EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C – Public Health and Risk Assessment
C7 Risk assessment
Scientific Committee on Consumer Products

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS
14TH PLENARY MEETING

Held on 18 December 2007 in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. R. Dubakiene, Prof. J. Krutmann and Prof. C. Lidén.

2. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No member declared any interest that could prevent him/her from participating in the discussion of the items on the agenda.

3. APPROVAL OF THE AGENDA

The agenda was approved as proposed.

4. APPROVAL OF THE MINUTES OF THE 13TH PLENARY MEETING

The Minutes of the 13th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White said that, during the 19th meeting of the Inter-Committee Coordination Group (ICCG) of 28 November 2007, Prof. T. Hardy and Dr. A. Hart of the Central Science Laboratory, UK-York, gave a presentation on Risk Assessment Training and Terminology in the non-food area.

The results of the following two projects, developed on behalf of DG SANCO, were presented and discussed:

1) an inventory of risk assessment training relevant to the non-food scientific committees.
2) a comparative review of risk terminology used by the non-food scientific committees.

6. EMERGING ISSUES

No issues were raised.

7. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

The adopted opinions will be published at:
http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm

7.1. ALTERNATIVES

Report of the Co-ordinator

Prof. V. Rogiers said that the following memorandum was prepared during the meetings of the WG that had taken place since the last plenary of 2 October 2007.

Memorandum on the *in vitro* test EPISKIN for skin irritation testing, doc. n° SCCP/1145/07

At its 26th meeting, held on 26-27 April 2007, ESAC (ECVAM Scientific Advisory Committee) made the following statement on the validity of *in vitro* tests for skin irritation: "*The EPISKIN™ method is considered to be a reliable and relevant stand-alone test for predicting rabbit skin irritation, when the endpoint is evaluated by MTT*[1] *reduction, and for being used as a replacement for the Draize skin irritation test (OECD TG 404 & Method B.4 of Annex V to Directive 67/548/EEC) for the purposes of distinguishing between R38 skin irritating and non-skin irritating substances*."

A second endpoint, IL-1α[2], was found to increase the sensitivity of the test, without reducing its specificity. This endpoint is advised to be used to confirm negatives obtained with the MTT endpoint (*http://ecvam.jrc.it/index.htm*, consulted November 2007).

The SCCP welcomes the availability of the validated EPISKIN™ method, which is a replacement alternative highly needed for the animal-free assessment of skin irritation of cosmetic ingredients. As only one substance of the test set used for validation, however, is present on the Annexes to Dir. 76/768/EEC and as no information is available to the SCCP with respect to colouration effects, potentially important in the case of colorants and hair dyes, the SCCP is of the opinion that additional data are necessary to fully support the EPISKIN™ method for the safety assessment of cosmetic ingredients present on the Annexes of Directive 76/768/EEC. The problem of dyes interfering with the MTT colorimetric method was already mentioned in a study assessing the applicability of the EPISKIN™ model for photo-toxicity testing (Lelièvre et al. 2007).

Therefore additional work specifically addressing substances present on the Annexes would be highly welcomed.
For a number of cosmetic ingredients present in the annexes, data have recently been received and are presently under review, while further information on coloured substances has been

[1] 3-(4,5)-dimethyl-2-thiazolyl-2,5-dimethyl-2H-tetrazolium bromide
[2] Interleukin 1-α

announced. Should review of these data reveal remaining knowledge gaps, an additional set of compounds could be determined based on the *in vivo* skin irritation data described in the publicly available SCC(NF)P opinions and stored in a databank accessible to the SCCP, and included in an additional validation step of the EPISKIN™ method for cosmetic ingredients present on the Annexes, should this be necessary. The SCCP offers its help for such an additional study and would welcome any information that sectors of industry may already have and be useful as part of the evaluation.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

Prof. T. Platzek reported on the work done during the meetings of the WG that had taken place since the last plenary of 21 March 2007.

Draft opinions were prepared on:

A117, 5-Amino-4-chloro-o-cresol HCl, doc. n° SCCP/1120/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 5-Amino-4-chloro-o-cresol hydrochloride safe for consumers, when used as a precursor in any hair dye formulation with a concentration on the scalp of maximum 1.5% taking into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of 5-Amino-4-chloro-o-cresol hydrochloride in any hair dye formulations?*

The SCCP concluded that the use of 5-amino-4-chloro-o-cresol HCl, at a maximum concentration of 1.5% (calculated for the hydrochloride salt) on the head, does not pose a risk to the health of the consumer.

