Brussels, 23 July 2010

“DRAFT REPORT ON ALTERNATIVE (NON-ANIMAL) METHODS FOR COSMETICS TESTING: CURRENT STATUS AND FUTURE PROSPECTS - 2010”

PUBLIC CONSULTATION

I. INPUT EXPECTED FROM THIS CONSULTATION

The Commission would like to consult the public on the “Draft Report on Alternative (non-animal) methods for cosmetics testing: current status and future prospects - 2010”. This draft report was prepared by experts nominated by stakeholders to gain a broad and objective picture of the scientific/technical issues that relate to establishing alternative test methods for the five human health(-related) effects falling under the 2013 deadline for the marketing ban of the EU Cosmetics Directive. The draft report also contains, where possible, a science-based estimate of the time necessary to achieve full replacement of animal testing for the respective endpoints. Please note that this report is not a Commission document.

The public is invited to comment on the 5 individual chapters of the draft report, each representing one human health(-related) effect. The focus of the consultation is to ensure that each chapter correctly reflects the current state of the art and the prospects. As regards prospects the experts evaluated how long it will take to develop and optimise such approaches up to a level that fulfills the ECVAM criteria for entering prevalidation. The time required for the validation and regulatory acceptance of these alternative approaches was not considered for the purpose of this exercise. In addition, justified comments on the conclusion (i.e. the timelines given to achieve full replacement) are sought.

The Commission is inviting factual comments, which complement the information provided. Comments should include references and other substantiation where possible. The 5 individual chapters have not undergone final editing. The Commission is therefore not seeking editorial comments.

II. BACKGROUND OF THE CONSULTATION
The Cosmetics Directive 76/768/EEC is a regulatory framework for the placing on the market of cosmetic products. It aims at phasing out animal testing for these purposes. Besides the complete testing ban, a marketing ban applies since 11 March 2009 for all human health(-related) effects with the exception of repeated-dose toxicity (including skin sensitisation and carcinogenicity), reproductive toxicity and toxicokinetics, for which the deadline is extended to 11 March 2013.

In 2011, the Commission will have to inform the European Parliament and the Council in case alternative non-animal methods will not be developed and validated before 2013 for the remaining endpoints. This information must form part of the Commission yearly report on alternatives to animal testing. If appropriate the Commission will prepare a legislative proposal.

III. THE DRAFT TECHNICAL REPORT

The individual chapters of the Draft Technical Report have been elaborated by experts proposed by the different stakeholders and chaired by the Commission's Joint Research Centre. In total 37 experts contributed, nominated based on proposals received by Cosmetic Regulators (Member States as represented in the Standing Committee operating under the Cosmetics Directive), the Scientific Committee on Consumers Safety (SCCS), the European Cosmetics Association (Colipa) and European Federation for Cosmetic Ingredients (EFFCI) and the European Coalition to End Animal Experiments (ECEAE). Participants were appointed in their personal expert capacity, not as stakeholder representatives.

The draft report is composed of the following five chapters:

Chapter 1 - Repeated dose – including chronic, sub-chronic and sub-acute exposure
Chapter 2 - Skin sensitisation
Chapter 3 - Carcinogenicity
Chapter 4 - Toxicokinetics
Chapter 5 - Reproductive toxicity

The experts could make reference to prior work done in this context, notably when establishing the timetables for the implementation of the animal testing and marketing bans provisions under the 7th Amendment to the Cosmetics Directive (http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm) and the yearly technical reports prepared by ECVAM (http://ecvam.jrc.ec.europa.eu/). The latest ECVAM report has been recently finalized.

IV. HOW TO PROVIDE INPUT

______________

Any comments and information on this public consultation should be submitted using the provided comment template form by mail, fax or e-mail by **15 October 2010** at the latest to:

European Commission  
Health and Consumers Directorate-General (DG SANCO)  
Unit SANCO B2, Cosmetics and Medical Devices  
B-1049 Brussels, Belgium  
Fax: 00 32 (0) 2 296 64 67  
e-mail: SANCO-COSMETICS-REPORT@ec.europa.eu

Respondents should indicate **whether they reply as an individual or whether they represent an interest** (i.e. whether they are a national authority, consumer, industry, trade association, academia, etc.).

Submissions will be published on the “cosmetics” website of the European Commission.

Respondents should indicate whether they wish the Commission to treat their submission as **confidential** by clearly indicating the word “confidential” on the first page of the contribution. Please note that a standard confidentiality disclaimer in the e-mail transmission will not be considered as a request to treat the submission as confidential.

* * *