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Formaldehyde Exposure in the European Mineral Fibre Manufacturing Industry

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Abstract

Formaldehyde has been classified as a carcinogen (Group 1) by the International Agency for Research on Cancer. In the mineral wool industry formaldehyde is traditionally used as an ingredient in the resins used to prepare the binder. In this study results from 9,004 formaldehyde exposure measurements were obtained from five member companies of the European mineral wool industry (EURIMA) across 55 sites located in 22 European countries. The measurements were originally carried out between 1983 and 2009, using a wide variety of sampling and analytical methods. The majority of measurements were grab samples (n=6,989), with only 658 personal and 1,291 static measurements, while for 66 measurements the sample type was unknown. The arithmetic mean (AM) for all personal full-shift measurements across all sites was 0.08 mg.m^{-3} (range 0.00 - 1.64 mg.m^{-3}). For static full-shift measurements the AM was 0.18 mg.m^{-3} (range 0.00- 3.75 mg.m^{-3}), while for grab measurements the AM was 0.12 mg.m^{-3} (range 0.001 - 9.73 mg.m^{-3}). The maximum exposures were observed for the binder station workers (AM=0.31 mg.m^{-3}, based on 8 personal full-shift measurements). Static full-shift measurements were higher in the line production (AM=0.22, n=52) compared to the off-line production (AM=0.17, n=52). Eighty percent of the personal full-shift concentrations were below 0.10 mg.m^{-3} with only 10% being in excess of 0.246 mg·m^{-3}, which is well below the current occupational exposure limit (OEL) in most European countries (8-hrs OELs in EU range from 0.15-2.5 mg.m^{-3}). Formaldehyde exposure concentrations declined by 2% to 3% per annum. These results suggest that although average full-shift personal exposures are below current OELs, exceedances of these limits are possible in certain areas. Exposure should continue to be monitored to ensure that concentrations continue to reduce with time and to assess the impact of any additional control measures implemented to reduce the formaldehyde levels. Adoption of a standard method for measuring formaldehyde is recommended to facilitate comparisons between sites, companies and countries, and with appropriate OELs.

Keywords: Exposure; Formaldehyde; Mineral Wool

Introduction

Formaldehyde is a component of the resin used to prepare the binder which is used in the mineral wool manufacturing. Mineral wool is a form of synthetic fibre made from volcanic rock, blast furnace slag, sand or glass. Inorganic rock or slag are the main components (typically 98%) of stone wool. The remaining 2% organic content is generally a thermosetting binder (an adhesive) and a little oil. The binders in most mineral wools are based on phenol-formaldehyde resins. The binder is applied to the product as the fibres are being formed which is then either cured shortly afterwards or, if the fibre is to be used to produce a more complex shaped product, at a secondary processing workstation. No free formaldehyde should be left in the material once it has been cured. The association of formaldehyde with cancer has been studied extensively with the first studies dating back to 1980s. In 2004 the International Agency for Research on Cancer (IARC) classified formaldehyde as a Group 1 carcinogen for Nasopharyngeal Cancer (NFC) and for leukemia in 2009 [1,2]. The US Environmental protection agency also concluded a causal association between formaldehyde exposure and nasopharyngeal cancer, nasal and paranasal cancer, all leukemias, myeloid leukemia and lymphohematopoietic cancers as a group (EPA, 2010).

The association of formaldehyde exposure with NFC was mostly based on results from the National Cancer Institute (NCI) historical cohort of industrial workers exposed to formaldehyde [3]. A reanalysis of the same data a year later argued that the increased NPC mortality was restricted to one plant [4]. In a second reanalysis of the data Marsh et al. (2007)[5] showed the NCI cohort failed to account for an interaction between peak exposures and the plants structure, concluding that the associations could not be generalised outside of the cohort. Later studies did not find convincing conclusions on the links between exposures to formaldehyde NFC [6]. However, IARC reiterated its conclusion that "Formaldehyde cause's cancer of the nasopharynx" in 2012.

