ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME: Formaldehyde and formaldehyde releasers

IUPAC NAME: Formaldehyde and formaldehyde releasers

EC NUMBER: 200-001-8

CAS NUMBER: 50-00-0

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

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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

Formaldehyde and formaldehyde releasing substances (i.e. formaldehyde releasers) are manufactured and used in multiple sectors in the EU. While formaldehyde is mostly used as a chemical intermediate and has limited applications as biocide, substances manufactured from formaldehyde are used primarily in the production of articles.

For certain formaldehyde releasing materials 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. 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 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 released from articles

The proposal is to restrict the placing on the market or the use of all articles releasing formaldehyde at concentrations greater than or equal to 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1. 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. Articles subject to the CMRs in textiles restriction as well as the use of formaldehyde and formaldehyde releasers as biocide are exempted from the proposed restriction.

Formaldehyde EC No 200-001-8 CAS No 50-00-0	1. Articles shall not be placed on the market or used if formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1. 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 subject to Regulation (EU) 2018/1513. 4. 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.

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.

Identified hazard and risk

Formaldehyde is a high production volume chemical with a wide array of uses. 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 (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. 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 and 0.3 ppm, 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 with a NOAEC of 2 ppm. 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.

In the EU there is no harmonised limit value for formaldehyde in indoor air, however 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 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 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 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 wood-based materials used in construction and finished articles (e.g. furniture and laminate flooring).

Justification that action is required on a Union-wide basis

The risks associated with articles that may release formaldehyde 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.
- 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). 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 articles are already in place at the EU level in some industry sectors. 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. 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.
- The risks of health issues for consumers exposed to formaldehyde released from articles are considered not adequately controlled EU-wide.
- The free movement of goods within the Union.

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 formaldehyde 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 (performed in accordance with EN 717-1 or under similar 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. 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.

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.[2] 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 Annex V of 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.

[2] 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

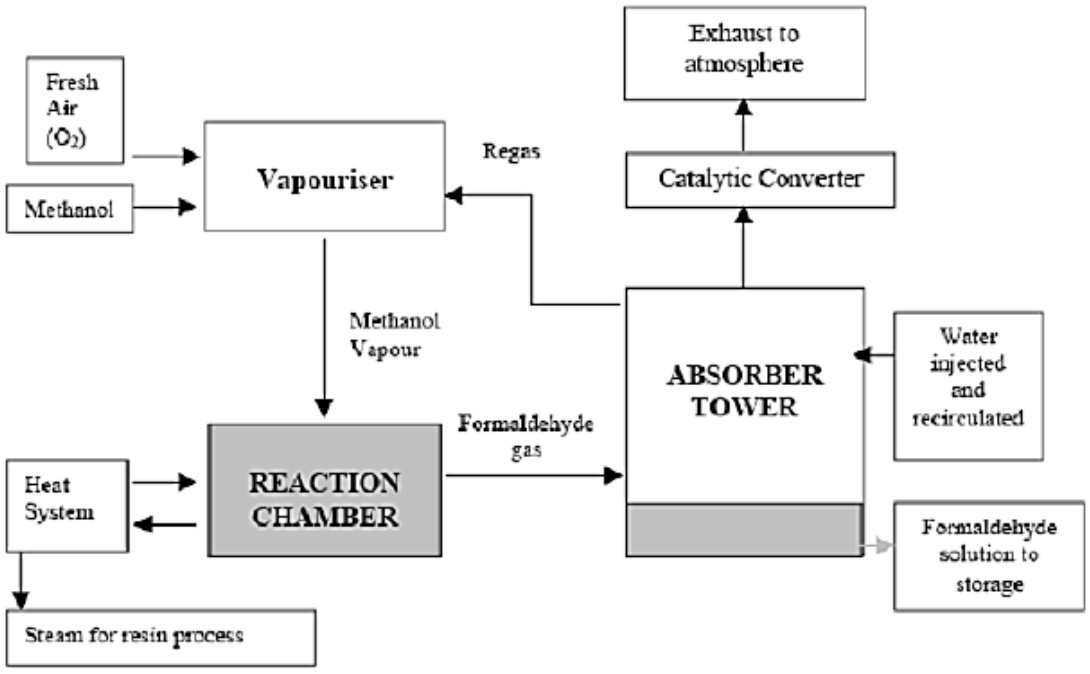
1.2.1. Manufacture of formaldehyde

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[3], 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.

