Rubber is a versatile material flexible and resistant used for many applications. The majority of the industry producing from rubber articles in Europe is organized in two main blocks. The most visible and known is Tyres present in vehicles. The other is the General Rubber Goods (GRG) sector whose main application fields can be summarized as follows: the automotive and transport sector 63%, the industrial appliances sector 8-10%, the household applications 10%, energy / offshore 10-12%, food contact materials 4-5% and leisure 1-2%. The majority of the GRG sector are small medium size companies, SMEs.

The use of chemicals in the tyre and rubber industry is of outmost importance due to the necessary quality, safety and performance of the products. To give an example of the complexity, there are more than 1600 substances registered under REACH for its use in the sector of rubber manufacturing. The strong and robust chemical regulatory framework in Europe has placed the rubber industry at the foreground on chemical compliance, and strengthened its position worldwide.

The producers of rubber articles, as downstream users of substances and mixtures to produce rubber goods, are in a unique position in the value chain. Rubber articles are in many cases part of more complex articles serving to a large variety of sectors. This central position in the value chain boosts the industry importance and knowledge on legislation on products, articles, chemicals and mixtures.

Since its approval in 2006, the REACH legislation has evolved, from focusing on registration and evaluation of substances, to define restrictions and requirements on products in articles. An evolution, which has been emphasized even more in the recent chemical strategy for sustainability, placing in the front row the use of substances in articles. This evolution is demanding an adaptation of rubber sector to new regulatory requirements at an extreme fast pace, in an environment where competitiveness and global trends already pressure the sector⁶.

ETRMA would like to share the following considerations and points of attention in the coming CLP revision

**It is positive to increase the information on hazardous substances across the value chain with the inclusion of new hazard classes. However, the inclusion should aim to be a global harmonization with affordable, robust and agreed tests and methods.**

Every chemical used in the production of rubber articles is carefully selected to secure performance including resistance, safety, durability, anti-aging protection, and in some cases, protection under extreme conditions such as temperatures and pressures.

The majority of chemicals used in the production of rubber articles do not meet the requirements as Endocrine Disruptors (ED). Only a minority of substances such as process aids, impurities and substances present in the value chain of rubber production meet the requirements of ED. The amount of substances that could potentially meet the ED criteria in the future, if suspected ED are finally considered ED, would reach up to a 20% increase. The lack of reliable information impedes producers of rubber articles to have trustable

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⁶ European market, LMC Tyre & Rubber for ETRMA, October 2020
information to redirect efforts. Similar conclusions can be drawn with other hazard classes such as PBT, vPvB to name some.

The proposal to include new hazard classes under the CLP is promising and advisable. Setting trustable, reliable and agreed criteria to classify substances and mixtures will increase the information and safety provisions across the value chain. It will benefit rubber producers, placed in a central position between substances / mixtures and articles for many sectors such as automotive, aerospace, construction and oil and gas to name some.

However, the benefits of having new hazard classes could be undermined with no trusted, no-feasible and unaffordable set of criteria to define new classes. Too demanding conditions and too strict methods would increase the number of substances that meet the ED, creating confusion and hampering the ability, the feasibility and the flexibly of manufacturers of articles to focus efforts.

Further, introducing new hazard classes in Europe that are non-globally harmonized risks of creating a false impression of security across the value chain. In the absence of an EU harmonized classification, the information on new hazard classes will in many cases be omitted or not be present in chemicals’ supporting documents, like safety data sheets, of substances or mixtures imported from non-EU countries. Manufacturers and end users of rubber articles, that wish to use non-classified chemicals, might take no-information as no-classification, creating a false impression of absence of risk across the value chain.

**Proportionate transition periods for setting new hazard classes are essential to overcome the impacts on access low tonnage specialty chemicals of a deviation of the Global Harmonized System.**

Rubber articles used in automotive, aerospace, oil and gas and construction sectors, to mention some, are required to perform in extreme conditions. Some examples are O-rings in diesel engines, hoses off-shore installations and tyres for mining, agriculture, aviation. Specific and technical requirements demand the use, in many cases of specialty chemicals and polymers. Those are produced in low tonnages and in some cases imported and acquired for relatively low tonnages. Access to those raw materials is more and more difficult, as beyond global trends on increase production in Asian countries, the COVID-19 crises has drastically hampered the access to raw materials.

