As a follow-up to its opinion on the use of permanent hair dyes and bladder cancer risk, adopted during the 17th Plenary meeting of 12 June 2001, the SCCNFP drafted the attached discussion paper on "Assessment strategies on hair dyes".

The Commission services invite interested parties for their comments.

Please send your comments before 6 May 2002 at the following e-mail address :

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THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS

DISCUSSION PAPER

ON

ASSESSMENT STRATEGIES FOR HAIR DYES

adopted by the SCCNFP during the 19th Plenary meeting
of 27 February 2002

There is epidemiological evidence to indicate that the regular and long term use of hair dyes in women may be associated with the development of bladder cancer (Gago-Dominguez M, Castelao JE, Yuan J-M, Yu MC, Ross RK. Use of permanent hair dyes and bladder cancer. Int J Cancer 2001; 91: 575-9).
Although there are criticisms of the study, the finding that the association between permanent hair dye use and bladder cancer is more pronounced in individuals who are slow acetylators of N-acetyltransferase 2 (NAT2), an enzyme involved in the detoxification of aromatic amines, provides important biological support for the assumption that aromatic amines in hair dyes may be putative bladder carcinogens (Miller AB, Bartsch H. Hair Dye use and Bladder Cancer. Int J Cancer 2001; 94: 901-902).

The above data was generated in the USA. Although it is unknown whether the same exposure pattern applies in Europe, in the absence of information to the contrary, and in the interests of consumer safety, it should be assumed that it is similar.
Any robust epidemiological investigation within Europe would take years to complete but there is a need for measures to be introduced to protect the European consumer in the interim.

The European cosmetic industry uses a considerable number of permanent hair dyes and the safety of many of these has not yet been assessed by public authorities. The reasons for this include incomplete dossiers and non-conformation of experimental data to modern (current) methods of collection.

European industry has submitted a list of those permanent hair dyes used at levels of > 2000 kg per year in Europe. This should be used as a priority list of substances requiring urgent assessment by the SCC NFP. It is recommended that dossiers submitted for review must conform to the Notes of Guidance (http://europa.eu.int/comm/food/fs/sc/sccp/index_en.html) produced by the SCC NFP, the critical data must conform to modern methods of determination and the comments in Memorandum SCC NFP/0461/01 adhered to. Further, the dossier should have a 'checklist' confirming that each of the endpoints of the toxicological profile conforms to modern methods or if not, a statement of why it should be accepted with scientific reasons.

In particular, for the risk assessment of hair dyes, the following must be submitted :

* The chemical specifications (purity and impurities) of the hair dyes used to generate the data must be defined and be representative of that used in commercial products;

* According to the intended use, the dyes/dye-precursors must be tested alone and/or in combination with other substances to simulate the conditions of use;

* *In vivo* and *in vitro* studies are necessary to identify the nature and the level of the possible hazards of hair dyes;

* Data on genotoxicity – the studies must conform to internationally accepted guidelines (OECD, EU) and to modern testing strategy;

* All available data on carcinogenicity;

* Deviations from the above must be justified.

Safety assurance and with this, health protection of the consumer, can be applied only to those hair dyes and complexes that have been subject to the above assessment.

When a dossier reviewed contains incomplete or inadequate data, the SCCNFP may conclude as follows :

The SCCNFP is of the opinion that the information submitted is insufficient to allow an adequate risk assessment to be carried out.
Accordingly, the SCCNFP considers that it is not possible to assess the safe use of the substance.