

Brussels, 9th of May 2019

Subject: ETRMA contribution to TRIS/(2019) 00547. Draft Joint Ministerial Decision of the Hellenic Republic laying down essential requirements for industrially processed rubber products

ETRMA, the European Tyre and Rubber Manufacturers' associations, would like to raise its concerns on the proposed decisions. ETRMA identifies the proposed Joint Ministerial Decision as a serious threat for the continuation of the single market specifically on rubber products and recommends the Commission issue a detailed opinion on the Greek Joint Ministerial Decision for the reasons hereunder explained.

The draft Joint Ministerial Decision clearly constitutes a breach of EU law. In particular the additional national provisions with regard to the legal limit values for the 8 PAHs regulated at EU level in entry 50(5) and (6) of Annex XVII of the REACH Regulation clearly constitute a breach of law. Following the ECJ ruling of 7 March 2013 in the *Lapin luonnonsuojelupiiri* case, the restrictions pursuant to Article 67 (1) and Annex XVII of the REACH Regulation finally harmonise the requirements for the manufacture, placing on the market or use of substances regulated there. The consequence of this is that national law of a Member State may not lay down other conditions for the manufacture, placing on the market, and use of a substance within the meaning of Article 67 (1) of the REACH Regulation. If a Member State intends to make the preparation, placing on the market or use of a substance which is the subject of a restriction under Annex XVII to the REACH Regulation subject to new conditions, it may do so only in accordance with Article 129(1) of the REACH Regulation, in order to respond to an urgent situation to protect human health or the environment, or in accordance with Article 114(5) TFEU on the basis of new scientific evidence relating inter alia to the protection of the environment. The adoption of other conditions by the Member States is incompatible with the objectives of that regulation.¹

Entry 50 paragraph of the REACH regulation, Regulation (EC) No 1907/2006, establishes that articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed 8 PAHs.

The scope of this entry is further clarified in the *Guideline on the scope of restriction entry 50 of Annex XVII to REACH: Polycyclic aromatic hydrocarbons in articles supplied to the general public*, published in 7th of March 2018 by the European Chemical Agency, ECHA. The members of CARACAL

¹ See ECJ, C-358/11, *Lapin luonnonsuojelupiiri*, EU:C:2013:142, paragraph 33 et seqq with reference to Joined Cases C-281/03 and C-282/03 *Cindu Chemicals and Others* [2005] ECR I-8069, paragraph 44.

endorsed the Guideline at the 26 meeting as indicated in the minutes of the meeting, Doc. CA/34/2018. It has been officially released by ECHA and has been published on its Internet site.²

Noted that CARACAL – the meeting of the Competent Authorities for REACH and CLP – is composed among others of representatives of Member States competent authorities for REACH and CLP, including the Hellenic competent authorities.

The draft Joint Ministerial Decision clearly is in violation of EU law. It introduces conditions other than those laid down by the REACH regulation. These provisions do not meet the need for ‘action on a Community-wide basis’ as set out in Articles 68 (1) and 69 of the REACH regulation. Furthermore, the Greek Joint Ministerial Decision fails to meet the requirements under Article 129 (1) of the REACH Regulation or in accordance with Article 114(5) TFEU.

This is for the following reasons:

1. Additional requirements for rubber products exceeding Entry 50 No 4 and 5 of Annex XVII of the REACH Regulation

The Greek Joint Ministerial Decision lays down additional national requirements exceeding the restriction in the REACH regulation. According to Art. 3 of the Greek Joint Ministerial Decision, rubber products must conform to the requirements in point 1 of Annex II of the Joint Ministerial Decision. Among the requirements set out in the seven paragraphs in Annex II, only one states the products must conform to the provisions of Regulation (EC) No 1907/2006 (REACH) as in force. The others contain additional provisions that are in excess of the REACH regulation and are, therefore, a clear breach of EU law.

2. The scope of the restriction in Entry 50 No 4 and 5 of Annex XVII of the REACH Regulation is being exceeded by the Greek regulation.

Entry 50 No 4 and 5 of Annex XVII of the REACH Regulation establishes that the part of the product that might be in contact with the skin, is the part of the product that shall be in compliance with the restriction. This is particularly relevant for rubber products like tiles or rubber mats. Often the surface of the products, the part in contact with the skin, is coated. The guideline clearly specifies that in this case the coating is subject to be compliant with entry 50, rather than the rubber under layer. This is explained in more detail by ECHA in its Guideline.³ The proposed Joint Ministerial Decision describes how the Hellenic republic will undertake the enforcement of entry 50 paragraph 5 and 6. In Annex I of the decision, Products *within the scope of this decision*, references to products inside the decision scope are made. It includes *rubber products, surface under layers or components in items placed on the market*. The compliance requirements are requested to any part of the product, regardless of whether these are to come in contact with the skin or not.

3. Additional national requirement of a specific quality management system

Article 5 of the Greek Joint Ministerial Decision stipulates a quality management system be introduced by manufacturers. The quality management system must meet the requirements laid down in Annex IV of the national Greek decision. Conformity to the requirements in Annex IV must be certified by an accredited conformity assessment body in the context of the provisions of Regulation (EC) No 765/2008. No such requirement is set out in the REACH regulation. It is up to economic operators to decide how they want to organize their own factory production control and whether they want to introduce a specific quality management system and to have an accredited conformity assessment body certify this.

² https://echa.europa.eu/documents/10162/106086/guideline_entry_50_pahs_en.pdf/f12ac8e7-51b3-5cd3-b3a4-57bfc2405d04.