As previously raised, the inclusion of new hazard classes under the CLP will deviate EU’s system from the Global Harmonized System. It will add additional efforts and increase the requirements for importers of raw materials. For low tonnage products, this deviation could disincentive the import of chemicals, reducing the choice and the options on raw materials for EU rubber manufacturers, and place the industry in a competitive disadvantage face to non-EU countries with larger production.

ETRMA has estimated that approximately 30-40% ² of the chemicals used in the production of rubber articles are currently registered under lower tonnage. The potential impact of increasing the administrate and scientific requirements to access to 30% of the raw materials used in the rubber industry is not trivial³. Therefore, any deviation from the global harmonized system should secure access, and address the impacts for niche, specialty chemicals and SMEs. In this sense, generous transition periods are essential to minimize impacts allowing all the actors across the globe to adapt to the new and specific EU requirements of CLP.

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² Source: ETRMA. The term *substances used in the production of rubber* used includes, process chemicals, aids, impurities and substances present in the value chain of rubber production. The percentage does not refer to the substances present in rubber articles. The percentage might vary deepening of the type of article and sector.

³ Note: Not all raw materials are used in every application or article.
The criteria to classify mixtures should remain affordable and adaptable to all shapes, sizes, textures and matrices of chemistry

Clarifications on the provisions to classify mixtures should enforce and boost the flexibility to address all the matrices, shapes, compositions and behaviors of chemistry. This is particularly important for rubber mixtures. Rubber has a characteristic matrix effect; chemical substances are encapsulated in the rubber matrix and migration of only occurs by design. The provision on the classification of mixtures shall embrace and allow flexibility to coherently address the hazards of rubber mixtures, taking into account rubber’s matrix effect.

Digitalization of safety data sheets, labels of other requirements should be free open-access and user-friendly.

The use of electronic formats to share information across the value chain and such as safety data sheets or labels already occurs in the rubber value chain. Unfortunately, in many cases, downstream users of mixtures or chemical substances, as rubber articles producers, are requested to purchase a particular software license in order to access to electronic safety data sheets. Having to purchase a specific software impedes a true and broad spread of digitalization and particularly affects rubber SMEs. Digitalization requirements have to go hand in hand with user-friendly software, accessible to everyone with no cost, and comprehensive for basic computer skills users.

About ETRMA
The European Tyre & Rubber Manufacturers Association (ETRMA) represent nearly 4.400 companies in the EU, directly employing about 370,000 people. The global sales of ETRMA’s corporate members represent 70% of total global sales and 7 out of 10 world leaders in the sector are ETRMA Members. The product range of its members is extensive from tyres to pharmaceutical, baby care, construction and automotive rubber goods and many more applications. We have a strong manufacturing and research presence within the EU and candidate countries, with 93 tyre plants and 16 R&D centres.

See outcomes of STANPAH JRC’s project https://publications.jrc.ec.europa.eu/repository/handle/JRC111476 quantifying migration of PAH from rubber and plastic matrices.
See article ERASSTRI Part 2: Migration on End Of Life Tires derived rubber granules in sweat and saliva gastric fluids for more than 10 substances were performed with negligible realises for the majority of substances https://www.sciencedirect.com/science/article/pii/S0048969720306835

ETRMA’s membership: APOLLO VREDESTEIN, BRIDGESTONE EUROPE, BRISA, COOPER TIRES, CONTINENTAL, GOODYEAR, HANKOOK, MARANGONI, MICHELIN, NOKIAN TYRES, PIRELLI, PROMETEON, SUMITOMO RUBBER INDUSTRIES and TRELLEBORG WHEEL SYSTEMS. Furthermore, members include Associations in the following countries: Finland, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain and the UK.