**Draft Project plan for the CEN Workshop on "Absorbent hygiene products – Test method for analyzing trace chemicals"**

**Requests to participate in the Workshop and/or comments on the project plan are to be submitted by**

**2023-03-21 to annett.mueller@din.de[[1]](#footnote-2)**

Recipients of this project plan are kindly requested to name all patent rights known to them to be relevant to the Workshop and to make available all supporting documents.

**Berlin, 2023-01-19 (Version 1)**

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Summary

Following publications in consumer magazines, the topic of chemical safety of absorbent hygiene products (AHPs) like baby diapers, has got a lot of attention throughout the last 6 years. The discussion focuses on the toxicological effects of substances that are potentially present.

However, for an adequate assessment of these effects, it is important to base the toxicological assessment on reliable test results. Such a method was not available at the time.

The industry has made an effort to develop a test method to assess the potential presence of trace chemicals in AHPs. The aim of the CWA is to review the method with other stakeholders, and make it accessible to all interested parties.

# Status of the project plan

**Draft project plan** for public commenting (Version 1.0)

This draft project plan is intended to inform the public of a new Workshop. Any interested party can take part in this Workshop and/or comment on this draft project plan. Please send any requests to participate or comments by e-mail to **annett.mueller@din.de**.

All those who have applied for participation or have commented on the project plan by the deadline will be invited to the kick-off meeting of the Workshop on **2023-03-28**.

# Workshop proposer and Workshop participants

## Workshop proposer

|  |  |
| --- | --- |
| **Person or organisation** | **Short description and interest in the subject** |
| EDANA | EDANA is the leading trade association for the nonwovens and related industries. This includes the absorbent hygiene products (AHP) industry. EDANA represents a large part of the AHP manufacturers in greater Europe, including the global leaders. |

## Other potential participants

This CWA will be developed in a Workshop (temporary body) that is open to any interested party. The participation of other experts would be helpful and is desired. It is recommended that:

* industry, manufacturers of absorbent hygiene products,
* commercial laboratories involved in consumer product testing,
* institutions working on consumer product safety,
* consumer organisations

take part in the development of this CWA.

## Participants at the kick-off meeting

The following persons or organisations already signed up to the kick-off meeting prior to the publication of the draft project plan.

| **Person** | **Organisation** |
| --- | --- |
| Marines Lagemaat | EDANA |
| Marta Roche Diez | EDANA |
| Dr. Eckard Jantzen | GALAB Laboratories GmbH |
| Annett Müller | The DIN German Standardization Institute, DIN - Standards Committee Medicine (NAMed) |

## Registered Workshop participants

*((List all participants at the kick-off meeting who have adopted the project plan here or as Annex. Participants are not named as Workshop participants until the project plan has been adopted.))*

The following persons or organisations have registered as Workshop participants at the kick-off meeting and will actively participate in the development of the CWA.

|  |  |
| --- | --- |
| **Person** | **Organisation** |
| Workshop Chair | Workshop Chair |
| Workshop Vice-Chair | Workshop Vice-Chair |
|  |  |
|  |  |
| Workshop secretariat: Annett Müller | Workshop secretariat: DIN |

# Workshop objectives and scope

## Background

For the last six years there has been a recurring debate in Europe on the trace chemicals found in absorbent hygiene products (AHPs). This debate was triggered by articles on this topic published in consumer magazines which raised questions on the safety of AHPs, and led to a so-called restriction proposal for the European Chemical Agency (ECHA) to restrict the use of chemicals in absorbent hygiene products. The process concluded in 2022, and while it found that the risks could not be demonstrated, it did conclude that there is a strong need for a harmonized analytical method that delivers robust and accurate test results.

In 2018, EDANA members started working on such a method, as part of the [EDANA Stewardship programme](https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products) on Absorbent Hygiene Products (AHPs). At the heart of the programme lies the CODEX™, which contains a list of agreed substances, and sets the limiting values and test methods that were developed for these substances.

The first version of the method was released in 2020 and focused on baby diapers. In 2022 it was expanded to include menstrual products. In order to make this method available to stakeholders outside the industry, EDANA is striving to develop and produce a CEN workshop agreement (CWA). This will also provide the opportunity for other stakeholders to review and revise the method where needed.

