EXECUTIVE SUMMARY

The overall scope of ISO/TC 45 is the development of rubber and rubber product standards. The wide variety of rubber and rubber products makes the task of standards development very challenging and requires careful planning and prioritization of projects while addressing the changing market needs and consumer trends. The world’s rubber (both raw rubber and rubber products) industry is continuously expanding. In 2017, the world consumption of rubber stands at 28.40 million tonnes with 13.22 and 15.18 million tonnes for natural rubber (NR) and synthetic rubber, respectively. The value of world trade in rubber products is in excess of USD 500 billion. Thus, there is a compelling need for International Standards on rubber, rubber products and rubber compounding ingredients, which encompass their specifications and testing.

The ready global acceptance of ISO/TC 45 standards reflects the international nature of its P-membership, which is split almost 50:50 between the developed and developing countries. In many countries, standards developed by ISO/TC 45 have been adopted as national standards and technical regulations. This is a manifestation of their relevance to the rubber industry. One important instance was the roles of ISO/TC 45 to facilitate a solution to the latex allergy problems with the manufacturing of natural rubber gloves. ISO/TC 45 has developed a standard for the determination of water-extractable proteins in medical rubber gloves. Moreover, ISO/TC 45 embarked on a project to develop an International Standard for elastomeric earthquake bearings in response to the earthquake in Turkey of 1999 which left 17,000 people dead. The standard facilitates their use of the elastomeric earthquake bearings to protect buildings and their occupants from the devastating effects of earthquakes.

ISO/TC 45 is a mature technical committee of ISO with a large number of standards within its remit. The relevance of these standards has to be maintained, taking into account the rapid development in rubber science and technology as well as economic and market trends in rubber industry. Increasingly, there is a need for standards on rubber and rubber products to take into account factors related to health, safety, environment and more recently sustainability. Issues of product environmental performance, recycling and safety of rubber chemicals will feature prominently in the work of ISO/TC 45 in the short and medium terms. Indeed, ISO/TC 45 has made an early start in this direction by setting up a Working Group on Environmental Aspects to review issues of safety, environment and sustainability of rubber and rubber products, with the objective of establishing standards development programs to address them.
1. **INTRODUCTION**

1.1 **ISO technical committees and business planning**

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 **International standardization and the role of ISO**

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 161 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the [International Standard](#).

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its [Technical Committees](#) are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.
2. BUSINESS ENVIRONMENT OF THE ISO/TC

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

SUPPLY AND DEMAND

World rubber consumption and production

In 2018, global elastomer consumption was reported to be 29.18 million tonnes. The International Rubber Study Group (IRSG) anticipates world elastomer usage to grow to 34.04 million tonnes in 2025. Demands for elastomers, both synthetic rubber (SR) as well as natural rubber (NR), are well secured, in line with the growth of population and improvements in living standards around the world.

Synthetic rubber is purely an industrial raw material. The producing and consuming industries are in general closely related and dominated by large and global enterprises. Being a petroleum- derived product and manufactured by polymerisation process in chemical plants, the management of supply against demand is relatively straightforward. To a certain extent, the prices of its basic ingredients namely the monomers are more or less influenced by the price of petroleum. The consumption of SR was 15.40 million tonnes in 2018.

Natural rubber on the other hand, is also consumed as an industrial raw material. Consumption of NR grew to 13.78 million tonnes in 2018. In rubber articles, the two kinds of elastomers are never distinguished by users. It could be natural, synthetic or blends of various rubbers in different proportions. The choice on the kinds of rubbers to be used depends on the grounds of technological merit and economic availability. For example, in radial passenger car tyres, the ratio of NR and SR can be 60:40, but the percentage of NR could be higher for off the road tyres.
Trend in NR and SR production

Virtually all NR producing countries saw an increase with the Asian region accounting over 90 % of NR output. The major exporters of NR today are Thailand and Indonesia, which accounted for approximately 64.9 % of the total world exports in 2018. Rubber planting projects are on the rise as the price of NR increased drastically in recent years especially between 2010-2014, driven by growing demands from tyre manufacturer's which consume over 75 % of the world's NR. As area and yield have continued to increase in Thailand and Indonesia, the gap between the leading producers and the rest has widened. Growth in other countries is relatively low, especially in Africa. It is estimated that in 2025, the global NR production and consumption will be 16.1 and 16.0 million tonnes respectively (IRSG, ANRPC).

