Voluntary Agreement regarding the implementation of OELs for formaldehyde by Formacare members

1. INTRODUCTION

Today, the formaldehyde industry faces the situation where different national Occupational Exposure Limits (OEL) for formaldehyde apply in the production plants in the EU 28 and Norway. So exposure conditions for workers vary significantly.

The Commission is about to adopt a single and harmonized limit for workplace exposure - a Binding Occupational Exposure Limit (BOEL). The regulatory process will last several years until it is adopted and implemented in all EU member states. The new low BOEL is based on the scientific assessment of the European Scientific Committee on Occupational Exposure Limit (SCOEL).

Formacare, a sector group of Cefic, representing all major European formaldehyde producers, is committed to adopting the future BOEL in advance as a voluntary OEL within its membership – well in advance of there being a legal requirement to do so. The official national exposure data for the member companies is the basis for the reporting to Formacare which will occur under this Agreement. Formacare will summarize the data from the member companies in a clear and informative annual report. This report shall assist in the implementation of this voluntary Agreement and be a useful tool to assess progress . The EU regulators (e.g. OSHA, European Commission, European Parliament) and other stakeholders with a legitimate interest (e.g. trade unions) will have access to the report but will not have the right[1] to audit the data contained therein. The report will be drawn up in full compliance with EU antitrust rules. Formacare may only collect such exposure data from its members. However, if any formaldehyde producer which is a non-member is willing to join this agreement, Formacare will not impose any limitations on its participation in this Agreement.

The members' exposure measurements will be carried out by accredited laboratories. The exposure measurements are conceptually designed and planned in accordance with applicable national legal requirements. The results will be transparently presented and discussed with workers or their representatives.

In detail:

In the framework of REACH, an analysis of the most appropriate **Risk Management Options (RMOA)** is led by France. France is in charge of performing the RMOA on the basis of workers' exposure to formaldehyde. At the same time, formaldehyde was assessed by SCOEL for deriving an **OEL** (Occupational Exposure Limit) both for short (STEL: Short term Exposure Limit) and long term exposure (TWA: Time Weighted Average). Since its classification as Carc. 1B, formaldehyde falls within the scope of the CMD and will be subject to Binding OEL values (BOELs) included in Annex III of the CMD. SCOEL recommendations (**8 hour TWA: 0.3 ppm and STEL: 0.6 ppm**) have been formally approved by the Advisory Committee for Health and Safety at work (ACHS), which recommends a prompt adoption of the BOELs. Additionally, the REACH registration dossier has been updated with refined DNELs which are now aligned on the SCOEL values.

Nevertheless, the process of the BOELs' adoption and their implementation at EU and national level might take longer than industry's expectations. Some EU countries (e.g. Czech Republic, Germany, Sweden, Belgium, Finland, Denmark, Italy, Spain, Slovakia, and Portugal) decided to anticipate the future BOELs and have already implemented an OEL of 0.3 ppm. **Formacare has decided to launch proactively a voluntary Agreement for**

[1] Compliance with EU competition law does not permit individual company data audit from external persons. Access to collated data will however be possible.

implementing the SCOEL recommendations as a pan-European maximum OEL. all member states where its members operate, depending on national legislation (This voluntary agreement shall accelerate workers' protection and prevention of exposure.

The voluntary Agreement should been seen as a **facilitating tool to prepare the entry into force of the BOELs in all member states**. For those reasons, the voluntary agreement takes into consideration the manner of implementing and checking the effectiveness of OEL in member states. The revised EN689 (prEN689 version submitted to public consultation in June 2016), **existing regulations in force in member states** have been taken into consideration.

This voluntary Agreement aims to address the most important expectations of the authorities. In particular it provides for **quantitative measurements of workplace concentrations** which will be compared to OELs, followed by a reporting of consolidated measurement results, **action plans aimed at complying with the OELs proposed by SCOEL, and exchanges of best available practices to achieve the required low values.**

2. MAIN OBJECTIVES OF THE AGREEMENT

This voluntary Agreement pursues the following main objectives:

- **to continue improving health through prevention and protection of workers** exposed in the workplace to formaldehyde. This Agreement confirms the voluntary commitment of Formacare's members to continuously improve health and safety at work.
- **to anticipate the future enforcement at national level of the OELs proposed by SCOEL and endorsed by the ACHS**. This Agreement should prepare producers and downstream users to practically implement the 0.3 ppm and 0.6 ppm BOELs and their related Risk Management Measures.
- **to exchange between signatories best Risk Management Measures (RMM) practices.**
- **to bring trust and re-assurance to EU regulators and third parties, especially trade-unions, regarding the safe use of formaldehyde in the workplace**. By gathering measurement campaigns data, it aims to increase transparency and shall lend credibility to the BOELs as the best Risk Management Options for formaldehyde.