The objective of the workshop is to publish a test method suitable for assessing the potential presence of trace chemicals in absorbent hygiene products. This method is needed as methods that haven’t been devised for this purpose, may end up with unreliable results that confuse the wider discussion. The planned CEN Workshop Agreement is intended to be used by manufacturers of absorbent hygiene products, authorities, retailers and other stakeholders, as NGO’s and consumer organizations. The focus will be on establishing a unified test method.

## Scope

The planned CEN Workshop specifies a test method to analyze the potential presence of trace chemicals, that are of interest for authorities, stakeholders and for the manufacturers.

The CEN Workshop is not intended to describe product safety requirements. Limit values of trace chemicals are not defined in the CEN Workshop Agreement.

## Related activities

The subject of the planned CWA is not at present the subject of a standard. However, there are committees, standards and/or other technical specifications that deal with related subjects and thus need to be taken into account and involved, where necessary during this Workshop:

* ISO/TC 38/WG 9 (Nonwoven);
* ISO/TC 338 (menstrual products).

# Workshop programme

## General

The kick-off meeting is planned to take place on 28 March 2023 in Berlin at DIN. A draft for public commenting will be published for 60 days.

A total of 5 Workshop meetings (kick-off meeting and Workshop meetings) and web conferences will be held, during which the content of the CWA will be presented, discussed and approved.

The CWA will be drawn up in **English** (language of meetings, minutes, etc.). The CWA will be written in **English**.

## Workshop schedule

The following project schedule is for orientation only and is to be modified as the Workshop progresses. The amount and the duration of the various Workshop phases are particularly dependent on the requirements and wishes of the Workshop proposer.

Table 1: Workshop schedule (preliminary)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CEN/CENELEC Workshop** | **M01** | | | | **M02** | | | | **M03** | | | | **M04** | | | | **M05** | | | | **M06** | | | | **M07** | | | | **M08** | | | | **M09** | | | | **M10** | | | | **M11** | | | | **M12** | | | | **…** |
| **Initiation** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Proposal form submission and TC response |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2. Project plan development |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3. Open commenting period on draft project plan (mandatory) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Operation** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4. Kick-off meeting |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 5. CWA(s) development |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 6. Open commenting period on draft CWA(s) (optional) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7. CWA(s) finalised and approved by Workshop participants |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Publication** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8. CWA(s) publication |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Dissemination (see 7)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Milestones** |  |  |  |  |  |  |  |  |  |  | **K** |  |  |  | **V** |  |  |  | **V** |  |  |  | **V** |  |  |  |  |  |  |  |  |  |  |  |  |  | **M/A** |  |  |  |  |  | **P** | **D** |  |  |  |  |  |

**B** CEN/CENELEC BT meeting deciding on establishment of a CEN/CENELEC Workshop

**K** Kick-off

**M** Workshop meeting

**V** Virtual Workshop meeting

**A** Adoption of CWA

**P** Publication of CWA

**D** Online distribution of CWA

## Work already delivered

As stated above EDANA started developing the test method as an industry initiative, resulting in a method with the industry reference NWSP 360 ‘Determination of trace chemicals extracted from absorbent hygiene products (AHPs) using simulated urine/menses Part 1: Milling of AHPs to produce a homogenized sample; Part 2: Extraction of trace chemicals from homogenized AHPs into a simulated urine/menses solution; and Part 3: Analysis of trace chemicals in aqueous extracts (biological fluid simulants) of AHPs’.

This test method has been in used since 2020, and is the starting point for the CWA.

# Resource planning

All costs related to the participation of interested parties in the Workshop’s activities have to be borne by themselves. Each member of the consortium bears its own expenses incurred within the framework of the project.

If the Chairman of the Management Board of DIN approves the implementation of the project, the initiator concludes a contract with DIN.

The membership in the consortium and the participation in the project meetings is free of charge, since the costs incurred by DIN due to the implementation of the project are financed by EDANA.

# Workshop structure and rules of cooperation

## Participation in the Workshop

The Workshop will be constituted during the course of the kick-off meeting. By approving this project plan, the interested parties declare their willingness to participate in the Workshop and will be formally named as Workshop participants, with the associated rights and duties. Participants at the kick-off meeting who do not approve the project plan are not given the status of a Workshop participant and are thus excluded from further decisions made during the kick-off meeting and from any other decisions regarding the Workshop.

