Checklist for Responsible Persons: What to Look Out for in a Cosmetic Product Safety Report

Annex I of the UK and EU Cosmetics Regulations provides the requirements for compiling the Cosmetic Product Safety Report (CPSR). As a Responsible Person, you need to ensure that the CPSR you receive from your safety assessor complies with the legal requirements. To support you with this task, CTPA developed the below checklist that you can use during this assessment.

- ✓ Is the CPSR traceable to the product under inspection?
  - Product name matching, product type or formulation matching
- ✓ Are all Annex I of the UK Cosmetics Regulation sections for the CPSR present?
- ✓ Check the credentials of the safety assessor: do they comply with Article 10 requirements? [*diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent*]
- ✓ Is a comprehensive list of ingredients provided, including chemical names, CAS numbers and % used?
  - Do the concentrations of the ingredients add up to 100%?
- ✓ Is the function of each ingredient present in the formulation details?
  - Check for any substances marked as colorants, preservatives or UV filters that are not included in Annex IV, V and VI respectively. [*Only colorants (with the exception of hair dyes), preservatives and UV filters listed in Annex IV, V and VI respectively can be used in cosmetic products*]
- ✓ Is there any reference to the results of stability testing for the cosmetic product?
  - If not, has a plausible justification been provided as to why stability testing was not conducted?
- ✓ Is there any reference to the results of Preservative Challenge Test, demonstrating the efficacy of the preservative system?
  - If not, has a plausible justification been provided as to why the Preservative Challenge Test was not conducted?
- ✓ Is there any reference to the results of microbiological testing and/or quality of each of the ingredients or of the product? *[This is particularly important for some product types, but not applicable to all products; please refer to the guidance 'Special considerations for Specific Product Types in the CPSR']*
  - If not, has a plausible justification been provided as to microbiological testing was not conducted?
- ✓ Is there any relevant technical information about the packaging materials to support safety by design?
- ✓ Has the safety assessor considered the compatibility of the product with the packaging material?
- ✓ Is there a clear justification for the durability assessment, the Best Before End date or the Period After Opening?
- ✓ Has the safety assessor carried out an exposure assessment, based on product use and application? Is the exposure assessment relevant for the product type? E.g. leave on/rinse

off, use patterns/frequency, site of application, amount of product per use, exposure routes, etc.

- ✓ Is there any reference to scientific literature, or raw material information, or other relevant document on the toxicological profile of each ingredient?
    - Each ingredient should include presence of impurities (if any) that are technically unavoidable, with a justification on consumer safety, if present.
- ✓ Are any specific warnings advised? Either from the assessment, or because the product contains an ingredient which has got mandatory warnings specified in the Annexes to the Regulation for specific ingredients?
- ✓ Is the CPSR up to date?
    - Relevant updates to the formulation, based on new scientific research, or new ingredients restrictions/prohibitions, or any post-market surveillance data.
- ✓ Are the RP or manufacturer details consistent throughout the report?