EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) Formaldehyde is a highly reactive gas at ambient temperature and atmospheric pressure conditions. It is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] as carcinogen category 1B, mutagen category 2, acute toxicant category 3, skin corrosive category 1B and skin sensitiser category 1.

(2) Formaldehyde is a high production volume chemical with a wide array of uses. It is also produced endogenously in humans and animals, and it is an essential metabolic intermediate in all cells. 98 % of the formaldehyde manufactured or imported in the Union is used as a chemical intermediate in the production of formaldehyde-based resins, thermoplastics and other chemicals, which are further used in a broad range of applications. Formaldehyde-based resins are used in the production of a wide variety of articles, which, as a result, may release formaldehyde. The primary use of formaldehyde-based resins is in the manufacturing of wood-based panels, where they act as a bonding agent for wood particles. Such resins are also used in the production of other wood-based products like furniture and flooring, and for wallpapers, foams, parts for vehicles and aeroplanes, textile and leather products.

(3) On 20 December 2017[3], pursuant to Article 69(1) of Regulation (EC) No 1907/2006 the Commission asked the European Chemicals Agency ('the Agency') to prepare a dossier which conforms to the requirements of Annex XV to that Regulation

[1] OJ L 396, 30.12.2006, p. 1.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[3] https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

(hereinafter 'the Annex XV dossier'), in order to assess the risk to human health from formaldehyde and formaldehyde releasing substances in mixtures and articles for consumer uses.

(4) On 11 March 2019, the Agency (to be known as 'the Dossier Submitter' in the context of submission of a dossier) submitted the Annex XV dossier[4], which demonstrated that the risk to human health from formaldehyde released from consumer articles in indoor environments is not adequately controlled under all scenarios, and that action on a Union-wide basis is necessary to address that risk.

(5) The Dossier Submitter assessed the hazard of formaldehyde by considering the effects of the substance on several endpoints, concluding that the risk from inhalation leading to sensory irritation is the most sensitive effect in humans. The Annex XV dossier assessed the risks from inhalation of formaldehyde associated to consumer exposure against the World Health Organization (WHO) Guideline for Indoor Air Quality for formaldehyde (30-minute average concentration based on sensory irritation in humans)[5]. The Guideline provides for a short-term value (0,1 mg/m^3) with a view to preventing detrimental effects on lung function, as well as long-term health effects, including nasopharyngeal cancer. The Dossier Submitter used that value as the level above which humans should not be exposed (derived no-effect level ('DNEL') and to calculate the proposed emission limit of 0,124 mg/m^3.

(6) Based on available literature and the outcome of the exposure estimation, the Dossier Submitter concluded that human health risks from formaldehyde release from mixtures for consumer use are adequately controlled.

(7) The Annex XV dossier therefore proposed to prohibit the placing on the market of formaldehyde and formaldehyde releasing substances in articles generating consumer exposure where the formaldehyde releases lead to concentrations exceeding 0,124 mg/m^3 in the air of a test chamber. Moreover, the Annex XV dossier specified that formaldehyde in road vehicles and aircraft, where formaldehyde or formaldehyde releasing substances were intentionally added during their production, should not be placed on the market if the formaldehyde measured in their interior exceeds a concentration of 0,1 mg/m^3 and where exposure of formaldehyde to consumers can occur there.

(8) The Dossier Submitter's original proposal established EN 717-1 as the standard method to measure in a test chamber the emissions for formaldehyde released from wood based panels. To clarify that other suitable test methods can also be used and to cover articles other than wood-based panels, the Dossier Submitter replaced the reference to standard EN 717-1 in its proposal by a wider description of conditions and methods. Ambient conditions may have an influence on formaldehyde emissions from articles and therefore relevant testing parameters were also listed in the Annex XV dossier.