This Agreement applies without prejudice to existing regulatory provisions including but not limited to those derived from the implementation at national level of the OSH framework directive and the CMD.

3. SCOPE OF THE AGREEMENT

The present Agreement covers Formacare members, which are producers of formaldehyde, paraformaldehyde, polyols, aminoplast glues and resins, and POM (Polyacetal), accounting for a significant share of total supply of those products in the EU. By entering into this voluntary Agreement, the **members of Formacare are to comply with its provisions.**

Formacare is in charge of promoting the Agreement among EU downstream user associations. Specifically, Formacare shall inform these organisations of the existence of this voluntary Agreement.

This voluntary Agreement covers all potential exposure to formaldehyde regardless of its status: intermediate or non-intermediate within the meaning of REACH[2], deliberately added in mixtures or released by processes both intentionally and unintentionally. All exposure which will fall within the scope of the future BOELs, set in the context of the CMD, will be covered by this Agreement. **It may be signed by downstream users organizations concerned about formaldehyde exposure.**

4. COMMITMENT OF SIGNATORIES

Signatories agree to voluntarily implement the occupational exposure limit values proposed by SCOEL and adopted by the ACHS, namely **0.3 ppm for the 8 hour TWA OEL and 0.6 ppm for the STEL OEL**.

In addition, **signatories commit to collect available data resulting from the implementation of national requirements or, if national provisions do not exist, to perform a quantitative assessment** of workplace exposure in all affected plants and to report the results to Formacare (the reporting template is included as Annex 2). The frequency of the reassessment is determined according to national requirements Notwithstanding, it should be carried out in the event of significant changes in the manufacturing process, which may have an impact on exposure levels.

Depending to the results of the assessment, **signatories agree to set up an action plan for improving worker prevention and protection**.

Members are committed to **sharing best available technical know-how** with other members that may face difficulties in improving and reaching the lower OEL in their production plants. This technical assistance commitment is intended to ensure that all Formacare members will be able to fulfil the new, low OEL, within the shortest possible time.

It is expected that each Formacare member representative will voluntarily sign the Agreement.

5. IMPORTANT DEFINITIONS

ACHS: Advisory Committee on Health and Safety

BOEL: Binding Occupational Exposure Level, in the framework of the Agreement it refers to future values which shall be included in Annex III of CMD and transposed at national level

CMD: Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version), incorporating all amendments during the duration of this Agreement.

DNELs: Derived No-Effect Levels

[2] https://echa.europa.eu/documents/10162/23036412/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641

EN689: European Standard of the European Committee for Standardization (CEN) - Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values

OEL: Occupational Exposure Limit, in the framework of the Agreement it refers to value proposed by SCOEL and endorsed by ACHS

OSH framework directive: Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), incorporating all amendments during the duration of this Agreement.

REACH: Regulation (EC) No 1907/2006 of the Eureopan Parliemant 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, incorporating all amendments during the duration of this Agreement.

RMM: Risk Management Measures

SCOEL: Scientific Committee on Occupational Exposure Limit)

SDS: Safety Data Sheet

Similar Exposure Group (SEG): Group of workers having the same general exposure profile for the chemical agent(s) being studied because of the similarity and frequency of the tasks performed, the materials and processes with which they work, and the similarity of the way they perform the tasks

Stationary measurement: fixed point measurements for mapping the facilities

STEL: Short term Exposure Limit

8-hour TWA: 8 hours Time Weighted Average

6. RISK ASSESSMENT PROCESS

By signing this Agreement, each signatory undertakes to follow each step of the following risk assessment process. In several member states these steps are already standard and in accordance with national requirements:

1. Inform the workers' council or the ombudsman and the Hygiene, Health and Safety Committee about the Agreement
2. Refer to OELs proposed by SCOEL reflecting the hazard of formaldehyde
3. Define activities and areas subject to assessment
4. Define and carry out measurement campaigns at workplace according to national provisions or the EN689
5. Implement an action plan, if necessary
6. Update the risk assessment, if necessary
7. Document exposure data and risk assessment
8. Report at the appropriate level

The philosophy of the voluntary Agreement is to rely on national provisions as several member states already adopted OELs at least equal to the SCOEL recommendation and/or measurement strategies. For countries not having already implemented such an approach, it is recommended to refer to the EN689 (prEN689).

