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Title Guidelines for the measurement of formaldehyde releases from articles and formaldehyde concentrations in the interior of articles

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European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

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PREFACE

The purpose of these explanatory guidelines is to describe the test methods and test conditions to be applied to measure formaldehyde emissions from articles and concentration of formaldehyde in line with the requirements defined in Regulation (EU) 2023/1464 amending Annex XVII to REACH Regulation ((EC) No 1907/2006)¹ as regards formaldehyde and formaldehyde releasers (entry 77 of REACH, Annex XVII). The guidelines also provide information on suitable methods to be used to establish a scientific data correlation between test results obtained under the reference conditions laid down in Appendix 14 to the REACH Regulation and non-reference conditions and examples on how the scientific correlation should be applied to practical cases.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, corrected version in OJ L136, 29.5.2007, p.3).

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1. About these Guidelines

On 14 July 2023 the European Commission adopted Commission Regulation (EU) 2023/1464² amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers. The Regulation introduced entry 77 to Annex XVII which sets the limit value for formaldehyde emissions to:

- 0,062 mg/m³ for furniture and wood-based articles and 0,080 mg/m³ for all other articles (paragraph 1 of the restriction).
- 0,062 mg/m³ for formaldehyde concentration in the interior of road vehicles (paragraph 2 of the restriction).

The limit values are referred to the test conditions specified in Appendix 14 to REACH. However, according to the Regulation, it may also be possible to use data from testing under other test conditions provided that there is a scientifically valid correlation of test results.

On 15 February 2024, ECHA received a request from the Commission services (Ref. Ares (2024)1162320)³ to prepare guidelines for the measurement of formaldehyde releases from articles and formaldehyde concentrations in the interior of vehicles in accordance with Appendix 14 of Commission Regulation 2023/1464 amending Annex XVII to REACH as regards formaldehyde and formaldehyde releasers (entry 77 of REACH, Annex XVII).

The Commission's mandate stipulates that the guidelines should include:

- a) Description of appropriate test methods to measure formaldehyde emissions from articles and formaldehyde concentrations in indoor space of vehicles and examples of data obtained with these methods.
- b) Clarification of the reference conditions listed in Appendix 14 and additional factors that may affect the test results.
- c) Correlation of results obtained by testing under other than reference conditions. Information on suitable methods to be used for which a scientific data correlation exists between test results obtained under the reference conditions laid down in Appendix 14 and non-reference conditions and examples on how the scientific correlation should be applied to practical cases.

The scope of these guidelines is limited to these three points. Further clarification on the scope of the restriction⁴, i.e., articles covered by other regulations and exempted from this restriction, will be developed by ECHA and the European Commission via published support on 'Questions and Answers on Restriction'.

During the development of the guidelines and in close collaboration with the European Commission, ECHA has gathered information via engagement with stakeholders/experts, including relevant representatives from industry, competent authorities and/or laboratory

² <u>Commission Regulation (EU) 2023/1464 of 14 July 2023 amending Annex XVII to Regulation (EC)</u> <u>No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and</u> <u>formaldehyde releasers (Text with EEA relevance)</u>

³ Request to the European Chemicals Agency (ECHA) to prepare guidelines for the measurement of formaldehyde releases from articles and formaldehyde concentrations in the interior of vehicles in accordance with Appendix 14 of Commission Regulation 2023/1464 amending Annex XVII to REACH (entry 77).

⁴ Annex XVII to REACH- Conditions of the restriction - ECHA

experts and Forum representatives.

2. Reference conditions in Appendix 14 of Commission Regulation 2023/1464 (Annex XVII to REACH (entry 77))

2.1. Reference conditions for measurement of formaldehyde released from articles to indoor air

Appendix 14 to REACH provides the following requirements for determination of formaldehyde emissions from articles to indoor air:

1. 'Measurement of formaldehyde released to indoor air from articles referred to in paragraph 1, first subparagraph, of entry 77

The formaldehyde released from articles referred to in paragraph 1, first subparagraph of entry 77 shall be measured in the air of a test chamber under the following cumulative reference conditions:

a) The temperature in the test chamber is (23 ± 0.5) °C.

b) The relative humidity in the test chamber is $(45 \pm 3)\%$.

c) The loading factor, expressed as the ratio of the total surface area of the test piece to the volume of the test chamber, is $(1 \pm 0.02) m^2/m^3$. This loading factor corresponds to the testing of wood-based materials; for other materials or other products, if such a loading factor is clearly not realistic under foreseeable conditions of use, loading factors in accordance with clause 4.2.2 of standard EN 16516⁵ may be used.

d) The air exchange rate in the test chamber is $(1 \pm 0.05) h^{-1}$.

e) An appropriate analytical method is used to measure the formaldehyde concentration in the test chamber.

f) An appropriate method is used for sampling the test pieces.

g) The formaldehyde concentration in the air of the test chamber shall be measured at least twice daily throughout the test, with a period of at least 3 hours between two consecutive samplings; the measurement is repeated until there is enough data to determine the steady state concentration.

h) The duration of the test is sufficiently long to carry out the determination of the steady state concentration and must not exceed 28 days.

(i) The steady state concentration measured in the test chamber shall be used to verify compliance with the limit value for formaldehyde released from the products referred to in the first subparagraph of paragraph 1 of entry 77.

If data from a test method using the reference conditions mentioned above are not available or suitable for measuring formaldehyde released from a specific article, data

⁵ EN 16516: Construction products- Assessment of release of dangerous substances – Determination of emissions into indoor air.

obtained from a test method that does not have reference conditions may be used, where there is a scientifically valid correlation between the results of the test method used and the reference conditions.'

