

Formaldehyde and formaldehyde releasers - Strategy for future work

Scope of this document

This document aims to advise the Commission on a possible strategy for the work on a future restriction on formaldehyde and formaldehyde releasers in light of the preparation of an Annex XV restriction dossier concerning certain uses of these substances.

During the workshop on restrictions on 17-18 May 2017, ECHA made a presentation on the strategy for a possible restriction dossier on formaldehyde and formaldehyde releasers which was followed by a discussion.

Background

Formaldehyde is classified as category 1B carcinogen with a CLP concentration limit of $\geq 0.1\%$ ¹.

The Commission has proposed to include formaldehyde and some formaldehyde releasers² in the next amendment to Annex XVII to include CMR substances 1A and 1B in the Appendixes to restriction entries 28-30 to Annex XVII. This will restrict the placing on the market for supply to the general public of formaldehyde and included formaldehyde releasers in mixtures with the respective concentration limits set by the CLP regulation. will be included. The Commission draft Regulation will be adopted in the first quarter 2018 and the restriction on formaldehyde and some releasers for their placing on the market for supply to the general public will apply from the date of entry into force of the Regulation.

Formaldehyde will also be proposed by the Commission for a restriction in textile and clothing articles for consumer articles under Article 68(2) of REACH.

A substance evaluation on formaldehyde under Title VI of REACH was jointly undertaken by France – responsible for addressing concerns for workers - and the Netherlands – who addressed concerns for consumers - in 2014. France has analysed the risk management options to control risks to workers during manufacturing and use of formaldehyde in the framework of the Risk management options analysis (RMOA)³. The conclusions, when available will be published in the public activities coordination tool (PACT)⁴. Based on the outcome of substance evaluation performed by the Netherlands it was concluded that additional information is needed and ECHA has decided, on March 2015, to request registrants to include additional information on consumers uses and exposure by updating their registration dossiers. More than hundred registration dossiers were updated within the deadline of 13 October 2017. The Netherlands will update the substances evaluation within one year.

It is also noted that the Commission is considering to propose an occupational exposure limit value on formaldehyde to be included in the third amendment to the Directive 2004/37/EC, possibly in the beginning of 2018.

¹ Whole classification: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/55163>

² 4,4'-methylenedimorpholine; [MBM], Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); [MBO] and Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1); [HPT]

³ RMOA was published for public consultation: <http://www.consultations-publiques.developpement-durable.gouv.fr/consultation-publique-sur-le-rapport-de-l-anses-a1421.html>

⁴ <https://echa.europa.eu/pact>

Possible Annex XV dossier for restriction

In December 2017, Commission has requested ECHA to prepare an Annex XV restriction proposal to cover exposure of consumers to formaldehyde released from articles whether such release is caused by formaldehyde itself or other substances (which may or may not be classified) and which release formaldehyde. The request does also cover the exposure to consumers to formaldehyde in mixtures containing either formaldehyde in concentration below 0.1% or formaldehyde releasers. In parallel with the request for Annex XV dossier, Commission has also requested ECHA to gather information to assess potential exposure to formaldehyde for workers.

The restriction proposal will be developed in parallel and in liason, with the Netherlands' work on consumer exposure to formaldehyde. ECHA is looking for opportunities to support Netherlands in their work based on new information provided by industry in registration dossiers.

The restriction will therefore focus on the placing on the market and use of formaldehyde and formaldehyde releasers in mixtures and articles for supply to consumers.

A possible future extension of the restriction proposal to cover exposure to formaldehyde for industrial and professional workers will be considered even in the case when an Occupational Exposure Limit (OEL) for workers will be established by the Commission Release of formaldehyde from formaldehyde-based resins used in various application (e.g. production of wood products and panels) and its possibility to cause risks to workers will also be considered.

The uses of formaldehyde releasers covered by the Biocidal Product Regulation or the Cosmetic Product Regulation, will not be taken into account in the restriction proposal. However these uses will be taken into account when calculating the cumulative exposure to formaldehyde.

What is the risk for consumers and workers?

Formaldehyde has been classified⁵ as a category 1B carcinogen, and it is classified as category 1 skin sensitiser (among other classifications) under the Commission Regulation No 605/2014.

Risks to consumers

Formaldehyde may be released to indoor air as it is found in articles present in our daily environment such as offices, homes, schools, hotels, shopping malls, restaurants, bus/train/ship/car interior, mobile homes etc.

The uses of formaldehyde and formaldehyde releasers and the sources of emissions and releases (such as building and construction materials, furniture, plywood panelling and fibreboard, wallpapers, textiles and carpets) are already identified in the substance evaluation report prepared by the Netherlands and included in the subsequent ECHA decision to request further information from registrants.