6.1. Inform workers and Hygiene, Health and Safety Committee

Before initiating any risk assessment activities leading to measurement campaigns resulting from the implementation of this Agreement, it is recommended to inform workers and the Hygiene, Health and Safety Committee and, if relevant, workers' representatives.

6.2. Refer to OELs proposed by SCOEL reflecting the hazard of formaldehyde

As explained in the introduction to this Agreement, Formacare decided to launch proactively a voluntary Agreement for implementing the proposed SCOEL values.

Consequently the following Occupational Exposure Limit Values shall be the reference values for the purpose of this Agreement:

- **8-hour TWA: 0.3 ppm (0.369 mg/m^3)**
- **STEL: 0.6 ppm (0.738 mg/m^3)**
- **BLV: - Additional categorisation: SCOEL carcinogen group C (genotoxic carcinogen with a mode-of action** based threshold)

6.3. Define activities and areas subject to assessment

During the manufacturing and downstream uses of formaldehyde, the substance can potentially be released and workplace concentrations of formaldehyde may exceed the new OELs. The present Agreement covers all workplaces where workers can be exposed to formaldehyde during the production, downstream uses of the substance as such, and in mixtures and process emitted releases.

Usually, **activities and areas subject to assessment have already been determined according to national provisions**. Nevertheless, in the absence of national regulations or recommendations, the following approach is suggested to signatories.

The first step, before any measurements, includes the reassessment of available measurement results and the performance of a **qualitative assessment** in order to collect relevant information on exposure determinants and available information on exposure in dedicated workplaces - considering both tasks and functions and exposed areas. This also includes information on variation of exposure depending on the time of day, and the season of the year, in order to get representative measurements.

If the qualitative assessment shows that exposure is probably higher than the OELs, **it is then recommended to reduce exposure by** RMM before planning measurements for compliance testing.

6.4. Define and carrying out measurement campaigns at workplace

Measurement results are already generated according to the implementation of national provisions. For the purpose of the Agreement, signatories are authorized to reuse existing data to comply with this Agreement.

However these results should be reassessed referring to the SCOEL OELs. Signatories are entitled to reuse existing data provided they have been generated within 2 years before entry

into force of the Agreement and only in case no significant changes impacting exposure levels have occurred.

Further measurement campaigns will be performed according to the frequency determined at national level Results will be analysed according to national provisions (to comply with national regulation) and to SCOEL OELs.

In the absence of national provisions, signatories agree to perform workplace quantitative assessment to assess compliance to the OELs. The following approach takes into account EN689.

It is expected to perform an **initial quantitative assessment** covering all exposed functions and tasks, regardless of the expected concentrations in the workplace. Existing measurements results occurring from voluntary initiatives can be taken into account if they follow a compatible approach.

Depending on the characteristics of the work organisation and existing practices, two distinct approaches are available:

1) Assessment based on personnel monitoring and Similar Exposure Groups (SEG), subject to technical feasibility
2) Assessment based on stationary measurements and defined exposure level areas

Personnel monitoring is the preferred approach. Due to spatial variability of chemical air concentrations, stationary samples are generally less representative of worker exposure. Nevertheless, in some cases, stationary measurements can be performed requiring an additional calculation to derive individual exposure which can be compared to limit values.

Sampling and analytical techniques shall be in accordance with standards or national recommended methods. Sensitivity, specificity, capacity of samplers, transportation and stability of the sample shall be particularly checked (see EN 482).

There are no accredited rules to perform stationary measurements. However, methods as described below are preferred .

The limits of quantification shall be sufficiently low to enable comparison with OEL.

The sampling can be either active or passive.

The recommended method must provide the determination of Formaldehyde in ambient air using an adsorbent DNPH coated cartridge followed by High Performance Liquid Chromatography (HPLC); (e.g. NIOSH methods or equivalent).