As a rule, the request to participate in the Workshop is closed once it is constituted. The current Workshop participants shall decide whether any additional members will be accepted or not.

Any new participant in the Workshop at a later date is decided on by the participants making up the Workshop at that time. It is particularly important to consider these aspects:

1. the expansion would not result in the Workshop taking longer to complete;
2. the new Workshop participant would not address any new or complementary issues beyond the scope defined and approved in the project plan;
3. the new Workshop participant would bring complementary expertise into the Workshop in order to incorporate the latest scientific findings and state-of-the-art knowledge;
4. the new Workshop participant would actively participate in the drafting of the manuscript by submitting concrete, not abstract, proposals and contributions;
5. the new Workshop participant would ensure wider application of the CWA.

All Workshop participants who voted for the publication of the CWA or its draft will be named as authors in the European Foreword, including the organisations which they represent. All Workshop participants who voted against the publication of the CWA, or who have abstained, will not be named in the European Foreword.

## Workshop responsibilities

The Workshop Chair is responsible for content management and any decision-making and voting procedures. The Workshop Chair is supported by the Workshop Vice-Chair and the responsible Workshop secretariat, whereby the Workshop secretariat will always remain neutral regarding the content of the CWA(s). Furthermore, the Workshop secretariat shall ensure that CEN-CENELEC's rules of procedure, rules of presentation, and the principles governing the publication of CWA(s) have been observed. Should a Workshop Chair no longer be able to carry out her/his duties, the Workshop secretariat shall initiate the election of a new Workshop Chair. The list below covers the main tasks of the Workshop Chair. It is not intended to be exhaustive.

* Content related contact point for the Workshop
* Presides at Workshop meetings
* Ensures that the development of the CWA respects the principles and content of the adopted project plan
* Manages the consensus building process, decides when the Workshop participants have reached agreement on the final CWA, on the basis of the comments received
* Ensures due information exchange with the Workshop secretariat
* Represents the Workshop and its results to exterior

The Workshop secretariat, provided by a CEN/CENELEC national member, is responsible for organising and leading the kick-off meeting, in consultation with the Workshop proposer. Further Workshop meetings and/or web conferences shall be organised by the Workshop secretariat in consultation with the Workshop Chair. The list below covers the main tasks of the Workshop secretariat. It is not intended to be exhaustive.

* Administrative and organisational contact point for the Workshop
* Ensures that the development of the CWA respects the principles and content of the adopted project plan and of the requirements of the CEN-CENELEC Guide 29
* Formally registers Workshop participants and maintains record of participating organisations and individuals
* Offers infrastructure and manage documents and their distribution through an electronic platform
* Prepares agenda and distribute information on meetings and meeting minutes as well as follow-up actions of the Workshop
* Initiates and manage CWA approval process upon decision by the Workshop Chair
* Interface with CEN-CENELEC Management Centre (CCMC) and Workshop Chair regarding strategic directions, problems arising, and external relationships
* Advises on CEN-CENELEC rules and bring any major problems encountered (if any) in the development of the CWA to the attention of CEN-CENELEC Management Centre (CCMC)
* Administrates the connection with relevant CEN or CENELEC/TCs

## Decision making process

Each Workshop participant is entitled to vote and has one vote. If an organisation sends several experts to the Workshop, that organisation has only one vote, regardless of how many Workshop participants it sends. Transferring voting rights to other Workshop participants is not permitted. During voting procedures, decisions are passed by simple majority; abstentions do not count.

If Workshop participants cannot be present in the meetings when the CWA or its draft is adopted, an alternative means of including them in the voting procedure shall be used.

# Dissemination and participation strategy

# Contacts

* Workshop Chair:

**<name>**

**<Organisation>**

**<address>**

**<tel>**

**<fax>**

**<e-mail>**

**<web>**

* Workshop Vice-Chair:

**<name>**

**<Organisation>**

**<address>**

**<tel>**

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* Workshop Secretariat:

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1. Applications for participating in the Workshop and comments on the project plan that are not received by the deadline do not need to be taken into consideration. Once constituted, the Workshop will decide whether or not to consider the comments received in good time. [↑](#footnote-ref-2)