Based on the scientific studies referred in the investigation report on formaldehyde and formaldehyde releasers prepared by ECHA (see reference below), there are divergent views on what can be regarded as protective limit value of formaldehyde in indoor air. WHO provided guideline for indoor air quality for 30 minutes average concentration: 0.1 mg/m³ (0.08 ppm)

⁵ Regulation (EU) No 605/2014 of 5 June 2104.

(prevents also long term health effects). However, JRC (2005) recommended the limit value of 1 µg/m³ for indoor air, due to increasing evidence indicating children being more sensitive to formaldehyde respiratory toxicity than adults. After the JRC recommendation, some scientific articles supported WHO's approach. However, the Biocidal Products Committee (ECHA, 2015) has agreed an acceptable exposure concentration of 0.1 ml/m³ (0.1 ppm).

Risks to workers

The risk management option analysis (RMOA) prepared by France was targeting mainly the uses of formaldehyde which cause risk to workers. The RMOA notes that 99 % of the uses are intermediate uses and 20 % of those could fall under restriction due to being transported isolated intermediates. However, as no information is available to justify that the risk is or is not controlled, a restriction does not seem to be the preferred regulatory management option to pursue. The remaining 1 % of use is in laboratories for research and development activities, for which there seem not to be alternatives.

The possibility to restrict industrial and professional uses of resins by workers should be further explored as it was not covered by France in its RMOA.

What information is available?

On 15 March 2017 ECHA published a report⁶ on the results of the investigation on formaldehyde and formaldehyde releasers and their uses, prepared upon request from the Commission⁷. The report included information from different sources (registration dossiers, published scientific literature, stakeholder responses to a call for evidence⁸ which was open between 13 July and 4 October 2016, Member States assessments etc.).

The report identified:

- substances which may release formaldehyde during use (either intentionally or unintentionally)⁹, and
- uses of substances known as formaldehyde releasers (or potential formaldehyde releasers) with reference, in particular, to consumer uses and available exposure information.

The report includes information on release of formaldehyde in indoor environment from different sources (e.g. construction materials, textiles, cleaning products, disinfectant etc.) concluding that levels of exposure to the skin and the respiratory system may vary. However, the currently available information is not sufficient to assess whether the risk is adequately controlled.

According to the information included in the registration dossiers of formaldehyde, this

⁶ Available at: https://echa.europa.eu/documents/10162/13641/annex_xv_report_formaldehyde_en.pdf/58be2f0a-7ca7-264d-a594-da5051a1c74b

⁷ Available at: https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf

⁸ Available at: <https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/13967/term>

⁹ The report also provides list of substances registered and which have formaldehyde in their composition (concentration range of formaldehyde indicated). Whether to include those or some of those substances in the future work to be discussed.

substance is present in mixtures (for use as cleaning agent, adhesives and paints) in concentrations <0.1%, thus mixtures containing formaldehyde are not classified as carcinogenic.

The finalisation of the substance evaluation (consumer part) by the Netherlands is expected in 2018).

The conclusion of the analysis of risk management option (RMOA) by France is expected at the beginning of 2018. As already indicated by France in their preliminary report (published on June 2016) occupational risks will be, most probably, addressed by workplace legislation (as defined by CMD directive) and the establishment of appropriate OELs. DNEL's proposed by France as a conclusion of their RMOA are the same as the SCOEL recommendations¹⁰.

In addition, formaldehyde emissions from articles (for example, wood panels) are regulated in some countries and voluntary emission standards also exist (see annex). Some of these limits are considered to be based on a risk assessment, which could be used as information basis for the Annex XV dossier for restriction.

The expert group on chemicals in toys is discussing the establishment of limits for formaldehyde to be included in Appendix C of the Toy Safety Directive. Information on analytical methods and on the use of formaldehyde as a monomer in polymeric materials and on resin-bonded wood products could be obtained from this group.

What additional information is needed?

- a) *Information to be provided in registration dossiers due to ECHA's decision on substance evaluation (concerning consumer uses)*

The substance evaluation for formaldehyde prepared by the Netherlands covering exposures to consumers concluded that further information is needed in registration dossiers. As a result ECHA issued a decision on 6 October 2015¹¹ to request specific information from the registrants. The most relevant information requested in ECHA's decision, includes:

- the lifecycle of formaldehyde with the exclusion of environmental aspects, as the environmental related endpoints of the substance were not evaluated neither by France nor by the Netherlands
- information on releases and emissions of formaldehyde from different materials including the release of formaldehyde from the resins.

a review of literature data including registrant(s)' own data on the emission rates (in µg/m²/h), comprising time dependency (where available) for the major sources and their relative contribution to the total indoor air concentration of formaldehyde.