5-Amino-4-chloro-o-cresol HCl itself has no mutagenic potential. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

This risk assessment relates to the use of 5-amino-4-chloro-o-cresol HCl in oxidative hair dye formulations only.

The opinion was adopted.

B67, HC Orange n° 2, doc. n° SCCP/1103/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider HC Orange n° 2 safe for use as a non-oxidative hair dye with a concentration of maximum 1.0 % taken into account the scientific data provided?*

2. *Does the SCCP recommend any further restrictions with regard to the use of HC Orange n° 2 in non-oxidative hair dye formulations?*

The SCCP concluded that, apart from the risks associated with the use of a strong sensitiser, the use of HC Orange n° 2, at a maximum concentration of 1.0% on the head, does not pose any other risk to the health of the consumer.

HC Orange n° 2 is a secondary amine, and thus is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

This risk assessment relates to the use of HC Orange n° 2 in non-oxidative hair dye formulations only.

The opinion was adopted.

B73, HC Blue n° 12, doc. n° SCCP/1135/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider HC Blue n° 12 safe for use as a non-oxidative hair dye with an on-head concentration of maximum 1.5 % taken into account the scientific data provided?*

2. *Does the SCCP consider HC Blue n° 12 safe for use in oxidative hair dye with an on-head concentration of maximum 0.75 % taken into account the scientific data provided 3. Does the SCCP recommend any further restrictions with regard to the use of HC Blue n° 12 in any non-oxidative or oxidative hair dye formulations?*

The SCCP concluded that the information submitted is insufficient to allow a final risk assessment to be carried out.

Before any further consideration, the equivocal result obtained with the *in vivo* Comet assay has to be clarified. It is suggested to repeat the Comet assay taking appropriate protocol modifications into consideration.

Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

B89, 2-Chloro-6-ethylamino-4-nitrophenol, doc. n° SCCP/1090/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2-chloro-6-ethylamino-4-nitrophenol safe for use as a non-oxidative hair dye with an on-head concentration of maximum 3.0% taken into account the scientific data provided?*

2. *Does the SCCP consider 2-chloro-6-ethylamino-4-nitrophenol safe for use in oxidative hair dye formulations with an on-head concentration of maximum 1.5% taken into account the scientific data provided?*

3. *Does the SCCP recommend any further restrictions with regard to the use of 2-chloro-6-ethylamino-4-nitrophenol in any non-oxidative or oxidative hair dye formulations?*

The SCCP concluded that the use of 2-chloro-6-ethylamino-4-nitrophenol, at a maximum on-head concentration of 1.5% in oxidative hair dye formulations and at a maximum on-head concentration of 3.0% in non-oxidative hair dye formulations, does not pose a risk to the health of the consumer, apart from its sensitising potential.

However, no documentation is provided for the characterisation and composition of various batches of 2-Chloro-6-ethylamino-4-nitrophenol.

2-Chloro-6-ethylamino-4-nitrophenol is a secondary amine, and thus it is prone to nitrosation. It should not be used in combination with nitrosating substances.
The nitrosamine content should be < 50 ppb. The nitrosamine content in 2-Chloro-6-ethylamino-4-nitrophenol was not reported.

Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

B100, 4-hydroxypropylamino-3-nitrophenol, doc. n° SCCP/1082/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 4-hydroxypropylamino-3-nitrophenol and its salts safe for use in non-oxidative or oxidative hair dye formulations within the specified concentrations taken into account the data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of 4-hydroxypropylamino-3-nitrophenol in non-oxidative or oxidative hair dye formulations?*

The SCCP concluded that the use of 4-hydroxypropylamino-3-nitrophenol as a hair dye ingredient in non-oxidative and oxidative hair dye formulations at a maximum on-head

concentration of 2.6% does not pose a risk to the health of the consumer. No data were submitted on its salts.

