The European Assessment Strategy for Hair Dyes

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Agenda

- Legal situation
- Scientific advice to the EC
- History and structure of the EU Hair Dyes strategy
- Current status of the evaluation
- Legal implementation
The Cosmetics Directive

- Cosmetic products must not cause damage to human health
- Safety of cosmetics is the responsibility of the manufacturer
- Provisions with regards to certain substances in the Annexes of the Cosmetics directive have to be respected
  - Annex II: substances banned from use in cosmetic products
  - Annex III: substances subject to restrictions
  - Annex IV, VI, VII: authorised colouring agents, preservatives, UV-filters
Scientific Advice to the EC

- Substance lists in Annexes are updated according to technical progress, based on scientific advice.
- Safety evaluations performed by an independent expert Committee.
- Scientific Committee on Consumer Safety (SCCS), formerly aka SCCP, SCCNFP, SCC.
- 17 members plus external experts organised in various Working Groups.
- “Private” experts, not nominated by MS, but selected based on their scientific merit.
History of the hair dye assessment strategy

- 2001: scientific publication reports a link between use of permanent hair dyes and bladder cancer, showing correlation with frequency/time of use
  

- Scientific data raise concerns about a connection of permanent hair dyes and leukaemia
  
  Conflicting data from a large number of studies, some indications for increased risk for acute and chronic lymphoid leukaemia
History of the hair dye assessment strategy (cont’d)

- Scientific advisory committee urged EC to act
  - collect information on hair dyes in use
  - gather available mutagenicity and carcinogenicity data
  - initiate priority review of these substances
  - take steps to control hair dye use

- 2003: agreement with MS and stakeholders on strategy to assess and regulate hair dye substances

- Review and regulation of all hair dye substances present on the European market
Assessment strategy

- Step 1: submission of scientific data for hair dye substances (deadlines Sept 2003/July 2005)
- Step 2: evaluation of files by the Scientific Committee
- Step 3: submission of data on combination of ingredients/reaction products (deadline Dec 2007)
- Step 4: Legal implementation: positive list for hair dyes
Current status of evaluation

Individual hair dye substances

298 hair dye substances identified

181 not further supported

117 dossiers submitted
Current status of evaluation

Individual hair dye substances

Evaluation of submitted dossiers

- 52 safe for use (may be sensitisers)
- 4 not safe
- 25 insufficient data
- 36 remaining for evaluation (+ 6 new submissions)
Current status of evaluation

Sensitising potential

- 27 out of 46 hair dye fulfilled the EU criteria for classification as skin sensitiser (R43)
- 10 extreme sensitisers
- 13 strong sensitisers
- 4 moderate sensitisers
Current status of evaluation

Intermediates and end products of oxidative hair dyes

- Oxidative hair dying systems consist of a combination of reactive chemicals
- During the dying reaction, transient intermediates and final dye products are formed
- Consumer exposed to all compounds
- In the case of relevant systemic exposure, data on genotoxic potential required
Current status of evaluation

Intermediates and end products of oxidative hair dyes

- Development of analytical methods to detect and quantify reactants and reaction products
- Determination of reaction kinetics
- Determination of dermal penetration of reaction products
- Qualitative and quantitative analysis of reaction products for 27 precursor/coupler combinations
- Dermal absorption data available for 9 combinations, data on 13 more expected
Legislative implementation

- 156 hair dye substances without dossiers have been included in Annex II of banned substances.

- 17 hair dyes with positive evaluation and without strong sensitising properties regulated with maximal use concentrations in Annex III.

- Enhanced labelling of sensitising hair dyes to be introduced.
The hair dye strategy – a worthwhile effort

- Significant investment of resources by all parties involved

But the hair dye strategy:

- Fostered development of methodologies for analysis of oxidative hair dye systems
- Increased the knowledge about toxicological properties of all hair dyes on the market
- Gives confidence that hair dyes used in the market are safe for consumers