SR output has similarly increased in all producing regions. There is a continued rise in the growth of output in North America, Latin America, Other Europe, Asia/Oceania and the European Union. The world total production in 2018 was 15.23 million tonnes and the consumption was 15.40 million tonnes.

World rubber consumption

World total rubber consumption rose from 23.98 million tonnes in 2010 to 29.18 million tonnes in 2018. Generally, the largest consumers of rubber are the Asia/Oceanic region with the increase in usage in China raising the nation’s position as the world’s leading rubber consuming country.

Natural rubber accounted for 47.68 % consumption in 2018 while synthetic rubber accounted for the balance. The NR, SR consumption ratio averaged around 45.9 % over the last few years. SR consumption has been rising in major rubber producing countries whose economies are being increasingly industrialised.
NR latex sector consumption

The world NR latex consumption has increased steadily from 1.21 million tonnes in 2010 to 1.66 million tonnes in 2018. Malaysia is the world largest consumer of NR latex concentrate. Thailand is the world largest NR latex producing country, producing more than 1,000,000 tonnes in 2018. Asia consumed about three quarter of the global NR latex, with North America a distant second consuming followed by EU. NR latex is widely used in medical gloves, thread, foams and condom applications. Gloves are by far the largest market sector, consuming around 60 % by weight.

The main reason for the increase consumption arises from the increased use of disposable gloves in the medical industry because of the AIDS scare. NR latex gloves have been shown to provide the best barrier protection against the transmission of viruses and other bloodbourn pathogens. However, because of the latex protein sensitisation to certain individuals, other non-NR latex gloves, notably nitrile gloves are being steadily used in the market. These synthetic alternatives must have adequate barrier protection, which is the most important reason for wearing protective gloves. This in turn has led to new and improved International Standards being developed for these new materials.

Major factors impacting development of markets

Natural rubber as an agricultural product is stable in its supply in a short term. There is, however, concern that the balance of demand and supply in a long term is subject to the expansion of tyre demand and rubber consumption in China and also India. Although the demand is steadily increasing, the concerns on the supply persist due to the limited source of the production and the price hike caused by that of crude oil. Synthetic rubber accompanies the concerns on the stable supply of the raw materials used since the oil price is rising. Volatile situation in Middle East and the increase in consumption of oil especially in China and India might lead to the shortage of raw materials in the future.

As environmental awareness and more stringent regulations on chemicals especially in Europe (ROHS, REACH, etc.) are becoming more prominent, their influence on the manufacturing and cost of rubber products is unavoidable. The aspect of sustainability is also becoming an important factor that could potentially change the entire supply chain in the rubber industry and necessitates review of pertinent approaches for standard development activities of ISO/TC 45.
DIVERSITY OF END USES

Industrial rubber goods (IRG)

Beside tyres, industrial rubber goods (IRG) made from bale synthetic and natural rubbers include items such as belts, hoses and tubes. While IRG are used by virtually all industries, the dominant market is automotive but applications are also found in other product sectors. The global market for industrial rubber products is forecast to reach $67 billion by the year 2018. Factors driving growth include ease of processing and diverse applications of industrial rubber products, expansion of the manufacturing sector and ongoing efforts towards large-scale industrialization in developing markets. It is to be noted that the market for industrial rubber products will very much depend on the general economic situation, the consumption of agricultural and industrial products made of rubber. Key factors influencing competitiveness in the IRG are scale of production, relative level of technology, service to customers and proximity to market.