4-Hydroxypropylamino-3-nitrophenol is a secondary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

C22, Acid Red 33, doc. n° SCCP/1102/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Acid Red 33 safe for use as non-oxidative hair dye with an on-head concentration of maximum 0.5 % taken into account the scientific data provided?*

2. *Does the SCCP recommend any further restrictions with regard to the use of Acid Red 33 in any non-oxidative hair dye formulations?*

The SCCP concluded that the use of Acid Red 33, at a maximum concentration of 0.5% in non-oxidative hair dye formulations, does not pose a risk to the health of the consumer.

Acid Red 33 contains several 'CMR'-impurities. 8% of the content are unknown.

The Margin of Safety relates to the use of Acid Red 33 in hair dye formulations only. Acid Red 33 may also be used as a colorant in other types of cosmetic products. These other types of exposure have not been considered.

The opinion was adopted.

Sensitivity to hair dyes – consumer self testing, doc. n° SCCP/1104/07

The SCCP was asked to answer the following questions:

In the light of the data available,

1. *Does the SCCP consider that there is a risk that:*

   - *Self-tests lead to false-negative results?*
   - *Self-tests lead to induction of contact allergy?*

2. *Does the SCCP consider that self-tests are beneficial for a specific population of hair dye users in order to detect existing sensitisations?*

The SCCP concluded that:

- There is a risk that “self tests” with hair dye products and with separate kits lead to misleading and false-negative results, thus giving individuals who are allergic to hair dye

substances the false impression that they are not allergic or not at risk of developing an allergic reaction by dyeing their hair.
- There is potential risk that "self tests" result in an induction of skin sensitisation to hair dye substances.
- Self testing may offer protection to those individuals who perform the recommended test and develop a positive reaction. However, the proportion of hair dye chemical allergic individuals who do produce a positive reaction from this *in vivo* diagnostic test is unknown.

When a hair dye product is applied to the skin for the purpose of providing an indication as to whether the individual consumer may or may not have contact allergy to hair dye chemicals(s), the product is being used for *in vivo* diagnostic purposes.

The SCCP wishes to point out that the use of hair dye products on the skin and for *in vivo* diagnostic purposes is not covered by the current Cosmetics Directive.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that no opinions had been prepared by the Working Party since the plenary meeting of 2 October 2007.

7.4. UV FILTERS AND AD HOC SUBSTANCES

Prof. Sanner said that the following opinion had been prepared:

Hydrogen peroxide, in its free form or when released, in oral hygiene and tooth whitening products, doc. n° SCCP/1129/07

The SCCP was asked to answer the following questions:

Considering all data, those already submitted in support of previous opinions and those identified since its last opinion (15 March 2005, SCCP/0844/04) and submitted to the SCCP, can the Committee assess the possible health risks associated with the use of hydrogen peroxide, in its free form or when released, in oral hygiene products?

In doing so, the Committee is asked, wherever it is scientifically justified, to make a distinction in the assessment of hydrogen peroxide and to identify any specific health risks regarding the use of hydrogen peroxide in oral hygiene products, or equivalent for substances that release hydrogen peroxide, taking account of:

- *Types of oral hygiene products: mouth-rinses and tooth pastes on the one hand and tooth whitening products (strips, trays with gel…) on the other, as the SCCP has done in its previous opinions;*

- *Concentration limits (for example 0.1%, 6%, more than 6%);*

- *Different usage conditions which can create differences in the resulting exposure of consumers to hydrogen peroxide.*

The SCCP concluded that for practical reasons, the following concentration limits of hydrogen peroxide, when used in oral hygiene and tooth whitening products, should be considered: up to 0.1%, up to 6%[3], and more than 6%. The limit of 0.1% is based on a level at which there is no risk to the consumer from the use of hydrogen peroxide in oral hygiene and tooth whitening products under normal or reasonable foreseeable conditions of use. In toothpastes and mouth rinses, the hydrogen peroxide concentration should not exceed 0.1% (SCCNFP/0158/99). The limit of 6% for tooth whitening products refers to the limit given in the Terms of Reference in relation to the Opinion SCCP/0844/04. It should also be noted that for hydrogen peroxide concentrations above 6%, the MOS will be below 100; therefore, products containing more than 6% hydrogen peroxide are not safe for use by the consumer.

The present opinion refers to the concentration of hydrogen peroxide in its free form or when released (some hydrogen peroxide releasing substances may not be specifically mentioned in this opinion). In the case of the substances discussed in Appendix 1 (sodium percarbonate, sodium perborate, and potassium peroxymonosulphate), it refers to the concentrations of the substances that will result in the same amount of hydrogen peroxide or reactive oxygen species being available as the specified concentrations of hydrogen peroxide above.