A best practice document has been developed by Formacare to guide companies and can be accessed at the following link:
http://www.formacare.org/wp-content/uploads/2014/09/AM-01-Determination-of-volatile-aldehydes-in-ambient-air-180614.pdf

6.5. Implement an action plan

Signatories should comply with the hierarchy principle presented in annex 1.
The action plan can include one or all of the following improvements:

- level of containment of facilities and/or equipment,
- capture of canalized emissions
- control of fugitive emissions
- general ventilation
- efficiency of local exhaust ventilation
- work organisation to reduce duration of exposure
- training and information of workers and their representative
- selection, storage and maintenance of PPE and training of workers

6.6. Update the risk assessment

Periodic reassessment will depend on national requirement and the exposure to concentrations levels, compared to OELs. Members should focus their periodic assessment on tasks, functions, areas where the workplace concentrations exceed the OELs or where such levels are close to them.

It is expected that members will undertake a yearly reassessment unless signatories declare that no significant change impacting the exposure level has occurred.

6.7. Communication of results

Aggregate results should be communicated to workers, their representatives and to the health and safety plant committee according to applicable laws and practices. Individual and nominative results do not have to be reported to workers or their representatives. Nominative results should only be communicated to workers individually by the plant management or the occupational physician in full compliance with national regulations.

6.8. Documentation

Measurement campaigns, irrespective of the measurement methods, should systematically be summarized in measuring reports, which should include, in particular, details of workplace and production conditions, results by SEG or task, as the case may be.

Results of measurement campaigns and R&D / literature search regarding formaldehyde substitution should be made available in case of inspection by enforcement authorities.

7. REPORTING AND COMMUNICATION OF RESULTS

7.1. Reporting to Formacare

The final results of each company will be collected, aggregated and then transferred on a yearly basis to Formacare for consolidation, further analysis and communication. The name

and location of each member's plants will not be communicated to Formacare. Details on the reporting to Formacare are shown in Annex 2.

7.2. Evaluation of the results by Formacare

Formacare is in charge of collecting the results from each member company. Formacare commits that the company results will be managed confidentially. This means that the results of any analyses to be performed by Formacare and any subsequent communication on the results will be appropriately anonymized (using averages/means, aggregate comparisons against the OEL benchmarks, overall trends, and industry-wide indicators) so as to ensure that recipients of Formacare communications will not be able to identify the individual members, their plants and locations. Such anonymization is necessary in order to ensure compliance with applicable laws, including EU competition law.

The various analyses will be performed by Formacare and recorded and anonymized in an annual European report. The full European report will be drawn up and circulated by Formacare to the attention of its members, while a simplified version of the report will be prepared and made available for communication to EU regulators and third parties.

7.3. Communication of results by Formacare

Formacare is solely responsible for any external communication of the European report to EU regulators and third parties. Any external communication and messages on the results contained in the European report should be pre-approved by Formacare, its Executive Committee and Cefic to ensure compliance with applicable laws, including European competition law.

8. BEST PRACTICES

Depending of the type of use, best practices may differ. Each use sector shall define the best RMM and best available practices and organize best practices exchanges on a yearly basis.

9. VOLUNTARY AGREEMENT GOVERNANCE

9.1. Governance Committee

A dedicated committee is set up within Formacare. It involves Company member representatives, Formacare's general manager and observers (e.g. European trade unions representatives and others relevant stakeholders). The committee shall meet once a year and assess the measurement campaigns and outside communication. It is chaired by the Formacare General Manager or a member Company Representative. Minutes ilwl be taken on this meeting. Decision making processes will follow usual Formacare rules.

The Committee shall:

- ✓ ensure the propper implementation of the Agreement
- ✓ provide solutions when issues are identified

- ✓ analyse measurement campaigns (only after consolidation and anonymization by Formacare staff)
- ✓ approve the annual European report providing an overview of the relevant data and analyses, as set forth in Article 7, and making recommendations, if necessary, to Formacare staff
- ✓ approve the communication of the simplified annual European report to stakeholders, national and EU regulatory authorities

10. DURATION OF THE AGREEMENT

This Agreement is established for four years or until the EU BOEL enters into force. Six months prior to the end of the Agreement, an assessment of the Agreement will be performed by Formacare and will be presented to the Governance Committee.

11. MISCELLANEOUS

This Agreement is without prejudice to an employer's obligation to comply with national and EU law in the area of workers health and safety. In so far as National Practices in force are shown to be more stringent than the requirements under this Agreement, the Employers and Employees shall adhere to and comply with these National Practices.