2.2. Reference conditions for measurement of formaldehyde concentration in the interior of vehicles

Appendix 14 to REACH provides the following requirements for the measurement of formaldehyde concentration in the interior of vehicles:

2. Measurement of formaldehyde concentration in the interior of vehicles referred to in paragraph 2, first subparagraph, of entry 77

For road vehicles, including trucks and buses, the formaldehyde concentration shall be measured in ambient mode in accordance with the conditions specified in ISO 12219-1⁶ or ISO 12219-10⁷, and the concentration measured shall be used to verify the compliance with the limit value referred to in paragraph 2, first subparagraph, of entry 77'.

3. How to measure formaldehyde emissions from articles and concentration in the interior of road vehicles

Appendix 14 to REACH allows producers and importers of articles indicated in paragraph 1 (a) and (b) of restriction entry 77 to test by a suitable test method based on reference conditions to measure formaldehyde releases from articles they place on the market. Data obtained from the test methods using non-referenced conditions can be used to demonstrate compliance if there is a scientifically valid correlation between the results from the test method used and the results obtained by applying the reference conditions.

Appendix 14 to REACH also indicates specific test methods to measure formaldehyde concentration in the interior of vehicles to demonstrate compliance with paragraph 2 of restriction entry 77. No alternative test methods are allowed for these cases.

In the following sections test methods for measurement of formaldehyde releases from articles and methods to measure formaldehyde concentration in the interior of road vehicles are discussed. Guidance is also provided on specific test-chamber parameters and procedures not specifically indicated in Appendix 14. Guidance on testing of different categories of articles is also provided. Furthermore, available non-chamber-based methods are indicated.

⁶ ISO 12219-1: Interior air of road vehicles – Part 1 Whole vehicle test chamber – Specification and method for the determination of volatile organic compounds in cabin interiors.

⁷ ISO 12219-10: Interior air of road vehicles – Part 10 Whole vehicle test chamber – Specification and methods for the determination of volatile organic compounds in cabin interiors – Trucks and buses.

3.1. Relevant test chamber methods for measurement of formaldehyde emissions from articles

A test chamber is a type of enclosure that mimics the effects of environmental conditions a product may encounter during its usage. In a test chamber, parameters such as temperature, humidity, air flow, chamber material, background concentrations, air mixing, air velocity, air tightness, recovery, sink effect and other variables are rigorously controlled. The design of a test chamber may vary depending on the type of test that has to be performed and products to be tested.

Test chambers parameters and the criteria to measure emissions of formaldehyde and other substances from articles are defined in specific test methods developed over the years. These methods have been designed to measure emissions of hazardous substances from different type of articles.

Test chamber-based standards include further important requirements for testing (e.g. chamber size, air velocity, edge preparation, calculation of steady state concentration etc.) that are not specified in Appendix 14. Specific criteria for the preparation of test pieces and analytical methods for measuring the formaldehyde concentration in the air of the test chamber are also not defined in Appendix 14.

3.1.1. EN 717-1

The standard EN 717-1⁸ was developed to specifically determine formaldehyde emissions from wood-based panels. This method is the reference method for determining formaldehyde emissions of wood-based panels for use in construction according to EN 13986⁹.

Table 1 contains a list of the reference conditions included in Appendix 14 and their correlation with EN 717-1 and/or other related standards.

⁸ EN 717-1: Wood-based panels. Determination of formaldehyde release. Formaldehyde emission by the chamber method.

⁹ EN 13986: Wood-based panels. Determination of formaldehyde release. Formaldehyde emission by the chamber method.

Table 1. Appendix 14 reference conditions and complying test methods

Appendix 14 reference conditions	Appendix 14 requirements	Standard
Temperature		
(a) temperature in the test chamber	(23 ± 0,5) °C	EN 717-1
Relative humidity		
(b) relative humidity in the test chamber	(45 ± 3) %	EN 717-1
Loading rate		
(c) loading factor, expressed as the ratio of the total surface area of the test piece to the volume of the test chamber. This loading factor corresponds to the testing of wood-based panels.	(1 ± 0,02) m²/m³	EN 717-1
Loading factors for other material or products, to be considered if the loading factor for wood-based panels is clearly not realistic under foreseeable conditions of use	Product specific: • floor, ceiling: 0,4 m ² /m ³ • small surfaces (e.g. doors, window, heating system): 0,05 m ² /m ³ • very small surfaces (e.g. sealants): 0,007 m ² /m ³	EN 16516 clause 4.2.2
Air exchange rate		

(d) air exchange rate in the test chamber	(1 ± 0,05) h ⁻¹	EN 717-1			
Number of measurements					
(g) formaldehyde concentration in the air of the test chamber	Shall be measured at least twice a day with a time interval of 3 hours at a minimum. The measurement shall be repeated until sufficient data are available to determine the steady state concentration	EN 717-1 ¹⁰			
Test Duration and calculation of the steady state concentration					

¹⁰ Testing is required during 7 days of the first 10 days. Everyday testing is not required.

(h) duration of the test.	The duration of the test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days	EN 717-1 Annex C The test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days. Procedure for the calculation of steady-state concentration: the steady-state is reached when the decline of the calculated concentration curve is equal or lower than 5% over a testing time of 4 days (δ =0,05). If this condition is not reached within 10 days the test shall be continued. Note: the minimum testing period is 10 days to demonstrate the steady-state concentration. The chamber test can be stopped earlier (minimum test period: 4 days) if all test results collected on four consecutive days are below the quantification limit and the linear regression function from the four daily test values does not show an increase of more than 2µg/m ³
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EN 717-1 indicates that the test is concluded when a steady state concentration is reached or, if not reached, the test continues for a maximum of 28 days. In addition, EN 717-1 requires that the edges of the test pieces must be partly sealed for small chamber testing (1 m³ and 0,225 m³) or not sealed for large chamber testing (\geq 12 m³). Adjustments in terms of loading are permitted with reference to EN 16516- clause 4.2.2.

The standard EN 717-1 complies with the Appendix 14 reference conditions and can be directly used to assess compliance with the requirements in paragraph 1 of entry 77 of REACH, Annex XVII (formaldehyde released from articles).