[3] 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.[4]

- ***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 diisocyanate (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.

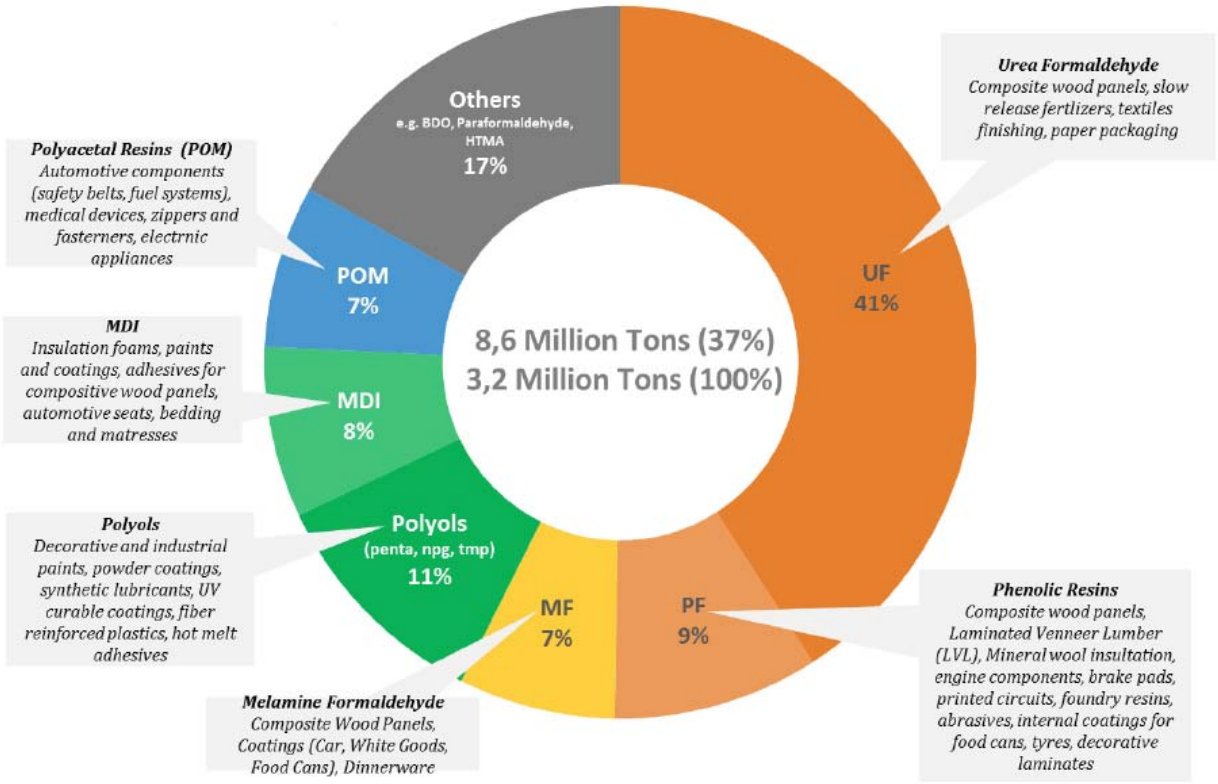
- ***1,4-Butanediol (BDO)***: Used as intermediate in the production of tetrahydrofuran (THF) and polybutylene (PBT) resins. These resins are used to produce fibres in the textile industry and other products such as buttons and rollers. PBT resins are also used to produce components for automotive and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

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

[4] 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 in the manufacture of resins. These resins 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).[5] 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 40% of the formaldehyde manufactured in and imported into the EU is used in the production of paints for industrial use, in the production of mineral wool, in the textile and leather industry, and in the production of foams for insulation of buildings and cars.