Asia-Pacific constitutes the largest as well as the fastest growing market for industrial rubber products worldwide, followed by Europe. As the global automotive production is shifting to the Asia-Pacific region, the demand for rubber-based automotive components is poised to increase significantly in the region in the coming years. Rubber hose and belting represent the other prominent product sectors. In the industrial rubber sector, rubber is facing strong competition from thermoplastic elastomers, principally due to increased cost savings achieved during their processing and their improved properties. Thermoplastic vulcanisate is posing an even larger threat to rubber especially in several demanding applications, such as industrial parts and automotive under-hoods, which are normally exposed to significantly high temperatures during applications.

Under the ISO/TC 45 structure, TC 45/SC 1 covers rubber and thermoplastic tubes and hoses for a wide range of applications from aerospace and automotive to industry and agriculture. Over the years, new polymers continually improve their technical performance. This has given rise to work to develop new standards or extend rubber only standards to encompass these innovations in materials and hose technologies. The car manufacturers have drawn up their own specific automotive standards in the past, but now the trend is to use ISO standards wherever possible.

Tyre industry

The tyre industry, which includes truck, aircraft, earthmover, passenger car and cycle tyres, tubes and curing bladders consumes two-thirds of the solid forms of natural and synthetic rubber produced and is characterised by the dominance of a few large global companies. NR is largely consumed by the tyre industry because of its excellent properties both during manufacture and in the end product. According to a report from the International Rubber Study Group (IRSG), global tyres production has reached 1,906 million unit in 2018 and expected to increase by 1.4% in 2019 before recovering to 1.9% in 2020.

Outside of the tyre and engineering sectors, demand for thermoplastic elastomers (TPEs) has become a significant force outstripping those of conventional elastomers. The rapid increase in consumption is driven by low production costs, including zero waste, recyclability and new uses such as overmoulded soft touch application. The continued growth at the expense of conventional elastomers presents challenges as well as opportunities to the rubber industry. The automotive market will remain the largest consumer of TPEs at the global level. Global TPE sales will remain concentrated in the US, Japan and Western Europe, but many developing countries, particularly in Asia are rapidly increasing demand for the material. China is the leader in this area with most of its use directed to its footwear industry.
Standards and specifications for tyres are under the ISO/TC 31 which ISO/TC 45 has a liaison with.

General rubber goods (GRG)

In the general rubber goods sector, there is a strong increase in Asia, while a steady increase in all other regions. The dipped goods sector especially for NR is a major contributor in the GRG. SR lost quite a number of end-uses to thermoplastic elastomers in automotive components. The statistics for the general rubber goods sector in selected countries indicates that this sector has recovered slightly with improvement in economy, tightened capacity and cost cutting measures. Over capacity, rising cost of materials and increasing competition have been important factors influencing the weakness in the markets.

Safety, Health, Environmental and Sustainability Issues related to Rubber Industry

The rubber industry has long appreciated the need for safety both in the workplace and in the service environment. The industry also recognizes that rubber products need to be made of materials that do not impose a health hazard or risk. In recent years, the industry has been equally aware of environmental needs including recycling and safe management of end of life of rubber and rubber products.

In this context, contributions from ISO/TC 45 are needed in developing new test methods and specifications for rubber and rubber products, including recycled rubber materials, to meet existing legislations and impending legislative developments related to safety, health, the environment and ultimately addressing the approaches towards sustainable rubber industry. Thus it is expected that the standards development activities of ISO/TC 45 that supports green or environmentally-friendly manufacturing of rubber and rubber products would be enhanced.

REAL OR POTENTIAL TBT

Technical barriers to trade often occur in international trade when countries have their own unique national standards and technical regulations. Several IRGs and GRGs are regulated within ISO member countries. In the area of medical devices such as medical gloves, the requirements set by non-harmonised national and regional standards pose a barrier to trade.

Close liaison with regulatory and health authorities is necessary, given their influence on standards and technical resolutions in respect of medical gloves and other rubber based products. In addition, the added cost of production in order to satisfy these non-harmonised requirements adversely affect the glove manufacturers and increase costs for consumers.

The fulfilment of requirements set by the purchasers is another concerned. Trade and business practices dictate regional standards or national standards to be preferred in cases where international standards are not widely adopted. For EC countries, adoption of ISO standards as the Europeans standards under the European Committee for Standardization (CEN) will automatically make them the national standards of the CEN member countries. ISO/TC 45 thus has an on-going cooperation with CEN under the Vienna Agreement framework to facilitate harmonisation.