3.1.2. EN 16516 and EN-ISO 16000 series

The standard EN 16516: 2017 + A1 2020-10 was developed from CEN/TC 351 WG2 with EU Commission Mandate M/366 for implementation of a horizontal emission test standard for CE-marking of products to cover the Annex 1, basic requirement 3 of the Construction Products Regulation (CPR). The standard provides the methodology for measuring emissions of dangerous substances, including formaldehyde, from construction products and legal values indicated in the "Declaration of performance and Conformity (DoP)" are based on EN 16516. It was published in 2017. The standard defines a chamber test for the determination of area specific emission rates for these substances under defined test conditions and their expression as concentrations in a reference room. EN 16516 also defines this so-called European Reference Room, which is not a test room but rather serves as exposure scenario to which all test results are calculated back. EN 16516 allows – depending on product type –closure of the backside (side that does not face to the indoor air) and edges sealing.

The standard EN-ISO 16000 series outline a comprehensive laboratory testing procedure for measuring the specific emission rates of volatile organic compounds (VOCs) from building materials or furnishings under defined climatic conditions. The data obtained from this method can be used to calculate concentrations in a simulated room environment. The series include EN ISO 16000-9 (chamber parameters) ¹¹, ISO 16000-3 (sampling and analyses of formaldehyde)¹², ISO 16000-11 (sample preparation)¹³. The parameters are very similar to EN 16516 and considered **as equivalent**.

EN 16516 requires lower air exchange rate and higher relative humidity than the values indicated in Appendix 14 to REACH. The application of these conditions (with other test parameters in line with Appendix 14) leads to higher formaldehyde releases from articles and consequent higher formaldehyde concentrations in the test chamber, compared to the concentrations that would be obtained by applying all the reference conditions set in Appendix 14.

Using EN 16516 might give higher test results than the reference conditions method specified under entry 77, Appendix 14. However, the direct use of test results obtained by EN 16516 is only possible if the results are equal or lower than the limit values defined in paragraph 1 of entry 77 of REACH. In case of higher results, a scientifically valid correlation (to be established for each article type – as explained in chapter 4.1) with data obtained with a test method complying with the reference conditions described in Appendix 14

¹¹ ISO 16000-9: Indoor air -Part 9: Determination of the emission of volatile organic compounds from samples of building products and furnishing- Emission test chamber method.

¹² ISO 16000-3: Indoor air -Part 3: Determination of formaldehyde and other carbonyl compounds in indoor and test chamber air – Active sampling method.

¹³ ISO 16000-11-Indoor air-Part 11: Determination of the emission of volatile organic compounds from samples of building products and furnishing – Sampling, storage and preparation of test specimens.

(such as EN 717-1) is required to demonstrate compliance.

3.1.3. Other test chamber methods

An additional typically used chamber test method is ISO 12460-1-04¹⁴. The ISO 12460-1 is used to measure formaldehyde emissions in different types of articles. The method has very similar parameters as EN 717-1 and is considered as equivalent to EN 717-1. Therefore, the results obtained by ISO 12460-1 can be considered to correspond to those obtained under the reference conditions specified in Appendix 14 of the REACH Regulation.

The standard method ISO 12460-1 uses testing conditions in line with those in Appendix 14. Therefore, it can be directly used to assess compliance with the requirements in paragraph 1 of Restriction entry 77 (formaldehyde released from articles).

Table 2 contains an overview of test parameters used in the chamber-based test methods mentioned above in this section.

¹⁴ISO 12640-1:2007/Amd 1:2023- Wood-based panels_Determination of formaldehyde release_Part 1: Formaldehyde emission by 1-cubic-metre chamber method-Amendment 1:Other analytical procedures

Subject	Appendix 14 of REACH Regulation	EN 717-1:	ISO 12460-1:	EN ISO 16000-9: 2024-03	EN 16516:2017 +A1:2020-10
Scope		chamber method with three options of test chambers for the determination of the formaldehyde emission from wood-based panels in terms of the steady-state concentration	1 m ³ chamber method for the determination of the formaldehyde emission from wood- based panels	determination of the area specific emission rate of volatile organic compounds (VOCs) from samples of newly produced building products ¹⁵ or furnishing under defined climate conditions, can be applied to aged products	determination of emissions of regulated dangerous substances from construction products into indoor air
Applications of the test method		used for coated and uncoated wood based panels and all other wood-based materials (mentioned in several harmonized standards), furniture, other articles	used for coated and uncoated wood-based panels	building products; wood-based panels and other building products, in order to determine the emission rate of formaldehyde (Page v	construction products

¹⁵ The international standard ISO 16000-9 refers to building products and furnishing, while the harmonized standard EN 16516 refers to construction products. Construction products are defined in Regulation (EU) No 2024/3110 (construction products regulation or CPR repealing regulation (EU) No 305/2011) as " *any* formed or formless physical item, including 3D-printed products, or a kit that is placed on the market, including by means of supply to the construction site, with the exception of items that need first to be integrated into a kit or another construction product prior to being incorporated in a permanent manner into construction works. "Building products are defined in ISO 16000-9 as "products produced for incorporation in a permanent manner in construction works or parts thereof with the exception of items that need first to be integrated into a kit or another construction product prior to being incorporated in a permanent manner into construction works. "Building products are defined in ISO 16000-9 as "products produced for incorporation in a permanent manner in construction works or parts thereof with the exception of items that need first to be integrated into a kit or another construction product prior to being incorporated in a permanent manner into construction work". The definitions from both standards for construction products and building products are comparable.