Sodium perborate fulfils the criteria of a classification of toxic to reproduction category 2 (R61). Additionally, there is a current proposal that sodium perborate should be so classified (http://ecb.jrc.it/classification-labelling/search-classlab/ (Search Working Database)).

The available data does not permit a distinction between the different tooth whitening products (e.g. tray-based gel, gel strips, paint-on gel) with regards to adverse effects.

This opinion only concerns the cosmetic use of oral hygiene and tooth whitening products.

Oral hygiene and tooth whitening products containing up to 0.1% hydrogen peroxide

- The use of oral hygiene and tooth whitening products containing up to 0.1% hydrogen peroxide does not pose a risk to the health of the consumer.

Tooth whitening products containing > 0.1% and ≤ 6% hydrogen peroxide

- Based on the available data, the SCCP is not in a position to define a level of hydrogen peroxide and a frequency of application that would result in exposure which would be considered safe for the consumer.

- With increasing concentration of hydrogen peroxide and frequency of application there will be an increasing risk associated with the use of these products. It cannot be anticipated what

[3] Higher concentrations may be used provided that the total amount of hydrogen peroxide is equal or lower than in products using 6% hydrogen peroxide and 0.2 g gel load and that studies have demonstrated that the concentration of hydrogen peroxide in the saliva and on the gingiva is not higher than in products containing 6% hydrogen peroxide.

the exposure would be if the products were to be freely and directly available to the consumer.

- Potential risks associated with the use of products containing more than 0.1% and up to 6% hydrogen peroxide may be reduced if:

  a) they are used only after clinical examination to ensure the absence of risk factors identified below or other oral pathology of concern.

  - Particular care in using them should be taken by persons with gingivitis and other periodontal diseases or defective restorations. Conditions such as pre-existing oral tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the possible toxic effects of hydrogen peroxide (see e.g. section 3.3.15).

  - Their use is not recommended prior to or immediately after dental restoration.

  b) exposure to tooth whitening products containing 0.1 to 6% hydrogen peroxide is to be limited in a manner that ensures that the products are used only as intended in terms of frequency and duration of application to avoid reasonably foreseeable misuse.

- There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity (see SCCP/0974/06). The SCCP recommends that, in consideration of public health, independent long-term safety evaluations should be performed (see SCCP/0974/06).

- In the absence of specific data on the safety of tooth whitening products in children/adolescents, the SCCP is not in a position to assess the potential health risks associated with their use in this population subgroup.

Tooth whitening products containing > 6 % hydrogen peroxide

Because of the increasing risks of acute and long-term effects, tooth whitening products containing > 6.0% hydrogen peroxide are not considered safe for use by the consumer.

The opinion was adopted.

Nano-materials, safety in cosmetic products, doc. n° SCCP/1147/07

The SCCP was asked to answer the following questions:

1. *In view of the concerns recently raised about the use of nanomaterials in cosmetics the SCCP is requested to review and, if appropriate, to amend its notes of guidance for the testing of cosmetic ingredients and their safety evaluation as concern cosmetic ingredients in the form of nanomaterials, including nanoparticles and nanoliposomes, and in particular as regards skin absorption and resorption of these substances. In assessing this, regard should be made to differing skin conditions, different sizes of particles and to question whether mass unit is the appropriate basis for regulating the exposure to nanomaterials. Possible implications on animal testing of nanoparticles and nanoliposomes should be addressed.*

2. In the light of the findings under (1), does the SCCP consider it is necessary to review existing opinions on nanosized TiO_2 and ZnO as cosmetic ingredients and if appropriate to identify which additional elements are required for the submission of a safety file?

The SCCP concluded that:

"In the safety evaluation of nanomaterials, actual or intended marketed nanomaterials should be used for material characterisation and hazard identification. Furthermore, distinction should be made between soluble and/or biodegradable versus insoluble and/or biopersistent nanomaterials. Nanoparticles which disintegrate into molecular species upon application have to be distinguished from insoluble particles. For the former, conventional risk assessment methodologies based on mass metrics ***may*** be adequate for their use in cosmetic products, whereas for the latter (e.g. TiO_2, ZnO, fullerenes, carbon nanotubes, and quantum dots) other metrics are needed. A complete characterisation of physico-chemical characteristics and properties is required for these nanomaterials. Particle size, particle number, shape and surface characteristics are considered essential additional metrics. Consideration should also be given to certain moieties (e.g. surface modifications) on nanomaterials which could possibly enhance or reduce potential adverse health effects.

