EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion

Title **DG SANCO - Impact Assessment on Amendment of the Animal Testing Provisions in Regulation (EC) 1223/2009 on Cosmetics**

(draft version of 25 April 2012)

(A) Context

The Cosmetics Directive 76/768/EEC (to be repealed by the Regulation 1223/2009/EC as of 11 July 2013) has already phased-out animal testing inside the EU. Since March 2009, it also prohibited the marketing within the EU of cosmetic products and their ingredients which have been the subject of animal testing carried out in order to meet the requirements of the Regulation 1223/2009/EC. This marketing ban applies to all but the most complex human health effects to be tested, the so called endpoints (repeated-dose toxicity, reproductive toxicity and toxicokinetics), for which the legislator extended the deadline to March 2013. The Commission has monitored the progress of the development of alternative methods to animal testing and presented its final report to the European Parliament and the Council on 13 September 2011 (COM(2011) 558 final). It concluded that alternatives to animal testing in relation to the endpoints in question will not be available by 2013. The present impact assessment examines the possibility of revising the 2013 deadline.

(B) Overall assessment

Although the report approaches the key issues in a transparent way, it should be improved in a number of aspects to better inform the decision making process. The report should better estimate the negative impact of the 2013 marketing ban, as well as the number of animals tested specifically for marketing purposes in the EU. The report should then explain the rationale behind the design of policy options and describe in greater detail how the new derogation mechanism would work in practice, and how the concerns of stakeholders related to its efficient operability have been addressed. The expected magnitude of the impacts and its broad distribution along the value chain should be better assessed, particularly the extent to which the derogation option would mitigate the overall negative impacts of the 2013 marketing ban. Impacts on Member States/regions, up-/downstream operators and SMEs/micro-enterprises in particular, competitiveness of the EU cosmetics industry and the trade relations with third countries should be analysed in greater detail while clearly indicating when evidence does not exist, or is inconclusive. On that basis the policy options should be better compared, particularly in terms of their effectiveness, efficiency and coherence. Finally, the report should clarify if all affected stakeholders could express their views on the issues at stake, mainly the design and impact of the policy options.

(C) Main recommendations for improvements

(1) Improve the presentation of problems. The report should briefly explain how the Directive has been implemented so far, particularly concerning the impacts of the 2009 marketing ban and the application of the derogation from animal testing bans by Member States. It should then provide a clearer overview of the EU cosmetics markets (including a description of the supply side across the EU) and better estimate the negative impact of the 2013 marketing ban, mainly in relation to sales and employment changes. The report should substantiate the claim that the EU cosmetics requirements account for a considerable part of the currently 15000-27000 animals used for cosmetics specific testing worldwide. In doing so, it should explain how the animal testing for cosmetic purposes is regulated in third countries, as well as other EU sectors, and how likely it is that the number of animal tested would in reality diminish. The report should also clarify if the incentives of industry to develop alternative testing methods are considered as insufficient, and therefore a problem. Given the high uncertainty in the underlying data, further effort should be made to validate key estimates and/or to present a wider range of plausible scenarios. In case data is not available (e.g. for part of the industry), this should be explained in the report. Furthermore, the report should better explain the difficulties related to the enforcement of the existing Directive (including examples) and justify that they have no relevance for the current analysis (particularly in relation to internet sales and the risk of non-compliant products imported to the EU).

(2) Better explain the options. The report should better explain the rationale behind the design of policy options, and describe in greater detail how the additional derogation mechanism would work in practice. In doing so, it should clarify the likelihood that the 7 years postponement would indeed allow for a full replacement of animal tests in the area of skin sensitisation in place, and why the option of postponing the 2013 deadline without a fixed deadline is considered the most coherent in relation to other EU legislation addressing animal testing issues. In defining the key principles of the new derogation mechanism, and in view of the criticism raised by stakeholders, the report should clarify (i) the operational definition of the criteria of "considerable technical progress" and "significant added value", (ii) the additional information that would be required from manufactures, (iii) the duration of the verification process (including the opinion of the Scientific Committee on Consumers Safety), (iv) why there is a need for manufacturers to demonstrate their commitment to investment in research, (v) how the access for SMEs/micro-enterprises would be facilitated and (vi) how the data sharing between manufacturers would be encouraged.

(3) Strengthen the assessment of impacts. In order to better assess the proportionality of the policy options, the report should better indicate the expected magnitude of the analysed impacts and its distribution along the value chain. In particular, it should clearly present the likely number of animals tested exclusively for the EU cosmetics requirements per option, and analyse in more detail to what extent the derogation option would mitigate the impacts of the 2013 marketing ban, at what costs and for which market players. Impacts on Member States/regions, SMEs/micro-enterprises, up- and-downstream operators, competitiveness of the EU cosmetics sector (including its ability to maintain its competitive position on key export markets requiring de jure or de facto animal testing) and the risk of trade problems with third countries (no longer able to export animal-tested products to the EU) should be assessed in a more concrete manner. Where such evidence does not exist, or is inconclusive, this should be clearly highlighted in the report.

(4) Improve the comparison of options. Based on the strengthened analysis of impacts, the report should clearly summarise qualitatively and quantitatively all positive and negative economic, social and environmental impacts for each policy option (also in a tabular format). On that basis it should better compare the policy options in terms of their effectiveness, efficiency and coherence and in more balanced manner (particularly in relation to the derogation option). In doing so, the report should refrain from calculating the average of the plus and minus signs and should demonstrate how the number of avoided animals tested compares to the changes in costs under each of the policy options. When assessing coherence with other objectives of the EU policies, trade-offs between the economic and social domain should be more clearly presented. Finally, the appropriateness of identifying a preferred policy solution should be re-considered.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The report should clarify if all affected stakeholders could express their views on the issues at stake, including the design and impacts of the policy options. It should then present the different views of stakeholders in a more detailed and balanced manner throughout the main text, clearly identifying stakeholders in favour and against the extension of the 2013 marketing ban. Finally, the report should clarify how each of the objectives would be monitored and evaluated.

(E) IAB scrutiny process	
Reference number	2011/SANCO/025
External expertise used	No
Date of IAB meeting	23 May 2012