Subject	Appendix 14 of REACH Regulation	EN 717-1:	ISO 12460-1:	EN ISO 16000-9: 2024-03	EN 16516:2017 +A1:2020-10
		emitting formaldehyde		reference to EN 717-1)	
Chamber volume (m ³)	not defined	> 12 1 0.225	(1 ± 0,01)	not defined – model room and reference to EN 16516 (Appendix B)	≥ 0,02
Temperature (°C)	(23 ± 0.5)	(23 ± 0,5)	(23 ± 0,5)	(23 ± 1)	(23 ± 1)
Rel. humidity (%)	(45 ± 3)	(45 ± 3)	(50 ± 3)	(50 ± 5)	(50 ± 5)
Air change rate (h ⁻¹)	(1 ± 0,05)	(1 ± 0,05)	(1 ± 0,05)	0,5 ± 5%	0,5 (reference room) 0,25 to 1,5 \pm 5%, but results shall be recalculated to an air exchange rate of 0,5 /h ⁻¹
Air velocity (m/s)	not defined	0,1 to 0,3	0,1 to 0,3	0,1 to 0,3	0,1 to 0,3
Product loading rate/factor (m²/ m³)	$(1 \pm 0,02)$ Loading factors for other material or products, to be considered if the	(1 ± 0,02)	(1 ± 0,02)	see appendix B (informative): ref. to the model room: 30 m ³ , n=0,5h ⁻¹	clause 4.2.2: model 30 m ³ and n=0,5h ⁻¹ • walls: 1,0

Subject	Appendix 14 of REACH Regulation	EN 717-1:	ISO 12460-1:	EN ISO 16000-9: 2024-03	EN 16516:2017 +A1:2020-10
	loading factor for wood-based panels is clearly not realistic under foreseeable conditions of use: • floor, ceiling: 0,4 • small surfaces (e.g. doors, window, heating system): 0,05 • very small surfaces (e.g. sealants): 0,007.			 floor/ceiling area: 0,4 wall area: 1,0 small surfaces (e.g. doors, windows, heating systems): 0,05 very small surfaces (e.g. sealants, fillers, putty):0,007 	 floor, ceiling: 0,4 small surfaces (e.g. doors, window, heating system): 0,05 very small surfaces (e.g. sealants): 0,007
Test duration	Until steady state emission is reached. Measurements at least 2 times per day. Time interval between the two consecutive samplings/measu rements more	Until steady state emission is reached. Time interval between two consecutive samplings/measurements more than 3 h, Minimum testing period is 10 days or 4 days, if all test results collected on four consecutive days are below the quantification limit and	Until steady state emission is reached. The time interval between the two samplings/measuremen ts more than 3 h Minimum testing period is 3 days	3 days 28 days	3 days 28 days

Subject	Appendix 14 of REACH Regulation	EN 717-1:	ISO 12460-1:	EN ISO 16000-9: 2024-03	EN 16516:2017 +A1:2020-10
	than 3 h	the linear regression function from the four daily test values does not show an increase of more than 2µg/m3			
Can be used to assess compliance with restriction entry 77	n/a	YES	YES	YES – if obtained test results are equal or below the limits established in restriction entry 77 In case test results are beyond the limit in the REACH restriction a scientifically valid correlation is needed	YES – if obtained test results are equal or below the limits established in restriction entry 77 In case test results are beyond the limit in the REACH restriction a scientifically valid correlation is needed

3.1.4. Derived test methods for measurement of formaldehyde from wood based panels

There are several small-scale test methods described in EN or ISO standards to determine the formaldehyde content or release from wood-based panels and related articles. Most of these standards are so called "derived" test methods because they show correlations to the chamber test method EN 717-1. Derived test methods, e.g. ISO 12460-2, ISO 12460-3, ISO 12460-5 and Dynamic Micro Chamber (DMC), can be used for guidance purposes to determine the worst case or as a factory production control method as part of the producer's quality assurance system.

For factory production control methods, the main focus lays on simple, fast, but also robust methods. All test methods concern the measurement of formaldehyde emissions in different kind of boards and the duration of the test lays between the complete chamber test method and a fast method with short measuring time. The measuring time including sometimes a conditioning phase is on the range from 15 minutes (45 litre - 4 litre chambers) up to 4 hours, and even up to 7-28 days for a full chamber test.

In the past, for these small-scale (derived) test methods general correlations were established and limit values fixed. For classification and testing of "E1" and "E2" products regarding formaldehyde e.g. the harmonized standard EN 13986 "Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking" is used.

Because of the continuous reduction of formaldehyde emissions using new production parameters and/or e.g. scavengers, experience over more than 15 years showed that general correlations are no longer valid, and correlations must be established for specific article types. It is worth considering that a small-scale method determining formaldehyde release under test conditions close to reference chamber test methods will lead to more reliable correlations.

A summary of small-scale test methods is given in Table 3. Here the most used EN and ISO standards suitable for wood-based panels are listed including an overview of test parameters and duration.

Table 3.	able 3. Overview of mostly used derived testing methods							
Determ ination of formal dehyde	Method	Standa rd	Test conditions / Results	Type(s) of articles	Examples	Direct use or scientific valid correlation needed		
release	Gas analysis	ISO 12460- 3: 2023	 T: (60 ± 0,5) °C RH: ≤ 3% air flow: 60±3 L/min test period: 4h result: mg/h.m² 	all kinds of wood-based panels, raw or otherwise covered	particleboard , fibreboard, OSB, flaxboard, plywood, solid wood panels, LVL, all types of melamine faced boards	Correlation needed		
release	Desiccator	ISO 12460- 4: 2016	- T: $(20 \pm 0,5)$ °C - test period: 24h ± 5min - pre-conditioning of samples: 7d ± 3h $(20\pm2/65\pm5)$ - result: mg/L	Raw or otherwise covered boards	particleboard , MDF, PLY	Correlation needed		
content	Perforator	ISO 12460- 5: 2015	 extraction with toluene test period: app. 2h plus pre-heating (app. 30min) result: mg/100g oven-dry board 	raw particle and fibre- based boards	particleboard , fibreboard, OSB, flaxboard	Correlation needed		
release	Dynamic micro chamber (DMC)	DMC Manual (2007 / 2012)	- T: $(25 \pm 1) \circ C$ - RH: $(50 \pm 4) \%$ - q: depending on WBP - test period: min 15 min - pre-conditioning of samples: min 2h or 7d ± 3h $(24\pm3/50\pm5/AE)$ - result: ppm	raw particle, fibre-based boards and raw laminar composites	particleboard , Medium Density Fiberboard (MDF) plywood	Correlation needed		
release	Flask	EN 717- 3: 1996	-T: (40 ± 1) °C - test period: 3h - result: mg/kg dry board	all kinds of wood-based panels		Correlation needed		

Furthermore, laser spectroscopy is a new method for formaldehyde measurement and is already described in EN ISO 12460-3 and EN ISO 12460-1. This method offers the possibility to obtain quick indication of formaldehyde emissions from articles and provides

the possibility to measure even very low concentrations of formaldehyde and a high degree of automation of the formaldehyde measurement¹⁶.

