The EDANA Stewardship Programme for Absorbent Hygiene Products

The Guidance Document
Absorbent hygiene products (AHPs) such as diapers, adult incontinence and feminine hygiene products, such as tampons and sanitary towels, help millions of Europeans, from early childhood to old age, live active and healthy lives. These products comply with all relevant EU legislation relating to chemicals and product safety.

Although present at trace levels, the chemical impurities found in AHPs are well below all regulatory limits and pose no risk to health. Nevertheless, the industry believes it is their responsibility to initiate harmonised consumer relevant testing methodologies on their amount in the final product and to pioneer science-based transparent communication to inform the public.

The main objective of the Stewardship Programme for Absorbent Hygiene Products is to reassure consumers on the safety of the products adhering to this programme. Adhering companies commit to not exceed guidance values in a defined list of substances in Absorbent Hygiene Products tested using harmonised, consumer relevant test methods.

This EDANA Stewardship Programme is open to any company manufacturing and/or placing absorbent hygiene products on the European Market, regardless of whether these companies are members of EDANA.
Section 4. The foundations

The EDANA Stewardship Programme for Absorbent Hygiene Products consists of:

1) The Stewardship Programme Charter
2) The Stewardship Programme Codex
3) A governance structure for the programme

1. The Stewardship Programme Charter

The Stewardship Programme Charter is the formal signatory document to the EDANA Stewardship Programme for Absorbent Hygiene Products. By means of the Charter, there is a commitment to continuous improvement in safeguarding the quality of absorbent hygiene products, by means of a standardised approach, strengthening cooperation throughout the value chain, engaging with stakeholders, and creating more transparency to customers.

In signing to the EDANA AHP Stewardship Programme Charter a company actively commits to:

Product

1) Participate in the development of:
   a) Recommended guidance values of trace impurities and
   b) EDANA harmonised test methods to self-assess the presence of impurities

Product Information & Communication

2) Reinforce transparency by publishing product composition to enable consumers to make informed choices

Consumer Communications

3) Take part in communication activities across the EU to further enhance consumer understanding of trace impurities.
2. The Stewardship Programme Codex

The Stewardship Programme Codex is a toolbox that enables companies to meet the Charter. It consists of 3 elements:

1) a list of chemicals potentially present as impurities at trace levels
2) guidance values, these are the levels not to be exceeded for each substance listed in the Codex
3) relevant test methods to determine the presence of substances at trace level and to check that the amount of possible trace impurities in products does not exceed the defined guidance values

The Stewardship Programme Codex is under development. Companies signing up to the Stewardship Programme Charter before the Codex is published, are committing to the further development of that Codex, followed by compliance and self-assessment of the presence of trace impurities upon publication of the Codex.

List of trace impurities

The list of trace impurities covers chemical substances that are not intentionally used to manufacture absorbent hygiene products (AHPs) but that may be present in trace amounts. Trace impurities have a long history of being tracked within the membership of EDANA and/or are subject to regulatory scrutiny, ongoing investigation by competent authorities or general consumer concern.

Chemicals or classes of chemicals involved in this industry effort include PAHs, PCBs, dioxins, furans, phthalates and formaldehyde.

Guidance values

The guidance values will not be exceeded when AHPs are investigated for the potential presence of certain chemical substances. The guidance values may evolve over time if new scientific data and insights are available or regulatory limits are updated.

The development of guidance values follows a tiered approach. The guidance values do not affect the requirement to have the necessary safety assessments for individual products to comply with the General Product Safety Directive 2001/95/EC.

Relevant test methods

The relevant test methods, corresponding to the different trace impurities, check that the presence of these impurities in a product are below the guidance values. These test methods will, once developed, be based on experimental extraction/exposure settings that are geared to real life usage conditions and address the respective sample preparation in detail. Once established, the new test methods will be added to the existing catalogue of Nonwoven Standard Procedures (NWSP) available at EDANA.

To check compliance with the Codex, AHP manufacturers are recommended to have their products tested against the newly developed, validated and endorsed NWSP method in any independent laboratory, working according to Good Laboratory Practice (GLP), who can demonstrate its ability to meet the analytical requirements described in the NWSPs.
Section 5. Governance

The Stewardship Programme will be governed by two complimentary structures:

1. The Stewardship Programme steering committee
2. The scientific review panel

Each of these structures will have its specific set of rules. Persons cannot participate in more than one governance structure, with exception for EDANA staff. Transparency is an integral part of the governance model. Therefore, EDANA will make public, via a specific website, the following elements of the Stewardship Programme:

- Stewardship Programme Charter
- Stewardship Programme Codex
- this guidance document
- register of companies signed up to the Charter

1. The Stewardship Programme Steering Committee

The overall Stewardship Programme will be governed by the Stewardship Programme Steering Committee. This Steering Committee shall consist of the following members:

a) The chair of the three following EDANA Working/Steering Groups
   a. Absorbent Hygiene Product Working Group
   b. Product Stewardship Steering Group
   c. Communications and Advocacy Steering Group
b) 1 delegate per convertor company (member of EDANA)
c) delegates representative for the suppliers
d) a member of the EDANA Board
e) General Manager of EDANA

Each person participating to the Stewardship Programme Steering Committee will represent only one potential membership. The Steering Committee will be chaired by the chairs of the aforementioned EDANA Steering Groups in an annual rotating system.

The Stewardship Programme Steering Committee will:

- meet at least 2 times/year
- take a long-term view on the challenges with respect to trace impurities
- publish the composition of the scientific review panel

Any budget requirements for the work of the Stewardship Programme Steering Committee and the scientific review panel will be defined by the Steering Committee based on benchmarks with similar structures and proposed for financing to EDANA.

The Steering Committee should take the initiative to consult with relevant stakeholders at appropriate times. This may cover, for example, advice on all elements related to the Stewardship Programme, such as purpose, governance, compliance and reporting and how the programme is perceived by other parties.
2. The scientific review panel

The scope of the mandate of the scientific review panel, which will be published online, covers the review of the content of the Stewardship Programme Codex, being

a) The list of chemicals
b) The guidance values for these chemicals
c) The test methods in order to check for the presence of these chemicals

On top of the above, the scientific review panel may advise on Exposure-Based Risk Assessment (EBRA) parameters.

Any recommendation of the scientific review panel:

- will be formulated by consensus within the scientific review panel
- will be directed to the Steering Committee

In order to assemble a scientific review panel, the following principles will be considered:

- The Steering Committee shall appoint the members of the scientific review panel by a majority vote. Appointment shall be based on scientific competence, expertise in an area relevant to trace impurities, balance of scientific disciplines with the technical panel, willingness to devote enough time to the work of the scientific review panel and the lack of any disqualifying conflict of interest
- All members shall have expertise regarding the review of trace impurities, they shall have diverse professional education and experience so that the panel reflects a balanced composition of scientific expertise in order to function as a review panel
- A panel member may be removed from membership by the Steering Committee for a substantiated reason such as (but not excluded to):
  - More than 50% absenteeism from panel meetings over the course of 2 years
  - A demonstrated conflict of interest by which the independent character is compromised
- The panel will consist of at least six up to maximum 12 members, each member having an equal vote
- The panel will meet at least twice a year, once in the first semester, and once in the second semester
- Within a delay of three months after the preformulated questions have been received by the Chair of the scientific review panel, an answer will be formulated by this panel
- Members of the scientific review panel shall serve as individuals and not as representatives of any group or organisation with which they may be affiliated

For more information contact us: www.edana.org