

## **ETRMA views of ECHA proposed restriction on formaldehyde releasers: Legal clarifications needed to guarantee proper implementation**

European Chemical Agency, ECHA, final background document on the *Formaldehyde and Formaldehyde releasers restriction* and the final opinion of the Risk Assessment Committee, RAC, and the Socio Economic Assessment Committee, SEAC, of ECHA were released on March 2021. The proposal restricts any article produced using formaldehyde or formaldehyde releasing substances, if the formaldehyde released exceeds a concentration of 0.124 mg/m<sup>3</sup>.

The restriction aims to control the potential releases from wood-based panels and similar articles used indoors. The restriction includes derogations for articles that use formaldehyde resins for which no risk is identified, for instance, those used outdoors, in industrial sites or by professional workers.

Formaldehyde releasing resins are used in the formulation of specific rubber mixtures for Tyres and General Rubber Goods. Formaldehyde is generated by the reaction of hardener resins with phenolic resins, and is mainly released during the manufacturing process at industrial sites. Once the article is finished, the residual formaldehyde is embedded in the cured rubber matrix. There has not been any risk identified on the presence of formaldehyde and its potential emission from rubber articles.

SEAC's opinion<sup>1</sup> puts in evidence this lack of risk stating that in page 96 *formaldehyde resins [...] in rubber mixtures for tyres make only a very small contribution to the emission of formaldehyde. SEAC therefore sees no reason to replace [formaldehyde resins]*

SEAC' opinion also explains that the definition of *Articles exclusively used outdoor* of the proposed restriction applies to (Page 99), *tyres as those are considered mostly outdoors articles tyres for bicycles (e.g. larger than 24"), wheelbarrows, motorcycles, motor scooters, cars, motorhomes, vans, light trucks are, in SEAC's view, intended for outdoor use although SEAC acknowledges that there might be cases of seasonal storage of tyres intended for outdoor use in/near the home. SEAC supports an exemption according to paragraph 3 of the Dossier Submitter's proposal as far as these types of tyres intended for outdoor use are concerned.*

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<sup>1</sup>Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on Formaldehyde and formaldehyde releasers. ECHA/RAC/RES-O-000006740-76-01/F, ECHA/SEAC/RES-O-000006931-71-01/F. <https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f>

SEAC's opinion also clarifies that (on page 99) *SEAC supports the derogation for articles exclusively for industrial and professional use, if formaldehyde released from them does not generate exposure to consumers (paragraph 4 of the proposed restriction)*. ETRMA understands that industrial tyres such as mining or agricultural tyres and general rubber goods, such hoses, conveyor belts to mention some, are articles covered by paragraph 4 of the proposed restriction.

**ETRMA welcomes SEAC's opinion clarifications that are supported by the extensive technical and scientific information that ETRMA shared with ECHA over the course of the public consultations.**

**On small size wheels and bicycle wheels** SEAC states in Page 99 *Tyres for children's pushchairs, wheelchairs, folding bikes and toys, including children's bicycles and scooters, can in SEAC's view be considered for both indoor storage/use and outdoor use. SEAC does not consider these types of tyres to be exempted from the proposed restriction.*

In addition, the proposed restriction includes in paragraph 10 a derogation for articles subject to Directive 2009/48/EC – Toy Safety. <sup>2</sup>

Not including small size wheels (diameter < 24'') into the definition of outdoor articles creates uncertainties and unclarity in the implementation and enforcement of the restriction. Adult size bicycle wheels (diameter > 24'') are derogated under paragraph 3. Children bicycle wheels not designed to circulate on roads, are covered under the Toys' Safety regulation and therefore derogated under paragraph 10. However small bicycle wheels (diameter < 24'') such as those for children, teenagers, foldable bikes or other more specialized bikes such as *BMX* bikes, that can be used outdoors and designed to circulate on roads, are explicitly excluded from the derogation of outdoor articles and therefore subject to compliance.

It shall be noted that, in many cases, small bicycle wheels (diameter < 24'') are designed to circulate and meet concrete performance conditions. Further, there is not risk identified from the potential use of formaldehyde releasers in rubber articles, as recognized and discussed in SEAC's opinion.

The storage of the above mentioned small and medium size bikes (wheels of <24'') is similar to those described for adults, mainly based on the type of housing and societal conditions rather than the size of the bike.

ETRMA sees the need to include a derogation for all types of bicycle wheels, regardless of the size. This will allow an adequate and clear implementation of the restriction.

**On food contact materials**, SEAC considers that it is unlikely that food contact materials will be stored in house and therefore potentially be a risk P 101 *Articles in the scope of Regulation 2011/10 on food contact materials, as emitting substances used in food contact materials (mostly MF plastics) are expected to have a very low potential of releasing formaldehyde in indoor environments [...]* SEAC sees room to reflect on whether the exemption should be extended to other food contact materials (i.e. those covered by Regulation 1935/2004).

ETRMA welcomes this reflection, and in order to be applicable for general rubber goods used as food contact materials indoors, a reference to regulation 1935/2004<sup>3</sup> is needed. The current proposed

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<sup>2</sup> Directive 2009/48/EC of the European parliament and of the council of 18 June 2009 on the safety of toys

<sup>3</sup> Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

restriction on paragraph 9 only derogates food contact materials covered under regulation 2011/10<sup>4</sup>, plastic materials, and it does not include general rubber goods.

All in all, there is a need to clearly state the scope of derogations of paragraph 3, 4 and 9. These clarifications are not trivial. The wide scope of the restriction, the lack of official reference of articles considered in each derogation, together with the use of formaldehyde releasers in the rubber industry makes further clarifications essential. Industry and Members states need legal certainty and security for a successful implementation.

Therefore ETRMA requests the following:

- A recital on the restriction that states that tyres are considered outdoor articles under this restriction and derogated under paragraph 3
- A modification of paragraph 9 for derogations of articles covered under the food contact materials regulations with references to regulation 1935/2004, and not exclusively a reference to 2011/10, as it is the case now, because it covers exclusively plastic articles in contact with food, and not rubber articles.
- A derogation for all types of bicycle wheels designed to circulate regardless of the diameter's size.

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<sup>4</sup> Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

## Annex I

### ETRMA suggested recitals in final legal text

Whereas:

(i) For some articles formaldehyde-based or formaldehyde-free resins might have to be used in rubber mixtures for tyres and general rubber goods and make only a very small contribution to the emission of formaldehyde.

(ii) Wheels for bicycles regardless of its diameters size to be used under circulation, scooter wheels, wheelbarrows, and tyres for: motorcycles, motor scooters, cars, motorhomes, vans, light trucks, are intended for outdoor and considered articles to be used outdoors under the meaning of this regulation, although It is acknowledged that there might be cases of seasonal storage of tyres / wheels intended for outdoor use in/near the home.

## Annex II: ETRMA explanatory slides

**Annex III: ETRMA contribution to the 1<sup>st</sup> public consultation on Annex XV restriction proposal on Formaldehyde and formaldehyde releasers restriction**

**Annex IV: ETRMA contribution to the 2<sup>nd</sup> public consultation on Annex XV restriction proposal on Formaldehyde and formaldehyde releasers restriction**

*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<sup>1</sup>. 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 centers..*

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