The association of formaldehyde exposure with leukemia has also been subject to debate. Collins and Lieker (2004) in a meta-analysis of 18 epidemiological studies found a small increase in the rate of leukaemia for embalmers and pathologist but not for industrial workers. Results from a US cohort study of formaldehyde exposed workers suggest a possible link between formaldehyde exposure and lymphohematopoietic malignancies, particularly myeloid leukemia but also perhaps Hodgkin lymphoma and multiple myeloma [7]. However, the results do not appear to be unequivocal and meta-analyses studies on formaldehyde did not find consistent evidence for a link between exposure to formaldehyde and elevated risk of NFC and leukemia [6,8] and LHM [9]. Cole et al. (2010) [10] in a review of two epidemiological studies reported a weak and transitory relationship between peak exposure to formaldehyde and the myeloid leukemias but no association was found with lymphohematopoietic cancers. However, Hauptmann et al. (2009)[11] found significant association with cumulative years of embalming and Zhang et al. (2009)[12] showed numerical chromosomal aberrations in myeloid progenitor cells consistent with myeloid leukaemia in a group of workers, what led to their classification as human carcinogen for this type of cancer. Nevertheless, a study looking at the mode of action concluded the risk estimates derived by EPA were largely conservative.

The Scientific Committee on Occupational Exposure Limits (SCOEL) of the European Union (EU) has so far retained a Category C classification (i.e., genotoxic carcinogen with a mode of action-based threshold) (SCOEL, 2016). Formaldehyde is also classified as carcinogenic category 1B (presumed to have carcinogenic potential for humans largely based on animal evidence) and mutagen category 2 (Regulation 605/2014) under the EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP).

Occupational exposure data to formaldehyde is actually quite limited especially in the mineral wool industry. Estimated personal exposures in 2002 in the French chemical industry ranged from 0.10 to 0.29 mg.m^{-3} (Time Weighed Averaged (TWA), Geometric Means) [13]. Given this uncertainty the European Mineral Wool Manufacturers Association (EURIMA) decided to collect and analyse existing exposure data and store the exposure data in a centralized database. This study presents the exposure concentrations to formaldehyde in different segments of the industry and estimate trends in exposure over time.

Methodology

Existing formaldehyde exposure data in member companies from the EURIMA were collated. together with results of the measurements, information on the sampling and analytical method, the sampling principle, duration and the job title / process area were sampling took place, as well as other contextual information (Table1).

Variable	Type	Description
Year	Continuous (integer)	1983-2009
		Raw materials (stone glass): unload the un-cured wool or stones and refill cupola
		Raw materials (binder)
		Resin production
		Binder station worker; add the binding agents to the cupola, cleaning the binder tank
		Control room operator: supervise the entire process
		Melting/furnace worker: control the melting process
		Collecting worker:

Job	Nominal (30 categories)	Forming worker
		Curing inlet: workers in the curing inlet area
		Curing outlet: workers in the curing outlet area
		Packer
		Quality Control worker
		Pipe Section Machine (PSM) operator; control of the PSM machine
		PSM curing worker: work in the PSM
		Stitching machine operator: feeding stitching machine with material
		Cutting worker: feeding the cutting machine with material
		Pressing & Moulding operator
		Acoustic Slab Production facing
		Curing oven operator
		Mechanical Maintenance
		Cleaning-collection area
		Wash water & forming cleaning
		Cleaning -mineral wool filter
		Cleaning-curing oven
		Quality Control technicians: taking samples for analysis
		General worker: workers working on general tasks involving manual handling of the material
		Other
		Unknown
Sampling device	Nominal (4 categories)	Impingers, sorbent tubes, colorimetric tubes, passive badges
Sampling principle	Nominal (2 categories)	Active and passive (without the use of a sampling pump)
Sampling principle	Nominal (2 categories)	Active and passive (without the use of a sampling pump)
Sampling reason	Nominal (13 categories)	Routine, checking compliance with OEL, following up complaint by staff, checking effectiveness of control measures, occupational hygiene research; baseline study; epidemiological study; emergency, risk assessment, risk management, other, unknown
Process	Nominal (4 categories)	Raw materials handling; Resin production; Line production
Sampling strategy	Nominal (7 categories)	Convenient sampling (whoever is available in a particular day); task specific, works case scenario, representative sampling, random sampling program, other and unknown.

