Worker exposure to formaldehyde and formaldehyde releasers

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In December 2017, the Commission requested ECHA to prepare an Annex XV dossier on the use of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses. This was submitted on 11 January 2019 and published on ECHA's website on 30 January 2019. In addition to the Annex XV restriction report, the Commission requested ECHA to gather existing information to assess potential exposure to formaldehyde or formaldehyde releasers at the workplace. This document reports on that latter task.

Formaldehyde was included in the Community Rolling Action Plan (CoRAP) under REACH in 2013 because of its CMR[1] properties. The resulting substance evaluation was undertaken jointly by France (leading the evaluation and addressing risks for workers) and the Netherlands (addressing risks for consumers). The substance evaluation on workers was finalised in 2014 with the conclusion that there were risks for workers in some sector activities. As a result the French Competent Authority on REACH prepared a draft Risk Management Option Analysis (RMOA) in 2016 wherein several Risk Management Options (RMO) were identified to control risks to workers. The RMOA was subject to a public consultation held from July to December 2016 to obtain clarification on current uses of formaldehyde in the EU. France and the Netherlands submitted jointly the conclusions of their RMOA to ECHA in April 2019. The conclusions of French RMOA, finalised in June 2019[2], have been taken into account in this document.

Formaldehyde is classified as Carc. 1B as from January 2016 and formaldehyde containing mixtures are similarly classified if they contain formaldehyde in concentrations ≥0.1%. As a result of this classification, consumer uses of such mixtures were restricted by the Commission (spring 2018) pursuant to entries 28 and 30 of Annex XVII of REACH, which prohibits the use of CMR substances in concentrations ≥0.1% in consumer products. Formaldehyde is also on the list of CMR substances (Cat. 1A and 1B) that are restricted under certain conditions for use in textile articles and clothing for consumer use[3] and it is classified as Category 1 skin sensitiser.

Formaldehyde releasers are substances that release formaldehyde during use. Release may be intentional (e.g. the case when formaldehyde is released by another substance because of its biocidal properties) or unintentional (e.g. due to degradation of another substance). These substances have been investigated by ECHA and a report with the results of the investigation was published in 2017[4]. Certain formaldehyde releasers are also classified as Carc. 1B if they release certain concentrations of formaldehyde.

One large group of formaldehyde releasers are formaldehyde based resins that may

[1] CMR stands for Carcinogenic Mutagenic and Toxic for Reproduction

[2] https://echa.europa.eu/documents/10162/0e49a55b-acde-0d6b-d18a-7b30d13dd4c1

[3] Regulation (EU) 2018/1513

[4] ECHA's investigation report on formaldehyde and formaldehyde releasers (March 2017) is accessible here: https://echa.europa.eu/documents/10162/13641/annex_xv_report_formaldehyde_en.pdf/58be2f0a-7ca7-264d-a594-da5051a1c74b

release formaldehyde during use or further down in the life cycle when they become part of an article. This is the case with wood based panels. The draft RMOA by France provides further information on other substances that might release formaldehyde, such as urea- formaldehyde (UF) resins, melamine-formaldehyde (MF) resins, phenol-formaldehyde (PF) resins, polyacetal resins and polyoxymethylene (POM)). Formaldehyde and formaldehyde releasers are widely used in many industry sectors such as wood and wood-based products, production of resins and adhesives, inks, paints and coatings, textiles and automotive. Formaldehyde is also an intermediate used in the synthesis of industrial chemicals and plastics but are outside of the scope of any potential restriction if they are on-site isolated intermediates (article 68(1)).

Formaldehyde and its releasers have also applications in pathology and embalming, for its sterilising, preserving and stabilising properties.

Formaldehyde releasers are relevant for the scope of this report because they release formaldehyde, the hazards and risks from exposure to formaldehyde releasers will be equivalent to formaldehyde and are not separately covered. Exposure to workers occurs mainly through inhalation of the gaseous form of formaldehyde. In some cases exposure may occur through dermal contact to the liquid form of formaldehyde. The effects of exposure differ a lot depending on type and the duration of the exposure.

Groups of workers at potential risk include healthcare professionals, medical lab technicians, veterinary and mortuary workers as well as teachers and students who handle biological specimens preserved in formaldehyde or formalin, agricultural workers, workers employed in the sector of wood and wood products where formaldehyde based resins are used (and, in some cases, produced) and workers of chemical industry where formaldehyde based products are manufactured. Uses of formaldehyde and certain formaldehyde releasers as biocide or in cosmetics are already regulated under the Cosmetic Product Regulation (Regulation (EC) No 1223/2009) and Biocidal Product Regulation (Regulation (EU) No 528/2012).

The Commission has adopted a Binding Occupational Exposure Limit (OEL) for Formaldehyde (inhalation) of 0.3 ppm (as 8 hrs TWA[5]) and 0.6 ppm as Short Term Exposure Limit (STEL) (15 min). in the middle of 2019. European Formaldehyde manufacturers and EU producers of wood based panels and EU federation of Building and woodworkers have already signed voluntary agreements to limit workers' exposure to formaldehyde to levels below the BOEL. However, available data on occupational exposure demonstrate that there could be a number of sectors where exposure to workers may exceed the OEL. It may be the case of Small and Medium Enterprises (SME) not part of industry associations, older factories where manual operations are still predominant and professional workers. In fact information in registration dossiers, shows that risks can only be controlled if technical risk management measures such as containment of the process general and local exhaust ventilation are applied. In some cases, also respiratory protection is required to limit exposure to workers to safe levels. These measures are unlikely to be implemented by professional workers and are of difficult implementation in small companies. Although exposure to formaldehyde from inhalation is the main risks, this substance is also a known skin sensitiser and may pose

[5] Time Weighted Average

risks from dermal contact. These risks are not addressed by the proposed OELs however a skin sensitiser notation is proposed by COM.

Therefore, ECHA is proposing:

- A further assessment of exposure to formaldehyde for workers employed in sectors not covered by voluntary agreements (in particular SME) where formaldehyde and formaldehyde based substances / mixtures are used to verify how and if compliance with adopted binding OEL is achieved;
- an assessment of exposure to formaldehyde for professional and self-employed workers and an analysis of available regulatory risk management options to address possible risks including the possibility to use, for these categories of workers the same risk management approach taken for consumers. A potential restriction under REACH could be a suitable regulatory risk management option in these cases;
- to encourage EU producers and importers of formaldehyde and formaldehyde based products to extend the participation to the voluntary agreement they have already committed to, also to their downstream users. This action will support the implementation of an EU wide multi annual monitoring plan for many industry sectors which will be of help for authorities to understand if industrial and professional workers of these sectors not currently meeting OEL will do that in the future.

Investigation report

1. Problem identification

Formaldehyde is a colourless, strong-smelling gas. It is quickly broken down in the air and dissolves easily in water (but does not last long there either). When dissolved in water it is called formalin. Formalin is mostly used as an intermediate in the manufacturing of other substances (e.g. formaldehyde-based resins that are, in turn, used in the production of a number of articles including wood based products), as a disinfectant for industrial and professional uses, and as a preservative in funeral homes and medical labs. Formaldehyde and some formaldehyde releasers can also be used as preservative in some foods and in products such as antiseptics, medicines, and cosmetics. Because of formaldehydes' hazardous properties (carcinogenicity, respiratory irritation and skin sensitisation), exposure to formaldehyde may generate adverse effects on human health.

In almost all relevant identified uses of formaldehyde and formaldehyde releasers, worker tasks may result in formaldehyde exposure. These include but are not limited to: transferring operations, mixing or blending processes, surface applications (e.g. roller or brushing application, spraying, dipping and pouring), sampling, laboratory analysis, maintenance and repair operations, cleaning and waste management, handling of products that may release formaldehyde (e.g. panels, building materials etc.). The main factors that affect occupational exposures to formaldehyde include the level of automation of the facility including amount and frequency of manual operations and maintenance activities, the condition of the piping and equipment, the presence and efficiency of fume hoods or local collection systems at the source of the emissions, the efficiency of the general ventilation system, training and appropriate use of PPE (TNO, 2013).

2. Human health hazard assessment (summary)

Formaldehyde is a highly reactive, acutely toxic substance which can cause 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.

Related to carcinogenicity, SCOEL[6] (2016) considered that a mode-of-action based limit value can be derived. This is because 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

[6] SCOEL stands for Scientific Committee on Occupational Exposure Limits. It is a committee of experts set by the European Commission to evaluate potential health effect of occupational exposure to chemicals.

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[7] 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; 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). In its proposal for amending the Directive 2004/37 (CMD) on the protection of workers from the risk related to exposure to carcinogens and mutagens at work[8], the Commission has proposed to adopt a Binding Occupational Exposure Limit (OEL) for formaldehyde in line with the SCOEL recommendation. The proposal, submitted in April 2018 has been adopted with the Directive (EU) 2019/983 of 5 June 2019 amending the CMD [9]. Based on the adopted OEL, the DNEL for long-term inhalation exposure will be considered for the purposes of this report as 0.3 ppm (0.369 mg/m^3) for workers.

For the assessment of excess cancer risk from inhaled formaldehyde, the German Environmental Agency – UBA - (2016) used a non-linear approach due to the results of animal studies showing an exponential increase in excess risk: 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 ECHA's concludes that inhalation excess cancer risk posed by formaldehyde in the air at the OEL for workers of 0.3 ppm (0.369 mg/m^3) can be considered negligible in relation to the endogenous formaldehyde concentration.

Dermal effects are most likely to be from sensitisation or irritation rather than any carcinogenicity (as formaldehyde is somewhat poorly absorbed and transformed in the skin). Formaldehyde is a known skin sensitiser, which has the classification: Skin Sens 1; H317 with a concentration limit for mixtures of 0.2%. The sensitising properties of formaldehyde have been confirmed in guinea pig maximisation test, in the Buehler test in guinea pigs and in the mouse local lymph node assay. Formaldehyde is also a dermal allergen in humans. France, in its RMOA has indicated a threshold of 3 µg/cm^2 (occluded test condition) in sensitised humans (Fischer et al. (1995)) and a threshold of 37 µg/cm^2 (Basketter et al. (2008)) in non sensitised humans for induction of skin sensitisation. The biocidal assessment for formaldehyde (ECHA, 2017) 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)*

[7] No Observed Adverse Effect Concentration

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018SC0088

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.164.01.0023.01.ENG

Information on other effects can be found in draft RMOA by France, in the SCOEL (2016) recommendation on Formaldehyde and in ECHA proposal for restriction of formaldehyde and formaldehyde releasers in articles and mixtures for consumer uses (2019)[10].