Test methods described in this section cannot be directly used to assess compliance with the requirements in paragraph 1 of Restriction entry 77 (formaldehyde released from articles). A scientific valid correlation (to be established for each article type, see chapter 4.1) with data obtained with a test method complying with Appendix 14 reference conditions (such as EN 717-1) is required to demonstrate compliance.

3.2. Methods for measurement of formaldehyde concentration in the interior of road vehicles

For road vehicles, the formaldehyde concentration shall be measured according to the conditions specified in ISO 12219-1 (passenger cars) and ISO 12219-10 (trucks and buses) methods and the value set out in paragraph 2 of the restriction entry shall not be exceeded when measured in ambient mode according to ISO 12219-1.

ISO standard 12219-1 and 12219-10 are used to assess compliance with Appendix 14 requirements. Additional testing (e.g., individual parts under the control of Original Equipment Manufacturer (OEM)) is not needed if it can be demonstrated by OEM that these parts were installed in the interior of the road vehicle which was tested in accordance to ISO standard 12219-1 or 12219-10.

Spare parts not under OEM control should be tested individually for compliance with formaldehyde emissions from articles.

Appendix 14 to REACH provides specific indication on the standard **methods ISO 12219-1**, and **ISO 12219-10** to measure formaldehyde concentration in the interior of vehicles. Other test methods cannot be used to demonstrate compliance to paragraph 2 of Restriction entry 77.

Table 4 provides an overview of standard methods designed to measure formaldehyde concentration in vehicle interior, the column on the right hand of the table indicates the methods that can be used to assess compliance with the requirements set in entry 77 of Annex XVII to REACH.

¹⁶ Presentation Dresden 15.12.2023 – IHD Kolloquium "Laserspektroskopie als Schlüssel zur schnellen Emissionsprüfung und ihr Einfluss auf die Normung" Manuel Fleisch, Bettina Meyer

Table 4. Non-exhaustive overview of standard methods applicable to measurements of formaldehyde concentration in vehicle interior

Sample	Name	Standard	Temp Celsius	Humidity %	Load Factor	ACH (h-1)	Analytical Procedure	Measure rate	Duration	Sample size	Appropriate to assess compliance with Restriction entry 77
Part	Interior of road vehicles – Part 3 – micro scale chamber method	ISO 12219-3	65	N/A	n.d	250 ml/min	Iso 16000-3 DNPH cartridges with HPLC- MS or UV	n.d.	Seal sample after production and measure 7d after ventilation at room conditions	10- 1000 cm3	No
Part	Interior of road vehicles – Part 4 Small chamber method	ISO 12219-4	65	45% in supply air at 23 C	n.d	0.4	Iso 16000-3 DNPH cartridges with HPLC- MS or UV	n.d.	Seal sample after production and measure 7d after ventilation at room conditions	0.5-4 m3	No

Sample	Name	Standard	Temp Celsius	Humidity %	Load Factor	ACH (h-1)	Analytical Procedure	Measure rate	Duration	Sample size	Appropriate to assess compliance with Restriction entry 77
Part	Interior of road vehicles – Part 5 – static chamber method	ISO 12219-5	65	n.d	n.d.	0	Iso 16000-3 DNPH cartridges with HPLC- MS or UV	n.d.	Seal sample after production and measure 7d after ventilation at room conditions	10-500	No
Part	Interior of road vehicles – Part 6 Small chamber method	ISO 12219-6	65	45% in supply air at 23 C	n.d.	0	Iso 16000-3 DNPH cartridges with HPLC- MS or UV	n.d.	Seal sample after production and measure 7d after ventilation at room conditions	0.5-4 m3	no

Sample	Name	Standard	Temp Celsius	Humidity %	Load Factor	ACH (h-1)	Analytical Procedure	Measure rate	Duration	Sample size	Appropriate to assess compliance with Restriction entry 77
Material	Moulded composites and fleeces for vehicles . Test procedure called modified flask method	VDA 275	60	N/A	N/A	0	Photometric detection of Di- acetyldihydrotoluidine	n.d.	n.d	40*100 mm2	No
Part	Interior air of road vehicle part 2 – Bag method	ISO 12219-2	65	N/A	n.d	0	ISO 16000-6 DNPH cartridges with HPLC- MS or UV	n.d.	Seal sample after production and measure 7d after ventilation at room conditions	0.01-1 m3	No
Passenger Car	Interior air of road vehicles Part 1. (Ambient mode)	ISO 12219-1	25	50±10	N/A	2	ISO 16000-6 DNPH cartridges with HPLC- MS or UV	Min 2 samples. Time interval not specified	Within 23- 33 days after production	Vehicle interior	Yes

Sample	Name	Standard	Temp Celsius	Humidity %	Load Factor	ACH (h-1)	Analytical Procedure	Measure rate	Duration	Sample size	Appropriate to assess compliance with Restriction entry 77
Passenger Car	Interior air of road vehicles Part 1. (Parking mode)	ISO 12219-1	>25	50±10	N/A	2	ISO 16000-3 DNPH cartridges with HPLC- MS or UV	Min 2 samples. Time interval not specified	Within 23- 33 days after production	Vehicle interior	No
Passenger Car	Interior air of road vehicles Part 1. (Driving mode)	ISO 12219-1	23	50±10	N/A	Highest rate from climate system fan	ISO 16000-3 DNPH cartridges with HPLC- MS or UV	Min 2 samples. Time interval not specified	Within 23- 33 days after production	Vehicle interior	No