Table 1: Variables included in the model.

Companies provided the exposure data using a standard template in MS Excel spreadsheet using a standard coding system, previously agreed with EURIMA, to ensure consistency of the data. Upon receipt, exposure and contextual data were checked and if necessary further clarification of the exposure and contextual information provided was requested. Exposure data were requested from 2003 to 2009, although some measurements that were collected between 1987 and 2002 were also provided by the sites. Limits of detection were provided by three of the five surveyed companies (0.0005-0.06; 0.0025-0.27 and 0.01 mg per sample).

Statistical analyses were carried out to investigate time trends in the exposure data and the effect of the different variables on the formaldehyde exposure levels. In order to take into account the fact that multiple measurements have been taken from within the same sites, and as such may be correlated, we fitted General Linear Mixed Models (GLMM) to the log-transformed exposure data (personal and static measurements). All personal and static measurements were included, but results from the grab samples were excluded. Analyses were repeated with only personal measurements. Manufacturing site was considered a random effect in the analyses, to allow for correlations amongst the measurements taken at individual sites and to take account of within site variation. A priori we considered that year and job were important determinants of exposure, and these factors were included as the first fixed variables, in the model. Subsequently, step-wise modelling was carried out so that at each step the variable which improved the fit of the model the most (i.e. reduced the deviance the most relative to the change in degrees of freedom) was included. Other variables were then included in the model if they had a significant effect on the log transformed exposure while not actually improving the fit of the model to the data.

The model can be described by the following equation:

$$\text{Log (Exposure)}=C + \beta_1 \log(\text{site}) + \beta_2 \log(\text{year}) + \beta_3 \log(\text{job}) + \ldots + \beta_n \log(\text{variable}) + \varepsilon$$

The variables included in the model are described in Table 1. Analysis were carried out in Genstat v.12

The temporal trend in formaldehyde concentrations were expressed as the annual change in exposure using the following expression:

$$\% \text{ change per year} = 100 \times (\exp[\beta_1] - 1)$$

Results

Data Availability and Contextual Information

Five out of the eleven EURIMA member companies provided a total of 9,004 formaldehyde measurements, of which 658 were personal, 1,291 static and 6,989 grab sample measurements, while for 66 measurements no information on the sample type was provided. The measurements data were obtained from 55 manufacturing sites located in 22 European countries and were originally collected by the sites between 1983 and 2009. For the personal measurements 399 were full-shift (> 6 hrs), 154 part-shift (2-6 hrs), 49 short-term (< 10-30 mins) and for 56, the measurement period was not reported (the majority collected before 1989). For the static -measurements, 117 were full-shift, 513 part-shifts and 398 short-term and 10 "task"-specific measurements, while for 253 the measurement period was not provided.

Contextual information was reported for most of the measurements. Approximately 12% of the measurements did not have information on the sampling device, sampling strategy and sampling reason. The analytical method was not reported in 22% of the measurements. All full-shift area samples have information on the manufacturing process, whilst 8.1 % of the full-shift personal measurements did not have information on the job title. The majority of the measurements (81%, n=7,317) were reported to have been collected within a representative sampling strategy. Routine monitoring was the most frequently reported reason for sample collection (78%, n=7,011), while "checking compliance with Occupational Exposure Limits (OEL)" was reported for 847 measurements (9%).

