

Prioritization Process for the Selection of HERA Substances

HERA was established to develop risk assessments for human health and the environment for all substances used in household cleaning detergents if their properties or usage were of sufficient interest to merit completion of an assessment or if their risk was not yet assessed elsewhere. HERA is to be considered as a model of risk assessment processes but it was not designed as a response to the evolving Chemicals Policy in Europe, indeed it pre-dated the EU White Paper "Strategy for a new Chemicals Policy" on this subject. Therefore the selection or non-selection of a substance or group of substances by HERA must not be taken as endorsing any stakeholder's particular view, nor should it be used to imply support by HERA companies for or against any external agenda. Initially HERA was solely established in order to respond to public concern. However, in the light of the current EU Chemicals Policy Review it is obviously important that HERA risk assessments should be recognised in the future regulatory framework.

HERA interest in a substance may be generated for any combination of the following reasons:

- i) **high tonnage chemicals**; (This is especially relevant for an Industry characterised by chemicals used in very large quantities sold directly to consumers.)
- ii) **main or sole use is in detergents and cleaning products**; (This ensures that the targeted RA covers the majority of uses in a manner which is as convincing as possible.)
- iii) **initially, at least one substance per important function**, eg surfactants, builders, bleaches, etc; (In this way HERA ensures as representative a sample as possible of substances used in our Industry.)
- iv) **chemical selection covers a wide range of hazard profiles** (This allows us to cover a broad range of risk assessment situations and to demonstrate that HERA is not selecting only the 'easy' cases.)
- v) **chemicals on the EU Priority Lists** are included; (Even if the chemical is of low tonnage this can be relevant from a risk assessment perspective - and it is especially important that HERA is seen to assess chemicals that other stakeholders see as problematic.)
- vi) **complementarity with other programmes** eg the EU Existing Chemicals Programme, the ICCA HPV Initiative, the OECD HPV Chemicals Programme. (By this means HERA avoids duplication of effort and resources and covers the widest spectrum of substances.)
- vii) **prioritisation of substances that HERA suspects of potential issues**; (The intention is to point out the need for appropriate risk management decisions on these substances, *if risk assessment demonstrates the need*, and to provide *information on which to base communications if no significant risk is identified under our exposure scenarios.*)

Notes:

1. The order of listing criteria is not intended to indicate priority.
2. Not all substances meet all criteria.
3. One of the HERA principles is that risk assessments will be performed without any preconceived ideas of the outcome.

4. Some substances previously used as ingredients by AISE companies have already undergone risk reduction measures, including substitution, on basis of a risk assessment leading to health or environmental concerns; these have not been included in the HERA programme.
5. From the above it should be assumed that, without exception, all substances currently used by AISE companies (the formulators) are examined for their relevance as candidates for HERA assessment.

Substances with the following functions have already been examined in Phase 1 of HERA:

Antifoams
Bleach Precursors
Builders
Perfume Ingredients
Soap
Surfactants – anionic
Whiteners

The above constituted about 73% of the tonnage of laundry detergents in Europe and include over 100 CAS Numbers.

Substances for Phase 2 need to include the following additional functions, unless, for example, these are covered elsewhere in obligatory or voluntary programmes:

Anti-redeposition agents
Enzymes
Hydrotropes / Processing Aids and Thickeners
Optical Brighteners
Perfume Ingredients (cont'd)
Solvents
Fabric Softeners / Surfactants – cationic
Ion Exchangers / Zeolites (cont'd)
Surfactants – nonionic
Surfactants – amphoteric

HERA is currently committed to:

- develop risk assessment techniques;
- complete the assessments as part of responsible chemicals management;
- inform all stakeholders of the safety profile of all HERA substances;
- participate in the current debate on the management of chemicals;

and in due course

- to contribute assessments to the REACH process.