Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on formaldehyde and formaldehyde releasers

ECHA/RAC/RES-O-0000006740-76-01/F
ECHA/SEAC/[Opinion No (same as opinion number)]

EC Number	CAS Number
n/a	n/a

This document is a working document from the Committees for Risk Assessment and Socio-economic Analysis of the European Chemicals Agency (ECHA) intended for internal use only. It has not been agreed and/or adopted by the Committee. In addition to Committee participants the document may only be disclosed to experts and advisors for the purpose of facilitating the work of the Committees.

Draft

23 March 2020

Change history

Revision n.	Reason for change	Date	Prepared by
1	Annex XV report turned into BD. This version includes updates based on RAC/SEAC recommendations as well as discussions in the first rapporteurs' dialogue: mainly clarifications on scope and testing, hazard and exposure	30 April 2019	Dossier Submitter
2	Additional clarifications on scope, exposure (including uncertainties) and enforcement costs	12 July 2019	Dossier Submitter
3	Appendix X added and clarifications on scope (incl. derogations), hazard and testing costs mainly as a result of consultation comments	23 October 2019	Dossier Submitter
4	Smaller edits made in the following sections: Summary, 1.5.1, 2.2.2.1, 2.7.2, Annex D.3 and Appendix X	24 January 2020	Dossier Submitter
5	RAC and SEAC assessment added in boxes, small editorials in the text	23 March 2020	ECHA Secretariat

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

Preface

The preparation of this restriction dossier on formaldehyde and formaldehyde releasers was initiated on the basis of Article 69(1) of the REACH Regulation on request of the Commission.[1]

The proposal has been prepared using version 2 of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of annexes with more detailed information and analyses that underpin the report.

This version of the report has been reviewed for confidential information.

1 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e [Accessed 7 January 2019]

Summary

ECHA has been requested by the Commission to prepare an Annex XV restriction dossier according to Article 69(1) of REACH on formaldehyde (EC No 200-001-8, CAS No 50-00-0) and formaldehyde releasers in mixtures and articles for consumer use. The focus of this report is therefore on consumer exposure to formaldehyde while worker exposure is outside the scope. Worker exposure is further discussed in a document prepared by ECHA upon specific request from the Commission.

Formaldehyde and formaldehyde releasing substances (i.e. formaldehyde releasers) are manufactured and used in multiple sectors in the EU. Formaldehyde is mostly used as a chemical intermediate to manufacture formaldehyde based-resins and other chemicals and has limited applications as biocide. Formaldehyde releasers are used primarily in the production of articles such as wood-based products, furniture, wallcoverings, foams and textiles from which formaldehyde can be released during use.

For certain formaldehyde releasing articles the direct use by consumers is limited. For instance, articles used in construction, such as wood-based panels, laminate flooring, and wallpapers, are rarely for direct use of consumers as they are typically used by construction workers. Formaldehyde emissions from such articles however can affect the general population. The same consideration apply to mixtures. Therefore, for the purpose of this Annex XV restriction report, mixtures and articles for consumer use are defined as all mixtures and articles that generate formaldehyde exposure to consumers.

The conclusion of the Dossier Submitter's risk assessment is that human health risks from formaldehyde released from consumer articles in indoor environments is not adequately controlled in all scenarios. Formaldehyde release from the consumer use of mixtures for non-biocidal use is adequately controlled and the use of formaldehyde in mixtures for consumer use in concentration ≥ 0.1% is prohibited according to Commission Regulation (EU) 2018/675.

To identify the most appropriate measure to address the identified risk, an analysis of risk management options (RMOs) was conducted, including regulatory measures under REACH, other existing EU legislation and other possible Union-wide RMOs. It was concluded that a restriction under REACH is the most appropriate EU-wide RMO. Several different restriction options were analysed.

On the basis of an analysis of the effectiveness, proportionality and practicability of these RMOs the following restriction option is proposed:

Proposed restriction

Brief title: Restriction on formaldehyde and formaldehyde releasing substances in articles

The proposal is to restrict the placing on the market of articles intended for indoor[2] use that release formaldehyde under reasonably foreseeable conditions resulting in consumer exposure. The restriction establishes a maximum emission limit value for articles of 0.124 mg/m^3 in a test chamber (as measured in accordance with the conditions specified in Appendix X to the restriction proposal).[3]

Articles that are exclusively used in outdoor environments are not intended to be included within the scope of the proposal.

The proposal is intended to cover articles where formaldehyde or formaldehyde releasing substances[4] (also termed formaldehyde releasers) are used in their production (either as such or in mixtures) and where formaldehyde releases occur during use as a result of either the “off-gassing” of residual formaldehyde or from the degradation and chemical reactions of other substances used in the production.

The proposal is not intended to cover articles produced without using formaldehyde or formaldehyde releasing substances. In such articles formaldehyde is either not released (because it is not present in the article, e.g. glass articles) or it can be only released by the decomposition of substances naturally present in the materials used to produce the article (e.g. lignin degradation in solid wood) or as a result of combustion.

As well as the interiors of buildings, the proposal aims also to reduce consumer exposure to formaldehyde in the interiors of vehicles (road, rail, air and water vehicles). In the specific case of road vehicles (e.g. cars, trucks, vans, buses and motor-homes) and aeroplanes the proposal is intended to restrict the placing on the market of articles where the interior concentration of formaldehyde exceeds 0.1 mg/m^3 under reasonably foreseeable conditions of use.

Articles subject to the existing restriction on CMR substances in clothing and footwear (entry 72 of Annex XVII of REACH), articles subject to Regulation (EU) 2017/745 on medical devices, articles subject to Regulation (EU) 2016/425 on personal protective equipment (PPE), articles subject to Regulation 2011/10 on food contact materials, articles subject to Directive 2009/48/EC on toy safety, articles exclusively for industrial and professional use, second-hand articles

---

[2] Indoor environments are not limited to buildings but also other environments such as cars, trucks, buses, trains, aeroplanes, mobile homes, or container homes.

[3] As external conditions (such as temperature, air exchange rate, relative humidity) have direct influence on the releases of formaldehyde form articles, it is necessary to indicate under which conditions the releases of formaldehyde are defined. These conditions are defined in the test methods specified in Appendix X.

[4] Formaldehyde releasers include both formaldehyde-based substances and other substances that, although not produced with the addition of formaldehyde, may still release formaldehyde from their degradation. In this report the term *formaldehyde releasing substances* will be used to refer to all substances that may release formaldehyde while the term *formaldehyde-based substances* is used to refer to substances produced using formaldehyde as precursor.

as well as the use of formaldehyde and formaldehyde releasers as a biocide are intended to be exempted from the proposed restriction.

Formaldehyde EC No 200-001-8 CAS No 50-00-0	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/m^3 as measured in accordance with the conditions specified in Appendix X. Road vehicles and aeroplanes 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/m^3 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. 5. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2018/1513. 6. By way of derogation, paragraph 1 shall not apply to the use of formaldehyde and formaldehyde releasers as biocide subject to Regulation (EU) 528/2012. 7. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2017/745. 8. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2016/425. 9. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2011/10. 10. By way of derogation, paragraph 1 shall not apply to articles subject to Directive 2009/48/EC. 11. By way of derogation, paragraph 1 shall not apply to second-hand articles.

Summary of the justifications

Uses

Formaldehyde is predominantly used as a chemical intermediate in the production of formaldehyde-based resins and other chemicals. The most common substances manufactured from formaldehyde include urea formaldehyde resins, phenol formaldehyde resins and melamine formaldehyde resins. Such formaldehyde-based resins are the biggest group of formaldehyde releasers, a broader group of substances with the common element that they can release formaldehyde under foreseeable conditions of use. Formaldehyde-based resins are widely used as adhesives and binders in the woodworking, pulp and paper, as well as the synthetic vitreous fibre industries, in the production of plastics and coatings, and in textile finishing. The likelihood and amount of formaldehyde release from articles depend mostly on the type and amount of substances used in the production process.

Identified hazard and risk

In humans (as in animals) formaldehyde is an essential metabolic intermediate in all cells. It is produced endogenously and it is an essential intermediate in the biosynthesis of purines, thymidine and certain amino acids. The endogenous concentration of free and reversibly bound formaldehyde is relatively high with about 0.1 mmol/L (IARC, 1995).

At ambient temperature and atmospheric pressure, formaldehyde is a gas that is highly irritating to the upper respiratory tract. Effects of gaseous formaldehyde are limited to the upper respiratory tract at the site of contact. Exposure of humans to 1.9 ppm formaldehyde (2.3 mg/m^3) for 40 minutes or of monkeys to 6 ppm (7.4 mg/m^3) for 4 weeks (6 h/day, 5 days/week) did not increase endogenous concentrations of formaldehyde. Due to its reactivity, formaldehyde will react with several components present in the body (e.g. water, proteins etc.). The most sensitive effects in rats are DNA adducts and DNA-protein crosslinks (DPX) in the nasal mucosa which could be detected at the lowest concentrations investigated [0.7 ppm (0.9 mg/m^3) and 0.3 ppm (0.4 mg/m^3), respectively]. At such exogenous formaldehyde concentrations, the endogenous concentration of formaldehyde is not increased and the body has sufficient capacity to repair formaldehyde-induced DNA-damage. Nasal tumours in rats have been reported at formaldehyde concentrations of 6 ppm (7.4 mg/m^3) with a NOAEC of 2 ppm (2.5 mg/m^3). Tumour induction in the nasal mucosa of rats and mice is considered the result of chronic proliferative processes caused by the cytotoxic effects of the substance in combination with DNA alterations by endogenous and exogenous formaldehyde. The dose-response relationships for all parameters investigated, such as damage to the nasal epithelium, cell proliferation, tumour incidence, the formation of DPX and DNA adducts, is very flat for low-level exposures and becomes much steeper at higher concentrations. A threshold for the carcinogenic action of formaldehyde is assumed, for which a mode-of-action based limit value can be derived.

The WHO Guideline for Indoor Air Quality for formaldehyde (WHO, 2010) sets an exposure limit to 0.1 mg/m^3 (30-minute average concentration). The value established by WHO functions as EU-LCI value,[5] in the frame of the Construction Products Regulation. The WHO guideline value is considered protective against both acute and chronic sensory irritation in the airways in the general population and in particular in potential sensitive subpopulations

---

[5] Lowest concentration of interest: https://ec.europa.eu/growth/sectors/construction/eu-lci/values_en [Accessed 28 June 2019]

including children and the elderly. The short-term guideline will also prevent detrimental effects on lung function as well as long-term health effects, including nasopharyngeal cancer. Risks associated with consumer exposure to formaldehyde from inhalation are therefore assessed against this value.

Other risks from formaldehyde have been considered but the Dossier Submitter has concluded that the risks from inhalation of formaldehyde are the most significant.

Human exposure

Consumer exposure to formaldehyde has been extensively investigated. Adverse health effects from indoor exposure to formaldehyde, especially irritation of the eyes and upper airways, were first reported in the 1960s in Germany (Wittmann, 1962), where formaldehyde emissions from materials bonded with urea formaldehyde (UF) resins were identified as the cause of complaints. Since then, further investigations have been conducted in different EU Member States and, in the majority of cases, the major source of consumer exposure to formaldehyde was identified in the use of formaldehyde-based resins, in particular UF resins, in wood-based materials used in construction and finished articles (e.g. furniture and laminate flooring). For this reason, while formaldehyde emissions from a number of articles have been investigated, the assessment of impacts arising from the proposed restriction focuses on wood-based panels. Risks have been identified specifically in indoor environments.

Justification that action is required on a Union-wide basis

The risks associated with articles that may release formaldehyde in indoor environments need to be addressed on a Union-wide basis because of the following factors:

- Exposure takes place in all Member States from articles produced in the EU as well as from imported articles manufactured with the addition of formaldehyde or formaldehyde releasing substances and these goods are free to move within the Union.
- A number of EU Member States have established legislation to prevent or reduce the risk associated with indoor consumer exposure to formaldehyde from articles (in particular wood-based products). Despite these initiatives in individual Member States, to date no EU-wide harmonised regulation of formaldehyde emissions from articles exists. This results in different levels of risk reduction across the EU and the potential for consumer exposure to formaldehyde levels above the WHO guideline value persists in indoor environments under certain circumstances.
- Voluntary agreements to self-restrict formaldehyde emissions from wood-based products are already in place at the EU level. European manufacturers of wood-based panels adopted a voluntary industry agreement to produce only panels complying with the formaldehyde emission class E1 as defined in the harmonised European Standard EN 13986. The E1 emission class sets a limit on the release of formaldehyde from wood-based panels at a concentration of 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in the European Standard EN 717-1. The voluntary emission limit adopted by the manufacturers of wood-based panels is also supported by the European furniture industry. In the absence of a legally binding Union-wide measure non-compliant articles can however still be placed on the EU market, due to manufacturers who have not subscribed to such voluntary agreements and/or extra-EU imports.

- A voluntary agreement is also in place by the automotive industry to limit the formaldehyde concentration in the interior of road vehicles to a maximum of 0.1 mg/m^3 in the context of a UN project on vehicle interior air quality.[6]

- The risks of health issues for consumers exposed to formaldehyde released from articles in indoor environments are considered not adequately controlled EU-wide.

Effectiveness and proportionality to the risk

Formaldehyde levels in indoor environments have been declining significantly since the 1980s. Due to improved quality of materials, advances in production processes, and substitution, formaldehyde concentrations in indoor environments are, in most cases, already below the WHO guideline value. It is however to be considered that, where no national regulation exists, the adoption of an EU-wide emission limit for formaldehyde will prevent the risk of consumers being exposed to formaldehyde levels above the WHO guideline value from high formaldehyde emitting articles, including those imported from non-EU countries. The proposed restriction is considered proportionate with limited costs to EU society expected. The annual costs of achieving formaldehyde concentrations below the WHO guideline value have been estimated at €28 million with 300 thousand homes or 690 thousand individuals potentially benefitting from the proposed measure. This translates into annual costs of €93 per affected home and €41 per affected individual and is considered marginal compared to the costs of a new dwelling.

Implementability

The proposed restriction is considered to represent an implementable option for the actors within the timeframe of 12 months. The measures foreseen in this restriction report are already to a large extent applied in the EU as a result of voluntary agreements within specific industry sectors and national legislation in a number of EU Member States that is broadly in line with the restriction proposal.

Enforceability

Some EU Member States (e.g. Austria, Denmark, Germany, Italy and Sweden) have already implemented or are planning to implement legislation to limit formaldehyde emissions from specific categories of articles, in particular wood-based products. Formaldehyde emission limits are therefore already enforced in a number of EU Member States and chamber tests are prescribed to enforce the legislative requirements. Chamber tests as well as other test methods exist to monitor the release of formaldehyde from articles and enforcement authorities have already experience in applying them. Enforcement authorities of other Member States can therefore set up an efficient supervision mechanism to monitor compliance with the proposed restriction.

Manageability

Considering that most relevant industry sectors have already signed voluntary agreements to reduce formaldehyde emissions from articles, the manageability of the restriction is anticipated to be high.

---

[6] https://www.unece.org/info/media/news/transport/2015/unece-to-tackle-the-issue-of-vehicle-interior-air-quality/unece-to-tackle-the-issue-of-vehicle-interior-air-quality.html [Accessed 18 October 2019]

Monitorability

The effectiveness of the current restriction could be monitored by quantifying, over time, the amount of EU-manufactured and imported articles with compliant formaldehyde emissions compared to the current situation.

Stakeholder information

In the preparation of this Annex XV restriction report, ECHA have maintained an open and interactive dialogue with interested parties, including industry and authorities, to ensure that different views were accounted for in the assessment. Further information on stakeholder contacts is presented in Annex F.

Report

1. The problem identified

1.1. Background

ECHA has been requested by the Commission to prepare an Annex XV restriction dossier according to Article 69(1) of REACH on formaldehyde (EC No 200-001-8, CAS No 50-00-0) and formaldehyde releasers in mixtures and articles for consumer use.[7] The Commission request was received on 20 December 2017.

In a previous investigation report on formaldehyde and formaldehyde releasers published in March 2017, ECHA analysed a number of substances that have been found to be intentional or unintentional formaldehyde releasers (ECHA, 2017b). Although the assessment in this restriction report is based on substances reported in the scientific literature as known formaldehyde releasers, the specific source (formaldehyde or formaldehyde releasers) of the formaldehyde emissions is not relevant for the restriction proposal.

Formaldehyde is used in making a variety of products by industrial and professional workers, such as building materials including wood-based panels, automobile and aeroplane parts. Formaldehyde is quickly broken down in the air and dissolves easily in water. When dissolved in water it is called formalin, which is mostly used as intermediate in the manufacturing of other substances (e.g. formaldehyde-based resins), as industrial disinfectant, and as a preservative in funeral homes and medical labs. Formaldehyde can also be used as a preservative in some foods and in products such as antiseptics, medicines, and cosmetics.

Biocide uses account for about 2% (around 65 000 tonnes) of the total production volume of formaldehyde in the EU (Andersen et al., 2014). Substances used as biocides under the Biocidal Products Regulation (BPR), i.e. Regulation (EU) 528/2012, have not been included in the scope of this restriction proposal because the Commission is already developing regulatory activities under BPR (see Section 2.2.2.1). Substances included in the Cosmetic Products Regulation, i.e. Regulation (EU) 1223/2009, have not been considered in this report because title VIII of REACH does not apply to the health risks of substances in cosmetics.

Formaldehyde releasers are also used in the production of fertilisers, as process chemicals in the textile and leather industry, as well as in aerospace and car applications. The most important category of formaldehyde releasers, formaldehyde-based resins, are used in a broad range of applications.

Formaldehyde is also produced as the result of cooking and smoking, and from candles and ethanol fireplaces. Therefore there is often a background level of formaldehyde to which consumers are exposed that may contribute to overall consumer exposure. These exposures are not directly covered by the current investigation, although emissions from some temporary sources, such as ethanol fireplaces, have been identified as significant sources of exposure.

[7] For the purpose of this Annex XV restriction report, mixtures and articles for consumer use are defined as all mixtures and articles that generate formaldehyde exposure to consumers.

1.2. Manufacture and uses

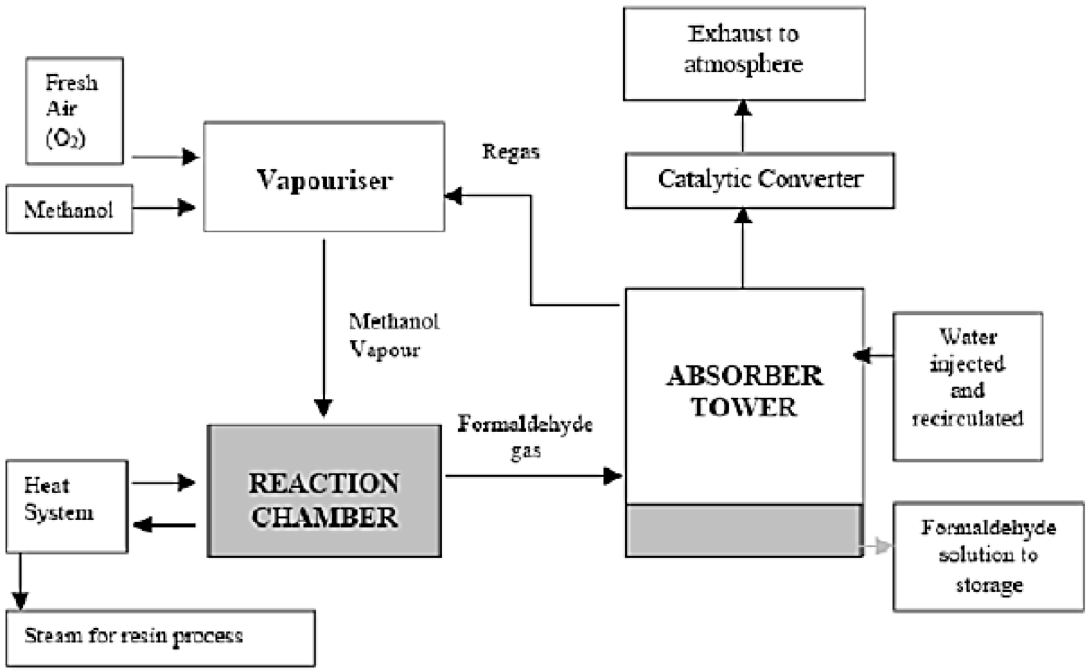
1.2.1. Manufacture of formaldehyde

At an industrial scale, formaldehyde is manufactured by catalytic oxidation of methanol via either a silver or metal-oxide catalyst process. Production capacity is split almost equally between the two processes. In the metal-oxide process, methanol is oxidised with excess air in the presence of a modified iron-molybdenum-vanadium oxide catalyst at 250-400 °C and atmospheric pressure (methanol conversion, 98-99%) (IARC, 2006). In the silver process methanol is directly converted into formaldehyde and hydrogen at 600-780 °C. Figure 1 presents an illustrative summary of the formaldehyde manufacturing process (metal-oxide conversion).

Formaldehyde is manufactured at 73 sites in 21 EU Member States (Table 1). At all these sites formaldehyde manufacturing is integrated with the manufacturing of formaldehyde-based resins and/or other chemicals, representing the vast majority of the intermediate use of formaldehyde. In addition, ± 11 non-integrated sites produce large volumes of formaldehyde-based organic chemicals – mainly methylene diphenyl diisocyanate (MDI) and polyols – and some others may use rather small quantities of formaldehyde to produce specialty chemicals.

Formaldehyde is registered in REACH in quantities > 1 million tonnes per year. The total formaldehyde production in Europe (EU-28 + Norway + Switzerland) in 2015 was around 3.2 million tonnes (as 100% pure formaldehyde) which is equivalent to 8.6 million tonnes as 37% water solution (Formacare, 2018). According to Eurostat (2018b) data, formaldehyde imports into the EU from extra-EU countries were in the range of 20-30 thousand tonnes annually between 2015 and 2017, which accounts for less than 1% of the amount produced in Europe.

Figure 1: Formaldehyde manufacturing process



Source: Formacare (2018)

Table 1: EU producers of formaldehyde, 2015

Member State	Number of sites	Member State	Number of sites
Austria	3	Lithuania	1
Belgium	5	Netherlands	4
Bulgaria	1	Poland	6
Czech Republic	1	Portugal	2
Denmark	1	Romania	3
Finland	3	Slovakia	1
France	1	Slovenia	2
Germany	12	Spain	6
Hungary	2	Sweden	3
Ireland	1	United Kingdom	5
Italy	10	***Total***	***73***

Source: Formacare (2018)

1.2.2. Uses of formaldehyde

According to information in the registration dossier[8], formaldehyde is used at industrial sites, by professional workers and by consumers. It is used as a substance (either in pure state or diluted in water), in mixtures and in articles.

Consumer uses include: adhesives and sealants, paints and coating products, fillers, putties, plasters, modelling clay, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing and cleaning products, cosmetics, personal care products, machine wash liquids/detergents, automotive care products, fragrances and air fresheners, metal, wooden and plastic construction and building materials, flooring, furniture, toys, textiles (e.g. curtains, carpet, clothing), footwear, leather products, paper and cardboard products, electronic equipment. Formaldehyde can be found in complex articles with no release intended: machinery, mechanical appliances, electrical/electronic products not covered by the Waste Electrical and Electronic Equipment (WEEE) directive (e.g. large-scale stationary industrial tools).

Professional uses of formaldehyde include: adhesives and sealants, paints and coating products, polymers, laboratory chemicals, building and construction materials, textile, leather or fur, wood and wood products, pulp, paper and paper products, machine wash liquids/detergents, automotive care products, fragrances and air fresheners.

At industrial sites, formaldehyde is mostly used as intermediate in the production of chemicals, plastic products, textile, leather or fur, pulp, paper and paper products, mineral products (e.g. plasters, cement) and rubber products.

[8] In this report, references to the registration refer to the lead registrant's dossier (BASF, 2017).

1.2.2.1. Formaldehyde-derived products

Almost 98% of the total formaldehyde produced and/or imported in the EU is used as an intermediate to produce formaldehyde-based resins, thermoplastics and other chemicals. Formaldehyde and formaldehyde-derived products are used in a broad range of applications. Figure 2 provides an overview of the main uses of formaldehyde and formaldehyde-derived products. The most common substances manufactured from formaldehyde are:

- ***Urea formaldehyde (UF) resins***: The vast majority (~95%) of UF resins are used as binders or adhesives in wood-based panels due to their technical and economic properties including low cost, dimensional stability, hardness, clear glue line, and fast curing times (Global Insight, 2007). UF polymers are also used in agriculture to improve the physical characteristics of urea-based fertilisers.[9]

- ***Phenol formaldehyde (PF) resins***: Approximately 60% of PF resins are used in the building and construction industry for applications including insulation binder, wood-based products, and laminates. Other important end uses include automobile applications (e.g. friction materials) and foundry binders (Global Insight, 2007).

- ***Melamine formaldehyde (MF) resins***: Used widely in the building and construction industries in the form of laminates and surface coatings, which account for more than 95% of its consumption (Global Insight, 2007). Applications are also found in the automotive sector and for housewares.

- ***Methylene diphenyl diisocyanates (MDI)***: Used in the production of polyurethane foams for use as insulation materials in construction and automotive applications. Foam applications include also appliances (e.g. refrigerators, freezers, air conditioners), packaging for electronics, and transportation (Global Insight, 2007).

- ***Polyoxymethilenes (POM)***: Used to make precision parts in a wide range of industrial and automotive applications.

- ***1,4-Butanediol (BDO)***: Used as intermediate in the production of tetrahydrofuran (THF) and polybutylene (PBT) resins. These resins are used to produce fibres in the textile industry and other products such as buttons and rollers. PBT resins are also used to produce components for automotive and electrical industry.

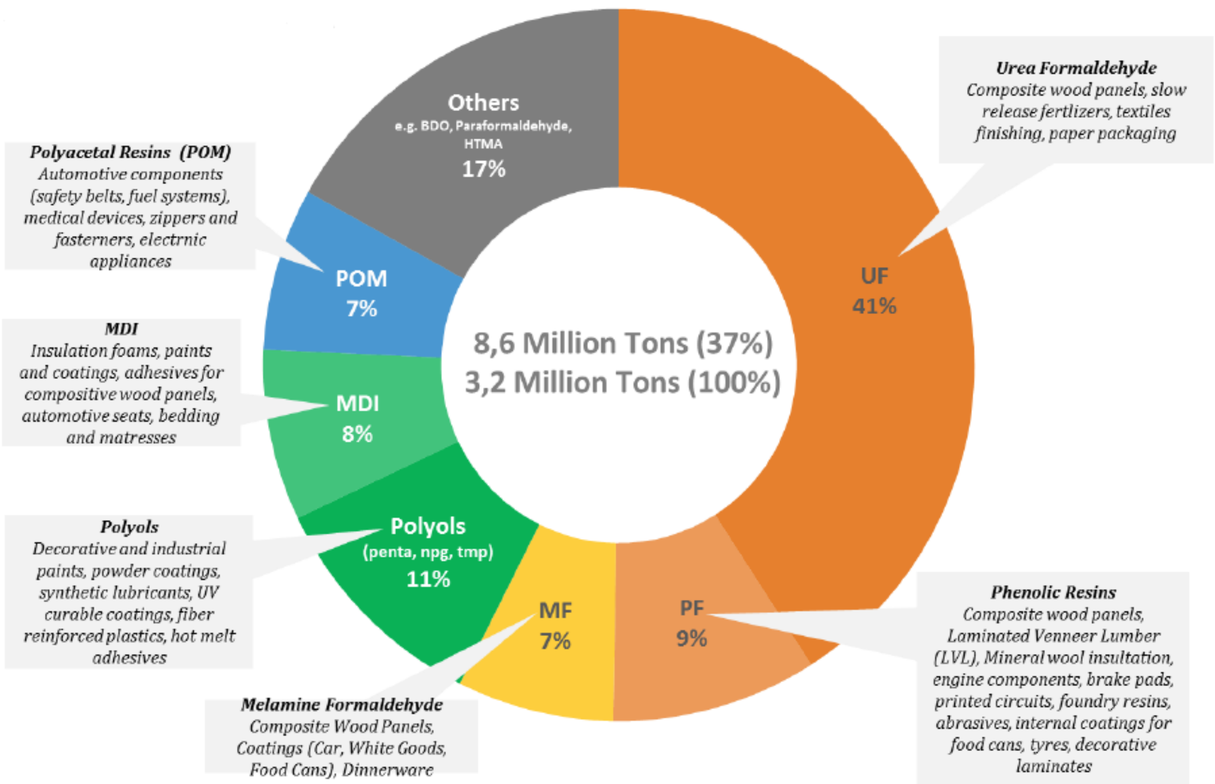
- ***Pentaerythritol (Penta)***: Used in the production of alkyd resins, which are found in paints and product finishes for automobiles. It is also used to make polyol esters, an important ingredient of engines lubricants in heavy duty applications (e.g. aeroplane turbines and automobiles).

- ***Methenamine***: Used to make epoxy resins and as accelerator in rubber vulcanisation.

---

[9] Formaldehyde, mainly in the form of UF reaction products, is used in the manufacture of controlled release fertilisers (CRFs). CRFs release their nutrients at a specific rate over a period of time, providing a constant source of nutrients to plants, soils and turf (ANSES, 2016; Global Insight, 2007). Around 20% of CRFs are used in agricultural applications. Non-agricultural applications include professional horticulture and landscaping (Global Insight, 2007). CRFs are for outdoor use and, for this reason, are not considered further in this report. Impacts of the total outdoor formaldehyde concentration on the indoor environment are however taken into account in the exposure scenario (Section 1.3.6.5).

Figure 2: Main uses of formaldehyde and formaldehyde-derived products, 2015



Note: 3.2 million tonnes as 100% pure formaldehyde, 8.6 million tonnes as 37% water solution

Source: Formacare (2018)

1.2.2.2. Articles for consumer use

Around 60% of the whole amount of formaldehyde used in the EU is used to manufacture UF (41%), PF (9%) and MF (7%) resins which are used in the production of a broad range of articles for consumer use (see Table 2). The primary use of such resins is in the manufacturing of wood-based panels, where they act as a bonding agent for wood particles. The main types of wood-based panels include plywood, particleboard, oriented strand board (OSB), medium density fibreboard (MDF), and other fibreboard (including hardboard and softboard).[10] Formaldehyde-based resins are also used in the production of other wood-based products (e.g. furniture, flooring and building elements for indoor and outdoor use). The remaining approximately 40% of the formaldehyde manufactured in and imported into the EU is used as biocide (~2%), in the manufacturing of other types of resins such as Polyols (~11%), MDI (~8%), Polyacetals (~7%), Penta (~5%), 1,4 BDO (~4%), Methenamine (~3%), and other substances (3%). Table 2 includes the most relevant uses of the most relevant formaldehyde-based products. Other uses include paints for industrial use, mineral wool, textile and leather industry, and parts used in interior and exterior of vehicles.

---

[10] Annex A.1 provides an overview of the main types of wood-based panels.

Table 2: Formaldehyde-based substances with relevant consumer use

Substance name	CAS number	EC number	Uses
Urea polymer with formaldehyde (UF)			Used as adhesives and to make building materials such as particleboard and plywood. UF polymers are also used in agriculture to improve the physical characteristics of urea-based fertilisers (i.e. allow low release of fertilisers into the plants).
Phenol polymer with formaldehyde (PF)			Applications include fibreglass insulation, laminates and automobile components.
Melamine polymer with formaldehyde (MF)			Used in production of laminates, surface coatings for automobiles and housewares.
Polyoxymethylenes (POM)	66455-31-0		Used to make precision parts in a wide range of industrial and automotive applications.
4,4'-methylene diphenyl diisocyanate (MDI)	101-68-8	202-966-0	Used in the production of polyurethane foams which are used as insulation materials in construction and automotive applications.
1,4-Butanediol (BDO)	110-63-4	203-786-5	Used as intermediate in the production of tetrahydrofuran (THF) and polybutylene (PBT) resins. These resins are used to produce fibres in the textile industry and other products such as buttons and rollers. PBT resins are also used to produce components for the automotive and electrical industry.
Pentaerythritol (Penta)	115-77-5	204-104-9	Used in the production of alkyd resins. These resins are found in paints and product finishes for automobiles. Also used to make polyol esters, an important ingredient of engines lubricants in heavy duty applications (e.g. aeroplane turbines and automobiles).

Source: Formacare (2018)

1.2.2.3. Mixtures for consumer use

Based on information in the registration dossier, formaldehyde is used in a number of mixtures intended for consumer use, including: adhesives and sealants, paints and coating products, fillers, putties, plasters, modelling clay, inks and toners, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing and cleaning products, cosmetics, personal care products, machine wash liquids/detergents, automotive care products, fragrances and air fresheners, etc. The presence of formaldehyde in mixtures for use by consumers is mostly due to the use of formaldehyde or formaldehyde releasers as biocide. In a limited number of cases, formaldehyde can be produced as degradation products of other substances (e.g. surfactants or resins) that are part of the mixtures. Over the past 10 years, manufacturers have reduced the levels of residual formaldehyde in consumer mixtures due to the health related hazards of the substance and increasing regulatory action.[11]

[11] Formaldehyde has been classified as Carc. 1B in 2016.

1.3. Hazard, exposure and risk

1.3.1. Identity of the substance and physical and chemical properties

Annex B.1 lists the substance identities of formaldehyde and a number of known formaldehyde releasers, not subject to cosmetics or biocides legislation, with the substance identifiers (name, CAS and EC numbers), registration quantity and identified uses (for substances registered under REACH).