3. Exposure to workers

3.1. Manufacture of formaldehyde

About 85% of the total formaldehyde consumption in various industrial sectors of the EU economy is used as a chemical intermediate in the production of formaldehyde-based resins and other chemicals. 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 production processes which use the silver catalyst process and those which use oxide manufacturing 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 of 98-99%) (IARC[11], 2006).

Formaldehyde is commonly not produced in pure form as it is not stable. Formal or Formalin is usually produced instead with 30-50% of formaldehyde. The world production capacity of Formalin is 40 million tonnes per year of which Europe represents around 25% with a production capacity of 9.5 million tonnes per year (Merchant Research and consulting, 2012, quoted in RPA/TNO, 2013).

Formaldehyde is registered under REACH in quantities >1 million tonnes per year. The total formaldehyde production in Europe (EU28 + Norway + Switzerland) is around 3.2 million tonnes as 100% pure formaldehyde, which is equivalent to 8.6 million tonnes as 37% water solution.

3.2. Industrial uses of formaldehyde

The French RMOA provides information on the major applications for formaldehyde-based resins. According to an industry report (Formacare, 2015), formaldehyde is used at industrial and professional level as:

1. Starting material for the production of FA-based resins such as:

- condensed resins (62% of total FA consumption) including:
  - Urea-Formaldehyde (UF) resins
  - Melamine-Formaldehyde (MF) resins
  - Phenol-Formaldehyde (PF) resins
- Polyacetal resins (polyoxymethylene – POM): 8% of total FA consumption Polyols: 9% of total FA consumption Polyurethanes (MDI): 6% of total formaldehyde consumptions

2. Other uses, accounting for 15% of total FA consumption in the EU include:

- Use as an intermediate in the chemical synthesis of:

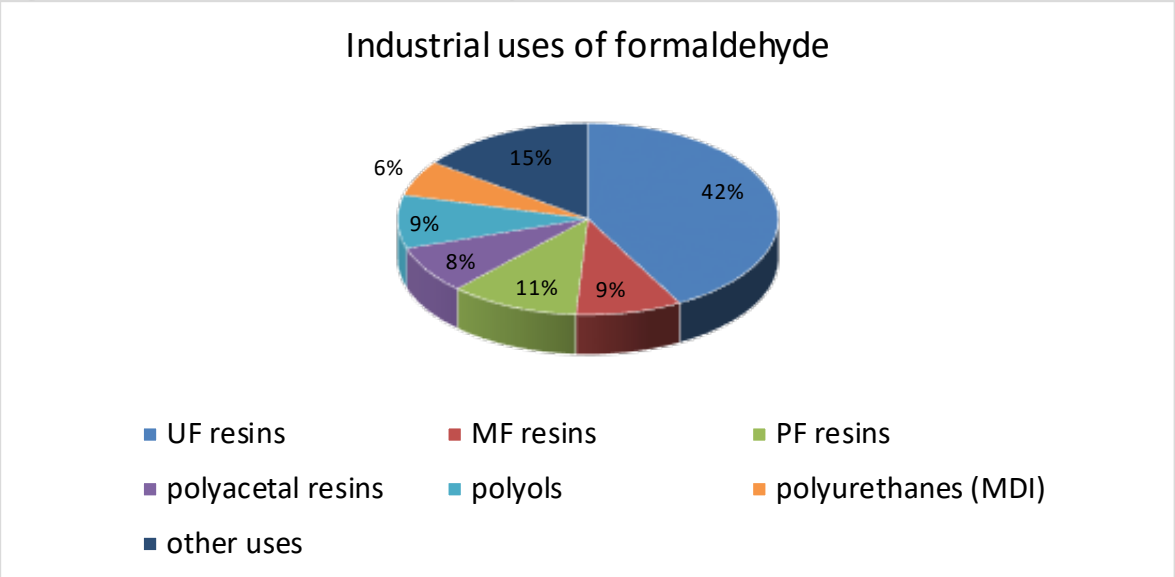
[10] https://echa.europa.eu/documents/10162/019ab915-c3a6-3441-00eb-69e970c1c315

[11] International Agency for Research on Cancer

  - methylene dianiline (MDA)
  - diphenylmethane diisocyanate (MDI)
  - hexamethylenetetraamine (HTMA - hexamine)
  - trimethylol propane
  - neopentylglycol
  - pentarythritol (for production of alkyd resins and neopolyol esthers)
  - butanediol (BDO) acetylenic agents
- Use as reagent and bactericidal agent used in healthcare applications such as tissue preservation, embalming fluids in autopsy rooms and pathology departments, disinfectant in operating rooms, vaccines, animal medicines, etc.
- Use as preservative, biocidal and cleaning agent in food applications
- Biocidal use in germicides, bactericides and fungicides as well as an ingredient in fertilizers in agriculture and non-agricultural sector.

According to a study conducted by ICF International (2013) in the context of developing criteria for implementing article 68(2) of REACH, major intermediate applications of formaldehyde-based resins are in the construction, automotive, aircraft, clothing and healthcare industries. In addition to resin production, formaldehyde is used also as an 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. The average percentages from different industrial uses of formaldehyde are presented in Figure 1.

Figure 1. Industrial uses of formaldehyde.



3.2.1. Production of formaldehyde-based resins

UF, MF and PF resins are the three major commercially-used resins formulated with formaldehyde and the primary use of formaldehyde.

3.2.1.1. Urea-formaldehyde (UF) resins

UF resins are the main use of formaldehyde accounting for around 42% of the EU formaldehyde consumption. UF resins are primarily used as binders (adhesives) in non-

structural wood-based panels (WBP), and wooden furniture. Other uses include industrial coatings, slow release fertilisers, textile finishing and paper packaging (Formacare, 2015). 80% of the UF resins that are manufactured in the EU are currently used to produce building materials such as particle board, PW (plywood), MDF (medium-density fibreboards) and components of melamine-phenolic resins for production of laminated flooring board. Formaldehyde is also used to manufacture different types of paper (RMOA, 2016).

3.2.1.2. Melamine-formaldehyde (MF) resins

MF resins account for about 9% of the EU formaldehyde consumption and are used predominantly as paper impregnating resins for the surfacing of panels, in the production of composite wood panels for construction and in wooden furniture. MF resins are also used in the production of external coatings for cars and other applications (industrial) and in production of adhesives, internal coatings for food cans and dinnerware (Formacare, 2015).

3.2.1.3. Phenol formaldehyde resins (PF)

PF resins account for about 11% of the EU formaldehyde consumption. They are divided into two groups: resols and novolacs. Resols (no cross linked) are hard, stable and resistant to heat, moisture and chemicals. Novolacs (cross linked) are more resistant to impact. Both resins are used as a binder in insulation, wood product applications and paper impregnations.

3.2.1.4. Polyacetals resins (POM)

POM (also known as acetal polymers or polyoxymethylene) are thermoplastics, which are inherently self-lubricating and are particularly suited to a wide range of applications particularly in automotive industry (e.g. safety belt components, fuels system components). They are also used in the manufacture of gears, bearings and housings, medical devices, snow and water ski bindings and straps, flow meters and electric/electronic equipment. Gears account for the largest segment across all markets in automobile and industrial products, but also in consumer articles and appliances such as cameras, DVD players and printers. The demand for polyacetals in Europe is growing and accounts currently for about 8% of the EU formaldehyde consumption (RMOA, 2016).

3.2.2. Use of formaldehyde as intermediate in the synthesis of industrial chemicals and plastics

Formaldehyde is used as a starting material in chemical synthesis, such as the synthesis of diphenylmethane diisocyanate (MDI), butanediol (BDO) or polyols hexamethylen-etetraamine (HTMA - hexamine) and as an intermediate in the production of Paraformaldehyde (PFA). MDI accounts for about 6% of formaldehyde EU consumption. MDI constitutes an important material for the manufacturing of polyurethane (PUR) products which are widely used in the footwear, household appliance, construction, automotive and furniture manufacturing industries. PUR are produced in a variety of forms: rigid and flexible foams and used in binders, coatings, adhesives, sealants and elastomers (RMOA, 2016).

3.2.3. Wood furniture manufacturing

In wood furniture manufacturing, formaldehyde is primarily used in coatings. Coating are either laminated-resin-based or phenolic-resin-based. The latter is used only for metal furniture; aminated-resins are used in the manufacture of wood and metal furniture. Formaldehyde is released during the preparation of varnishes and paints, their application and drying. When the paint is applied inside a well-ventilated booth, the formaldehyde is exhausted and does not contaminate the work environment. However, the painter inside the booth can be exposed if they are located in the direction of flow of the varnish mist. For other tasks such as finishing, hardware installation and shipping, airborne formaldehyde can come from furniture that is drying, from applying the varnish and from drying zones. The most exposed workers are finishing painters, preparation painters, colourists and some manual labourers, including those working at the dryer or oven outfeeds, as well as maintenance personnel (mechanics, electricians), foremen and supervisors (IRSST, 2006a).

3.2.4. Wood panel manufacturing

Formaldehyde comes primarily from the resin used in the adhesive when it is heated. Several factors affect HCHO emission, such as the type of resin, the pressing time, the thickness of the panel, etc. Phenol-based resins have a very low emission rate compared to urea-based and melamine-based resins. Urea-formaldehyde resin has the highest rate. The most exposed workers are those assigned to the press operating tasks (usually in the control rooms) and maintenance tasks (press operator, mechanic, electrician, cleaner, foreman, etc.) when action must be taken during a breakdown or a production shutdown. Sample collection can also expose workers to high concentrations for short periods (IRSST, 2006b).

3.2.5. Biocidal uses of formaldehyde

Biocidal uses represent an important part of the uses of formaldehyde as a substance in particular by professional workers. These uses include, but they are not limited to embalming and use as disinfectant in the healthcare sector.

3.2.5.1. Embalming

Formaldehyde is the most widely used substance in the thanatopraxy sector. It is registered in PT22 under the Biocidal Products Regulation (Embalming or taxidermist fluids). Formaldehyde is used to delay the process of natural decomposition of bodies by the injection of formaldehyde-based solutions. It is used as a preservative, bactericidal and dehydrating agent for this purpose (RMOA, 2016).

Embalmers are likely to be exposed by skin contact through spills or splashes onto skin or eyes during handling processes, such as dilution, arterial and cavity embalming, cleansing and disinfections of body surfaces and orifices, and equipment cleaning by hosing. Spills and splashes during embalming were observed at the site visited (IRSST, 2006c).

