



# 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 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  
Gago- Dominguez *et al.* (2001). Use of permanent hair dyes and bladder cancer risk. *Int J Cancer*:91,575-579
- 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

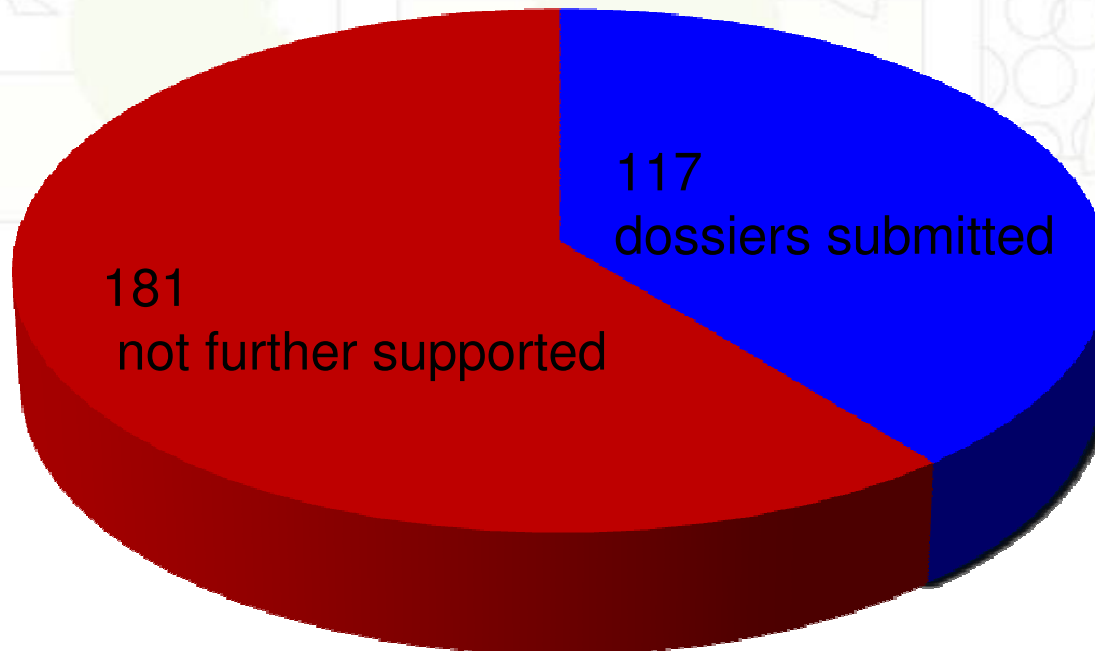
## Assessment strategy

- 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**

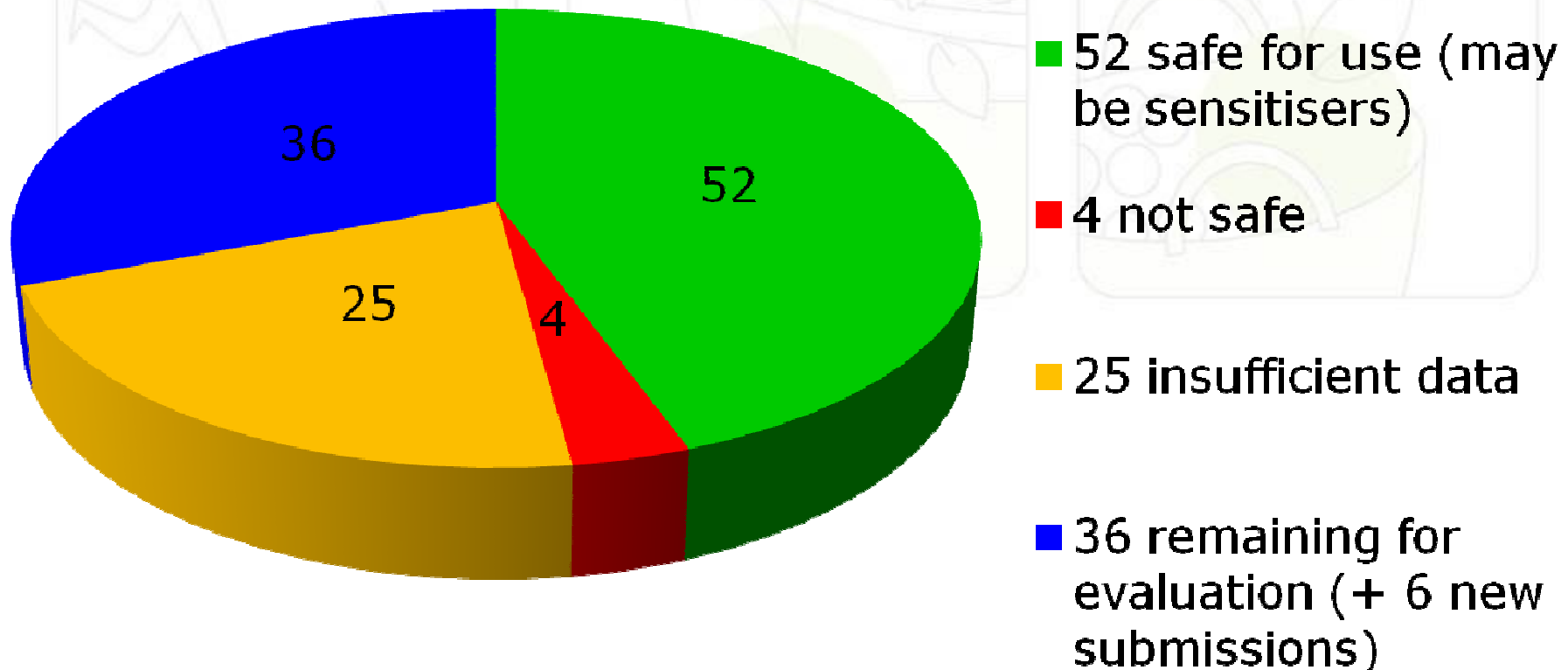




# Current status of evaluation

Individual hair dye substances

## Evaluation of submitted dossiers



# 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 dyeing systems consist of a combination of reactive chemicals
- During the dyeing 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