In traditional risk assessment, skin penetration studies are carried out using healthy or intact skin. Possible enhanced uptake in the case of impaired skin is considered to be covered in the Margin of Safety (MoS) approach. However, in the case of nanomaterials the conventional MoS may not give an adequate expression of the safety. If there is any penetration into the vital layers of the skin there may be a transfer to the systemic circulation. It may be anticipated that any systemic absorption will be more likely in conditions of abnormal skin e.g. sunburnt, atopic, eczematous, psoriatic skin. There is evidence that physical, in particular mechanical, and/or chemical action on the skin may have an effect on nanoparticle penetration.

At present, the *in vitro* diffusion cell chamber is the standard device for estimating percutaneous absorption. However, because mechanical factors may be important in potential penetration/absorption of nanoparticles, this standard model may not be ideal. Therefore, modified or new optimized methodologies to assess percutaneous penetration pathways are required.

There are large data gaps in risk assessment methodologies with respect to nanoparticles in cosmetic products. To evaluate possible pulmonary effects (and the linked systemic effects), simple *in vitro* systems exist, e.g. to study cytotoxicity, pro-inflammatory effects. However, these are not suitable for studying effects that reflect the complexity of the lung. *In vitro* models for systemic and (sub-)chronic toxicity do not yet exist and need to be developed, in particular for translocation, biodistribution, accumulation and clearance studies. Therefore, *in vivo* studies on potentially toxic nanomaterials are still necessary.

Size dependence of the deposition probability of inhaled nanoparticles is reasonably understood in the respiratory tract of healthy subjects; however, for individuals with respiratory disorders, predictions for nanoparticle deposition probability are limited.

The biodistribution (toxicokinetics) of nanomaterials has not been studied in detail. Therefore, it is impossible to model, *in silico*, hazard characterization and the distribution of nanomaterials. In particular, there is limited information on the role of physico-chemical parameters of

nanoparticles determining their absorption and transport across barriers, e.g. skin, gut, lungs and eye, and their subsequent uptake in the systemic circulation, metabolism, potential accumulation in secondary target organs and excretion.

Mutagenicity/genotoxicity testing is required in general for cosmetic ingredients, including nanomaterials, but the specific characteristics of nanoparticles may require further consideration. The mutagenic/genotoxic *potential* of nanoparticles could probably be assessed in mammalian cells *in vitro*. The presently validated *in vivo* genotoxicity tests, however, do not cover the expected target organs of nanoparticles (particularly the respiratory tract) and have not been validated or optimized for reference substances including nanomaterials for cosmetics.

All *in vivo* and *in vitro* risk assessment methods for nanomaterials are still under development. Although some validated *in vitro* methods do exist they have not yet been validated and/or optimized with nanoparticles as reference compounds. This implies that for safety assessment of cosmetic ingredients, there are no validated *in vitro* methods available for nanoparticles.

Although animal testing can be largely reduced for skin penetration studies, it remains essential for translocation and accumulation studies as well as for chronic toxicity studies. Finally, the SCCP emphasizes that for the safety assessment of cosmetics, the 7th Amendment of the Cosmetic Directive (76/678/EEC) imposes animal testing and marketing bans, which will soon prohibit *in vivo* testing of cosmetic ingredients. Only validated *in vitro* methods are to be used for risk assessment.

Each safety dossier concerning nanomaterials needs to be evaluated on a case by case basis.

Regarding question 2, the following was concluded:

"A complete safety dossier on micronised and nanosized ZnO was requested by SCCNFP in its opinion on ZnO in 2003 (SCCNFP/0649/03). An opinion on the safety of such materials will be dependent on the availability of on an adequate dossier.

The SCCNFP opinion from 2000 (SCCNFP/0005/98) is on micro-crystalline preparations of TiO_2 and preparations of coarse particles. However, since this opinion new scientific data on nanosized particles, including TiO_2 has become available. Therefore, the SCCP considers it necessary to review the safety of nanosized TiO_2 in the light of recent information. Also, a safety assessment of nanosized TiO_2, taking into account abnormal skin conditions and the possible impact of mechanical effects on skin penetration need to be undertaken."