[5] 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 formaldehyde (UF) resins	68002-18-6	614-201-1	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 formaldehyde (PF) resins	68610-07-1	614-660-8	Applications include fibreglass insulation, laminates and automobile components.
Melamine formaldehyde (MF) resins	68002-20-0	614-203-2	Used in production of laminates, surface coatings for automobiles and housewares.
Polyoxymethilenes (POM)	66455-31-0	613-936-5	Used to make precision parts in a wide range of industrial and automotive applications.
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.[6]

[6] 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% ≤ C < 25%, Skin Sens. 1; H317: C ≥ 0.2%, Eye Irrit. 2; H319: 5% ≤ C < 25%, STOT SE 3; H335: C ≥ 5% and Skin Corr. 1B; H314: C ≥ 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 ≥ 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[7]

1.3.4.1. Endogenous formaldehyde

In humans (as in animals) formaldehyde is an essential metabolic intermediate in all cells. It is produced endogenously from serine, glycine, methionine and choline, and it is generated in the demethylation of N-, O- and S-methyl compounds. It is an essential intermediate in the biosynthesis of purines, thymidine and certain amino acids (IARC, 1995).

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).

[7] 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, 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 formaldehyde for 40 minutes, in rats exposed to 14.4 ppm for 2 hours (Heck et al., 1985), or in monkeys exposed to 6 ppm for 4 weeks (6 h/day, 5 days/week) (Casanova et al., 1988).

Formaldehyde is poorly absorbed following dermal application. 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 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. 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 formaldehyde for 4 hours on 10 consecutive days. In addition, a group with 0.3 ppm continuous formaldehyde exposure with 4-times 15-minutes peaks of 0.6 ppm and a group with 0.5 ppm continuous exposure with 4-times 15-minutes peaks of 1 ppm 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 with peaks of 1 ppm. 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 in case of a constant exposure level and 0.3 ppm with peaks of 0.6 ppm 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 and 0.7 ppm and to 0.3 ppm with peak exposures (4-times, 15 minutes) of 0.6 ppm, and to 0.4 ppm with peak exposures of 0.8 ppm, 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 for 4 hours and to 0.4 ppm for 4 hours with peaks of 0.8 ppm 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 for 4 hours and of 0.4 ppm for 4 hours with peaks of 0.8 ppm 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 for continuous exposures and of 0.3 ppm for continuous exposure with peak exposure (4-times 15 minutes) of 0.6 ppm. 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 (range 0.02 to 0.5 ppm) (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, 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 for 2 years no histopathological changes were observed (no observed adverse effect concentration, NOAEC; Woutersen et al. (1989)). From concentrations of 2 ppm, rhinitis, epithelial dysplasia and even papillomatous adenomas and squamous metaplasia of the respiratory epithelium of the nose were found, from 6 ppm 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 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, but not after continuous exposure to 2 ppm. 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 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 (Kerns et al., 1983).

In hamsters exposed to FA concentrations of 10 ppm (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 for 26 weeks, metaplasia and hyperplasia were observed in 1/6 and 6/6 animals of the 1 and 2 ppm groups, respectively. In the animals exposed to concentrations of 0.2 ppm, 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).

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 in Fischer 344 rats; for rhesus monkeys the slope is less well defined. At concentrations above 6 ppm 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, 5.8, 9.1 or 15 ppm [$^{13}CD_2$]-formaldehyde 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 for 0.7, 2.0, 5.8, 9.1 and 15.2 ppm [$^{13}CD_2$]-formaldehyde, 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 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. DPX formation in the nose was identified still at the lowest formaldehyde concentrations tested of 0.3 ppm in rats (Casanova et al., 1989) and 0.7 ppm in rhesus monkeys (Casanova et al., 1991).

In summary, taking into account the relatively high endogenous concentrations of formaldehyde and the endogenous mechanisms to repair DNA adducts and DPX formed by endogenous formaldehyde, exogenous formaldehyde concentrations that do not lead to a significant increase in endogenous formaldehyde levels are not expected to lead to a significant contribution in genotoxic effects.

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 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)	Rats with SCC/group size (% with SCC)
0	0/453 (0)
0.3	0/32 (0)
0.7	0/90 (0)
2	0/364 (0) (apparent NOAEC)
6	3/325 (0.9) (apparent LOAEC)
10	20/90 (22)
14	102/232 (44)
15	120/278 (43)

Source: Nielsen et al. (2017)

SCOEL (2016) in its opinion has recommended an Occupational Exposure Limit Value (OEL) of 0.3 ppm (8h TWA) with a short term exposure limit of 0.6 ppm. 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), adducts were still detected. However, adducts caused by endogenous, physiological formaldehyde by far exceeded the amounts caused by exogenous formaldehyde. At 0.3 ppm 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 poorly absorbed through intact skin; 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 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 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 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 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 (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 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 (LOAEC) with no effects observed at 20 ppm (NOAEC). A slight foetotoxic effect (reduced weight in male foetuses) was observed ≥ 20 ppm with a NOAEC at 10 ppm (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.

