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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT ON THE ANIMAL TESTING PROVISIONS IN REGULATION (EC) 1223/2009 ON COSMETICS Accompanying the document Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics

Delegations will find attached the Commission document SWD(2013) 67 final.

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{COM(2013) 135 final}
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INTRODUCTION

The Cosmetics Directive[1] foresees a phasing-out of animal testing for cosmetic products. A ban of animal testing of finished cosmetic products has been in force since September 2004 and a testing ban on ingredients or combinations of ingredients in order to meet the requirements of the Directive since March 2009. As from March 2009, it is also prohibited in the EU to market cosmetic products and their ingredients which have been tested on animals in order to meet the requirements of the Directive, irrespective of the origin of these products. This marketing ban applies to all but the most complex human health effects to be tested to demonstrate the safety of cosmetic products (repeated-dose toxicity including skin sensitisation and carcinogenicity, reproductive toxicity and toxicokinetics), for which the legislator extended the deadline to March 2013.

The assessment of the 2013 marketing ban deadline is foreseen in the Cosmetics Directive itself. Article 4a (2.3) of the Cosmetics Directive obliges the Commission to study the progress and compliance with the implementation deadlines in relation to animal testing and to report to the European Parliament and the Council. In particular, the Directive provides that if alternatives to animal testing in relation to the endpoints covered by the 2013 marketing ban are not developed and validated by the 2013 implementation date, the Commission shall inform the European Parliament and the Council and put forward a legislative proposal. These provisions were not changed by the recast of the Cosmetics Directive by Regulation 1223/2009/EC[2]. The Cosmetics Regulation repealing the Cosmetics Directive as of 11 July 2013, any proposal would amend the Cosmetics Regulation only.

The Commission has monitored the progress in the development of alternative methods to animal testing on a yearly basis and presented its final report to the European Parliament and the Council[3] on 13 September 2011. It concludes that alternatives to animal testing in relation to endpoints in question will not yet be available by 2013. It is against this background that the potential impacts of the possible policy options in relation to the 2013 deadline are assessed.

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1 Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169.

2 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products; OJ L 342, 22.12.2009, p. 59

3 Report on the Development, Validation and Legal Acceptance of Alternative Methods to Animal Tests in the Field of Cosmetics (2009), 13.9.2011, COM(2011) 558 final

1. PROBLEM DEFINITION

Efforts to completely end animal use for cosmetic purposes go back a long time. First provisions in relation to the marketing ban of cosmetic ingredients or combinations of ingredients tested on animals in order to meet the requirements of the Directive were introduced to the Cosmetics Directive in 1993, with a foreseen application by 1998, and then postponed three times because alternative methods were not yet available. The current provisions were introduced in 2003.

Virtually every European citizen uses a multitude of cosmetic products every day, from soap, shampoo, conditioner, deodorant, toothpaste, shaving cream, aftershave, cleanser, perfume, make-up to a whole range of other products. The objective of the Cosmetics legislation is on the one hand to ensure that consumer health is not put at risk by their use and on the other hand to ensure that these products can circulate freely in the Union. To this end the responsible person must carry out a safety assessment, which includes a study of the intrinsic properties of all ingredients contained in the product. A number of key human health endpoints need to be addressed in this assessment, such as whether the ingredient can cause allergies or damages health as a result of its repeated use.

Some of the questions that must be addressed in the safety assessment can currently only be answered by relying on toxicological data obtained from animal testing. Alternative methods to replace these tests will according to the Commission findings not be available by 2013. The problem is therefore in a nutshell that the marketing ban would apply as of 11 March 2013 in the absence of full alternative methods. Under the Cosmetics legislation only cosmetic products that are safe for human use can be placed on the market. As a result, ingredients with insufficient data packages and for which the safety is not established shall not be allowed to be placed on the market, leading to a reduced access to new ingredients and ultimately innovative products.

1.1. Subsidiarity

The use of Union competences is governed by the principles of subsidiarity and proportionality (Article 5 TEU). The current EU legislation on cosmetics is based on Article 114 TFEU (ex-article 95 TEC) and its aim is to ensure a high level of protection of human health as well as the proper functioning of internal market. The Cosmetics Directive/Regulation exhaustively harmonises rules on consumer safety of cosmetic products placed on the Community market. Thus, changes to this legal framework can only be achieved by Community action. The marketing ban directly addresses the free movement of cosmetic products in the Union. This is already subject to harmonized legislation and can not be addressed at Member State level. It can therefore only be achieved at Union level.