1.3.2. Justification for grouping

The current investigation considers the risks to human health of exposure to formaldehyde. This approach is regardless of its original source either formaldehyde or formaldehyde releasers and both are within the scope of the report and considered together.

1.3.3. Classification and labelling

1.3.3.1. Regulation (EC) No 1272/2008 (CLP Regulation)

Classification and labelling of formaldehyde has been revised to: Carc. 1B, Muta. 2, Acute Tox. 3 (oral), Acute Tox. 3 (dermal), Acute Tox. 3 (inhalation), Skin Corr. 1B and Skin Sens. 1. The revision entered into force on 1 January 2016 (EC, 2014). The specific concentration limits for classification of a mixture containing formaldehyde are as follows: Skin Irrit. 2; H315: $5\% \leq C < 25\%$, Skin Sens. 1; H317: $C \geq 0.2\%$, Eye Irrit. 2; H319: $5\% \leq C < 25\%$, STOT SE 3; H335: $C \geq 5\%$ and Skin Corr. 1B; H314: $C \geq 25\%$. For the carcinogenicity no specific concentration limit is given, thus the general concentration limit in the CLP Regulation will apply: category 1B carcinogen $C \geq 0.1\%$. Table 3 shows the entries in Annex VI of CLP for formaldehyde and two formaldehyde releasers.

1.3.3.2. Self-classification

Concise information on self-classification for formaldehyde and known formaldehyde releasers are reported in Annex B.2. It should be noted that the lead registrant self-classified formaldehyde as Acute Tox. 2 (H330, fatal if inhaled) based on a study (see Section 1.3.4.3 below). More detailed information on self-classification is available in the C&L inventory on the ECHA website (ECHA, 2018).

Table 3: Entries in Annex VI of CLP for substances identified as formaldehyde releasers

Index #	International Chemical Identification	EC #	Classification	Specific Conc. Limits, M-factors	Notes	ATP inserted / updated
605-001-00-5	formaldehyde ...%	200-001-8	Carc. 1B Muta. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1	STOT SE 3; H335: C ≥ 5% Skin Corr. 1B; H314: C ≥ 25% Skin Irrit. 2; H315: 5% ≤ C < 25% Eye Irrit. 2; H319: 5% ≤ C < 25% Skin Sens. 1; H317: C ≥ 0.2%	B D	CLP00/ ATP06
612-101-00-2	methenamine; hexamethylenetetramine	202-905-8	Flam. Sol. 2 Skin Sens. 1			CLP00/ ATP01
613-114-00-6	2,2',2"-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol; 1,3,5-tris(2-hydroxyethyl)hexahydro-1,3,5-triazine	225-208-0	Acute Tox. 4 * Skin Sens. 1	Skin Sens. 1; H317: C ≥ 0.1%		CLP00

***Note B**: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid … %'.In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.*

***Note D**: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.*

1.3.4. Human health assessment[12]

1.3.4.1. Endogenous formaldehyde

In humans (as in animals) formaldehyde is a metabolic intermediate in most living organisms. Physiological amounts of formaldehyde are endogenously formed from serine, glycine, methionine and choline by demethylation of N-, O- and S-methyl compounds (IARC, 1995; Liteplo et al., 2002). Formaldehyde in blood may be present in its free form (Mashford and Jones, 1982) and also bound to proteins such as serum albumin (Heck et al., 1982).

The endogenous concentration of formaldehyde in the blood of human subjects not exposed to formaldehyde was 2.61 ± 0.14 µg/g of blood (mean ± SE; range, 2.05-3.09 µg/g) (Heck et al., 1985), i.e. about 0.1 mmol/L. This concentration represents the total concentration of endogenous formaldehyde in the blood, both free and reversibly bound (IARC, 1995).

[12] A more detailed version of the human health assessment is presented in Annex B.3.

1.3.4.2. Toxicokinetics (absorption, distribution, metabolism and excretion)

Due to the high water solubility and reactivity, airborne formaldehyde is absorbed mainly in the upper respiratory tract, the site of first contact. The localisation of uptake in each species is determined by nasal anatomy, mucus coating and clearance mechanisms. At an exposure concentration of 1 ppm (1.2 mg/m^3), predicted formaldehyde nasal uptake was 99.4%, 86.5%, and 85.3% in the rat, monkey, and human, respectively (Schroeter et al., 2014).

In biological systems, formaldehyde first reacts reversibly with water to form an acetal (methanediol). At physiological temperature and pH, > 99.9% of formaldehyde is present as methanediol, with < 0.1% as free formaldehyde (Andersen et al., 2010; Golden, 2011).

Formaldehyde reacts at the site of first contact virtually instantaneously with primary and secondary amines, thiols, hydroxyls and amides to form methylol derivatives. Due to its electrophilic properties, formaldehyde also reacts with macromolecules such as DNA, RNA and protein to form reversible adducts or irreversible cross-links (WHO, 2010).

The concentration of formaldehyde in the blood was not increased immediately after the exposure period in humans exposed to 1.9 ppm (2.3 mg/m^3) formaldehyde for 40 minutes, in rats exposed to 14.4 ppm (17.1 mg/m^3) for 2 hours (Heck et al., 1985), or in monkeys exposed to 6 ppm (7.4 mg/m^3) for 4 weeks (6 h/day, 5 days/week) (Casanova et al., 1988).

Dermal absorption of formaldehyde was calculated with 4% formaldehyde systemically available and with 15% locally available (ANSES/RIVM, forthcoming) based on data generated by monkeys with open dermal administration of 1% (10 µL) and 10% (40 µL) ^{14}C-formaldehyde (Jeffcoat et al., 1983). Absorption appears to be limited to cell layers immediately adjacent to the point of contact and formaldehyde is rapidly metabolised at the initial site of contact. Due to rapid metabolism, distribution of formaldehyde molecules to other more distant organs is not likely, except from exposure to high concentrations (Lyapina et al., 2012).

The simplified metabolism of formaldehyde (acetal) involves (Andersen et al., 2010; Golden, 2011; Tulpule and Dringen, 2013; WHO, 2010):

1. reduction to methanol by alcohol dehydrogenase 1;
2. oxidation to formate by aldehyde dehydrogenase 2;
3. spontaneous reaction with glutathione (GSH) to form S-hydroxymethyl GSH, which is subsequently oxidised by alcohol dehydrogenase 3 (also known as formaldehyde dehydrogenase) to the intermediate S-formyl GSH, which is metabolised by S-formylglutathione hydrolase to formate and reduced glutathione.

Due to high circulating concentrations of glutathione in human blood, the S-hydroxymethyl GSH is the major form of formaldehyde seen *in vivo* (Sanghani et al., 2000).

Formate is oxidised to 10-formyl tetrahydrofolate (THF) by methylene tetrahydrofolate dehydrogenase 1; 10-formyl THF is either metabolised to CO_2 by 10-formyl THF dehydrogenase or further metabolised within the one-carbon metabolism pathway that is centred around folate (Tulpule and Dringen, 2013).

After exposure of rats to ^{14}C-formaldehyde at 0.63 or 13.1 ppm (0.8 or 16.1 mg/m^3) for 6 hours, about 40% of the inhaled ^{14}C was eliminated as expired ^{14}C-carbon dioxide over a 70-h period; 17% was excreted in the urine, 5% was eliminated in the faeces and 35% to 39% remained in the tissues and carcass (IARC, 2006).

1.3.4.3. Acute toxicity

Formaldehyde is acutely toxic following ingestion, dermal and inhalation exposure and has the following classifications: Acute Tox. 3; H331; Acute Tox. 3; H311; Acute Tox. 3; H301.

In the Chemical Safety Report (BASF, 2017) the LC_{50} of formaldehyde is reported with < 463 ppm (569.5 mg/m^3). The test was performed in the year 2015 following OECD Guideline 403 in rats with 4 hours whole-body exposure. All animals died on study day 1 or 2. Consequently, the registrant self-classified formaldehyde as Acute Tox. 2 (H330, fatal if inhaled).

1.3.4.4. Irritation and corrosivity

In concentrations between 5 and < 25%, formaldehyde has irritating properties: Skin Irrit. 2; H315: 5% ≤ C < 25%; Eye Irrit. 2; H319: 5% ≤ C < 25%.

Formaldehyde is also irritating to the respiratory tract: STOT SE 3; H335: C ≥ 5%.

Formaldehyde has corrosive properties and has the classification: Skin Corr. 1B; H314, with a concentration limit C ≥ 25%.

The most sensitive effects in humans following inhalation exposure to formaldehyde is sensory irritation. High quality studies in volunteers are available examining sensory irritation under controlled exposure to formaldehyde. In two most relevant volunteer studies from one working group, objective signs of eye and upper respiratory tract irritation were measured following defined formaldehyde exposure (Lang et al., 2008; Mueller et al., 2013).

In the study by Lang et al. (2008), 21 male and female subjects were exposed continuously to 0 (control), 0.15, 0.3, and 0.5 ppm (0, 0.18, 0.37, and 0.61 mg/m^3) formaldehyde for 4 hours on 10 consecutive days. In addition, a group with 0.3 ppm (0.37 mg/m^3) continuous formaldehyde exposure with 4-times 15-minutes peaks of 0.6 ppm (0.74 mg/m^3) and a group with 0.5 ppm (0.61 mg/m^3) continuous exposure with 4-times 15-minutes peaks of 1 ppm (1.2 mg/m^3) were included. Ethyl acetate (12 to 16 ppm) was used to mask the odour of formaldehyde. The results indicated eye irritation as the most sensitive parameter. Minimal objective eye irritation was observed at a level of 0.5 ppm (0.61 mg/m^3) with peaks of 1 ppm (1.2 mg/m^3). The subjective complaints of ocular and nasal irritation noted at lower levels were not paralleled by objective measurements of eye and nasal irritation and were strongly influenced by personality factors and smell. It was concluded that the no-observed-effect level for subjective and objective eye irritation due to formaldehyde exposure was 0.5 ppm 0.61 mg/m^3) in case of a constant exposure level and 0.3 ppm (0.37 mg/m^3) with peaks of 0.6 ppm (0.74 mg/m^3) in case of short-term peak exposures.

The study by Mueller et al. (2013) was conducted to examine chemosensory effects of formaldehyde in so-called “hyposensitive” and “hypersensitive” persons. Forty-one male volunteers (aged 32 years ± 9.6) were exposed for 5 days (4 h/day) to formaldehyde concentrations of 0, 0.5 ppm (0.61 mg/m^3) and 0.7 ppm (0.86 mg/m^3) and to 0.3 ppm (0.37 mg/m^3) with peak exposures (4-times, 15 minutes) of 0.6 ppm (0.74 mg/m^3), and to 0.4 ppm (0.49 mg/m^3) with peak exposures of 0.8 ppm (0.98 mg/m^3), respectively. During exposure, subjects had to perform four cycle-ergometer units at 80 watts for 15 min. Subjective pain perception induced by nasal application of carbon dioxide (CO_2) served as indicator for sensitivity to sensory nasal irritation. The division between “hypersensitive” and “hyposensitive” subjects was based on the median in sensitivity towards the irritating effect of CO_2. The following parameters were examined before and after exposure: subjective rating of symptoms and complaints (Swedish Performance Evaluation System, SPES), conjunctival redness, eye-blinking frequency, self-reported tear film break-up time and nasal flow rates. In addition, the influence of personality factors on the volunteer's subjective scoring was examined (Positive And Negative Affect Schedule, PANAS). Formaldehyde exposures to 0.7 ppm (0.86 mg/m^3) for 4 hours and to 0.4 ppm (0.49 mg/m^3) for 4 hours with peaks of 0.8 ppm (0.98 mg/m^3) for 15 min caused no significant sensory irritation of the measured conjunctival and nasal parameters (conclusion by the authors). In all groups, the mean sum score of the individual symptoms, the eye irritation score and the nasal irritation score were within a range of less than 2.5 mm on a 100 mm Visual Analogue Scale (VAS).

No differences between hypo- and hypersensitive subjects were seen. Statistically significant differences were noted for olfactory symptoms, especially for the “perception of impure air”. These subjective complaints were more pronounced in hypersensitive subjects. But after a detailed analysis the authors concluded that these effects were mainly induced by unpleasant smell and the situational and climatic conditions in the exposure chamber. Formaldehyde concentrations of 0.7 ppm (0.86 mg/m^3) for 4 hours and of 0.4 ppm (0.49 mg/m^3) for 4 hours with peaks of 0.8 ppm (0.98 mg/m^3) for 15 min did not cause adverse effects related to irritation, and no differences between hypo- and hypersensitive subjects were observed (Mueller et al., 2013).

In conclusion, the studies by Lang et al. (2008) and Mueller et al. (2013) provide a NOAEC of 0.5 ppm (0.61 mg/m^3) for continuous exposures and of 0.3 ppm (0.37 mg/m^3) for continuous exposure with peak exposure (4-times 15 minutes) of 0.6 ppm (0.74 mg/m^3). The studies also indicated no sex differences and no differences between hypo-and hyper-sensitive individuals.

The odour threshold of formaldehyde was identified with 0.1 ppm (0.12 mg/m^3) with a range from 0.02 to 0.5 ppm (0.02 to 0.61 mg/m^3) (Berglund et al., 2012).

1.3.4.5. Sensitisation

Formaldehyde is a known skin sensitiser, which has the classification: Skin Sens 1; H317. The concentration limit for mixtures for skin sensitisation is 0.2%.

Related to skin sensitisation, the registration dossier (BASF, 2017) clearly sets out that formaldehyde is a strong skin sensitiser with positive results in several studies including Local Lymph Node Assay (LLNA). Formaldehyde solution is a primary skin sensitiser inducing allergic contact dermatitis Type IV and may induce contact urticaria Type I (WHO, 1989). The EC3 value (3-fold stimulation of proliferation as an index of the relative potency of a contact allergen) was 0.93% formalin or 0.35% formaldehyde. No induction was detected at 0.04% formaldehyde and first sensitising effects were seen at 0.2% (BASF, 2017). This is consistent with the special concentration limit in CLP for substances in mixtures. Concentrations leading to elicitation of effects are lower than the concentrations leading to induction.

The biocidal assessment for formaldehyde (ECHA, 2017a) concluded: *“However, the currently available methodology is not considered suitable for derivation of an acceptable exposure level protecting from sensitisation by formaldehyde which is relevant to human health. Nevertheless, the available data is in support of the current legal classification limit for formaldehyde formulations of ≥ 0.2% (w/w) with regard to its sensitising properties and the resulting labelling provisions with EUH208 at ≥ 0.02% (w/w).”*

Formaldehyde might also lead to respiratory sensitisation. However, against the background of a widespread use, respiratory sensitisation has been reported only in single cases (DFG, 2010).

During the last decade a number of human exposure studies in children and adults have been carried out with lung function testing. From such studies WHO (2010) concluded that consistent cause-effect and dose-response relationships between formaldehyde and measurable lung effects have not been found in controlled human exposure studies and epidemiological studies below 1 mg/m^3. In general, associations between formaldehyde and lung effects or sensitisation in children in homes and schools have not been convincing owing to confounding factors and chance effects. Well known confounders for asthma are e.g. dust mites, cockroach allergen, pets or mould.

The German Umweltbundesamt (UBA, 2016) also reviewed the results from epidemiological studies investigating if there is an association between formaldehyde exposure and the induction or exacerbation of asthma in children. UBA concluded that there is no clear association between formaldehyde exposure in the indoor environment and asthma in children. Mainly, the epidemiological studies suffer from small sample sizes, implausible formaldehyde concentrations, and the fact that other substances or factors initiating asthma and asthma-like complaints were not adequately considered. Results derived from controlled human exposure studies as well as animal experiments support this opinion.

1.3.4.6. Repeated dose toxicity

The repeated dose toxicity studies with inhalation exposure are summarised by SCOEL (2016):

In rats exposed to FA concentrations of 10 ppm (12.3 mg/m^3), daily for 6 hours on 5 days a week, rhinitis, hyperplasia and squamous metaplasia of the respiratory epithelium of the nasal mucosa were described in all studies. In rats exposed to 1.0 ppm (1.2 mg/m^3) for 2 years no histopathological changes were observed (no observed adverse effect concentration, NOAEC; Woutersen et al. (1989)). From concentrations of 2 ppm (2.5 mg/m^3), rhinitis, epithelial dysplasia and even papillomatous adenomas and squamous metaplasia of the respiratory epithelium of the nose were found, from 6 ppm (7.4 mg/m^3) squamous cell carcinomas (Kerns et al., 1983; Swenberg et al., 1980). At this concentration also the cell proliferation rate in the nasal mucosa was increased transiently, and from 10 ppm (12.3 mg/m^3) increased permanently (Monticello et al., 1996).

Uninterrupted exposure of rats for 8 hours/day ("continuous") was compared with 8 exposures for 30 minutes followed by a 30-minute phase without exposure ("intermittent") in two 13-week studies with the same total dose. Effects were seen only after intermittent exposure to FA concentrations of 4 ppm (4.9 mg/m^3), but not after continuous exposure to 2 ppm (2.5 mg/m^3). The authors concluded that the toxicity in the nose depends on the concentration and not on the total dose (Wilmer et al., 1989).

In mice exposed to FA concentrations of 2.0, 5.6 or 14.3 ppm (2.5, 6.9 or 17.6 mg/m^3) for 2 years (6 hours/day, 5 days/week), rhinitis and epithelial hyperplasia was observed, from 5.6 ppm dysplasia, metaplasia and atrophy. Squamous cell carcinomas were observed only after concentrations of 14.3 ppm (17.6 mg/m^3) (Kerns et al., 1983).

In hamsters exposed to FA concentrations of 10 ppm (12.3 mg/m^3) (5 hours/day, 5 days per week) for life, survival was reduced and the incidence of hyperplasia and metaplasia (4/88, 5%) was slightly increased, but not that of tumours (Dalbey, 1982).

In Cynomolgus monkeys exposed almost continuously to FA concentrations of 0.2, 1 or 3 ppm (0.25, 1.2 or 3.7 mg/m^3) for 26 weeks, metaplasia and hyperplasia were observed in 1/6 and 6/6 animals of the 1 and 3 ppm groups, respectively. In the animals exposed to concentrations of 0.2 ppm (0.25 mg/m^3), no histopathological changes were found (Rusch et al., 1983).

1.3.4.7. Mutagenicity

Formaldehyde has the following harmonised classification: Muta. 2; H341.

This classification is based on genotoxic effects observed *in vivo* in somatic cells at the site of contact. No evidence of an effect on germ cells by a relevant route of exposure is available (RAC, 2012). There is also no evidence for systemic genotoxic effects of formaldehyde (ANSES/RIVM, forthcoming).

SCOEL (2016) summarised the data: There is consistent evidence for the genotoxicity of FA in in vitro systems, laboratory animals and exposed humans. DNA-protein crosslinks have been reproducibly detected in the nasal mucosa of rats and monkeys exposed to FA and provide a useful marker of genotoxicity. The biphasic behaviour of the dose-response curve for this genotoxic endpoint points to a steeper slope at 2-3 ppm (2.5-3.7 mg/m^3) in Fischer 344 rats; for rhesus monkeys the slope is less well defined. At concentrations above 6 ppm (7.4 mg/m^3) of FA, genotoxicity is greatly amplified by cell proliferation, resulting in a marked increase of malignant lesions in the nasal passages (IARC, 2006).

The most sensitive effects in the nose and upper respiratory tract following inhalation formaldehyde exposure are DNA adducts and DNA-protein crosslinks.

DNA adducts (N^2-hydroxymethyl-dG adducts) were detected in the nasal DNA of rats exposed to 0.7, 2.0, 5.8, 9.1 or 15.2 ppm [$^{13}CD_2$]-formaldehyde (0.86, 2.5, 7.1, 11.2 or 18.7 mg/m^3) for 6 hours. The number of exogenous N^2-hydroxymethyl-dG adducts induced was 0.039 ± 0.019, 0.19 ± 0.08, 1.04 ± 0.24, 2.03 ± 0.43 and 11.15 ± 3.01 adducts/10^7 dG, respectively (Lu et al., 2011). The concentration of endogenous N^2-hydroxymethyl-dG adducts was 4.7 ± 1.8 adducts/10^7 dG. Therefore, the exogenous N^2-hydroxymethyl-dG adducts formed following 0.7 ppm (0.86 mg/m^3) formaldehyde exposure were less than 1% of the endogenous N^2-hydroxymethyl-dG adducts.

DNA-protein-crosslinks (DPX) – the covalent linkage of proteins with a DNA strand – are one of the most deleterious and understudied forms of DNA damage, posing as steric blockades to transcription and replication. If not properly repaired, these lesions can lead to mutations, genomic instability, and cell death (Heck and Casanova, 2004). Endogenously, DPX are commonly derived through reactions with aldehydes, as well as through trapping of various enzymatic intermediates onto the DNA. Proteolytic cleavage of the protein moiety of a DPX is a general strategy for removing the lesion. This can be accomplished through a DPX-specific protease and/or proteasome-mediated degradation. Nucleotide excision repair and homologous recombination are each involved in repairing DPX, with their respective roles likely dependent on the nature and size of the adduct (Klages-Mundt and Li, 2017). DPX have been identified in the nasal mucosa of rats and in the upper respiratory tract of monkeys exposed to formaldehyde but not in the bone marrow of rats exposed to ^3H and ^{14}C-formaldehyde at concentrations as high as 15 ppm (18.5 mg/m^3). DPX formation in the nose was identified still at the lowest formaldehyde concentrations tested of 0.3 ppm (0.37 mg/m^3) in rats (Casanova et al., 1989) and 0.7 ppm (0.86 mg/m^3) in rhesus monkeys (Casanova et al., 1991).

1.3.4.8. Carcinogenicity

Formaldehyde has the harmonised classification Carc. 1B; H350.

The classification is mainly based on nasal tumours (site of contact) observed in rats of both sexes exposed to formaldehyde at concentrations of 2 ppm (2.5 mg/m^3) and higher for ≥ 24 months. Details on the data are reported in RAC (2012).

In Table 4, nasal epithelial squamous cell carcinomas (SCC) in combined groups of male and female rats from long-term inhalation studies with formaldehyde exposures (Kamata et al., 1997; Kerns et al., 1983; Monticello et al., 1996; Sellakumar et al., 1985) are presented according to Nielsen et al. (2017):

Table 4: Nasal epithelial squamous cell carcinomas (SCC) in rats

Formaldehyde (ppm)	Formaldehyde (mg/m^3)	Rats with SCC/group size (% with SCC)
0		0/453 (0)
0.3	0.37	0/32 (0)
0.7	0.86	0/90 (0)
2	2.5	0/364 (0) (apparent NOAEC)
6	7.4	3/325 (0.9) (apparent LOAEC)
10	12.3	20/90 (22)
14	17.2	102/232 (44)
15	18.5	120/278 (43)

Source: Nielsen et al. (2017)

In the list of agreed EU-LCI values[13] (as of July 2018) it is mentioned in the summary fact sheet for formaldehyde that "Concerning occupational investigations in man, the available data do not provide clear evidence of carcinogenicity. Nasal tumours were not observed. Leukemia/lymphomas related to formaldehyde could not be ruled out reliably, possibly for statistical reasons. From a mechanistic point of view a causal link appears to be remote due to the very low bioavailability of formaldehyde in the blood. At least for air concentrations below 0.5 ppm Nielsen and Wolkoff (2010) and Nielsen et al. (2013) ruled out a leukemogenic effect. More recently, Checkoway et al. (2015) evaluated associations between cumulative and peak formaldehyde exposure and mortality risks from acute myeloid leukemia (AML) and other lymphohematopoietic malignancies and could not confirm that formaldehyde is a risk factor for AML. There were associations based on small numbers with Hodgkin lymphoma and chronic lymphatic leukemia which had not been seen in prior cohorts. In light of the unclear epidemiological data which do not convincingly confirm a leukemogenic or carcinogenic effect

[13] Lowest concentration of interest: https://ec.europa.eu/growth/sectors/construction/eu-lci/values_en [Accessed 28 June 2019]

in humans, the animal studies need to be employed for the quantification of a carcinogenic risk in humans." (EC, 2018b).

SCOEL (2016) in its opinion has recommended an Occupational Exposure Limit Value (OEL) of 0.3 ppm (0.37 mg/m^3; 8h TWA) with a short term exposure limit of 0.6 ppm (0.74 mg/m^3). This is based on their assessment that formaldehyde is a genotoxic carcinogen for which a mode-of-action based limit value can be derived.

As described by SCOEL (2016) the endogenous formaldehyde concentrations are relatively high with an appreciable amount of endogenous DNA adducts formed, whereas the background incidence of nasal tumours in rodents and of nasopharyngeal tumours in humans is very low. One of the reasons may be the low physiological proliferation rate of the respiratory epithelium, and as long as this is not increased, the probability of tumour formation also is low. Tumour induction in the nasal mucosa of rats and mice is the result of chronic proliferative processes caused by the cytotoxic effects of the substance in combination with DNA alterations by endogenous and exogenous formaldehyde. The dose-response relationships for all parameters investigated, such as damage to the nasal epithelium, cell proliferation, tumour incidence, the formation of DPX and DNA adducts, is very flat for low level exposures and becomes much steeper at higher concentrations. For these endpoints no-effect concentrations were demonstrated with the exception of the formation of DPX and DNA adducts. At the lowest concentrations investigated so far (0.7 ppm; 0.86 mg/m^3), adducts were still detected. However, adducts caused by endogenous, physiological formaldehyde by far exceeded the amounts caused by exogenous formaldehyde. At 0.3 ppm (0.37 mg/m^3) no sensory irritation in humans, which is considered the most sensitive endpoint, was observed (Lang et al., 2008; Mueller et al., 2013).

For the assessment of the cancer risk of inhaled formaldehyde, UBA (2016) used a non-linear approach due to the results of the animal studies showing an exponential increase of the risk curve: the additional theoretical cancer risk of a non-smoker following a continuous (80 years) inhalation exposure to 0.1 mg formaldehyde per cubic meter is assumed to be 3×10^{-7}.

In summary, the inhalation cancer risk opposed by formaldehyde in the air at the OEL for workers of 0.3 ppm (0.369 mg/m^3) recommended by SCOEL and at the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m^3 (0.08 ppm; see Section 1.3.4.10) can be considered as negligible in relation to the endogenous formaldehyde concentrations.

Related to dermal exposure and carcinogenesis, formaldehyde is absorbed through intact skin only to a small extent (4% formaldehyde systemically available) and rapid metabolism makes systemic effects unlikely following dermal exposure. In dermal initiation/promotion studies, formaldehyde did not initiate or promote skin tumorigenesis in mice. From a mouse skin painting study, no skin tumours were observed in 16 male and 16 female mice with topical application of 200 µg formaldehyde twice a week at the end of the study after 60 weeks (Iversen, 1986).

1.3.4.9. Reproductive toxicity

Formaldehyde is not classified for toxicity to reproduction.

Multiple studies have been published on reproductive and developmental effects of formaldehyde in human and animal studies. Epidemiological studies focus for example on male and female fertility, pre-term birth or abortions, and birth weights. Animal studies focus on male and in few studies on female fertility as well as on developmental toxicity with different routes of administration including, inhalation, oral administration, intraperitoneal, intravenous or subcutaneous injections or dermal administration.

Collins et al. (2001) performed a review of adverse pregnancy outcomes and formaldehyde exposures in humans and in animal studies and summarised that "*Formaldehyde is unlikely to reach the reproductive system in humans in concentrations sufficient to cause damage since it is rapidly metabolized and detoxified upon contact with the respiratory tract. While there are effects seen in in vitro studies or after injection, there is little evidence of reproductive or developmental toxicity in animal studies under exposure levels and routes relevant to humans. Most of the epidemiology studies examined spontaneous abortion and showed some evidence of increased risk (meta-relative risk = 1:4, 95% CI 0.9-2.1). We found evidence of reporting biases and publication biases among the epidemiology studies and when these biases were taken into account, we found no evidence of increased risk of spontaneous abortion among workers exposed to formaldehyde (meta-relative risk = 0:7, 95% CI 0.5-1.0). The small number of studies on birth defects, low birth weight, and infertility among formaldehyde workers; the limitations in the design of these studies; and the inconsistent findings across these studies make it difficult to draw conclusions from the epidemiology data alone. However, information from experimental studies and studies of metabolism indicate reproductive impacts are unlikely at formaldehyde exposures levels observed in the epidemiology studies.*"

A different conclusion was reached in a systematic review by Duong et al. (2011) including meta-analyses. The authors concluded the following: "*The mostly retrospective human studies provided evidence of an association of maternal exposure with adverse reproductive and developmental effects. Further assessment of this association by meta-analysis revealed an increased risk of spontaneous abortion (1.76, 95% CI 1.20-2.59, p = 0.002) and of all adverse pregnancy outcomes combined (1.54, 95% CI 1.27-1.88, p < 0.001), in formaldehyde-exposed women, although differential recall, selection bias, or confounding cannot be ruled out. Evaluation of the animal studies including all routes of exposure, doses and dosing regimens studied, suggested positive associations between formaldehyde exposure and reproductive toxicity, mostly in males. Potential mechanisms underlying formaldehyde-induced reproductive and developmental toxicities, including chromosome and DNA damage (genotoxicity), oxidative stress, altered level and/or function of enzymes, hormones and proteins, apoptosis, toxicogenomic and epigenomic effects (such as DNA methylation), were identified*."

Nielsen et al. (2013) critically evaluated the review by Duong et al. (2011) considering the effects observed in human and animal studies in quantitative terms and in relation to the general toxicity of formaldehyde. With respect to epidemiological studies on females, the authors concluded that the review by Duong et al. (2011) describes 18 human studies, but only one study (Zhou et al., 2006) was published after the review of Collins et al. (2001); this study did not find differences in "preterm birth", "small for gestation age" and "major malformations". Nielsen et al. (2013) also found that the results from the meta-analysis by Collins et al. (2001) and the first meta-analysis by Duong et al. (2011) are not substantially different. No significant increase was observed in studies with low recall bias. A somewhat increased meta-relative risk observed in both studies can be explained by the lack of confounder control. Thus, no convincing effect of formaldehyde was observed in pregnant women. With respect to epidemiological studies on males, Nielsen et al. (2013) commented that although the effect of formaldehyde exposure on male reproduction has been studied only to a limited extent, there is no convincing indication that it is affected. The lack of effects on female and male reproduction is in agreement with the toxicokinetic studies indicating that formaldehyde does not reach the internal organs.

With respect to testicular effects observed in male animals, several studies are reported by Duong et al. (2011) and Nielsen et al. (2013). After exposure of male rats for 4 and 13 weeks to 10 and 20 ppm (12.3 and 24.6 mg/m^3) formaldehyde (5 days/week, 8 h/day), reduced body weight gains, reduced testes weights and changed concentrations of trace elements including copper, zinc and iron were reported (Ozen et al., 2002). Thirteen weeks exposure to 5 and 10 ppm (6.2 and 12.3 mg/m^3) led to reduced testosterone levels, reduced diameters of seminiferous tubules and immunohistochemical changes in the testes (Ozen et al., 2005). Two week formaldehyde exposure of male rats to 10 mg/m^3 (8 ppm, 12 h/day) led to reduced testicular weights and histopathological changes in the testes such as atrophication of seminiferous tubules, decreased spermatogenic cells, seminiferous epithelial cells disintegrated and shed into lumina, edematous interstitial tissue with vascular dilatation and hyperemia, azoospermia of the lumina (Zhou et al., 2006). Exposure to 2.46 mg formaldehyde/m^3 (2 ppm) for 60 consecutive days resulted in significantly decreased sperm quantity and quality, decreased testicular seminiferous tubular diameter, reduction in the activities of superoxide dismutase and glutathione peroxidase, increased levels of malondialdehyde, atrophy of seminiferous tubules, decreases of spermatogenic cells and the lumina were oligozoospermic. No effects were reported at 0.5 mg/m^3 (0.4 ppm) (Zhou et al., 2011).

Nielsen et al. (2013) indicated that none of the inhalation studies reviewed by Duong et al. (2011) interpreted the formaldehyde-induced testicular effects in the context of known biological effects of formaldehyde. The prominent clinical symptoms reported at 5 ppm (6.2 mg/m^3) included unsteady breathing, an increase in nose cleaning, excessive licking, frequent sneezes and haemorrhage in nasal mucosa (Ozen et al., 2005) and are in agreement with expected occurrence of more severe irritation-induced stress. Also, decreased food consumption may reasonably explain the observed decrease in body weight gain. The reduced testicular levels of zinc and copper may be due to one or more of the potential indirect mechanisms causing testicular damage; these include stress from irritation, hypoxia and reduced intake of food. The latter may cause insufficient supply of the metals. The increased iron (Ozen et al., 2002) would be in line with an increase in hyperaemia in the testes, which was observed after. The LOAEL of 2 ppm (2.5 mg/m^3) for testicular effects in rats (Zhou et al., 2011) was a level that causes moderate sensory irritation-induced stress and hypoxia-induced stress (20% decrease in respiratory minute volume); higher levels caused exposure dependent increase in testicular effects. At the LOAEL, no increase is expected in formaldehyde absorption. The NOAEL for testicular effects in rats was 0.4 ppm (0.50 mg/m^3) (Zhou et al., 2011) where neither sensory irritation nor decreased respiratory minute volume was observed; no effect was observed in the absence of sensory irritation, which is the case at the indoor air guideline value. Nielsen et al. (2013) further commented, that recent toxicokinetic studies do not support that formaldehyde reaches the sexual organs.

