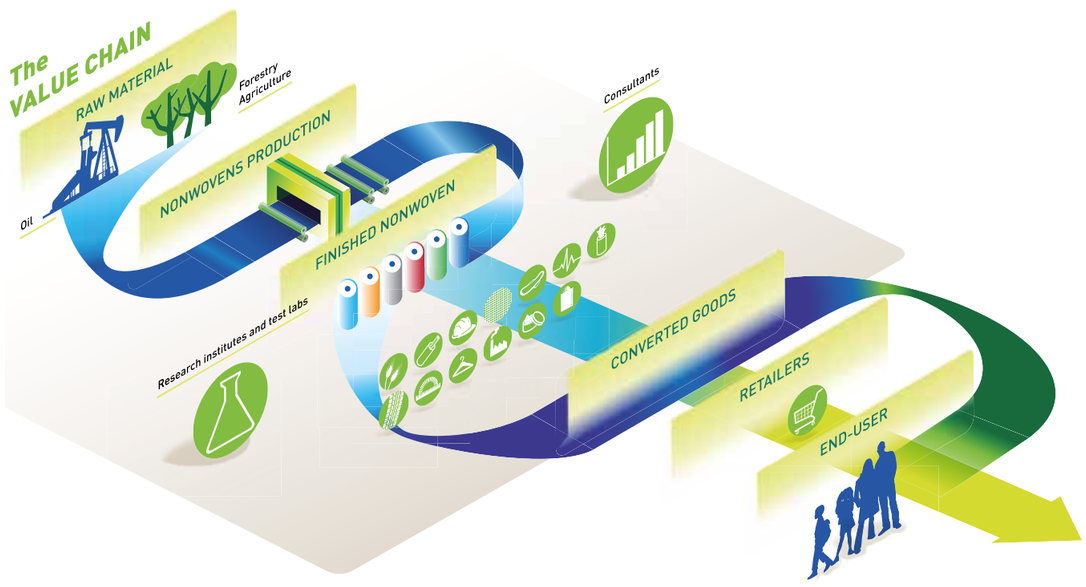
Principles for the Risk Assessment of Trace Substances in Absorbent Hygiene Products (AHP)

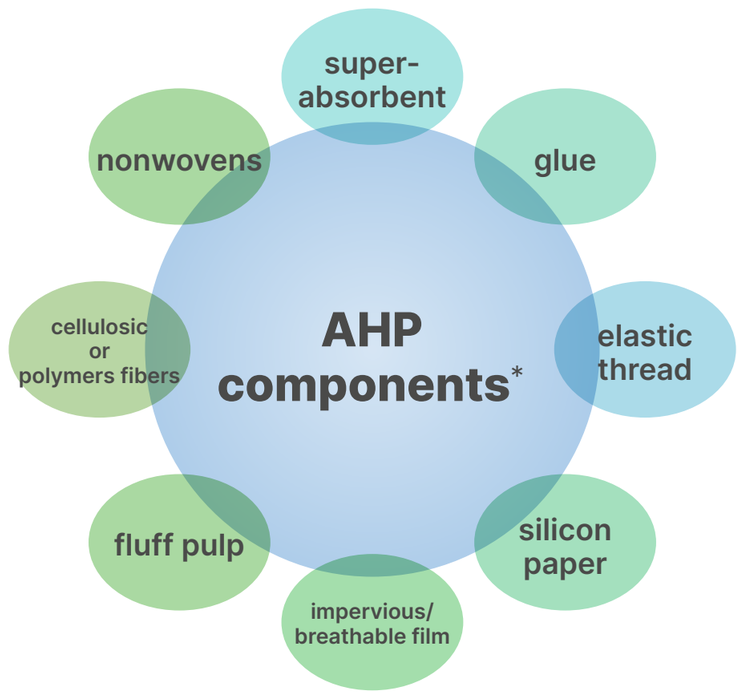
EDANA represents the vast majority of suppliers and manufacturers of AHPs covering a large market share of branded and private label products in Europe, Middle East and Africa.

