

## **HEALTH RISK ASSESSMENT: FORMALDEHYDE FROM LAMINATED FLOORING**

---

November 2020

Jeff Fowles, Ph.D.  
Alisha Curtis, MPH

**PREPARED FOR:**

Ministry of Health

**CLIENT REPORT No:**

FW20044

**REVIEWED BY:**

Peter Cressey, Risk Assessment and Social  
Systems Group

Author



**Jeff Fowles**

Tox-Logic

Management Reviewer



**Rob Lake**

Group Leader, Risk Assessment and  
Social Systems Group

Peer Reviewer



**Peter Cressey**

Science Leader, Risk  
Assessment and Social  
Systems Group

## DISCLAIMER

The Institute of Environmental Science and Research Limited (ESR) has used all reasonable endeavours to ensure that the information contained in this client report is accurate. However, ESR does not give any express or implied warranty as to the completeness of the information contained in this client report or that it will be suitable for any purposes other than those specifically contemplated during the Project or agreed by ESR and the Client.

**E/S/R**

**HEALTH RISK ASSESSMENT: FORMALDEHYDE FROM LAMINATED FLOORING**

## TABLE OF CONTENTS

Acronyms and Abbreviations	4
EXECUTIVE SUMMARY	1
1 INTRODUCTION	2
1.1 Formaldehyde in the Environment	2
1.2 Formaldehyde in Consumer Wood Products	2
1.3 Case Studies and Regulatory Action	3
1.3.1 Japanese “Sick-House Syndrome” (SHS)	3
1.3.2 U.S. 60 Minutes Investigation of Formaldehyde from Laminate Flooring	3
2 FORMALDEHYDE TOXICITY	5
2.1 Toxicological Properties of Formaldehyde	5
2.2 Health Based Assessments and Guidance Values	5
2.2.1 World Health Organization	5
2.2.2 New Zealand and Australia	6
2.2.3 European Union	7
2.2.4 Health Canada	8
2.2.5 International Agency for Research on Cancer (IARC)	8
2.2.6 Agency for Toxic Substances and Disease Registry (ATSDR)	9
2.2.7 U.S. Environmental Protection Agency (USEPA)	9
2.2.8 California EPA (CalEPA)	10
2.3 Regulations and Standards for FA Emissions from Wood-Based Materials	12
2.3.1 Europe	12
2.3.2 Canada	13
2.3.3 Australia, New Zealand, and Japan	15
2.3.4 United States	15
2.4 Laminated Flooring Indoor Air FA Surveys	17
3 DISCUSSION	19
4 RISK MITIGATION MEASURES	20
5 CONCLUSIONS	21
6 REFERENCES	22

## ACRONYMS AND ABBREVIATIONS

---

AF	assessment factor
ATSDR	Agency for Toxic Substances and Disease Registry
CalEPA	California Environmental Protection Agency
CARB	California Air Resources Board
CDC	Center for Disease Control and Prevention
CPSC	US Consumer Product Safety Commission
CSA	Canadian Standards Association
DNEL	derived no effect level
EBF	eye blinking response
ECHA	European Chemicals Agency
ESR	Institute of Environmental Science and Research Limited
EU	European Union
FA	formaldehyde
g	gram
HDF	high density fibreboard
HWPW	hardwood plywood
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
JIS	Japanese Industrial Standard
L	liter
LP	laminated product
LOAEC	lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level

m <sup>3</sup>	cubic meter
MDF	medium density fibreboard
MF	melamine formaldehyde
MfE	Ministry for the Environment
mg	milligram
MRL	minimal risk level
MUF	melamine-urea formaldehyde
NICNAS	National Industrial Chemical Notifications and Assessment Scheme
NAF	no-added formaldehyde resin
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NSRL	no significant risk level
OSB	orientated strandboard
PB	particleboard
PF	phenol-formaldehyde
PLY	plywood
POD	point of departure
ppb	parts per billion
ppm	parts per million
RAC	risk assessment committee
REL	reference exposure level
RfC	reference concentration
SE0	super E0
SHS	sick-house syndrome
ULEF	ultra low-emitting formaldehyde resin

U.S.	United States
U.S. EPA	United States Environmental Protection Agency
USD	United States dollar
UF	urea-formaldehyde
VOC	volatile organic chemical
WHO	World Health Organization



# EXECUTIVE SUMMARY

---

Formaldehyde (FA) is a volatile reactive irritant chemical, with carcinogenic properties that forms from degrading resins and adhesives that are used in some types of wood-based materials, including laminated wood flooring, particle board, medium-density fibre board, wood panel siding, and other materials. Manufactured and newer homes typically have higher concentrations of FA indoors depending on the type of these materials, when they were installed, and the extent of their presence in the building. Studies have shown that, over time, FA emissions decrease in rate, reaching a steady state indoors after a number of months.

A “Sick-House Syndrome” (SHS) was reported to be related to indoor volatile chemicals, including FA in the 1990s, which was part of the public health impetus for the development of FA emissions standards worldwide. A “60-minutes” investigation in the U.S. found significant excursions of FA emissions above emission standards in some wood-panel laminate flooring materials, which resulted in legal action and additional studies, leading to standard reviews in the U.S. and Canada.

Standards have been subsequently developed in New Zealand and by numerous countries over the past 15 years, to manage the FA emissions from these products to limit public health impacts. These standards use differing test methods. The general aim of the standards is to keep estimated indoor air concentrations below the World Health Organization (WHO) health based air guideline value of  $0.1 \text{ mg/m}^3$ , to protect against respiratory and eye irritation. Although FA is considered a human carcinogen, respiratory and eye irritation are believed to be the most sensitive health endpoints, and chronic localised respiratory irritation is widely considered to be a prerequisite to the initiation of the cancer process for FA. More recently, risk assessments in Canada, U.S., and the European Union (EU) have indicated a lowering of the health-based guideline to  $0.05 \text{ mg/m}^3$ , to protect sensitive individuals, presenting some compliance issues for some products available overseas. The New Zealand FA emission standard, developed in concert with Australia and Japan, originally in 2004 and revised in 2017, is among the most stringent FA emission standards worldwide, with the most stringent standard “Super E0” (SE0) approaching the level of FA emitted from unprocessed natural wood. The joint New Zealand/Australia/Japan standard is consistent with the internationally proposed lower FA health-based indoor air guidelines, and the corresponding health risk of FA from wood-based panels.

Although indoor air exposure studies in New Zealand homes containing wood-based paneling are not available, comparable studies have been conducted overseas using less stringent FA emitting materials, and the risks of FA from wood-based materials in New Zealand meeting these standards are anticipated to be low.

Considering that New Zealand standards for FA emission of wood-based products are stringent in comparison to those found internationally, there appears to be no evidential health risk basis to revisit existing FA emission standards from these products at this time. A random survey of FA in New Zealand homes containing these wood-based panels would provide additional certainty around this conclusion.

# 1 INTRODUCTION

---

The purpose of this report is to describe and compare international standards and health risk assessments for indoor formaldehyde (FA) inhalation exposures resulting from installed laminated flooring. This report will only consider domestic, non-occupational, incidental exposure to FA from laminated flooring products.

## 1.1 FORMALDEHYDE IN THE ENVIRONMENT

Formaldehyde is a volatile gas with reactive chemical properties that lead to respiratory, skin and eye irritation, as well as carcinogenicity. Formaldehyde is formed through chemical processes in most living systems. It occurs naturally in some foods, and it is formed endogenously in mammals, including humans, as a consequence of oxidative metabolism (WHO, 2010). It is ubiquitous in the environment, being formed by numerous natural and anthropogenic activities. In the outdoor environment, it is released during forest and bush fires, or during decomposition of organic matter. Direct atmospheric anthropogenic sources include industrial chemical emissions and combustion processes such as power plants, incineration, and vehicle fuel exhaust (ECHA, 2020). It is also a commonly found indoor air contaminant worldwide, associated with numerous emerging health concerns, which has prompted international guidance and industry regulation. The industrial application for FA in consumer products and the variable contribution of secondary chemical processes to ambient and indoor FA concentrations and health risks have been assessed by numerous public health and environmental agencies internationally. A summary of these characterised exposures and risks, and the existing standards aimed at mitigation is provided in this report.

## 1.2 FORMALDEHYDE IN CONSUMER WOOD PRODUCTS

Wood-based panels and flooring materials have been identified as important indirect sources of FA emission contributing to poor indoor air quality. Various reconstituted wood panel products such as particle board (PB), plywood (PLY), medium density fibreboard (MDF) and high density fibreboard (HDF), have become increasingly popular building materials, and are being used for manufacturing furniture, flooring, and various consumer products (Salem et al., 2012). These products are mainly bonded with FA-based resin adhesives such as urea-formaldehyde (UF) resin, melamine formaldehyde resin (MF), melamine-urea formaldehyde (MUF) resin, and phenol-formaldehyde (PF) resins. Formaldehyde-based resins have been the standard adhesives used to bind the particles together in many composite wood products and account for over 90% of the wood adhesives market volumes (NTL, 2018).

Relevant products include three types of wood flooring: laminate wood flooring, engineered flooring and solid wood flooring. Laminate wood flooring consists of HDF as the core material and consists of four main components bonded together: a wood composition-based core and a wear-resistant, decorative surface made MF and an aluminum oxide cap bonded to make it moisture resistant (Salem et al., 2012). The wood composition-based core varies based on the manufacturer and, for example, can consist of multiple wood plies or more of a particle-board like material, all of which may include varying degrees of FA-based resin and thus, FA emissions. Engineered flooring consists of PLY, with a thin veneer bonded to the face of the PLY using UF and MF resins as hot press adhesives. Solid wood flooring is composed of multiple layers of solid timber, usually bonded with MUF.