The sources of exposure to formaldehyde considered by the registrant(s) shall include, but need not be limited to, the following:

¹⁰ SCOEL REC/125, Formaldehyde: "Based on these experimental studies in human volunteers SCOEL derives an OEL of 0.3 ppm (8 h TWA) with a STEL of 0.6 ppm. As sensory irritation is a concentration rather than a cumulative dose-driven effect, a STEL value is appropriate. This OEL based on sensory irritation will also protect workers from undue annoyance and discomfort at the workplace."

¹¹ Available at: <https://echa.europa.eu/documents/10162/1cc58141-07a2-49ed-9ef9-c6c4fcf9d74b>

- I. building/construction materials such as wood based plate materials for ceiling and flooring and mineral wool;
- II. furniture and other urea formaldehyde (UF) pressed wood products like hardwood plywood panelling and fibre board;
- III. paints;
- IV. wallpapers;
- V. textiles such as curtains, carpets;
- VI. cleaning agents;
- VII. combustion sources such as cooking.

The sources of exposure (i), (ii), (iv) and (v) also include the use of formaldehyde releasing substances. Formaldehyde emitted from paints and cleaning agents is, in most cases, due to biocidal uses of formaldehyde or formaldehyde releasers and it is therefore covered by the Biocidal Products Regulation. Formaldehyde originated from combustion sources such as cooking will not be part either of the future work. The deadline for registrants to submit the required information was 13 October 2017. The Netherlands will finalise the substance evaluation having received this information.

b) Information from other sources

ECHA's report on substances that can be regarded as formaldehyde releasers provides general information on key uses of these substances. However, more detailed information on consumer uses including releases, tonnages, etc. is needed to prepare exposure scenarios. It cannot yet be anticipated if this information will become available from the updated registration dossiers following the Substance Evaluation as the evaluation of the new information is ongoing. In addition, to prepare an Annex XV report, information on alternative substances or techniques is required and their cost compared to formaldehyde and formaldehyde releasers. This information gathering could be contracted out.

Analysis on availability of alternatives and the socio-economic analysis will be included in the restriction dossier and will be based on information gathered during the process. Information from the United States and Canada activities on formaldehyde in wood products and from OECD work on socio-economic impacts will be also taken into account.

Additionally, more information could be needed on the possibility to further lower the limits of formaldehyde in some specific clothing and textile articles (such as upholstery and coats) that will be set in the Art. 68(2) restriction on CMRs 1A and 1B. In that case, industry claimed that higher limits were needed for such articles.

The technical availability of analytical methods already in use to detect the release of formaldehyde from the main material sources should be further investigated related to the enforcement of any EU measure introduced.

The exposure assessment of formaldehyde as released from articles or mixtures could take inspiration from the restriction of inorganic ammonium salts in cellulose insulation mixtures and

articles¹², where the risk from ammonia was modelled inside a dwelling.

It is therefore proposed to further investigate if a lower limit of concentration than 0.1% by weight of formaldehyde and its releasers in mixtures is necessary if the scenario will be focused on the migration and release.

In addition to the preparation of a restriction proposal to cover risks to consumers, ECHA will investigate the possible risks to workers, in order to foresee possible further restriction actions under REACH. Further information will be gathered for this purpose.

Timeline and Milestones

The following time schedule is based on the consideration that ECHA has received the Commission request to prepare the Annex XV dossier on 20 December 2017 and the formal Dossier preparation starts in January 2018 (with the ROI entry).

This timeline fits with the finalisation of the substance evaluation (consumer part) by the Netherlands expected in 2018. The submission date would be of the 11th of January 2019.

Tasks and milestones in the preparation of the report (and the work done by the Netherlands and France on formaldehyde):

The substance evaluation by the Netherlands on formaldehyde:

- 13 October 2017 – Information submitted by the registrants on consumer exposure
- The Netherlands finalises the substance evaluation within one year from the above deadline. ECHA has offered to support their work.

The RMOA by France on formaldehyde:

- Finalisation of the RMOA and publishing the conclusions in the Public Activities Coordination Tool (PACT) in early 2018

ECHA's future work with the restriction proposal:

- Request from the Commission received on 20/12/2017
- Entry of Annex XV restriction proposal into the Registry of Intention – 11/01/2018
- January - March 2018 - initial information gathering
 - o January 2018 – March 2018 market research
 - o January 2018 – April 2018 - Involvement of stakeholders (Industry, NGO, Member States, Universities...), e.g. via call for evidence and possible stakeholder meeting
- April 2018 - December 2018 – Dossier preparation
- January 2019 - Submission of the Annex XV report.