(9) On 13 March 2020, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion. In its opinion, RAC considered the WHO guideline value not sufficiently protective for the general population and concluded in particular that short-term sensory irritation effects in humans cannot be used to predict long-term effects such as cancer. RAC instead set a DNEL of 0,05 mg/m^3 derived from data on chronic effects

[4] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477

[5] WHO 2010-WHO Guidelines for Indoor Air quality: Selected Pollutants. Geneva. World Health Organization, p. 103.

in animals for the inhalation route and concluded that a limit value of 0,05 mg/m^3 for formaldehyde released from articles and for formaldehyde in the interior of road vehicles was needed to control the risk.

(10) RAC concluded that the risk to passengers from formaldehyde in aircraft is adequately controlled.

(11) RAC recommended a transitional period of 24 months from the entry into force until the application of the proposed restriction, compared to the 12 months suggested by the Dossier Submitter, as a longer time was considered necessary to allow for the development of standard analytical methods in all sectors affected. RAC concluded that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks to human health arising from consumer exposure to formaldehyde, in terms of its effectiveness in reducing the risk, its practicality and the manner in which it can be monitored.

(12) On 17 September 2020, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, concluding on the Dossier Submitter's proposed restriction and the modifications proposed by RAC.

(13) In its opinion, SEAC acknowledged that the Dossier Submitter's proposal entails costs in terms of production, sampling, testing and enforcement in the order of tens of millions of euros. However, SEAC concluded that those costs are expected to be limited for the concerned sectors, as most of the articles, including road vehicles, placed on the market in the Union today are already compliant with the proposed limit value. SEAC also concluded that benefits from the Dossier Submitter's proposed restriction would result from restricting the placing on the market of articles emitting high concentrations of formaldehyde, including imports. The restriction would result in reduced adverse health effects related to irritation of the eyes, upper airways and nasopharyngeal cancer, mainly for individuals living in new dwellings.

(14) SEAC considered that the benefits deriving from limiting formaldehyde emission from consumer articles indoors and in the interior of vehicles, as proposed, could be achieved at limited costs for society. Therefore, SEAC concluded that the Dossier Submitter's proposal is the most appropriate Union-wide measure to address the identified risk to human health, in terms of its socio-economic benefits and its socio-economic costs, if certain derogations are included and proposed testing conditions accepted.

(15) To provide sufficient time for stakeholders to implement the restriction, SEAC recommended a deferral of 24 months for all sectors as regards the application of the restriction. For trucks and buses, however, SEAC recommended 36 months due to the need to develop standard analytical methods for measuring formaldehyde concentrations in the interior of these vehicles.

(16) SEAC concluded further that the proposed restriction, as modified by RAC, entails major socio-economic costs, in the order of tens of billions of euros, in terms of investment in research and development, new technologies, higher production costs, sampling and testing costs, as well as job losses. Furthermore, it potentially has negative effects on recycling sectors and the circular economy. SEAC recognised that to achieve the limit proposed by RAC, technically feasible alternatives exist for certain applications; however, they require far-reaching technological changes and, in specific cases, the use of less sustainable alternatives.

(17) SEAC acknowledged that RAC's proposal has potential additional benefits in terms of reduced exposure that may lead to a greater reduction in eye and upper airway irritation and nasopharyngeal cancers compared to the Dossier Submitter's proposal. However, RAC did not quantify the risk reduction associated with lowering the limit value; hence, the magnitude of the additional health benefits remains unknown. Furthermore, as part of its assessment, SEAC carried out an analysis by which it calculated that, given the high socio-economic costs, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 200 times higher than the actual observed incidence, for the RAC proposal to break even. Taking into account this break-even analysis, the information received from industry during the consultations, and the absence of data or information that would allow the quantification of additional health benefits, SEAC concluded that the restriction based on the limit value proposed by RAC does not appear to be an appropriate measure to address the identified risk in terms of socio-economic benefits and socio-economic costs.

(18) The Forum for Exchange of Information on Enforcement was consulted on the Dossier Submitter's proposal and its recommendations on its implementability and enforceability have been taken into account; the Forum did not consider the modifications recommended by RAC, as they were presented after the consultation of the Forum.