The likelihood of exposure by inhalation is also high during embalming, such as during dilution of concentrated formalin solutions, application of the solution by spraying, and

handling viscera covered with paraformaldehyde powder. The duration of embalming a body varies depending on body conditions and customers' requirements, but usually takes 1-3 hours. The majority of the embalmers operate on a daily basis and exposure durations vary from 1-10 hours a day. Other staff involved in handling embalmed bodies, such as body dressing up and body lifting, may also be exposed to formaldehyde (NICNAS, 2006).

3.2.5.2. Healthcare sector

Formaldehyde is used as a biocidal and cleaning agent in hospitals (disinfection of surfaces, medical devices, linen) in the form of diluted formaldehyde as well as in dental surgery. It is a broad spectrum disinfectant and is active against bacteria, fungi and many viruses and spores. Its mechanism of action is based on protein denaturation. (RMOA, 2016) The EU Biocidal Products Regulation (BPR) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products aims to protect professional users and general population from the use of hazardous substances such as formaldehyde.

In October 2015, the French Ministry of Labour published a French occupational exposure survey of the private healthcare sector and the number of workers registered (153 600 in 2003 and 122 500 in 2010, i.e. a decrease of 20%).

3.2.5.3. Veterinary sector

Formaldehyde is used as biocide and as a fumigant in the poultry sector to eliminate microorganisms on eggs and as disinfectant for egg cases, chick boxes, poultry houses and hatchery equipment. According to British Poultry Council, use of formaldehyde in poultry industry decreases chick mortality[12] . Aqueous solutions of formaldehyde are also used in dairy industry to prevent cattle hoof diseases and in aquaculture to reduce fish diseases. Formaldehyde is also used in veterinary school in the gross anatomy.

3.2.6. Food applications

In human food production and storage, formaldehyde is used as a technological auxiliary for its biocidal property in the manufacture of sugar as a preservative agent for the production of food additives or as food additive itself, as a cleaning agent for surfaces, as a synthetic reactive substance for the food contact materials, as an ingredient for specific MF resin in the water treatment, as a formulation agent in glues and adhesives for plastic pipes in contact with drinking water (RMOA, 2016).

3.2.7. Fertilizers

Formaldehyde is used in the manufacture of CRFs (controlled release fertilizers). The CRFs release their nutrients at a specific rate over a period of time, providing a constant source of nutrients to plants, soils and turf. The main form of formaldehyde used in CRFs

[12] https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations/-/substance-rev/5401/term

is urea-formaldehyde reactions products (Formacare, 2007; RMOA, 2016). The manufacture of urea-formaldehyde CRFs include is mainly operated by a few leading producers in Europe. 22 % of the end markets for CRFs are agricultural markets (strawberries, vegetable crops, citrus, melons and fruit trees) and 78% are non-agricultural markets (28% professional horticulture; 28% landscaping; 22% consumers) (Formacare, 2007).

3.2.8. Other uses

More exhaustive information on uses of formaldehyde is included in the Impact Assessment document prepared by the EU Commission to support the proposal for revision of CMD directive[13]

3.3. Number of EU workers in different industry sectors

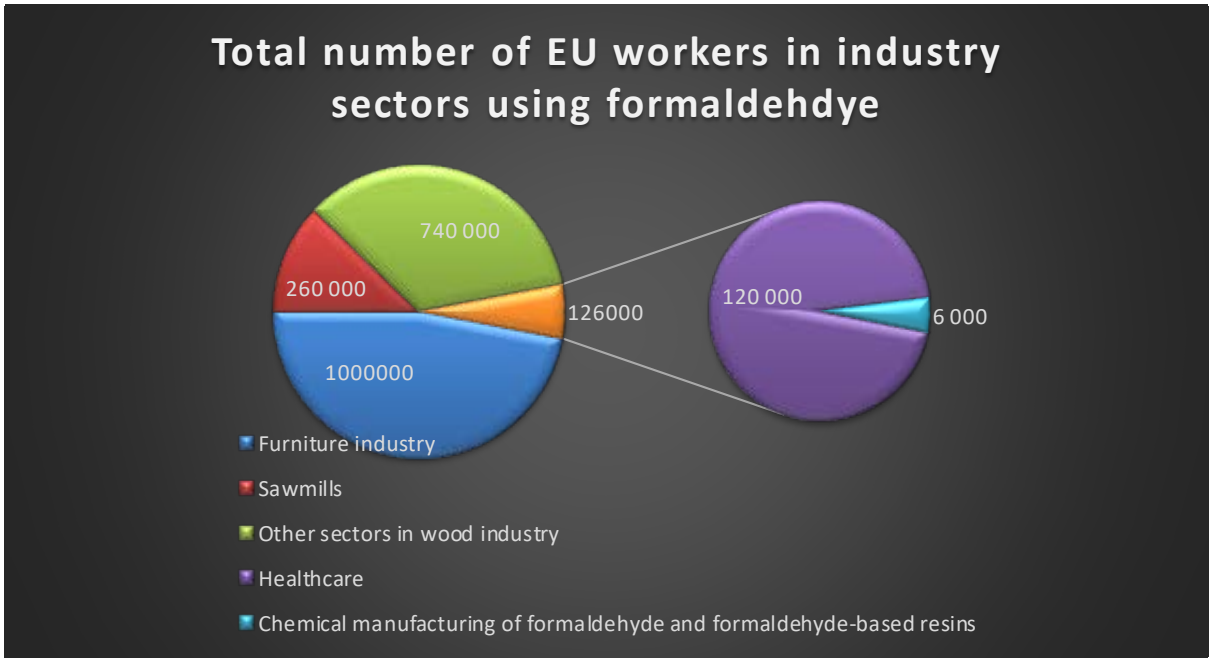
Limited information is available on number of EU workers employed in sectors where formaldehyde and formaldehyde releasers are used. Based on information provided by Formacare in their response to the call for evidence for the French RMOA, it is assumed that around 6 000 workers are employed in the EU in chemical manufacturing of formaldehyde and formaldehyde-based resins. This number only accounts for workers employed in the chemical sector. It should be considered that, in most cases, producers of wood-based panels, also produce formaldehyde and FA based resins for their own uses. It is estimated that around 2 million workers are employed in the EU in the woodworking sector, however not all of them are exposed to formaldehyde. In terms of employment, the furniture industry accounts for 50% of the jobs in woodworking sector, sawmills account for around 13%, and other sectors (e.g. panel manufacturing) account for about 37% (EPF annual report 2016-2017). Around 120 000 workers in the EU are employed in the healthcare sector.

Based on available data, workers in furniture industry, paper manufacturing and healthcare are exposed to higher level of formaldehyde compared to other sectors. The Commission proposal for a binding OEL on formaldehyde (2018) reports that overall about 1 million workers are potentially exposed to formaldehyde[14]. Figure 2 provides the number of EU workers in different industry sectors.

Figure 2. Number of EU workers in different industry sectors where formaldehyde is used.

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018SC0088

[14] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018SC0088



3.4. Routes of exposure

Workers may be exposed to formaldehyde in all life cycle stages of the substance including manufacturing, formulation, industrial use and end use of formaldehyde and formaldehyde based products. Exposure can occur by inhalation, skin and eye contact during loading and unloading of means of transport and recipients, sampling, laboratory tests, maintenance, repair and cleaning of equipment, repackaging, transfer, mixing and application of formaldehyde products. Occupational exposure during unloading of drums and containers, transportation and storage of formaldehyde or formaldehyde based products is limited to accidental spills or leaks of the chemical.

The presence of airborne formaldehyde in work environment comes from different types of sources: residual unreacted formaldehyde in formaldehyde-based resins, thermal or chemical decomposition of formaldehyde-based products, formaldehyde emissions from aqueous solutions, or emissions resulting from chemical reactions (e.g. combustion) of a variety of organic compounds (for example, exhaust gases). Workers can inhale formaldehyde as a gas or vapour or absorb the aqueous form (formalin) through the skin (dermal exposure). However the principle occupational exposure route for formaldehyde is inhalation (NIOSH, 2011).

3.4.1. Inhalation exposure

The use of more advanced technologies, improvement in quality and stability of formaldehyde based products and automated process have produced a significant reduction in workers exposure to formaldehyde over time. Inhalation exposure in different industrial fields have reduced significantly from the measured period of 2000-2006 to 2007-2013 (see section 4.2 below).

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.

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 (Golden, 2011; Andersen et al., 2010).

When inhaled, 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). This concentration represents the total concentration of endogenous formaldehyde in the blood, both free and reversibly bound (IARC, 1995).

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 CO2 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 [14C] formaldehyde at 0.63 or 13.1 ppm for 6 hours, about 40% of the inhaled 14C was eliminated as expired [14C]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).

3.4.2. Dermal exposure

As discussed earlier, the main occupational exposure route for formaldehyde is inhalation, but workers can be also exposed to formaldehyde dermally when formalin

solutions or liquid resins come into contact with the skin (IARC, 2006)[15].

Formaldehyde reacts at the site of first contact virtually instantaneously with primary and secondary amines, thiols, hydroxyls and amides to form methylol derivatives.

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).

Solutions containing formaldehyde in concentrations ≥25% need to be classified as skin corrosive while solutions with concentrations between ≥5% and <25% are classified as skin irritant. Dermal exposure to formaldehyde solutions is expected to occur only acutely or accidentally, but duration is expected to be short due to the irritating property. For solutions containing formaldehyde in concentrations below 5%, exposure duration could be repeated and even continuous (see section 2 for more information).

Available data is limited for a quantitative evaluation of formaldehyde exposure by the dermal route. However, the following aspects should be considered:

- the irritating property of solutions containing ≥5% formaldehyde will limit dermal exposure;
- dermal exposure over a longer time period to solutions containing <5% formaldehyde could be relevant;
- in monkeys only less than 1% of the applied dose was excreted or exhaled;
- formaldehyde is an endogenous substances at relatively high concentrations (i.e. about 0.1 mmol/L); and
- the endogenous metabolism of formaldehyde is fast.

Taking into account these aspects, the local irritating potential of formaldehyde seems to be of higher concern than skin exposure at non-irritating concentrations.

3.5. Exposure assessment

3.5.1. Implementation of a reference exposure value

3.5.1.1. DNEL and OEL setting

After the proposal in 2008 for a national OEL of 0.2 ppm for long-term exposure and 0.4 ppm for short-term exposure in France (ANSES[16], 2009), a discussion has been opened about DNEL/OEL for formaldehyde in order to align both sets of values. In its 2014 REACH Substance Evaluation, FR-Member Stage Competent Authority concluded that the long-term DNEL by inhalation should be based on the study by Lang et al. (2008) using

[15] IARC 2006. Formaldehyde. IARC Monographs on the Evaluation of Carcinogenic Risks to Human. Lyon, France: World Health Organisation.