2. OBJECTIVES

The general objective is to ensure a proper functioning of the internal market and maintain a high level of protection of human health, while paying full regard to the welfare requirements of animals.

The specific objectives followed are accordingly on the one hand linked to the functioning of the internal market (specific objectives 1 and 2, Article 114 TFEU) and on the other hand to the animal welfare objective (specific objectives 3 and 4, Article 13 TFEU):

- To maintain consumer safety and consumer choice (specific objective 1 – Consumer Safety and Choice)

- To maintain innovation and competitiveness of the European cosmetics industry (specific objective 2 – Innovation and competitiveness)

- To provide animals with a high level of protection and welfare (specific objective 3 - Animal Welfare)

- To maintain the incentive for continued research on alternative methods to animal testing (specific objective 4 – Research into alternatives)

3. POLICY OPTIONS

The policy options discussed in the assessment are:

Option 1: Baseline/No Action

Under option 1 the Commission would not make a proposal and the marketing ban would enter into force on 11 March 2013. The rationale is that this is the most effective way to obtain the overarching political objective that led to the current provisions – to end animal testing for cosmetic purposes.

Option 2: Postpone the 2013 deadline

Under option 2 the deadline would be postponed. Three sub-options are considered, to postpone with a fixed deadline, to postpone in relation to certain endpoints only or to postpone without fixed deadline. All sub-options follow the rationale to maintain the overall objective to end animal testing for cosmetic purposes. They take account of the finding that alternatives are not yet available and thus make reaching the objective one way or the other dependant on the availability of alternative methods. Option 2 (a) would postpone the application of the marketing ban by 7 years, the time by when alternatives at least for skin sensitisation are expected to be available. Option 2 (b) would equally postpone the deadline, but would limit the postponement only to those endpoints most needed to demonstrate the safety of the cosmetic products, ie. skin sensitisation and repeated dose. Option 2 (c) would foresee a postponement without a fixed deadline. The ban would apply as soon as alternatives actually become available. The rationale behind this option is that it would let science deliver and that it follows a similar logic to those in other regulatory fields.

Option 3: Maintain the deadline and introduce an additional derogation mechanism

Option 3 would allow cosmetics and cosmetics ingredient manufacturers to request a derogation from the marketing ban for ingredients or combinations of ingredients under limited circumstances. A derogation would be granted in case the ingredient brings innovation and a significant benefit to consumer health, consumer wellbeing and/or the environment. Each case would come under the scrutiny of the Commission and would require weighing benefits of any new ingredients against the stated objective of ending all testing of cosmetics on animals. Since it would be a derogation, the cases in which it would be granted should represent the exception, not the rule.

Manufacturers would also need to demonstrate that toxicological data needed for the safety assessment is not available and cannot be obtained using alternative methods to animal testing. Details on the proposed place of testing, the protocol followed, the number of animal involved and the animal welfare standards applied must be provided.

The commitment of the manufacturer in relation to investment in research for alternative methods would need to be substantited and provisions would be included to avoid duplication of testing. In terms of procedure, a derogation would be granted in the form of a Commission Decision, after consultation of the appropriate expertise.

4. COMPARISON OF POLICY OPTIONS AND THE ASSESSMENT OF THEIR IMPACT

Option 1 would be the most effective of the options in relation to the animal welfare related objectives. It would end animal use for EU cosmetic purposes by March 2013. This would mean that a sub-set of the 15 000 – 27 000 animals estimated to be used for EU cosmetic purposes outside the EU per year would be spared. Option 1 is expected to maintain or even increase the current research on alternative methods, simply because in most cases it will only be possible to bring new cosmetic ingredients on the market once alternatives are available. It would thus have effects beyond the Cosmetics legislation and beyond the EU in that it can act as a critical accelerator in the development of new approaches to human risk assessment. Specific impacts on consumer safety are not expected from option 1. In case insufficient data is available for ingredients products containing them cannot be brought on the market.

Option 1 could however come with certain negative economic and social impacts. It could lead to a more reduced access to cosmetic ingredients, since ingredients for which insufficient data packages exist cannot be placed on the market or may not be able to be defended. This loss of ingredients and product innovation could lead to a certain loss of competitiveness of the cosmetics industry. It is estimated by industry stakeholders that large companies will have an overall significant loss in turnover and profitability, with losses ranging from 3 to 20% in the short term (2013-2015), 7 to 20 % in the medium term (2015 – 2018) and 1 to 25% in the long term (2018 and beyond). Reduced competitiveness could also affect employment. Industry stakeholders expect a reduction of several thousand R&D staff, up to 8 000 in the worst case, as well as other staff.

