EDANA Stewardship Program for Absorbent Hygiene Products (AHPs) Safety

Test method for detection of trace chemicals, guidance values, and exposure-based risk assessment

A. Introduction

Single-use absorbent hygiene products (AHPs)—such as diapers and menstrual products—play a vital role in supporting quality of life for millions of people. Absorbent hygiene products manufacturers ensure that all products comply with all relevant regulations and are safe for their intended and foreseeable use.

Absorbent hygiene products and their raw materials are mainly produced from natural and/or synthetic polymers. While the intentional ingredients of AHPs are generally well understood and safe, the potential unintentional presence of trace chemicals might raise perceived safety concerns. Heavy metals are ubiquitous in nature and can be present in bio-based materials such as cotton or rayon due to their presence in soil and water. As such, they are also part of our daily life and intake via food, and some are essential nutrients (e.g. zinc, copper).

Regulators and manufacturers alike strive to reduce the levels of such traces to as low as reasonably achievable levels. This is why raw materials are selected according to strict quality criteria and during manufacture, rigorous quality control systems and good manufacturing practices are in place to ensure the highest hygienic standards are met.

In this context, the European Disposables and Nonwoven Association (EDANA) set out in 2020 the Stewardship Program to self-regulate substances possibly present at trace level in some AHPs, using scientific and standardized methodologies, and to demonstrate industry's willingness to go voluntarily beyond existing product legislation. The Stewardship Program ("CODEX") applies a standardized methodology to monitor trace impurities in AHPs and provides both

1) A harmonized test method - CEN CWA (Workshop Agreement) 18062[1]

This test method is used for consumer relevant assessment of exposure to unintentional presence of substances. This method is the result of a long-lasting collaboration between EDANA and CEN (the European Committee for Standardization) and has been recognized by the European Commission (Petition No 1331/2023 and Answer to parliamentary question E-001083/2025[2] (ASW)) as a harmonized analytical method for assessing the potential presence of trace chemicals in AHPs and "*useful for manufacturers as well as market surveillance authorities to test their safety*". The European Commission furthermore stated that "*CEN CWA can be used to assess the safety of consumer products under the GPSR, in line with Article 8 of the GPSR.*"

2) CODEX Guidance values for a defined list of substances[3]:

Dioxin and Dioxin-like Furans and Polychlorinated Biphenyls	2 ng/kg sum TEQ of the detected congeners
PAHs	0.2mg/kg

[1] https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:78414,3235264&cs=12D27C0D8FC7D89DE017D8E491055FACE

[2] https://www.europarl.europa.eu/doceo/document/E-10-2025-001083-ASW_EN.html

[3] The list of individual CAS numbers is available at codex stewardship program AHP May2025.pdf

Phenols	10 mg/kg
Phthalates	50 mg/kg
Pesticides	0.5 mg/kg
Organotins	2/10 µg/kg
Formaldehyde	16 mg/kg
Antimony (CAS 7440-36-0)	<30 mg/kg
Cadmium (CAS 7440-43-9)	<0.10 mg/kg
Chromium (CAS 7440-47-3)	<1.0 mg/kg
Lead (CAS 7439-92-1)	<0.20 mg/kg
Mercury (CAS 7439-97-6)	<0.020 mg/kg

The guidance values are reflective of the current regulatory landscape and are derived from existing related product regulations, guidance or standards.
The CEN CWA 18062 test method (referred to above) analytical approach is intentionally conservative and any detection of substances below the guidance values only indicates the mere presence of certain trace chemicals in a complex product like an AHP. Importantly, detection of trace chemicals below the guidance values is neither indicative of any risk of causing harm to consumers when using the product, nor indicative of any risk of causing environmental harm or disturbances. To determine whether any such risk could exist requires an exposure-based risk assessment (EBRA). In fact, even exceeding the CODEX guidance values does not necessarily mean the products are objectively unsafe.

B. Exposure Based Risk Assessment of AHPs

Before EDANA members release AHPs onto the market, the composition and safety of all raw materials are reviewed, taking into account potential toxicity to the consumer and the environment. Addressing this requires a robust toxicological framework that integrates hazard identification, exposure assessment, and risk evaluation for both intentionally added and unintentional substances. EDANA members also carry out post-marketing surveillance of their products in which they actively respond to consumer comments to ensure continuously the quality and safety of their products.
The toxicological assessment referred to above integrates hazard (= potential of doing harm) and exposure (= the condition under which the harm could occur) to determine the risk (= likelihood of harm). This starts with a robust understanding of the product's composition, either through testing and/or through investigation deep within the supply chain, and the product's actual use. Test results based on the CEN CWA 18062 analytical test method represent the detected level of as substance that is extractable from the AHP under experimental conditions and are relevant information for the toxicologist.
To assess whether the detected concentration of a substance of interest carries any risk from a consumer safety perspective, toxicologists conduct an exposure-based risk assessment (EBRA) following the principles established by the World Health Organization, the United States National Academy of Sciences, and the United States Environmental Protection Agency. These principles are also recognized under EU regulatory frameworks such as REACH and the Cosmetics Regulation, and EU scientific agencies such as SCCS (Scientific Committee for Consumer Safety, *inter alia* responsible for cosmetics) and SCHER (Scientific Committee for Health and Environmental Risk) carry out exposure-based risk assessments in support of their mandates. EBRA is based on appropriate, conservative parameters for product usage (including duration and frequency of use), transfer to

skin/mucosa, absorption through skin/mucosa, etc. EDANA has described conservative exposure parameters for absorbent hygiene products, incl for tampons, that can be used as inputs into the EBRA. AHP manufacturers can then compare the values in the EBRA to established limits, such as tolerable daily intake levels, to ensure the product can be used without risk of causing harm of adverse health effects.

C. Summary

EDANA and their industry members have implemented a conservative, voluntary standard to ensure that potentially present trace chemicals in AHP products which might be perceived as a safety concern by consumers are not exceeding the conservative CODEX guidance values. These guidance values are reflective of the current regulatory landscape including those of neighbouring sectors such as textile and toys, acknowledged standards etc. Further, EDANA has developed and validated an analytical test method - CEN CWA 18062 – that establishes a robust, standardized, consumer relevant approach for detecting and quantifying these trace chemicals in AHPs. State of the art exposure-based risk assessment (EBRA) parameters have been defined that are appropriate for the product use which will result in relevant risk assessments. With this, industry proactively assures consumer and confirms that AHP products continue to be safe for consumers, in particular those tested to not exceed the CODEX Guidance Values.