## 1.3 CASE STUDIES AND REGULATORY ACTION

### 1.3.1 Japanese “Sick-House Syndrome” (SHS)

The phenomenon of SHS, caused by exposure to volatile organic chemicals (VOCs) given off by building materials, first came to public attention in the 1980s. It was exacerbated in the 1990s, when newly constructed or refurbished homes had installed new types of building materials and included an airtight sealing for energy efficiency (Shinohara et al., 2011). This new design not only resulted in significantly reduced natural ventilation but was also later found to result in high levels of VOCs, most notably, FA. SHS was widely reported in the media and residents reported symptoms including eye and respiratory irritation, headaches, dizziness, itchy skin, heavy coughing and fatigue (Harada et al., 2010).

These issues were addressed by establishing guideline values for indoor FA concentration in 2000, and, in 2003, the Ministry of Land, Infrastructure and Transport of Japan amended the Building Standard Law to control indoor chemical concentrations (Harada et al., 2010). The amended law restricts the use of building materials containing FA, and requires that all rooms have adequate ventilation (Azuma et al., 2015). Additionally, new standards were added to the Japanese Industrial Standard (JIS) for the method of measuring the FA emission rate and thus the F-star grade (F\* - F\*\*\*\*) was created, F\* indicating the lowest grade (highest FA emission) and F\*\*\*\* indicating the best grade (lowest FA emission). F\*\*\*\* is widely considered to be the most stringent FA emission level internationally and is close to the FA emission levels of solid, untreated wood (Nwaogu et al., 2013). These standards were developed jointly with New Zealand, and equivalent New Zealand standards, with a different nomenclature, have since been in force.

### 1.3.2 U.S. 60 Minutes Investigation of Formaldehyde from Laminate Flooring

In 2015, the American CBS news program *60 Minutes* reported that an American company, Lumber Liquidators, had sold a laminate wood-flooring product, sourced from China, that released elevated levels of FA (CBS 60 Minutes, 2015). FA levels in 31 boxes of commercially available laminate flooring purchased from Lumber Liquidator stores in five states (Florida, Illinois, New York, Texas, and Virginia) were tested. The *60 Minutes* investigation reported that some test results were higher than the California Air Resources Board (CARB) health based emission standards for FA.

In 2019, a U.S. court ruled that the company had misled investors and imposed a 33 million dollar (USD) settlement. As a result of the concerns raised by the *60 Minutes* report, the US Consumer Product Safety Commission (CPSC 2015) tested laminate flooring products manufactured in China during 2012-2014 (this was presumed to represent the relevant time period of material manufacture in the investigation) that were sold at Lumber Liquidators stores. CPSC subsequently requested that the Agency for Toxic Substances and Disease Registry (ATSDR) evaluate the test results for possible health significance. The Centers for Disease Control and Prevention (CDC) and the ATSDR estimated (modelled) indoor FA levels that may be present in typical homes with this laminate flooring. The model claims to have used near worst-case conditions, in order to conservatively assess public health risks. Flooring in small chamber tests had lower emission rates than flooring in large chamber tests. Across all testing, the ATSDR model results showed that, in 95% of the samples, the amount of FA released indoors by new laminate flooring alone ranged from 185  $\mu\text{g}/\text{m}^3$  up to 930  $\mu\text{g}/\text{m}^3$  (CDC/ATSDR, 2016).

Following these studies, regulatory authorities in Europe and Canada carried out exposure and risk assessments and, in some instances, placed into effect new regulations for FA release from laminated flooring, PLY, PB, fibreboard, and other similar building products that utilize adhesives that are known to contribute to indoor air FA (ECHA, 2019; ECHA, 2020). These regulations are aimed at protecting sensitive individuals from acute and chronic respiratory health effects from FA.

## 2 FORMALDEHYDE TOXICITY

---

The toxicology and epidemiological literature database for FA is large, and numerous summaries of the many relevant studies exist. It is not the purpose of this report to duplicate those summaries, but several authoritative summaries that illustrate key aspects of FA toxicity are described, including those that have been used by international authorities as the basis for risk assessment.

### 2.1 TOXICOLOGICAL PROPERTIES OF FORMALDEHYDE

FA is a small reactive carbonyl, with a significant vapour-phase, that interacts with proteins, DNA and RNA. The interaction with protein results from combination with primary amide bonds and the amino groups. FA also reacts with carboxyl, sulfhydryl and hydroxyl functional groups (ECHA, 2017). These chemical interactions may result in altered nucleic acid (i.e. mutations) and protein qualities (i.e. forming immunogenic protein derivatives) that have implications for mutagenesis and allergy, respectively, and can be highly irritating to the upper respiratory tract.

The non-cancer adverse health effects of FA are largely due to its ability to irritate mucous membranes of the eyes and upper respiratory tract. As a result of its solubility in water and high reactivity, FA is efficiently absorbed into the mucous layers protecting the eyes and respiratory tract where it rapidly reacts, leading primarily to localized irritation. Acute high exposure may lead to eye, nose and throat irritation, and in the respiratory tract, nasal obstruction, pulmonary edema and dyspnea. Prolonged or repeated exposures have been associated with allergic sensitisation, respiratory symptoms (coughing, wheezing, shortness of breath), histopathological changes in respiratory epithelium, and decrements in lung function. Children, especially those with asthma, may be more likely to show impaired pulmonary function and symptoms than adults, following chronic exposure to FA (WHO, 2010; CDC/ATSDR, 2016).

Formaldehyde is considered to be a human carcinogen by IARC, the U.S. EPA, California EPA, and the EU.

### 2.2 HEALTH BASED ASSESSMENTS AND GUIDANCE VALUES

A summary of international health based air quality values for formaldehyde is presented in Table 1.

#### 2.2.1 World Health Organization

The WHO ambient air quality guideline value for FA is 0.1 mg/m<sup>3</sup> (100 µg/m<sup>3</sup>), 30-minute average, for protection of the general population (Table 1). The WHO guideline value was primarily derived from the study of Lang et al. (2008), which exposed 21 healthy volunteers (11 males and 10 females) to FA concentrations of 0, 0.19, 0.37 or 0.62 mg/m<sup>3</sup> (0, 0.15, 0.3 or 0.5 ppm) for 4 h, with four peak exposures of 1.24 mg/m<sup>3</sup>. The study authors concluded that eye-blinking frequency was the most sensitive parameter for sensory irritation, with a reported no observed adverse effect concentration (NOAEC) of 0.62 mg/m<sup>3</sup> without peak exposures, and a lowest observed adverse effect concentration (LOAEC) of 1.24 mg/m<sup>3</sup> (1 ppm) FA. The no observed adverse effect concentration (NOAEC) of 0.62 mg/m<sup>3</sup> for the eye blink response was adjusted using an assessment factor of 5 derived from the standard deviation of nasal pungency (sensory irritation) thresholds, leading to an adjusted NOAEC of 0.12 mg/m<sup>3</sup>, which was rounded down to 0.1 mg/m<sup>3</sup> (Table 1).

The WHO notes that there is substantial inter-individual variability in human responses to FA exposure. An increase in signs of irritation occurred at peak levels above 0.38 mg/m<sup>3</sup> in healthy subjects, and a progression of symptoms occurs above 1.2 mg/m<sup>3</sup>. No lung function alterations were noted in healthy non-smokers and asthmatics exposed to FA levels up to 3.7 mg/m<sup>3</sup>. The WHO concluded from reviewing volunteer studies that the observed irritant effects were related more to short term peak FA concentrations than to mean concentrations (WHO, 2010).

According to WHO, there is no indication of accumulation of effects over time with prolonged (chronic) exposure. This is based on the observation that the chemical reaction of FA on the TRPA1 receptor site, a chemical irritation receptor in airways (Gerhold and Bautista, 2008), is reversible (WHO, 2010). Inflammation may increase the receptor sensitivity, but neither eye nor airway inflammation has been reported at typical indoor concentrations of FA. Further, neither nasal damage nor inflammation were observed in rats during life-long exposure to 1.2 mg/m<sup>3</sup> (1 ppm) FA (WHO, 2010).

The threshold of FA odour detection is lower than concentrations triggering sensory irritation of the eyes and upper airways. This may result in some individuals reporting subjective symptoms at concentrations below the sensory irritation threshold. Individuals may perceive FA at concentrations below 0.1 mg/m<sup>3</sup>. However, this was not considered to be an adverse health effect. Neither increased sensitivity nor sensitisation were considered plausible at such indoor FA concentrations in adults and children.

The short-term WHO guideline concentration for FA was assessed for its associated cancer risk, and WHO concluded that the non-cancer guideline value would also be protective for effects on lung function as well as long-term health effects, including nasopharyngeal cancer and myeloid leukaemia (WHO, 2010).

### 2.2.2 New Zealand and Australia

Indoor air quality guidelines for FA in domestic settings are not available in New Zealand. The New Zealand outdoor air quality guidelines, developed by the Ministry for the Environment (MfE, 2002), utilize the above WHO 30-min 0.1 mg/m<sup>3</sup> guideline value to guard against “eye, nose and throat irritation, coughing, wheezing, chest pains, and bronchitis”. The use of outdoor air quality guidelines for indoor air quality risk assessments is less than ideal due to the differing breakdown kinetics in the two settings.