Simultaneously with the preparation of the restriction proposal for formaldehyde covering the risks to consumers, ECHA collects information on risks to workers. A separate report will be

¹² Annex XV dossier and Committee opinions available at: <https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1895/term>

delivered to the Commission by end of 2018.

Who could contribute?

In addition to ECHA, key contributors to the preparation of Annex XV report could be:

- Member States who have already some (draft) measures at national level on formaldehyde, in particular related to its release in indoor environment, from furniture, from resins, etc. (e.g. the NL, DK, SE, IT, FR, DE and possibly others) (see Annex 1).
- Industry (to provide detailed information on uses of formaldehyde and formaldehyde releasers).
- NGOs such as consumer protection organisations who may have made some research or studies on the release of formaldehyde from articles and mixtures.
- ECHA internal experts on exposure assessment, risk assessment and socio-economic analysis.
- Consultants (information gathering).

ANNEX 1**Member States Notifications/Intentions to restrict/regulate furniture/wood based products releasing formaldehyde.**

In 2017 the following Notifications/Intentions to restrict/regulate release of formaldehyde from furniture products have been submitted by Member States to the Commission

France

Notification: labelling of furniture products in regard to their emission of volatile pollutants

Proposal: Modification of the regulatory part of the French Environmental code. More specifically the proposal includes: inserting subsection 4 (articles 221-38 to 221-44), amending title of paragraph 7 of chapter VI Heading II book II to reference to furniture products and including Article R226-14bis concerning applicable fines.

Content of Subsection 4

Applicability: the provisions apply to furniture products containing wood-based panels for indoor or outdoor use. Does not apply to furniture manufactured in runs of less than 10 identical items (thus excluding artisanal products) and to second hand furniture.

Requirement: The products included in the range of applicability shall only be placed on the market if they bear a label giving details of volatile pollutants emitted by the product. The label should be either applied to the product or added to the description to the product in case of distance selling or applied on the package. The order sets out the list of volatile pollutant to be taken into account when characterising the emissions from the products. It also define the classes on the basis of the emission levels of volatile pollutants and corresponding threshold levels.

Furniture products included in the range of applicability of the law, have to be provided by a label giving details of the precautions to be taken due to their emissions of volatile pollutants. This information can be included in the technical identification sheet, usage or assembly instructions for the product instead of a label.

Entry into force

The provisions of this Decree shall apply from 1 January 2020. However, for products that have been placed on the market before 1 January 2020 and are still on the market, these provisions shall apply as of 1 January 2021.

France

Notification: testing of volatile pollutants emission from furniture products:

Proposal: Issue of an order pursuant to Articles R-221-40, R221-41 and R221-43 of the French Environmental code. The Order sets out how the label is presented, the volatile pollutants concerned and the values corresponding to emission classes for each volatile pollutant. It gives also details of the precautions to be taken regarding the volatile pollutants emissions of furniture products.

Requirement: The substance comprising the list of volatile pollutants (as referred in Article 221-40 of the Environmental Code) is Formaldehyde (CAS Nr 50-00-0). The following emission

classes are introduced A+, A, B, C (with A+ representing the lowest emission level and C representing the highest) for products releasing formaldehyde. Technical methods are established to measure emissions from furniture products.

Method for characterising formaldehyde emissions from furniture products in indoor air

PARAMETER	Reference METHOD	Publication DATE
Sampling and preparation of test specimens	Technical guide 'Test protocol for characterising emissions of volatile pollutants by furniture products'	2017
Emission test chamber method	NF EN ISO 16000-9	2006

Method for measuring exposure concentration

PARAMETER	UNIT	METHOD	Publication DATE
Sampling and analysis	$\mu\text{g}\cdot\text{m}^{-3}$	NF EN ISO 16000-3	2011