Measurements were collected using a wide variety of sampling and analytical methods. Most measurements were grab samples collected with direct reading instruments (76%, n=6,832). Other sampling methods included impingers (n=483, 5%), sorbent tubes (n=325, 4%), colorimetric tubes for 144 (2%), passive badges for 52 and filters were used for 24 measurements. For 1,144 measurements (13%), information on the sampling device was unknown.

Formaldehyde Concentrations

The arithmetic means (AM) of personal exposure based on full-shift and part-shift measurements were 0.08 and 0.20 $mg.m^{-3}$, respectively (Table 3). The AM personal exposure based on short-term measurements was 0.17 $mg.m^{-3}$, while average exposure based on measurements for which the sampling period was unknown was 0.97 $mg.m^{-3}$.

Sampling period	n	AM	GM	GSD	Min	Max
Full-shift	399	0.08	0.03	4.4	0	1.64
Part-shift	154	0.2	0.07	4.6	0	1.84
Short-term	49	0.17	0.06	5.2	0	1.62
Unknown	56	0.97	0.03	7	0	50.6

Table 2: Exposure concentrations for personal measurements by sampling period ($mg.m^{-3}$).

For static full-shift, part-shift and short-term measurements the AMs were 0.18, 0.22 and 0.27 mg.m^{-3}, respectively, while for task-specific measurements the AM was 0.18 mg.m^{-3}. There were 253 static measurements with no time period reported. For these measurements the AM was 0.26 mg.m^{-3}.

The AM for grab sample measurements was 0.12 mg.m^{-3} (range 0.001- 9.73 mg.m^{-3}).

Sampling period	n	AM	GM	GSD	Min	Max
Full-shift	117	0.18	0.08	4.5	0	3.75
Part-shift	513	0.22	0.08	4.3	0	8.3
Short-term	398	0.27	0.19	2.6	0	2.13
Task-specific	10	0.18	0.15	1.9	0.05	0.35
Unknown	253	0.26	0.08	3.7	0	16

Table 3: Exposure concentrations for static measurements by sampling period (mg.m^{-3}).

The variability in the results was much higher for personal measurements (Geometric Standard Deviations (GMD) ranged from 4.40 to 7.00) than for static measurements (GSDs ranged from 1.90 to 4.50). Table 4 and 5 show the results of the full-shift personal and static measurements by job title and of the full-shift static measurement by process. Highest exposures were observed for the binder station operator (AM= 0.31 mg.m^{-3}, n=8) with a maximum concentration of 1.64 mg.m^{-3}, followed by forming worker (AM= 0.23 mg.m^{-3}, n=23), control room operators (AM= 0.16 mg.m^{-3}, n=5), collecting workers (AM= 0.15 mg/m^3, although based on only 1 measurement), curing outlet (AM= 0.13 mg.m^{-3}, n=27), Pipe Section Machine (PSD) curing worker (0.14 mg.m^{-3}, n=3) and cleaning of the curing oven (0.12 mg.m^{-3}, n=4), furnace worker (0.11 mg.m^{-3}, n=35). The rest of jobs had concentrations below 0.10 mg.m^{-3} (Table 4).