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

Nielsen et al. (2013) also referred to several Russian inhalation studies with formaldehyde exposures from 0.01 to 1.2 ppm 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 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).

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). WHO (2010) explicitly stated that this value should 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 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), adducts were still detected. However, adducts caused by endogenous, physiological formaldehyde by far exceeded the amounts caused by exogenous formaldehyde (0.7 ppm).

The most sensitive effect of formaldehyde in humans is sensory irritation, for which a NOAEC of 0.5 ppm for continuous exposure and of 0.3 ppm for continuous exposure with peak exposure (4-times 15 minutes) of 0.6 ppm 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.

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 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 reasonable worst case 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, textiles and footwear which was adopted on 10 October 2018 (EC, 2018a). The CMRs in textiles restriction 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 at very high concentrations. Very high concentrations are unlikely as concentrations in textiles are limited by Regulation (EU) 2018/1513. In addition, the contribution of textiles subject to the CMRs in textiles restriction, with formaldehyde at either of the two limits, is unlikely to significantly contribute to any inhalation exposure. 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 the CMRs in textiles restriction, such as wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners, will be subject to this current restriction proposal and must comply with the emission limit proposed.

Formaldehyde present in clothing and other textiles could theoretically cause skin sensitisation. However, the low concentration limits to be expected from compliance with the CMRs in textiles restriction or from compliance with this current restriction proposal would mean the exposure to formaldehyde from all sources would be very low. Formaldehyde has a special concentration limit of 0.2% for skin sensitisation and the concentration 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 the concern for the induction of sensitisation is very low with a margin of safety of at least 100 from the concentration limit. No lower limit for elicitation of an effect has been identified but this is not an effect 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.

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 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.[8] 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[9] 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 other UF pressed wood products like hardwood, paints, wallpapers, curtains and carpets, cleaning agents, combustion sources such as cooking (ECHA, 2015).

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

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

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, 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 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.
- **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:
    - 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

Source: Adapted from Salthammer and Gunschera (2017)

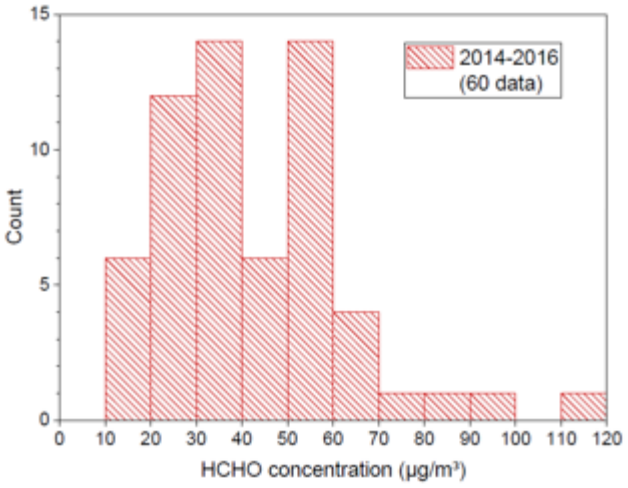
1.3.6.4. Measured formaldehyde concentrations in indoor air

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.

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 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. 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 assumes the reasonable worst 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. The exposure scenario is further subdivided into three sub-scenarios where different amounts of wood-based panels are assumed. 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 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%		

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.