Sample	Name	Standard	Temp Celsius	Humidity %	Load Factor	ACH (h-1)	Analytical Procedure	Measure rate	Duration	Sample size	Appropriate to assess compliance with Restriction entry 77
Buses and Trucks	Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses (Ambient mode)	ISO 12219-10	25		N/A	0	ISO 16000-3 DNPH cartridges with HPLC- MS or UV			Vehicle interior	Yes

3.3. How to measure formaldehyde emissions in specific cases

The following sections describe how to measure formaldehyde emissions for certain type of articles using the standard methods described in the sections above.

3.3.1. Furniture

The term furniture is used to identify a wide range of articles with different size (e.g. a chair or other furniture with non-flat surfaces are considered furniture). The different dimensions and variety of shapes (e.g. in shape flat or irregularly) of furniture, require different testing strategies. No specific test method is currently available that describes test specimen preparation and test chamber conditions in detail for all type of furniture, however it is possible to test furniture using EN 717-1, ISO 16000-9 or EN 16516, or following the test conditions indicated in DE UZ 38¹⁷, DE-UZ 117 (for upholstered furniture) and RAL-GZ-430.

For furniture produced by simple assembling of different parts (e.g. panels, textiles, foams etc), it is possible to assess compliance with the requirements of the restriction entry 77 by testing individual parts/components from which a piece of furniture is manufactured.

Testing of assembled pieces of furniture (e.g. individual cabinets, drawers, beds) or complete furniture or furniture group (e.g. full kitchen or sleeping room) is only required if, during assembly, additional formaldehyde emitting materials (such as adhesives, paints, surface coatings etc.) were added by the furniture producer. For assembled furniture the emitting surface area be calculated including edges, and testing has to be conducted with all surfaces exposed (e.g. open doors and drawers).

When testing the complete furniture is not possible (e.g. no availability of high-volume test chambers), the **test could be limited to specific parts of the furniture (e.g. parts where the formaldehyde emitting materials have been added).** In these cases, an adequate part of the small sized furniture (e.g. vertical dividing) should be tested. If open edges are created by cutting the piece of furniture, new edges shall be sealed gas-tight with aluminium tape. The small test sample must be representative for respective whole furniture with regard to the material composition (type and ratio of the individual materials).

For upholstered seating furniture (e.g. sofas and chairs) the emitting surface is difficult to measure (outside and – specially - inside emission surface area). The test conditions indicated in DE-UZ 117 can be used for testing of upholstered furniture.

CEN/TC207 WG9/TG-4 has initiated the work to develop a standard for measuring emissions from furniture. It could be feasible to create a corresponding standard by August 2026. According to the working group members, this standard aims to serve as the foundation for consistent and reliable measurement of emissions, including formaldehyde, from parts/components, as well as all types of furniture (both flat and irregularly shaped) and to assess compliance with the relevant regulation.

CEN TC351 has published a document on a broader application of CEN/TC 351 reference room in order to test other products than construction products ¹⁸.

¹⁷ The scope of application of DE-UZ 38 includes wooden furniture.

¹⁸ CEN/TR 17965 Guidance for a broader application of the CEN/TC 351 reference room

3.3.2. Articles different from furniture and wood-based articles

Restriction entry 77 sets to 0,080 mg/m³ the limit for emission of formaldehyde for all other articles than furniture and wood-based articles. Similarly to wood-based articles and furniture, the limit relates to the emissions in a test chamber used under the conditions set in Appendix 14.

Test methods **EN 717-1, EN 12460-1 and EN 16516** are suitable to measure formaldehyde emissions from other articles (in addition to wood-based panels and construction products), but some adaptations are needed (e.g. in relation to loading factor and size of the test chamber) for certain articles. As indicated in section 3.1.2 the direct use of test results obtained by EN 16516 to demonstrate compliance is only possible if the results are equal or lower than the limit values defined in the Restriction entry 77. In case of higher results, a scientifically valid correlation to the reference conditions described in Appendix 14 (such as EN 717-1) is required to demonstrate compliance.

Reference to test methods and conditions that can be used to assess compliance with Restriction entry 77 are shown in Table 5 below.

Description of test condition
General considerations
 For toys, test conditions specified in Appendix 14 to REACH regulation could hardly be realised for the following reasons: Surface areas of three-dimensional toys with complicated shapes can hardly be measured reproducibly. Dimensions of toys and corresponding surface areas are often very small. Consequently, a test chamber loading factor of 1 m²/m³ for three-dimensional finished toys is very difficult to achieve.
 - Calculation of a surface area: If the surface of a toy cannot be determined accurately and reproducibly using simple measuring instruments the surface area of the smallest three-dimensional geometric shape/fit (e.g. cuboid, pyramid, cylinder, etc.) representative for the toy - resulting in the highest packing density for a toy to be tested - should be considered. This simplified surface area should be taken into account for calculation of test chamber loading. For complex toys consisting of various loose parts, the surface area of different parts can be determined using different procedures. Parts with easily determinable surfaces can be measured using exact dimensions. For parts with complicated shapes, the described approach with simplified surface areas determination should be followed. The total surface area represents the sum of all individual determined surfaces.
 Test conditions: Chamber loading factor: 0.5 to 2 m²/m³ (corresponds to EN 16516) Area-specific air flow rate: 1 m³/m²*h Temperature: 23 °C ± 0.5 °C Rel. Humidity: ≥45 % ±5 % Analytical determination of formaldehyde: See information in table 11

Table 5. Examples of article-specific test conditions that can be applied to assess compliance with entry 77 of REACH