[16] ANSES is the French Agency for Food, Environmental and Occupational Health and Safety

a NOAEL of 0.3 ppm. This resulted in a DNEL for long-term exposure of 0.1 ppm and for short-term exposure 0.2 ppm. In 2015, SCOEL proposed OEL values for short and long term exposure for public consultation until the 17th of February, 2016. At end of 2016, SCOEL released a final recommendation based comments received during public consultation. The occupational exposure limits recommended by the SCOEL are:

- The worker long-term DNEL for inhalation is 0.3 ppm (0.37 mg/m^3); and
- The worker short-term DNEL for inhalation is 0.6 ppm (0.74 mg/m^3).

These OELs for formaldehyde are based on two key studies (Lang et al. 2008; Mueller et al. 2013). These values have been used by France in their RMOA. Registrants of formaldehyde updated their CSR[17] in December 2015, proposing the following DNELs to be considered for risk characterisation: 0.3 ppm for long-term exposure and 0.6 ppm for short-term exposure, based on the key studies. The long-term DNEL is supported by mathematical risk extrapolations from experimental animals to humans. Considerations related to the assessment of excess cancer risk are reported in section 2 above.

3.5.1.2. National OELs in the EU

A number of Member States of the EU have already set national OELs for formaldehyde. These OELs are slightly different across European countries in relation to the legal and advisory framework which affects the way the limit is interpreted and applied.

Danish EPA survey (2013) had defined that OEL is an upper limit on the acceptable concentration of hazardous substance in workplace air. OEL values are usually reported as Time Weighted Averages (TWA) for 8 hours of exposure, but some countries report their limits as 15 minutes values. OEL values for formaldehyde emissions in air in different European countries are presented in Table 1.

[17] CSR, Chemical Safety Report, 2017. IUCLID 6 v1.3.0

Table 1. OELs for formaldehyde in place in European countries (Taken from COM impact assessment study to support the proposal for amendment of CMD directive – 2018).

Country	OEL (8h) mg/m^3 and ppm	STELs mg/m^3 and ppm
UK	2.5 (2 ppm)	2.5 (2 ppm) 15 min
Ireland	0.24 (0.2 ppm)	0.5 (0.4 ppm) 15 min
Sweden	0.37 (0.3 ppm)	0.74 (0.6 ppm) 15 min
Hungary	0.6 (0.5 ppm)	0.6 (0.5 ppm) 15 min
France	0.6 (0.5 ppm)	1.2 (1.0 ppm)
Austria	0.37 (0.3 ppm)	0.74 (0.6 ppm) 15 min
Germany	0.37 (0.3 ppm)	0.74 (0.6 ppm) 15 min
Poland	0.5 (0.42 ppm)	1.0 (0.8 ppm) 15 min 0.74 (0.6 ppm) intended change
Latvia	0.5 (0.42 ppm)	
Spain		0.37 (0.3 ppm)
Finland	0.37 (0.3 ppm)**	1.2 (1.0 ppm) 15 min
Denmark	0.4 (0.3 ppm)	0.4 (0.3 ppm) ceiling
The Netherlands	0.15 (0.12 ppm)	0.5 (0.42 ppm) 15 min
Bulgaria	1.0 (0.83 ppm)	2.0 (1.7 ppm)
Cyprus	3.0 (2.0 ppm)	
Czech Republic	0.5 (0.42 ppm)	1.0 (0.8 ppm) ceiling
Estonia	0.6 (0.5 ppm)	1.2 (1.0 ppm) ceiling 15 min
Greece	2.5 (2.0 ppm)	2.5 (2.0 ppm)
Lithuania	0.6 (0.5 ppm)	1.2 (1.0 ppm) ceiling
Portugal	0.37 (0.3 ppm)	
Romania	1.2 (1.0 ppm)	3.0 (2.0 ppm)
Slovakia	0.37 (0.3 ppm)	0.74 (0.6 ppm) 15 min
Slovenia	0.62 (0.5 ppm)	0.62 (0.5 ppm)
Croatia**	2.5n(2.0 ppm)	2.5 (2.0 ppm)
Belgium		0.38 (0.3 ppm)
Italy		
Luxembourg		
Malta		

** Value recommended. When no OEL is established it is assumed that allowed exposure

limit is above COM recommendations.

 Values above COM recommendation

 Values below COM recommendation

 Values in line with COM recommendation

In some cases national OELs are lower than the OELs recommended by COM for formaldehyde. The reason for this difference should be further investigated.

3.6. EU Regulations addressing worker exposure

3.6.1. Chemical Agents Directive, and Carcinogens and Mutagens Directive

The EU has defined some principles for workers' protection under 'Framework Directive', which establishes duties on employers and workers to identify and manage workplace risks as well as prevention of them. The key Framework Directives are the Directive 98/24/EC (also called Directive "CAD") on the protection of the health and safety of workers from the risks related to chemical agents at work and Directive 2004/37/EC on carcinogens or mutagens at work (also called Directive "CMD") which aims to protect workers from chemical risks at the workplace.

These directives may lay down limit values of exposure (Occupational Exposure Limits Values – OELs) and recommend the implementation of very similar risk management measures (RMMs) in order to control the risk at the workplace.

Directive CAD 98/24/EC

Directive CAD 98/24/EC sets indicative occupational exposure values (IOELs) or binding occupational exposure limit values (OELs) as well as biological limit values (BLs) at Union level (biological limit values are always binding). Binding OELs take account of socio-economic and technical feasibility factors as well as the factors considered when establishing IOELs. For any chemical agent for which a binding OEL is established at EU level, Member States must establish a corresponding national binding OEL which can be stricter, but cannot exceed the Union limit value. "Indicative" means that Member States are free to follow or not the proposed value when transposing it into national laws.

In between 2005 and 2007 SCOEL (Scientific Committee on Occupational Exposure Limits) recommended an 8-hr TWA OEL of 0.2 ppm or 0.2 mg/m3 and a short term OEL (15 minutes value – STEL) of 0.4 ppm or 0.5 mg/m3. These values are indicative OELs. The same year, formaldehyde was included on a draft list of 20 substances to be included in the 3rd IOEL Directive (2009/161/EC) establishing a third list of IOELs in implementation of the CAD.

Directive CMD 2004/37/EC

Directive CMD 2004/37/EC aims at the protection of workers from risks from exposure to carcinogens and mutagens at work. The Directive sets BOELs for substances which met the criteria as carcinogen or mutagen according to Annex I of the CLP. As soon as a chemical agent enters in the material scope of the CMD, it is not legally possible to establish an OEL for that agent on the basis of the CAD. For any carcinogen or mutagen for which a BOEL is established at European level, Member States must establish a corresponding national BOEL that does not exceed the Union limit value. However national OELS can be stricter. As a direct consequence of the recent classification as Carc. 1B, formaldehyde is subject to control under the CMD Directive, being part of the current consideration for BOELs among other 25 candidate substances. BOELV for formaldehyde has been adopted at EU level in the spring of 2019.

"Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible". The Commission can make at any time a proposal for setting BOEL under CMD Directive especially when a limit value has already been recommended by the SCOEL. BOELs are somehow different than workers DNELs as they are adjusted to the technical feasibility of European companies and Member States in order to ensure a harmonized implementation in Europe. Socio-economic aspects are taken into consideration whatever the status of the value is (especially for binding OEL).

Setting an OEL in the existing legal framework is always a tripartite agreement with representatives of Employers, workers trade unions and governments that allow its social acceptance and thus facilitate its implementation.

3.6.2. Other workplace EU legislation

Risk at workplace arising from exposure to hazardous substances may also be managed at European level by the following Directives related to the protection of occupational safety and health:

Directive 89/656/EEC lays down minimum requirements for personal protective equipment (PPE) used by workers at work.

Directive 92/85/EC (pregnant workers Directive)

Directive 94/33/EC (young workers Directive) lays down minimum requirements for the protection of young people at work.

Seveso III Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances.

Regulation (EC) No 1907/2006 (REACH)

Under REACH Regulation EC/1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals, formaldehyde is submitted to the requirement of Registration of production, import and uses since it is a HPVC (high production volume chemical) with a tonnage band of 1,000,000 tonnes + per year.

Authorisation

The purpose of the Authorisation procedure is to ensure that the risks from SVHC

(Substances of Very High Concern) are properly controlled and these substances are progressively replaced by less hazardous or safe substances. The authorisation does not distinguish uses: all uses of a substance submitted to authorisation under REACH are covered by the authorisation obligation, except manufacturing of substances, uses as intermediates and other case specific uses (e.g. substance only used in scientific research and development and uses in "product and process orientated research and development" - PPORD). The authorisation is granted for a limited time, provided that no alternatives are available and/or economically pursuable and that risks from uses are considered to be adequately controlled. The applicant has also to propose a substitution plan for the substance.

A prerequisite for a substance to be included on the Annex XIV of REACH is to be identified as a SVHC and thus included in the Candidate List of substances for authorisation. According to Article 57 of REACH, SVHC substances are substances classified as CMR category 1A or 1B, PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent very bioaccumulative) substances and substances of equivalent level of concern. Once listed on the Annex XIV, its continued use, beyond an agreed sunset date, will only be allowed if an authorisation for a specific use has been applied for, has been scrutinized by the ECHA committees and finally granted by the European Commission, or if the use is exempted from authorisation requirements. The prioritisation criteria for inclusion in Annex XIV from the candidate are more risk-based than hazard-based (as the criteria triggering the SVHC identification). The process for the prioritisation of SVCH to be included into Annex XIV of REACH is driven by the criteria set in the Article 58.3 of REACH. These criteria are implemented by ECHA following a methodology that has been agreed by the Committee of the Member States of the EU (MSC).

As formaldehyde fulfils the criteria for SVHC it could be included in the candidate list. Indeed, the wide dispersive use of formaldehyde and its high tonnage would make formaldehyde a good candidate for Annex XIV inclusion according to Art. 58.3. However the prioritisation of formaldehyde and the proportionality of authorisation route to address its related risks could be questioned because of its identified intermediate uses that are exempted from authorisation. In fact more than 95% of total formaldehyde used in the EU is used as intermediate in production of other substances mostly FA based resins. Substances produced from formaldehyde are substances *per se*. For this reason the tonnage related to the wide dispersive uses of formaldehyde (intended as substance) would be quite low ranking the substance very low in the prioritisation list.