(19) On 23 February 2021, the Agency submitted the opinions of RAC and SEAC to the Commission[6]. The opinions of RAC and SEAC concluded that there is a risk to the health of consumers that is not adequately controlled and needs to be addressed on a Union-wide basis due to the emissions of formaldehyde from articles into indoor air and from road vehicles into their interior.

(20) The Commission notes that, while the proposed restriction by the Dossier Submitter as well as the opinions by RAC and SEAC refer to consumers, the assessment underpinning the proposal addresses the risk to the population that could be exposed to formaldehyde in indoor air other than workers, including persons that are not direct consumers. For the sake of legal clarity, it is therefore appropriate to refer to the general public as the population targeted by the restriction.

(21) The Commission, taking into account the Annex XV dossier as well as the RAC and SEAC opinions, considers that there is an unacceptable risk to human health arising from formaldehyde released from articles, and that a restriction establishing an emission limit for articles emitting formaldehyde to decrease exposure of the general public to formaldehyde via inhalation is the most appropriate Union-wide measure to address the risk.

(22) The Commission agrees with the Dossier Submitter that the proposed limit value of 0,124 mg/m^3 prevents articles that emit high amounts of formaldehyde from being placed on the market in the Union and that it is appropriate to limit exposure to formaldehyde in indoor environments. However, the Commission considers that the risk reduction realised by achieving the WHO Guideline value is modest because of existing voluntary and national emission limits and the fact that the majority of articles placed on the market today are already expected to be compliant with the limit value

[6] Compiled version prepared by the ECHA secretariat of RAC's opinion (adopted 12 March 2020) and SEAC opinion (adopted 17 September 2020) https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f

of 0,124 mg/m^3. Achieving the WHO guideline value would also be insufficient to address the risk identified, taking into account RAC's opinion. Likewise, current interior concentrations in road vehicles mostly comply with the proposed limit value of 0,1 mg/m^3.

(23) The Commission also acknowledges, based on SEAC's conclusions on the socio-economic assessment, that the limit value of 0,05 mg/m^3 , as proposed by RAC, would entail major socio-economic impacts for the Union; and that such a limit value requires, in specific cases, shifting to less sustainable alternatives with negative effects on the circular economy and recycling, in particular in view of the absence of an assessment of the additional health benefits of such a limit compared to the limit proposed by the Dossier Submitter.

(24) The Commission therefore examined the appropriateness of the intermediate limit values of 0,08 mg/m^3 and 0,062 mg/m^3 that had been partly assessed by SEAC based on input received from stakeholders in the consultations. The Commission concluded that the adoption of such intermediate values would entail a higher protection of human health, in particular that of vulnerable populations, compared to the limit proposed by the Dossier Submitter, while entailing a lower socio-economic burden and fewer technological challenges than the limit proposed by RAC, particularly if taken in combination with adequate transitional periods and specific derogations.

(25) The Commission recognises the exponential increase in costs when lowering the limit value, and that the estimated combined costs for industry would be at minimum in the range of hundreds of millions of euros for the limit value of 0,08 mg/m^3 , compared with billions of euros for the limit value of 0,062 mg/m^3. The Commission has further analysed the break-even analysis by SEAC, which calculates that, for the limit value of 0,062 mg/m^3 to break even, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 70 times higher than the actual observed incidence, and 30 times higher for the limit value of 0,08 mg/m^3. However, the Commission also considers that formaldehyde is a carcinogenic substance, for which the limit value of 0,062 mg/m^3 would provide higher health benefits to the population in the Union. The Commission, although recognising that the differences in costs between the two values are significant, considers, in view of the potential additional health benefits, in particular to vulnerable groups such as children, that the higher costs for the lower limit value are justified for articles contributing the most to indoor air quality.