Nielsen et al. (2013) also reviewed the studies on developmental toxicity in animals. In a developmental toxicity study in 25 rats per group with formaldehyde exposure to 5, 10, 20 or 40 ppm (6.2, 12.3, 24.6 or 49.2 mg/m^3) on gestational days 6 to 20 (6 h/day), a decreased body weight gain was observed in the dams at the highest exposure level of 40 ppm (49.2 mg/m^3; LOAEC) with no effects observed at 20 ppm (24.6 mg/m^3; NOAEC). A slight foetotoxic effect (reduced weight in male foetuses) was observed ≥ 20 ppm (24.6 mg/m^3) with a NOAEC at 10 ppm (12.3 mg/m^3) (Saillenfait et al., 1989). No data were reported on clinical signs or local effects; however, local irritant effects are to be expected at ≥ 10 ppm (12.3 mg/m^3).

Another developmental toxicity study was conducted in 25 rats per group exposed to 2, 5 or 10 ppm (2.5, 6.2 or 12.3 mg/m^3) formaldehyde for 6 h/day from gestational day 6 to 15. This study showed an NOAEC for maternal toxicity at 5 ppm (6.2 mg/m^3) with reduced food consumption at 10 ppm (12.3 mg/m^3) and no relevant developmental effect up to 10 ppm (12.3 mg/m^3) (Martin, 1990).

Nielsen et al. (2013) also referred to several Russian inhalation studies with formaldehyde exposures from 0.01 to 1.2 ppm (0.012 to 1.5 mg/m^3) in female rats that showed adverse reproductive and developmental outcomes. However, with unusual methods. These results are inconsistent with the above-reviewed studies, which showed no teratogenic effect up to 40 ppm (49.2 mg/m^3) in spite of potential pain-induced and hypoxia-induced stress.

In summary, there is no convincing evidence that formaldehyde would lead to reproductive or developmental effects in human or in experimental animals at concentrations in the air that do not lead to irritation in the respiratory tract.

1.3.4.10. DNEL Setting

The lead registrant of formaldehyde has derived a DNEL of 0.375 mg/m^3 for long-term inhalation exposure, local effects for workers (BASF, 2017). This DNEL is in agreement with the 8-hour TWA of 0.3 ppm (0.369 mg/m^3) recommended by SCOEL (2016) which is based on studies in volunteers examining sensory irritation following 4 hour daily exposure for 5 days with 15 minutes peak exposure (Lang et al., 2008; Mueller et al., 2013).

The registrant has derived a DNEL of 0.1 mg/m^3 for long-term inhalation exposure, local effects in the general population (BASF, 2017). This DNEL is in agreement with the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m^3 (WHO, 2010) which is a short-term value (30-minutes) and based on the human studies in volunteers examining sensory irritation (see long-term DNEL for workers). The NOAEC of 0.6 mg/m^3 for eye blinking response was adjusted by using assessment factor 5 derived from the standard deviation of nasal pungency (sensory irritation) threshold, leading to a value of 0.12 mg/m^3, which has been rounded down to 0.1 mg/m^3. WHO calculated an alternative approach using biologically motivated models. Their assessment led to a predicted additional cancer risk of 2.7 x 10^{-8} for continuous lifetime exposure to 0.125 mg/m^3 and a predicted additional cancer risk of 10^{-6} or less for non-smokers continuously exposed to 0.25 mg/m^3. WHO (2010) explicitly stated that the use of the short-term (30-minute) guideline value of 0.1 mg/m^3 will also prevent long-term health effects, including nasopharyngeal cancer. A re-evaluation of this indoor air quality guideline concluded that the credibility of the WHO guideline value has not been challenged by new studies (Nielsen et al., 2017).

1.3.4.11. Conclusion of the human health assessment

Formaldehyde is a highly reactive, acutely toxic substance leading to skin and respiratory tract irritation and corrosion, skin sensitisation, genotoxicity (such as DNA-protein cross links and DNA adducts) and carcinogenicity. Nasal tumours were observed mainly in rats and mice following inhalation exposure of 6 ppm (7.4 mg/m^3) formaldehyde and higher.

Even if formaldehyde is a genotoxic carcinogen, SCOEL (2016) considered that a mode-of-action based limit value can be derived. Formaldehyde is an essential metabolic intermediate in all cells at relatively high concentrations (i.e. about 0.1 mmol/L). Mechanisms are in place to repair lesions and genetic damage elicited by endogenous formaldehyde. SCOEL considers that tumour induction in the nasal mucosa of rats and mice is the result of chronic proliferative processes caused by the cytotoxic effects of the substance in combination with DNA alterations by endogenous and exogenous formaldehyde. At the lowest concentrations investigated so far (0.7 ppm; 0.86 mg/m^3), DNA adducts in the nasal mucosa were still detected. However, DNA adduct levels in the nasal mucosa caused by endogenous, physiological formaldehyde by far exceeded the amounts caused by exogenous formaldehyde (0.7 ppm; 0.86 mg/m^3).

The most sensitive effect of formaldehyde in humans is sensory irritation, for which a NOAEC of 0.5 ppm (0.62 mg/m^3) for continuous exposure and of 0.3 ppm (0.37 mg/m^3) for continuous exposure with peak exposure (4-times 15 minutes) of 0.6 ppm (0.74 mg/m^3) was derived based on controlled volunteer studies (Lang et al., 2008; Mueller et al., 2013). Those effects were the basis for the OEL of 0.3 ppm (0.369 mg/m^3) for workers proposed by SCOEL (2016) and for the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m^3 (WHO, 2010).

Hence, the DNEL for long-term inhalation exposure can be considered as 0.3 ppm (0.369 mg/m^3) for workers and 0.1 mg/m^3 for the general public.

For the assessment of the cancer risk of inhaled formaldehyde, UBA (2016) used a non-linear approach due to the results of the animal studies showing an exponential increase of the risk curve: the additional theoretical cancer risk of a non-smoker following a continuous (80 years) inhalation exposure of 0.1 mg/m^3 is assumed to be 3 x 10^{-7}.

Hence it is the Dossier Submitter's opinion that the inhalation cancer risks opposed by formaldehyde in the air at the OEL for workers of 0.3 ppm (0.369 mg/m^3) recommended by SCOEL and at the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m^3 (0.08 ppm) can be considered as negligible in relation to the endogenous formaldehyde concentrations. Risks associated with consumer exposure to formaldehyde from inhalation are therefore assessed against the WHO guideline value of 0.1 mg/m^3.

Dermal effects are most likely to be from sensitisation or irritation rather than any carcinogenicity.

RAC ASSESSMENT

RAC takes note of the proposed DNEL which was suggested by the Dossier Submitter by reference to the WHO Guideline for Indoor Air Quality for formaldehyde (WHO, 2010). The WHO considers 0.1 mg/m^3 (0.08 ppm) as protective against acute (sensory) and chronic irritation in the airways of the population. As the calculated WHO guideline value of 0.21 mg/m^3 (0.17 ppm) for long-term effects was higher than the WHO guideline value for acute effects, the WHO selected the lower acute value of 0.1 mg/m^3 formaldehyde as the more appropriate guideline value (see below for further reflections on the assessment factors applied by the WHO in risk assessment).

RAC has conducted a review to allow confirmation on whether the proposed DNEL follows the principles of the REACH framework for risk assessment, including whether the chosen point of departure for carcinogenic effects is most sensitive and it is based on robust data, hence, it is appropriate and can be considered sufficiently protective for the target population of consumers.

In conclusion of the comparison of calculated DNELs and taking a weight of evidence approach into account, RAC does not agree to base the DNEL on the WHO value of 0.1 mg/m^3 formaldehyde as proposed by the Dossier Submitter.

For the purpose of this restriction, mainly DNELs for long-term inhalation exposure and with regard to local effects are relevant, as carcinogenic effects of formaldehyde were only observed locally in nasal tissue of test animals after long-term inhalation exposure. RAC considers calculations of DNELs for long-term effects identified from precursor events in the development of malignant tumours (see Table 3 of the RAC opinion) as more appropriate than derivation of acute DNELs.

RAC proposes a lower DNEL of 0.05 mg/m³ (0.04 ppm) based on the weight of evidence taking into account data on various tumour precursor events from several studies on monkeys and rats and applying assessment factors according to the ECHA Guidance[14] to ensure a sufficient margin of safety.

RAC considered separate data sets on the full range of precursor events to the carcinogenic effect (irritation/cytotoxicity, cell proliferation, epithelial dysplasia, metaplasia/hyperplasia, tumour response) and applies assessment factors (AF) according to the ECHA Guidance. Selected studies NOAEC/LOAECs were consistent to those identified and considered robust by RAC (RAC, 2012). RAC proposes a DNEL of 0.05 mg/m³, which is mainly based on monkey data for relevant precursor effects and taking into account consistent data from rat studies, as more robust than the short-term WHO guideline value.

See "RAC conclusion(s)" on "Information on hazard(s)" in the RAC opinion.

1.3.5. Environmental assessment

The conclusion from the registrant is that formaldehyde does not need to be classified for environmental effects because

- Formaldehyde is readily biodegradable;
- Its aquatic toxicity is > 1 mg/l for all tropic levels;
- NOAEC (21d) is ≥ 6.4 mg/l (daphnia magna).

As a consequence, the registrant concluded that an environmental exposure assessment was not required as no environmental hazard was identified.

Mackay Level I calculation (water 99% equilibrium distribution) has indicated that the favourite target compartment for formaldehyde is water. In air, formaldehyde tends to photodegrade indirectly, with a half-life of 1.71 days. The substance is readily biodegradable. Under environmental conditions, no hydrolysis is expected to happen. However under water formaldehyde undergoes essentially complete hydration to yield the gem-diol, methylene glycol. The log POW has been measured to be 0.35 at 20 °C, which is why bioaccumulation is unlikely to occur.

The lowest valid effect value of 5.8 mg/l was found for *Daphnia pulex* (48h-EC50). For fish the lowest effect value of 6.7 mg/l (96h-LC50) was found for *Morone saxatilis* (marine). For freshwater fish the lowest effect value (96h-LC50 = 24.8 mg/l) was found for *Ictalorus melas*. For the green alga *Scenedesmus subspicatus* a 24h-EC50 of 14.7 mg/l and a 24h-EC10 of 3.6 mg/l is available for the endpoint oxygen production and consumption. Applying an

[14] ECHA (2012). *Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health.* Helsinki: European Chemicals Agency. Available: https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/e153243a-03f0-44c5-8808-88af66223258 [Accessed 23 March 2020].

assessment factor of 1 000 according to EU Risk Assessment procedure to the lowest valid effect value, a PNEC aqua of 5.8 µg/l can be derived.

1.3.6. Exposure assessment (consumers)

Consumers can be exposed to formaldehyde by breathing air containing off-gassed formaldehyde. In addition, in its liquid form formaldehyde can be absorbed through the skin to a limited extent. Formaldehyde is found as a natural product in most living systems and in the environment. It occurs naturally in fruits and some foods, and it is formed endogenously in mammals, including humans, as a consequence of oxidative metabolism. People can be exposed to small amounts by eating foods or drinking liquids containing formaldehyde. Studies performed in recent years show that the formaldehyde released from articles into indoor air is the primary route for consumer exposure. This report, therefore, focuses on consumers' exposure to formaldehyde contained in indoor air through inhalation.

Worker exposure is outside of the scope of this report but is further examined in relation to the second part of the Commission's request "to gather existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses" received on 20 December 2017. Environmental exposure is not further assessed due to the absence of risks to the environment (see Section 1.3.5). Skin contact from the use of articles or mixtures by consumers as well as inhalation exposure from mixtures are not considered further in this report, as explained in Sections 1.3.6.1 and 1.3.6.2, respectively.

After providing the rationale for not further considering dermal exposure and inhalation exposure from mixtures, the exposure assessment goes on to give an overview of relevant formaldehyde emission sources in indoor air. Next, evidence on measured formaldehyde concentrations in indoor air in the EU from the past two decades is presented. Finally, formaldehyde indoor air concentrations are estimated to assess if there is a risk from inhalation exposure under the assumption of conservative conditions.

1.3.6.1. Dermal exposure

Skin contact from the use of articles or mixtures by consumers is not considered further in this report. For textiles worn on or near the skin, this exposure route has been addressed by Regulation (EU) 2018/1513 to restrict the use of CMR substances in clothing and footwear adopted on 10 October 2018 (EC, 2018a) – implemented via entry 72 of Annex XVII of REACH. Restriction entry 72 sets a maximum concentration limit for the use of 33 CMR substances, including formaldehyde, and prohibits the placing on the market after 1 November 2020 of clothing and textile products exceeding these limits. The concentration limit for formaldehyde is set at 75 mg/kg (0.0075%). A higher concentration limit of 300 mg/kg (0.03%) applies to jackets, coats and upholstery for the period between 1 November 2020 and 1 November 2023, the 75 mg/kg limit value applies thereafter. As discussed in Section 1.3.4.8, formaldehyde is very unlikely to cause cancer through dermal exposure unless present at very high concentrations, which cannot occur according to entry 72 of Annex XVII of REACH. In addition, the contribution of articles subject to entry 72 of Annex XVII of REACH is unlikely to significantly contribute to formaldehyde exposure via inhalation, at either of the two concentration limits. A study by Aldag et al. (2017) reports that emissions from clothing (e.g. pants, T-shirts and shirts) are in the ppb range (0.4-3.2 ppb) from clothes with 11-75.9 mg/kg extractable formaldehyde. It should be noted that textile articles not subject to restriction entry 72, such as wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners, are intended to be subject to this restriction proposal and must comply with the emission limit proposed.

Formaldehyde present in clothing, footwear and other textiles could theoretically cause skin sensitisation. However, the low concentration limits to be expected from compliance with the restriction on CMR substances in clothing and footwear or from compliance with this current restriction proposal would mean the exposure to formaldehyde from all sources would be very low. Formaldehyde has a specific concentration limit of 0.2% for skin sensitisation and the concentration limit in textiles is significantly lower (0.0075% or 0.03%). In addition, the concentration limit in CLP is for substances in mixtures and is based on direct exposure of the mixture to skin. The amount of formaldehyde skin is exposed to from textiles is likely to be much lower than its content in the textile. For example, in one study between 0.5 and 5% of the content in the article migrated to the skin (bluesign, 2014). This means that the concern for the induction of sensitisation is very low with a margin of safety of at least 100 from the concentration limit.

The Dossier Submitter notes that no lower limit for elicitation of sensitisation has been identified but this is not a risk that this restriction is intended to address. This analysis is confirmed by Aalto-Korte et al. (2008) where the authors analysed four samples of textiles used in protective clothing and one other textile sample: in three cases, the analysis was negative (< 10 ppm), one sample of protective clothing contained 18 ppm formaldehyde, and the formaldehyde content of a sample of mattress textiles was 19-21 ppm. The paper concluded that these concentrations were probably too low to cause sensitisation to formaldehyde or elicitation in previously sensitised patients.

The risk of skin sensitisation from other articles in the scope of this restriction proposal is also assumed to be limited due to the low concentration limits that would occur due to the emission limit imposed.

The restriction proposal from Sweden and France to limit the concentration of certain categories of skin sensitisers (including formaldehyde) in textile, leather, hides and furs intended to come into direct and prolonged contact with the skin[15] establishes a maximum concentration limit for formaldehyde of 75 mg/kg (0.0075%), which corresponds with the limit set in entry 72 of Annex XVII of REACH.

Also for these types of articles the same considerations as for textile articles apply and it can be concluded that the low concentration limit set for formaldehyde in textile, leather, hides and furs intended to come into direct and prolonged contact with the skin is unlikely to significantly contribute to inhalation exposure.

1.3.6.2. Inhalation exposure from mixtures

There is very limited information in the literature on consumer exposure to formaldehyde from mixtures such as cleaning products, paints or adhesives (Lefebvre et al., 2012; Maneli et al., 2014). Moreover, registrants have not assessed exposure to consumers from the use of the mixtures described in Section 1.2.2.3 because the concentration of formaldehyde in mixtures for consumer use is assumed to be below 0.1%.

In response to the Dossier Submitter's questions, the adhesives and sealants industry declared that mixtures for consumer use do not release formaldehyde. The cleaning and detergents industry has confirmed that formaldehyde may be present in the mixture in concentrations not

---

[15] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136 [Accessed 17 October 2019]

exceeding 200 ppm (0.02%). Furthermore, a voluntary industry agreement was signed with the intention to not exceed the WHO guideline value of formaldehyde in indoor environments (0.1 mg/m^3) from the use of cleaning products.[16] The paints and inks industry confirmed that formaldehyde-based resins are used only in mixtures intended for industrial use and that the use of formaldehyde as biocide in consumer products has been phased out since the substance has been classified as Carc. 1B.

Formaldehyde emissions in indoor environments from the use of consumer mixtures (as temporary sources) have been determined in test chambers in recent years. The contribution of floor cleaning agents to the formaldehyde content in indoor air was in the rage of 1-30 ppb (Trantallidi et al., 2015), while formaldehyde emissions from photocatalytic paints did not exceed 80 ppb (Salthammer and Fuhrmann, 2007). These emissions are far below formaldehyde emissions from other temporary sources (such as candle burning, ethanol fireplaces, incense burning, or cooking activities) which may account for indoor air formaldehyde concentrations that are up to 10 times higher.

The Dossier Submitter assessed consumer exposure to formaldehyde using the Consexpo[17] web tool version 1.0.5 developed by the Dutch National Institute for Public Health and the Environment (RIVM) for a number of mixtures typically used by consumers – see Annex B.4.1 for additional information. The results of the exposure estimation show that in all cases analysed the daily exposure for consumers to formaldehyde released from mixtures does not exceed the WHO guideline value of 0.1 mg/m^3.

Based on available literature information and the outcome of the exposure estimation, the Dossier Submitter concluded that consumer risks from formaldehyde in mixtures seem adequately controlled. Therefore exposure to formaldehyde from mixtures is not considered further in this report. However, formaldehyde release from consumer articles where mixtures are used (e.g. glues, fillers and foams used in construction materials and in furniture) and from dried wall paints is covered in the exposure scenario presented in Section 1.3.6.5.

1.3.6.3. Formaldehyde emission sources in indoor air

Adverse health effects (i.e. eye and upper airways irritation) from indoor exposure to formaldehyde released from materials bonded with UF resins are known since the 1960s (Wittmann, 1962). Since then, further investigations have been conducted and, in the majority of cases, the major source of consumer exposure to formaldehyde was identified in the use of formaldehyde-based resins in wood-based materials used in furniture, construction and other areas. Criteria for the limitation and regulation of formaldehyde emissions from wood-based panels for different applications have been established since the early 1980s in some EU Member States (see Section 1.5.1).

In 2014, formaldehyde was subject to Substance Evaluation under REACH from France (addressing risks for workers) and the Netherlands (addressing risks for consumers). The Substance Evaluation concluded that further information was needed in relation to uses by consumers where potential risks have been identified, including: building and construction materials such as wood-based materials for ceiling and flooring and mineral wool, furniture and

[16] https://www.aise.eu/documents/document/20160607155536-3_letter_of_commitment_(2).pdf [Accessed 7 January 2019]

[17] https://www.rivm.nl/en/consexpo [Accessed 7 January 2019]

other UF pressed wood products like hardwood, paints, wallpapers, curtains and carpets, cleaning agents, combustion sources such as cooking (ECHA, 2015).

A report by Fraunhofer WKI (Salthammer and Gunschera, 2017) in response to the Substance Evaluation is part of the formaldehyde registration dossier and includes a review of the literature on emissions from major formaldehyde sources, their contribution to indoor air formaldehyde concentrations and an estimation of consumer exposure to formaldehyde. The Fraunhofer WKI report distinguishes between permanent (or area) sources (such as flooring, furniture, panels, curtains and carpets, etc.) and temporary (or point) sources (such as candles and incense burning, cooking, fireplaces, cleaning, etc.) of formaldehyde.

Although emissions from temporary sources are of relevance for the overall formaldehyde concentration in indoor air, the present report focuses on exposure from articles that are considered permanent sources such as wood-based materials, furniture, and textiles.

Formaldehyde emissions mainly originate from formaldehyde-based resins that are used in the manufacturing of articles, in particular wood-based products. Over time, the formaldehyde from these products is emitted or off-gassed. The emission rate declines quickly during the first days after manufacturing and then gradually over a longer time period. This two-phase process, consisting of a faster initial decline of formaldehyde emissions associated with higher releases and a slower subsequent decline associated with lower releases, has been described in the literature (Sheehan et al., 2018). According to Salthammer and Gunschera (2017) only few studies deal with the long-term emission behaviour of specific products and materials: taking the 28 days value from chamber tests as a starting point, Colombo et al. (1994) derived emission reductions of 33% after one year and 42% after two years for plywood and 45% after one year and 66% after two years for particleboard; Brown (1999) found formaldehyde emission rates from particleboard and MDF of 300-400 mg/(m^2h) in the first few weeks after product manufacture and 80-240 mg/(m^2h) after six to ten months; studying formaldehyde emissions from MDF boards in an experimental room, Liang et al. (2015) found concentration reductions of 20-65% in the corresponding months of the second year.

Annex B.4.2 gives an overview of a broad range of permanent formaldehyde releasing sources together with information on measured emission rates and/or steady-state concentrations, the test method used for obtaining the measurements as well as the source of the information. The information contained in Annex B.4.2 covers the following types of products which are considered further in this report:

- **Solid wood**: Formaldehyde is a decomposition product of lignin and is therefore released in small quantities from solid wood products. Solid wood, if not treated with formaldehyde releasing substances, is outside of the scope of this restriction proposal.

- **Wood-based products**: Wood-based panels used as construction material and/or in finished articles, such as furniture and flooring, are a major formaldehyde emission source in indoor air (Marquart et al., 2013). These materials are usually covered with layers (e.g. primer, gypsum board, paint) that significantly reduce emissions of formaldehyde (Salthammer and Gunschera, 2017). A number of formaldehyde-based resins are used in the manufacturing process of plywood, particleboard, and MDF, and in a variety of agents used in the treating process of wood surfaces depending on the desired properties of the finished product:

    - o UF resins are used in raw and covered wood-based materials, laminates, furniture, windows, and doors. UF resins are suitable only for indoor applications as wood-based materials containing UF resins are not water resistant. Moisture causes depolymerisation which releases formaldehyde. Average formaldehyde emission rates for UF-based wood products (raw) are 164 µg/(m^2h) (range 8.6-1 580 µg/(m^2h)) (Salthammer et al., 2010).

  - PF resins are water resistant and they are suitable for indoor as well as outdoor uses. The emission rates for PF-based wood products (raw) are in the range of 4.1-9.2 µg/(m^2h) (Salthammer et al., 2010).

  - MF resins can be used in indoor and outdoor applications. They are water resistant and the formaldehyde emission rate is estimated to be around one-fifth of that related to UF resins (BAAQMD, 2012). Melamine urea formaldehyde (MUF) resins are also water resistant and their formaldehyde emissions are low compared to UF resins – in the area of 50% of the emissions related to UF resins (Salem et al., 2011).

- **Furniture**: Wood-based panels are not only used in construction but also feature prominently in the production of furniture which might also contribute to indoor air formaldehyde concentrations. Veneering and preparation of furniture with acid-curing lacquer may also cause long-term emissions of formaldehyde (Jensen et al., 2001). Formaldehyde used as a fumigant and preservative in fabrics and foams applied in the furniture is an additional source of formaldehyde emissions (Andersen et al., 2016).

- **Wallcoverings**: There has been a substantial decline in the release of formaldehyde from wallcoverings over the years. While in the past the basic material used for wallcoverings was paper (simplex or duplex) and the layers were assembled with glue, nowadays formaldehyde-free fleece is commonly applied as the backing material of wallcoverings (Salthammer and Gunschera, 2017).

- **Paints**: Some polymers used in paints and lacquers are manufactured with small percentages of monomers containing methanol groups, which may release small amounts of formaldehyde. Acid curing lacquers made of modified UF resins, which are considered a potentially high emitting source, have almost completely been replaced (Formacare, 2018). Photocatalytic indoor wall paints contain modified TiO_2, which is used as a catalyst under indoor daylight or artificial light. Organic binders like acrylic blends, vinyl acetate, styrene and unsaturated fatty acids are also typical constituents of wall paints. Formaldehyde might be formed from degradation of the paint ingredients during irradiation (Salthammer and Gunschera, 2017).

- **Mineral wool**: Mineral wool is used for insulation purposes in walls, floorings and house tops. Inorganic rock or slag is the main component (typically 97%) of stone wool. The remaining 3% is generally a thermosetting resin binder and oil. Glass wool is made from sand and recycled glass, lime-stone and soda ash. It usually contains 95-96% inorganic material. Urea-modified PF resins are used as binders, producing low emissions of formaldehyde during use (Salthammer and Gunschera, 2017).

- **Foams**: UF foams as insulation material are used today only in gaps with good ventilation or when the foam is placed into closed cavities. Open-cell, tempered foams from MF resins are used for specific applications, e.g. seats in airplanes or noise insulation in concert halls. Also PF resins are used extensively to manufacture foams. However the formaldehyde emissions have been detected to be extremely low from these resins (Formacare, 2018).

- **Textiles (curtains and carpet)**: Formaldehyde is commonly used in textile production processes. For example, after treatment of substantive dyeing, hardening of casein fibres, as a wool protection agent, anti mould and above all as a cross linking agent in resin finishing.

Among the permanent emission sources studied, uncovered wood-based materials appear to be the main formaldehyde emission sources whereas products like paints, mineral wools and foams have lower emissions. Formaldehyde emissions from products and materials decrease over time.

Temporary emission sources, in the form of different combustion processes (e.g. wood burning, smoking, candle burning, cooking, ethanol fireplaces), may have a high short-term impact on the indoor air quality (see Annex B.4.3).

Based on their review of the formaldehyde emissions literature, Salthammer and Gunschera (2017) calculated reference room concentrations for different formaldehyde emission sources using Monte Carlo simulations. The results are presented in Table 5 and allow to compare the impact of individual emission sources on the formaldehyde concentration under the specific conditions of the European Reference Room (see Section 1.3.6.5). Again, this comparison shows that wood-based panels (here: particleboard and OSB used in wall construction) as well as furniture made from such materials are the highest contributing permanent sources. The calculations also underline that the various temporary combustion sources – in particular ethanol fireplaces – might also lead to high formaldehyde concentrations in indoor air.

Table 5: Simulated reference room concentrations for different emission sources

	Product	P25 [µg/m³]	P50 [µg/m³]	P75 [µg/m³]	P90 [µg/m³]	P95 [µg/m³]	Remark
Permanent sources	Textiles	2.6	3.6	5.2	7.0	8.4	L = 1 m^2/m^3
	Solid wood	5.4	7.5	10.3	13.6	16.0	L = 1 m^2/m^3
	Flooring (laminate)	4.0	6.5	10.9	16.5	21.3	L = 0.4 m^2/m^3
	Flooring (carpet)	1.9	3.0	4.6	6.7	8.5	L = 0.4 m^2/m^3
	Wall (covered PB)	27.0	38.3	53.4	72.2	86.0	L = 1 m^2/m^3
	Wall (covered OSB)	12.3	20.2	31.5	46.2	57.5	L = 1 m^2/m^3
	Wall (covered MW)	5.0	8.6	14.7	24.0	31.9	L = 1 m^2/m^3
	Wall (surface coating)	2.9	4.4	6.6	9.4	11.7	L = 1 m^2/m^3
	Wall (wallcovering)	0.5	1.0	1.8	3.0	4.2	L = 1 m^2/m^3
	Doors	0.9	1.7	3.6	6.9	10.3	L = 0.05 m^2/m^3
	Windows	2.0	2.0	2.0	2.0	2.0	L = 0.05 m^2/m^3
	Furniture	20.5	38.1	66.3	105.3	148.8	L = 1 m^2/m^3
	Miscellaneous	2.0	3.0	4.0	4.6	4.8	1 item
	Outdoor air	2.6	4.3	7.2	11.3	14.9	
	Indoor chemistry	1.7	2.6	3.9	5.8	7.3	
Temporary sources	Burning candles	8.5	12.3	17.6	24.3	29.6	1 item
	Burning incense	12.0	21.0	30.0	35.4	37.2	1 item
	Cooking	33.2	44.2	59.0	76.0	88.7	
	Ethanol fireplaces	77.8	152.2	244.6	347.3	419.5	1 item
	Wood combustion	15.7	26.5	37.3	43.7	45.8	
	Air cleaning devices	7.7	13.5	19.2	22.7	23.8	1 item

PB = Particleboard, OSB = Oriented strand board, MW = Mineral wool

Note: Ageing and sink effects have not been considered. Emission reductions from covering are assumed to be 75% for PB and OSB and 85% for MW. For further details on ageing, sink and covering effects see Section 1.3.6.5.

Source: Adapted from Salthammer and Gunschera (2017)

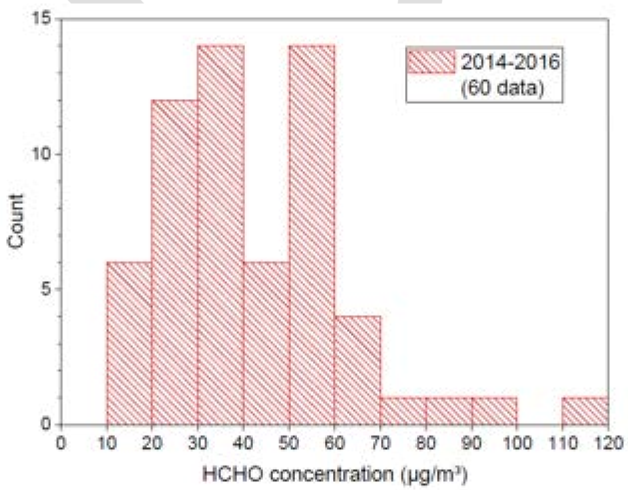
1.3.6.4. Measured formaldehyde concentrations in indoor air

The concentration of formaldehyde in indoor air depends upon multiple factors such as the amount and type of emission sources present, physical conditions in the indoor environment (e.g. temperature, humidity), age of emitting materials, air exchange rate, presence of air cleaning devices, absorption and desorption from walls and flooring ("sink effect"), chemical reactions, etc. Indoor air concentrations and personal exposure to formaldehyde have been measured for decades in different indoor environments in the EU. Since the 1980s formaldehyde levels in indoor environments have been declining significantly (Salthammer et al., 2010). Under normal living conditions, the average measured formaldehyde concentration varies between 20 and 40 µg/m^3 in Europe, which is clearly below the WHO guideline value of 0.1 mg/m^3 (= 100 µg/m^3). This conclusion is based on the literature reviews from Marquart et al. (2013) and Salthammer and Gunschera (2017) and indoor formaldehyde exposure measurements taken in 12 European cities (Bruinen de Bruin et al., 2008).

Similar concentration measurements (median: 19.7 µg/m^3, maximum: 86 µg/m^3) were obtained from 567 dwellings in France (Langer et al., 2016). Experimental studies conducted in conventional and passive houses in Sweden showed median concentrations of formaldehyde between 11.1 and 15.7 µg/m^3, respectively (Langer et al., 2015). Formaldehyde concentrations in low-energy or passive houses equipped with a ventilation system and heat recovery and in conventional houses with manual ventilation via windows have been investigated in Austria in 2015. The 50th and 95th percentile for indoor air formaldehyde concentrations were found to be, respectively, 22-27 µg/m^3 and 46-53 µg/m^3 for low-energy/passive houses and 31-40 µg/m^3 and 59-67 µg/m^3 for conventional houses (Wallner et al., 2015).

The report by Salthammer and Gunschera (2017) contains recent measurements of formaldehyde concentrations from newly built prefabricated houses in Germany. Measurements performed on 60 houses during years 2014-2016 showed that only in one case the formaldehyde concentration in indoor air exceeded the WHO guideline value (Figure 3). The indoor air measurements were performed under a so-called worst case scenario meaning that doors and windows were closed for several hours before measuring. The median value for formaldehyde was 38 µg/m^3.

Figure 3: Formaldehyde concentrations in newly built prefabricated houses in Germany



Source: Salthammer and Gunschera (2017) based on data from Bundesverband Deutscher Fertigbau e. V.

Villanueva et al. (2015) measured formaldehyde concentrations in indoor air in 22 houses in a heavily industrialised area in Spain. The age of the houses varied from < 1 to > 17 years. Specific characteristics (e.g. recent renovation, age of furniture, smoking, carpets) were also taken into account in the study. Indoor formaldehyde concentrations varied from 17.1 to 91.4 µg/m^3 with a median of 55.5 µg/m^3. The study showed that smoking and the age of furniture had a high impact on indoor formaldehyde concentrations.

Kolarik et al. (2012) measured formaldehyde levels in newly fabricated houses in Denmark. Formaldehyde concentrations ranged from 0.018 to 0.110 mg/m^3 with a mean concentration of 0.05 mg/m^3. In the same study, formaldehyde emissions were determined for 22 different specimens prepared from purchased products and consumer products including wood-based panels, insulation materials, carpets, textiles, paints and detergents. MDF and chipboard were identified as the strongest formaldehyde sources, though all of the tested samples fulfilled the Danish requirements of formaldehyde concentrations of less than 124 µg/m^3 when measured in a standard test chamber. According to model calculations in the study, formaldehyde concentrations in a small room can exceed the WHO guideline value of 100 µg/m^3 markedly if wood-based panels with the highest permissible emission (124 µg/m^3) are used for flooring, in walls and ceiling. However, these high concentrations are obtained under the unrealistic assumption of only using uncovered materials. The study authors conclude that CE marking for construction products (see Section 1.5.1) does not exclude the possibility of exceeding the WHO guideline value.