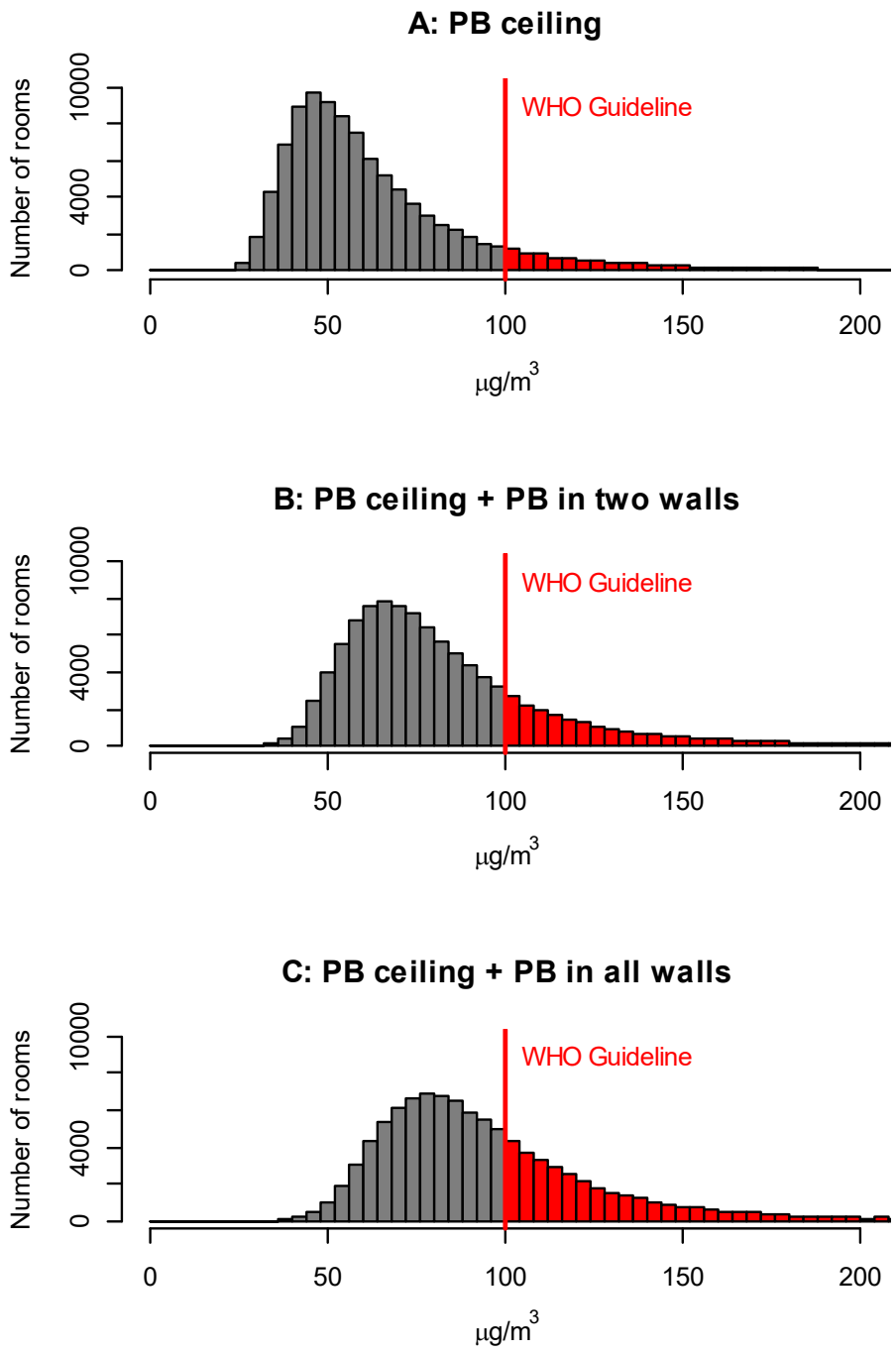
Table 9: Summary of simulated formaldehyde concentration in 100 000 rooms

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

Scenario / Source	A: PB ceiling		B: PB ceiling + PB in two walls		C: PB ceiling + PB in all walls	
	Median [µg/m³]	P95 [µg/m³]	Median [µg/m³]	P95 [µg/m³]	Median [µg/m³]	P95 [µg/m³]
Wall 1	0	0	24	40	40	66
Ceiling 1	16	27	16	27	16	27
Wall 2	5	10	5	10	5	10
Ceiling 2	2	4	2	4	2	4
Flooring	7	18	7	18	7	18
Furniture	27	124	27	124	27	124
Textiles	1	2	1	2	1	2
Door	2	9	2	9	2	9
Window	2	2	2	2	2	2
Outdoor air	4	15	4	15	4	15
Indoor chem.	3	6	3	6	3	6
Sink (-)	19	43	25	50	29	55

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. However, 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.

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 is first and foremost intended to harmonise risk management measures related to the use of formaldehyde and formaldehyde releasers in 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.

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)[10] 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[11] 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).

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

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

Currently, eight EU Member States – Austria, Denmark, Germany, Greece, Italy, Lithuania[12], the Netherlands[13] 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).