Restriction

According to REACH regulation, "when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Union-wide basis, Annex XVII shall be amended (...) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles (...)" (article 68-1). A restriction proposal under REACH has to meet the REACH Annex XV requirements aiming at tackling a risk by reducing the exposure to the hazardous substance down to a safe level, otherwise at removing it. For this purpose, a restriction proposal may have several forms such as e.g. limiting the concentration or the migration of a substance in one specific article to protect consumers and users; or, more specifically in the case of workers protection, it may also consist in

limiting the exposure from the devices handled and/or occurring during the processing operations. The proposed exposure limits may be so low that the restriction might be equivalent to a total ban of the use of the substance. In those cases, the existence of available and suitable alternatives is crucial. Restriction proposal under REACH can be submitted by one (or more) Member States or by ECHA upon request from the Commission. A restriction dossier to restrict formaldehyde emissions from articles has been prepared by ECHA and submitted to the Commission in January 2019.

4. Comparison of the exposure to the hazard information

4.1. Occupational sectors at potential risk

The exposure data and risk characterisation based on SCOEL OELs of 0.3 ppm (0.37 mg/m^3) and 0.6 ppm (0.74 mg/m^3) identified concerns in a number of use scenarios based on sensory irritation. The risk of sensory irritation in embalmers and workers in medicine related industries, such as forensic/hospital mortuaries and pathology laboratories and in veterinary sector, is high due to high concentrations of formaldehyde products handled and relative long exposure durations. The risk of sensory irritation is also relevant in industrial settings in particular:

- **formaldehyde and formaldehyde resin manufacture:** during loading of raw materials into chemical reactors or unloading of reacted products, maintenance and cleaning, (in particular where there is a need to break open or enter the enclosed system),
- **formulation of formaldehyde based product:** during raw material weighing and transfer, open mixing process, and equipment cleaning and maintenance
- **end use of formaldehyde based products**: when formaldehyde products are heated and/or in contact with high humidity, during use of formaldehyde resins that contain high levels of free formaldehyde and during certain modes of application that may generate formaldehyde vapour e.g. brushing and spraying applications) (RMOA, 2016).

Workers can also be exposed to formaldehyde during the treatment of textiles. In healthcare and research sectors, in addition to healthcare professionals, medical lab technicians and mortuary workers, groups at potentially high risk include also teachers and students who handle biological specimens preserved with formaldehyde or formalin (OSHA, 2011).

4.2. Occupational exposure data

The initial phase of the substance evaluation performed by France (2013-2014) on risks for workers expose to formaldehyde was based on information provided by registrants (lead registrant dossier updated in July 2013) and information from the COLCHIC database. COLCHIC is a French database collecting occupational exposure measurements carried out by French Health Insurance Institute (CARSAT) and the INRS institute. These measures are not undertaken for regulatory control but for the purpose of prevention. Monitoring of workers' exposure at workplace can be requested by occupational physicians or directly by the employers (in particular in SMEs). COLCHIC measurement data are gathered without any respiratory protective equipment and without applying

any exposure reducing factor. Table 2 provides an overview of sectors for which COLCHIC collected formaldehyde concentrations exceeding the threshold values set by SCOEL (2016).

Table 2. Occupational sectors at potential risk (exposure data from French Colchic database for the period 2007-2013).

Long-term exposure	DNEL 0.3 ppm
Activity sector at risk (as cited in COLCHIC)	Building industry and civil engineering; Chemicals, rubber and plastic industries; Wood, paper, furniture, textile, clothes, leather and hide and earthenware; Public health services; Private health services
Short-term exposure	DNEL 0.6 ppm
Activity sector at risk (as cited in COLCHIC)	Public health services; Private health services

In the construction industry and civil engineering average workers' exposure to formaldehyde by inhalation dropped from 1.54 mg/m^3 for the 2000-2006 period to 0.48 mg/m^3 for the 2007-2013 period. In chemicals, rubber and plastic industries workers' average exposure decreased from 0.27 for the 2000-2006 period to 0.15 mg/m^3 for the 2007-2013 period. In wood, paper, furniture, textile, clothes, leather and hide, and earthenware industries, the average exposure decreased from 0.48 mg/m^3 for the 2000-2006 period to 0.4 mg/m^3 for the 2007-2013 period. In public health services the exposure decreased from 0.67 mg/m^{3}for the period of 2000-2006 to 0.33 mg/m^3 for the period of 2007-2013 and in private health sectors the exposure concentrations decreased from 1.19 mg/m^3 to 0.65 mg/m^3 for the same period. Information provided by registrants in registration dossiers (updated dossiers submitted on 2013) has been based on measured data (obtained from downstream users and literature) and model estimates. Modelled exposure estimates were calculated with ECETOC TRA-3.0 (Tier 1) and ART (higher tier tool) when necessary[18]. Exposure data from 2013 showed that, in some cases, the DNELs adopted by SCOEL and proposed by COM as BOEL were exceeded (see Table 3 below).

Table 3. Sectors at potential risk (based on information included in registration dossiers updated in 2013)

Long-term exposure	DNEL 0.3 ppm (0.37 mg/m^3)
Monitoring data from downstream users (90th Percentile, personal)	Manufacturing of formaldehyde and Resins (during transfer of formaldehyde and Resins)

[18] ECETOC TRA 3.0, personal long-term, 75th Percentile. Except for Formalin (60% formaldehyde): ART 1.0, 75th Percentile.

	Resin / chemicals manufacturing (during control of the Resin / chemicals manufacturing process) Panel production (during paper impregnation of wood based panels and maintenance in the wood panel industry)
Modelling data (75th Percentile)	Production of fertilizer granules (PROC 8b) Industrial production of foams, bonded particulate, bonded fibers/mats, paper and impregnation of leather and textile (PROC 3,4,7,8a,8b,9,10,13) Professional production of foams and use of resins in wood applications (PROC 10,23,25)
Short-term exposure	DNEL 0.6 ppm (0.74 mg/m^3)
Monitoring data from downstream users (90th Percentile, personal)	Panel production (during paper impregnation of wood based panels and maintenance in the wood panel industry)
Modelling data (75th Percentile)	Industrial production of foams, bonded particulate, bonded fibers/mats, paper and impregnation of leather and textile (PROC 1,2,5,6,14) Professional production of foams and use of resins in wood applications (PROC 10)

Based on this information, France, concluded the initial phase of SEV with the assumptions that risks for workers were identified. Further updates of registration dossiers were performed by registrant in 2015 and 2017. In latest updates, expose estimates for workers exposed to formaldehyde were based on the outcome from a modelling tool (EasyTra 4.0.0 – see Table II-1 in Annex II to this document) showing that DNELs values were not exceeded in any sectors. The information provided in the latest updated of the dossiers, was considered insufficient to demonstrate control of risks by French Competent Authority in the context of the SEV. Such conclusion has been based on the uncertainties related to the model estimations and the selection of modelling parameters, in particular the corrective factors assumed for the Risk Management Measures (such as LEV and PPEs) that have to be implemented to reduce the exposure levels. Based on the conclusions from France, in this report ECHA has taken into account information on measured exposure data when available.

Table 4 reports exposure data for workers of different industrial sectors gathered from a Formacare document published in 2013. The document is based on the report prepared by TNO[19] on analysis of worker exposure in manufacture and use of formaldehyde in

[19] TNO Triskelion (Triskelion BV since 2016) is a Dutch contract research organisation operating in

Europe, including downstream users. The source of Formaldehyde is either formaldehyde itself or formaldehyde based products used at the workplace (TNO, 2013).

Table 4. Occupational exposure values (Long- and short- term) in different industrial uses (TNO, 2013).

Use	Type (unit)	Exposure value mg/m^3 (N)	DNEL (Long-term) mg/m^3	DNEL (Short-term) mg/m^3
Formaldehyde manufacturing	Personal Long-term (90th perc)	0.23 (N=94)	0.37	0.74
	Personal Short-term (95th perc)	0.30 (N=39)	0.37	0.74
Resins manufacturing	Personal Long-term (90th perc)	0.37 (N=116)	0.37	0.74
	Personal Short-term (95th perc)	0.64 (N=17)	0.37	0.74
Wood panel production	Personal Long-term (90th perc)	0.075 (N=81)	0.37	0.74
	Personal Short-term (95th perc)	0.15 (Estimation)	0.37	0.74
Formulation	Personal Long-term (90th perc)	0.11 (N=13)	0.37	0.74
	Personal Short-term (95th perc)	0.23 (Estimation)	0.37	0.74
Fertilizer granules production	Personal Long-term (90th perc)	0.15 (N=1)	0.37	0.74
	Personal Short-term (95th perc)	< 0.25 (N=8)	0.37	0.74
Tyre & Rubber manufacturing	Personal Long-term (90th perc)	0.26 (N=10)	0.37	0.74
	Personal Short-term (95th perc)	0.52 (Estimation)	0.37	0.74
Healthcare sector	Long-term	0.174	0.37	0.74
Paper manufacturing	Personal Long-term (90th perc)	0.65 (N=123)	0.37	0.74
	Personal Short-term (95th perc)	1.43 (N=73)	0.37	0.74

the field of pharmaceutical, chemical and food industry.

Textile impregnation	Personal Long-term (90th perc)	0.59 (N=126)	0.37	0.74
	Personal Short-term (95th perc)	2.29 (N=50)	0.37	0.74
Furniture industry	Personal & Stationary Long & Short-term (90th perc)	0.88 (N=36)	0.37	0.74

The colour green in the Table 4 indicates the cases when average measured exposure was lower or equal (yellow colour) than the recommended DNEL value while the red colour indicates the cases when exposure values have been detected to be above the DNEL value.

Table 5 (TNO 2013) summarises the outcome of the exposure assessment for workers exposed to formaldehyde through inhalation. The assessment is based on the following data sources: measured data from manufacturers and downstream users is, literature data and model estimations. Measured data were provided to TNO directly by manufacturers and downstream users of formaldehyde. Workplace exposure data available in literature have been investigated taking into account only information published after 1983 and modelling data were obtained using ECETOC TRA Version 3 modelling tool. Safe use is defined by exposures below the DNEL of 0.3 ppm for long term inhalation exposure and 0.6 ppm for short term inhalation exposure. The assessment shows that for some uses (e.g. paper impregnation during panel production, textile impregnation, paper production and furniture manufacturing) the exposure may exceed the DNEL of 0.3 ppm (long term) and/or 0.6 ppm (short term) Furthermore, the assumptions taken in assessing exposure with modelling tools (for specific process categories – PROCs -) consider that Risk Management Measures such as LEV in addition to general ventilation are applied as well as stringent operational conditions (e.g. short exposure time and frequency). For professional uses presence of LEV, use of PPEs and good general ventilation have to be assumed in modelling tools in order to guarantee safe use. Nevertheless in some cases (such as rolling and brushing applications of wood resins), safe use is not demonstrated even if RMM are applied.