A number of studies investigated the relationship between indoor formaldehyde concentrations and age of residential buildings. Generally, formaldehyde concentrations in indoor air have been found to be higher in new homes and concentrations decrease over time (Brown, 2002; Marquart et al., 2013; Wallner et al., 2015). Controlled studies in unoccupied homes suggest a reduction of 25-40% in formaldehyde concentration during four to eight weeks and a half-life of 18-24 months (Groah, 2005). In some cases formaldehyde concentration may also increase during the first year after the completion of construction. A Finnish study performed on newly finished buildings showed that the formaldehyde concentration in indoor air varied between 13 and 37 µg/m^3 and the mean concentration increased from 19 to 26 µg/m^3 during the first year due to the appearance of new formaldehyde sources, such as furniture, in the inhabited buildings (Jarnstrom et al., 2006).

Table 6 contains a summary of measured formaldehyde concentrations in the indoor environment. The information is taken from representative studies conducted in the EU in recent years and indicates that formaldehyde concentrations in indoor environments are higher for new buildings and when new products are used. Measured data show that, even though in the majority of the cases formaldehyde concentrations in indoor air do not exceed the WHO guideline value, there are a few cases where this value is exceeded. To better understand how formaldehyde emissions from different sources may contribute to the concentration of formaldehyde in indoor environments the Dossier Submitter used a modelling approach based on the European Reference Room.

Table 6: Recently measured indoor air formaldehyde concentrations in the EU (µg/m³)

	Study performed (N, year, Member State)	P50/GM	P95/max	Exceeding WHO Guideline	Reference
Conventional houses	60, 2014-2016 (new prefabricated houses), Germany	38	/118	1 case (2%)	Salthammer and Gunschera (2017) based on data from Bundesverband Deutscher Fertigbau e. V.
	21, 2012-2014 (newly built), Sweden	16 (conventional houses) 17 (housing stock)	< 55 < 95	0% 0%	Langer et al. (2015)
	22, 2011 (all ages), Spain	56	/91	0%	Villanueva et al. (2015)
	61, I: 2010-2012 (3 months), II: 2011-2013 (one year), Austria	I: 40 II: 31	I: 67 II: 57	I: 1% II: 0%	Wallner et al. (2015)
	59, 2008, Italy	16 (+8)			Lovreglio et al. (2009)
	19, 2007 (new), Denmark	40/45	/110	2 buildings (11%)	Kolarik et al. (2012)
	567, 2003-2005, France	20/20	/86	0%	Langer et al. (2016)
	≥ 4, 1999-2001, I: 0 months, II: 6 months, III: 12 months, Finland	I: 19 II: 21 III: 26	Max values I: 26 II: 28 III: 37	0%	Jarnstrom et al. (2006)
	11, 2014 (new), Lithuania	31	/52.3	0%	Kaunelienė et al. (2016)
Passive/low energy houses	20, 2012-2014 (newly built), Sweden	11	< 20	0%	Langer et al. (2015)
	62, I: 2010-2012 (3 months), II: 2011-2013 (one year), Austria	I: 27 II: 22	I: 53 II: 46	I: 2% II: 0%	Wallner et al. (2015)
	7, 2009-2010 (newly built), France	/23			Derbez et al. (2014)

1.3.6.5. Estimated formaldehyde concentrations in indoor air

In this section indoor air formaldehyde concentrations have been estimated under an exposure scenario that reflects the situation in the indoor environment of newly built homes that use wood-based panels as construction material and feature a number of other formaldehyde emitting articles. To construct the exposure scenario a standard room (European Reference Room) is equipped with typical formaldehyde emitting products, i.e. articles that have been produced with the intentional addition of formaldehyde or formaldehyde releasing substances (either as such or in mixtures). Only permanent formaldehyde emission sources are taken into account. Indoor air formaldehyde concentrations have been estimated, using Monte Carlo simulations, for 100 000 such equipped rooms to get a better understanding of the potential risk in the status quo given the specific conditions of the exposure scenario.

The approach in this report follows the approach taken by Salthammer and Gunschera (2017) when estimating formaldehyde concentrations for a real-room scenario but the exposure scenario developed here deviates in some important aspects: the focus is on new homes – that is no reduction in formaldehyde emissions due to ageing of materials is taken into account – and the composition and loading factors of the products used in the standard room is somewhat different.

European Reference Room

Indoor air formaldehyde concentrations are estimated for a standard room which is based on the European Reference Room. The parameters of the European Reference Room are defined in the European Standard EN 16516 and are summarised in Table 7. The loading factor (L) refers to the ratio between the surface of the used product (expressed in m^2) and the total volume of the empty room (expressed in m^3). For example, if the reference room's volume is 30 m^3 and the floor surface is 12 m^2 and is made up of laminate, this implies a loading factor for laminate flooring of 12 m^2/30 m^3 = 0.4 m^2/m^3.

Table 7: European Reference Room (EN 16516)

Parameter name	Parameter value	Loading factor (L)
Temperature	23 °C	
Relative humidity	50%	
Air exchange rate (ACH)	0.5 h^{-1}	
Room volume	30 m^3	
Room dimensions	4 x 3 x 2.5 m (1 door, 1 window)	
Surface floor	12 m^2	0.4 m^2/m^3
Surface ceiling	12 m^2	0.4 m^2/m^3
Surface walls	31.4 m^2	1 m^2/m^3 (rounded)
Surface door	1.6 m^2	0.05 m^2/m^3 (rounded)
Surface window	2 m^2	0.05 m^2/m^3 (rounded)
Sealing	0.2 m^2	0.007 m^2/m^3

Source: CEN (2017)

Exposure scenario

The exposure scenario constructed in this report focuses on indoor environments in residential buildings[18] and it conservatively assumes the case of newly built homes where wood-based panels are used as construction material and where other typical formaldehyde emitting sources, such as furniture made from wood-based materials or textiles, are present. It does not include any combustion or other temporary sources. As wood-based panels are considered the most significant permanent source of formaldehyde emissions in indoor environments, the exposure scenario is further subdivided into three sub-scenarios where different amounts of wood-based panels are assumed. The exposure scenario based on the European Reference room is considered to also cover the situation in rooms other than in residential buildings, such as a standard school classroom (see Annex B.4.6). The following parameters are used in the exposure scenario and are summarised in Table 8:

- In all sub-scenarios the room's ceiling is made up of particleboard (PB) resulting in a loading factor of 0.4 m^2/m^3 (Ceiling 1 in Table 8). While in sub-scenario A the room's walls are assumed to be made up of non-formaldehyde emitting materials, in sub-scenario B two of the walls and in sub-scenario C all of the walls are made up of particleboard implying loading factors of 0.6 m^2/m^3 and 1 m^2/m^3, respectively (Wall 1).
- In real-life situations particleboard used in construction is covered with layers (e.g. gypsum board, paint) leading to a substantial reduction in formaldehyde emissions. As described by Salthammer and Gunschera (2017), the reduction in formaldehyde emissions from covering wood-based materials varies with the number and types of layers applied. A 75% reduction of the formaldehyde emission rate is assumed for a particleboard covered with a primer and then with dispersion paint.
- The room's walls and ceiling are painted (regardless of whether they are made up of particleboard or not) resulting in a loading factor for paint of 1 m^2/m^3 for the walls (Wall 2) and 0.4 m^2/m^3 for the ceiling (Ceiling 2).
- The room's flooring is made up of laminate resulting in a loading factor of 0.4 m^2/m^3.
- A loading factor of 0.75 m^2/m^3 is assumed for furniture. This has been derived from a study on formaldehyde emissions from furniture carried out by the Danish EPA (Andersen et al., 2016), in which the authors describe three typical furnishing scenarios (see Annex B.4.3) which result in loading factors of 0.72 m^2/m^3, 0.75 m^2/m^3 and 0.88 m^2/m^3. For the purpose of the exposure scenario presented here, a loading factor of 0.75 m^2/m^3 has been chosen.
- For textiles, a loading factor of 0.3 m^2/m^3 is assumed. This approximately corresponds to having 5 m^2 of curtain (≈ 2 curtains of 175 x 140 cm each) and 3.5 m^2 carpet (≈ 1 carpet of 160 x 220 cm) in the 30 m^3 reference room.
- The room has one 1.6 m^2 door and one 2 m^2 window – both assumed to be wood-based – with dimensions resulting in a rounded loading factor of 0.05 m^2/m^3 each.
- In line with Salthammer and Gunschera (2017), the exposure scenario here also considers outdoor air formaldehyde concentrations and chemical reactions occurring in

[18] Exposure to formaldehyde in vehicles is discussed in Annex C.1.2.

the indoor environment where formaldehyde is produced (“indoor chemistry”) as permanent formaldehyde emission sources.

- The assumption of a 25% reduction in formaldehyde concentration due to adsorption (“sink effect”) is directly taken from Salthammer and Gunschera (2017).
- The simulations are based on test chamber results of newly produced materials measured after 28 days. No reduction in formaldehyde concentration due to ageing of materials is assumed in this exposure scenario as the focus is on newly built homes.

Table 8: Exposure scenario and sub-scenarios

Scenario / Source	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
Wall 1	PB, L = 0 (non-FA emitting material used)	PB, L = 0.6 Covering: -75%	PB, L = 1 Covering: -75%
Ceiling 1	PB, L = 0.4, Covering: -75%		
Wall 2	Paint, L = 1		
Ceiling 2	Paint, L = 0.4		
Flooring	Laminate, L = 0.4		
Furniture	L = 0.75		
Textiles	L = 0.3		
Door	L = 0.05		
Window	L = 0.05		
Outdoor air			
Indoor chem.			
Sink	-25%		

Note: Total loading factors are 3.35, 3.95 and 4.35 for sub-scenarios A, B, and C, respectively.

Source: Adapted from Salthammer and Gunschera (2017)

Monte Carlo simulations

Indoor air formaldehyde concentrations have been estimated, in this report, using Monte Carlo simulations. This approach uses random sampling from probability distributions of formaldehyde emission rates. A log-normal distribution of emission rates is assumed for each of the formaldehyde emission sources in the exposure scenario. This type of distribution is frequently used to represent environmental data in statistical analysis. For each of the emission sources, the input parameters for the log-normal distribution (i.e. geometric mean and geometric standard deviation) are based on a review of the formaldehyde emission literature (Salthammer and Gunschera, 2017).

In this way, 100 000 emission rates have been obtained for particleboard (used in Wall 1 and Ceiling 1), paint (Wall 2 and Ceiling 2), laminate (Flooring), furniture, textiles, door and window. Using these emission rates and taking into account the loading factors specified in Table 8 as well as the air exchange rate specified in Table 7, reference room concentrations are calculated for the various sources in the exposure scenario. Indoor air formaldehyde concentrations for 100 000 rooms are derived by considering the contribution of the reference room concentrations obtained for the different sources and the contribution of outdoor air, indoor chemistry and taking into account the sink effect.

Additional explanations on the approach taken are provided in Annex B.4.5.

Results

Table 9 provides summary measures for the simulated formaldehyde concentration in the 100 000 rooms. It shows that the formaldehyde concentration increases with the amount of wood-based panels used (going from sub-scenario A to B to C). In all three sub-scenarios the median (P50) concentration for the 100 000 rooms remains however below the WHO guideline value.

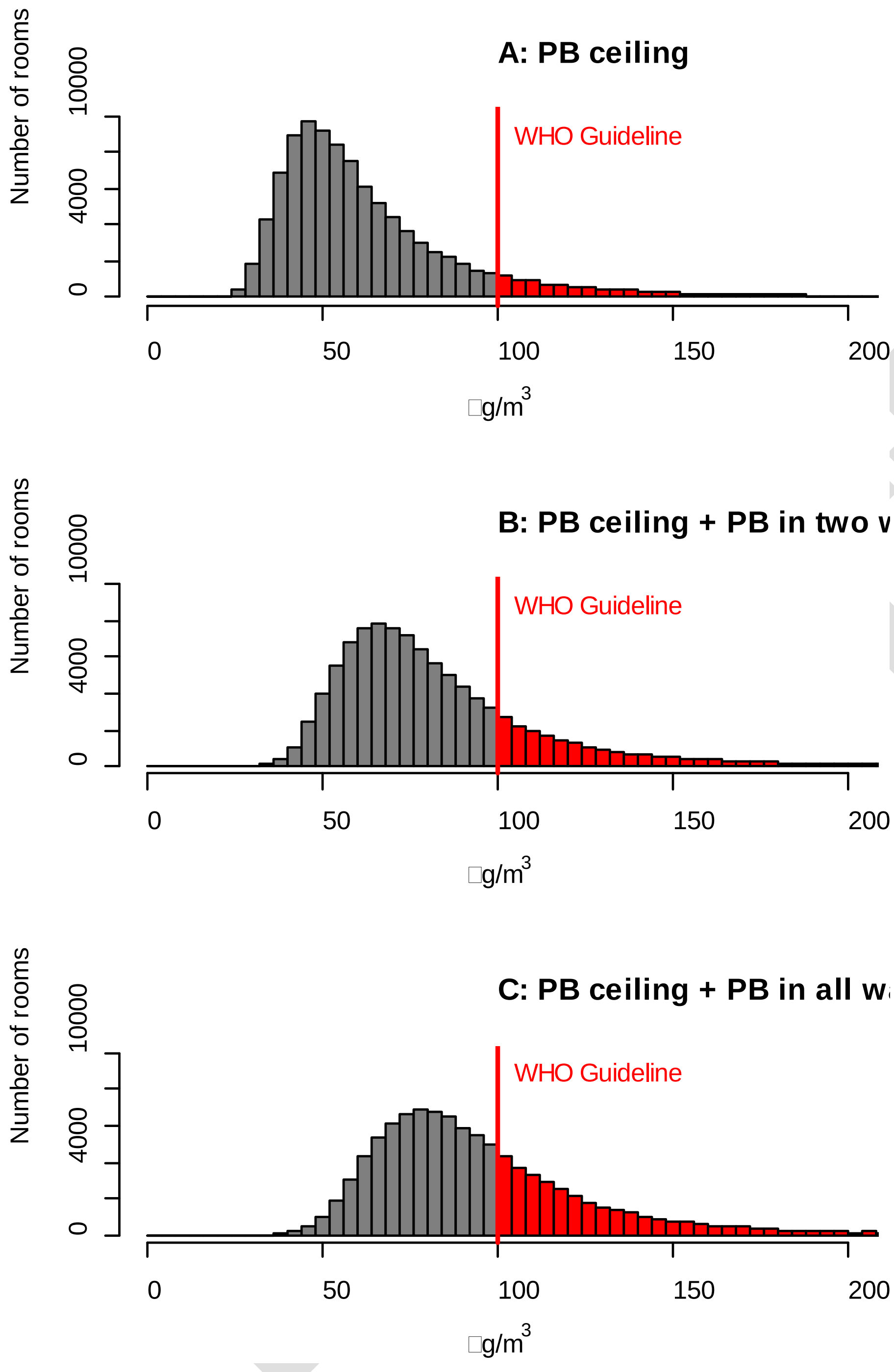
Table 9: Summary of simulated formaldehyde concentration in 100 000 rooms

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m^3]	56	76	88
P75 [µg/m^3]	74	95	109
P90 [µg/m^3]	103	124	138
P95 [µg/m^3]	129	149	164
Above WHO Guideline	***10.9% of rooms***	***20.9% of rooms***	***34.3% of rooms***

Within each of the three sub-scenarios moving towards the upper end of the distribution – that is, towards those rooms where the simulation yielded higher formaldehyde concentrations – indicates that the WHO guideline value can, in some cases, be exceeded under the specific conditions of the exposure scenario. At the 90th percentile all three sub-scenarios exceed the WHO guideline value, albeit to varying degrees depending on the amount of particleboard used.

The number of rooms exceeding the WHO guideline value depends on the sub-scenario. As Figure 4 illustrates, the portion of rooms to the right of the WHO guideline value (100 µg/m^3) increases with increased use of wood-based panels. The share of the 100 000 rooms with a simulated formaldehyde concentration above the WHO guideline value ranges from around one-tenth of rooms in sub-scenario A to around one-third of rooms in sub-scenario C (see also Table 9).

Figure 4: Histograms of simulated formaldehyde concentration in 100 000 rooms



Finally, Table 10 shows for each of the sources in the exposure scenario the median and the 95th percentile of the 100 000 simulated reference room concentrations. This gives a sense of the relative importance of the individual sources in terms of their contribution to the simulated indoor air formaldehyde concentration. The major formaldehyde emitting sources in the exposure scenario are the wood-based panels used in ceiling and walls as well as furniture made from wood-based materials. The comparatively high reference room concentrations of Wall 1, Ceiling 1 and Furniture at the 95th percentile in particular suggest that high-emitting wood-based materials are a major contributing factor leading to exceedances of the WHO guideline value under the specific conditions of the exposure scenario.

Table 10: Simulated reference room concentrations by source (µg/m³)

Scenario	A: PB ceiling				B: PB ceiling + PB in two walls				C: PB ceiling + PB in all walls			
Source	P50	P75	P90	P95	P50	P75	P90	P95	P50	P75	P90	P95
Wall 1	0	0	0	0	24	29	35	40	40	49	59	66
Ceiling 1	16	20	24	27	16	20	24	27	16	20	24	27
Wall 2	5	6	8	10	5	6	8	10	5	6	8	10
Ceiling 2	2	2	3	4	2	2	3	4	2	2	3	4
Flooring	7	10	14	18	7	10	14	18	7	10	14	18
Furniture	27	50	89	124	27	50	89	124	27	50	89	124
Textiles	1	1	2	2	1	1	2	2	1	1	2	2
Door	2	4	6	9	2	4	6	9	2	4	6	9
Window	2	2	2	2	2	2	2	2	2	2	2	2
Outdoor air	4	7	11	15	4	7	11	15	4	7	11	15
Indoor chem.	3	4	5	6	3	4	5	6	3	4	5	6
Sink (-)	19	25	34	43	25	32	41	50	29	36	46	55

Contribution of temporary sources to indoor air formaldehyde concentrations

Although temporary emission sources may significantly contribute to the concentration of formaldehyde in indoor air, they have not been taken into account in the estimations. This choice is based on the following considerations:

- Emissions from temporary sources have limited duration and, except for the case of cleaning, formaldehyde released into the environment is a by-product of a combustion reaction (e.g. candles and incense burning, operation of ethanol fireplaces, cooking, smoking, etc.).
- These sources only contribute to peak exposure (which has limited duration) and their contribution to indoor air formaldehyde concentrations varies widely and depends on the type of source, the number of sources that are active simultaneously (e.g. number of candles burning in a room, number of persons smoking, whether an ethanol fireplace is in use, etc.) and the duration for which they are active.
- The inclusion of a number of temporary sources (based on reasonable case assumptions) would generate formaldehyde concentrations in the reference room above the WHO guideline value solely as a result of formaldehyde released from these sources (e.g. presence of people smoking or cooking) even if no formaldehyde is released from articles (e.g. wood-based panels, flooring, furniture, carpets, etc.). Such a situation would make it difficult to reach any conclusion on the need to limit emissions from articles as peak exposure from temporary sources would be mostly unaffected by a measure targeting articles.

- A restriction under REACH may not be the most effective regulatory action to limit formaldehyde emissions from temporary sources as in some cases (e.g. cooking) REACH does not apply or other regulatory measures (e.g. imposing closed burning chamber and local exhaust system for ethanol fireplaces under building code) could be more effective and proportionate than a restriction under REACH.

Further considerations on the identification of suitable regulatory risk management options are recommended to the Commission by the Dossier Submitter to address releases of formaldehyde from temporary sources.

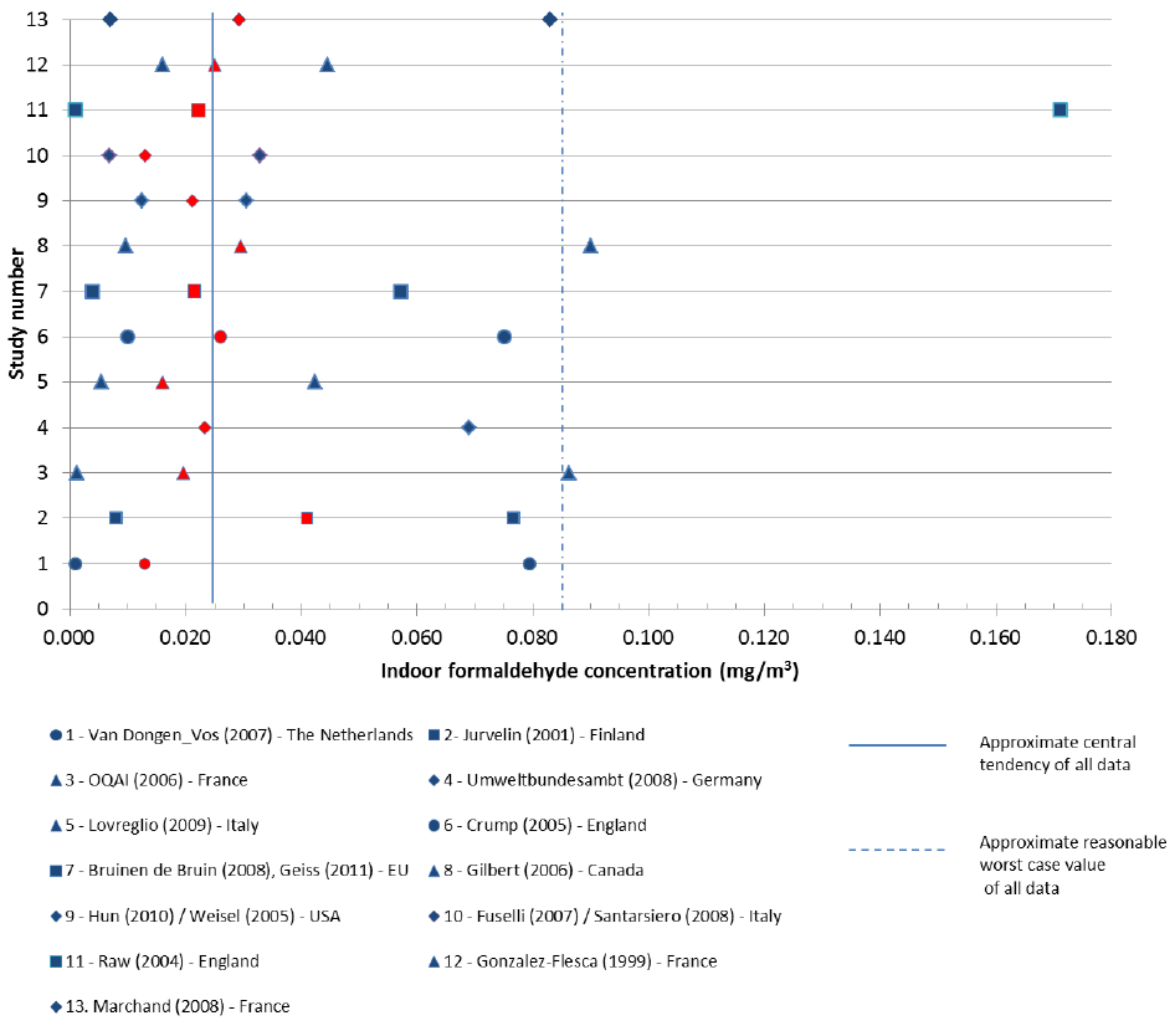
1.3.6.6. Conclusion of the exposure assessment

A review of the literature on measured formaldehyde emissions in indoor air in the EU shows that formaldehyde levels do not exceed the WHO Guideline for Indoor Air for formaldehyde in most cases, as shown in Table 6. The representative studies reported in Table 6 show that average formaldehyde concentrations are generally within a range of 20-40 $\mu g/m^3$. Even measurements performed with closed windows and doors show a median concentration of 40 $\mu g/m^3$ and a P95 value of 67 $\mu g/m^3$ for new buildings (Wallner et al., 2015).

The literature review by Marquart et al. (2013), which includes an overview of formaldehyde indoor air concentration in houses of varying ages reported in different EU studies performed between 1999 and 2011, arrives at a similar conclusion. Figure 5 gives an overview of the 13 studies (covering more than 2 500 measurement points) included in the authors' review. For each study the minimum, mean (in red) and maximum values are presented. The WHO guideline was exceeded only in six homes (0.2% of all measurement points), all from the same study in England (study number 11 in Figure 5). Marquart et al. (2013) also reported an estimate of the central tendency of all data (0.025 mg/m^3) as well as a "reasonable worst case value" (0.085 mg/m^3).

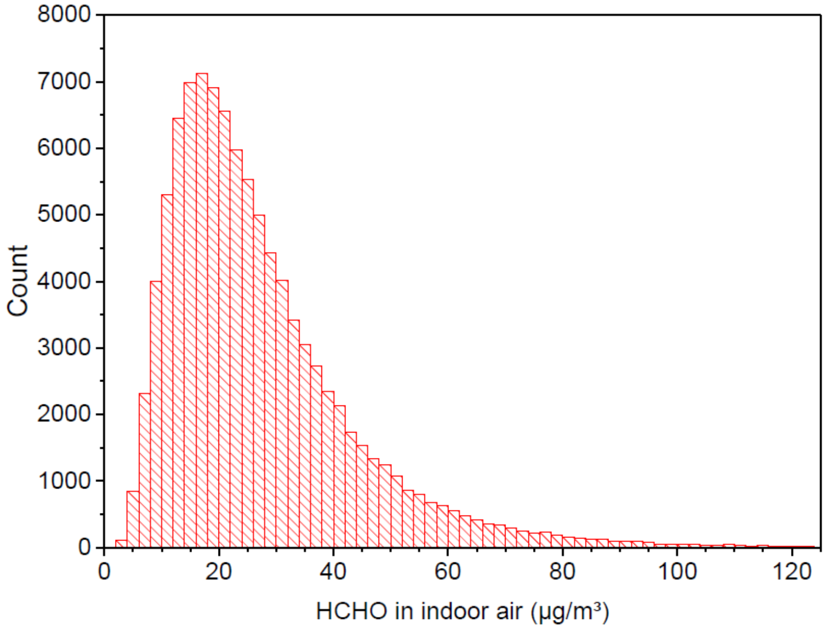
Furthermore, taking into account the available measurement data from a number of different studies, Salthammer and Gunschera (2017) conducted a Monte Carlo simulation of formaldehyde concentrations under normal living conditions in European homes with 100 000 runs. The simulation assumed a log-normal distribution with a geometric mean of 23.1 $\mu g/m^3$ and a geometric standard deviation of 1.78 $\mu g/m^3$ (Figure 6). This simulation resulted in a median indoor air formaldehyde concentration of 23.1 $\mu g/m^3$ and a P95 of 59.4 $\mu g/m^3$ and therefore concentrations far below the WHO guideline value.

Figure 5: Overview of formaldehyde indoor air concentrations in different EU studies



Source: Marquart et al. (2013)

Figure 6: Distribution of formaldehyde concentrations in European homes under normal living conditions derived from a Monte Carlo simulation based on measured data



Source: Salthammer and Gunschera (2017)

Even though measured indoor air formaldehyde concentrations do not exceed the WHO guideline value in most cases, the Dossier Submitter concludes that, based on test data, emission rates of formaldehyde in wood-based panels and other articles can significantly contribute to indoor air formaldehyde concentrations particularly in newly built houses where wood-based panels are used in construction or in finished articles (e.g. furniture).

An exposure scenario reflecting such situations has been developed in this report and indoor air formaldehyde concentrations have been estimated. It has been concluded that the WHO guideline value could be exceeded in new homes, depending on the amount and quality of wood-based panels and articles used. It is important to note that the exposure scenario in this report only takes into account permanent formaldehyde emission sources. Temporary sources (such as cooking, burning candles, fireplaces, etc.) may further contribute to formaldehyde concentrations in indoor environments.

A comparison of measured indoor air formaldehyde concentrations with the results of the estimations in Section 1.3.6.5 shows that the measured concentrations are considerably lower than the estimated concentrations. Average formaldehyde concentrations are generally within a range of 20-40 µg/m^3 and do not exceed the WHO guideline value in the majority of cases (Table 6). On the other hand, depending on the sub-scenario, estimations resulted in median formaldehyde concentrations of 56-88 µg/m^3, P95 concentrations of 129-164 µg/m^3 and 10.9-34.3% exceedances of the WHO guideline value (Table 9).

Some of this discrepancy between measured and estimated formaldehyde concentrations may be explained by limitations inherent to the approach chosen. Based on test data for individual formaldehyde emitting sources, Monte Carlo simulations of formaldehyde emission rates were conducted for the various emission sources included in the exposure scenario described in Table 8. For each source, these simulated emission rates were then translated into formaldehyde concentrations in the European Reference Room and added up (taking into account the various assumptions in the exposure scenario). According to Salthammer and

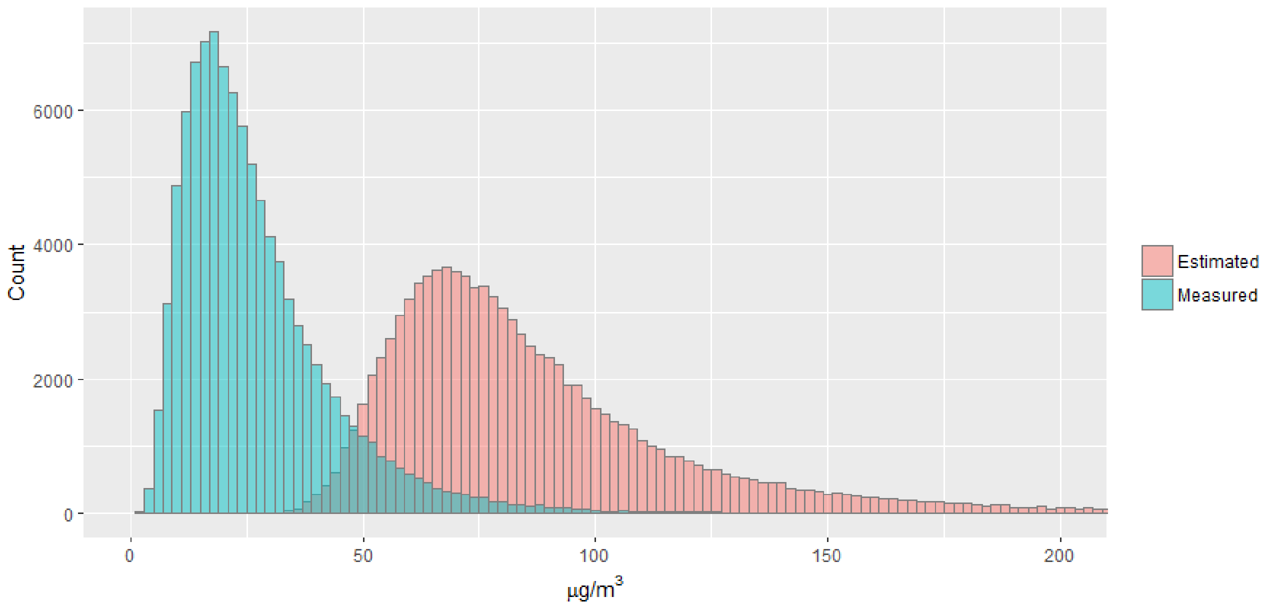
Gunschera (2017), the Reference Room concept greatly overestimates the formaldehyde concentrations in indoor areas when diverse sources are simply added together and that overestimations remain even when taking into account ageing and sink effects.

It is however also important to point out that at least part of the discrepancies may be explained by the conservative assumptions made in the exposure scenario, which are not necessarily representative of the situation in EU homes. This is true in particular for the assumed presence of a considerable amount of formaldehyde emitting materials, particularly wood-based products including wood-based panels in walls and ceiling, furniture and laminate flooring. In addition, the assumption of a 75% emission reduction from covering wood-based panels with a primer and dispersion paint is conservative as it is towards the lower end of the 70-98% range of emission reductions that Salthammer and Gunschera (2017) observed for different types of coverings. Furthermore, the Dossier Submitter did not assume a reduction of formaldehyde emissions due to ageing of materials. This focus on newly produced materials makes the Dossier Submitter's estimation even more conservative.

Figure 7 illustrates the difference between measured and estimated indoor air formaldehyde concentrations. The histogram towards the left of the figure corresponds to the histogram shown in Figure 6 above and represents the distribution of formaldehyde concentrations in European homes under normal living conditions derived by Salthammer and Gunschera (2017) from a Monte Carlo simulation based on measured data. The histogram towards the right corresponds to sub-scenario B in Figure 4 above. This comparison clearly shows that the estimated formaldehyde concentrations are conservative even if the assumptions underlying the exposure scenario may not reflect a "worst case".

Given that the chosen estimation approach appears to overestimate formaldehyde concentrations for the reasons mentioned above, the Dossier Submitter considers the presented evidence on measured formaldehyde concentrations as more reliable and representative of the situation in the EU today. While these measurement data show that the WHO guideline value is met in the majority of cases, occasional exceedances have been observed in the reported studies. Together with the estimation results, which the Dossier Submitter considers to be conservative, this indicates that, if no action is taken to limit formaldehyde emissions from articles used in indoor environments, situations can arise in which the WHO guideline value is exceeded, such as in new buildings that use large quantities of high formaldehyde emitting materials.

