Brussels, 15 November 2021

ETRMA accompanying document to the Open Public Consultation on the Revision of EU legislation on hazard classification, labelling and packaging of chemicals

Introduction

Rubber is a versatile material flexible and resistant used for many applications. The majority of the industry producing 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.

This document completes and adds information to the ETRMA answers to the Open Public Consultation survey on the Revision of the EU legislation on hazard classification labelling and packaging

Part I (general questions)

Question 1 - Please indicate how important it is for you to know a chemical is ED …

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.

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 be made in the framework of the GHS system to ensure 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 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.

Question 2 - Imagine you want to buy or use a product which bears a label with one of the following hazards. Would you be ready to pay more for alternative products that have the same performance, but which do not have that hazard?

In general price is one the most important criteria when purchasing articles. For tyres, safety is still the most important, followed by price[1] when selecting Tyres. There are not studies so far to understand what would be the consumers behaviour and how much users are interested in hazard aspects related to tyres, and – even more importantly – to what extent those hazard aspects would effectively drive purchasing decisions..

It shall also be pointed that the presence of substance in articles does not necessary poses a risk for the environmental and the human health when the article is used or at the end of life. A label has to be able to share information in hazard without creating confusion on whether the article is safe for its use.

Question 4 - In your view, how clear and easy to understand are labels of chemicals in general, and Question 5: which pieces of the label would you like to keep

Labels on chemical products mean to help consumers but also professional workers and users at industrial sites, as producers of rubber articles. Some substances that will be used at industrial sites for which the label information is essential are for instance: washing products, solvents or paints.

Information on the label of all chemicals cannot be compromised to simplify consumers´ use.

In other, links to web specific sites with further information on the hazard, risk and precautionary measures would be more and more common and the CLP shall also foresee web communication as a tool to complement current labels.

Question 6 - Would you like to be able to consult labels of chemicals digitally in the future (e.g. on your computer or smartphone?)?

With the implementation of digital solutions in all parts of every day activities, it is unavoidable that the information of the label and also of the safety data sheets would become more digital than now in the medium term.

It is crucial that the **digitalization of safety data sheets, labels of other requirements is free open-access and user-friendly.** The use of electronic formats to share information across the value chain 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.

Question 7 - Imagine you buy a detergent in bulk in a grocery. You have brought your own bottle which does not bear a label for this detergent. What would be the best option to inform you on the hazards and safety instructions?

Information at the point of sale on the characteristic of the article is essential as helps users to make choices before acquiring the product. Particularly the provision for use or disposal might affect the choice. Having

[1] COM(2017) 658 final on the Assessment of the need to review Regulation (EC) No 1222/2009 of the European Parliament and the Council on the labelling of tyres with respect to fuel efficiency and other essential parameters

this information after-sale will not be beneficial for the final users, which could find that special precautions are needed that are not possible to implement for them.

Question 9 - Online shopping of chemicals is becoming more and more common. Do you think it is important to receive the same safety information when you buy chemicals in a shop or online?

As explained in the question 7 the information at the point of sale is important regardless of a physical or on-line site. Understanding the characteristic of the article is essential as helps the users to make choices before acquiring the product. Particularly the provision for use or disposal might affect the choice. Having this information after-sale will not be beneficial for the final users, which could find that special precautions are needed that are not possible to implement.

Part II - Questions for experts

Question 14 - Are you in favour of a sub-categorisation for chemicals with a high level of certainty on their endocrine disrupting properties, as for mutagenic chemicals (e.g. Categories 1A and 1B)?

Providing that the definition of an ED substance is the same that the one used for the biocide regulation i.e.

- Acts via an ED mode of action
- Lead to harmful effect
- There is a causal link between the effect and the mode of action.

We support the sub-categorisation for chemicals with a high level of certainty on their endocrine disrupting properties, 1A and 1B.

Having that said, we believe that it is highly important, that European Commission define its position on the following scientific key points:

- The existence (or not) of a threshold mode of action.
- The relevance of a linear dose-response curve instead of the NMDRC.
- The potency.

We acknowledge that there is still not a scientific consensus as demonstrated by the discrepancy between SCC position

When possible, and on a case-by-case basis, taking into account a threshold mode of action for ED substances, together with a usual dose response curve, and potency are helpful to set risk management measures and operational conditions at the work place for the users of the substance, securing the safety of workers.