The opinion was adopted.

Nitrosamines and nitrosatable compounds, presence and release from rubber balloons, doc. n° SCCP/1132/07

The SCCP was asked to answer the following questions:

1. *Critically review the evidence concerning the migration of nitrosamines from balloons and the risk assessments conducted by the RIVM and BgVV and BfR on the potential risks arising from the exposure of young children (ages 6 months to 4 years).*

2. *In light of its response to question 1, pronounce itself as to whether there may be reasons for concern arising from the exposure of young children to nitrosamines when young children mouth and/or lick balloons. In elaborating its point of view, the Committee is asked to take into account known/published exposures of young children to nitrosamines from other known sources of exposure (food and non food products, environment, etc) and previous or ongoing assessments of nitrosamine exposure (e.g. SCF opinions or work by EFSA panels).*

3. *In light of its response to question 2, assess whether a limit of nitrosamines and nitrosatable compounds can be established that will lead to exposure of young children to balloons not giving reasons for health concerns (e.g. the 0.05 mg of nitrosamines and 1.0 mg N-nitrosatable compounds per kg rubber recently proposed for balloons by the Federal Republic of Germany). In answering this question, consideration should also be given to other sources of nitrosamines and nitrosatable compounds than rubber.*

4. *Identify any additional investigative work that needs to be done concerning both the specific issue of nitrosamines in balloons and the presence and release of nitrosamines from other rubber or non-rubber consumer products (non-food and food) resulting in eventual consumer exposure, that would enable an integrated risk assessment to be conducted concerning the total children exposure to nitrosamine from all known sources.*

The SCCP concluded that:

- The risk assessments of RIVM focussed on average exposure, whereas BfR considered peak exposure.
- Peak exposure can lead to a potential health hazard when balloons with high nitrosamine levels are mouthed by a child on a day with high background exposure. However, when a pragmatic approach is used in which the levels are compared to a level of 3840 ng/kg bodyweight per day, associated with a negligible risk for peak exposure to nitrosamines in children, exposure levels are far below this safe level.
- Food and passive smoking are the main sources for nitrosamine exposure by children. The underlying exposure assessments are not very robust or are based on a worst case scenario and crucial data are lacking. Additional investigative work with regard to exposure of children, especially on the endogenous formation of nitrosamines and on the contribution of passive smoking, is needed. Furthermore, other potential sources for nitrosamine exposure in children should be identified and taken into account.
- A limit for nitrosamine levels for balloons is recommended, since minimisation of nitrosamine formation in the production process of balloons is possible using state-of-the-art technology and thus exposure to nitrosamines via balloons is largely avoidable. The migration level of 50 µg/kg nitrosamines results in a negligible exposure level of 13.5 ng nitrosamines per day, not contributing to a potential health risk.
- The use of vulcanisation accelerators which result in non carcinogenic nitrosamines should be encouraged.

The opinion was adopted.

8. NEXT PLENARY MEETING

The 15th plenary meeting of the SCCP will take place on 15 April 2008.

9. ANY OTHER BUSINESS

- **Dates of WG meetings:**

8 January	Hair Dyes
18 January	TTC (Threshold of Toxicological Concern)
22 January	ad hoc substances + Fragrances & Preservatives
19 February	Hair Dyes
26 February	ad hoc substances + Fragrances & Preservatives
4 March	Alternatives to Animal Testing
13 March	TTC

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
14th Plenary Meeting

Held on 18 December 2007
in Brussels

List of Participants

Members of the SCCP
Dr. C.M. CHAMBERS, Prof. G. DEGEN, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. J.-P. MARTY, Prof. T. PLATZEK, Dr. S.C. RASTOGI, Prof. J. REVUZ, Prof. V. ROGIERS (Vice chair), Prof. T. SANNER (Vice chair), Prof. G. SPEIT, Dr. J. VAN ENGELEN, Dr. I.R. WHITE (Chair)

SCCP Secretariat (DG SANCO)
Mrs. I. COPPOLA, Mrs. K. KILIAN, Mr. A. VAN ELST

DG ENTR F3
Mr. S. FUEHRING, Mrs. B. MENTRE, Mrs. A. ORLOFF