Figure 7: Distribution of measured vs estimated indoor air formaldehyde concentrations



Note: "Measured" corresponds to the histogram shown in Figure 6. "Estimated" corresponds to the histogram for sub-scenario B shown in Figure 4.

Source: Salthammer and Gunschera (2017) and own calculations

RAC ASSESSMENT

RAC shares the view of the Dossier Submitter that the inhalation route is the relevant route to consider for this proposal. The exposure assessment is plausible but uncertainties exist in both (higher and lower) directions. The measured emissions from the reviewed literature reflects mostly average housing situations in newly built or refurbished homes but some aspects of typical reasonable worst case situations are not covered, e.g. (very) small sleeping chambers with a full wall-unit for furniture, tighter building envelopes for renovated houses meeting higher energy efficiency standards, etc. Such living situations are nevertheless likely to be representative e.g. for metropolitan areas where rental or buying prices are particularly high. The same holds true for the parameters chosen for the modelling of indoor concentrations of formaldehyde in the reference room.

The reference room is intended to cover a reasonable standard scenario but not realistic worst case situations like very small and less ventilated rooms as mentioned above. No exposure assessment has been performed for vehicle cabin interiors, including road, rail and water vehicles, and aircraft cabins. Some literature references and information from the consultation reporting formaldehyde concentrations in cars and aircrafts were considered by RAC.

RAC notes that worker exposure is out of the scope of the restriction.

Building interior scenario

RAC noted that the overall database on formaldehyde concentrations in homes/dwellings showed that formaldehyde concentrations in conventional houses (furnished or assumed to be furnished) exceed the RAC DNEL at percentages of 6-7 %, 21 % or 50 % depending on the study considered. This is interpreted as an average housing situation. Modern prefabricated houses measured *without* furniture in it – although produced using low emitting wood-based panels (with emission levels in the range of 0.3 ppm) – revealed in 36 % of tested buildings formaldehyde levels higher than the RAC DNEL. The derived P90/P95/Max values taken from individual studies in the majority of the cases exceeded the RAC DNEL to a certain extent (see Table 5 in the RAC opinion) and in some studies, exceeded also the WHO guideline value.

RAC concludes that the RCR is > 1. The summarised exposure obtained from different studies leads to a RCR = 1.7, when the reasonable worst case estimate of 0.085 mg/m³ reported by Marquart (2013) is used. The housing situations reported by the Dossier Submitter reflect rather average living conditions and not realistic worst case situations; some reported P95 and maximum concentrations exceed 0.1 mg/m³ with resulting RCR > 2.

RAC noted that the Dossier Submitter also estimated formaldehyde concentrations in indoor air by modelling an exposure scenario that is intended to reflect the situation in newly built homes to better understand the exposure in addition to the measurement data available in the literature.

RAC is of the opinion that the applied modelling approach can be considered conservative. However, it needs to be acknowledged that the modelling approach has its uncertainties. The presented modelling does not fully address the variety of parameters and living situations such as different construction standards, seasonal variations, public buildings, tiny houses/mobile homes, very small chambers with potentially high loading which would be required for a worst case exposure scenario. On the other hand, the chosen approach leads to an overestimation of the formaldehyde concentration in indoor environments as the contributions from a variety of emission sources are simply added up. Such concentrations aim to reflect the situation in newly built houses where no decrease of formaldehyde concentrations due to off-gassing is considered.

Contribution of furniture in the building construction scenario

RAC notes that furniture products are significantly contributing to the formaldehyde indoor concentrations. Furniture alone can, under certain conditions, contribute up to 50 % of the overall room formaldehyde concentration.

Contribution of textiles in the building construction scenario

Data on textiles are limited and indicate rather low emissions for these types of articles; older data may not be representative for today's fabrics.

Uncertainties in the exposure assessment of the building interior scenario

In order for RAC to tackle some of these uncertainties and suggestions from the consultation, as a sensitivity analysis on exposure influencing parameters, the Monte Carlo simulations carried out by the Dossier Submitter have been verified and repeated considering some variations. In the RAC opinion the results are presented with reference to the RAC DNEL and the WHO guideline value. As in the Background Document the simulation of sub-scenarios A-C of the Dossier Submitter was applied. RAC concluded that the Monte Carlo simulation results suggest that the DNEL is likely exceeded under real exposure situation under certain conditions.

Acknowledging the uncertainties, exceedance of the DNEL in the range of 2-3-fold appears to be a reasonable estimate. The modelling approach has its uncertainties. While it does not fully address the variety of parameters, lacks important exposure determinants (climatic conditions) and also considers refinements (such as sink effect), the chosen approach leads to overestimation to some extent that needs to be acknowledged (as discussed above). Although the model is an approximation only, the results are useful because they highlight general uncertainties in the risk assessment of formaldehyde emissions from articles and also strongly suggest exceedance of the DNEL in realistic exposure situations.

<u>Temporary emission sources and peak exposure</u>

Emissions from temporary sources are of relevance for the overall formaldehyde concentration in indoor air. The Dossier Submitter excluded temporary emission sources from the scope of the restriction and includes only articles where formaldehyde or formaldehyde releasers have been intentionally added (or were used) in the production process. Temporary emission sources include, but are not limited to, burning candles and incenses, cooking and related activities, ethanol fireplaces, wood combustion, smoking and formaldehyde containing mixtures.

RAC acknowledges that mixtures, even cleaning products releasing formaldehyde, may not be used daily, they are used normally only for a short time (minutes up to very few hours) and exposure would last only very transiently for the use duration. Therefore, RAC considers it acceptable to not consider peak exposure arising from discontinuous use of mixtures in the exposure scenario for building interiors.

RAC notes that formaldehyde emissions arising as by-product from combustion of incenses and ethanol fireplaces lead to considerably high indoor concentrations exceeding both the long-term DNEL of 0.05 mg/m^3 and the WHO guideline value of 0.1 mg/m^3. In the view of RAC, regulatory measures should be considered elsewhere to limit formaldehyde emissions and consumer risk arising from ethanol fireplaces.

Exposure scenario: Vehicle interior – articles used as car and vehicle cabin components

The use of formaldehyde releasing materials in the automotive industry sector is considered significant and the scope of the restriction as proposed by the Dossier Submitter covers formaldehyde emissions from articles used not only in buildings but also in other indoor environments, i.e. interior of vehicles such as cars and public transport.

RAC assessed the exposure scenario for vehicle cabin/cars based on information available in the public domain and based on information provided in the consultation.

At testing conditions in the ambient mode of the sector-specific measurement standard, the RAC DNEL was frequently exceeded. The maximum concentration in the above mentioned studies was 91 µg/m^3. For 7/10 car manufacturers the maximum figures exceeded the DNEL, only three companies stayed with their measurement range below the DNEL.

RAC concludes that the RCR > 1 < 2 (measured in ambient mode in accordance with the standard ISO 12219-1). Consumers may stay typically up to 2 hours per day in cars and the remaining time in their homes. While a task-related RCR for car cabin interiors would be accordingly lower, combined exposures from homes/buildings and car cabin interiors may still exceed the DNEL under average exposure conditions (RCR > 1).

<u>Uncertainties in the exposure assessment on vehicles</u>

Road public transport

RAC has no information on formaldehyde emissions, cabin interior concentrations and applicable standards for these specific road vehicles and no information has been provided in the consultation. RAC therefore considers that it is not possible to attempt risk characterisation and considers a relevant contribution of formaldehyde-emitting articles to consumer risk during commuting considerably uncertain but notes that public transport/bus commuting is a relevant means of daily transportation of consumers.

Rail vehicle cabin interior

Relevant information is not available and has neither been submitted in the consultation. Based on these uncertainties, RAC considers it not possible to attempt exposure assessment and risk characterisation.

Exposure scenario: Aircraft interior

RAC concludes that based on available test reports, formaldehyde cabin interior measurements in aircrafts were below the RAC DNEL (0.05 mg/m^3) including the maximum concentrations presented. The sources of formaldehyde emissions in aircrafts may be several including ozone reaction products, oil and fluids and their degradation/pyrolysis products, cleaning products/disinfectants, passengers themselves. RAC cannot identify a risk due to articles used in aircraft construction and interior design to long-term health risk of passengers.

1.4. Justification for an EU-wide restriction measure

A number of EU Member States have established legislation to prevent or reduce the risk associated with consumer exposure to formaldehyde from articles (in particular wood-based products). However these measures are not established in all Member States and the scope of the enacted measures is not harmonised across the EU.

In addition, major EU industry sectors (e.g. wood-based panels) have already put in place voluntary agreements to self-restrict formaldehyde emissions from articles. However, these measures may not prevent producers who have not subscribed to such voluntary agreements and importers of articles from outside the EU from marketing high formaldehyde releasing materials in the absence of a legally binding EU-wide measure.

These disparities result in different levels of risk reduction across the EU and the potential for consumer exposure to formaldehyde levels above the WHO guideline value persists in indoor environments under certain circumstances. Hence, it is concluded that the risks of health issues for consumers exposed to formaldehyde released from articles are considered to be not negligible if these releases are not controlled on an EU-wide basis.

The proposed restriction under REACH would lead to a harmonisation of risk management measures related to the release of formaldehyde from articles across EU Member States at a level sufficient to address the identified risks for consumers. Since articles can be manufactured and imported into any EU Member State and freely moved within the Union, an EU-wide restriction is likely to ensure the strongest possible protection. Whilst the enforceability of the proposed restriction has been considered as part of the restriction proposal, the enforcement of any subsequent restriction, particularly the enforcement strategy adopted, is primarily the responsibility of individual Member States.

RAC ASSESSMENT

RAC agrees with the Dossier Submitter's justification on the need of a Union-wide legislation. Due to Union-wide similarities in building construction and the Union-wide distribution of the broad range of articles, indoor exposure will occur in all Member States. RAC notes that the risk level should be equally low across all Member States. Available legislation concerns mainly construction materials/wood-based panels. Although some Member States have national regulations in place to limit formaldehyde emissions or to indicate emission classes (which alone has no effect on the placing on the market of formaldehyde-emitting articles), there is no enforceable EU-wide legislation. In line with the view of the Dossier Submitter, RAC supports the need of an EU-wide legislation.

For the same reasons (Union-wide use of vehicles, lack of legislations) an EU-wide legislation that covers vehicles of all kind will be the only option for vehicles.

1.5. Baseline

1.5.1. Problem definition

Formaldehyde and its risks to human health from inhalation exposure as well as its role as an indoor air pollutant is well-studied. As discussed in Section 1.3.4.10 of this report, the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m³ (30-minute average concentration) should be protective against both acute and chronic sensory irritation in the airways in the general population and in particular in potential sensitive subpopulations including children and the elderly. The short-term guideline will also prevent detrimental effects on lung function as well as long-term health effects, including nasopharyngeal cancer.

A number of measures exist – both at the European and the national level – that aim at limiting formaldehyde emissions from articles in indoor environments. Of particular relevance to the restriction proposal at hand are the EU's Construction Products Regulation, a voluntary agreement of the European wood-based panels industry, as well as national legislation in a number of EU Member States.

The **Construction Products Regulation** (EU) No 305/2011 (CPR) entered fully into force on 1 July 2013 and sets out harmonised rules for the marketing of construction products in the EU. The CPR requires a CE marking for construction products before they can be placed on the internal market. Construction products for which a harmonised European standard exists must comply with the relevant standard to obtain the required CE marking. The harmonised European standard for wood-based panels used in construction is EN 13986 (CEN, 2004b). This standard defines two formaldehyde classes in Annex B and requires formaldehyde containing wood-based panels to be tested and classified as either E1 or E2, depending on their release of formaldehyde (see Table 11 and Table 12). The harmonised standard, however, does not restrict the placing on the market of class E2 wood-based panels, i.e. panels with formaldehyde release > 0.124 mg/m³.

Table 11: Formaldehyde emission class E1 according to EN 13986

		Panel product		
		Unfaced	Unfaced	Coated, overlaid or veneered
		Particleboard OSB MDF	Plywood Solid wood panels LVL	Particleboard OSB MDF Plywood Solid wood panels Fibre boards (wet process) Cement bonded particleboards LVL
Initial type testing [a]	Test method	ENV 717-1		
	Requirement	Release ≤ 0,124 mg/m³ air		
Factory production control	Test method	EN 120	EN 717-2	
	Requirement	Content ≤ 8 mg/100 g oven dry board See NOTE 3	Release ≤ 3,5 mg/m²h or ≤ 5 mg/m²h within 3 days after production	

[a] For established products, initial type testing may also be done on the basis of existing data with EN 120 or EN 717-2 testing, either from factory production control or from external inspection.

Source: EPF (2017)

Table 12: Formaldehyde emission class E2 according to EN 13986

			Panel product		
			Unfaced	Unfaced	Coated, overlaid or veneered
			Particleboard OSB MDF	Plywood Solid wood panels LVL	Particleboard OSB MDF Plywood Solid wood panels Fibre boards (wet process) Cement bonded particleboards LVL
Initial type testing	either	Test method	ENV 717-1		
		Requirement	Release > 0,124 mg/m^3 air. See NOTE 4.		
	or	Test method	EN 120	EN 717-2	
		Requirement	Content > 8 mg/100 g to ≤ 30 mg/100 g oven dry board	Release > 3,5 mg/m^{2}h to ≤ 8 mg/m^{2}h or > 5 mg/m^{2}h to ≤ 12 mg/m^{2}h within 3 days after production	
Factory production control		Test method	EN 120	EN 717-2	
		Requirement	Content > 8 mg/100 g to ≤ 30 mg/100 g oven dry board	Release > 3,5 mg/m^{2}h to ≤ 8 mg/m^{2}h or > 5 mg/m^{2}h to ≤ 12 mg/m^{2}h within 3 days after production	

Source: EPF (2017)

Even though there are currently no EU-wide legally binding limit values for formaldehyde emissions from consumer articles, a **voluntary industry agreement** exists at the European level since 2007 with respect to formaldehyde emissions from wood-based panels. Specifically, the members of the European Panel Federation (EPF)[19] adopted an internal agreement to produce only class E1 wood-based panels as defined in EN 13986 and to no longer place higher formaldehyde emitting class E2 panels on the EU market (EPF, 2017). According to industry information, the vast majority of wood-based panels manufactured in the EU are classified as E1. However, class E2 panels are still marketed in the EU either because of EU manufacturers that are not compliant with the voluntary agreement[20] or because of extra-EU imports into Member States that still allow the marketing of class E2 panels. Voluntary agreements or commitments with respect to limiting formaldehyde emissions exist also in the European furniture and automotive industries (see Annex C.1).

[19] http://europanels.org/ [Accessed 7 January 2019]

[20] See, for example, a recent RAPEX alert submitted by Germany on high formaldehyde emitting particleboard originating from the Czech Republic (EC, 2018c).

Currently, eight EU Member States – Austria, Denmark, Germany, Greece, Italy, Lithuania[21], the Netherlands[22] and Sweden – have adopted **national legislation** to limit formaldehyde emissions from wood-based panels. These legally binding emission limits generally correspond to the E1 emission class (EPF, 2017). There are however Member States (such as Germany[23]) where more stringent test requirements (and thus lower emission limits) have been recently introduced.

Despite these risk reduction measures and despite the fact that formaldehyde emission levels in indoor environments are, in most cases, below the WHO Guideline for Indoor Air Quality, the estimations in Section 1.3.6.5 illustrate that, under conservative assumptions, consumers can be exposed to formaldehyde concentrations that exceed the WHO guideline value. In particular the use of high formaldehyde emitting materials, such as class E2 wood-based panels, in construction (e.g. in ceilings and walls) or finished articles (e.g. furniture) can lead to elevated formaldehyde concentrations in indoor air. In addition, temporary formaldehyde emission sources – e.g. cooking, smoking, burning candles, ethanol fireplaces – can contribute to peak formaldehyde concentrations in indoor air. Yet these sources are outside the scope of this restriction proposal.

1.5.2. How the situation would evolve without any regulatory measures

If no legislative action would be taken to restrict formaldehyde emissions from articles for consumer use, high formaldehyde emitting articles could still be marketed in the EU, potentially contributing to indoor air formaldehyde concentrations that exceed the WHO guideline value under specific circumstances. This is true in particular for the placing on the market of class E2 wood-based panels (or finished articles made from such panels) as discussed above.

Figure 8 gives an overview of the wood-based panels market by the main types of panels. Particleboard is by far the most produced panel type in the EU constituting nearly two-thirds (63%) of the overall production volume, followed by fibreboard (29%) and plywood (7%). Wood-based panels imported from outside the EU amount to around one-tenth of the EU's production volume with plywood accounting for more than 60% of the total import volume.

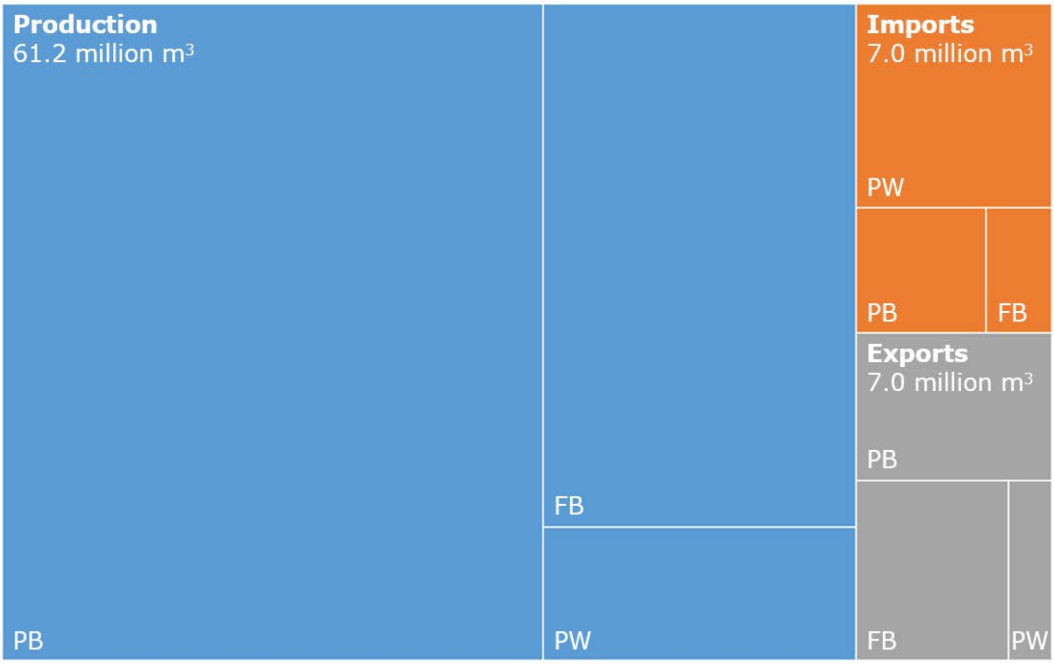
---

[21] EPF (2017) lists the Czech Republic instead of Lithuania but this was clarified in a subsequent exchange.

[22] National legislation in the Netherlands only refers to particleboard and the emission limit is somewhat higher than the one corresponding to the E1 emission class.

[23] In Germany although the emission limit values for wood-based panels have not been changed, it has been made mandatory to test these in accordance with EN 16516 starting from 1 January 2020. An adjustment factor of 2 has to be applied to results of chamber tests performed in accordance with EN 717-1.

Figure 8: EU production and extra-EU trade of wood-based panels, 2016

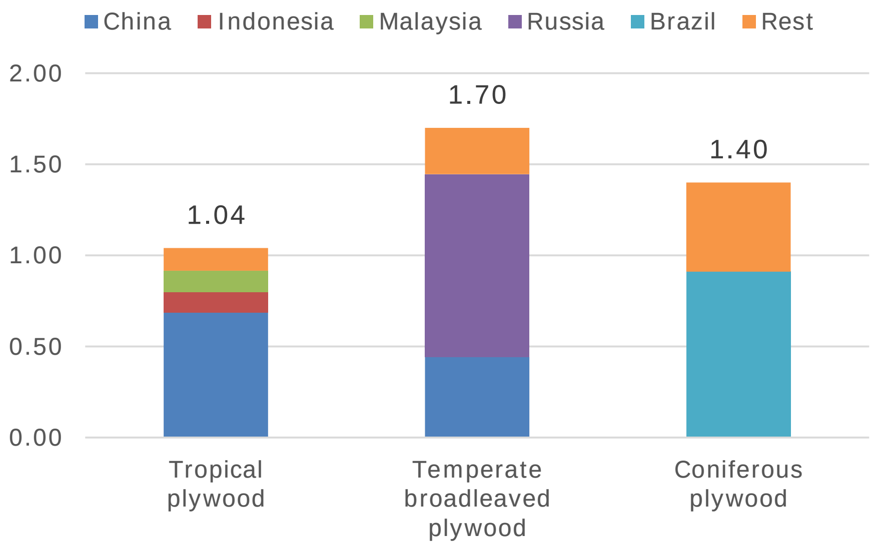


PW = Plywood, PB = Particleboard (incl. OSB), FB = Fibreboard (comprises MDF, hardboard and other fibreboard)

Source: Eurostat (2018c) and FAO (2018)

Figure 9 breaks down the main import category, plywood, by tree species and main trading partners. Coniferous plywood, mainly imported into the EU from Brazil, is generally assumed to fall into the E1 emission class. On the other hand, according to industry information, a substantial portion of tropical plywood and temperate broadleaved plywood – mainly supplied by China, Indonesia, Malaysia and Russia – can be assumed to be class E2 panels.

Figure 9: Extra-EU imports of plywood, 2016 (million m³)



Source: EPF (2017)

Table 13 shows the EU's total consumption of wood-based panels divided into the two formaldehyde emission classes – further information on the derivation of the E1/E2 breakdown is provided in Annex C.2 and detailed information by EU Member State on production, extra-EU trade in Annex C.3. Around 1.9 million m³ or just over 3% of the EU's total wood-based panel production are assumed to be class E2. Out of the wood-based panels imported from outside the EU, another 2.3 million m³ are assumed to be class E2 – corresponding to around one-third of all extra-EU imports. Taking into account also extra-EU exports, one can derive an apparent EU consumption of wood-based panels amounting to 61.2 million m³, of which an estimated 4 million m³ fall into the E2 formaldehyde emission class.

In other words, an estimated 6.5% of all wood-based panels consumed in the EU could be class E2 and potentially contributing to elevated formaldehyde concentrations in indoor air. An EU-wide restriction could help to avoid high formaldehyde emitting wood-based panels and other articles from being marketed in the EU. Such a restriction would at the same time lead to a harmonisation of the rules on formaldehyde emissions across the EU and ensure a level playing field between E1 compliant manufacturers and non-compliant manufacturers as well as imports.

Table 13: EU consumption of class E1 and E2 wood-based panels, 2016 (1 000 m³)

	All panels	E1 panels	E2 panels
EU production	***61 166***	***59 235***	***1 932***
Plywood	4 559	4 423	137
Particleboard	38 687	37 140	1 547
Of which: OSB	6 997	6 997	0
Fibreboard	17 920	17 672	248
Of which: MDF	12 381	12 133	248
Extra-EU imports	***6 974***	***4 716***	***2 258***
Plywood	4 303	2 797	1 506
Particleboard	1 784	1 231	553
Of which: OSB	67	50	17
Fibreboard	887	688	199
Of which: MDF	523	324	199
Extra-EU exports	***6 963***	***6 778***	***186***
Plywood	842	817	25
Particleboard	3 177	3 050	127
Of which: OSB	1 052	1 052	0
Fibreboard	2 944	2 911	33
Of which: MDF	1 670	1 637	33
Apparent EU consumption [1]	***61 177***	***57 173***	***4 004***
Plywood	8 020	6 402	1 617
Particleboard	37 294	35 321	1 973
Of which: OSB	6 013	5 996	17
Fibreboard	15 863	15 450	413
Of which: MDF	11 233	10 821	413

1. EU production plus extra-EU imports minus extra-EU exports.

Source: Eurostat (2018c), FAO (2018) and own calculations based on industry information

2. Impact assessment

2.1. Introduction

The impact assessment presented in this report employs a semi-quantitative approach to estimating the benefits and costs of the proposed restriction on formaldehyde emissions from articles for consumer use. In particular, the analysis includes an examination of the compliance costs of the proposed restriction and its cost-effectiveness in terms of reducing risk.

The following boundaries of the assessment were defined to capture the main impacts of the proposed restriction, the actors impacted and the timeframe these impacts are likely to occur:

- **Articles**: Although all consumer articles for indoor use where formaldehyde or formaldehyde releasing substances have been used in their production process would fall under the scope of the proposed restriction, the impact assessment focuses on wood-based panels. This is because wood-based panels used in both construction (e.g. in walls and ceilings) and finished articles (e.g. furniture and flooring) represent the major source of formaldehyde emissions within the scope of the Commission's request and, based on the evidence reviewed during the preparation of the proposed restriction, are expected to be the articles most affected. In terms of compliance costs the focus is therefore on impacts affecting the wood-based panels industry, even though other articles and the relevant industry sectors (e.g. automotive industry) would also have to comply with the proposed restriction. The impacts on these other industries are assumed to be negligible relative to the wood-based panels industry.

- **Supply chain**: The focus of the analysis is on EU-manufacturers and importers of wood-based panels and their upstream and downstream supply chains, from substance manufacturers to end-users.

- **Geographic**: The focus of the assessment is on the EU-28, as the final decision on whether or not to implement a restriction focuses mainly on weighing the various impacts of the proposed measure for the EU society. The impacts of the proposed restriction on actors in other jurisdictions, such as producers and suppliers of wood-based panels, are considered insofar as these may result in impacts to EU actors such as importers, wholesalers, retailers and consumers.

- **Temporal**: The impact assessment is presented for one reference year (2016) even though the costs and benefits of the restriction are assumed to continue further into the future. Impacts occurring in the reference year are therefore assumed to be representative for impacts occurring in future years. For the purpose of comparing the benefits and costs of the restriction, all monetised values are based on evidence and plausible assumptions about the 2016 EU production and extra-EU imports of wood-based panels.

2.2. Risk management options

2.2.1. Potential restriction options

As non-REACH legislation and other measures described in Section 1.5.1 and Annex D.1 are not suitable for managing the identified risks, a number of potential restriction options have been considered. These options are summarised in Table 14 with more detailed considerations provided in Annex D.2.

Table 14: Considerations related to potential restriction options

Potential restriction options (ROs)	Risk considerations	Impact considerations	Efficiency considerations	Risk reduction considerations
RO1: A full ban of formaldehyde releasing articles and mixtures	*Not consistent with the risk assessment*	*Substitutes for all uses unavailable, not proportionate to the risk*	*Enforceable but not practicable*	*High for articles, low for mixtures as already considered low risk*
RO2: Concentration limit for formaldehyde or specific formaldehyde releasing substances in articles and mixtures	*Difficult to link formaldehyde emissions to a concentration limit*	*Uncertain if proportionate to the risk*	*Enforceable but uncertain if practicable*	*Uncertain for articles, low for mixtures as already considered low risk*
RO3: Emission limit for wood-based panels consistent with formaldehyde emission class E1	*Consistent with the risk assessment*	*Proportionate to the risk*	*Enforceable and practicable*	*Medium to high*
RO4: Emission limit for articles consistent with formaldehyde emission class E1	*Consistent with the risk assessment*	*Proportionate to the risk*	*Enforceable and practicable*	*High*

2.2.2. Proposed restriction

Taking into account the initial analysis in Section 2.2.1 (and Annex D.2), the best risk management option appears to be RO4. The proposal is to restrict the placing on the market of articles releasing formaldehyde at concentrations greater than 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X to the restriction proposal. The conditions in Appendix X refer to the standard EN 717-1, which is the test method applied in most cases to obtain formaldehyde emissions from articles presented in this report (see Table B.8 in Annex B.4.2).

An emission limit lower than the one defined by the E1 emission class would not be consistent with the risk assessment. Not only are measured indoor air formaldehyde concentrations in most cases below the WHO guideline value, but the assessment in Section 2.5 also finds that the E1 emission class ensures that the WHO guideline value would be achieved under reasonable worst case assumptions. A lower emission limit would also lead to additional production costs and possibly additional investment costs, at least for some producers, depending on the level of such a limit (Nwaogu et al., 2013). Compared to the E1 emission limit, a lower emission limit is not supported by the available information from a proportionality point of view (see Annex D.2 for further details).

RAC ASSESSMENT

RAC supports a broad restriction with an emission limit for all articles. RAC agrees that other measures are not considered applicable to reduce the identified risks from articles placed on the market for consumer use. Concentration limits may actually be effective in reducing formaldehyde releases. However, the emission behaviour under the various article use conditions and types of materials and articles do not allow establishing a safe concentration limit, while what matters is the actual inhalation exposure resulting from the emissions. Other measures on parameters that have significant influence on the level of formaldehyde indoor concentrations like humidity, temperature and air ventilation may be taken into consideration, however achieving EU-wide building performance guaranteeing permanent low levels of humidity, low temperature and effective ventilation is neither realistic nor practicable. Generally, preventing emission from the sources is the measure of first choice to control indoor air quality, and user-dependent risk management measures (such as ventilation) to reduce air concentrations resulting from source emissions are not the most appropriate regulatory options.

The assessment performed by RAC has shown that the (P95/Max) indoor air concentrations of formaldehyde in houses/dwellings exceed 0.05 mg/m³ in the majority of the available studies (see Table 5 of the RAC opinion) and thus indicated an elevated RCR > 1. The existing voluntary agreements (e.g. to comply with formaldehyde emission class E1) did not succeed to demonstrate that sufficiently low concentrations were achieved. However, considering the RAC long-term DNEL, the existing E1 standard (0.124 mg/m³ as proposed by the Dossier Submitter) is not considered to represent an appropriate regulatory risk management measure for consumer protection from formaldehyde releasing articles, instead 0.05 mg/m³ (i.e. 40 %-E1, measured under the conditions specified in Appendix X) is proposed by RAC as emission limit.

Although limited, data for road vehicles (automobiles) also indicate frequent exceedance of the DNEL in the interior. RAC proposes therefore a limit concentration of 0.05 mg/m³ for vehicle cabin interior. As formaldehyde may be released from a wide range of vehicle components (articles and mixtures used in the production of vehicles), the options proposed under RO1, RO2 and RO3 will not be effective to control the formaldehyde concentration in the interior of vehicles. Compliance with an appropriate limit concentration of 0.05 mg/m³ will ensure that consumer risk arising from a multiplicity of potentially formaldehyde releasing components will be adequately controlled in the vehicles within the scope of the restriction proposal.

2.2.2.1. Scope of the proposed restriction

Articles covered by the restriction proposal

The proposed emission limit corresponds to the E1 emission class, which is defined for wood-based panels in EN 13986 and extends the E1 class to other articles, including, but not limited to, wood-based panels. The proposal covers consumer articles that are used only in indoor environments[24] as well as articles that can be used both indoors or outdoors (e.g. wood-based panels). The proposal covers articles where formaldehyde or formaldehyde releasing substances (formaldehyde releasers) are used in their production (either as such or in mixtures) and where formaldehyde releases occur during use as a result of either the "off-gassing" of residual formaldehyde or from the degradation and chemical reactions of other substances used in the production. The substances (releasing formaldehyde) used in the production of articles are not relevant to the restriction as only formaldehyde emissions will be

[24] Indoor environments are not limited to buildings but also include other environments such as cars, trucks, buses, trains, airplanes, mobile homes, or container homes.

considered. Proposing a formaldehyde emission limit is also consistent with legislation already in force in a number of Member States (see Section 1.5.1) and third countries.

Articles not subject to the restriction on CMR substances in clothing and footwear (entry 72 of Annex XVII of REACH), such as wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners, are within the scope of this current proposed restriction.

With regard to articles used in construction (e.g. wood-based panels, laminate flooring, wallpapers), it has to be considered that, although formaldehyde emissions from these articles affect the general population, they are mostly used by workers and professionals operating in the construction sector. In order to protect consumers from risks related to formaldehyde exposure, it is necessary to limit formaldehyde emissions from these articles at the time when they are placed on the market. For this reason, the restriction proposal is not strictly limited to articles intended for consumer use but relates more broadly to articles through which consumers can become exposed to formaldehyde.

Based on the information provided by stakeholders in the consultation, articles made of specific formaldehyde-based substances (e.g. POM, PF and MF resins) and articles with specific applications (e.g. PU foams) do not significantly contribute to formaldehyde concentrations in the indoor environment due to limited emissions of formaldehyde (already below the limit set by the restriction proposal) and due to their limited volume resulting, in the majority of the cases, in a very low loading factor (i.e. below 0.01 m^2/m^3). The Dossier Submitter has considered that for these articles, even though the health benefits for consumers deriving from their inclusion in the restriction proposal may be low, the costs incurred by industry would be very low (if any) and limited only to testing. However, the Dossier Submitter has clarified that alternative test methods can be used to measure formaldehyde releases from articles (see Appendix X) and has concluded that these articles are in the scope of the restriction proposal.

Road vehicles (e.g. cars, trucks, vans, buses and motor-homes), rail vehicles (e.g. passenger trains and trams), air vehicles (e.g. passenger aeroplanes) and water vehicles (e.g. passenger ships and boats) are complex articles. Some of the components used in the production of these articles are produced with formaldehyde or formaldehyde releasing substances and therefore they may release formaldehyde during reasonable foreseeable conditions of use.