Type of article	Description of test condition
Article containing a PUR foam core in particular with close body contact	Test based on the requirements of Decision (EU) 2014/391 criteria for bed mattresses (EN) ¹⁹ Test chamber conditions: Minimum chamber volume: 0,5 or 1 m ³ (whole mattresses can be tested in ≥ 1 m ³) Loading factor: 1 m ² /m ³ Area-specific air flow rate:: 0.5 m ³ /m ² *h Temperature (supplied air): 23 °C ± 0.5 °C Rel. Humidity (supplied air): 45% ± 3 % Sampling: Water/ DNPH cartridge
	Analysis: ISO 16000-3 (DNPH)
Electric household appliances	Test method based on DIN ISO/IEC 28360:2009-11 and ISO 16000-9 Test chamber conditions: Minimum chamber volume: 1 m ³ Loading factor: 1 unit/chamber Air change rate: 1 h-1 Temperature (supplied air): 23 °C ± 0.5 °C Rel. Humidity (supplied air): ≥45 % ± 3% (Possibly test in operating mode with operation time and sampling time depending on real usage scenario of tested device.) Test method for toaster can be performed based on former criteria of DE-UZ 167 (Blue Engel) Sampling: Water/ DNPH cartridge
	Analysis: ISO 16000-3 (DNPH)

¹⁹ <u>https://environment.ec.europa.eu/system/files/2022-08/User%20Manual%20-%20Mattresses.pdf</u>

Type of article	Description of test condition
Construction products for example: Thermal insulations made of foam, mineral glass and rock wool Floor coverings Acoustic panels Wall panels Wall paper 	Test chamber loading acc. to clause 4.2.2 of EN 16516 (considering the application scenario)
Printed circuit boards made of hard paper	Reference conditions specified in Appendix 14 to REACH regulation can be applied with deviating test chamber loading factor in the range of 0.5 to 2 m ² /m ³ (acc. to EN 16516) and corresponding area-specific air change rate of 1 m ³ /m ² *h, Temperature: 23 °C ± 1 °C, rel. Humidity \geq 45 % ±5 %

4. Correlation of test data

Appendix 14 to REACH specifies that any test method can be used to assess compliance to paragraph 1 of restriction entry 77. However, in order to apply "*a test method that does not use the reference conditions*", it is necessary to calculate the 'formaldehyde concentration under reference conditions' from the test data by using a regression formula. Such formula is obtained by correlating the test results from the chosen method with data obtained by testing the same (or same type of) article with a test method which uses the reference conditions defined in Appendix 14. This section provides information on how to make such correlations and derive the regression formula.

It is worth noting that formaldehyde release from articles depends on a number of variables, such as the material of which the article is made, its shape, the size, presence of coated/covered surfaces etc. For this reason, a single formula that works for all types of articles, cannot be reliably derived. It is therefore recommended to use correlation to determine a conversion factor on a case-by-case basis.

4.1. Basic principles of correlation

For establishing a correlation (as per Appendix 14) for a "given" test method at least 5 data pairs are necessary. These data are obtained by testing the same (or same type of) article with the "given" test method (e.g. Method A such as EN 16516) and with a method that has the reference conditions (e.g. Method B such as EN 717-1). In some cases, it should be possible to group products with similar emission behaviour e.g. for recipes, thickness, production lot etc.

Once the data pairs are obtained, a linear regression can be calculated for a wide range of formaldehyde concentrations (min 0.05 ppm) and a correlation factor between method A and method B can be derived. It is important to highlight that correlation must always be made with data obtained with a method that has the reference conditions set in Appendix 14 of REACH.

In some cases, it is not possible to establish a correlation due to the small spread or variation of formaldehyde concentrations (clouds of values around small variations in formaldehyde emission). This could be the case for articles with low formaldehyde emissions (e.g. low emitting wood-based panels, or articles made of plastic materials). In these cases, an additional zero point or blank value should be set.

A further correlation, between multiple methods must be avoided "due to the risk of error propagation.

The procedure of establishing a correlation for wood based panels is described in detail in ISO 12460-2: 2024. **The ISO 12460-2: 2024 standard should be used as a reference**, as it can clarify a number of open points (e.g. related to establishing a correlation).

In addition to what is described in the standard, other parameters should be considered, e.g. the time frame of Factory Production Control (FPC) testing, status of Factory Production control (FPC) sample (e.g. wood-based panels: unsanded, sanded and other).

The following details should be considered as well:

- type of article to be tested
- type of FPC method (shall be discussed in detail with the -possible- involved test

institute)

- sampling of test material and status of material used for FPC (e.g. 'fresh from production', or other time-specific status of FPC samples: one or more)
- possible 'clouds' of values for reference chamber vs. FPC results see ISO 12460-2.

Table 6 below shows some examples of regression formulae available in literature derived by testing certain type of articles with the EN 717-1 test method (based on standard conditions) and other methods. These are not valid for all products and, as stated Appendix 14 "*a scientifically valid correlation between the results of the test method used and the reference conditions*". Therefore, a regression formula have to be established on a case-by-case basis. The values can only be used as an indication for resulting correlation factors.

Test method	Article types	Reference method (based on Appendix 14)	Regression formula *	Source
EN 16516	Wood based materials	EN 717-1	y=x/2	German Chemical Prohibition Act (ChemVerbostV) ²⁰
EN 16516 ²¹	Wooden boards	EN 717-1	y=0.625x	Olaf Wilke, Oliver Jann (2018) ²²
ASTM D6007	Particle Boards (3-25 mm)	EN 717-1	y=0.7609x+0.02**	Venla Hemmilä, Bettina Meyer and others (2019) ²³
ASTM D6007	MDF (3- 25mm)	EN 717-1	y=0.9793x**	Venla Hemmilä, Bettina Meyer and others (2019) ¹⁰
EN 717-2	Particle boards (16mm)	EN 717-1	y=-0.08+0.41x***	Mohamed Z.M. Salem,Martin Böhm et al. (2012) ²⁴

Table 6. Examples of regression formulae found in literature.

