


Assessment Strategy for Hair Dyes Safety

In view of safety concerns expressed in relation to the use of hair dyes, the Commission agreed in April 2003 together with Member States and the stakeholders on an overall strategy to regulate hair dye substances within the framework of the Cosmetics Directive. The strategy was published as an ["Information note on the use of ingredients in permanent and non-permanent hair dye formulations \(dye precursors and direct dyes\)"](#)  (62 KB).

The main element of the strategy is a three step modulated approach requiring industry to submit, by certain deadlines, safety files on hair dye substances for a risk assessment by the Scientific Committee on Consumer Products (SCCP) according to the most recent safety requirements.

The hair dye strategy foresees to ban all permanent and non-permanent hair dyes for which industry has not submitted any safety files and those for which the SCCP has given a negative opinion.







The overall objective of this assessment process is to establish a positive list of hair dye substances which are considered safe for human health and allowed for use by the cosmetics industry.

Implementation

There are currently 318 substances with hair dyeing properties which can be used in hair dye products. At the beginning of the implementation of the strategy 17 substances out of 318 substances had been already banned and 3 substances were banned due to their CMR (Carcinogenic, Mutagenic and Toxic for Reproduction) properties.

Step 1: Submission of dossiers for hair dyes by cosmetics industry



In the framework of the strategy the industry should submit safety files on hair dye substances to allow a risk assessment by the SCCP according to the following timetable:

- End of September 2003 - submission of safety files for those substances for which no scientific data have ever been delivered for evaluation.
At this stage 181 substances could be derived and identified as without no safety file or with the remark "no further commitment" by industry to submit additional data. The result was that 117 substances (318-201) will be further assessed by the SCCP on the basis of submitted safety data by the industry.
- End of July 2005 - submission of safety files according to the new SCCP requirements (except data on combinations of ingredients, see step 3) for all permanent and non-permanent hair dye substances.
The new requirements were set out in the opinion [SCCNFP/0553/02](#)  and supplemented with the requirements for the genotoxicity/mutagenicity testing in the opinion [SCCNFP/0566/02](#)  updated by the opinions [SCCNFP/720/03](#) , [SCCNFP/0755/03](#)  and [SCCP/0971/06](#) .
- By this deadline [117 updated safety files](#)  (18 KB) were submitted and delivered to the SCCP for a risk assessment.

Step 2: Evaluation of the submitted safety files by the Scientific Committee

- Presently, the safety of 117 hair dye substances is being assessed by the SCCP whose final opinions will serve the Commission as a basis to take further decisions on appropriate regulatory measures.
- 22 hair dye substances for which industry has not submitted any safety files at all were banned by Commission Directive of 20 July 2006.

Step 3: Submission of dossiers by the industry for combinations of ingredients and evaluation by the SCCP (deadline 31 December 2007)

- For the oxidative hair dyes up to now toxicological testing is performed only on precursors, couplers and developers. But in the reaction process during hair dying transient intermediates as well as reaction products are formed on the scalp to which the consumer is exposed. This situation has been addressed in detail by the SCCP opinions [SCCP/0941/05](#)  and [SCCP/1004/06](#) . Studies or dossiers of any possible and reasonable combinations must be submitted for evaluation by the end of 2007.