2.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the ISO/TC:

World consumption of elastomers is about 29.18 million tonnes in 2018 of which NR accounted for 47.2 % while the rest was by SR. Generally, the largest consumers of rubber in the developed countries are also the principal producers of SR. The Asian region accounts for over 90 % of NR output with about 80 % from the South East-Asian countries, Bangladesh,
Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Thailand and Vietnam. Africa and Latin America are accounted for the remaining production. The major producers of SR are North America, European Union, other Europe (includes Commonwealth of Independent States), and Asia/Oceania.

The major consumer for NR is Asia/Oceania accounting for about 60% of the global consumption, followed by North America and European Union. The Americas and Western Europe together continue to account for about 1/3 of global consumption of NR.

Synthetic rubber now accounts for approximately 55% of the world elastomer consumption. Its share of global consumption has been declining since reaching its peak in 1979, but the decline now appears to be slowing down because of increased elastomer demand from Central and Eastern Europe. In addition, synthetic rubber consumption has been rising in major natural rubber producing countries whose economies are becoming increasingly industrialised.

3. BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

The main benefit expected from activities in this committee would be reaching a global market for rubber and its products with the elimination of technical barriers to global trade.

The harmonization of national and regional standards throughout the world related to rubber and rubber products for a global approach is also carried out. An example is the determination of the extractable protein level in latex of which the ASTM, CEN and ISO methods are currently being harmonized.

Preparation of original international standards for developing and emerging technologies for which national standards do not exist can result in benefits for the rubber industry. With the adoption of these international standards as national standards, member bodies can then gain in resources by not duplicating work.

Internationally accepted test procedures developed by ISO/TC 45 of process, raw materials, semi-finished products and products on their suitability for use will assist in mutual recognition amongst the industry fraternity, hence avoiding repetition of testing. In addition to the cost reduction, the standardised test procedures serve as tools to increase market access and development of trade.

Countries such as Japan, China, Thailand and Malaysia have aligned their national standards for rubber and rubber products with the international standards. Regional fora such as ASEAN Consultative Committee for Standards and Quality (ACCSQ) have identified 61 ISO standards for harmonization at ASEAN level.

ISO/TC 45 provides guidelines for inclusion of environmental and social aspects in standards for rubber and rubber products. It proposes an approach, which is directed at minimizing the adverse environmental impact of the products under consideration without detracting from the primary purpose of ensuring their adequate fitness for use.

ISO/TC 45 published standards have been a support for regulatory authorities to set up regulations, such as REACH and Food Contact Regulation in Europe. For example ISO 21461, which provides a method for the selective determination of polyaromaticity of oil in vulcanized rubber compounds is referred in REACH.
4. REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Membership

Countries/ISO member bodies that are P and O members of the ISO committee

4.2 Analysis of the participation

ISO/TC 45 is represented by principal players of this field that is by the western countries. The most important and active groups represented are the main producers and consumers of rubber and rubber products notably North America, Europe and Japan. Small but growing downstream rubber industries such as those of Thailand, Malaysia, Viet Nam and Indonesia are also represented.

Japan has shown strong growing interest in rubber by sending the largest number of delegates to the annual ISO/TC 45 meetings for the past few years.


Malaysia, as one of the major NR producing countries, and the world largest producer of latex based products, holds the secretariat of ISO/TC 45, SC 1 and SC 4. Two other developed countries, Japan holds the secretariat of SC 2 and the secretariat of SC 3 is held by France.

The breakdown in the number of countries holding Convenorships of Working Groups is as follows:

USA (4), UK (4), Sweden (4), Thailand (4), France (1), Japan (4), Germany (1), the Netherland (1), and Malaysia (3). Based on these figures, nearly 75 % of the Convenorships of Working Groups are held by developed countries.