The Australian National Industrial Chemical Notifications and Assessment Scheme (NICNAS)<sup>1</sup>, in 2006, recommended to Safe Work Australia that the occupational exposure standard for FA be lowered from 1 ppm (0.12 mg/m<sup>3</sup>) to 0.3 ppm (0.04 mg/m<sup>3</sup>) for an 8-hour average exposure and 0.6 ppm for short term exposure, based on irritation of the eyes and nose (NICNAS, 2006; ACT, 2020). This level is stated to provide “adequate protection against discomfort from irritation, and is intended to protect against the risk of cancer”. However, this occupational exposure limit is not relevant for domestic indoor air quality risk assessment purposes.

Due to public concern in Australia around childhood chemical exposure and cancers, together with the findings of relatively high levels of FA in mobile homes and relocatable buildings at the time, a worst-case scenario risk estimation incorporating higher exposures during childhood was derived using a Chemical Industry Institute of Toxicology model (NICNAS, 2006). The worst-case scenario was identified to be for children, up to 17 years of age, who live in mobile homes and spend all of their schooling time in classrooms made with

---

<sup>1</sup> Now known as the Australian Industrial Chemicals Introduction Scheme (AICIS)

press-board. The predicted additional risk of respiratory tract cancer for a full 80-year lifetime, including childhood exposure to FA under this worst-case scenario was estimated to be 0.45 in a million (NICNAS, 2006). According to NICNAS, the estimated cancer risk from chronic exposure to 300 ppb (380 µg/m<sup>3</sup>) formaldehyde was 1 x 10<sup>-6</sup>, indicating that a chronic exposure to the WHO guideline of 0.1 mg/m<sup>3</sup> would be associated with a cancer risk of 2.6 x 10<sup>-7</sup> (NICNAS, 2006). These cancer risks were assessed to be practically negligible.

### 2.2.3 European Union

The EU Risk Assessment Committee (RAC), when reviewing proposed FA emission levels for wood-based paneling, critically reviewed the 0.1 mg/m<sup>3</sup> WHO FA guideline value, and expressed concern that the value was insufficiently protective of public health. The following is a summary of the EU criticisms and their recommendation for a lowering (by half) of a chronic FA derived no effect level (DNEL) value for the general population.

A sensory irritation (eye blinking response, or EBF) NOAEC was used as the point of departure (POD) for the DNEL. This was assumed, as with the WHO assessment, to be protective for long-term carcinogenic effects. The RAC acknowledged that data on sensory irritation could be one option to derive a DNEL for FA assuming that at very low FA concentrations, sensory irritation of the eye and upper respiratory tract is an initial event (essentially a threshold) preceding the cascade of precursors in the tumour development shown as follows:

irritation → inflammation → hyperplasia → metaplasia → tumour

However, depending on the availability and robustness of data and considering duration-related effects, RAC considered that sensory irritation data do not necessarily represent the most sensitive POD for DNEL derivation. The RAC considered that, due to the small number of volunteers ("small" in relation to sample size and setting of assessment factors is considered to be 10-30 people), and the very high variability in EBF in the study by Lang et al. (2008), the study design and the assessed parameter were not considered to be sensitive enough to detect concentration-related effects unless they were marked (i.e. only an exposure concentration of 0.62 mg/m<sup>3</sup> (0.5 ppm) with 4 peak exposures to 1.24 mg/m<sup>3</sup> (1 ppm) FA resulted in a significant increase by doubling of the EBF rate). Due to the enormous variability of the measured effect (~100 fold min-max EBF at baseline and in exposure groups, resulting in very high standard deviations) and the low number of volunteers, yielding low statistical power, the absence of an effect at lower FA concentrations was considered uncertain in the Lang et al. study. Thus, the probability of false negative results at the lower concentrations (below 1.24 mg/m<sup>3</sup>) could not be excluded based on the study results.

The RAC further noted that subjective scores for olfactory symptoms and for eye irritation significantly increased at ≥0.37 mg/m<sup>3</sup> (0.3 ppm) FA in the study of Lang et al. (2008). The small number of volunteers, and the subjective self-reporting of symptoms was considered to not allow for the derivation of a robust DNEL. The RAC noted the high variability in EBF seen in a follow-up study by the same group, testing 20 'hyposensitive' and 21 'hypersensitive' male volunteers (Mueller et al., 2013). This study was not available to WHO in 2010 and reported no evidence for effects on EBF at concentrations up to 0.87 mg/m<sup>3</sup> (0.7 ppm) FA (4 hours exposure). In this further study, EBF measured during the last 15 minutes of the FA exposure was compared to pre-exposure EBF for the same individual and revealed a trend towards lower mean differences instead of the expected higher EBF. Thus, there was greater individual variability early as compared with late in the exposure. No differences between hypo-, and hypersensitive subjects were seen in the study.

The RAC considered that the lower assessment factors (AF) used by the WHO compared to AF used by the European Chemicals Agency (ECHA) and the short exposure duration basis of the key study (4 hours) suggested that the WHO guideline value may not be protective for long term exposure.

RAC also expressed concerns as to whether the selected parameter (EBF, during acute exposure) is the most appropriate measure for prediction of carcinogenic effects after long-term inhalation exposure to FA. The RAC noted that there are indications from animal studies that prolongation of FA exposure (up to 24 months) leads to an exacerbation of (non-neoplastic, potentially precursor) nasal effects. The frequency of metaplasia increased with the duration of treatment in rats (Kerns et al, 1983), and in monkeys the percentage of affected nasal area increased with the duration of exposure (Monticello, 1989).

RAC concluded that risks to consumers are insufficiently addressed by the WHO guideline value of 0.1 mg/m<sup>3</sup> (0.08 ppm) and instead proposes:

- *“Limiting emissions exceeding concentrations of 0.05 mg/m<sup>3</sup> measured in the air of a test chamber under conditions specified in Appendix X for articles, and*
- *A limit concentration of 0.05 mg/m<sup>3</sup> formaldehyde for vehicle cabin interiors.”* (ECHA, 2020).

Although the New Zealand standards appear to be based on the previous WHO guideline, they are sufficiently stringent to meet this lower value proposed by the RAC.

#### 2.2.4 Health Canada

Health Canada’s Residential Indoor Air Quality Guideline for FA provides recommended health-based maximum exposure limits for FA in Canadian homes (Canada Gazette, 2019). The short-term and long-term limits are as follows:

- Short-term exposure: 123 µg/m<sup>3</sup> (100 parts per billion [ppb]) based on irritation of the eyes, nose or throat; and
- Long-term exposure: 50 µg/m<sup>3</sup> (or 40 ppb) based on hospitalization for asthma in children.

Testing carried out in Canadian homes between 2007 and 2015 suggested that approximately 8% of Canadian homes had average FA levels above the recommended long-term exposure limit. These exposure limits are also considered to be protective against adverse health effects in all individuals, including children with asthma. It is not known to what extent the compliance with FA emissions standards varies between Canada and New Zealand, but the more stringent New Zealand standards (Table 5) would suggest that risks of exceeding these health based values are low.

#### 2.2.5 International Agency for Research on Cancer (IARC)

Formaldehyde is an IARC Group 1 carcinogen (known to cause cancer in humans) (IARC, 2006). IARC concluded that there is sufficient evidence in humans for the carcinogenicity of FA, and that there is also sufficient evidence for carcinogenicity in experimental animals. The cancers caused by FA include localized tumours of the upper respiratory tract, and myeloid leukaemia (IARC, 2006). However, since exposures to FA concentrations up to 2.5 mg/m<sup>3</sup> do not increase measured circulating blood FA levels, it has been assumed that the non-cancer threshold and the 0.1 mg/m<sup>3</sup> irritation standard are protective against carcinogenicity (WHO, 2010).

### 2.2.6 Agency for Toxic Substances and Disease Registry (ATSDR)

The ATSDR derived inhalation minimal risk levels (MRLs) for formaldehyde for acute (1-14 days), intermediate (15-364 days), and chronic (1 year or longer) durations (ATSDR, 2010) (Table 2).

The acute MRL of 0.04 ppm derives from a human volunteer study by Pazdrak et al. (1993), which observed nasal and respiratory irritation symptoms and biomarkers (transient albumin and eosinophil increases) after a 2-hour exposure to 0.4 ppm in room air. Uncertainty factors of 3 were applied to account for extrapolation from a mild reversible lowest observed adverse effect level (LOAEL) and the limited human variability represented in a small scale study. The cumulative uncertainty factor (9) was rounded to 10 and applied to the LOAEL of 0.4 ppm to derive the MRL of 0.04 ppm.

The intermediate MRL for FA of 0.03 ppm was derived from a study in groups of 6 cynomolgus monkeys exposed to FA 22 hours/day, 7 days/week, for 26 weeks (Rusch et al., 1983). Nasal irritation pathological signs were observed at an exposure concentration of 2.95 ppm, but not at 0.98 ppm. Uncertainty factors of 3 for extrapolation from an animal species to humans and 10 for inter-individual variation were applied, giving an overall uncertainty factor of 30.

The chronic MRL (0.01 ppm) was derived from a human occupational study in Swedish workers in a furniture factory, with mean duration of work of 10.4 years (Holmstrom et al., 1989). Clinical symptoms and signs of nasal and eye irritation were found in workers with an estimated average exposure to 0.24 ppm. Uncertainty factors of 3 for extrapolation from a LOAEL, and 10 for inter-individual variability were applied, giving an overall uncertainty factor of 30.