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 reasonable worst case 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

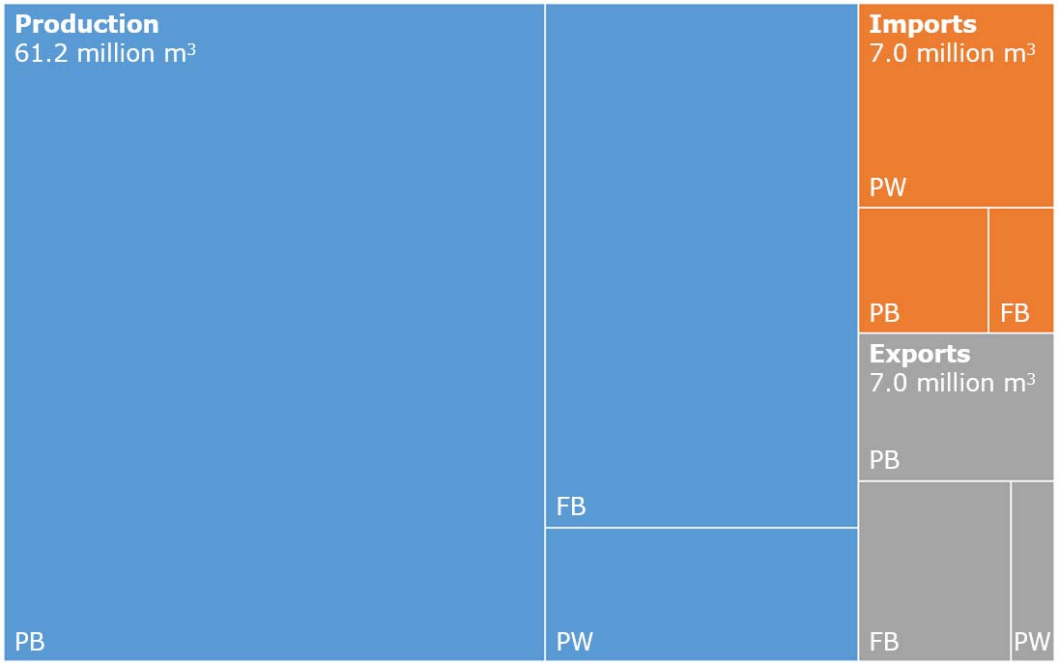
If no legislative action would be taken to restrict formaldehyde emissions from articles for consumer use, high formaldehyde emitting articles could still be marketed in the EU, potentially contributing to indoor air formaldehyde concentrations that exceed the WHO guideline value under specific circumstances. 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 5 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.

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

[13] 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.

Figure 5: EU production and extra-EU trade of wood-based panels, 2016

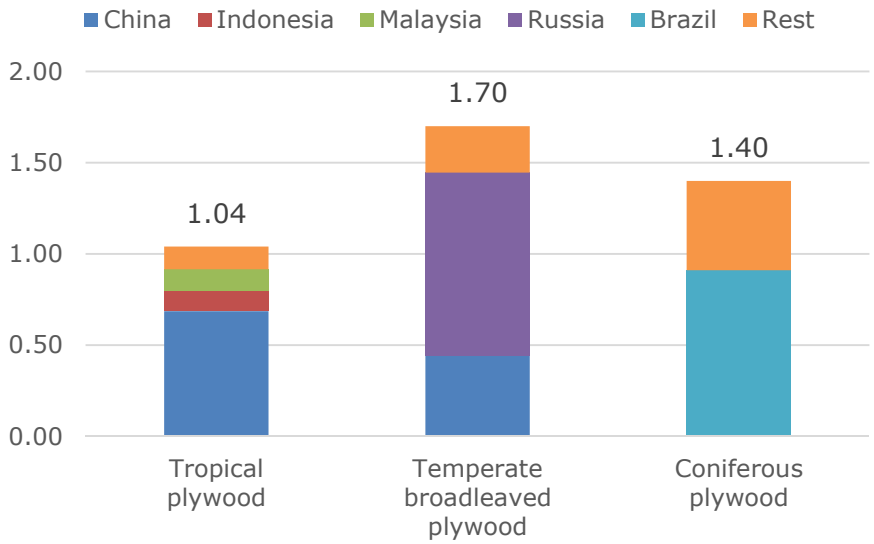


PW = Plywood, PB = Particleboard (incl. OSB), FB = Fibreboard (comprises MDF, hardboard and other fibreboard)

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

Figure 6 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 6: 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 m^3 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 m^3 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 m^3, of which an estimated 4 million m^3 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 formaldehyde releasing articles for consumer use 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. furniture industry, 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 all 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 option appears to be RO4. The proposal is to restrict the placing on the market or the use of all articles releasing formaldehyde at concentrations greater than or equal to 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1.