It has to be stressed however that these figures are estimates from the industry stakeholders. Cosmetic manufacturers that work under the 'Leaping Bunny' label, thus already now are not relying on animal testing after certain cut-off dates, consider that the economic impacts could be positive. The cosmetics industry may also be able to counterbalance these effects by other approaches to innovation.

Option 2 would be the least effective in relation to the animal welfare objectives in that it would lead to a continued animal use for cosmetic purposes. While it maintains the overall objective to end animal testing, it would postpone ending it beyond 2013. Under option 2 (a) this would mean a continued use of the 15 000 to 27 000 animals for next 7 years. Under option 2 (b), less animals would be used as the postponement would not cover certain tests, about 12% less animals are likely to be used. Under option 2 (c) there would be no fixed end date to the yearly use of 15 000 to 27 000 animals, but numbers would reduce in the future when alternatives become available.

Option 2 would however have no or very limited negative economic and social impacts. Under option 2 the current situation is basically maintained, a situation which has allowed the

European cosmetics industry to be home to some of the most advanced and luxurious cosmetic product brands and to largely resist the economic crisis.

Option 3 would lead to better impacts for animal welfare than option 2, but worse impacts than optimal. It would lead to the possibility to request derogations and, thus, in a number of cases to testing outside the EU for EU cosmetics purposes beyond 2013. The number of animals impacted would depend on how often such a derogation would be granted. At a minimum about 100 animals would be used per derogation. Assuming 10 to 15 derogations would be granted per year this would mean that between 1 000 and 1 500 animals would be used.

As regards the economic and social impacts, option 3, while leading to a similar situation as option 1, could mitigate the possible impacts by allowing introducing the most valuable ingredients and product innovations with particular benefit for consumers. The operational application of Option 3 would however be challenging, as every single derogation would require difficult and controversial judgements by the Commission, in particular whether the potential benefit of the cosmetic would be significant and hence justify animal tests.

Overall, the quantitative assessment of the different options faces limitations in relation to the animal welfare objective, because the total number of animals involved is relatively low in comparison with other sectors and because the differences in animal use between the options are difficult to quantify beyond the overall estimates. In relation to the internal market objectives, while there will be a reduced access to existing and new ingredients and economic and social impacts are likely to result from this, they remain extremely difficult to quantify.

All stakeholders concerned share the overall objective to end animal testing for cosmetics. None of the stakeholders has an interest in animal testing as such, other than as a tool to ensure and demonstrate consumer safety. Indeed alternative methods may turn out to be beneficial for industry.

However, the views of stakeholders voiced throughout the consultation process on what to do in cases in which alternatives are not available were split. Animal welfare stakeholders took a clear position against any proposal in relation to the 2013 deadline, be it a postponement or the introduction of a derogation mechanism. This position is based on ethical principles. Industry stakeholders have underlined that they expect significant negative impacts on availability of ingredients, product innovation and on their competitiveness from the 2013 deadline and have therefore overall supported a postponement of the deadline. Industry stakeholders nevertheless recognised that - as a fall-back position in case the Commission does not propose a postponement - a derogation will at least allow access to the most innovative and beneficial ingredients.

Options 1 and 2 do not raise any specific additional administrative costs for the industry, Member States or the Commission. Option 3 however does raise administrative costs at industry and Commission level.

These costs would arise on the industry side for the preparation and the follow-up of a derogation file and are estimated to be approximately EUR 15 000 per file. In addition, for each application the company would have to demonstrate financial commitment in research of alternative methods.

Costs arise also for the Commission, as it would require additional resources to assess derogation requests. Assuming that about 10 to 15 derogations per year would be dealt with it is estimated that 2 full time staff would be needed.

5. CONCLUSIONS, MONITORING AND EVALUATION

The report does not recommend a preferred option. It recognises that the choice is a political one.

In order to ensure monitoring, the Cosmetics Directive/Regulation foresees a regular reporting mechanism to the European Parliament and the Council.

Implementation and enforcement issues will in addition be reviewed in the various fora already in place, such as the Cosmetics Committee, the Working Group on Cosmetics and the Platform of European Market Surveillance Authorities (PEMSAC).