A review of epidemiological studies by ATSDR concluded that, in relation to the predisposition of sensitive individuals:

*“The results of these studies indicated that low residential indoor air levels of formaldehyde may predispose young children to asthma or allergies. However, the dose-response relationship has not been clearly established and further research is necessary.”*

ATSDR is currently in the process of re-evaluating the MRLs for formaldehyde. The evaluation is pending review of US EPA toxicological review of formaldehyde by a committee of the National Research Council (NRC).

### 2.2.7 U.S. Environmental Protection Agency (USEPA)

The U.S. Environmental Protection Agency (USEPA) published a draft assessment of FA, which, at 1043 pages, illustrates the degree to which FA has been exhaustively studied from a toxicology and epidemiology perspective (USEPA 2010).

Numerous chronic reference concentration (RfC) calculations from “co-critical” studies are presented in this draft document, following consideration of animal and human volunteer and occupational studies. Proposed RfCs were derived from two alternative calculations, using different uncertainty factors for human (inter-individual) variability, resulting in RfCs of 4 ppb and 9 ppb. Their basis is shown below, but it is noted that the USEPA have not, to date, finalised their RfC assessment.<sup>2</sup>

<sup>2</sup> [https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance\\_nmbr=419](https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance_nmbr=419) Accessed 26 November 2020

Three studies of related health effects: asthma, allergic sensitization, pulmonary function, and symptoms of respiratory disease in children from in-home exposure to formaldehyde (Rumchev et al., 2002; Garrett et al., 1999; Krzyzanowski et al., 1990) were chosen as the basis for the derivation of the RfC. These co-critical studies are mutually supportive and lead to similar cRfCs (candidate RfCs). Therefore, the RfC is taken as the mean of the cRfCs from the three co-critical studies. For two of these studies (Rumchev et al., 2002; Garrett et al., 1999), USEPA provided alternatives for the application of the uncertainty factor for inter-individual variability (Table 2).

The USEPA classified FA as Group B1 (probable human carcinogen), and developed a unit risk value for FA of  $1.3 \times 10^{-5}$  per  $\mu\text{g}/\text{m}^3$  (USEPA, 2010). The basis for the USEPA's classification was an increased incidence of nasal squamous cell carcinomas, observed in long-term inhalation studies in rats and in mice. The classification is supported by *in vitro* genotoxicity studies and formaldehyde's structural relationships to other carcinogenic aldehydes, such as acetaldehyde.

### 2.2.8 California EPA (CalEPA)

The California Environmental Protection Agency (CalEPA) "no significant risk level" for chronic exposure and cancer risk from FA, is 40  $\mu\text{g}/\text{day}$ , and the inhalation unit risk value is slightly lower than that of USEPA, at  $6.0 \times 10^{-6}$  per  $\mu\text{g}/\text{m}^3$ . The Office of Environmental Health Hazard Assessment (OEHHA) in California have developed acute and chronic inhalation reference exposure levels for FA, of 0.055  $\text{mg}/\text{m}^3$  and 0.009  $\text{mg}/\text{m}^3$ , respectively (Table 2). The risk assessment from the California Air Resources Board (CARB) utilised a FA air concentration of 0.034  $\text{mg}/\text{m}^3$ , based on protection against acute respiratory effects (CARB, 2004).

**Table 1. International health based air quality values for formaldehyde**

Entity	Regulatory or Guidance value	Toxicological basis	Uncertainty factor(s)	Receptor	Reference
MfE	0.1 $\text{mg}/\text{m}^3$ (30 min)	See WHO, 2010	5	Human volunteers	MfE, 2002
WHO	0.1 $\text{mg}/\text{m}^3$ (30 min)	NOAEC = 0.6 $\text{mg}/\text{m}^3$ , eye blink reflex	5 (for sensory irritation standard deviation), 0.12 $\text{mg}/\text{m}^3$ rounded to 0.1 $\text{mg}/\text{m}^3$ .	Human volunteers	WHO, 2010
EU RAC	DNEL = 0.05 $\text{mg}/\text{m}^3$ (proposed)	Respiratory irritation, eye blink reflex	10	Human	ECHA, 2020
Canada	Indoor Air Quality Guideline = 0.05 $\text{mg}/\text{m}^3$	Chronic: Respiratory irritation, eye blink reflex	10	Human	Health Canada, 2006
ATSDR	0.05 $\text{mg}/\text{m}^3$	Acute: Respiratory irritation	9	Human	ATSDR, 1999; Pazdrak et al., 1993
	0.04 $\text{mg}/\text{m}^3$	Intermediate	30		
	0.01 $\text{mg}/\text{m}^3$	Chronic: Respiratory Irritation	30		
U.S. EPA	0.005 $\text{mg}/\text{m}^3$	Asthma, respiratory irritation, lung function	3	Human volunteers, occupational	USEPA, 2010
	0.01 $\text{mg}/\text{m}^3$		1		
CalEPA	0.034 $\text{mg}/\text{m}^3$	Acute: Eye irritation	10	Human volunteers	CARB, 2004; OEHHA, 2008; Kulle et al., 1987;
	0.055 $\text{mg}/\text{m}^3$				

0.009 mg/m <sup>3</sup>	Chronic: Respiratory irritation	10	Workers	Wilhelmsson and Holmstrom, 1992
-------------------------	---------------------------------	----	---------	---------------------------------

**Table 2. USEPA draft formaldehyde RfC calculations**

<p><b><u>RfC Calculation Alternative A</u></b> Application of a Cumulative Uncertainty Factor of 3 for Human (inter-individual) Variability</p> <p><u>Key Studies:</u> Rumchev et al., 2002; Krzyzanowski et al., 1999; Garrett et al., 1999</p> <p><u>Critical Endpoints:</u> Asthma, allergic sensitization, pulmonary function, and symptoms of respiratory disease in children</p> <p><u>Candidate RfCs:</u> cRfC = 5.6 ppb—decreased PEFR (Krzyzanowski et al., 1999) cRfC = 3.3 ppb—increased physician-diagnosed asthma (Rumchev et al., 2002) cRfC = 2.8 ppb—increased asthma, atopy and respiratory symptoms (Garrett et al., 1999)</p> <p><b><u>Mean of three cRfCs: 4 ppb</u></b></p> <p><b><u>RfC Calculation Alternative B</u></b> Application of a Cumulative Uncertainty Factor of 1 for Human Variability (UF of 3 remains for the Krzyzanaowski study)</p> <p><u>Key Studies:</u> Rumchev et al., 2002; Krzyzanowski et al., 1999; Garrett et al., 1999</p> <p><u>Critical Endpoints:</u> Asthma, allergic sensitization, pulmonary function, and symptoms of respiratory disease in children</p> <p><u>Candidate RfCs:</u> cRfC = 5.6 ppb—decreased PEFR (Krzyzanowski et al., 1999) cRfC = 11 ppb—increased physician-diagnosed asthma (Rumchev et al., 2002) cRfC = 9.3 ppb—increased asthma, atopy and respiratory symptoms (Garrett et al., 1999)</p> <p><b><u>Mean of three cRfCs: 9 ppb</u></b></p>
---

## 2.3 REGULATIONS AND STANDARDS FOR FA EMISSIONS FROM WOOD-BASED MATERIALS

The scope of international risk assessments and standards for FA emanating from building materials includes numerous consumer products in addition to laminated flooring, all of which contain FA-based resin adhesives.

### 2.3.1 Europe

European regulatory standards initially established that building materials, including flooring, should not exceed 0.124 mg/m<sup>3</sup> in the air of a test chamber used under the conditions prescribed in regulation EN 717-1 (ECHA, 2019) (summarised in Table 3). An assumption in the EU risk assessment is that the room's flooring is made up of laminate resulting in a FA loading factor of 0.4 m<sup>2</sup>/m<sup>3</sup>. The comparative health-based FA concentration used at the time, was the WHO 30-minute FA concentration of 0.1 mg/m<sup>3</sup> (ECHA, 2019). As previously mentioned, ECHA subsequently proposed to use a lower health-based value for FA of 0.05 mg/m<sup>3</sup>, which is in line with Canadian and U.S. assessments.

In an updated EU risk assessment, ranges and maximal emission rates/concentrations were reported for various types of wood-based products (Table 3) (ECHA 2020). Salthammer

(2019) reported mean area specific emission rates of 58.5 µg/(m<sup>2</sup>h) for particle boards based on European inter-laboratory comparison data from Yrieix et al. (2010). Steady state (28 days) air concentrations related to laminate flooring were reported by Salthammer (2019) and ranged from 0.005 ppm for high density flooring, up to 0.03 ppm for high and medium density flooring, and particle board, at conditions of 23°C, RH 45% with a range from < 3.8 to 28.3 µg/m<sup>3</sup>.

**Table 3. EU Risk Assessment FA Emission Data\* for Wood Products**

Wood-based product type	Emission rate or concentration
<b>Area-specific emission rates</b>	
plywood	0.18-2.65 mg/(m <sup>2</sup> h)
particle board	0.04-2.52 mg/(m <sup>2</sup> h)
MDF	0.2-3.6 mg/(m <sup>2</sup> h)
different kind of laminate flooring	0.028-0.35 mg/(m <sup>2</sup> h)
<b>Steady-state air concentrations</b>	
OSB	0.042 mg/m <sup>3</sup>
multi-layer solid wood flooring	0.008-0.125 mg/m <sup>3</sup>

\*ECHA, 2020.