	Full-shift					
Job title	**n**	**AM**	**GM**	**GSD**	**Min**	**Max**
Raw materials (stone glass)	5	0.04	0.03	1.3	0.02	0.04
Raw materials (binder)	7	0.05	0.03	3.1	0.01	0.12
Resin production	8	0.1	0.06	2.7	0.02	0.35
Binder station worker	8	0.31	0.16	2.6	0.08	1.64
Control room operator	5	0.16	0.09	3.3	0.03	0.45
Melting/furnace worker	35	0.11	0.08	2.3	0.02	0.62
Collecting worker	1	0.15	0.15	-	0.15	0.15
Forming worker	23	0.23	0.12	4.7	0	0.91
Curing inlet	34	0.06	0.04	3.4	0	0.32
Curing outlet	27	0.13	0.03	10.3	0	0.45
Packer	27	0.07	0.02	6.6	0	0.25
Quality Control worker	7	0.03	0.01	4.8	0	0.15
PSM operator	25	0.09	0.07	1.8	0.03	0.5
PSM curing worker	3	0.14	0.07	5.9	0.01	0.26
Stitching machine operator	9	0.04	0.04	1.8	0.01	0.06
Cutting worker	15	0.05	0.05	1.8	0.01	0.1
P & M operator	13	0.09	0.08	1.7	0.04	0.25
ASP facing	3	0.03	0.03	1	0.03	0.03
Curing oven operator	8	0.05	0.04	1.9	0.02	0.15
Mechanical Maintenance	7	0.01	0.01	2.3	0	0.02
Cleaning-collection area	4	0.05	0.05	1.1	0.05	0.06
Wash water & forming cleaning	21	0.05	0.03	3	0	0.24
Cleaning -mineral wool filter	1	0	0	-	0	0
Cleaning-curing oven	4	0.12	0.11	1.6	0.06	0.2
Quality Control technicians	-					
General worker	61	0.02	0.01	3.5	0	0.15
Other	8	0.02	0.01	7.3	0	0.05
Unknown	30	0.03	0.03	1.8	0.01	0.1

Table 4: Exposure concentrations for personal full-shift exposure measurements by job title (mg.m^{-3}).

The area with the highest average formaldehyde concentration was the line production (AM: 0.22 mg.m^{-3}) where maximum concentration were 3.75 mg.m^{-3} (Table 5).

Process	n	AM	GM	GSD	Min	Max
Raw materials handling	1	0.2	0.2	-	0.2	0.2
Resin production	10	0.02	0.01	5	0	0.07
Line production	54	0.22	0.07	5	0	3.75
Off-line production	52	0.17	0.15	1.9	0.02	0.4

Table 5: Area full-shift measurements.

The AM in the off-line production process was 0.17 mg.m^{-3} and in the resin production 0.02 mg.m^{-3}.

Eighty percent of the personal full-shift concentrations were below 0.10 mg.m^{-3} with only 10% being in excess of 0.246 mg.m^{-3} (Figure 1).

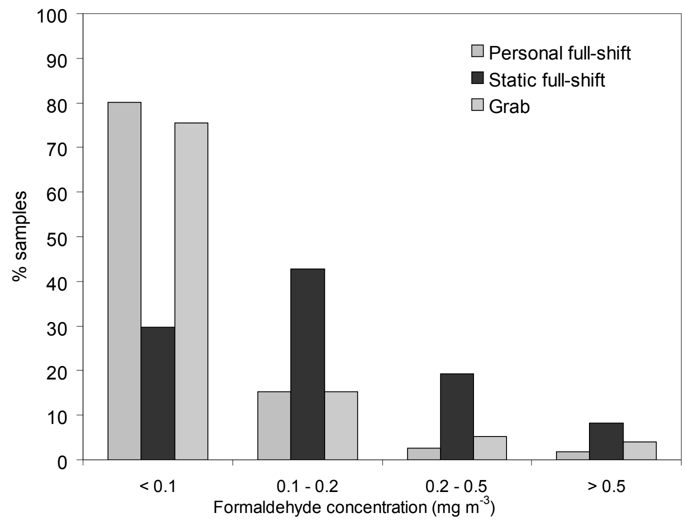

Figure 1: Percentage of measurements within the indicated concentrations.

For static measurements, 22% full and part-shift measurements were higher than 0.246 mg.m^{-3}. For short-term personal and static measurements, 12% and 18% of the measurement, respectively, were higher than 0.369 mg.m^{-3}. (Table 6).