In 2018 voluntary agreements have been signed by relevant industry sectors to implement the occupational exposure limits set by the SCOEL for formaldehyde. A voluntary agreement has been signed by the members of Formacare (a sector group of CEFIC representing EU formaldehyde producers). A similar agreement was signed by the members of European wood working industry[20] (the European Wood Based Panels Federation – EPF and the European Federation of Building and Woodworkers – EFBWW). All agreements aim to implement the occupational exposure limits recommended by SCOEL for formaldehyde by establishing minimum requirements and an action guide for setting up on site risk management measures and monitoring plans in order to keep

[20] https://europanels.org/wp-content/uploads/2018/12/Action-Guide-on-Formaldehyde-signed-on-28-Nov-2018-in-Lisbon.pdf

workers' exposure to formaldehyde in the workplace below the limits set by SCOEL.

Although previous exposure data show that a number of industrial sectors are at potential risk, applicability of risk management measures to control workers' exposure to formaldehyde in industrial uses appears feasible at least for the sector of wood panels for producers of formaldehyde and formaldehyde based substances who signed voluntary agreements. It is however unclear how control of workers exposure below the proposed Binding OELs can be achieved by other downstream users of formaldehyde or formaldehyde based substances (e.g. furniture, textile, paper) as these sectors are not included in the voluntary agreements mentioned above.

Further considerations can be made for professional workers. Based on measured and modelling data, exposure can only be controlled if stringent RMM (such as enclosed processes, good general ventilation, LEV and RPE) are applied. These risk management measures are difficult to implement for professional workers in particular when their activity is performed in non-industrial settings (e.g. construction, housing remodelling and repair, car repair etc.). In addition, self-employed workers are not covered by CMD, therefore additional measures have to be considered for these workers. A possible strategy could be to adopt for professional and self-employed workers the same approach taken for consumers. Therefore a restriction under REACH, limiting concentration to formaldehyde in mixtures and emissions of formaldehyde from articles, could be a suitable RMO for protection of professional workers and self-employed workers from exposure to formaldehyde while an encouragement from manufacturers and importers of formaldehyde to extend voluntary agreements to all relevant downstream users of formaldehyde and formaldehyde based substances may significantly contribute to guarantee safe use of this substance.

Table 5. Summary of workers exposure levels based on available data sources (TNO 2013) compared with proposed OEL (0.3 ppm long term TWA and 0.6 ppm short term).

Life cycle stage	Identified use	Risk assessment					
		User		Literature		Model	
		short term	long term	short term	long term	short term	long term
Manufacture	Manufacture + aq. Solutions						
	Manufacture chemicals / resins /polymers						
Formulation	Formulation						
Industrial end use	Prod. Wood-based						

	materials						
	Panel prod. paper impregnation						
	Panel packing						
	Prod. Fertilizer granules						
	Prod. Rubber						
	Prod. Foams						
	Prod. Leather						
	Prod. Paper						
	Impregnation of Textile						
	Furniture manuf.						
	Prod. Bonded particulates						
	Prod. Bonded fibers/ mats						
	Use adhesives/ coatings						
Professional end	Use adhesives/ coatings						
	Prod. foams						
	Use resin						

	wood applications						

Green: exposure values or estimates are below the reference value and are sufficient to indicate safe use. Measured exposure values are however insufficient for sole basis of conclusions. Exposure estimates demonstrate safe use assuming specific risk management measures;; Red: Exposure values presented in literature and/or from modelling tool are above the reference value.

5. Conclusion

Industrial and professional use of formaldehyde and formaldehyde releasers covers the waste majority of industrial sectors and involves a significant number of workers EU wide. Available data on occupational exposure, and new OELs for inhalation proposed by SCOEL and adopted on EU wide basis, show that there are sectors where exposure to workers may exceed the recommended exposure limits. Some sectors (e.g. chemical and panels industry[21]) have voluntarily agreed to an action plan to gradually comply with the occupational exposure limits by implementing specific RMM to reduce workers exposure and by adopting a multi annual monitoring plan to control compliance. However it is unclear at moment how other sectors achieve compliance with binding OELs. Implementation of required RMM to control exposure to formaldehyde may be challenging for professional workers as engineering controls and use of RPE are required in most cases to guarantee safe use. It has also to be considered that adoption of binding OELs under the Directive 2004/37/EC (CMD) does not affect self-employed workers as this category of workers are not covered by CMD directive. The number of self-employed workers accounts for around 14% of total employment in the EU (Source Eurostat 2016[22]), they work in different sectors (e.g. wholesale, agriculture, forestry and technical activities) and their number is increasing over the years. A possible approach is to apply risk management strategies normally applied to consumers, also to professional and self-employed workers and to consider a restriction under REACH.

In conclusion the following recommendations are provided for further consideration by the Commission:

- to further assess of the exposure to formaldehyde for workers employed in sectors not covered by voluntary agreements (in particular SMEs) where formaldehyde and formaldehyde based substances / mixtures are used to verify if and how compliance with binding OELs can be achieved.
- to assess exposure to formaldehyde for professional and self-employed workers and to perform an analysis of available regulatory risk management options to address possible risks including the possibility to apply, for these categories of workers, the risk management measures applied to consumers. A potential restriction under REACH could be a suitable regulatory risk management option in these cases.
- to encourage EU producers and importers of formaldehyde and formaldehyde based products to extend to all downstream users the participation to the voluntary agreement to implement a multi annual action and monitor plan to achieve compliance with adopted binding OELs. This action may help authorities to decide if further regulatory risk management actions could be required in the case meeting the binding OELs will not be achieved by all industry sectors.

[21] http://www.efbww.org/pdfs/Agreement%20Formaldehyde%2028%20November%202018%20-%20FINAL.pdf

[22] https://ec.europa.eu/eurostat/statistics-explained/index.php/Labour_market_and_Labour_force_survey_(LFS)_statistics

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Annex I- Risk Characterisation Ratios (RCRs) for workers calculated by FR CA / ANSES

Table I-1. Inhalation long term risk assessment for scenarios based on monitoring data from 2013 Registrant CSR and a Long-term DNEL of 0.3 ppm (0.375 mg/m3)

Use	Scenario	Risk Management Measures (RMM)	RCR
Formaldehyde manufacturing process and related worker exposure			
Formaldehyde manufacturing	Worker exposure to formaldehyde in process control at manufacturing sites of formaldehyde	Closed system Dedicated sampling points	<1
Formaldehyde manufacturing	Formaldehyde worker exposure during maintenance/cleaning of the manufacturing process	Handling/Transfer in closed system Drain down/Flush prior opening	<1
Manufacturing of Formaldehyde and Resins	Formaldehyde worker exposure during transfer of Formaldehyde and Resins	Indoor; Closed filling + **LEV** Outdoor; Closed filling + **LEV** or clearing	>1
Manufacturing of Formaldehyde and Resins -	Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins	General ventilation Fume cupboard Closed sampling	<1
Worker exposure data and workplace concentrations provided by Formaldehyde based resin / chemical producers			
Resin / chemicals manufacturing	Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process	Closed system LEV	1.00
Resin / chemicals manufacturing	Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process	Closed system LEV	<1

Resin / chemicals manufacturing -	Formaldehyde worker exposure during management as part of Resin / chemicals manufacturing process		General ventilation	<1
Resin / chemicals Manufacturing	Formaldehyde worker exposure during maintenance/cleaning of the resin / chemicals manufacturing process		Drain down/Flush prior opening and/or **LEV** RPE PF 10x	<1
Resin / chemicalsmanufacturing	Formaldehyde worker exposure during transfer of solid resin		Closed system + **LEV**	<1
Worker exposure data and workplace concentrations provided by wood panel producers				
Panel production	Formaldehyde worker exposure during production of wood based panels		No/Partial enclosure Part of work in control room General ventilation (Natural and/or mechanical) LEV Use of RPE PF 10x The use of RPE is specifically needed when working close to emission points and may not be needed elsewhere outside of the control room. Each company needs to define where the use of RPE is needed.	<1
Panel production	Formaldehyde worker exposure during paper	Paper impregnation	Partial enclosure General ventilation (Natural and mechanical) LEV	>1

	impregnation and lamination of wood based panels	Paper lamination	No/Parti1.00al enclosure General vent3.58ilation (Natural and/or m1.67echanical) LEV	<1
Panel production	Formaldehyde worker exposure during sanding & sawing of wood based panels	Operation of sanding & sawing line Indoor 0.008 -1% Formaldehyde	No/Partial enclosure No/part of work in control room General ventilation (Natural and/or mechanical) +/-LEV	<1
		Operation of sanding & sawing line Indoor 0.004 -1% Formaldehyde	General ventilation (Natural and/or mechanical) +/-LEV Use of RPE PF 10x	<1
Panel production	Formaldehyde worker exposure during maintenance & cleaning in the wood panel industry	Maintenance/Intervention of devices	No/Partial enclosure No/part of work in control room General ventilation (Natural and mechanical) +/-LEV	>1
		Cleaning (e.g. degreasing, blowing, sweeping)	No/part of work in control room General ventilation (Natural and/or mechanical) LEV RPE PF 10x	<1
Panel production	Formaldehyde worker exposure during	Sorting/Packing panels	General ventilation (Natural and mechanical) LEV	<1

	logistics & laboratory activities in the wood panel industry	Physical/Chemical testing	General ventilation (Natural and/or mechanical) LEV	<1
Worker exposure data and workplace concentrations provided by other downstream users				
Formulation	Formaldehyde exposure levels provided by Formulators of Formaldehyde based products		General ventilation (Natural and mechanical) LEV	<1
Fertiliser granules production	Formaldehyde exposure levels provided by producers of Fertiliser granules		General ventilation (Natural and mechanical) Enclosed transfer Time duration max 4 hours	<1
Formaldehyde worker exposure data and concentrations during Tyre and Rubber production				
Tyre & Rubber manufacturing	Formaldehyde worker exposure during weighing and loading during Tyre & Rubber manufacturing		General ventilation (Natural and mechanical) +/- LEV	<1
Tyre & Rubber manufacturing	Formaldehyde worker exposure during the mixing part of Tyre & Rubber manufacturing		General ventilation (Natural or mechanical) +/- LEV	<1
Tyre & Rubber manufacturing	Formaldehyde worker exposure during the shaping part of Tyre & Rubber manufacturing		General ventilation (Natural and/or mechanical) +/- LEV	<1
Tyre & Rubber manufacturing	Formaldehyde worker exposure during the curing part of Tyre & Rubber manufacturing		General ventilation (Natural and/or mechanical) +/- LEV No/partial enclosure	<1