The values in Table 3, for the EU risk assessment indicate that plywoods and particleboard are generally higher FA emitters than laminates, and also shows that FA can be released to indoor air from a range of building materials.

The EU risk assessment considered the proposal by the industry applicant for a voluntary FA emission standard but concluded that the voluntary standard would fail to protect a substantial number of individuals from the health effects of FA. The proposal was that articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture, shall not be placed on the market if the formaldehyde released from them exceeds a concentration of 0.124 mg/m<sup>3</sup> and road vehicles and aeroplanes produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m<sup>3</sup>.

### 2.3.2 Canada

At present, there are no Government of Canada regulations that set out limits for the amount of FA released from composite wood products that can be used in Canadian homes. However, the Canadian Standards Association (CSA) has a proposed standard that is effectively the same as the one used in California (Section 2.3.4): Products that are in compliance with the voluntary standard can be labelled as complying with the CSA standard. According to the Government, most Canadian manufacturers have indicated that their products already comply with this voluntary standard (Canada Gazette, 2019). However, since the standard is voluntary, it is unknown precisely how many Canadian manufacturers currently meet the standard. Some limited testing by the National Research Council of Canada has been done and showed that at least some imported products currently produce FA emissions above the CSA standard.

The 2019 proposed Regulations in Canada would establish the following maximum FA emission levels from composite wood products:

- 0.05 ppm (0.0625 mg/m<sup>3</sup>) for hardwood plywood;
- 0.09 ppm (0.11 mg/m<sup>3</sup>) for particle board;
- 0.11 ppm (0.14 mg/m<sup>3</sup>) for medium-density fibreboard;
- 0.13 ppm (0.16 mg/m<sup>3</sup>) for thin medium-density fibreboard; and
- 0.05 ppm for laminated products.

*“Composite wood products that emit FA gas above these levels could not be sold in, offered for sale in, or imported into Canada under the proposed Regulations unless they are exempted from the Regulations.*

*Products such as pallets and packaging materials that are not intended to be kept in people’s homes, certain types of structural wood products, wood used in vessels and vehicles (other than mobile homes, motor homes, and recreational trailers), and a variety of highly specialized wood products would be exempted from the proposed Regulations. A full list of the exemptions is included in the Regulations.*

*Non-exempt composite wood products that are to be sold in Canada must be tested to ensure they meet the regulatory emission limits, and labelled as meeting the requirements before they may be sold in, offered for sale in or imported into Canada.*

*Product testing must be carried out on a routine basis, which is dependent upon the amount of manufacturing and product type, to ensure consistent emission levels (quality control). In addition, product testing must be conducted on a quarterly basis by an accredited laboratory to demonstrate consistency between the routine quality control test results and the emission test results generated by an accredited laboratory.*

*In certain cases, testing may be required less frequently, such as for manufacturers that are using no-added formaldehyde or ultra low-emitting formaldehyde resins. The specific testing requirements and testing frequency vary depending on the type and volume of products being tested. The testing requirements under the proposed Regulations would be essentially the same as the testing requirements under the U.S. rule.*

*All products that are required to be compliant with the proposed Regulations must be labelled prior to being sold or offered for sale in Canada. In some cases, if products are sold or offered for sale bundled together, then it may not be necessary to label each individual item. It may be sufficient to label the entire bundle. If the product is later unbundled for sale, then labelling may be required for each individual piece, as outlined in the proposed Regulations. Labels must be bilingual (English and French) and meet the other label requirements provided in the proposed Regulations. Some minor differences exist between the U.S. labelling requirements and those under the proposed Regulations, including, but not limited to, the bilingual requirement.”*

### 2.3.3 Australia, New Zealand, and Japan

A joint Australia/New Zealand/Japan standard, (AS/NZS 1859:2017) for FA emissions from particle board, fibreboards, and wood-based paneling was developed in 2004, and revised in 2017 (AS/NZS, 2017).

Standard AS/NZS 4266.1.17 was developed for measuring and assessing FA emissions in reconstituted wood-based panels by New Zealand, Japan, and Australia between the wood-based panel industries of each country, and has been accepted by the International Standardization Organization as ISO/CD 12460-4 (Salthammer et al., 2010; ACT, 2020; ISO, 2016; AS/NZS, 2002; AS/NZS, 2004a, b; AS/NZS, 2013; AS/NZS, 2017).

While this standard provides a method to analyse and report FA concentrations on these materials, the health-based risk assessment underlying this standard was not found. A report from a Japanese advisory group in 2002, indicated that the WHO air guideline of 0.1 mg/m<sup>3</sup> was used as the basis for national standards (Table 4) in Japan (CSHS, 2002).

Each standard defines a method of analysis for measurement of FA emissions. These methods do not produce equivalent results. The study of Zeleniuc (2016) provides a valuable comparison between the various methods of analysis, which is critical when comparing the stringency of different standards (Table 4).

**Table 4. Relationship between New Zealand/Australia/Japan standard and other standards for FA emissions test methods\***

FA Emission Class	Limit Value (Dessicator Method) (mg/L)	Perforator Value (European Method)	Chamber Method (EN 717-1) (mg/m <sup>3</sup> air)	Emission (ASTM E1333) (ppm)
E1 (F <sup>**</sup> )	< 1.5	6.5 mg/100 g	-	0.143
E0 (F <sup>***</sup> )	< 0.5	2.5 mg/100 g	< 0.054	< 0.055
SE0 (F <sup>****</sup> )	< 0.3	1.5 mg/100 g	< 0.034	< 0.035

\*from Zeleniuc, 2016

Table 4 indicates that the New Zealand standard E0 and SE0 would be expected to result in FA emissions less than 0.054 mg/m<sup>3</sup> and 0.034 mg/m<sup>3</sup> in test chambers, respectively. The FA emissions associated with the New Zealand standards would be expected to result in exposures below the international indoor air health based limits for FA.

### 2.3.4 United States

Nationally, in the U.S., the Formaldehyde Standards for Composite Wood Products Act, or Title VI of TSCA, 15 U.S.C. 2697, was enacted on July 7, 2010 (USEPA, 2017). The statute establishes FA emission standards that are identical to the CARB ATCM Phase 2 standards for hardwood plywood with a composite or veneer core, MDF, and particleboard sold, supplied, offered for sale, or manufactured in the United States. (Table 5).

*Formaldehyde emission standards:*

*(a) Except as otherwise provided in this part, the emission standards in this section apply to composite wood products sold, supplied, offered for sale, or manufactured (including imported) on or after December 12, 2017 in the United States. These emission standards apply regardless of whether the composite wood product is in the form of a panel, a component part, or incorporated into a finished good.*



(b) The emission standards are based on test method ASTM E1333-10 (incorporated by reference, see § 770.99), and are as follows:

(1) For hardwood plywood made with a veneer core or a composite core, 0.05 parts per million (ppm) of formaldehyde.

(2) For medium-density fiberboard, 0.11 ppm of formaldehyde.

(3) For thin medium-density fiberboard, 0.13 ppm of formaldehyde.

(4) For particleboard, 0.09 ppm of formaldehyde.

Table 5 summarises the international emission standards.

**Table 5. Summary of international FA emission standards**

Entity	Classification or Grade <sup>a</sup>	Wood-Based Panel Product <sup>b</sup>	FA Emission Limit <sup>c</sup>	Test Method	Source
<b>AS/NZS/ (Japan)</b>	E1/(F <sup>**</sup> )	All	1.5 mg/L	AS/NZS	AS/NZS
	E0/(F <sup>***</sup> )	All	0.5 mg/L	4266.16	1859:2017
	SE0/(F <sup>****</sup> )	All	0.3 mg/L	(Dessicator Method)	
<b>Canada</b>	Excluding NAF, ULEF	HWPW	0.05 ppm	ASTM E1333	Canada Gazette, 2019
		PB	0.09 ppm		
		MDF	0.11 ppm		
		Thin MDF	0.13 ppm		
		LP	0.05 ppm		
	NAF	HWPW	0.05 ppm		
		LP			
		PB	0.06 ppm		
	ULEF	MBF			
		Thin MBF			
		HWPW	0.05 ppm		
		LP			
	ULEF	PB	0.08 ppm		
		MDF	0.09 ppm		
		Thin MDF	0.11 ppm		
		Thin MDF	0.13 ppm		
<b>CARB</b>	Phase II	HWPW	0.05 ppm	ASTM E1333	17 CCR §93120-93120.12
		PB	0.09 ppm		
		MDF	0.11 ppm		
		Thin MDF	0.13 ppm		
<b>U.S. EPA</b>	TSCA Title VI Compliant	HWPW	0.05 ppm	ASTM E1333	40 CFR Part 770
		PB	0.09 ppm		
		MDF	0.11 ppm		
		Thin MDF	0.13 ppm		
<b>U.S. (HUD)</b>	-	HWPW	0.05 ppm	ASTM E1333 or ASTM D6007	85 FR §5562
		PB	0.09 ppm		
		MDF	0.11 ppm		
		Thin MDF	0.13 ppm		
<b>Europe</b>	E1	All	0.124 mg/m <sup>3</sup>	EN 717-1	ECHA, 2020



Entity	Classification or Grade <sup>a</sup>	Wood-Based Panel Product <sup>b</sup>	FA Emission Limit <sup>c</sup>	Test Method	Source
China	E1 (proposed)	All	0.05 mg/m <sup>3</sup>		
	E1	MDF HDF OSB PB HWPW Bamboo	9 mg/100g	Perforator	ECHA, 2020
	E2 (can be used indoor if surface treated beforehand)	MDF HDF OSB PB HWPW Bamboo	30 mg/100g	Perforator	
			5.0 mg/L	Dessicator	
<b>Natural Wood</b>	-	-	0.3 mg/L	Dessicator	Nwaogu et al., 2013

<sup>a</sup> Note: No-added FA resin (NAF), Ultra low-emitting FA resin (ULEF)

<sup>b</sup> Note: Hardwood plywood (HWPW), Laminated products (LP), orientated strandboard (OSB), High density fibre-board (HDF), Medium density fibre-board (MDF)

<sup>c</sup> Note: According to the study of Zeleniuc (2016) the lowest New Zealand emission limit (0.3 mg/L) is approximately equivalent to 0.04 ppm (ASTM E1333), 0.03 mg/m<sup>3</sup> (EN 717-1) or 1.5 mg/100 g (European perforator method)

When the limits presented in Table 5 are converted to an equivalent basis, using the analysis of Zeleniuc (2016), the most stringent AS/NZS emission limit (SE0, 0.3 mg/L) is more stringent than any other emission limit and is equivalent to FA emissions from natural wood.