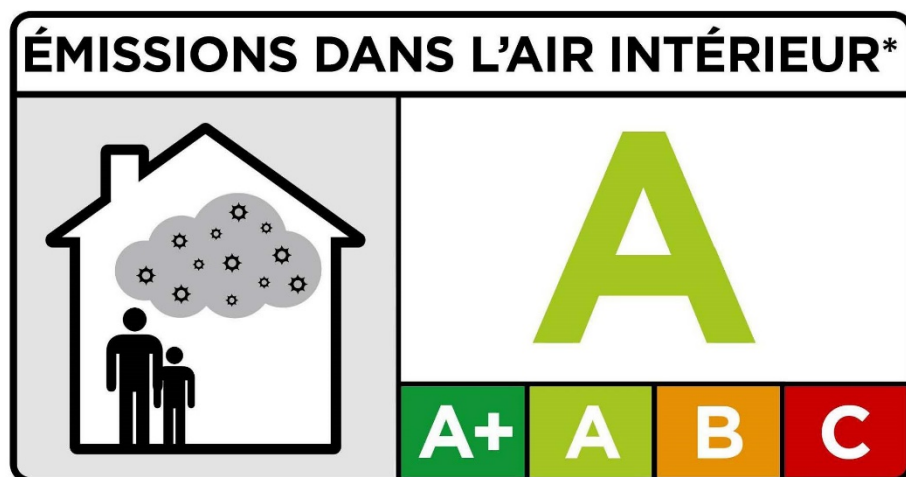
The formaldehyde emission factors in indoor air from wood-based panels used in the furniture product in question are characterised in accordance with the specifications of one of the following standards:

- NF EN ISO 16000-9: Determination of the emission of volatile organic compounds from building products and furnishing - Emission test chamber method (2006).
- NF ISO 16000-3: Determination of formaldehyde and other carbonyl compounds - Active sampling method (December 2011).
- NF EN 717-1: Wood-based Panels – Determination of Formaldehyde Release – Part 1: Formaldehyde emission by the chamber method (March 2005).

Maximum formaldehyde exposure concentration levels (in $\mu\text{g}\cdot\text{m}^{-3}$) and corresponding classes

CLASSES	C	B	A	A+
Formaldehyde	≥ 10	< 10	< 5	< 3

Model of the label



Entry into force

For products placed on the market for the first time from 1 January 2020: 1 January 2020;

For products placed on the market before 1 January 2020: 1 January 2021;

Denmark

Notification of draft revised: Order prohibiting the sale of furniture, equipment, etc. made of wood-based materials that release formaldehyde

Proposal: to establish a limit on the amount of formaldehyde that furniture, equipment, etc. made of wood-based materials may release to indoor climates, whether the wood-based material is untreated, surface-coated, or treated with a coating. The focus of the regulation is thus the cleavage of formaldehyde, which takes place when a coating hardens or upon the hardening of an adhesive used in the manufacture of a wood-based material or for application of a surface coating. This is not, as such, a regulation of formaldehyde itself as a substance in adhesive used in coatings or in furniture, equipment, etc. The focus of the order remains on wood-based materials made with formaldehyde-releasing adhesives. Compared to the order currently in force, however, the scope is expanded to also include wood-based materials that are surface-coated or treated with a coating. This is to ensure that the requirements of the order also encompass wood-based materials with surface coating applied by means of formaldehyde-releasing adhesive and wood-based products that are treated with acid-catalysed lacquer.

Furniture padding and upholstery is excluded from the scope of the order.

Requirement: prohibition to use wood-based materials that release formaldehyde in concentrations greater than 0.124 mg/m³ in the manufacture of furniture, equipment, etc. and parts thereof. The stipulated limit value shall be measured in accordance with testing standard DS/EN 717-1:2004. It is primarily distributors and manufacturers who make furniture, equipment, etc. and parts thereof – and trade as part of their business – who will be covered by the order. Manufacturers of wood-based materials will only be affected indirectly by the requirements of the order.

Entry into force

The order shall enter into force upon signature of the Minister following conclusion of the notification procedure (2017). The order will, upon entry into force, repeal and replace the current order in its entirety.

Italy

REACH competent Authority wrote a letter to the commission to invite them to promote a regulation aimed at harmonising the concentration limit of formaldehyde in wooden manufacture articles. By Decree of 10/10/2008 Italy has regulated the emission of formaldehyde for 1 ppm (1 mg/kg) for all wooden manufacture products similar to what has been established by Germany¹³. In March 2017, France has introduced a minimum limit on

¹³ In Germany the Chemical Prohibition Ordinance (Chemikalien-Verbotsverordnung) provides that coated and uncoated wood-based materials may not be placed on the market if concentration of FA from the material in the air (measured in a test chamber) exceeds 0.1 ppm or 124 ug/m³ - http://www.gesetze-im-internet.de/chemverbotsv_2017/BJNR009410017.html

emission of formaldehyde for furnitures of 3 ppb and it was asking comments to MS and COM according to Directive (EU) 2015/1535. Italy claims that such a low limit may create problems to wood trade among MSs and is therefore urging COM to establish a EU wide limit for formaldehyde.