Accelerators**

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

Activators

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

Additives

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

Antidegradant

Compounding ingredient used to retard deterioration by ageing

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

Antioxidant

Compounding ingredient used to retard deterioration caused by oxidation.

Antiozonant

Compounding ingredient used to retard deterioration caused by ozone

Coagulation

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

Compound

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

Compounding ingredient

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

Crosslink

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

Crosslinking(the act of)

Insertion of crosslinks between or within rubber chains to give a network structure.

Elasticity

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

Retarder

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

Softener

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

Vulcanization

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

Vulcanizing agent

Compounding ingredient that produces crosslinking in rubber.

II. MINIMUM REQUIREMENTS

II.1 Scope and field of application

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

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

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

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

II.2 Requirements

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

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

II.2.1 General provision

Good Manufacturing Practice (GMP) guidelines for rubber products represent a system for ensuring that products are consistently produced and controlled according to quality standards.

The guideline is designed to minimize the risks involved in any rubber products production that cannot be eliminated through testing the final product.

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

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

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

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

Basic elements of Good Manufacturing Practice (GMP) include:

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

II.2.2 Organisation and Personnel

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

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

II.2.3 Buildings and Equipment

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

II.2.4 Equipment

The fabrication of rubber products of consistent quality requires that equipment performs in accordance with its intended use. Equipment used in the manufacturing process, packing, or holding of a rubber product must be of appropriate design, adequate size, and suitably located to facilitate operations and for its cleaning and maintenance.

Equipment arranged in an orderly manner permits cleaning of adjacent areas and does not interfere with other processing operations. It also minimizes circulation of personnel and optimizes flow of material.

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

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

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

II.2.5 Control of components and Rubber Materials

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

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

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

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

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

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

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

II.2.6 Production and Process Controls

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

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

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

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

Before any processing operation is started, steps should be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels, or documents not required for the current operation. Any necessary in-process controls and environmental controls should be carried out and recorded.

Any significant deviation from the expected yield should be recorded and investigated. Measuring, weighing, recording, and control equipment and instruments should be serviced and calibrated at pre-specified intervals and records maintained.

II.2.7 Packaging, Labelling, Handling and Distribution

Where appropriate, procedures designed to assure that correct labels, labelling and packaging materials are used for rubber products are written

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to a product do not occur during handling. When the quality of a product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

II.2.8 Laboratory controls

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

II.2.9 Records and reports

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

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

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

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

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

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

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

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

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

II.2.10 Returned rubber products

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

ANNEX 1

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

Single use:

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

Multiple use:

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

III. EXTENSIVE REQUIREMENTS

III.1. Scope and Field of Application

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

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

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

III.2. Introduction

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

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

III.3. Normative reference

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

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

III.4. Requirements

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

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

III.4.1 General Provisions

Good Manufacturing Practice (GMP) guidelines for rubber products represent a system for ensuring that products are consistently produced and controlled according to quality standards.

They are designed to minimize the risks involved in any rubber product production that cannot be eliminated through testing that final product.

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

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

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

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

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

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

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

III.4.2 Organization and Personnel

RATIONALE

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

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

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

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

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

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

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

III.4.3 Building and Facilities

RATIONALE

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

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

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

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

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

III.4.4 Equipment

RATIONALE:

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

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

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

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

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

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

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

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

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

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

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

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

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

Log books are maintained daily and secured in a safe location

III.4.5 Control of components and Rubber Materials

RATIONALE

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

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

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

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

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

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

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

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

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

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

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

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

III.4.6 Production and Process Controls

RATIONALE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III.4.7 Packaging and Labelling

RATIONALE

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

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

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

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

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

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

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

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

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

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

III.4.8 Holding and Distribution

RATIONALE

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

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

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

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

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

III.4.9 Laboratory controls

RATIONALE

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

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

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

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

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

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

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

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

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

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

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

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

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

III.4.10 Records and reports

RATIONALE

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

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

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

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

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

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

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

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

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

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

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

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

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

III.4.11 Returned rubber products

RATIONALE

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

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

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

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

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

BGR APHY

- [1] ISO 9001:2000, Quality management systems – Requirements.
- [3] ISO 10012-1:1992, Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment.
- [4] ISO 10012-2:1997, Quality assurance for measuring equipment – Part 2: Guidelines for control of measurement processes.
- [5] ISO 1382:1996, Rubber – Vocabulary.
- [6] ISO 1629:1995, Rubber and lattices – Nomenclature
- [7] BS 3558:1980, Rubber terms
- [9] TRACEABILITY OF MATERIALS AND ARTICLES FOR FOOD CONTACT–Final Version: 2002 elaborated by the “Food Contact Materials & Traceability Industry Liaison Committee”.