(26) In its consideration, the Commission takes into account that wood-based panels and articles made of wood-based panels or other wood-based articles, as well as furniture that contains wood or other materials, to which formaldehyde has been intentionally added during their production, are the main emission sources of formaldehyde in indoor air, in particular in newly built homes. Therefore, the Commission considers that a lower emission limit for such articles and such products composed of more than one article ('complex products') that are the biggest sources of formaldehyde in indoor air is appropriate and provides for increased protection of the general public, while limiting the socio-economic costs for those sectors that do not contribute to the same extent to the emissions.

(27) Likewise, it is appropriate to establish a lower limit for the presence of formaldehyde in the interior of road vehicles where the general public is present to ensure adequate protection in particular of vulnerable populations also in the worst-case scenarios.

(28) The Commission therefore concludes that the most appropriate Union-wide measure to address the risk of formaldehyde in indoor air and in the interior of road vehicles is a restriction setting the limit value of 0,062 mg/m^3 for wood-based articles and furniture, applied to the whole complex product, as well as in the interior of road vehicles; and of the limit value of 0,08 mg/m^3 for all other articles.

(29) In order to mitigate the negative impacts and to lower the costs for the affected sectors, as well as to provide sufficient time for stakeholders to implement the restriction, the Commission considers appropriate a deferral of 36 months for all sectors as regards the application of the restriction. For road vehicles, however, a deferral of 48 months is deemed appropriate due to the long development and marketing time for vehicles, the high material requirements in the automotive industry, the complex supply chains including original equipment manufacturers, as well as the time needed to implement the standard analytical method for measuring emissions for trucks and buses[7].

(30) Articles that are exclusively used in outdoor environments under reasonably foreseeable conditions should not be included in the scope of the restriction, as they do not contribute to exposure to formaldehyde in indoor air.

(31) Articles that are exclusively for industrial or professional use should not be included in the scope of the restriction, as long as these uses do not lead to exposure of the general public. Furthermore, exposure of industrial and professional workers to formaldehyde is already regulated by Council Directive 98/24/EC[8], and Directive 2004/37/EC of the European Parliament and of the Council[9].

(32) Formaldehyde emissions from articles are expected to decrease over time due to 'off-gassing' of residual formaldehyde. Therefore, second-hand articles should not be included in the scope of the restriction. Moreover, the Forum for Exchange of Information on Enforcement also recommended a derogation for second-hand articles, as enforcing the restriction with regard to second-hand articles may be difficult.

(33) The following products are already subject to Union rules on limit values to formaldehyde and should therefore not be included in the scope of the restriction: articles within the scope of entry 72 of Annex XVII to Regulation (EC) No 1907/2006, articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council[10], devices within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council[11], and personal protective equipment within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council[12].

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7 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.

8 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

9 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

10 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

11 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

12 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

(34) Commission Regulation (EU) No 10/2011[13] establishes a limit value for formaldehyde for plastic materials and articles intended to come into contact with food. Although Union law does not set a specific formaldehyde limit for other materials and articles in contact with food, producers must be able to demonstrate their safety to the competent authorities. The requirements of food contact materials aim to protect human health by addressing the potential migration of substances into food. As due to those requirements significant release of formaldehyde from articles intended to come into contact with food, within the meaning of Regulation (EU) 1935/2004 of the European Parliament and the Council[14], into the surrounding atmosphere is highly unlikely, the Commission considers that those articles should not be included in the scope of the restriction.

(35) The Dossier Submitter, RAC and SEAC proposed a derogation for toys covered by Directive 2009/48/EC of the European Parliament and of the Council[15] which sets a limit of 0,1 mg/m^3 for formaldehyde emissions in resin-bonded wooden toys for children younger than 3 years. However, the Commission considers such a derogation not appropriate because children should not be protected less strictly than any other part of the population. The limit value for formaldehyde emissions into indoor air should therefore apply to toys for children of all ages.

(36) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(37) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

[13] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

[14] Regulation (EC) No 1935/2004 of the European Parliament and of the Council 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 (OJ L 338, 13.11.2004, p. 4).

[15] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).