The low participation amongst developing countries and countries with economies in transition is due to several factors including availability of technical resources, level of awareness, and lack of financial support for experts to attend meetings. The TC leadership recognises the importance of the involvement of developing countries in standards making and will continue to address and encourage developing countries to participate actively in areas of responsibility within TC and SC.
5. OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

ISO/TC 45’s main objective is to develop a package of international standards for rubber and rubber products covering the following aspects:

- Terminology, nomenclature and glossary
- Environmental and sustainability aspects of rubber and rubber products
- Physical and chemical test methods utilised
- Raw material (natural and synthetic rubbers including latex) and rubber compounding ingredients
- Grading systems for physical and chemical properties of rubber and rubber products
- Methods of sampling for analytical testing
- Finished and semi-finished rubber products
  - All types of general industrial, chemical and petrochemical hoses, hose assemblies and tubing, automotive hoses and hydraulic hoses, hoses and hose assemblies for compressed natural gas pipeline supply (rubber and thermoplastics, reinforced and non-reinforced)
  - Cellular material (flexible and semi-rigid cellular material made from natural and synthetic rubber materials)
  - Coated fabrics (rubber and thermoplastics coated)
  - Other miscellaneous products including rubber threads, sealing rings for pipes, rubber roof covering, rubber-covered rollers, elastomeric isolators for seismic protection, vibration mounts, rubber teats for feeding bottles, gloves and other latex products.

5.2 Identified strategies to achieve the ISO/TC’s defined objectives

The overall strategy of ISO/TC 45 is directed towards serving the global market and eliminating trade barriers whilst keeping close contact with the continuing changes in the industry and their user requirements including relevant international policy developments and trends. The specific strategies are to:

- produce terminology and classification standards for a more consistent and uniform use of definitions and to ease the development of the test method and product standards and interchangeability of products manufactured throughout the world.
- develop test method standards including precision data obtained from round-robin tests for reference in the product standards.
- implement the Vienna Agreement parallel procedure and keep close contact with other standards organization in order to avoid duplication of standardization work in this area.
- increase the efficiency of standard development by working through correspondence whenever possible and organize meetings only to discuss draft documents when active feedback and discussion are required.
- continuously review working procedures and internal structure with the aim of improving efficiency and timely delivery of documents.
- prepare new International Standards by using regional or national standards as starting documents in absence of appropriate ISO standards for use as a reference standard.
- use the five-year systematic review effectively and identify opportunities for quality improvements.
- include aspects of environmental, safety, health and sustainability.
6. FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

Common factors identified to influence the completion and implementation of ISO/TC 45 work programme include:

a. Reliance on progress in CEN for projects developed under the Vienna Agreement resulting in delays.

b. Lack of time dedicated on standardization activities by experts working on a part time and voluntary basis. Delays may arise from the late receipt of the amended texts for progression to the next stage of development. Similarly, if too many projects are approved without proper justification and feasibility studies, resources to develop quality work will be lacking.

c. Lack of experts within ISO/TC 45. Effective development of international standards depends on adequate experts available for specific projects. However, lack of participation of experts at international meetings could be overcome with participation of experts at the NMC level where constructive comments can be submitted during balloting period.

d. Limited delegation by member bodies. The parallel scheduling of committee work at the annual meetings of ISO/TC 45 makes it difficult for member bodies with small delegations to participate in all the meetings they consider important. Due to the growing number of working group meetings, it is not always possible to arrange the overall timetable to avoid conflicts amongst delegates attending various group meetings of interest to the member bodies. Some member bodies indicate that the low number of participation at international meetings is partly due to costs involved in sending experts to attend the meetings.

e. Slow progress a draft standard from one development stage to the next due to failure in securing copyright permission from the copyright owner.
7. STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

Information on ISO online

The link below is to the TC’s page on ISO’s website:
ISO TC 45 on ISO Online

Click on the tabs and links on this page to find the following information:
• About (Secretariat, Secretary, Chair, Date of creation, Scope, etc.)
• Contact details
• Structure (Subcommittees and working groups)
• Liaisons
• Meetings
• Tools
• Work programme (published standards and standards under development)

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans
General information on the principles of ISO’s technical work