Therefore, these articles are within the scope of the restriction proposal. In the case of road, rail, air or water vehicles, exposure to consumers to formaldehyde can only occur in the interior space, which can be defined as any space where people are present under normal and reasonably foreseeable conditions and are potentially exposed via inhalation.

Based on information received in the consultation, standard methods to measure formaldehyde in vehicle interiors are available and are commonly applied for road vehicles and aeroplanes. In such cases, the interior can be regarded as a “special test chamber” where the conditions for the measurement of the formaldehyde concentration are defined in the test standards (references included in the Appendix X on test methods).

For this reason, in the case of road vehicles and passenger aeroplanes, the restriction proposal sets a limit for the formaldehyde concentration in the interior space of 0.1 mg/m^3 corresponding to the WHO guideline value.

In the case of articles used in rail and water vehicles, the same requirements as for other articles apply as the interior can be reasonably assumed to be similar to living environments in homes and apartment buildings.

RAC ASSESSMENT

RAC agrees with the broad scope of the proposed restriction with the exemptions of the following: Aeroplanes.

RAC has come to the conclusion that passengers' risk in aeroplanes is adequately controlled and therefore proposes that a limit concentration for aeroplanes should not be applied.

RAC acknowledges that rail and water vehicles may be used by consumers for daily commuting but notes a lack of robust data on formaldehyde concentrations in the interior of rail and water vehicles. Even though no conclusion on a potential risk for these vehicles can be derived by RAC, the Commission may decide to include rail and water vehicles in the scope of the restriction. Thus, if agreed by the Commission that rail and water vehicles are in the scope of the restriction, the text of the entry should then indicate the requirements for all kind of vehicles within the scope of restriction (not only road vehicles and aeroplanes as in the original Dossier Submitter proposal).

Articles not covered by the restriction proposal

The following categories of articles are not intended to be covered by the restriction proposal (either out of the scope or exempted).

Articles that are only meant to be used in outdoor environments are not included in the restriction proposal.

Articles used by industrial and professional workers where such uses do not generate exposure to consumers. Formaldehyde exposure to workers is already regulated by other legislation. Binding occupational exposure limits of 0.3 ppm (8-hour exposure) and 0.6 ppm (short-term exposure) for workers exposed to formaldehyde have been included in the in the third amendment of Directive 2004/37/EC.[25]

The proposal does not cover articles produced without the use of formaldehyde or formaldehyde releasing substances or mixtures. In such articles formaldehyde is either not released (because it is not present in the article, e.g. glass articles) or it can be only released by decomposition of substances that are naturally present in the material of the article (e.g. lignin degradation in solid wood) or as a result of combustion.

Formaldehyde concentrations in textiles worn on or near the skin are already limited by the restriction of CMR substances in clothing and footwear, i.e. Regulation (EU) 2018/1513 (implemented as entry 72 of Annex XVII of REACH).

As formaldehyde is very unlikely to cause cancer through dermal exposure unless present at very high concentrations, the limits established by Regulation (EU) 2018/1513 are considered to be protective. In addition, the contribution of articles subject to entry 72, is unlikely to significantly contribute to inhalation exposure.

Likewise, with regards to skin sensitisation, the low concentrations to be expected from compliance with entry 72, are significantly below the concentration of 0.2% for skin

---

[25] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.164.01.0023.01.ENG [Accessed 24 January 2020]

sensitisation (see Section 1.3.6). Articles subject to entry 72 of Annex XVII of REACH are therefore exempted from the current restriction proposal.

Substances used as biocides under the Biocidal Products Regulation (BPR), i.e. Regulation (EU) 528/2012, are exempted from the current restriction proposal because the Commission is already developing regulatory activities under BPR. Specifically, formaldehyde is listed in Annex II to the Review Programme Regulation to be evaluated by Germany for the following product-types (PT):[26] disinfectants and algaecides not intended for direct application to humans or animals (PT2), veterinary hygiene (PT3), and embalming and taxidermist fluids (PT22). ECHA's investigation report on formaldehyde and formaldehyde releasers (ECHA, 2017b) provides an overview of all activities ongoing under BPR for known formaldehyde releasers. To date, no request has been submitted (or approved) under BPR for use of formaldehyde and/or formaldehyde releasers in wood preservatives (PT8) implying that such use is not permitted in the EU. BPR does not apply to imported articles (even if treated with biocides) and to articles releasing formaldehyde from the use of substances for other purposes than biocide. Such articles are therefore in the scope of the current restriction proposal.

Based on the information received from stakeholders and further advice from ECHA's Forum for Exchange of Information on Enforcement (Forum) and in line with the conclusions adopted by the Commission in regard to the restriction of CMR substances in clothing and footwear (restriction entry 72 of Annex XVII of REACH) the Dossier Submitter has concluded that articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and articles within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices should be exempted from the restriction proposal because of the need for such equipment and devices to fulfil specific requirements in terms of safety and functionality.

Articles covered by Regulation (EU) 10/2011 on food contact materials are considered unlikely to significantly contribute to the formaldehyde concentration in indoor environments and should be exempted from the restriction proposal. The food contact materials regulation establishes a migration limit for formaldehyde (expressed as mg of substance per kg of food) of 15 mg/kg. Although no information is available to the Dossier Submitter on the relationship between the migration limit of formaldehyde and emissions to indoor environments, formaldehyde emitting substances used in food contact materials (mostly MF plastics) have a very low release potential and it can be reasonably assumed that use by consumers is not continuous and limited to short periods.

There is a potential risk that formaldehyde migration from food contact materials to food may generate formaldehyde emissions from food during cooking. Food cooking, however, is considered a temporary source and it is not covered by the restriction proposal.

The Commission Directive amending Appendix C to Annex II to Directive 2009/48/EC[27] on toy safety (adopted in November 2019) establishes the following limit values for formaldehyde in toy materials:

- 1.5 mg/l (migration limit) in polymeric toy material

[26] Product-types are listed in Annex V of the BPR.

[27] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L1929&from=EN [Accessed 24 January 2020]

- 0.1 ml/m^3 (emission limit) in resin-bonded wood toy material
- 30 mg/kg (content limit) in textile toy material
- 30 mg/kg (content limit) in leather toy material
- 30 mg/kg (content limit) in paper toy material
- 10 mg/kg (content limit) in water-based toy material

The emission limit in resin-bonded wooden toy materials coincides with the emission limit of the current restriction proposal. With regard to other limits, the same consideration made for textile materials and food contact materials apply. For this reason, toys within the scope of the Directive 2009/48/EC should be exempted from the restriction proposal.

Second-hand articles are usually defined as articles that have already been sold to an end user in the EU but are subsequently transferred to another actor in the supply chain.[28] With regard to risks from formaldehyde emissions, the same considerations as for new articles apply (see Section 1.3.6.3) and hence wood-based products are considered the major contributors to formaldehyde concentrations in indoor air. However, based on information provided by stakeholders in the consultation, the likelihood that wood-based panels and construction materials are put on the second-hand market is very low whilst the presence of furniture on the second-hand market is more likely. For other types of articles, information provided by stakeholders shows that formaldehyde emissions are, in most cases, already below the limit of the restriction proposal when they are placed on the market. In relation to furniture, as well as for other articles, it has to be considered that formaldehyde releases decrease over time (as off-gassing of residual formaldehyde occurs) and that these releases are expected to be very limited in the majority of the cases, when these articles are sold (or transferred) as second-hand articles.

In addition, based on advice received from the Forum, the enforcement of second-hand articles is extremely problematic.

For these reasons, the Dossier Submitter concludes that second-hand articles should be exempted from the proposed restriction even though, based on the available information, it has not been possible to perform a quantitative assessment of the risks posed by second-hand articles.

RAC ASSESSMENT
RAC does not agree with the derogation for articles that are only intended for outdoor use under reasonably foreseeable conditions. From the perspective of enforceability, the Forum in their advice favoured the inclusion of articles for indoor and outdoor uses. RAC can follow this view and finds it likely that outdoor-only articles may be used (including storing) both indoors and outdoors contributing to indoor exposure and making a clear discrimination impossible. RAC agrees to the additional exemptions for second-hand articles and articles that are subject to other regulations.

[28] https://www.echa.europa.eu/documents/10162/13641/stocks_2nd_hand_goods_en.pdf/7cf76c3d-4e3a-a048-1233-8b3b9248b3df [Accessed 23 October 2019]

SEAC ASSESSMENT

Articles for industrial and professional use

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). In SEAC's understanding this derogation also covers articles which undergo further processing before being sold to industrial/professional end users, e.g. articles for the core of sealed doors for fire-protection, noise reduction and anti-burglar resistance, as well as for packaging, transportation and shielding/formwork of construction sites. The following provides further details for these examples.

Special doors

Special doors, such as doors for fire-protection, noise reduction and anti-burglar resistance, have to meet technical standards and are certified. Such doors usually consist of a functional core and a fixed enclosure, which also fulfils decorative purposes. Typical for such certified doors is the prohibition of subsequent processing by the customer. Drilling of holes, mechanical processing to change the size or replacement of the outer seal is prohibited or else the certificate is lost. In the event that a formaldehyde releasing material is used for the functional core, the fixed enclosure provides an almost gas-tight seal against possible formaldehyde emissions to the interior spaces.

The need to fulfil specific requirements in terms of safety and functionality (e.g. protection against fire, flue gas, burglary and noise) coupled with no/negligible residual formaldehyde emissions seem to justify an exemption for the core material of such doors from the proposed restriction.

Selected technical standards for special doors:

- DIN EN 1629:2016-03: Pedestrian doorsets, windows, curtain walling, grilles and shutters – Burglar resistance – Test method for the determination of resistance under dynamic loading

- DIN EN 1628:2016-03: Pedestrian doorsets, windows, curtain walling, grilles and shutters – Burglar resistance – Test method for the determination of resistance under static loading

- DIN EN 1627:2019-05 – Proposal: Pedestrian doorsets, windows, curtain walling, grilles and shutters – Burglar resistance – Requirements and classification

- DIN 18095-1:1988-10: Smoke control doors; concepts and requirements

- DIN EN 14351-2:2019-01: Windows and doors – Product standard, performance characteristics – Part 2: Internal pedestrian doorsets

- DIN EN 1634-1:2018-04: Fire resistance and smoke control tests for door and shutter assemblies, openable windows and elements of building hardware – Part 1: Fire resistance test for door and shutter assemblies and openable windows

- DIN 4109-1:2018-01: Sound insulation in buildings – Part 1: Minimum requirements – the technical standard also determines three sound insulation classes of sound insulation doors: sound insulation class 1 (32 dB Rw,P, e.g. doors leading from staircases into corridors), sound insulation class 2 (37 dB Rw,P, e.g. doors for schools) and sound insulation class 3 (42 dB Rw,P, e.g. for doctors' surgeries/hospitals)

Example of a certified sound insulation door of class 1 (32 dB), e.g. doors leading from staircases into corridors (Photo: Urban)

Packaging

SEAC welcomes this derogation also with regard to the packaging industry. Valuable and/or fragile cargo is often packed in large plywood or OSB boxes. There are also certified plywood/OSB boxes for the transport of dangerous goods which have to pass several tests to be granted a certification. These packaging materials are intended for the industrial sector and not for individual end users. There should also be no exposure for customers to formaldehyde in the intended use.

There are also certified plywood/OSB boxes for the transport of dangerous goods which have to pass several tests to be granted a certification. Essential cornerstones of the testing and approval requirements for wooden packaging are contained in the regulations of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Volume II, Appendix A, Part 6. The test requirements for rail, sea and air transport do not differ significantly.

A change in the material quality of plywood or OSB panels would, as with special doors, result in a wave of type tests to ensure the safety of the transport of e.g. chemicals, explosives, ammunition etc. Dangerous goods containers need to fulfil specific requirements in terms of safety and functionality are not intended for consumer use.

Example of a box for dangerous goods with UN classification (not visible) made of plywood and softwood with carrying ropes (Photo: Urban)

<u>Transportation</u>

Another example of an article that in SEAC's understanding would be exempted from the proposed restriction are EURO pallets used for transportation. EURO pallets are standardised equipment for handling a vast range of goods and consist of boards made of natural softwood and spacers between the boards made of a wood composite material. These composite materials consist of pressed wood sawdust and a binder/glue.

Example of a EURO pallet (Photo: Urban)

<u>Shielding/formwork of construction sites</u>

A comparable industrial/professional application without consumer exposure is the provision of wood-based materials (plywood, OSB, chipboard) for construction sites. The application is in the temporary protection of neighbouring areas against dust and noise as well as to restrict access. In addition, formwork for concrete construction is often also made of various wood-based materials.

Example of plywood and OSB are used for securing construction sites, for project signs and as formwork in concrete construction (Photo: Thiele)

2.2.2.2. Formaldehyde testing

Increasing concerns about formaldehyde exposure and the proliferation of regulations to limit such exposure generated a growing demand within industry to determine the formaldehyde emission potential of their products and hence the need for reliable test methods. Chamber tests as well as smaller scale derived test methods for formaldehyde (and other compounds) were developed to support the demand from industry and to fulfil regulatory requirements.

The test method EN 717-1 (CEN, 2004a) was developed to measure formaldehyde emissions from wood-based panels and it is the reference method for determining the formaldehyde emission classes E1 and E2 of wood-based panels defined in EN 13986 (see Table 11 and Table 12). EN 717-1 has also been successfully used, over the years, to measure formaldehyde emissions from a wide range of articles, such as flooring materials, furniture, textiles, insulation materials, and other articles suspected to release formaldehyde in the environment during foreseeable conditions of use (see column "Used method" in Table B.8 of Annex B.4.2). Over the last two decades, large test chambers (up to 48 m^3) have been built to measure the emissions of complete furniture groups (e.g. kitchens, bedrooms, living rooms, and office furniture) and smaller chambers (0.225 m^3 and 1 m^3) have been used to determine formaldehyde emissions of samples of construction materials, including wood-based panels. All methods are described in EN 717-1 including typical test situations.

In formaldehyde emitting articles in the scope of this restriction proposal, the release of formaldehyde is due to formaldehyde or formaldehyde releasing substances (e.g. resins) used in the manufacturing process of these articles. These substances may either constitute the material of which the article is made – as in the case of resins used in the production of wood-based panels, foams used in the production of car seats, insulation panels used in construction, or cross linked polyurethane polymers used in the production of a variety of articles – or used as glue to bind together two or more pieces constituting the article. The chamber method has no limitations with respect to the material of the article, though it may require some treatment in relation to the shape of the article to be tested. The results of testing performed on different types of articles are reported in the form of a formaldehyde concentration (mg/m^3) in the air of a test chamber. Table D.2 in Annex D.3 to this document includes a list of existing EN standards for articles with formaldehyde emissions classes based on EN 717-1. Other methods based on different techniques are available for the determination of formaldehyde emissions from articles. It is however crucial that, in order to comply with the requirements in this restriction proposal, a reliable correlation is established and documented between the method used and the conditions specified in Appendix X. The appendix also provides considerations on how to rely on alternative test methods to ensure compliance with the emission limit set by the restriction proposal. Further information on EN 717-1 and another standardised chamber method (EN 16516) are presented in Annex D.3. Testing of complex articles (e.g. pieces of furniture) is not needed if their components do not contain formaldehyde or formaldehyde releasing substances or if formaldehyde emissions of individual components are within the limit established in the current proposal. However, when formaldehyde or formaldehyde releasing substances or mixtures (e.g. lacquers or glues) are added during the production process of complex articles, testing requirements apply. It is the responsibility of producers and importers of articles to guarantee that articles placed on the market comply with the provisions of this restriction proposal.

RAC ASSESSMENT

Articles including wood-based panels

RAC concludes that a restriction using an emission limit of 0.05 mg/m³ measured in a test chamber for articles used in building interiors (wood-based panels and other consumer products releasing formaldehyde within the scope of the restriction, e.g. furniture, flooring, wall coverings, etc.) under the conditions specified in Appendix X is consistent with the risk assessment as outlined in the RAC opinion.

RAC agrees with the options included in the Appendix X for the measurement of formaldehyde releases from articles. The outline of applicable test methods and the conditions of their applications allows testing of a broad range of articles. It gives also flexibility and, if established, allows the use of already applied standard test methods preventing double testing if other test methods based on different conditions than those outlined in point 1 of Appendix X are preferred. As described in point 2 of Appendix X, if a test method based on different conditions is used, compliance shall be demonstrated based on an acceptable correlation with the prescriptions outlined in point 1 of Appendix X.

RAC agrees that no additional effort is needed for manufacturers of articles who have already adopted test methods based on EN 717-1. Manufacturers of construction products under CPR may continue to use their existing test methods (based on EN 16516 for CE marking) and product standards provided that they are able to confirm the equivalency to the reference conditions outlined in Appendix X for the article of concern.

Vehicles

The Background Document and consultation comments received informed on test methods following ISO 12219-1 for formaldehyde measurement in cars. RAC agrees with the European Automobile Manufacturers Association (ACEA) that testing of the vehicle cabin air instead of testing individual construction components is the most suitable way to control formaldehyde concentrations in vehicles' interiors.

In order to ensure protection of passengers and drivers, RAC supports the broad scope of the restriction – as compared to the mutual resolution UNECE (2017) – applicable to various kind of passenger road vehicles including cabin interior of trucks, buses, caravans and other road vehicles. RAC is not aware of specific industry testing standards for these vehicles and points out that the necessary flexibility as regards to the development, implementation and application of appropriate harmonised testing standards in the EU and also used internationally by non-EU manufacturers should be granted for. ISO 12219-10 on Interior air of road vehicles

(Part 10: Measurement methods of diffused volatile organic compounds (VOC) – Trucks and buses) is under development (drafting start date: June 2019).

No information on established test methods and standards is available for passenger ships, trains or aeroplanes (RAC recommends the latter not to be included in the scope). Indoor (cabin) measurements in vehicles have been established by the automotive industry and are considered to be adaptable to other vehicles. Starting from the ISO norms for automobiles specific adaptations are needed for rail and water vehicles to develop standard testing procedures specific for these vehicle types. These new standards could be developed as EU (ISO) norms that include the relevant conditions of testing (temperature, ventilation rate, closed doors, etc.). RAC notes that the text of Appendix X may be extended with regards to the application for all vehicles within the scope.

2.2.2.3. Transition period

The proposed emission limit has already been adopted by the vast majority of EU manufacturers of wood-based panels as per the voluntary industry agreement to only produce class E1 wood-based panels. Other types of articles, where lower formaldehyde emitting materials are used than those in the production of wood-based panels, are assumed to be already within the range of the proposed emission limit. For this reason, a transition period of 12 months after entry into force of the restriction is considered sufficient for industry to adjust.

RAC ASSESSMENT

RAC recommends a transition period of 24 months after entry into force for all articles including wood-based panels and all vehicles within the scope of this restriction.

Although 12-months transition time was initially considered by RAC for the sector producing wood-based panels where voluntary test standards are already in place, a longer transition period is considered appropriate taking into account the lower emission limit proposed by RAC, assumed changes in production processes, limitations on laboratory capacities and the need to test the articles after production changes not only in relation to the emission of formaldehyde (and possibly other substances) but also in relation to other essential properties/performance criteria.

RAC acknowledges that test methods are in place for voluntary measurements for automobiles and aeroplanes (note: RAC does not support the restriction proposal on aeroplanes). For other sectors (producing articles other than wood-based panels and for vehicles other than cars) it is unknown to RAC to what extent manufacturers have already established appropriate test methods on testing of articles and vehicles. Since June 2019, standard test methods for trucks and buses are under development (ISO 12219-10).

In order to allow the development/adoption of standard test methods and the establishing of the testing, a transition time of 24 months is considered appropriate for all articles and all vehicles within the scope.

2.3. Restriction scenario

2.3.1. Behavioural responses

The proposed restriction on formaldehyde release from consumer articles is based on the assumption that the market will be able to comply with the restriction within 12 months of its entry into force. It is assumed that this would take place around the year 2020. This should give sufficient time for all actors to adapt as a large part of industry is already in compliance due to voluntary agreements and national legislation. Moreover, actors outside the EU would also have time to adapt their production process in order to meet the proposed emission limit.

2.3.2. Transition to alternatives

Because of technical and economic properties and the substantial use of formaldehyde in the manufacturing of formaldehyde-based resins, large scale substitution is unlikely. Also, the proposed restriction sets a limit on the permissible formaldehyde release from consumer articles rather than restricting the use of formaldehyde or formaldehyde releasing products. This includes the use of UF resins which are the most commonly used formaldehyde-based resins in wood-based panels and are associated with higher release of formaldehyde than other formaldehyde and non-formaldehyde-based resins (see Section 1.3.6.3). The commitment of the European wood-based panels industry to only produce class E1 panels demonstrates the technical and economic feasibility of using UF resins in such a way as to be in line with the proposed restriction. Thus, no major transition away from UF resins towards alternative resins are expected as a result of the restriction proposal. It is however to be considered that the classification of formaldehyde as Carc. 1B is increasing industry's focus to develop formaldehyde-free or low formaldehyde emitting products. This is not only true for products for consumer use but also for professional and industrial uses of formaldehyde-based products, in particular in the wood-based products sector, as highlighted by France in their analysis of risk management options (ANSES, 2016). Annex D.4 provides an overview of alternatives to UF resins.

RAC ASSESSMENT

Limited information has been presented by the Dossier Submitter on potential risk from alternatives to formaldehyde-based resins. RAC compared hazards of the various alternatives based on C&L data (harmonised and self-classification) but for an assessment of human health risks, the individual ingredients need to be examined in more detail. Potential hazards can be expected due to various different chemicals used for making these resin alternatives.

2.4. Economic impacts

Given that for wood-based panels there is already a voluntary industry agreement in place which is consistent with the proposed restriction and that legally binding emission limits exist already in a number of EU Member States, the economic impact of the proposed restriction is expected to be limited. The majority of costs are expected to accrue from replacing the amount of class E2 panels marketed in the EU with costlier-to-produce class E1 panels. Additional costs are expected in the form of enforcement costs incurred by Member State authorities to ensure compliance with the restriction and the imposed emission limit. Investment costs and testing costs are expected to be negligible and were not estimated.

2.4.1. Production costs

According to EPF, the production of class E1 panels is expected to be associated with higher costs than the production of class E2 panels. The difference in production costs stems from the use of cheaper resins containing more free formaldehyde in class E2 panels, which means better/faster bonding and in turn cheaper production. The exact difference in production costs is however not known and an approximation had to be made. EPF provided a range of 10-15% for the production cost difference between class E1 panels and lower emitting panels complying with the E.LES standard[29] – a range that, according to EPF, was also confirmed by its members.[30] The Dossier Submitter chose the lower end of the range provided by EPF as an approximation for the production cost difference between class E1 and class E2 panels.[31] In other words, the production of class E1 panels is assumed to be associated with costs that are 10% higher than those for class E2 panels.

For EU-manufactured class E2 panels, the costs of changing production to class E1 panels will be borne by EU society – either by the manufacturers themselves and/or consumers, depending on the extent to which the manufacturers are able to pass through these costs. For imported class E2 panels, the economic impact associated with a switch to class E1 panels will depend on the ability of non-EU manufacturers to pass through increased production costs to consumers in the EU. The part of the extra costs that non-EU manufacturers are able to pass through to EU consumers represents a cost to EU society. However, in case a pass through is not possible, the extra costs are borne by non-EU manufacturers.

Combining the volume of class E2 panels marketed in the EU (see Table 13) with information on panel prices, Table 15 provides an order of magnitude estimate of the change in production costs expected as a result of the proposed restriction. For a reference year, 2016, this cost increase to the EU society is estimated to be in the range of €28-79 million, depending on the extent to which non-EU manufacturers are able to pass through production cost increases to EU consumers. The lower end of this range represents a situation in which non-EU manufacturers shoulder all additional costs, whereas the higher end refers to a situation where non-EU manufacturers are able to pass through the entire cost increase to consumers in the EU. While it is possible that non-EU manufacturers can pass through some of these extra costs to EU consumers, this is considered not very likely as they are assumed to compete on price. Hence, a value of €28 million represents the Dossier Submitter's central estimate for the production cost increase associated with the proposed restriction.

Investment costs are expected to be negligible as no new equipment or modification of existing equipment is needed to switch from the production of class E2 panels to the production of class E1 panels.

[29] In December 2016, EPF announced the so called European Low Emission Standard (E.LES), which sets different emission limits for different product groups. Under E.LES the formaldehyde emission limit for fibreboard and OSB is consistent with E1 (= 0.1 ppm or 0.124 mg/m^3) but is set to a lower value of 0.065 ppm (= 0.08 mg/m^3) for particleboard and plywood. E.LES is available to all EPF members for use but without any form of obligation (EPF, 2017).

[30] According to EPF, the price difference depends on the panel characteristics, with the price difference being smaller for standard grade boards and higher for boards that need high mechanical performance and/or strong resistance to humidity.

[31] The lower end of the range was chosen as it is assumed that an emission reduction from E2 level to E1 level is more easily achieved than a reduction from E1 level to lower emission levels foreseen by E.LES (for particleboard and plywood).

Table 15: Estimated increase in production costs following restriction, 2016

	Price E1 [2] [€/m^3]	Price E2 [3] [€/m^3]	Δ Price [€/m^3]	E2 panels [1 000 m^3]	Δ Costs [Million €]		
EU production [1]				***1 746***	***27.9***		
Plywood	620	564	56	112	6.3		
Particleboard	135	123	12	1 420	17.4		
Fibreboard	215	195	20	214	4.2		
Share of cost increase passed through to EU consumers:					**0 %**	**50 %**	**100 %**
Extra-EU imports				***2 258***	***0.0***	***25.5***	***51.0***
Plywood	310	282	28	1 506	0.0	21.2	42.4
Particleboard	108	98	10	553	0.0	2.7	5.4
Fibreboard	172	156	16	199	0.0	1.6	3.1
Total (EU production + extra-EU imports)				***4 004***	***27.9***	***53.4***	***78.9***

1. Extra-EU exports have been deducted.
2. Prices for EU-manufactured particleboard and fibreboard and for imported plywood are based on industry information. Based on own calculations using Eurostat (2018c) data, EU-manufactured plywood is assumed to be double the price of imported plywood and prices for imported particleboard and fibreboard are assumed to be 80% of EU-manufactured panels.
3. Calculated under the assumption that E1 panels are 10% more expensive than E2 panels.

Source: Own calculations based on industry information and Eurostat (2018c)

2.4.2. Testing costs

The proposed restriction sets an emission limit for formaldehyde released from articles measured in a test chamber used under the conditions described in Appendix X (these correspond to the conditions described in EN 717-1). Testing costs would concern all companies that supply, retail or import formaldehyde releasing articles within the scope of the restriction proposal as they would need to make sure that these comply with the formaldehyde emission limit. The definition of reference conditions is necessary as changes in these conditions (e.g. temperature, humidity or air exchange rate) may affect formaldehyde emissions from articles. However, as outlined in Appendix X, the restriction proposal does not impose the use of a specific test method and suitable test methods based on different conditions or different principles (hereafter alternative test methods) can also be used to demonstrate compliance. With regard to wood-based panels, only a limited number of manufacturers have their own test chambers according to industry information. In practice, wood-based panel producers control formaldehyde emissions during production via the smaller scale derived test methods, EN 717-2 and EN 120[32], in accordance with quality control limits based on correlations with EN 717-1.

Similarly, producers, retailers or importers of articles other than wood-based panels can use alternative test methods that better suit their needs to measure formaldehyde emissions. According to information received in the consultation, sector-specific methods are already in use by producers, retailers and importers in different industries. Under the proposed

[32] EN 120 has been replaced by ISO 12460-5 but EN 120 is still commonly referred to in relevant standards and publications. See Annex D.3 for further information on the derived test methods.

restriction, these actors can continue using test methods that are already in place, as long as they are suitable. Compliance with reference test conditions can be demonstrated by performing initial parallel testing and establishing a relationship between the results obtained with alternative test methods and results obtained with a test method based on the reference conditions. Parallel testing need only be repeated if the quality or the characteristics of articles produced change significantly (e.g. material type, production process, use of additional or different formaldehyde releasing substances). Producers, retailers and importers of articles can also rely on any existing correlations established (e.g. published in specialist literature) between alternative test methods and the reference test conditions. Appendix X provides considerations on how to rely on alternative test methods.

Overall, no significant additional testing costs for industry are expected from implementing the proposed formaldehyde emission limit for articles for consumer use. This is because routine testing appears to be established already among EU manufacturers, in particular with regard to the smaller scale test methods which are derived from the proposed reference test method or other alternative methods.

2.4.3. Enforcement costs

The average cost incurred by Member State enforcement authorities to ensure that EU-28 economic actors comply with the restriction are approximately €60 000 per year on average. This figure is considered as illustrative of the order of magnitude of the potential costs rather than a prediction of the actual costs of enforcing a particular restriction. As described in Annex D.5, the value is based on average enforcement costs over a whole year. However, in reality enforcement activities are often undertaken through specific campaigns and thus the costs are not divided evenly over the years. Furthermore, the value does not include the costs of testing carried out by a Member State during enforcement of a restriction.

An enforcement project carried out in 2014 by the Swedish Chemicals Agency (KEMI, 2015) also helps to illustrate the potential additional costs to enforcement authorities from the proposed restriction. In Sweden, permissible formaldehyde release from wood-based panels is regulated in Chapter 8 of the Swedish Chemicals Agency's Regulations on Chemical Products and Biotechnological Organisms (KEMI, 2017). This regulation stipulates that wood-based panels must not release formaldehyde in quantities exceeding 0.124 mg/m^3 in the air of a test chamber if analysed using the standard EN 717-1. In other words, only class E1 wood-based panels are allowed on the Swedish market.

To check industry's compliance with the national legislation, KEMI inspected nine suppliers and tested a total of 18 wood-based panels (i.e. two boards per supplier). The tested boards covered plywood, particleboard, OSB as well as MDF and were mainly bonded by UF resins. Five samples were taken from each of the 18 boards. These samples were subject to initial screening using the EN 717-2 test method because it is faster and cheaper than the reference method EN 717-1. If the initial screening indicated that the average emissions of the five samples of a given board could exceed the E1 limit value, the highest-emitting of the five samples was put into the EN 717-1 test chamber for further testing. In total, seven wood-based panels out of the original 18 boards were further tested in this manner. For one of these panels the EN 717-1 method confirmed that the E1 emission limit was clearly exceeded leading to a sales ban for the concerned supplier.

KEMI also found some limitations in the use of test method EN 120 for routine production control by companies since this method did not always correlate with the reference method

EN 717-1. This led KEMI to recommend that suppliers verify a reliable correlation between their used test methods and the reference method EN 717-1 prior to using them.

Overall, the enforcement project comprised 90 tests according to EN 717-2 (= 18 boards x five samples per board) and seven tests according to EN 717-1. Together with costs for sampling, a total of around €40 000 were spent on testing for which KEMI commissioned the SP Technical Research Institute of Sweden. In addition, three KEMI employees were working for a total of around 400-500 hours on the project.

2.4.4. Conclusion on economic impacts

Given that there is already a voluntary agreement in place in the EU's wood-based panels industry that is in line with the proposed restriction and that the proposed emission limit is already legally binding in a number of EU Member States (at least for wood-based panels) the economic impact of the proposed restriction is expected to be limited. The majority of costs are expected to be borne by EU manufacturers and importers of class E2 panels and result from a switch to more expensive class E1 panels. Table 16 provides a summary of the economic impacts.

Table 16: Summary of economic impacts

Economic impact category	Cost estimates for 2016 (and after)
Production costs	€27.9 – 78.9 million
Investment costs	Not estimated, likely negligible
Testing costs	Not estimated, likely negligible
Enforcement costs	€0.06 million
Total	***€28.0 – 78.9 million***

2.5. Human health impacts

The benefits of the proposed restriction in terms of reducing risks to human health are expected to be limited as indoor air formaldehyde concentrations are already today below the WHO guideline value in most cases. Nonetheless, the proposed restriction can help to avoid exposure to high formaldehyde concentrations in specific situations, such as when moving into a newly built home where high emitting materials have been used in construction and finished articles.

The human health assessment in Section 1.3.4 concluded that the WHO guideline value of 0.1 mg/m^3 (30-minute average concentration) should be protective against both acute and chronic sensory irritation in the airways and eyes in the general population and in particular in potential sensitive subpopulations. The short-term guideline will also prevent effects on lung function as well as long-term health effects, including nasopharyngeal cancer. From a human health perspective, the impact assessment is therefore concerned with the effectiveness of the proposed restriction in keeping formaldehyde concentrations in indoor air below (or at) the WHO guideline value.

This section first gives an estimate of the exposure reduction expected from the proposed restriction in a situation where class E1 wood-based panels replace class E2 panels as construction material in the reference room defined in Section 1.3.6.5. The section then goes on to estimate the number of new homes that could potentially be built using the current market volume of class E2 wood-based panels and the total number of inhabitants who would be the main beneficiaries of the exposure reduction resulting from a restriction.