2.2.2.1. Scope of the proposed restriction

The proposed emission limit corresponds to the E1 emission class which has been defined for wood-based panels in EN 13986 and extends the E1 class to all formaldehyde releasing articles. The substances (containing formaldehyde or formaldehyde releasers) used in the production process of articles are not relevant to the restriction as only formaldehyde emissions will be 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.

Formaldehyde concentrations in textiles worn on or near the skin are already limited by the CMRs in textiles restriction, i.e. Regulation (EU) 2018/1513. As formaldehyde is very unlikely to cause cancer through dermal exposure unless at very high concentrations, the limits established by Regulation (EU) 2018/1513 are considered protective. In addition, the contribution of textiles subject to the CMRs in textiles restriction, with formaldehyde at either of the two limits (i.e. 75 mg/kg or 300 mg/kg), is unlikely to significantly contribute to any inhalation exposure. Likewise, with regards to skin sensitisation, the low concentrations to be expected from compliance with the CMRs in textiles restriction, are significantly below the

concentration of 0.2% for skin sensitisation (see Section 1.3.6). Articles subject to the CMRs in textiles restriction are therefore exempted from the current restriction proposal. It should however be noted that articles not subject to the CMRs in textiles restriction, 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.

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):[14] 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.

In 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 limited to articles for consumer use but relates more broadly to articles through which consumers can become exposed to formaldehyde.

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 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 originally 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

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

formaldehyde emissions of samples of construction materials, including wood-based panels. All methods are described in EN 717-1 including typical test situations.

In all formaldehyde emitting articles, the release of formaldehyde is due to formaldehyde-based 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 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 (in particular EN 717-1) has no limitations with respect to the material or the shape of the article and it does not require any treatment of the article to be tested. It is therefore considered a reliable method to test formaldehyde emissions from all types of articles of any shape and any material. Further information on EN 717-1, a comparison with another standardised chamber method (EN 16516), as well as further justifications for using EN 717-1 as reference method, are presented in Annex D.3.

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.

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-based 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.

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[15] – a range that, according to EPF, was also confirmed by its members.[16] 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.[17] 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.

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[15] 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).

[16] 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.

[17] 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).

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.

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

	Price E1 [2] [€/m³]	Price E2 [3] [€/m³]	Δ Price [€/m³]	E2 panels [1 000 m³]	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

Testing costs would concern all companies that supply, retail or import wood-based panels and would need to make sure that these do comply with the formaldehyde emission limit of the proposed restriction. According to industry information, only a limited number of manufacturers have their own test chambers. In practice, wood-based panel producers are controlling formaldehyde emissions in their factory production control via the smaller scale

derived test methods, EN 717-2 and EN 120[18], in accordance with quality control limits based on correlations with EN 717-1.

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 test methods which are derived from the proposed reference test method.

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 (see Annex D.5).

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.

[18] See Annex D.3 for further information on the derived test methods.

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/m³ (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 7 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[19] 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.

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 7 by the vertical line labelled "E1" at 124 µg/(m^{2}h).[20] 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.