Model	Coefficient – year	SE (coefficient)	Between –Site Variation	Within-Site Variation	Deviance change	Df change
Null			0.1053	0.256		
+ year	-0.015	0.003	0.106	0.252	16.25	4
+ Job	-0.017	0.003	0.11	0.238	2.75	31
+ Sampling device	-0.021	0.003	0.101	0.233	28.41	6
+ Sampling principle	-0.02	0.004	0.087	0.231	10.21	3
+Measurement period	-0.019	0.004	0.085	0.23	-6.69	4
+ Sampling reason	-0.019	0.004	0.089	0.228	0.21	7
+ Process	-0.018	0.004	0.092	0.226	-22.15	10
+ Sampling strategy	-0.019	0.004	0.092	0.227	-3.48	5

Table 6: Results from General Linear Mixed Model.

Table 6 shows the results of the mixed effects model. The model output shows how the coefficient for year and the standard error of the coefficient, as well as the between- and within-site variation in log-transformed formaldehyde exposure levels. The table shows the results when variables are added into the model (year and job first, followed by other variables that improve the model, followed by variables that were statistically significantly associated with exposure). After including year, job, sampling device (sorbent tube, badge, impinger, filter, colourimetric tube, direct reading instrument, other or unknown) and sampling principle (active, passive, other or unknown), the model was not further improved by including other variables, although statistical significant differences between the categories within these variables were observed.

The variance in the exposure levels is larger within-site than between -sites. Both the between- and within-site variance component are reduced only slightly when entering the various fixed effects. Approximately 11% of the between-site and 11% or the within-site variance was explained by model. The results suggest that there are no systematic differences in formaldehyde concentration levels between the participating companies. The effect of year on the log-transformed formaldehyde exposure is reasonably constant and suggests that the formaldehyde exposure levels are reduced by approximately 2% per annum (3% when only personal samples were included in the analysis) between 1989 and 2009 (Figure 2).

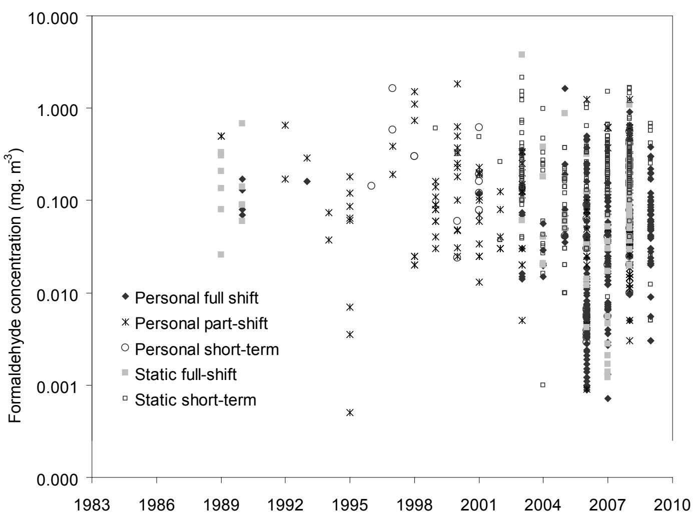

Figure 2: Formaldehyde concentrations (log-scale) over time.

Discussion

In general, few measurement data were available for most of the 55 manufacturing sites, with only 399 personal full-shift measurements collected in total across 55 sites over 16 years. Nearly twice as many static measurements (n=1,291) were made available while most of the measurements were taken over very short periods (grab samples) (n=6,989). Measurements were collected using a wide variety of sampling methods including sampling tubes, badges, filters, impingers and direct reading instruments. Contextual information was collected on most of the measurements, with only 3.4 % not reporting information on the measurement period, and 8.1 % not reporting information on the job title from the total personal full-shift. However, other contextual information as the analytical method, sampling reason and sampling strategy was less often available. The statistical analyses of the personal full-shift measurements revealed that the jobs with a higher exposure are those in the binder station.