## 2.4 LAMINATED FLOORING INDOOR AIR FA SURVEYS

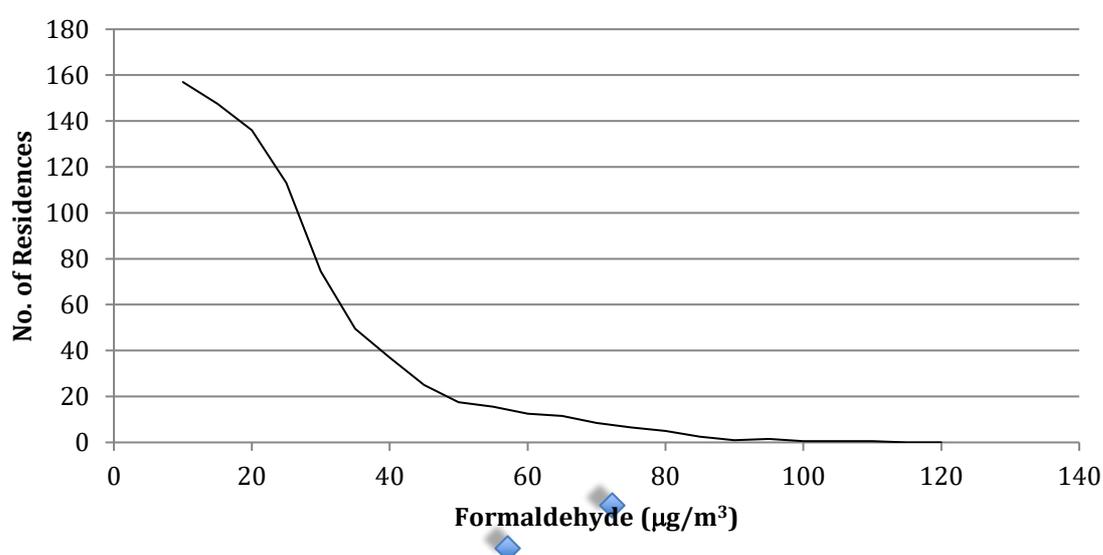
Sheehan and colleagues examined the FA concentrations in 899 homes in the U.S. with installed Lumber Liquidators products, measuring FA initially and over time (Sheehan et al., 2017). Figure 1 from the Sheehan study illustrates the initial high indoor air FA concentrations in these homes. The median and mean starting values were 18.5 and 23.3 µg/m<sup>3</sup>, respectively. While a small number of extreme values exceed the ECHA/Canada/USA or WHO health based guideline values of 50 or 100 µg/m<sup>3</sup>, these concentrations decline slowly over time to reach a steady state. It should be noted that the Sheehan study examined houses with the Lumber Liquidators flooring installed and would be expected to represent a higher level of FA exposure than that from typical flooring material meeting New Zealand wood-paneling standards (Figure 1).

A study conducted in the U.S., examined the emissions of compliant and non-compliant FA emitting flooring from China and concluded that there was no significant acute health risk from these products as installed in a real-world setting, with mean FA room concentrations of 0.038 ppm for non-compliant and 0.022 ppm for compliant products when installed (Pierce et al., 2016).

Newer homes tend to have higher FA concentrations. USEPA reported mean FA levels across 12 studies to range from 29.5  $\mu\text{g}/\text{m}^3$  in older residences, up to 1032  $\mu\text{g}/\text{m}^3$  in newer mobile homes (USEPA 2010). Again, the surveys from North America and Europe may not be reflective of typical New Zealand indoor air due to the less stringent FA emission standards historically in use overseas.

Fig. 1. Frequency distribution of laminate-flooring-attributable initial concentration of FA in 899 U.S. homes, estimated to have occurred just after Lumber Liquidators laminate flooring was installed in each of those homes. (adopted from Sheehan et al., 2017).

## Formaldehyde Concentrations in U.S. Houses with Laminated Flooring



In Australia, FA levels in established conventional homes and buildings are reportedly low at average levels of 15-30 ppb (19-38  $\mu\text{g}/\text{m}^3$ ) (NICNAS, 2006). However, limited monitoring data indicate that mobile homes and possibly relocatable buildings have higher levels of FA. There was an average of 29 ppb and a range from 8 to 175 ppb in occupied caravans<sup>3</sup>; an average of 100 ppb with a range from 10 to 855 ppb in unoccupied caravans; and an average of 710 ppb with a range from 420 to 830 ppb in offices (1992 data). This is primarily due to the higher usage of products that emit FA in these buildings, relatively low ventilation rate and/or small internal volume, and other potential sources of FA such as from combustion of gas used in cooking and refrigeration. There is a potential risk of sensory irritation for people living in these types of buildings, but the risk of cancer is estimated to be low (NICNAS, 2006).

A study in Japan found that dormitories that had used high grade (F<sup>\*\*\*</sup>) FA emitting materials, could still encounter FA excursions above the WHO Guideline in cases without adequate ventilation, and concluded that residents should be advised to ensure their dwellings are suitably ventilated (Azuma et al., 2015).

<sup>3</sup> The NICNAS report does not state whether a mobile home is the same as a caravan, but appears to use the terms interchangeably

Many wood-based flooring products, some also sourced from China, are available in New Zealand for sale, and some reviews online have anecdotally noted potential health effects from their installation in the home (Ecobob Info and News, 2019). A review by Taptiklis and Phipps found that survey data of indoor FA concentrations in New Zealand homes was not available (Taptiklis and Phipps, 2017).

### 3 DISCUSSION

---

Internationally, the health risks from indoor FA emissions have been assessed against exposure guidelines for acute and chronic respiratory and eye irritation, as well as carcinogenicity. The WHO short term, 30-minute FA air quality guideline value of 0.1 mg/m<sup>3</sup> has been the basis of wood product emission assessments and standards in New Zealand, Australia, Japan, and Europe, while the CARB health risk based value of 0.05 mg/m<sup>3</sup> was the indoor air basis for standards in California and the U.S. However, more recently, Canada and the EU have moved toward use of the 0.05 mg/m<sup>3</sup> indoor air value, with Canada and the U.S. increasingly converging on a common emissions standard. The FA emissions standard in New Zealand, although originally based apparently upon the WHO value, remains the most stringent internationally (Table 4).

Although FA is a human carcinogen, the estimated cancer risks of indoor FA from wood-based flooring or paneling have generally not been the driving factor for human health risk related to setting FA emissions standards. The CDC and ATSDR estimated the cancer risk stemming from laminated flooring in the U.S. to be between 6 and 30 extra cases for every 100,000 people breathing in FA from representative laminated flooring, when breathing indoor air all day, every day (CDC, 2016). The daily average FA inhalation exposure within the 899 homes in the Sheehan et al. study was estimated to be 17 µg/day. Using a U.S. EPA linear cancer risk model, 50th and 95th percentile values of expected lifetime cancer risk for residents of these homes were estimated to be 0.33 and 1.2 per 100,000 exposed, respectively. Based on more recent data and nonlinear cancer risk assessment models, FA emissions were concluded to pose negligible cancer risks to exposed residents (Sheehan et al., 2017). The European RAC has similarly concluded that cancer risks from FA in these exposure scenarios are below levels of concern, referring to the irritation and histopathology thresholds in chronic animal studies as a basis, and the low cancer risk estimates using linear models.

From a practical perspective, it is not possible to entirely eliminate FA from indoor air, since it is naturally emitted from solid wood furnishings, and released into the air from other natural sources. The health based chronic inhalation values for FA from ATSDR, OEHHA and USEPA (0.005 to 0.01 mg/m<sup>3</sup>) do not appear to be achievable for compliance with any of the FA emissions standards worldwide (Table 5), and may be more appropriately viewed as aspirational guidance values.

## 4 RISK MITIGATION MEASURES

---

The New Zealand Sustainable Building Authority, Level, provides some practical guidance for reducing FA exposures in buildings. FA is presumed to off-gas at room temperature, particularly when the building products are new, so new buildings should be well ventilated, particularly during construction and for the first 4–6 weeks of occupation, to allow new building products to off-gas most of their formaldehyde and thus reduce the risk of formaldehyde gas irritation (Level, 2020).

In the U.S., the CDC provides guidance on how to reduce exposure to indoor FA from products, including laminated flooring and press-board (Table 6) (CDC, 2016).