14. ANNEX 1: HIERARCHY PRINCIPLE

Since 1st (first) of January 2016, **formaldehyde is classified as a carcinogen 1B** according to CLP criteria and is included in the Annex VI.

According to the CMD, wherever a carcinogen is used, the employer shall apply all the following measures:

a) Substitution (at this time, there is no technical alternative to formaldehyde in most of uses)
b) limitation of the quantities at the workplace;
c) keeping the number of workers exposed or likely to be exposed at the lowest possible level;
d) design work processes and engineering control measures so as to avoid or minimise releases in the workplace;
e) evacuation at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
f) use of existing appropriate procedures for the measurement, in particular for the early detection of abnormal exposure resulting from an unforeseeable event or an accident;
g) application of suitable working procedures and methods;
h) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
i) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
j) information for workers;
k) demarcation of risk areas and use of adequate warning and safety signs including "no smoking" signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;
l) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
m) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;
n) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

15. ANNEXE 2: TEMPLATE FOR REPORTING TO FORMACARE

Name of the person reporting:
Email of the person:
Company name:
Location of the plant (country):
Type of production (FA, Para, POM, Penta, UF, MF,…):
Date of most recent analysis:
Date of previous analysis:
Norm of methology (e.g. OSHA):
Measuring principle (e.g. DNPH certified):

Report	*Formaldehyde OELs of all EU member states within Formacare membe*
Year of evaluation	2017
Date of issue:	15 December 2018
Issued by:	Jonathan Crozier
Approved by:	By the Excom of Formacare / Governance Committee

- Percentage of employees not exposed (no measurements needed)

- Number of employees/workers exposed:
  - 0.05 ppm +/- 0.025:
  - 0.1 ppm +/- 0.025:
  - 0.15 ppm +/- 0.025:
  - 0.2 ppm +/- 0.025:
  - 0.25 ppm +/- 0.025:
  - 0.3 ppm +/- 0.025:
  - 0.4 ppm + 0.05 / - 0.07
  - 0.5 ppm +/- 0.05:
  - 0.6 ppm +/- 0.05:
  - > 0.65 ppm:

16. ANNEXE 3: TEMPLATE FOR THE EXTERNAL REPORTING:

1. Descriptions of the methodology for OELs

The Formacare member companies in 18 EU member states follow their national regulations and

the results are regularly checked by the national competent authorities.

The technique in all these EU member states is very similar and is described below:

1. A committee identifies the workplaces with exposure to formaldehyde that needs to be measured.
2. The committee members consist of the plant manager, hygiene department, and members of the workers' council.
3. The measurement is done with personal air samplers by an internal or external department/institute with a national accreditation.
4. The OEL reports and results are communicated to the workers and stored safely in the HR departments for at least 10 years.

Proposal: OEL reporting structure

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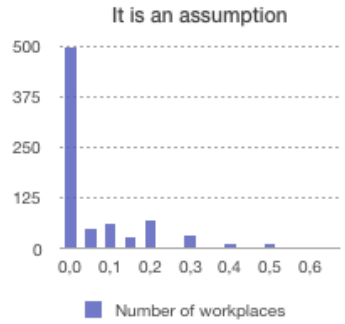
2. Combined Results

The histogram shows the results for the combined 18 EU member states, where Formacare members are producing.

70 to 85% of the workplaces are not exposed at all or to a negligible level. Due to the different national OEL limits some of the values are slightly above the voluntary OEL level of 0,3 ppm and STEL of 0,6 ppm. But from January 2018 theses few workplaces will be within due to an open knowledge transfer within Formacare.



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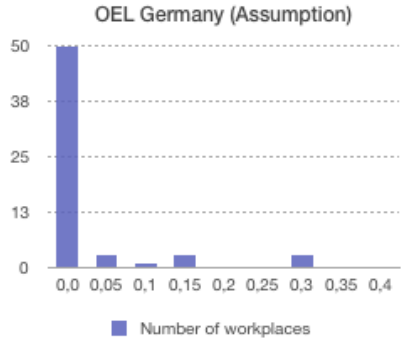
Proposal: OEL reporting structure

- The results of the individual EU member states

e.g.

4. Germany

The reports of all 10(?) member companies fulfill the national and voluntary limits. 80 to 85% of the workplaces are not exposed at all or to a negligible level.



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