Rubber & Tyre manufacturing	Formaldehyde worker exposure during the Finishing part of Tyre & Rubber manufacturing	Adherisation/ Gluing	General ventilation (Natural and/or mechanical) LEV No/partial enclosure	<1
		Cutting	General ventilation (Natural and mechanical) +/- LEV	<1
		Tyre building	General ventilation (Natural and mechanical)	<1

Table I-2. Inhalation long term risk assessment for scenarios based on modelling data from 2013 Registrant CSR and a Long-term DNEL of 0.3 ppm (0.375 mg/m3)

Use	Scenario	Risk Management Measures	RCR
Production of Fertiliser granules	Industrial Production PROC 1,2	Closed process (360 min) + dedicated transfer with medium level containment (120 min) RPE PF 10x for dedicated transfer	<1
	Industrial Transfer Solid, low dustiness PROC 8a	LEV	<1
	Industrial Transfer PROC 8b	**LEV** and enhanced general ventilation	>1
Industrial production of *Foams *Bonded particulates *Bonded fibers/mats *Paper Impregnation of *Leather *Textile	Industrial Production PROC 1,2	**LEV** and enhanced general ventilation	<1
	Industrial Production PROC 3,4	**LEV** and enhanced general ventilation + max 4 hours OR RPE PF 10x	>1
	Industrial Mixing/Blending PROC 5	**LEV** and enhanced general ventilation	<1
	Industrial Calendaring PROC 6	**LEV** and enhanced general ventilation	<1
	Industrial Spraying PROC 7	**LEV** and enhanced general ventilation + max 1 hours OR RPE PF 10x	>1
	Industrial Transfer PROC 8a, 8b, 9	**LEV** and enhanced general ventilation	>1
	Industrial Rolling/Brushing PROC 10	**LEV** and enhanced general ventilation	>1
	Industrial Dipping/Pouring PROC 13	**LEV** and enhanced general ventilation	>1
	Industrial compression/extrusion PROC 14	**LEV** and enhanced general ventilation	<1

Use	Scenario	Risk Management Measures	RCR
	Industrial cutting/cold rolling/assembly Solid, high dustiness PROC 21	**LEV** and enhanced general ventilation	<1
	Industrial processing of minerals Solid high dustiness, PROC 22 - 23	**LEV** and enhanced general ventilation	<1
	Industrial cutting/sanding Solid, high dustiness PROC 24	**LEV** and enhanced general ventilation + Max 4 hours	<1
	Industrial welding/soldering Solid, high dustiness PROC 25	**LEV** and enhanced general ventilation	<1
Professional * production of foams * use of resins in wood applications	Professional Mixing/Blending PROC 5	**LEV** and good general ventilation + **Max 1 hour OR RPE PF 10x**	<1
	Professional Transfer PROC 8a	LEV and good general ventilation + **Max 1 hour + RPE PF 10x**	<1
	Professional Transfer PROC 8b	**LEV** and good general ventilation + **Max 1 hour OR RPE PF 10x**	<1
	Professional Rolling/Brushing PROC 10	Outdoor + Max 1 hour + RPE PF10x Indoor with good general ventilation + **Max 1 hour + RPE PF 10x**	>1
	Professional Dipping/Pouring PROC 13	**LEV** and good general ventilation + **Max 1 hour**	<1
	Professional Lab use PROC 15	**LEV** and good general ventilation **+ Max 1 hour OR RPE PF 10x**	<1
	Professional cutting/cold rolling/assembly Solid, high dustiness PROC 21	**LEV** and good general ventilation + **Max 15 min OR RPE PF 10x**	<1

Use	Scenario	Risk Management Measures	RCR
	Industrial processing of minerals Solid, high dustiness PROC 23	LEV + Max 15 min OR RPE PF10x	>1
	Professional cutting/sanding Solid, high dustiness PROC 24	**LEV** and good general ventilation + **Max 15 min OR RPE PF10x**	<1
	Industrial welding/soldering Solid, high dustiness PROC 25	LEV + Max 1 hour OR RPE PF10x	>1

Table I-3. Inhalation short term risk assessment based on monitoring data from 2013 Registrant CSR and a short-term DNEL of 0.6 ppm (0.750 mg/m3)

Use	Scenario	Risk Management Measures	RCR
Formaldehyde manufacturing process and related worker exposure			
Formaldehyde manufacturing	Worker exposure to formaldehyde in process control at manufacturing sites of formaldehyde	Closed system + general ventilation/dedicated sampling points **RPE PF 10x**	<1
Formaldehyde manufacturing	Formaldehyde worker exposure during maintenance/cleaning of the manufacturing process	Handling/Transfer in closed system **RPE PF 10x**	<1
Manufacturing of Formaldehyde and Resins	Formaldehyde worker exposure during transfer of Formaldehyde and Resins	Closed filling **RPE PF 10x**	<1
Manufacturing of Formaldehyde and Resins -	Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins	General ventilation Fume cupboard Closed sampling	<1
Worker exposure data and workplace concentrations provided by Formaldehyde based resin / chemical producers			
Resin / chemicals manufacturing	Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process	Closed handling and sampling	<1
Resin / chemicals manufacturing	Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process	Mechanical/Natural ventilation **RPE PF 10x**	<1
Resin / chemicals Manufacturing	Formaldehyde worker exposure during maintenance/cleaning of the resin / chemicals manufacturing process	Drain down/Flush prior opening and/or **LEV** RPE PF 10x	<1
Resin / chemicals manufacturing	Formaldehyde worker exposure during transfer of solid resin	Closed system + **LEV**	<1

Worker exposure data and workplace concentrations provided by wood panel producers				
Panel production	Formaldehyde worker exposure during production of wood based panels The use of RPE is specifically needed when working close to emission points and may not be needed elsewhere outside of the control room. Each company needs to define where the use of RPE is needed.		No/Partial enclosure Part of work in control room General ventilation (Natural and/or mechanical) LEV Use of RPE PF 10x	<1
Panel production	Formaldehyde worker exposure during paper impregnation and lamination of wood based panels	Paper impregnation <0.2 – 1.5% Formaldehyde	Partial enclosure General ventilation (Natural and mechanical) LEV	>1
		Paper lamination 0.1 – 1% Formaldehyde	General ventilation (Natural and/or mechanical) LEV	<1
Panel production	Formaldehyde worker exposure during maintenance & cleaning in the wood panel industry	Maintenance /Intervention of devices	No/Partial enclosure No/part of work in control room General ventilation (Natural and mechanical) +/-LEV	>1
		Cleaning (e.g. degreasing, blowing, sweeping)	No/part of work in control room General ventilation (Natural and/or mechanical) LEV RPE PF 10x	<1
Panel production	Formaldehyde worker exposure during	Sorting/Packing panels	General ventilation (Natural and mechanical) LEV	<1

	logistics & laboratory activities in the wood panel industry	Physical/Chemical testing	General ventilation (Natural and/or mechanical) LEV	<1
Worker exposure data and workplace concentrations provided by other downstream users				
Formulation	Formaldehyde exposure levels provided by Formulators of Formaldehyde based products		General ventilation (Natural and mechanical) LEV	<1
Fertiliser granules production	Formaldehyde exposure levels provided by producers of Fertiliser granules	Process control including; sampling	Natural ventilation	<1
		Cleaning	General ventilation (Mechanical) LEV	<1
Formaldehyde worker exposure data and concentrations during Tyre and Rubber production				
Tyre & Rubber manufacturing	Formaldehyde worker exposure during weighing and loading during Tyre & Rubber manufacturing		General ventilation (Natural and mechanical) +/- LEV	<1
Tyre & Rubber manufacturing	Formaldehyde worker exposure during the mixing part of Tyre & Rubber manufacturing		General ventilation (Natural or mechanical) +/- LEV	<1
Tyre & Rubber manufacturing	Formaldehyde worker exposure during the shaping part of Tyre & Rubber manufacturing		General ventilation (Natural and/or mechanical) +/- LEV	<1
Tyre & Rubber manufacturing	Formaldehyde worker exposure during the curing part of Tyre & Rubber		General ventilation (Natural and/or mechanical)	<1

	manufacturing		+/- LEV No/partial enclosure	
Rubber & Tyre manufacturing	Formaldehyde worker exposure during the Finishing part of Tyre & Rubber manufacturing	Adherisation /Gluing	General ventilation (Natural and/or mechanical) LEV No/partial enclosure	<1
		Cutting	General ventilation (Natural and mechanical) +/- LEV	<1
		Tyre building	General ventilation (Natural and mechanical)	<1
Formaldehyde worker exposure data and concentrations during production of Leather				
Not presented due to the low number of measurements.				