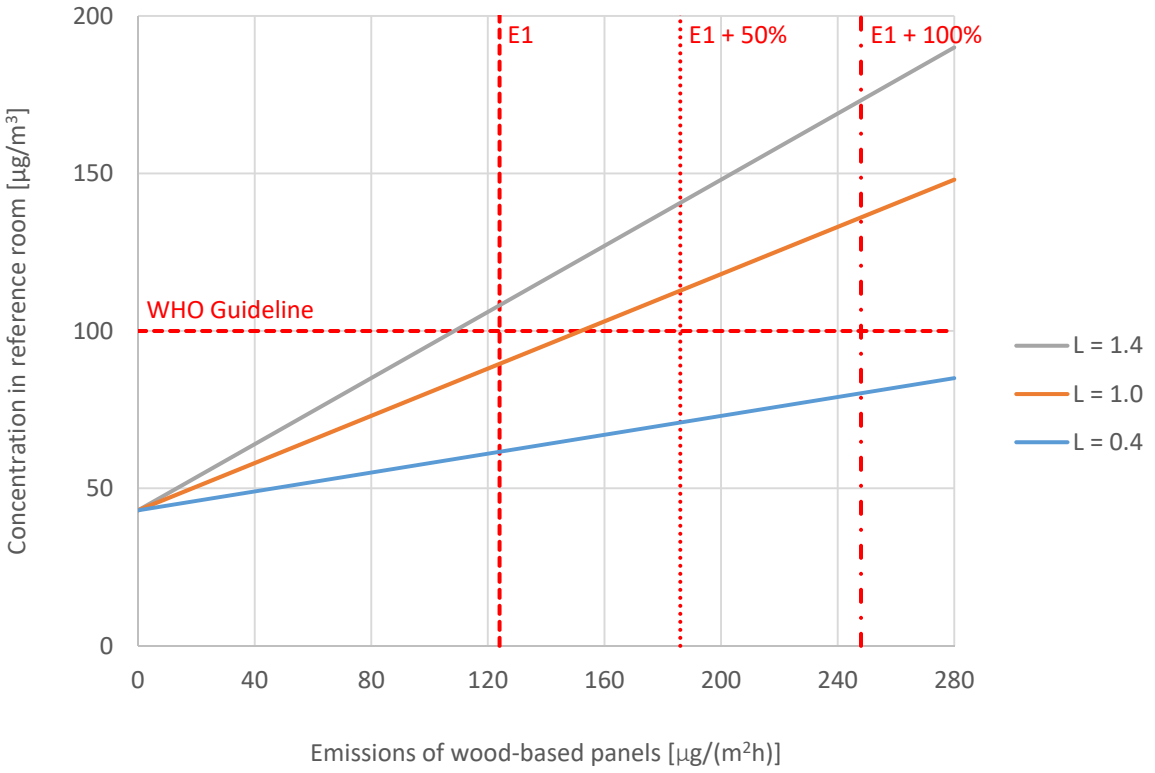
Although Figure 7 is constructed for three different loading factors of wood-based panels, the analysis here focuses on the central scenario, i.e. wood-based panels used in the ceiling and in two of the walls (L = 1.0 m^2/m^3). The other two scenarios are discussed as part of the uncertainty analysis 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 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.

[19] 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.

[20] The proposed restriction (and E1 as defined in EN 13986) refers to the formaldehyde concentration (C, µg/m^3) in the air of a test chamber (EN 717-1) rather than an area specific emission rate (SER_A, µg/(m^{2}h)). But since EN 717-1 sets the air exchange rate (ACH) to 1 h^{-1} and the loading factor (L) for wood-based panels to 1 m^2/m^3, 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).

Figure 7: Formaldehyde emissions vs reference room concentrations



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 m^3 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 m^3 or, assuming an average thickness of 16 mm, 71 699 000 m^2 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 m^3 E2 panels consumed in EU in 2016 [1]	% used in building/ construction	1 000 m^3 used in building/ construction	1 000 m^2 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 m^2 (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 m^3 for the average home in the EU. In the central exposure scenario (sub-scenario B in Table 8) the loading factor of 1.0 m^2/m^3 for wood-based panels implies that 240 m^2 of panels are used for a home measuring 240 m^3. 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 m^2 / 240 m^2). 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.

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[21] are small and medium-sized enterprises (SMEs), though large enterprises may play a more important role in the wood-based panel sub-sector (EC, 2018c). 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.

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

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.

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 similar 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)	Test chamber
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

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.

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.[22] 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 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.

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

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.[23] 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)*

[23] 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).

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 7 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.[24]

- **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.

[24] 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 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.

- **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.[25] 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

[25] 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).

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 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**: Additional testing costs to wood-based panel producers due to the proposed restriction are assumed to be negligible as formaldehyde emissions testing, at least according to the derived test methods EN 717-2 and EN 120, is generally part of factory production control. The increased focus on formaldehyde emissions may however lead some manufacturers to increase their testing efforts, meaning that testing costs could be underestimated.

- **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.[26] 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 7.

- **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.

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

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 or the use of all articles releasing formaldehyde at concentrations greater than or equal to 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1. 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).

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