*x is the formaldehyde concentration in test chamber (mg/m3) obtained with the reference method (e.g. EN 717-1) while x is the concentration obtained with the method indicated in the first column of the table; ** Values are in ppm; *** y is expressed in mg/m³, while x is in mg/m² h

 $^{^{20}}$ This formula is related to a loading factor of 1.8 m²/m³ (EN 16516)

²¹ For any correlation done with data obtained from EN 16516, it is necessary to specify the loading factor used. EN 16516 includes formulas (in section 9) to calculate formaldehyde concentration in the EU reference room for different loading factors and air exchange rates.

 $^{^{22}}$ Comparison of Formaldehyde Concentrations in Emission Test Chambers Using EN 717-1 and EN 16516 Conference Indoor Air (Philadelphia 2018)

https://www.researchgate.net/publication/327208565_Comparison_of_Formaldehyde_Concentrations in Emission_Test_Chambers_Using_EN_717-1_and_EN_16516

²³ Influencing factors, repeatability and correlation of chamber methods in measuring formaldehyde emissions from fiber- and particleboards – international journal of adhesion and adhesives volume 95 December 2019, 102420

²⁴ Evaluation of formaldehyde emission from different types of wood-based panels and flooring materials using different standard test methods – Building and Environment – Volume 49 March 2012 pages 86-96

Appendix 1: Overview of test parameters

Appendix 14 to the REACH Regulation describes a chamber method with main reference conditions as follows:

Temperature $(23 \pm 0,5)$ °CRelative humidity (45 ± 3) %Air exchange $(1 \pm 0,05)$ h-1Loading rate $(1\pm 0,02)$ m²/m³;based on wood-based panel loading rate *

* for other materials or products, if such a loading factor is clearly not realistic under the foreseeable conditions of use, loading factors according to clause 4.2.2 of EN 16516 may be used.

Beside the 'main' test parameters other relevant test parameter/procedures that are described in various standards concerning chamber methods are:

- chamber volume
- loading factor
- air velocity
- edges (e.g. handling/preparation of edges)
- period of measurement
- samples selection and preparation
- analytical procedures
- assessment of measurement results
- test report

An overview of test chamber parameters for most relevant test methods is reported in Table 7

Table 7. Overview of main test chamber parameters

Testing method ID	Type of testing	Typical application	Part / Plate / Article	Test chamber volume	Loading	Test temperature/ humidity	Ventilation conditions	Test duration	Unit
ISO 12460-3 (former EN 717-2)	emission rate	flat material	plate	4 L	1 x (50 x 400)mm	60 °C, ~3 %RH	60 L/hr	4 hours	mg/m² h
ISO 12460-4 (former JIS A 1460)	steady state testing	flat material	plate	1 m³	(50 x 150)mm, 1800 cm ²	20 °C, 65% RH	No	24 hours (after 7 days conditioning)	mg/L
ASTM D6007	steady state testing	flat material	plate	0,02 - 1,0 m ³	0,13 - 0,95 m²/m³	25 °C, 50 %RH	0,5/h	24 hours (after 7 days conditioning)	ppm
EN 14080 ²⁵	steady state testing	glued laminated timber (GLULAM)	block material	1 m³	0,3 m²/m³	23 °C, 45 %RH	1/h	28 days	mg/m ³
EN 16351 ²⁶	steady state testing	cross laminated timber (CLT)	block material	0.225, 1, >12 m ³	1 m²/m³	23 °C, 45 %RH	1/h	28 days	mg/m ³

 ²⁵ EN 14080 \timber structures – Glued laminated timber and glued solid timber – Requirements.
 ²⁶ EN 16351 Timber structures – Cross laminated timber - Requirements

Testing method ID	Type of testing	Typical application	Part / Plate / Article	Test chamber volume	Loading	Test temperature/ humidity	Ventilation conditions	Test duration	Unit
EN 14342 ²⁷	steady state testing	Flooring Wood flooring	plate	0.225, 1, >12 m ³	1 m²/m³	23 °C, 45 %RH	1/h	28 days	mg/m ³
ISO 16000-9	VOC conc	building products	materials or articles	not specified	variable	23 °C, 50 %RH	0.5/h	3 or 28 days	mg/m³
EN 16516:2017+A1:2020	Voc conc.	Construction products	Materials or article	Be able to accommodate the test specimen or European reference room	clause 4.2.2 of EN 16516	23°C±1°C, 50%±5%RH	(0.5 ± 0,05)	28 days or according to construction product standard	µg/m3
EN 717-1:2004	Steady state testing	Wood based panels	Articles	0.225, 1, >12 m ³	(1 ± 0,02)	23°C (± 0.5°C), 45 %RH	(1 ± 0,05)	4, 10 or up to 28 days	mg/m3

²⁷ EN 14342: 2013 Wood flooring and parquet. Characteristics, evaluation of conformity and marking

Testing method ID	Type of testing	Typical application	Part / Plate / Article	Test chamber volume	Loading	Test temperature/ humidity	Ventilation conditions	Test duration	Unit
EN 14041 ²⁸	Steady state testing	Flooring (Resilient, textile, laminate floor coverings)	plate	0.225, 1, >12 m ³	1 m²/m³	23 °C, 45 %RH	1/h	28 days	mg/m ³

Table 8. Test parameters for non test chamber based method

Testing method ID	Type of testing	Typical application	Part / Plate / Article	Loading	Test temperature/ humidity	Test duration	Unit
ISO 12460-5 (former EN 120)	solvent extraction	flat material	plate cut to (25 x 25)mm	110 g	Boiling toluene	2h	Mg formaldehyde/100g oven dry sample

²⁸ EN 14041 Resilient, textile, laminate and modular multilayer floor covering – Essential characteristics

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