Question 28 - Do you or your organisation/company already have an estimate of the number of impacted chemicals due to the potential new hazard classes?. Question 28a - What percentage of products would need to be re-classifed and re-labelled due to foreseen criteria for ED, PMT/vPvM, PBT /vPvB?

The majority of chemicals used in the production of rubber articles do not meet the criteria for Endocrine Disruptors (ED). Only a limited number of substances such as process aids, impurities in substances present in the value chain of rubber production would meet the criteria for ED.

The number of substances that could potentially meet the ED, PMT/vPvM or PBT /vPvB criteria in the future, if suspected are finally considered, would be in the range of 4-5% of the substances present in the value chain of rubber articles – not necessary present in the final product. This is a significant amount of substances taken into account the number of substances actually used by the rubber industry or present in the value chain, that are in the range of 1500.

Further, **the criteria to classify mixtures should remain affordable and adaptable to all shapes, sizes, textures and matrices.** The provisions to classify mixtures should include considerations on how to address all the matrices, shapes, compositions and behaviours of materials. This is important for rubber mixtures that in general exhibit a characteristic matrix effect[2] leading to chemical substances being encapsulated in the rubber matrix with a very limited possibility of migration[3][4].

Question 35 - Currently, where the notification to the classification and labelling inventory (C&L inventory) results

Currently, where the notification to the classification and labelling inventory (C&L inventory) results in different entries for the same substance, manufacturers and importers shall make every effort to come to an agreed entry in the inventory. Despite this obligation, different entries for the same substances are very frequent and significantly reduce the usefulness of the inventory

As downstream users of chemical substances on industrial sites, we receive adequate safety data sheets of the mixture or substances we use in order to adequately manage the risk hazardous substances might pose.

However, the classification and labelling inventory, C&L, as well as the info sheet of ECHA is confusing, as in many cases the entries in the C&L is sometimes different for some endpoints of classifications than the information directly received from the producers / importers of the substance.

[2] Appendix 2. SDS for Special Mixtures : https://echa.europa.eu/documents/10162/23036412/sds_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20,

[3] 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.

[4] 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

Question 40: How would you rate the need to apply the same CLP obligations (e.g. labelling, classification and notifications to poison centres) also to hazardous chemicals purchased online (compared to traditional purchase)? Question 44 - Do you think that the CLP regulation should address problematic issues arising from on-line sales of hazardous substances and mixtures

Effective enforcement and market surveillance are essential for existing and future rules. In this context, we expect to see continuous efforts by relevant EU and national authorities for proper implementation of relevant CLP provisions. Enforcement shall adapt to the new methods of distribution and it is essential to protect the single market.

Question 48 - What are in your view the most suitable transitional periods until the new rules become applicable for the different aspects amended under CLP and, Question 48a - Please provide the reasons for the above proposed timelines for the applicability period.

Proportionate transition periods for setting new hazard classes are essential to overcome the impacts on implementation and adaption for downstream users of new hazards classes.

Those can be summarized as follows:

- Changes on safety data sheets, PNECs / DNELs: Changes might drive the needed to adapt the conditions of use and the risk management measures on-site.
- Reformulation / alternative: Including new classes of Hazard in the classification and labelling regulation could trigger the need for substitution which could require more or less time depending on the availability of alternative solutions. And this for the purpose of either protecting workers, reduce risk for users from using the substances or to address explicit demand from the final user of the rubber good to phase out certain substance.

Among the lesson learnt from the COVID-19 pandemic let us mention the fact that the current global trends creates difficulties to access to low tonnages specialty chemicals. 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 for offshore 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 from Asian country as a result of the global trend of an increasing share of Asian productions ., The COVID-19 crisis has drastically hampered the access to raw materials.

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 disincentives the import of chemicals, reducing access on raw materials for EU rubber manufacturers. It places the industry in a competitive disadvantage face to non-EU countries with larger production.

ETRMA has estimated that approximately 30-40%[5] of the chemicals used in the production of rubber articles are currently registered under lower tonnages. The potential impact of increasing the administrate and

[5] 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.

scientific requirements to access to 30% of the raw materials used in the rubber industry is not trivial[6]. 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.

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[7]. 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

[6] Note: Not all raw materials are used in every application or article.

[7] 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.