Californian authorities provide numerous suggestions on how to reduce the exposure to indoor FA in the home, through selection of low FA commercial products or building materials, as well as actions to increase home ventilation (CARB, 2004). In California, FA emissions from pressed-wood products have been reduced 80-90% from levels up to the 1980s due to mandatory FA emission standards in California and national voluntary FA emission standards. Emissions are expected to steadily decrease for 6-10 months after initial testing (CARB, 2004). This is likely to encompass a period after installation of the products.

**Table 6. U.S. CDC guidance on reducing FA in the home**

Reduce formaldehyde already in the home.

- Open windows for a few minutes every few days to let in fresh air — unless you have asthma triggered by outdoor air pollution or pollen or you're concerned about safety.
- Install and use exhaust fans as much as possible.
- Keep the temperature and humidity inside your home at the lowest comfortable setting.
- Make your home smoke free. Tobacco smoke contains FA, so don't allow anyone to smoke in your home.

Choose home products with low or no formaldehyde for future purchases. Look for

- Furniture, wood cabinetry, or flooring made without UF glues
- Pressed-wood products that meet ultra-low emitting FA or no added formaldehyde requirements
- Products labeled "No VOC/Low VOC"
- Insulation that does not have UF foam

Reduce formaldehyde from new products.

- Wash permanent-press clothing and curtains before using them.

Let new products release formaldehyde outside of your living space before you install or use them inside, for example in a garage or on a patio. If possible, keep them out of your living space until you can no longer smell a chemical odor.

## 5 CONCLUSIONS

---

Laminated flooring, and related wood-based products are a source of FA from the degradation of FA-based adhesive resins that are widely used in wood-based paneling and flooring materials worldwide. This degradation can affect indoor air quality but occurs eventually at a steady state, over time, after an initial higher rate of formation.

International authorities and researchers have examined this issue and determined that some products can have unacceptably high levels of FA formation due to faulty production, exceeding in some cases, the WHO FA 30-min air guideline of 0.1 mg/m<sup>3</sup> for respiratory irritation. More stringent health-based air guideline levels of 0.05 mg/m<sup>3</sup> have been developed by the U.S., Canada, and Europe and it is anticipated that standards and regulations in these countries for FA emissions will be expected to satisfy these more stringent FA air guidelines. Additionally, the European RAC has recently concluded that voluntary industry standards fail to provide, in a significant proportion of homes, emissions consistent with EU or WHO health-based FA toxicity values, and is proposing mandatory standards.

A joint New Zealand/Australian/Japan standard exists for emissions of FA from wood-based panels and other wood products such as particle board. While the supporting documentation for the health risk basis of the joint New Zealand/Australia standard was not found, documents from Japan have indicated that the standard was developed to reduce “Sick-House Syndrome” which was reported in Japan and other parts of the world in the 1980s and 1990s before the advent of FA emissions standards. The FA emission rates in the joint standard are more stringent than European and North American equivalent standards that do have a recent health risk assessment basis for protection against the respiratory and eye irritation and carcinogenicity of FA. Exposures to FA in the home can be generally mitigated by a number of measures, including installing low VOC materials, such as E0 or SE0 grade materials, and ensuring adequate ventilation of new buildings. Considering that New Zealand standards for FA emission of wood-based products are stringent in comparison to those found internationally, there appears to be no evidential health risk basis to revisit existing FA emission standards from these products at this time. A random survey of FA in New Zealand homes containing these wood-based panels would provide additional certainty around this conclusion.

Should new and more stringent, health based indoor air standards for FA come into place in New Zealand or internationally, the health risk basis of the existing FA emissions standard may need to be re-assessed.

## 6 REFERENCES

---

Agency for Toxic Substances and Disease Registry (ATSDR). 1999. Toxicological Profile for Formaldehyde. <https://www.atsdr.cdc.gov/ToxProfiles/tp111.pdf>

Agency for Toxic Substances and Disease Registry (ATSDR). 2010. Addendum to the Toxicological Profile for Formaldehyde. [https://www.atsdr.cdc.gov/toxprofiles/formaldehyde\\_addendum.pdf?id=1167&tid=39](https://www.atsdr.cdc.gov/toxprofiles/formaldehyde_addendum.pdf?id=1167&tid=39)

Agency for Toxic Substances and Disease Registry (CDC/ATSDR). 2016. Possible health implications from exposure to formaldehyde emitted from laminate flooring samples tested by the consumer product safety commission. [https://www.cdc.gov/nceh/laminateflooring/docs/laminate-flooring-report-3-22-2016\\_508.pdf](https://www.cdc.gov/nceh/laminateflooring/docs/laminate-flooring-report-3-22-2016_508.pdf)

Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products. Ca. Code of Reg. (CCR) §93120-93120.12. <https://ww3.arb.ca.gov/regact/2007/compwood07/fro-final.pdf>

Australian Capital Territory (ACT). 2020. Formaldehyde Exposure from Pressed Wood Products. <https://www.accesscanberra.act.gov.au/ci/fattach/get/121406/1483586197/redirect/1/filename/Formaldehyde+exposure+from+pressed+wood+products.pdf>

Azuma M, Kubo H, and Isoda N. 2015. Effects of room specifications and lifestyles of residents on indoor formaldehyde concentrations: formaldehyde concentrations in student dormitories. *J Human Environ Syst* 18(1):1-9.

California Air Resources Board (CARB). 2004. Indoor Air Quality Guideline, No. 1. Formaldehyde in the home. <https://ww3.arb.ca.gov/research/indoor/formaldgl08-04.pdf> [site accessed 23/09/2020].

Canada Gazette. 2019. Part I, Vol 153, No. 26: Formaldehyde emissions from composite wood products regulations. <http://gazette.gc.ca/rp-pr/p1/2019/2019-06-29/html/reg3-eng.html> [site accessed 21/09/2020]

CBS 60-Minutes television programme. March 2015. Lumber liquidators linked to health and safety violations. <https://www.cbsnews.com/news/lumber-liquidators-linked-to-health-and-safety-violations/>

Centers for Disease Control and Prevention (CDC). 2016. Laminate flooring test results, health issues and solutions. <https://www.cdc.gov/nceh/laminateflooring/default.html>

CFR 2020. Streamlining and Aligning Formaldehyde Emission Control Standards for Certain Wood Products in Manufactured Home Construction With Title VI of the Toxic Substance Control Act. Fed. Register §5562. <https://www.federalregister.gov/documents/2020/01/31/2020-01474/streamlining-and-aligning-formaldehyde-emission-control-standards-for-certain-wood-products-in>

Committee on Sick House Syndrome (CSHS): Indoor Air Pollution Progress Report, No. 4. 2002. Guideline values of individual volatile organic compounds (VOCs).

Consumer Product Safety Commission. 2015. [https://www.cpsc.gov/s3fs-public/An-Update-On-Formaldehyde-725\\_1.pdf](https://www.cpsc.gov/s3fs-public/An-Update-On-Formaldehyde-725_1.pdf) [site accessed 09/20/20].

Ecobob Info and News website. 2019. <https://www.ecobob.co.nz/info-and-news/building-design-construction-and-renovations/toxic-floorboards-2447/>

European Chemicals Agency (ECHA). 2019. Annex XV Restriction Report: Formaldehyde. [https://echa.europa.eu/documents/10162/13641/rest\\_formaldehyde\\_axvreport\\_en.pdf/2c798a08-591c-eed9-8180-a3c5a0362e37](https://echa.europa.eu/documents/10162/13641/rest_formaldehyde_axvreport_en.pdf/2c798a08-591c-eed9-8180-a3c5a0362e37)

European Chemicals Agency (ECHA). 2020. RAC Opinion on an Annex XV dossier proposing restrictions on formaldehyde and formaldehyde releasers. ECHA/RAC/RES-O-0000006740-76-01/F. <https://echa.europa.eu/documents/10162/07116332-7ee9-c983-3976-35e85ac32bcb>

European Chemicals Agency (ECHA). 2017. European Chemicals Agency (ECHA) Regulation No 528/2012 concerning the making available on the market and use of biocidal products: Formaldehyde. <https://echa.europa.eu/documents/10162/59c9d260-a4a7-0b0e-dbd6-972470a84066>

Formaldehyde Standards for Composite Wood Products. Code of Federal Register (CFR) Part 770. <https://www.govinfo.gov/content/pkg/CFR-2019-title40-vol34/xml/CFR-2019-title40-vol34-part770.xml#seqnum770.10>

Garrett MH, Hooper M, Hooper B, Rayment P, and Abramson M. 1999. Increased risk of allergy in children due to formaldehyde exposure. *Allergy*. 54:330–337.

Gerhold K, and Bautista D. 2008. TRPA1: Irritant detector of the airways. *J. Physiol*. 586(pt 14):3303.

Harada K, Hasegawa A, Wei C, Minamoto K, Noguchi Y, Hara K, Matsushita O, Noda K, and Ueda A. 2010. A Review of Indoor Air Pollution and Health Problems from the Viewpoint of Environmental Hygiene: Focusing on the Studies of Indoor Air Environment in Japan Compared to Those of Foreign Countries. *J Health Sci*. 56(5): 488-501.

