

ETRMA views on the ECHA opinion on the restriction proposal on formaldehyde and formaldehyde releasers

March 2021



Formaldehyde proposal by the dossier submitter, ECHA published in March 2021, paragraphs 1-4

1. Articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture, shall not be placed on the market if the formaldehyde released from them exceeds a concentration of 0.124 mg/m³ as measured in accordance with the conditions specified in Appendix X. Road vehicles and aircraft produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m³ as measured in accordance with the conditions specified in Appendix X.
2. Paragraph 1 shall apply 12 months from the entry into force of the restriction.
3. By way of derogation, paragraph 1 shall not apply to articles that are only for outdoor use under reasonably foreseeable conditions.
4. By way of derogation, paragraph 1 shall not apply to articles exclusively for industrial and professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use.



Formaldehyde proposal by the dossier submitter, ECHA published in March 2021, paragraphs 5-11

By way of derogation, paragraph 1 shall not apply [...]

5. to articles subject to Regulation (EU) 2018/1513.
6. to the use of formaldehyde and formaldehyde releasers as biocide subject to Regulation (EU) 528/2012.
7. to articles subject to Regulation (EU) 2017/745.
8. to articles subject to Regulation (EU) 2016/425.
9. to articles subject to Regulation (EU) 2011/10.
10. to articles subject to Directive 2009/48/EC.
11. to second-hand articles.



Tyres and General Rubber Goods are included in the scope as described in paragraph 1

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 opinion recognizes that there is not identified risk from rubber goods

SEAC's opinion put in evidence this lack of risk stating that *P96 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]*

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



A worst-case release scenario for Tyres is a warehouse full of tyres. Formaldehyde concentration in the air do not pose a risk and are below formaldehyde DNEL 0.05 mg/m³

Derogations on paragraphs 3 and 4 exclude from the scope industrial tyres and the majority of rubber goods

3. By way of derogation, paragraph 1 shall not apply to articles that are only for **outdoor use** under reasonably foreseeable conditions.

4. By way of derogation, paragraph 1 shall not apply to articles exclusively for **industrial and professional use** if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use.



SEAC opinion considers that Tyres, such as passenger tyres or truck and bus are outdoor articles and derogated under p 4

*Articles exclusively used outdoor of the proposed restriction applies to P 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.*



Tyres consideration as outdoor article under SEAC's opinion will not secure a homogeneous implementation of the derogation

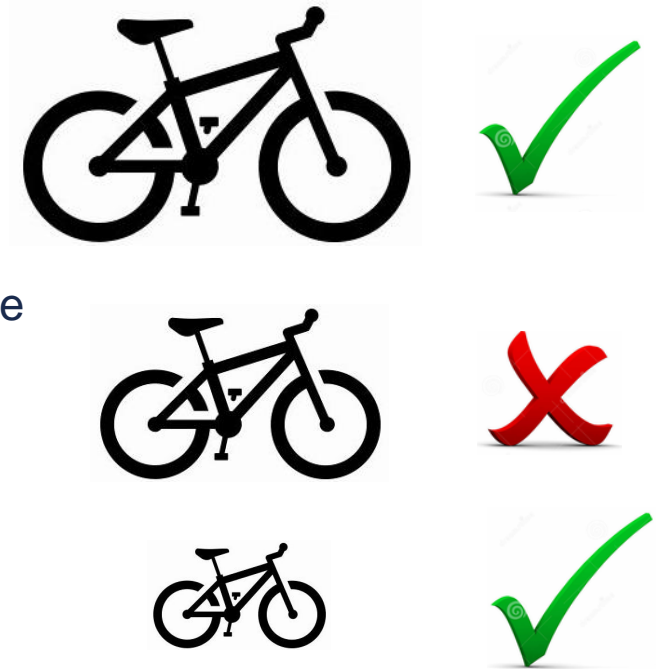
- SEAC's opinion on Tyres as outdoor articles will not have a legal validity when implementing the regulation
- The lack of references could lead to an heterogeneous implementation of the restriction across member states
- Industry and Members states need legal certainty and security for a successful implementation.
- Therefore the final legal text of the restriction shall include recitals to explicitly reference that Tyres are considered outdoor articles and under the scope of paragraph 4

Small size bicycle wheels shall also be included in the derogation as there are not risks identified from rubber

SEAC's opinion *Tyres for children's pushchairs, wheelchairs, folding bikes and toys, including children's bicycles and scooters,[...] does not consider these types of tyres to be exempted from the proposed restriction.*

This creates a confusing situation

- Adult size bicycle wheels (diameter > 24'') are derogated under paragraph 3.
- Small bicycle wheels (diameter < 24'') such as those for children, teenagers, foldable bikes or other more specialized bikes such as bmx bikes, that are to be used outdoors and designed to circulate on roads, are explicitly excluded from the derogation.
- Children bicycle wheels not designed to circulate on roads, are covered under the Toys' Safety regulation and therefore derogated under paragraph 10.



The Food Contact Materials regulation shall be referenced as Regulation 1935/2004 to cover rubber articles

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).

However derogation under paragraph 9 references 2011/10 for plastic materials, excluding rubber articles used as food contact materials.

In order to be applicable for general rubber goods used as food contact materials indoors, a reference to regulation 1935/2004 is needed - 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 -



There is a need to clearly state the scope of derogations of paragraph 3, 4 and 9 as follows

- 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
- A derogation for **all types of bicycle wheels** designed to circulate regardless of the diameter's size.

ETRMA suggested recitals in final legal text

(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.

Thank you