In discussion with representatives of EURIMA, we considered several threshold values for formaldehyde exposure: 0.369, 0.246, and 0.615 mg.m^{-3}. Eight hours OELs in the EU range from 0.15 mg.m^{-3} (0.1 ppm) in The Netherlands to 2.46 mg.m^{-3} (2 ppm) in the UK. Although the overall average full-shift exposures (0.08 and 0.18 mg.m^{-3} for personal and area respectively), are below current OELs, exceedances of the current limits were observed for certain jobs (e.g. binder station, where maximum concentration recorded for a full-shift was 1.64 mg.m^{-3}) or during certain activities (e.g. in the line production area where the maximum concentration recorded for a full-shift was 3.75 mg.m^{-3}). It would be possible that other processes where coded as "binder station" as for example resin preparation. Improved exposure control to reduce formaldehyde will need to be implemented in this area and exposure monitoring for formaldehyde should be continued to ensure that these controls are effective and that exposures are reduced.

Personal formaldehyde exposure levels observed in the mineral wool industry in Europe were generally lower than predicted exposure levels for year 2002 in France in the manufacture of wood, chemical industry and foundries (estimated GM=0.03, 0.29 and 0.20 mg.m^{-3}, respectively) [13]. Formaldehyde concentrations released during machining of medium density fibreboard in a factory in the UK were less than 0.17 mg.m^{-3} [14]. Results from another study in Quebec in the wood industry for the year 2004-2005 reported that only 1.7% of the workforce was exposed to concentrations over 0.369 mg.m^{-3} [15].

The results suggest that the formaldehyde levels in the 5 EURIMA member companies have been reduced 2% to 3% per year since 1989 (measurements previous to 1989 did not have information on the measurement period and where not included). Generally a reduction of about 5 to 10% in exposure per year has been found in studies of temporal trends in exposure for other substances [16-19], although some examples exist where exposure have remained constant over time (e.g. flour dust exposure in the UK) [19]. A study on the formaldehyde exposure in the French industry during the years 1986-2003 reported a decline of 7% and 9% per year for personal (n=1401) and static (n=1448) measurements, respectively [13]. A similar overall trend (5%) was observed in a further study that combined that data with data from the Integrated Management Information System (IMIS) US database [20].

Formaldehyde exposure levels varied between different manufacturing sites, although less so than within sites. Factors such as the sampling method and to a lesser extent the measurement period, process and sampling reason and strategy can affect the observed exposure levels. Sampling device and sampling principle are important determinants of the observed formaldehyde exposure concentration which emphasises the need for standardisation of the sampling and analytical methods. Lack of such harmonisation will seriously jeopardise the ability to interpret measurement results properly and compare results between jobs, sites and over time. Lavoué et al. (2006) [13] in a model built with formaldehyde data from different French industries found industry/task classification had the greatest influence on exposure variability while the measurement period were significant in some cases.

After taking into account the effect of year, job and sampling methods, there were no statistically significant systematic differences in formaldehyde levels between the five EURIMA companies.

Regarding the influence of the sampling method on the concentration sampled, formaldehyde is likely to evaporate from impingers when used in high flow-rates of sampled air or during long-period sampling [21]. Filters and tubes impregnated with 2,4-dinitrophenylhydrazine (DNPH) or silica gel do not present this disadvantage. However, in the presence of ozone DNPH can be oxidised, generating species that will interfere in the analysis and leading to the loss of performance of the sampling device. Moreover, sampling efficiency declines at high relative humidity of the air, as well as during wet precipitation events [21]. Despite these sampling methods are accepted [22,23] the variability between samplers makes data comparisons difficult.

Conclusion

Average personal full-shift exposures are generally below the current OELs in the EU, which range from 0.15-2.5 mg m^{-3}. However, exceedances of these limits were observed for individual measurements during certain activities (e.g. line production). Formaldehyde concentrations declined by 2% per annum. However, further improvements in control measures may be required to reduce exposure especially in case the OELs are to be reduced.

The survey revealed exposure measurements are collected with a variety of sampling and analytical methods and that the use of different methods can lead to different results. Therefore, harmonisation of sampling and analytical methods for measuring formaldehyde exposure and recording of contextual information is required to facilitate comparisons between sites, companies and countries, and with appropriate OELs.

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Conflict of interest

The authors declare no conflict of interests

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