Table I-4. Inhalation short term risk assessment based on modelling data from 2013 Registrant CSR and a short-term DNEL of 0.6 ppm (0.750 mg/m3)

Use	Scenario	Risk Management Measures	RCR
Production of Fertiliser granules	62% Formaldehyde Indoor, 300 degrees Industrial Production PROC 1,2	Closed process (360 min) + dedicated transfer with medium level containment (120 min) RPE PF 10x for dedicated transfer	<1
	62% Formaldehyde Indoor Industrial Transfer Solid, low dustiness PROC 8a	LEV	<1
	62% Formaldehyde Indoor, 60 degrees Industrial Transfer PROC 8b	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
Industrial production of *Foams *Bonded particulates *Bonded fibers/mats *Paper	1-5% Formaldehyde Indoor, 100 degrees Industrial Production PROC 1,2	**LEV** and enhanced general ventilation	>1
	1-5% Formaldehyde Indoor, 100 degrees Industrial Production PROC 3,4	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
Impregnation of *Leather *Textile	1-5% Formaldehyde Indoor, 60 degrees Industrial Mixing/Blending PROC 5	**LEV** and enhanced general ventilation	>1
	1-5% Formaldehyde Indoor, 60 degrees Industrial Calendaring PROC 6	**LEV** and enhanced general ventilation	>1

Use	Scenario	Risk Management Measures	RCR
	1-5% Formaldehyde Indoor, 20 degrees Industrial Spraying PROC 7	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 20-60 degrees Industrial Transfer PROC 8a, 8b, 9	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 20 degrees Industrial Rolling/Brushing PROC 10	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 60 degrees Industrial Dipping/Pouring PROC 13	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 60 degrees Industrial compression/extrusion PROC 14	**LEV** and enhanced general ventilation	>1
	1-5% Formaldehyde Indoor, 20 degrees Industrial cutting/cold rolling/assembly Solid, high dustiness PROC 21	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 60 degrees Industrial processing of minerals Solid high dustiness, PROC 22 - 23	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1

Use	Scenario	Risk Management Measures	RCR
	1-5% Formaldehyde Indoor, 20 degrees Industrial cutting/sanding Solid, high dustiness PROC 24	**LEV** and enhanced general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 60 degrees Industrial welding/soldering Solid, high dustiness PROC 25	**LEV** and enhanced general ventilation	<1
Professional *production of foams *use of resins in wood applications	1-1.5% Formaldehyde Indoor, 60 degrees Professional Mixing/Blending PROC 5	**LEV** and good general ventilation + **RPE PF 10x**	<1
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Transfer PROC 8a	**LEV** and good general ventilation + **RPE PF 10x**	<1
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Transfer PROC 8b	**LEV** and good general ventilation (**RPE PF 10x** only in case of using RPE option as RMM for long term exposure)	<1
	1-1.5% Formaldehyde Indoor/Outdoor, 20 degrees Professional Rolling/Brushing PROC 10	Outdoor + **RPE PF20x** Indoor with good general ventilation + RPE PF 20x	>1
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Dipping/Pouring PROC 13	**LEV** and good general ventilation + **RPE PF 10x**	<1

Use	Scenario	Risk Management Measures	RCR
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Lab use PROC 15	**LEV** and good general ventilation (**RPE PF 10x** only in case of using RPE option as RMM for long term exposure)	<1
	1-1.5% Formaldehyde Indoor, 20 degrees Professional cutting/cold rolling/assembly Solid, high dustiness PROC 21	**LEV** and good general ventilation + **RPE PF 10x**	<1
	1-1.5% Formaldehyde Indoor, 60 degrees Industrial processing of minerals Solid, high dustiness PROC 23	LEV + RPE PF 10x	<1
	1-1.5% Formaldehyde Indoor, 20 degrees Professional cutting/sanding Solid, high dustiness PROC 24	**LEV** and good general ventilation + **RPE PF 10x**	<1
	1-5% Formaldehyde Indoor, 60 degrees Industrial welding/soldering Solid, high dustiness PROC 25	LEV + RPE PF 10x	<1

Table I-5. Sectors at risk based on French Colchic database (2007-2013, mg/m^3) and a long-term DNEL of 0.3 ppm (0.375 mg/m3)

National technical committee	Risk	N of measures	Arith mean	Range	Med	Geom mean	Geom SD	90th percentile	RCR
B – Building industry and civil engineering	B – Building industry and civil engineering	113	0,23	<0.01-0.88	0,19	0,12	4,04	0,48	1,30
	452JA : Roofing with all materials (except plumbing)	36	0,42	0.19-0.88	0,38	0,38	1,51	0,75	2,03
	454CD : Joinery (manufacture and installation) including or not the structural wood	49	0,17	0.01-0.82	0,11	0,12	2,54	0,42	1,14
E – Chemicals, rubber and plastic industries	244AC : Production of base-products for pharmacy, alkaloids, glycosides and derivatives, algae extracts	28	0,19	0.02-1.08	0,08	0,11	2,65	0,55	1,49
	252GK: Casting machine operations and controls	23	0,2	0.06-0.72	0,13	0,19	2,17	0,66	1,79

National technical committee	Risk	N of measures	Arith mean	Range	Med	Geom mean	Geom SD	90th percentile	RCR
F – Wood, paper, furniture, textile, clothes, leather and hide and earthenware	F - Wood, paper, furniture, textile, clothes, leather and hide and earthenware	435	0,16	<0.01-1.22	0,09	0,08	3,54	0,4	1,08
	202ZB : Wood based panel production (chopped, ground, defibrillated wood)	73	0,21	<0.01-0.7	0,17	0,16	2,33	0,42	1,14
	203ZA : Production of wooden frame pieces, grinding and shaping including brush woods	63	0,37	0.03-1.22	0,27	0,28	2,16	0,73	1,98
	203ZA: Machining, assembling, welding, bonding, assembly lines	28	0,26	0.14-0.73	0,2	0,23	1,6	0,47	1,27
	203ZB : Serial production of building carpentry	22	0,16	0.01-0.55	0,06	0,07	4,36	0,47	1,27

National technical committee	Risk	N of measures	Arith mean	Range	Med	Geom mean	Geom SD	90th percentile	RCR
	211CF : Impregnated, tar, coated and paper production	20	0,14	0.01-0.91	0,01	0,02	5,61	0,69	1,87
H –Public health services	751AE : Hospitals	55	0,16	<0.01-1.2	0,09	0,09	3,07	0,47	1,27
	751AE : Anatomo-pathology	54	0,16	<0.01-1.2	0,06	0,09	2,98	0,47	1,27
I – Private health services	I – Private health services	199	0,26	<0.01-3.7	0,12	0,1	4,14	0,65	1,76
	851KA : Medical analysis outside hospital services	67	0,38	0.01-3.14	0,23	0,18	4,09	0,92	2,49
	851KA : Biological laboratories	42	0,43	0.02-3.14	0,23	0,24	2,84	1,07	2,90
	851KA : Anatomo-pathology	23	0,28	0.01-1.2	0,2	0,1	6,13	0,64	1,73

Table I-6. Sectors at risk based on French Colchic database (2007-2013, mg/m^3) and a short-term DNEL of 0.6 ppm (0.750 mg/m3)

National technical committee	N of measures	Arith mean	Range	Med	Geom mean	Geom SD	90th percentile	RCR
H –Public health services	73	0,41	0.01-6.38	0,15	0,16	3,44	0,78	1,06
I – Private health services	72	0,32	0.01-1.68	0,21	0,17	3,84	0,8	1,08

Annex II - Risk Characterisation Ratios (RCRs) for workers from registrant CSR 2017

Table II-1. Inhalation short term risk assessment based on modelling data from 2017 Registrant CSR and long-term DNEL of 0.3 ppm (0.375 mg/m3) and short-term DNEL of 0.6 ppm (0.750 mg/m3)

Use	Scenario	Risk Management Measures (most stringent cases)	RCR
INDUSTRIAL USE Manufacturing of Formaldehyde and FA solutions, use as intermediate or monomer, use of preparation or mixtures containing FA up to 60% Easy TRA model used to estimate workers exposure	PROC 1 Use in closed process no likelihood of exposure PROC 2 Use in closed continuous processes with occasional controlled exposure PROC 3 Use in closed attach processes (synthesis or formulation) PROC 4 Use in batch or other processes (synthesis) where opportunity for exposure arises PROC 5 Mixing or blending in batch processes PROC 6 Calendering operations PROC 8A Transfer of substance at non dedicated facilities PROC 8B Transfer of substance at dedicated facilities PROC 9 Transfer of substance into small containers	Enhanced ventilation (70% reduction) Vapour recovery sys (80% reduction) LEV (90% reduction) Use of RPE (90% reduction) Use of RPE (95% reduction)	<1

	PROC 10 Roller application or brushing PROC 13 Treatment of articles by dipping and pouring PROC 14 Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15 Use as laboratory reagent		
INDUSTRIAL USE Industrial use of preparations containing formaldehyde up to 5% Easy TRA model used to estimate workers exposure	PROC 1- Use in closed process no likelihood of exposure PROC 2- Use in closed continuous processes with occasional controlled exposure PROC 3 -Use in closed attach processes (synthesis or formulation) PROC 4- Use in batch or other processes (synthesis) where opportunity for exposure arises PROC 5 - Mixing or blending in batch processes PROC 6- Calendering operations PROC 8A -Transfer of substance at non dedicated facilities PROC 8B- Transfer of substance at dedicated facilities PROC 9- Transfer of substance into small containers PROC 10- Roller application or	Enhanced ventilation (70% reduction) LEV (90% reduction) Use of RPE (90% reduction) Use of RPE (95% reduction)	<1

	brushing PROC 13- Treatment of articles by dipping and pouring PROC 14 - Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15- Use as laboratory reagent PROC 16- Using material as fuel sources, limited exposure to unburned product to be expected PROC 21 -Low energy manipulation of substances in materials and/or articles PROC 22c - Potentially closed operations with minerals at PROC 23c - Open processing and transfer of minerals at elevated temperature PROC 24c - High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25c - Hot work operations with metals		
INDUSTRIAL USE Industrial use of preparations containing formaldehyde up to 25% Easy TRA model used to estimate workers exposure	PROC 5 - Mixing or blending in batch processes PROC 8A -Transfer of substance at non dedicated facilities PROC 8B- Transfer of substance at dedicated facilities PROC 9 - Transfer of chemicals into small containers PROC 13 - Treatment of articles by dipping and pouring PROC 15 - Use of laboratory	Enhanced ventilation (70% reduction) LEV (90% reduction) LEV (95% reduction) LEV (99% reduction) Use of RPE (90% reduction)	<1

	reagents in small scale laboratories		
PROFESSIONAL USE Professional use of preparations containing formaldehyde up to 1.5% Easy TRA model used to estimate workers exposure	PROC 5 - Mixing or blending in batch processes PROC 8A - Transfer of substance at non dedicated facilities PROC 8B- Transfer of substance at dedicated facilities PROC 10- Roller application or brushing PROC 11- Non industrial spraying PROC 13- Treatment of articles by dipping and pouring PROC 14 - Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15- Use as laboratory reagent PROC 16 - Using material as fuel sources, limited exposure to unburned product to be expected PROC 21 - Low energy manipulation of substances in materials and/or articles PROC 23c - Open processing and transfer of minerals at elevated temperature PROC 24c - High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25c - Hot work operations with metals	Good ventilation (30% reduction) LEV (80% reduction) LEV (90% reduction) LEV (99% reduction) Use of RPE (90% reduction) Use of RPE (95% reduction) Use of RPE (98% reduction) Use of RPE (99% reduction)	<1

PROFESSIONAL USE Professional use of preparations containing formaldehyde up to 5% Easy TRA model used to estimate workers exposure	PROC 8A - Transfer of substance at non dedicated facilities PROC 11- Non industrial spraying PROC 13- Treatment of articles by dipping and pouring PROC 15- Use as laboratory reagent	Good ventilation (30% reduction) LEV (80% reduction) LEV (99% reduction) Use of RPE (90% reduction) Use of RPE (95% reduction)	<1