2.5.1. Exposure reduction from proposed emission limit

Figure 10 is based on the results of the estimated formaldehyde concentrations in indoor air presented in Section 1.3.6.5 and illustrates the relation between formaldehyde emissions from wood-based panels and reference room concentrations for different loading factors of panels. The loading factors correspond to the three sub-scenarios shown in Table 8. The formaldehyde emission rate of wood-based panels shown on the horizontal axis refers to uncovered material[33] and it is assumed that all the wood-based panels emit at the same rate. All other assumptions regarding the reference room (see Table 7) and the exposure scenario (see Table 8) apply. At formaldehyde emissions of wood-based panels equal to zero, the vertical axis shows a reference room concentration of 43 µg/m^3. This vertical intercept refers to the median of the combined concentration resulting from all other sources (i.e. paint, laminate, furniture, textiles, etc.) in the exposure scenario. It should be noted that even though this vertical intercept refers to a median concentration, it is still a very conservative estimate as, despite the exclusion of wood-based panels, the resulting baseline concentration (43 µg/m^3) is already higher than what is generally observed in terms of average formaldehyde concentrations in indoor environments (20-40 µg/m^3, see Section 1.3.6.6).

The proposed restriction would limit the permissible formaldehyde release from wood-based panels (and other articles) in accordance with emission class E1 as defined in EN 13986. This emission limit is represented in Figure 10 by the vertical line labelled “E1” at 124 µg/(m^{2}h).[34] According to industry information class E2 panels are assumed to have on average formaldehyde emissions that are 50-100% above the E1 emission limit, which is indicated by the vertical lines labelled “E1 + 50%” and “E1 + 100%” at 186 and 248 µg/(m^{2}h), respectively.

Although Figure 10 is constructed for three different loading factors of wood-based panels, the analysis here focuses on the central scenario, i.e. wood-based panels used in the ceiling and in two of the walls (L = 1.0 m^2/m^3). The other two scenarios are discussed as part of the uncertainty analysis in Section 3.1. Considering a newly built room with a 1.0 m^2/m^3 loading factor of wood-based panels, formaldehyde concentrations between 113 and 136 µg/m^3 could be expected assuming that all panels are of emission class E2 and are emitting at the same rate between 186 and 248 µg/(m^{2}h). The WHO guideline value of 0.1 mg/m^3 (indicated by the horizontal line at 100 µg/m^3) would be exceeded in such a situation. If, however, all class E2 panels were replaced by panels emitting exactly at the E1 emission limit, i.e. 124 µg/(m^{2}h), the expected concentration would be 90 µg/m^3 and hence below the WHO guideline value. In

---

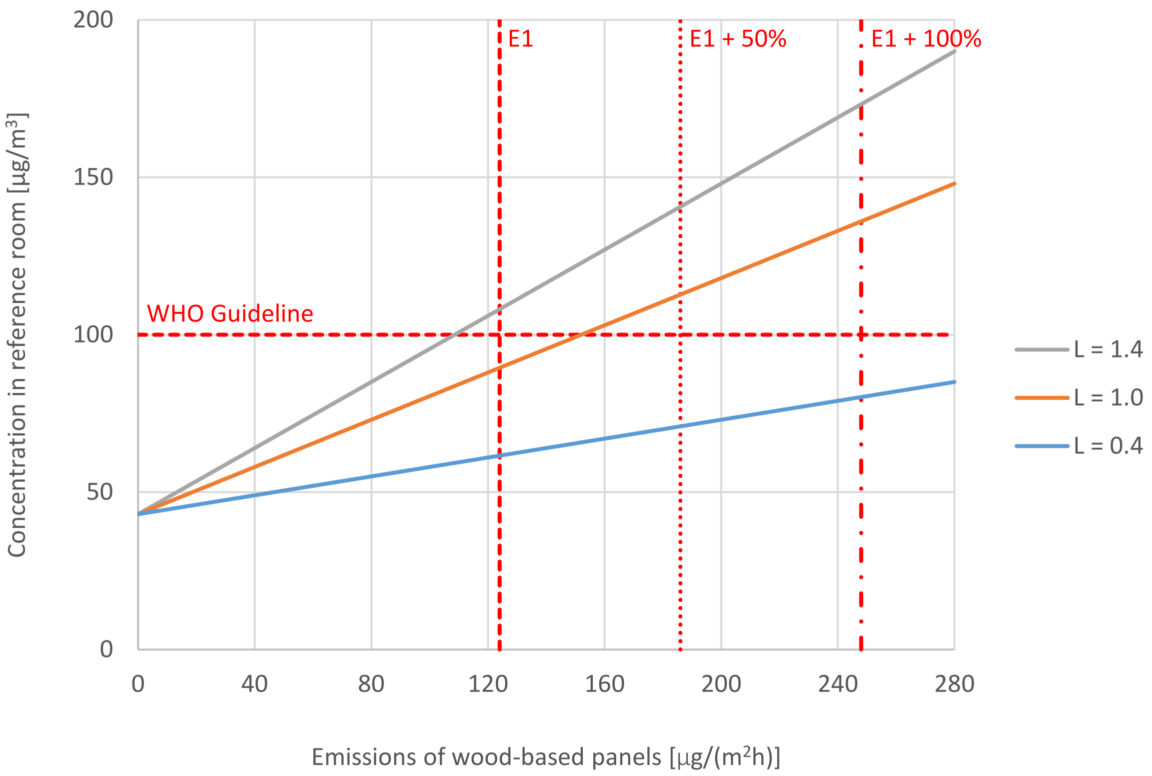
[33] Even though the emission rate pertains to uncovered wood-based panels, a 75% reduction of the formaldehyde emission rate is assumed as in the exposure scenario in Section 1.3.6.5.

[34] The proposed restriction refers to the formaldehyde concentration (C, µg/m^3) in the air of a test chamber used under the conditions set in Appendix X rather than an area specific emission rate (SER_A, µg/(m^{2}h)). But since Appendix X sets the air exchange rate (ACH) to 1 h^{-1} and the loading factor (L) to 1 m^2/m^3, similar to EN 717-1, 124 µg/(m^{2}h) is equal to 124 µg/m^3 according to equation $C = SER_A \cdot L/ACH$ (see Annex B.4.5).

other words, the proposed restriction would be effective in preventing exceedances of the WHO guideline value.

As discussed in Sections 1.3.6.3 and 1.3.6.4, formaldehyde emissions decline over time and formaldehyde concentrations are typically found to be higher in new homes. The analysis presented here focuses on newly built rooms/homes only. It is therefore expected that, with the passing of time, formaldehyde concentrations in homes above the WHO guideline value fall below the guideline value simply as a result of formaldehyde decay. Even if this is the case, the proposed restriction could help to avoid periods in the order of up to several months in which people in newly built homes are exposed to formaldehyde concentrations above the WHO guideline value.

Figure 10: Formaldehyde emissions vs reference room concentrations



Note : The baseline concentration represented by the vertical intercept (43 µg/m³) is the median of the combined concentration resulting from all sources except wood-based panels ("Wall 1" and "Ceiling 1") in the exposure scenario presented in Section 1.3.6.5. It has been derived under the same assumptions (i.e. loading factors, sink, etc.) that were applied in the exposure scenario in Section 1.3.6.5. The loading factors shown in the legend of the figure refer to only wood-based panels and not the total of all sources. The reference room concentration lines have been derived under the same assumptions (i.e. ACH, sink, emission reduction from covering, etc.) that were applied in the exposure scenario in Section 1.3.6.5.

Source: Adapted from Marquart et al. (2013)

2.5.2. Number of homes and individuals benefitting from exposure reduction

As shown in Table 13, the market volume of class E2 wood-based panels consumed in the EU was estimated at 4 004 000 m³ for the year 2016. However, not all of these are used for building and construction purposes. According to information provided by EPF (2017), 40% of plywood, 22% of particleboard and 16% of MDF are used as building or construction material. This translates into a total of 1 147 000 m³ or, assuming an average thickness of 16 mm, 71 699 000 m² of class E2 panels that were available as building and construction material in 2016 (see Table 17). Although this estimate likely includes outdoor applications, it is assumed that the entirety of the class E2 wood-based panels in building and construction is used indoors.

Table 17: Class E2 wood-based panels used as building and construction material, 2016

Type of wood-based panel	1 000 m³ E2 panels consumed in EU in 2016 [1]	% used in building / construction	1 000 m³ used in building / construction	1 000 m² used in building / construction [2]
Plywood	1 617	40	647	40 437
Particleboard	1 973	22	434	27 134
MDF	413	16	66	4 128
Total	***4 004***		***1 147***	***71 699***

1. See "Apparent EU consumption" in Table 13.
2. Assuming average thickness of 16 mm.

Source: Own calculations based on EPF (2017)

According to Eurostat (2016) data, the average dwelling size in the EU is 96 m² (see Annex D.6.1). Assuming a room height of 2.5 m – which corresponds to the height of the European Reference Room (see Table 7) – yields a volume of 240 m³ for the average home in the EU. In the central exposure scenario (sub-scenario B in Table 8) the loading factor of 1.0 m²/m³ for wood-based panels implies that 240 m² of panels are used for a home measuring 240 m³. This means that approximately 300 000 dwellings could be built per year with the amount of class E2 wood-based panels derived in Table 17 (= 71 699 000 m² / 240 m²). Eurostat (2018a) data shows that the average household in the EU had 2.3 members in 2016 (see Annex D.6.2). This means that under the central scenario up to 690 000 individuals (= 300 000 x 2.3) could benefit from the exposure reduction described in the previous section.

RAC ASSESSMENT

RAC concludes that employed materials (construction materials and other articles), which are compliant with the E1 class emission limit of 0.124 mg/m³ according to EN 717-1 chamber test, may lead to significantly high formaldehyde air concentrations in indoor environments that may exceed the long-term DNEL and also the WHO guideline value.

RAC conducted an additional assessment and based thereon RAC does not agree that the limit concentration proposed by the Dossier Submitter will be sufficiently effective for risk reduction. The emission limit for articles proposed by the Dossier Submitter is considered to have no significant effect in terms of risk reduction, in particular for Member States that have implemented E1 limit already for certain categories of articles.

RAC expects that lowering the emission limit for construction materials to 0.05 mg/m³ (measured under the conditions specified in Appendix X) will lead to a significant reduction of mean and maximum concentrations (see Figure 4 of the RAC opinion).

<u>Furniture</u>

As furniture products significantly contribute to the indoor formaldehyde concentrations it is expected that the proposed restriction will effectively reduce the risks.

Vehicles

Based on the literature data (see above) and the limited measurement data on cars submitted during the consultation, RAC expects a reduction of exposure in cars from the implementation of the RAC proposal. As cabin concentrations in aeroplanes are already below 0.05 mg/m³ (assumed that data are representative), no risk reduction effect is expected for this area. No statement on risk reduction is possible for other types of vehicle due to the lack of data.

RAC notes that the effectiveness of the proposed restriction can only be assessed for uses within the scope as outlined in the proposal. The Dossier Submitter identified other temporary sources of formaldehyde release (mainly as combustion product or from mixtures). RAC supports not to address these short-term risks within this restriction proposal.

2.6. Other impacts

2.6.1. Social impacts

This section presents an overview of potential impacts of the proposed restriction on various relevant actors. As mentioned in the introduction to the impact assessment (Section 2.1), the focus is on the supply chain of wood-based panels, as this is expected to be the sector most affected be the proposed restriction.

2.6.1.1. Producers of formaldehyde and formaldehyde-based resins

No major substitution of formaldehyde and formaldehyde-based resins is expected as a result of the proposed restriction owing to the technical and economic properties and the substantial use of formaldehyde in the manufacturing of formaldehyde-based resins. Furthermore, the proposed restriction does not foresee a ban of formaldehyde or formaldehyde-based substances. Therefore, no impacts on producers of formaldehyde and formaldehyde-based resins are expected.

2.6.1.2. EU manufacturers of wood-based panels

The majority of EU producers of wood-based panels, representing more than 95% of EU panel production, have already subscribed to a voluntary industry agreement to only produce class E1 wood-based panels. No major impact is expected on this category of actors. The impact on producers of wood-based panels which are not part of the voluntary agreement is taken into account in the calculation of economic impacts (Section 2.4.1). Finally, the producers of class E2 wood-based panels can still export to non-EU countries as manufacturing is not included in the scope of the proposed restriction.

2.6.1.3. Non-EU manufacturers of wood-based panels

Non-EU manufacturers of wood-based panels are not affected by the proposed restriction as long as their products comply with the E1 emission class. However, producers of class E2 panels are expected to face additional costs as they either have to exit the EU market or switch to the production of class E1 panels. The impact on non-EU manufacturers of wood-based panels is considered in the calculation of economic impacts (Section 2.4.1). In the central scenario, it was assumed that extra costs related to imports into the EU are not passed on to EU entities and are therefore borne by non-EU manufacturers. The distribution of these costs between non-EU manufacturers and EU consumers is not known and it is possible that some of the costs could also be borne by EU entities.

2.6.1.4. Exporters of wood-based panels

The proposed restriction bans the placing on the EU market of class E2 wood-based panels. Therefore, the export of such articles is not affected by the restriction, as the production processes are not specifically included in the scope of the proposed restriction.

2.6.1.5. Downstream users of wood-based panels

Downstream users of wood-based panels include, for example, the construction industry, furniture manufacturers, producers of laminate flooring, and consumers. These actors are only affected to the extent that they are currently using class E2 panels (either EU-manufactured or imported). For EU-manufactured panels, the costs to downstream users for switching to more expensive class E1 panels is already captured in the calculation of economic impacts (Section 2.4.1). For imported panels, it was assumed that in the central scenario non-EU manufacturers would fully bear any additional costs. It is however possible that some of the costs could also be borne by EU entities. No additional costs to downstream users stemming from changes in product characteristics are expected from the replacement of class E2 with class E1 panels.

2.6.1.6. Impacts on SMEs

The majority of actors in the EU's woodworking industry[35] are small and medium-sized enterprises (SMEs), though large enterprises may play a more important role in the wood-based panel sub-sector (EC, 2018d). Any effect of the proposed restriction on SMEs is expected to be limited as the vast majority of wood-based panel producers in the EU are already subscribers to the voluntary industry agreement of producing only class E1 panels.

2.6.2. Wider economic impacts

The proposed restriction would have minor impacts on article prices. Therefore, international trade flows are likely to remain unchanged and no substantial wider economic impacts can be anticipated as a result of the restriction. No wider impacts on the economic growth or development, changes to competition within the EU or direct impacts on the macroeconomic stabilisation have been identified by ECHA for the case that the proposed restriction was implemented.

2.6.3. Distributional impacts

Any negative impacts on manufacturers and importers of class E2 wood-based panels are anticipated to be offset by gains by manufacturers and importers of class E1 wood-based panels. As the vast majority of wood-panels placed on the EU market already complies with the formaldehyde emission class E1 and therefore with the proposed restriction, these distributional impacts are expected to be limited.

[35] The EU woodworking industry comprises the production of sawn wood, wood-based panels, and wooden construction materials and products.

2.7. Practicability, enforceability and monitorability

2.7.1. Implementability

The proposed restriction is considered to represent an implementable option for the actors within the timeframe of 12 months. The proposal is intended to limit formaldehyde released from articles. The measures foreseen in this restriction report are already to a large extent applied in the EU as a result of voluntary agreements within specific industry sectors and national legislation in a number of EU Member States that is broadly in line with the restriction proposal.

2.7.2. Enforceability

Some EU Member States have already implemented or are planning to implement legislation to limit formaldehyde emissions from specific categories of articles, in particular wood-based products (see Table 18). Formaldehyde emission limits are therefore already enforced in a number of EU Member States and chamber tests (performed in accordance with EN 717-1 or under other conditions) are prescribed to enforce the legislative requirements. Chamber tests as well as other test methods exist to monitor the release of formaldehyde from articles and enforcement authorities have already experience in applying them as illustrated by the Swedish enforcement project described in Section 2.4.3. Enforcement authorities of other Member States can therefore set up an efficient supervision mechanism to monitor compliance with the proposed restriction.

Table 18: Legislation to limit formaldehyde emissions in selected Member States

Member State	Legal act	Limit value	Test method
Austria	Formaldehydverordnung (BGBl. Nr. 194/1990) § 1	0.1 ppm (0.124 mg/m^3)	Test chamber
Denmark	BEK nr 289 af 22/06/1983	0.15 mg/m^3	Test chamber
Denmark	Draft Order 2017/89/DK	0.124 mg/m^3	EN 717-1
France	Draft Order 2017/0023/F	Emission classes	ISO 16000-9, EN 717-1
Germany	Chemikalien-Verbotsverordnung, Anlage 1 (zu § 3)	0.1 ppm (0.124 mg/m^3)	EN 16156[36]
Italy	DECRETO 10 ottobre 2008	0.1 ppm (0.124 mg/m^3)	EN 717-1
Sweden	KIFS 2017:7	0.124 mg/m^3	EN 717-1

[36] For wood-based panels, a correction factor of 2 has to be used for testing performed in accordance with EN 717-1.

RAC ASSESSMENT

Implementability and enforceability

With regards to the testing of articles, the Dossier Submitter considered the proposed restriction as implementable. This assessment will not change through a lower emission limit as derived by RAC.

RAC agrees with the options included in the Appendix X for the measurement of formaldehyde releases from articles and on the measurement of formaldehyde concentration in the interior space of vehicles. The outline of applicable test methods and the conditions of their applications allows testing of a broad range of articles. It gives also flexibility and, if established, allows the use of already applied standard test methods preventing double testing if other test methods based on different conditions than those outlined in point 1 of Appendix X are preferred. As described in point 2 of Appendix X, if a test method based on different conditions is used, compliance shall be demonstrated based on an acceptable correlation with the prescriptions outlined in point 1 of Appendix X. The text of Appendix X may be extended with regards to the applications for rail and water vehicles and others road vehicles than cars.

Testing of construction elements, furniture, flooring or other articles made from E1 panels and carrying the CE label is needed as formaldehyde may not only be released from the E1 (or E2) panel but can also be released from paints, glues, fillers, foam, coatings/varnish, impregnations and other products to which formaldehyde or formaldehyde releasers were added during production and which were used in the production of the articles. The measures to demonstrate compliance with the EU-wide E1 standard has been considered as to a large extent already being applied by the EU manufacturers (in particular for the manufacturers of wood-based panels). Instead of the previously certified (voluntary) limit concentrations producers and importers have to ensure that their test method complies with the provisions of the restriction (as outlined in Appendix X). In order to comply with a lower emission limit as proposed by RAC (instead of the level proposed by the Dossier Submitter), it is assumed that no additional effort is needed or, to the knowledge of RAC, no limitations are given.

Manufacturers and importers of articles who have not yet established test methods for their articles because no mandatory emission limit exists at present (e.g. as it is the case in many Member States for furniture) or because test methods are not yet available at all for some articles (e.g. carpets or matrasses), will have to establish an appropriate testing method for their articles and set up adequate quality assessment criteria for the comparison of the chosen method with the reference conditions outlined in Appendix X, if a test method based on these conditions cannot be applied by them. If methods based on different conditions are used, an acceptable correlation with other monitoring methods that are internally preferred by manufacturers has to be derived in order to continue with the preferred test method. It is to note that such a correlation will be specific for the article tested and the test method used in comparison to the reference method.

2.7.3. Manageability

Considering that most relevant industry sectors have already signed voluntary agreements to reduce formaldehyde emissions from articles, the manageability of the restriction is anticipated to be high.

2.7.4. Monitorability

The effectiveness of the current restriction could be monitored by quantifying, over time, the amount of EU-manufactured and imported articles with compliant formaldehyde emissions compared to the current situation.

RAC ASSESSMENT

RAC agrees that available test methods will allow monitoring of formaldehyde release from the EU-manufactured and imported articles, provided that data are published or made available to enforcement bodies or by enforcement authorities. RAC also notes that monitoring is already in place in Member States who have adopted national regulations (mainly on wood-based panels/construction products) and, on a voluntary basis, by EU producers of wood-based panels and cars.

Monitorability of the emissions and concentration limit as proposed by RAC will not differ from monitorability of the initially proposed emissions and concentration limits by the Dossier Submitter.

Comparison with the current situation will be limited for articles within the scope for which there is currently no mandatory testing. According to the Dossier Submitter proposal the amount of E2 panels and articles made of high emitting wood-based panels should decrease after entry into force. The actual low amount should disappear from the EU-market.

2.8. Proportionality

The proposed restriction would entail costs for the EU society due to increased production costs in the wood-based panels industry as well as costs related to enforcing the emission limit. Overall, these costs are expected to be limited in light of the already existing voluntary industry agreement in the wood-based panels sector. For a reference year, 2016, costs to the EU society are estimated to be in the order of €28 million (central estimate).

On the other hand, benefits are expected for individuals from limiting exposure to high formaldehyde emitting articles, including from imports, in indoor environments. This contributes to keeping the indoor air formaldehyde concentrations below the WHO guideline value and helps to prevent detrimental health effects linked to formaldehyde inhalation exposure. These include acute and chronic sensory irritation in the airways and eyes in the general population and in potential sensitive subpopulations including children and the elderly. Meeting the WHO guideline value will also prevent detrimental effects on lung function and long-term health effects, including nasopharyngeal cancer.

The proposed restriction is expected to be an effective measure for addressing the identified risks, in particular with regard to new articles imported into the EU. The overall risk reduction potential is however expected to be limited given that the measured indoor air formaldehyde concentrations in the EU are already today mostly below the WHO guideline value.[37] Still, a restriction would serve as a precautionary measure in that it prevents high formaldehyde emitting articles from being placed on the EU market. As such, it would help to reduce risks that can arise under specific circumstances, for example when individuals move into new

[37] Though this is in part also due to the ageing and sink effects described in Section 1.3.6.5. The ageing effect is not relevant for new articles.

homes in which high emitting materials have been used in large quantities. Furthermore, formaldehyde emissions from temporary sources can have a substantial short-term impact on indoor air formaldehyde concentrations leading to levels that far exceed the WHO guideline value. Even though such temporary sources are outside the scope of the Commission's request, the proposed restriction would help to reduce combined exposure of permanent and temporary sources and contribute to avoid unsafe levels of formaldehyde emissions. In addition, the proposed restriction would harmonise the existing rules on formaldehyde emissions for the entire Union.

Table 19 compares the identified costs – in terms of compliance costs (economic impacts) – and benefits – in terms of number of homes or individuals that could potentially benefit from formaldehyde concentrations below the WHO guideline value as a result of the restriction. The resulting costs of achieving formaldehyde concentrations below the WHO guideline value of €93 per affected home and €41 per affected individual are marginal compared to the costs of a new dwelling.[38] The Dossier Submitter therefore considers the proposed restriction as proportional to the risk.

Table 19: Cost-effectiveness of the proposed restriction for 2016 (and after)

Costs / Effects / Cost-effectiveness [Unit]	Central estimate (Range)
Compliance costs [Million €/year]	28.0 (28.0-78.9)
Homes benefitting from exposure reduction [Number of homes/year]	300 000
Individuals benefitting from exposure reduction [Number of individuals/year]	690 000
Cost-effectiveness of ensuring WHO Guideline [€/home]	***93*** *(93-263)*
Cost-effectiveness of ensuring WHO Guideline [€/individual]	***41*** *(41-114)*

RAC ASSESSMENT

RAC indicates that proportionality should also be weighed against the risk as estimated by RAC based on a DNEL of 0.05 mg/m³.

RAC notes from the consultation that the proposed limit value of 0.05 mg/m³ will affect production processes, however, considers adaption to the lower concentration as feasible especially in view of the numerous available voluntary limits on a broad spectrum of articles with the scope.

The already by EU manufacturers of wood-based panels voluntarily implemented E1, which is mandatory already in a range of Member States and even undercut by many voluntary labels

[38] Based on the average transaction price of a new dwelling in selected Member States, the Dossier Submitter estimates average costs for a new 96 m^2 dwelling (= EU average dwelling size, see Section 2.5.2) in the order of €100 000-€400 000 in 2016 (see Annex D.7).

and certification schemes for a range of articles, is considered by RAC to bring no significant benefits for those aforementioned groups of articles/countries.

In case the limit proposed by the Dossier Submitter would be implemented, some health benefits are expected in particular due to the limitation of E2 panel imports. Even if only very minor risk reduction effects will be gained with an emission limit of E1, RAC considers such a restriction preferable to no EU-wide restriction measure.

3. Assumptions, uncertainties and sensitivities

This section discusses the key assumptions and uncertainties used in the development of this restriction proposal. These relate to both the exposure and the impact assessment.

3.1. Uncertainty in the exposure assessment

Uncertainties in the exposure assessment are related to the assumptions made in setting up the exposure scenario, in particular regarding loading factors, emission reductions from covering materials and climatic conditions, as well as the scoping choices made, particularly with regard to the non-consideration of temporary emission sources and mixtures:

- **Loading factors**: Formaldehyde indoor air concentrations in Section 1.3.6.5 were estimated for three sub-scenarios representing different loading factors of wood-based panels. However, the estimated exposure reduction from the proposed restriction in Section 2.5.1 is only based on the central scenario (sub-scenario B), i.e. a situation in which wood-based panels are used in the ceiling and in two of the walls resulting in a loading factor of 1.0 m^2/m^3. Figure 10 also shows how the situation would look for loading factors of 0.4 m^2/m^3 (i.e. wood-based panels used in the ceiling only, sub-scenario A) and 1.4 m^2/m^3 (i.e. wood-based panels used in the ceiling and all walls, sub-scenario C). Class E2 panels emitting formaldehyde at 50-100% above the E1 emission limit are estimated to result in formaldehyde concentrations of 71-80 $\mu g/m^3$ and 141-173 $\mu g/m^3$ for loading factors of 0.4 m^2/m^3 and 1.4 m^2/m^3, respectively.

  For the lower loading factor, the formaldehyde concentration would be below the WHO guideline value even using class E2 panels. For the higher loading factor, the proposed emission limit would bring the concentration to 108 $\mu g/m^3$. While this is close to the WHO guideline value, it also illustrates that under very specific conditions, such as the presence of high formaldehyde emitting materials in large quantities, the WHO guideline value can be exceeded even with a restriction that limits formaldehyde emissions in articles at E1 levels.[39]

- **Covering**: The exposure scenario assumes that all used wood-based panels are covered with layers (e.g. gypsum board, paint) leading to a substantial reduction in formaldehyde emissions. The assumed 75% emission reduction is at the lower end of the range of emission reductions that can be expected from covering – 70-98% according to experiments reported in Salthammer and Gunschera (2017) – and is therefore expected to be a conservative assumption. Indoor air formaldehyde concentrations would be substantially higher when (unrealistically) assuming the use of uncovered wood-based panels, as shown, for example, by Kolarik et al. (2012).

- **Climatic conditions**: Air exchange, temperature and humidity in the indoor environment have an influence on formaldehyde concentrations. Lower air exchange rates are associated with higher formaldehyde concentrations and vice versa.

[39] A change in the loading factor would also mean a change in the number of homes/individuals that could potentially be exposed to class E2 panels. With a loading factor of 1.4 m^2/m^3, around 215 000 homes (= 494 500 individuals) would be exposed to the higher formaldehyde concentration resulting from the higher material load. With a loading factor of 0.4 m^2/m^3, around 750 000 homes (= 1 725 000 individuals) would be exposed to lower formaldehyde concentrations.

Formaldehyde concentrations also tend to increase with temperature and humidity. Jarnstrom et al. (2006), for example, measured higher formaldehyde concentrations in new residential buildings in Finland during summer, when temperature and humidity were higher, than during winter.

Climatic parameters may have an impact on the release of formaldehyde from articles (e.g. textiles, different types of wood-based panels, solid wood). In the case of particleboard, for example, Salthammer and Gunschera (2017) referencing Andersen et al. (1975) report a hyperbolic decrease in the concentration of formaldehyde in a test chamber as air exchange rates increase and a directly proportional relationship between the formaldehyde concentration and temperature and humidity. Based on these observations, Andersen et al. (1975) derived an algorithm, which was further modified by Meyer et al. (2014), to describe the influence of climatic parameters on the steady-state formaldehyde concentration in a test chamber. The algorithm can be used to calculate how formaldehyde concentrations obtained from a chamber test would be affected by changes in the climatic parameters but it does not indicate how different climatic conditions affect the formaldehyde concentration in indoor environments under living conditions.

Climatic parameters have been kept constant for the purpose of the analysis carried out in Section 1.3.6.5, even though variations can be expected under real-life conditions, with differences across regions, seasons and homes. This means that the exposure estimates could be higher or lower subject to the actual prevailing climatic conditions in real-life situations. With regard to the air exchange rate, a fixed value of 0.5 h^{-1} has been considered in the exposure scenario corresponding to the default value set for the European Reference Room (see Table 7). Although the assumption taken for the air exchange rate is considered sufficiently conservative by the Dossier Submitter, additional calculations have been performed to take into account a distribution of air exchange rates instead of a fixed value to cover a wider range of cases. In doing so, the Dossier Submitter adopted the approach by Salthammer (2019) assuming a log-normal distribution of air exchange rates with a geometric mean of 0.52 h^{-1} and a geometric standard deviation of 1.49 h^{-1}.The outcome of these calculations is reported in Annex E.2. Compared to the situation of a fixed air exchange rate, the tails of the distribution of simulated formaldehyde concentrations become more pronounced, i.e. a larger number of rooms with lower formaldehyde concentrations but also a larger number of rooms with higher formaldehyde concentrations. As a result, formaldehyde concentrations for the higher percentiles (P75, P90, P95) are higher than in the situation of a fixed air exchange rate and a somewhat higher share of households exceed the WHO guideline value (Table E.3 in Annex E.2).

- **Ageing**: As discussed in Section 1.3.6.5, formaldehyde emissions from articles decrease over time as a result of off-gassing. As the exposure scenario constructed in this report conservatively assumes the case of newly built homes in which newly produced materials are used, no such ageing effect has been taken into account. Nevertheless, additional calculations taking into account the ageing effect have been performed. In doing so, the Dossier Submitter adopted the approach by Salthammer (2019) who, based on data from various test studies, applied a normally distributed weighting factor with a mean of 0.4 and a standard deviation of 0.1 to walls (Wall 1), ceiling (Ceiling 1) and furniture to consider ageing effects of wood-based materials. Salthammer (2019) considered no ageing effect for other sources due to a lack of data. The results of the additional calculations taking into account both a distribution of air exchange rates (see previous bullet point) and ageing effects are shown in Table E.4 of Annex E.2. A comparison of Table E.3 and Table E.4 in Annex E.2 shows that the calculated formaldehyde concentrations in the reference room decrease significantly compared to the situation where no ageing effect is assumed.

- **Temporary sources**: Exposure estimates are based on a scenario that only considers permanent formaldehyde emission sources. Hence, exposure and risk may be underestimated as temporary sources have not been taken into account. Adding one or more temporary sources (e.g. wood burning, smoking, candle burning, cooking, or ethanol fireplaces) could contribute to the exposure scenario in such a way that, at least for a limited amount of time, peak concentrations could occur that far exceed the WHO guideline value and which cannot be addressed by an emission limit on articles.

- **Mixtures**: Formaldehyde releases from mixtures used to produce consumer articles, e.g. glues, fillers and foams used in construction materials and in furniture, are covered in the exposure scenario in Section 1.3.6.5. The release of formaldehyde from dried wall paints is also considered in the scenario. However, there are other mixtures for consumer use that may contain formaldehyde or formaldehyde releasers (e.g. consumer paints, cleaning products, disinfectants, adhesives, etc.) and thus some exposure during use cannot be excluded (e.g. during brush application of paint or during floor cleaning). Formaldehyde or formaldehyde releasers can be used as biocide or formaldehyde release may result from the degradation of other substances used for non-biocidal purposes. As such, there might be some unaddressed exposure from mixtures for consumer use but, as described in Section 1.3.6.2, based on available information, consumer risks from formaldehyde in mixtures seem adequately controlled.

3.2. Uncertainty in the impact assessment

Uncertainties in the impact assessment mainly relate to the lack of information about class E2 panels in terms of market volume, emissions and production costs. Furthermore, there is some uncertainty concerning the ability of non-EU manufacturers to pass through costs to EU consumers, testing costs, as well as the extent to which class E2 panels are concentrated in a number of homes. On a more general note, the focus of the impact assessment on wood-based panels despite the wider scope of the restriction proposal also introduces some uncertainty:

- **Market volume of class E2 panels**: Different data sources exist containing information on the total volume of EU-manufactured and/or imported wood-based panels.[40] However, the Dossier Submitter was unable to identify data on how this volume is divided into class E1 and class E2 panels. In the absence of such information, estimates provided by EPF were applied to FAO and Eurostat data. The exact volume of class E2 panels on the EU market is not known and could be higher or lower than the estimate given in Table 13.

- **Emissions from class E2 panels**: Class E2 panels, per definition, have formaldehyde emissions above 0.124 mg/m^3 but no data was available to the Dossier Submitter indicating how far above the E1 emission limit these emissions are on average. EPF

[40] These include the data published in the EPF Annual Report (EPF, 2017) based on an annual survey of EPF members, data based on the Joint Eurostat/FAO/ITTO/UNECE Forest Sector Questionnaire (UNECE, 2018), as well as trade statistics (Eurostat, 2018b).

communicated that they assumed formaldehyde emissions of class E2 panels in the order of 50-100% above the E1 emission limit. The Dossier Submitter adopted this assumption given the paucity of information.

- **Production costs**: The Dossier Submitter was able to rely on market information provided by industry and own calculations based on Eurostat (2018c) data for the derivation of prices of class E1 panels. No such information was however available for class E2 panels. To quantify the production cost differences between E1 and E2 panels, the Dossier Submitter made an approximation based on industry information that class E1 panels are 10-15% cheaper in production than lower emitting E.LES panels, as explained in Section 2.4.1. The exact difference in production costs is not known and could be higher or lower than the assumed 10%. The Dossier Submitter assumes that an emission reduction from E2 level to E1 level is more easily achievable than from E1 level to the even lower E.LES level. This would suggest that the 10% cost difference is an upper bound and hence represents a conservative estimate of economic impacts.