³ Cit. op., see paragraph 2.6. “Coated articles”.

4. National requirements of conformity with (unknown) and not notified ministerial decisions.

Under Article 5 of the notified Joint Ministerial Decision, processed rubber products which fall within the scope of Annex I point 1 must also conform to the requirements of Joint Ministerial Decisions Nos 28492/18.5.2009, 27934/25.7.2014 and 36873/2.8.2007, as in force. These ministerial decisions have not been submitted in the notification procedure at hand.

5. Additional national requirement of a specific declaration of conformity

Article 4 of the Greek Joint Ministerial Decision states that each batch of processed rubber products intended to be placed on the market [comment: this is the Greek market] after manufacture shall be accompanied by a suitable Declaration of Conformity issued by either the manufacturer or the importer [comment: the economic actor who imports the products into Greece] in accordance with the template in Annex III. No such declaration of conformity is being stipulated by the REACH regulation. It is, therefore, for the economic operators to decide in which way conformity of their products with the REACH regulation is being documented.

6. Inaccuracies in terms of standards and compliance requirements.

Under Article 6 of the Greek Joint Ministerial Decision (*General requirements for manufacture for specified uses*) indicates that in order to be compliant, products *must be in accordance with the relevant standards in the sector*. However, there are not specific standards for acceptability indicated. The article references to Annex V – where a list of standards is named as indicative, but not definitive for acceptance. It creates a situation of insecurity on how to show compliance.

Furthermore, standard EN 16143:2013 *Petroleum products*, is mentioned at Annex V for indicative compliance for *Manufacture of rubber*. This standard is indicated as present in entry 50 of Annex XV of REACH. However, EN 16143:2013 is present in entry 5 paragraph 1 – referred to tyres – and not entry 5 paragraph 5 – referred to rubber goods in contact with the skin. The inclusion of standard EN 16143:2013 on the list for *Manufacture of rubber* drives to confusion and hampers producers' ability to comply with the provision on the Joint Ministerial Decision.

7. Additional national obligations of economic operators

The obligations of economic operators set out in Article 8 exceed the provisions of the REACH regulation, the General Product Safety Directive, and the Market Surveillance Regulation. This applies, for example, for the obligation to “retain for at least five years at the manufacturing facilities or their registered offices a sample of the rubber or sample of the rubber product to verify the requirements of this article. The sample shall be retained in such a way as to ensure that its physico-chemical characteristics are not affected and that it remains possible to chemically analyse it.”

8. Penalties are in violation of EU law.

The provisions on penalties (administrative fines and criminal prosecution) set out in Article 9 of the Greek Joint Ministerial Decision constitute a violation of EU law as they refer to the aforementioned provisions.

9. Excessive transitional provisions

Joint Ministerial Decision Article 11, Transitional provisions, paragraphs 2 and 3, specifies that for products to be compliant, certificates and confirmations issued prior to the issuing of this decision [...] shall not apply. Consequently, this provision would render existing and approved certificates across Europe obsolete and oblige businesses to obtain suitable

conformity certificates or to reissue existing certificates. Such a disproportionate measure would not only lead to considerable administrative burdens and high operating costs for businesses, but it would also counteract the principles of legal certainty and protection of legitimate expectations, thus hindering the manufacture and import of processed rubber products

10. Unilateral market surveillance

In accordance with Joint Ministerial Decision Article 7, Market surveillance, paragraph 5, samples shall only be examined by the labs of the State General Laboratory. By not allowing the examination of samples by other labs, this measure would hamper the free movement of goods and knowledge, and thus would threaten to break up the basic principles of the European single market, thereby, inevitably leading to dominant monopolistic conditions and to unilateral decision-making.

The provisions specified at the Join Ministerial Decision will hamper the entrance of the market of compliant rubber goods approved for its use in other parts of the Europe, causing a clear threat to the single market.

We would like to draw attention to the fact that safety slabs produced of Styrene-Butadien-Rubber (SBR) are safe to use. There is, furthermore, an ongoing process of a legal review of the limit values in entry 50, items 5 and 6, Annex XVII of the REACH Regulation in light of new scientific information. The EU Commission (Mr. Carlo Pettinelli, DG Enterprise, and Mr. Kestutis Sadauskas, DG Environment) wrote to ECHA on 19 December 2016 requesting it to prepare statutory review of the restriction in entry 50, points 5 and 6.⁴ Findings produced by Fraunhofer Institute for Process Engineering and Packaging (Fraunhofer IVV) submitted along with other industry and stakeholder statements of position have in the meantime been validated by the Joint Research Center (JRC). The study Migration of Polycyclic Aromatic Hydrocarbons (PAHs) from plastic and rubber articles has even been published in the meantime.⁵ The European Commission issued a standardization mandate to CEN for the development of a measurement method for PAHs⁶. The study performed by Fraunhofer IVV, which has been submitted to ECHA and the European Commission, demonstrates and proves that under normal or reasonably foreseeable conditions of use safety slabs made out of SBR granulate cannot have any negative impact on the health of users, and recommends that a migration-related approach be introduced instead of the existing PAH content values. For these reasons, we believe that it is highly warranted for the legislative procedure on the EU level to be completed. There is absolutely no need for a national solo-attempt as it is currently being performed by Greece.

⁴ https://echa.europa.eu/documents/10162/13641/echa_lead_pah_commission_request_en.pdf/248461e1-cab2-9d23-9d54-42df72d26505

⁵ <http://publications.jrc.ec.europa.eu/repository/handle/JRC111476>.

⁶ Mandate M/556, C (2017) 2926 final.