Health Canada. 2006. Residential Indoor Air Quality Guideline: Formaldehyde. <https://www.canada.ca/content/dam/canada/health-canada/migration/healthy-canadians/publications/healthy-living-vie-saine/formaldehyde/alt/formaldehyde-eng.pdf>

Holmstrom M, Wilhelmsson B, Hellquist H, et al. 1989. Histological changes in the nasal mucosa in persons occupationally exposed to formaldehyde alone and in combination with wood dust. *Acta Otolaryngol (Stockh)* 107:120-129. (As cited in ATSDR 1999)

International Agency for Research on Cancer (IARC). 2006. Formaldehyde. Vol 88. <http://www.inchem.org/documents/iarc/vol88/volume88.pdf>

International Standards Organization (ISO). 2016. Wood-based panels — Determination of formaldehyde release — Part 4: Desiccator method. <https://www.iso.org/obp/ui/#iso:std:iso:12460:-4:ed-2:v1:en> [site accessed 22/09/2020]

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

Krzyzanowski M, Quackenboss J, and Liebowitz M. 1990. Chronic respiratory effects of indoor formaldehyde exposure. *Environ Res* 52(2):117-125.

Kulle, T.J. 1993. Acute odor and irritation response in healthy nonsmokers with formaldehyde exposure. *Toxicol Ind Health* 5: 323–332.

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

Level. 2020. Controlling airborne contaminants. <http://www.level.org.nz/passive-design/controlling-indoor-air-quality/controlling-airborne-contaminants/>. [site accessed 30/08/20].

Ministry for the Environment (MfE). 2002. <https://www.mfe.govt.nz/sites/default/files/ambient-guide-may02.pdf> [site accessed 30/08/20].

Monticello T, Morgan K, Everitt J, and Popp J. 1989. Effect of formaldehyde gas on the respiratory tract of rhesus monkeys. Pathology and cell proliferation. *Am J Pathol* 134(3):515-27.

Mueller J, Bruckner T, and Triebig G. 2013. Exposure study to examine chemosensory effects of formaldehyde on hyposensitive and hypersensitive males. *Int Arch Occup Environ Health* 86(1):107-117.

National Industrial Chemical Notification and Assessment Scheme (NICNAS). 2006. Priority Existing Chemical Assessment Report No. 28. Formaldehyde. Australia Department of Health and Ageing. <https://www.industrialchemicals.gov.au/sites/default/files/PEC28-Formaldehyde.pdf>

NTL Chemical Consulting (NTL). 2018. Resins in Panel Production. [https://www.ntl-chemicals.com/wp-content/uploads/2019/02/MDF\\_Yearbook\\_2017\\_2018\\_Article\\_NT](https://www.ntl-chemicals.com/wp-content/uploads/2019/02/MDF_Yearbook_2017_2018_Article_NT) [site accessed 14/11/20].

Nwaogu T, Bowman C, Marquart H, and Postle M. 2013. Analysis of the most appropriate risk management option for formaldehyde. TNO Triskelion B.V. and Risk and Policy Analysts Ltd.

Pazdrak, K, Gorski, P, Krakowiak, A, and Urszula, R. 1993. Changes in Nasal Lavage Fluid Due to Formaldehyde Inhalation. *Int Arch Occup Environ Health* 64: 515-519.

Pierce J, Abelman A, Lotter J, Ruestow P, Unice K, Beckett E, Fritz H, Bare J, and Finley B. 2016. An assessment of formaldehyde emissions from laminate flooring manufactured in China. *Reg Toxicol Pharmacol* 81:20-32.

Ruffing T, Shi W, Brown N, and Smith P. 2011. Review of United States and international formaldehyde emissions regulations for interior wood composite panels. *Wood Fiber Sci* 43(1):21-31.

Rumchev, K.B., Spickett, J.T., Bulsara, M.K., Phillips, M.R., and Stick, S.M. 2002. Domestic exposure to formaldehyde significantly increases the risk of asthma in young children. *Eur Respir J* 20: 403–406.

Rusch, G, Clary, JJ, Rinehart WE and Bolte, HF. 1983. A 26-Week Inhalation Toxicity Study with Formaldehyde in the Monkey, Rat and Hamster. *Toxicol Appl Pharmacol* 68: 329-343.

Salem M, Bohm M, Srba J, and Berankova J. 2012. Evaluation of formaldehyde emission from different types of wood-based panels and flooring materials using different standard test methods. *Building Environ* 49:86-96.

Salthammer T, Mentese S, and Marutzky R. 2010. Formaldehyde in the indoor environment. *Chem Rev* 110:2536-2572.

Salthammer T. 2019. Data on formaldehyde sources, formaldehyde concentrations and air exchange rates in European housings. Data Brief 22: 400-435. [cited in ECHA 2020]

Sheehan P, Singhal A, Bogen K, MacIntosh D, Kalmes R, and McCarthy J. 2017. Potential exposure and cancer risk from formaldehyde emissions from installed Chinese manufactured laminate flooring. *Risk Anal* 38(6):1128-1142.

Shinohara N, Mizukoshi A, Kataoka T, Takamine K, Gamo M, and Yanagisawa Y. 2011. Distribution of Indoor Concentrations and Emission Sources of Formaldehyde in Japanese Residences, *Advanced Topics in Environmental Health and Air Pollution Case Studies*, Prof. Anca Moldoveanu (Ed.), ISBN: 978-953-307-525-9.

Standards Australian/Standards New Zealand (AS/NZS). 2017. AS/NZS 1859:2017 *Reconstituted wood-based panels specifications. Superseding AS/NZS 1859.2004.*

Standards Australian/Standards New Zealand (AS/NZS). 2013. AS/NZS 1884:2013 *Floor coverings – Resilient sheet and tiles – Installation.*  
<https://www.standards.govt.nz/touchstone/building/2013/nov/new-zealand-floor-coverings-standard-published/>.

Standards Australia/Standards New Zealand (AS/NZS). 2004a. AS/NZS 1859.1:2004: *Reconstituted wood-based panels - Specifications – Particleboard.* Sydney, Standards Australia.

Standards Australia/Standards New Zealand (AS/NZS). 2004b. AS/NZS 1859.2:2004: *Reconstituted wood-based panels - Specifications - Dry-processed Fiberboard.* Sydney, Standards Australia.

Standards Australia/Standards New Zealand (AS/NZS). 2002. AS/NZS 1860.1:2002: *Particleboard flooring – Specifications.* Strathfield, Standards Australia.

Taptiklis P, and Phipps R. 2017. *Indoor Air Quality in New Zealand Homes and Schools.* Building Research. BRANZ.  
[https://www.researchgate.net/profile/Robyn\\_Phipps/publication/316598692\\_Indoor\\_Air\\_Quality\\_in\\_New\\_Zealand\\_Homes\\_and\\_Schools/links/5906a3f24585152d2e967503/Indoor-Air-Quality-in-New-Zealand-Homes-and-Schools.pdf](https://www.researchgate.net/profile/Robyn_Phipps/publication/316598692_Indoor_Air_Quality_in_New_Zealand_Homes_and_Schools/links/5906a3f24585152d2e967503/Indoor-Air-Quality-in-New-Zealand-Homes-and-Schools.pdf)

U.S. Environmental Protection Agency (USEPA). 2010. Toxicological review of formaldehyde – Inhalation assessment. EPA/635/R-10/002A. [www.epa.gov/iris](http://www.epa.gov/iris).

U.S. Environmental Protection Agency (USEPA). 2017. Formaldehyde emissions standards for composite wood products. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0461-0001> [site accessed 11/11/2020]

Wilhelmsstrom B and Homstrom M. 1992. Possible mechanisms of formaldehyde induced discomfort in the upper airways. *Scan J Work Environ Health* 18(6):403.

World Health Organization (WHO). 2010. WHO Guidelines for Indoor Air Quality. Selected Pollutants. [https://www.ncbi.nlm.nih.gov/books/NBK138705/pdf/Bookshelf\\_NBK138705.pdf](https://www.ncbi.nlm.nih.gov/books/NBK138705/pdf/Bookshelf_NBK138705.pdf) [site accessed 09/20/20].

Yrieix C, Dulaurent A, Laffargue C, Maupetit F, Pacary T, and Uhde E. 2010. Characterization of VOC and formaldehyde emissions from a wood based panel: results from an interlaboratory comparison. *Chemosphere* 79(4):414-419.

Zeleniuc O. 2016. Standards and regulations concerning the formaldehyde emissions from wood panels. 13th International Conference: Standardization, Prototypes and Quality. Brasov, Romania, November 3-4. *Recent* 17 3(49).



**INSTITUTE OF ENVIRONMENTAL  
SCIENCE AND RESEARCH LIMITED**

- ▶ **Kenepuru Science Centre**  
34 Kenepuru Drive, Kenepuru, Porirua 5022  
PO Box 50348, Porirua 5240  
New Zealand  
T: +64 4 914 0700 F: +64 4 914 0770
  
- ▶ **Mt Albert Science Centre**  
120 Mt Albert Road, Sandringham, Auckland 1025  
Private Bag 92021, Auckland 1142  
New Zealand  
T: +64 9 815 3670 F: +64 9 849 6046
  
- ▶ **NCBID – Wallaceville**  
66 Ward Street, Wallaceville, Upper Hutt 5018  
PO Box 40158, Upper Hutt 5140  
New Zealand  
T: +64 4 529 0600 F: +64 4 529 0601
  
- ▶ **Christchurch Science Centre**  
27 Creyke Road, Ilam, Christchurch 8041  
PO Box 29181, Christchurch 8540  
New Zealand  
T: +64 3 351 6019 F: +64 3 351 0010

**[www.esr.cri.nz](http://www.esr.cri.nz)**