- **Non-EU manufacturers' ability to pass through costs**: In the central scenario it is assumed that non-EU manufacturers are competing on price and will therefore not be able to pass through any additional costs to EU consumers. The possibility of some pass through can however not be excluded. To address this uncertainty, Table 15 provides a range of the estimated economic impacts depending on the share of costs passed through to EU consumers. Assuming that non-EU manufacturers can pass through half or all of the extra costs to EU consumers, the estimated economic impact amounts to €53 million and €79 million, respectively. The costs per home to ensure the WHO guideline value would be €178 (50% pass through) and €263 (100% pass through). These values are still considered marginal relative to the costs of a new dwelling.

- **Testing costs**: The proposed restriction refers, in Appendix X, to the conditions under which the formaldehyde emission limit is defined and it does not impose the use of a specific test method. Suitable test methods based on different conditions or principles can also be used to demonstrate compliance. Producers, retailers or importers of articles are responsible to calibrate any alternative test method they use to ensure that formaldehyde emissions from their articles do not exceed the limit of the restriction proposal if measured under the reference conditions specified in the appendix. Additional testing costs for wood-based panel producers due to the proposed restriction are assumed to be negligible. This is because formaldehyde emissions testing, at least using the derived test methods EN 717-2 and EN 120 in accordance with quality control limits based on correlations with EN 717-1, is generally part of routine production control in this sector. The increased focus on formaldehyde emissions may however lead some manufacturers to increase their testing efforts, meaning that testing costs could be underestimated.

  For articles other than wood-based panels, different sector-specific methods appear to be in use to measure formaldehyde emissions. Some additional costs to establish an acceptable correlation/calibration between the alternative method and the reference conditions may be incurred by producers, retailers or importers of such articles in the initial phase after entry into force of the proposed restriction. However correlation/calibration costs are one-off cost for many sectors as parallel testing or re-testing is not needed as long as the quality of the articles produced does not change. Moreover, some additional testing costs may be incurred by producers, retailers or importers of articles in the scope of the proposed restriction if suitable test methods are not yet in place.

- **Concentration of class E2 panels**: In Section 2.5.2 it is assumed that the entire volume of class E2 panels for building and construction purposes is concentrated in a number of homes. In effect, this means that such homes exclusively use class E2 wood-based panels, rather than a mixture of E1 and E2 panels. This conservative assumption is considered reasonable as panels for construction purposes can be expected to be bought in batches. The concentration assumption marks one end of a continuum. The spreading of class E2 panels across all newly built homes marks the other and is illustrated in following. The EU had an estimated housing stock of about 250 million dwellings in 2015 (OECD, 2016), with around 150 million of these dwellings located in Member States without legislation in place that stipulates an emission limit for wood-based panels in line with E1. An estimated 0.7% of the EU's housing stock comes from newly built/completed dwellings, which amounts to around one million dwellings (= 150 million dwellings x 0.7%) in Member States where the E1 emission limit is not mandatory.[41] In other words, class E2 panels could potentially be used in up to one million new dwellings every year. Evenly distributing the total volume of class E2 panels used in building and construction over all new dwellings would result in a loading factor of 0.3 m^2/m^3 per dwelling. This would imply formaldehyde concentrations below the ones shown for L = 0.4 m^2/m^3 in Figure 10.

- **Focus on wood-based panels**: The impact assessment presented in Section 2 focuses on wood-based panels because these are the articles expected to be most affected by the proposed restriction. Economic impacts on other industries are captured insofar as they relate to the downstream use of wood-based panels (e.g. in the production of furniture). Other articles, too, are subject to the proposed restriction but no additional impacts were estimated for the relevant industries. Impacts on other industries are assumed to be negligible relative to the impacts on the wood-based panels industry, e.g. for the automotive industry where voluntary industry agreements to limit formaldehyde emissions in car interiors exist. The presented impacts could be underestimated to the extent that the proposed restriction affects other articles and the relevant industries.

RAC ASSESSMENT

RAC has identified a number of uncertainties. Some of them have been identified and described by the Dossier Submitter and relate to the definition of exposure scenario and the scope which excludes temporary emission sources and mixtures. The potential for peak exposure and elevated exposure arising from other sources not in the scope of the restriction, such as combustion sources, is an uncertainty which RAC acknowledges. Further uncertainties are related to the exposure and risk assessment: in particular concerning the measurement data, their representativeness for a realistic worst case versus an average exposure situation and, on the other hand, the likely overestimation of indoor air concentrations obtained with Monte Carlo simulations. For certain vehicle interior situations no exposure data is available at all (trains, passenger ships, road vehicles other than cars). In contrast to vehicles (where a limit concentration in vehicle interior air is

[41] Annex E.1 contains the data underlying the derivation of the EU's housing stock and the share of dwellings built/completed.

proposed), the derivation of an appropriate emission limit for building interior articles, is based on calculation/simulation with its uncertainties due to the complexity of the emission scenario and its individual determinants.

Equally the actual risk reduction effects by limiting emissions at the level proposed by RAC with the proposed restriction are somewhat uncertain due to the difficulties in quantification. While the restriction will affect those indoor situations of most concern and a significant risk reduction is assumed, there may still be situations of concern with RCR > 1. The potential risk shifts by switching to ‘no added formaldehyde’ (NAF) alternatives which contain hazardous substances is acknowledged as an uncertainty because an in-depth toxicological and human health risk assessment is needed to come to robust conclusions for the individual alternatives.

The Dossier Submitter mainly assessed proportionality of risks from newly built homes and did not consider living conditions in existing building stock. RAC identifies in addition to residents of new homes additional groups of consumers potentially at risk which have not yet been addressed: residents of newly renovated homes with/without tight ventilation, residents of existing homes who (re-)furnish one or more rooms in their home resulting in high loading factors/high emission concentrations in that room, residents with existing homes at a high loading summed up from other articles (e.g. decoration articles, textiles, mattresses, carpets, etc.) at insufficient ventilation, and passengers in vehicles (road vehicles incl. public transport, rail, ships).

4. Conclusion

The conclusion of the Dossier Submitter's risk assessment is that human health risks from formaldehyde release in mixtures for consumer use seem adequately controlled. On the other hand, risks from release in consumer articles are not adequately controlled in all scenarios. To identify the most appropriate measure to address these risks, an analysis of various RMOs was conducted, including regulatory measures under REACH, other existing EU legislation and other possible Union-wide RMOs and it was concluded that a restriction under REACH is the most appropriate risk management option.

The proposal is to restrict the placing on the market of articles produced with the use of formaldehyde or formaldehyde releasing substances that release formaldehyde at concentrations greater than or equal to 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X. Articles exclusively used outdoors are excluded from the scope of the proposal. Formaldehyde released from an article may come from formaldehyde and/or other substances that release formaldehyde (formaldehyde releasers) used in the production process of the article.

Formaldehyde levels in indoor environments have been declining significantly since the 1980s. Due to improved quality of materials, production processes and substitution, formaldehyde concentrations in indoor environments are, in most cases, already below the WHO guideline value. It is however to be considered that, where no national regulation exists, the adoption of an EU-wide emission limit for formaldehyde will prevent the risk of consumers being exposed to formaldehyde levels above the WHO guideline value from high emitting articles including those imported from non-EU countries. The proposed restriction is considered effective, practicable and proportionate. It is expected that the benefits for individuals from reduced exposure to high formaldehyde emitting articles are achievable at limited costs to EU society in light of the already existing voluntary industry agreement in the wood-based panels industry.

Temporary emission sources, including various combustion sources (e.g. wood burning, smoking, candle burning, cooking, ethanol fireplaces), have been identified as having the potential to lead to high formaldehyde concentrations in indoor environments. These sources are typically active for only short periods but can lead to peak concentrations that far exceed the WHO guideline value. Formaldehyde emissions from temporary combustion sources cannot be addressed by an emission limit on articles and are outside the scope of the proposed restriction. With regard to ethanol fireplaces – which according to Table 5 are associated with particularly high formaldehyde emissions – the European Commission made a number of specific recommendations on how to address their effects on indoor air quality (EC, 2015).

RAC ASSESSMENT

RAC generally agrees with the intention of the restriction to protect consumers exposed to formaldehyde against adverse health effects (in particular carcinogenicity). However, RAC does not agree that risks to consumers are sufficiently addressed by the emission limit proposed by the Dossier Submitter for building interior articles and the limit concentration proposed for vehicles, because RAC considers that consumers are not sufficiently protected from health risks if they are exposed at the WHO guideline value of 0.1 mg/m^3 (0.08 ppm) and instead proposes:

- Limiting emissions exceeding concentrations of 0.05 mg/m^3 in the air of a test chamber used under conditions specified in Appendix X for articles, and

- A limit concentration of 0.05 mg/m³ formaldehyde for vehicle cabin interiors.

Articles temporarily contributing to peak levels are not a matter of the scope of this restriction proposal. It is however recommended by RAC that regulatory measures should be considered to limit formaldehyde emissions from ethanol fireplaces.

References

Aalto-Korte, K., Kuuliala, O., Suuronen, K., Alanko, K. (2008). Occupational contact allergy to formaldehyde and formaldehyde releasers. *Contact Dermatitis,* 59(5), 280-289.

Aldag, N., Gunschera, J., Salthammer, T. (2017). Release and absorption of formaldehyde by textiles. *Cellulose,* 24(10), 4509-4518.

Andersen, H. V., Klinke, H. B., Funch, L. W., Gunnarsen, L. (2016). *Emission of Formaldehyde from Furniture*. Copenhagen: The Danish Environmental Protection Agency.

Andersen, I., Lundqvist, G. R., Mølhave, L. (1975). Indoor air pollution due to chipboard used as a construction material. *Atmospheric Environment (1967),* 9(12), 1121-1127.

Andersen, M. E., Clewell, H. J., 3rd, Bermudez, E., Dodd, D. E., Willson, G. A., Campbell, J. L., Thomas, R. S. (2010). Formaldehyde: integrating dosimetry, cytotoxicity, and genomics to understand dose-dependent transitions for an endogenous compound. *Toxicol Sci,* 118(2), 716-31.

ANSES (2016). *Analysis of the most appropriate risk management option (RMOA)*. Maisons-Alfort: Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail.

ANSES/RIVM (forthcoming). *Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for Formaldehyde (EC No 200-001-8, CAS No 50-00-0)*.

BAAQMD (2012). *Compliance Advisory Wood Products Coatings: Formaldehyde Emissions Estimates*. San Francisco: Bay Area Air Quality Management District.

BASF (2017). *Chemical Safety Report: Formaldehyde*.

Berglund, B., Hoglund, A., Esfandabad, H. S. (2012). A Bisensory Method for Odor and Irritation Detection of Formaldehyde and Pyridine. *Chemosensory Perception,* 5(2), 146-157.

bluesign (2014). *bluesign criteria for chemical assessment (Homologation). Version 2.0*. bluesign technologies ag.

Brown, S. K. (1999). Chamber Assessment of Formaldehyde and VOC Emissions from Wood-Based Panels. *Indoor Air,* 9(3), 209-215.

Brown, S. K. (2002). Volatile Organic Pollutants in New and Established Buildings in Melbourne, Australia. *Indoor Air,* 12(1), 55-63.

Bruinen de Bruin, Y., Koistinen, K., Kephalopoulos, S., Geiss, O., Tirendi, S., Kotzias, D. (2008). Characterisation of urban inhalation exposures to benzene, formaldehyde and acetaldehyde in the European Union. *Environ Sci Pollut Res,* 15, 417-430.

Casanova, M., Deyo, D. F., Heck, H. D. (1989). Covalent binding of inhaled formaldehyde to DNA in the nasal mucosa of Fischer 344 rats: analysis of formaldehyde and DNA by high-performance liquid chromatography and provisional pharmacokinetic interpretation. *Fundam Appl Toxicol,* 12(3), 397-417.

Casanova, M., Heck, H. D., Everitt, J. I., Harrington, W. W., Jr., Popp, J. A. (1988). Formaldehyde concentrations in the blood of rhesus monkeys after inhalation exposure. *Food Chem Toxicol,* 26(8), 715-6.

Casanova, M., Morgan, K. T., Steinhagen, W. H., Everitt, J. I., Popp, J. A., Heck, H. D. (1991). Covalent binding of inhaled formaldehyde to DNA in the respiratory tract of rhesus monkeys: pharmacokinetics, rat-to-monkey interspecies scaling, and extrapolation to man. *Fundam Appl Toxicol,* 17(2), 409-28.

CEN (2004a). *EN 717-1 Wood-based panels - Determination of formaldehyde release - Part 1: Formaldehyde emission by the chamber method*. Brussels: European Committee for Standardization.

CEN (2004b). *EN 13986 Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking*. Brussels: European Committee for Standardization.

CEN (2017). *EN 16516 Construction products: Assessment of release of dangerous substances - Determination of emissions to indoor air*. Brussels: European Committee for Standardization.

Checkoway, H., Dell, L. D., Boffetta, P., Gallagher, A. E., Crawford, L., Lees, P. S., Mundt, K. A. (2015). Formaldehyde Exposure and Mortality Risks From Acute Myeloid Leukemia and Other Lymphohematopoietic Malignancies in the US National Cancer Institute Cohort Study of Workers in Formaldehyde Industries. *J Occup Environ Med,* 57(7), 785-94.

Collins, J. J., Ness, R., Tyl, R. W., Krivanek, N., Esmen, N. A., Hall, T. A. (2001). A review of adverse pregnancy outcomes and formaldehyde exposure in human and animal studies. *Regul Toxicol Pharmacol,* 34(1), 17-34.

Colombo, A., Jann, O., Marutzky, R. (1994). The estimate of the steady state formaldehyde concentration in large chamber tests. *Staub - Reinhaltung der Luft,* 54, 143-146.

Dalbey, W. E. (1982). Formaldehyde and tumors in hamster respiratory tract. *Toxicology,* 24(1), 9-14.

Derbez, M., Berthineau, B., Cochet, V., Lethrosne, M., Pignon, C., Riberon, J., Kirchner, S. (2014). Indoor air quality and comfort in seven newly built, energy-efficient houses in France. *Building and Environment,* 72, 173-187.

DFG (2010). Formaldehyde [MAK Value Documentation, 2010]. *In:* Hartiwig, A. (ed.) *The MAK-Collection for Occupational Health and Safety.* Weinheim: Wiley-VCH.

Duong, A., Steinmaus, C., McHale, C. M., Vaughan, C. P., Zhang, L. (2011). Reproductive and developmental toxicity of formaldehyde: a systematic review. *Mutat Res,* 728(3), 118-38.

EC (2014). Commission Regulation (EU) No 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures Text with EEA relevance. *Official Journal of the European Union OJ L 167*. Brussels: European Commission.

EC (2015). *Study on alcohol-powered flueless fireplace combustion and its effects on indoor air quality*. Brussels: European Commission, Directorate-General for Justice and Consumers.

EC (2018a). Commission Regulation (EU) 2018/1513 of 10 October 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B. Text with EEA relevance. *Official Journal of the European Union OJ L 256*. Brussels: European Commission.

EC (2018b). *EU-LCI Values - Formaldehyde* [Online]. European Commission. Available: https://ec.europa.eu/docsroom/documents/30861/attachments/39/translations/en/renditions/native [Accessed 9 October 2019].

EC (2018c). *The Rapid Alert System for Non-Food Products (RAPEX). Alert number: A12/1543/18* [Online]. European Commission. Available: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=viewProduct&reference=A12/1543/18&lng=en [Accessed 19 November 2018].

EC (2018d). *Woodworking* [Online]. European Commission. Available: https://ec.europa.eu/growth/sectors/raw-materials/industries/forest-based/woodworking_en [Accessed 19 November 2018].

ECHA (2015). *Decision on substance evaluation pursuant to Article 46(1) of Regulation (EC) No 1907/2006 for formaldehyde, CAS No 50-00-0 (EC No 200-001-8)*. Helsinki: European Chemicals Agency.

ECHA (2017a). *Assessment Report: Formaldehyde Product-type 02 (Disinfectants and algaecides not intended for direct application to humans or animals)*. Helsinki: European Chemicals Agency.

ECHA (2017b). *Investigation report: Formaldehyde and formaldehyde releasers*. Helsinki: European Chemicals Agency.

ECHA (2018). *C&L Inventory* [Online]. European Chemicals Agency. Available: https://echa.europa.eu/regulations/clp/cl-inventory [Accessed 16 November 2018].

EPF (2017). *Annual Report 2016-2017*. Brussels: European Panel Federation.

Eurostat (2016). *Average size of dwelling by tenure status, 2012* [Online]. Available: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Average_size_of_dwelling_by_tenure_status,_2012.png [Accessed 19 November 2018].

Eurostat (2018a). *Average household size - EU-SILC survey [ilc_lvph01]* [Online]. Eurostat. Available: http://ec.europa.eu/eurostat/data/database [Accessed 9 November 2018].

Eurostat (2018b). *EU trade since 1988 by CN8 [DS-016890]* [Online]. Eurostat. Available: http://ec.europa.eu/eurostat/data/database [Accessed 18 October 2018].

Eurostat (2018c). *Sawnwood and panels [for_swpan]* [Online]. Eurostat. Available: http://ec.europa.eu/eurostat/data/database [Accessed 4 January 2019].

FAO (2018). *Forestry Production and Trade* [Online]. Food and Agriculture Organization of the United Nations. Available: http://www.fao.org/faostat/en/#data/FO [Accessed 4 January 2019].

Formacare (2018). *Response from Formacare to the call for evidence in relation to the Annex XV dossier on formaldehyde and formaldehyde releasers*. Formacare.

Global Insight (2007). *Socio-Economic Benefits of Formaldehyde to the European Union (EU 25) and Norway. Prepared for Formacare*. Lexington: Global Insight.

Golden, R. (2011). Identifying an indoor air exposure limit for formaldehyde considering both irritation and cancer hazards. *Crit Rev Toxicol,* 41(8), 672-721.

Groah, W. J. (2005). *Decay or the Decrease in Formaldehyde Concentrations or Emissions over Time and UF-bonded Wood Panel Products.* Report prepared for the Composite Panel

Association, Formaldehyde Council Inc., Hardwood Plywood and Veneer Association, and the Kitchen Cabinet Manufacturers Association, Reston, VA, 2005.

Heck, H. D., Casanova-Schmitz, M., Dodd, P. B., Schachter, E. N., Witek, T. J., Tosun, T. (1985). Formaldehyde (CH2O) concentrations in the blood of humans and Fischer-344 rats exposed to CH2O under controlled conditions. *Am Ind Hyg Assoc J,* 46(1), 1-3.

Heck, H. D., Casanova, M. (2004). The implausibility of leukemia induction by formaldehyde: a critical review of the biological evidence on distant-site toxicity. *Regul Toxicol Pharmacol,* 40(2), 92-106.

Heck, H. D., White, E. L., Casanova-Schmitz, M. (1982). Determination of formaldehyde in biological tissues by gas chromatography/mass spectrometry. *Biomed Mass Spectrom,* 9(8), 347-53.

IARC (1995). Formaldehyde. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.* Lyon: Word Health Organisation, 217-374.

IARC (2006). Formaldehyde. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.* Lyon: World Health Organisation, 37-326.

Iversen, O. H. (1986). Formaldehyde and skin carcinogenesis. *Environment International,* 12(5), 541-544.

Jarnstrom, H., Saarela, K., Kalliokoski, P., Pasanen, A. (2006). Reference values for indoor air pollutant concentrations in new, residential buildings in Finland. *Atmospheric Environment,* 40(37), 7178-7191.

Jeffcoat, A. R., Chasalow, F., Feldman, D. B., Marr, H. (eds.) (1983). *Disposition of [14C] formaldehyde after topical exposure to rats, guinea pigs, and monkeys,* Washington, DC: Hemisphere Publishing.

Jensen, L. K., Larsen, A., Molhave, L., Hansen, M. K., Knudsen, B. (2001). Health evaluation of volatile organic compound (VOC) emissions from wood and wood-based materials. *Arch Environ Health,* 56(5), 419-32.

Kamata, E., Nakadate, M., Uchida, O., Ogawa, Y., Suzuki, S., Kaneko, T., Saito, M., Kurokawa, Y. (1997). Results of a 28-month chronic inhalation toxicity study of formaldehyde in male Fisher-344 rats. *J Toxicol Sci,* 22(3), 239-54.

Kaunelienė, V., Prasauskas, T., Krugly, E., Stasiulaitienė, I., Čiužas, D., Šeduikytė, L., Martuzevičius, D. (2016). Indoor air quality in low energy residential buildings in Lithuania. *Building and Environment,* 108, 63-72.

KEMI (2015). *Formaldehyd i träskivor. Tillsynsprojekt 2014*. Sundbyberg: Swedish Chemicals Agency.

KEMI (2017). Kemikalieinspektionens föreskrifter om kemiska produkter och biotekniska organismer. *KIFS 2017:7*. Sundbyberg: Swedish Chemicals Agency.

Kerns, W. D., Pavkov, K. L., Donofrio, D. J., Gralla, E. J., Swenberg, J. A. (1983). Carcinogenicity of formaldehyde in rats and mice after long-term inhalation exposure. *Cancer Res,* 43(9), 4382-92.

Klages-Mundt, N. L., Li, L. (2017). Formation and repair of DNA-protein crosslink damage. *Science China Life Sciences,* 60(10), 1065-1076.

Kolarik, B., Gunnarsen, L., Logadottir, A., Funch, L. W. (2012). Concentrations of Formaldehyde in new Danish Residential Buildings in Relation to WHO Recommendations and CEN Requirements. *Indoor and Built Environment,* 21(4), 552-561.

Lang, I., Bruckner, T., Triebig, G. (2008). Formaldehyde and chemosensory irritation in humans: a controlled human exposure study. *Regul Toxicol Pharmacol,* 50(1), 23-36.

Langer, S., Bekö, G., Bloom, E., Widheden, A., Ekberg, L. (2015). Indoor air quality in passive and conventional new houses in Sweden. *Building and Environment,* 93, 92-100.

Langer, S., Ramalho, O., Derbez, M., Ribéron, J., Kirchner, S., Mandin, C. (2016). Indoor environmental quality in French dwellings and building characteristics. *Atmospheric Environment,* 128, 82-91.

Lefebvre, M.-A., Meuling, W. J. A., Engel, R., Coroama, M. C., Renner, G., Pape, W., Nohynek, G. J. (2012). Consumer inhalation exposure to formaldehyde from the use of personal care products/cosmetics. *Regulatory Toxicology and Pharmacology,* 63(1), 171-176.

Liang, W., Yang, S., Yang, X. (2015). Long-Term Formaldehyde Emissions from Medium-Density Fiberboard in a Full-Scale Experimental Room: Emission Characteristics and the Effects of Temperature and Humidity. *Environmental Science & Technology,* 49(17), 10349-10356.

Liteplo, R. G., Beauchamp, R., Meek, M. E., Chenier, R. (2002). *Concise International Chemical Assessment Document 40: Formaldehyde*. Geneva: World Health Organization.

Lovreglio, P., Carrus, A., Iavicoli, S., Drago, I., Persechino, B., Soleo, L. (2009). Indoor formaldehyde and acetaldehyde levels in the province of Bari, South Italy, and estimated health risk. *Journal of Environmental Monitoring,* 11(5), 955-961.

Lu, K., Moeller, B., Doyle-Eisele, M., McDonald, J., Swenberg, J. A. (2011). Molecular dosimetry of N2-hydroxymethyl-dG DNA adducts in rats exposed to formaldehyde. *Chem Res Toxicol,* 24(2), 159-61.

Lyapina, M., Kisselova-Yaneva, A., Krasteva, A., Tzekova–Yaneva, M., Dencheva-Garova, M. (2012). Allergic contact dermatitis from formaldehyde exposure. *J of IMAB,* 18(4), 255-262.

Maneli, M. H., Smith, P., Khumalo, N. P. (2014). Elevated formaldehyde concentration in “Brazilian keratin type” hair-straightening products: A cross-sectional study. *Journal of the American Academy of Dermatology,* 70(2), 276-280.

Marquart, H., Verbist, K., Dieperink-Hertsenberg, S. (2013). *Analysis of consumer exposure associated with the use of products and articles containing formaldehyde-based resins*. Zeist: TNO Triskelion BV.

Martin, W. J. (1990). A teratology study of inhaled formaldehyde in the rat. *Reprod Toxicol,* 4(3), 237-9.

Mashford, P. M., Jones, A. R. (1982). Formaldehyde metabolism by the rat: a re-appraisal. *Xenobiotica,* 12(2), 119-24.

Meyer, B., Greubel, D., Schwab, H., Marutzky, R. (2014). Formaldehydemissionen aus Spanplatten: Aktualisierung des WKI-Rechenmodells. *Holztechnologie,* 55, 20-26.

Monticello, T. M., Swenberg, J. A., Gross, E. A., Leininger, J. R., Kimbell, J. S., Seilkop, S., Starr, T. B., Gibson, J. E., Morgan, K. T. (1996). Correlation of regional and nonlinear formaldehyde-induced nasal cancer with proliferating populations of cells. *Cancer Res,* 56(5), 1012-22.

Mueller, J. U., Bruckner, T., Triebig, G. (2013). Exposure study to examine chemosensory effects of formaldehyde on hyposensitive and hypersensitive males. *International Archives of Occupational and Environmental Health,* 86(1), 107-117.

Nielsen, G. D., Larsen, S. T., Wolkoff, P. (2013). Recent trend in risk assessment of formaldehyde exposures from indoor air. *Archives of Toxicology,* 87(1), 73-98.

Nielsen, G. D., Larsen, S. T., Wolkoff, P. (2017). Re-evaluation of the WHO (2010) formaldehyde indoor air quality guideline for cancer risk assessment. *Arch Toxicol,* 91(1), 35-61.

Nielsen, G. D., Wolkoff, P. (2010). Cancer effects of formaldehyde: a proposal for an indoor air guideline value. *Arch Toxicol,* 84(6), 423-46.

Nwaogu, T., Bowman, C., Marquart, H., Postle, M. (2013). *Analysis of the most appropriate risk management option for formaldehyde. Annex 2*. TNO Triskelion BV and Risk & Policy Analysts.

OECD (2016). *Affordable Housing Databse* [Online]. Available: http://www.oecd.org/social/affordable-housing-database.htm [Accessed 27 June 2018].

Ozen, O. A., Akpolat, N., Songur, A., Kus, I., Zararsiz, I., Ozacmak, V. H., Sarsilmaz, M. (2005). Effect of formaldehyde inhalation on Hsp70 in seminiferous tubules of rat testes: an immunohistochemical study. *Toxicol Ind Health,* 21(10), 249-54.

Ozen, O. A., Yaman, M., Sarsilmaz, M., Songur, A., Kus, I. (2002). Testicular zinc, copper and iron concentrations in male rats exposed to subacute and subchronic formaldehyde gas inhalation. *J Trace Elem Med Biol,* 16(2), 119-22.

RAC (2012). *Opinion proposing harmonised classification and labelling at EU level of Formaldehyde*. Helsinki: Committee for Risk Assessment.

Rusch, G. M., Clary, J. J., Rinehart, W. E., Bolte, H. F. (1983). A 26-week inhalation toxicity study with formaldehyde in the monkey, rat, and hamster. *Toxicol Appl Pharmacol,* 68(3), 329-43.

Saillenfait, A. M., Bonnet, P., de Ceaurriz, J. (1989). The effects of maternally inhaled formaldehyde on embryonal and foetal development in rats. *Food Chem Toxicol,* 27(8), 545-8.

Salem, M., Böhm, M., Barcík, Š., Beránková, J. (2011). Formaldehyde Emission from Wood-Based Panels Bonded with Different Formaldehyde-Based Resins. *Drvna industrija,* 62(3), 177-183.

Salthammer, T. (2019). Formaldehyde sources, formaldehyde concentrations and air exchange rates in European housings. *Building and Environment,* 150, 219-232.

Salthammer, T., Fuhrmann, F. (2007). Photocatalytic Surface Reactions on Indoor Wall Paint. *Environ Sci Technol,* 41(18), 6573-6578.

Salthammer, T., Gunschera, J. (2017). *Information requirements on formaldehyde given in the ECHA decision letter "Decision on substance evaluation pursuant to Article 46(1) of regulation (EC) No 1907/2006, for formaldehyde, CAS No 50-00-0 (EC No 200-001-8)"*. Braunschweig: Fraunhofer WKI.

Salthammer, T., Mentese, S., Marutzky, R. (2010). Formaldehyde in the Indoor Environment. *Chemical Reviews,* 110(4), 2536-2572.

Sanghani, P. C., Stone, C. L., Ray, B. D., Pindel, E. V., Hurley, T. D., Bosron, W. F. (2000). Kinetic mechanism of human glutathione-dependent formaldehyde dehydrogenase. *Biochemistry,* 39(35), 10720-10729.

Schroeter, J. D., Campbell, J., Kimbell, J. S., Conolly, R. B., Clewell, H. J., Andersen, M. E. (2014). Effects of endogenous formaldehyde in nasal tissues on inhaled formaldehyde dosimetry predictions in the rat, monkey, and human nasal passages. *Toxicol Sci,* 138(2), 412-24.

SCOEL (2016). *SCOEL/REC/125 Formaldehyde. Recommendation from the Scientific Committee on Occupational Exposure Limits*. Brussels: European Commission.

Sellakumar, A. R., Snyder, C. A., Solomon, J. J., Albert, R. E. (1985). Carcinogenicity of formaldehyde and hydrogen chloride in rats. *Toxicol Appl Pharmacol,* 81(3 Pt 1), 401-6.

Sheehan, P., Singhal, A., Bogen, K. T., MacIntosh, D., Kalmes, R. M., McCarthy, J. (2018). Potential Exposure and Cancer Risk from Formaldehyde Emissions from Installed Chinese Manufactured Laminate Flooring. *Risk Analysis,* 38(6), 1128-1142.

Swenberg, J. A., Kerns, W. D., Mitchell, R. I., Gralla, E. J., Pavkov, K. L. (1980). Induction of squamous cell carcinomas of the rat nasal cavity by inhalation exposure to formaldehyde vapor. *Cancer Res,* 40(9), 3398-402.

Trantallidi, M., Dimitroulopoulou, C., Wolkoff, P., Kephalopoulos, S., Carrer, P. (2015). EPHECT III: Health risk assessment of exposure to household consumer products. *Science of The Total Environment,* 536, 903-913.

Tulpule, K., Dringen, R. (2013). Formaldehyde in brain: an overlooked player in neurodegeneration? *J Neurochem,* 127(1), 7-21.

UBA (2016). On the Question of an Asthma-triggering and/or worsening Potential of Formaldehyde in the Indoor Air in Children Notification of the Committee on Interior Guideline (IGC). *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz,* 59(8), 1028-1039.

UNECE (2018). *Joint Forest Sector Questionnaire* [Online]. United Nations Economic Commission for Europe. Available: https://www.unece.org/forests/forestsfpmonlinedata/jfsq.html [Accessed 22 November 2018].

Villanueva, F., Tapia, A., Amo-Salas, M., Notario, A., Cabanas, B., Martinez, E. (2015). Levels and sources of volatile organic compounds including carbolyls in indoor air of homes of Puertollano, the most industrialized city in central Iberian Peninsula. Estimation of health risk. *International Journal of Hygiene and Environmental Health,* 218, 522-534.

Wallner, P., Munoz, U., Tappler, P., Wanka, A., Kundi, M., Shelton, J. F., Hutter, H. P. (2015). Indoor Environmental Quality in Mechanically Ventilated, Energy-Efficient Buildings vs. Conventional Buildings. *Int J Environ Res Public Health,* 12(11), 14132-47.

WHO (1989). *Formaldehyde. Published under the joint sponsorship of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization*. Geneva: World Health Organization.

WHO (2010). Formaldehyde. *WHO Guidelines for Indoor Air Quality: Selected Pollutants.* Geneva: World Health Organisation, 103-156.

Wilmer, J. W., Woutersen, R. A., Appelman, L. M., Leeman, W. R., Feron, V. J. (1989). Subchronic (13-week) inhalation toxicity study of formaldehyde in male rats: 8-hour intermittent versus 8-hour continuous exposures. *Toxicol Lett,* 47(3), 287-93.

Wittmann, O. (1962). Die nachträgliche Formaldehydabspaltung bei Spanplatten. *Holz als Roh- und Werkstoff,* 20(6), 221-224.

Woutersen, R. A., van Garderen-Hoetmer, A., Bruijntjes, J. P., Zwart, A., Feron, V. J. (1989). Nasal tumours in rats after severe injury to the nasal mucosa and prolonged exposure to 10 ppm formaldehyde. *J Appl Toxicol,* 9(1), 39-46.

Zhou, D., Zhang, J., Wang, H. (2011). Assessment of the potential reproductive toxicity of long-term exposure of adult male rats to low-dose formaldehyde. *Toxicol Ind Health,* 27(7), 591-8.

Zhou, D. X., Qiu, S. D., Zhang, J., Tian, H., Wang, H. X. (2006). The protective effect of vitamin E against oxidative damage caused by formaldehyde in the testes of adult rats. *Asian J Androl,* 8(5), 584-8.