ABSTRACT:

AHP safety requirements are covered by general ('horizontal') EU legislation applicable to multiple consumer goods[1, 2, 3]. Any approach to manage and control traces of chemicals that may potentially be found in very low amounts (e.g., ppm, ppb range) in AHPs should be based on applicable regulatory requirements and safety considerations. The EDANA Stewardship Program[4] for AHPs is a further supplement to monitor potentially present traces of chemicals. It is a voluntary industry initiative to provide transparency and reassurance for consumers regarding trace levels of impurities found in AHPs. Signatories of the program monitor the presence of a defined list of trace chemicals in AHPs.

Here, we present key requirements for traces management covering the detection and quantification of trace chemicals as well as the risk characterization linked to maximum acceptable exposure levels /safe limit concentrations.





*components made from precursors with own production chain

ORIGIN OF TRACE SUBSTANCES (PPM/PPB):

Traces substances are Not intentionally added substances (NIAS):
NIAS may be present, but not added for technical reasons,
have no function in the product. Traces may come from:

- anthropogenic pollutants: e.g. agriculture/forestry
- industry processes: e.g. catalysts, unreacted monomers, process aids
- naturally present in the environment

Trace substances can be divided into:

- Impurities – unintended constituents in a material emanating from production processes
- Contaminants – unintended substances with origin from sources outside the production process, e.g., storage, transportation, ubiquitous in the environment

TRACE SUBSTANCES MANAGEMENT ⇒ SAFE USE OF AHPs

Key aspects:

- Collaboration with raw material suppliers to:
  - monitor detailed raw material composition
  - understand source and nature of raw materials
  - QA of manufacturing process
  - assess likelihood of contamination for process aids
- Compliance with legislation (e.g., REACH Regulation[2])
- Test of raw materials via state-of-the-art analytical methods (as detailed in the EDANA Supply Chain information Guideline[5] for AHPs) for selected trace chemicals
- Test of finished products (using e.g., CEN CWA 18062 test method[7])
- Exposure based risk assessment (EBRA) to assure safe use of products

RISK ASSESSMENT OF TRACE SUBSTANCES

- Increasing sensitivity of analytical methods will lead to detection of traces in extremely low concentrations.
- Since detection is not the same as risk, a careful Exposure Based Risk Assessment (EBRA) is needed for the risk assessment. An EBRA should be grounded in a realistic assessment of exposure to the trace chemical.
- For AHP, detection and quantification of trace substances should be based on methods simulating extraction/ transport of substances by physiological fluids (salt solutions, synthetic urine etc.) from the product to the user. Organic solvents not recommended as they do not reflect real use conditions.
- Exposure calculation should be based on product usage data (e.g., product weight, products used per day and weight of product user) – often performed using generic usage data initially. If needed to refine data, a tiered approach is used.
- Exposure level expressed as mg trace substance/kg bodyweight/day

Exposure based risk assessment, Margin of Safety (MoS) calculation:

- For the risk assessment, the exposure is compared to a safe limit value (for the substance assessed) often referred to as a Margin of Safety (MoS) calculation (=safe limit value/exposure)
- If no safe limit value exist or there are alternative approaches: tox. data from structurally related chemicals using read-across approach, SAR (Structure-Activity Relationship) combined with TTC approach (Threshold of Toxicological Concern), endorsed by EFSA/WHO

REFERENCES

1. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0095-20100101 | 2. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-202205013
3. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX %3A02012R0528-20220415 | 4. https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products
5. https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:78414,3235264&cs=12D27C0D8FC7D89DE017D8E491055FACE
6. https://www.edana.org/docs/default-source/product-stewardship/edana-safety-and-regulatory-supply-chain-info-(2022).pdf?sfvrsn=ccc83bef_2