Implications of Postponement of the 2013 Deadline for Implementation of the 7th Amendment to the Cosmetics Directive

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ABSTRACT

The 7th Amendment to the Cosmetics Directive (76/768/EEC), adopted in 2003, was a political and social landmark in codifying widespread concern among the European public about the use of animals in cosmetics testing. The amendment was the result of a lengthy political process and has faced a number of challenges since. In addition to prohibiting animal testing within the European Union, the amendment introduced a two-stage ban on the marketing of cosmetics containing ingredients tested on animals for human health effects, irrespective of the availability or regulatory acceptance of alternatives, with a final deadline of March 2013. These deadlines have provided a positive impetus for the development of alternatives and their use outside the cosmetics sector, including meeting the requirements of other legislation such as REACH. There is, however, widespread consensus that validated alternatives to the tests still permitted will not be available by 2013 and the European Commission is therefore expected to propose legislation in 2011 that may postpone this deadline. In addition to the scientific challenges posed by developing alternative methods, the continued use of animals for cosmetics testing raises strong ethical and legal questions and can be seen as a test case for the principle of "harm-benefit" analysis enshrined in the new EU directive on animal experimentation. This poster examines the background to the current situation, the approaches taken by national governments and international bodies to the existing provisions and the implications of postponement of the deadline, especially in the context of the additional animal testing expected in order to meet REACH requirements in the period until 2018. It concludes that the ethical case against postponement remains compelling and that other advantages result from maintaining the current date. These factors must be addressed by scientists, companies and policymakers in formulating a response to the technical, commercial and political challenge posed by the deadline.

INTRODUCTION

The 7th Amendment of the Cosmetics Directive (subsequently translated fully into Regulation 1223/2009) introduced a rolling ban on the marketing of cosmetics products containing ingredients tested on animals. The first deadline in 2009 prohibited acute toxicity testing, and the second deadline, scheduled for 2013, prohibits repeat dose, reproductive toxicity and toxicokinetics tests on animals. Article 18.2 of the Regulation states that in the event of an expert assessment that validated alternatives to all the tests will not be available two years before the final deadline, the European Commission "shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty [ie to proceed by co-decision]" (EU, 2009). Current expectations are that these alternatives will not be available and that the Commission will therefore propose a postponement of the 2013 deadline by March 2011.

This question is not one that is exclusively scientific in scope, however. The original policy was adopted to give expression to social concern about cosmetics testing on animals and to postpone the final deadline at this point on the basis that availability of alternatives alone would fail to take account of all relevant issues that should inform the policy process. This poster examines those issues, identifying key aspects of the background to the original proposal, its subsequent effects and the issues of relevance to the decision that is now expected to face the institutions of the European Union in considering any legislative proposal.

7th Amendment Timeline

1993 76/768 Directive 93/35/EEC (6th Amendment) – proposes marketing ban to take effect in 1998

1997 Ban postponed to 2000

2000 Ban postponed to 2002

2000 7th Amendment introduced to EU legislative process

2002 Conciliation reaches agreement on amendment

2003 Amendment passed as 2003/15

2004 11 March: Entry into force; ban on cosmetics products testing

2005 French government appeal against Cosmetics Directive rejected

2009 11 March: Marketing ban for short-term endpoints; ban on testing of ingredients in EU

2009 Directive 76/768 replaced by Regulation 1223/2009

2011 March 11: Deadline for legislative proposal to postpone deadline

2013 March 11: Deadline for complete marketing ban

Public Opinion

The original impetus for the ban was public opinion against cosmetics testing on animals. For instance, a 1996 UK poll found 73 per cent of respondents in favour of a cosmetics test ban (Body Shop, 1996), and the significance of public opinion was acknowledged by the European Commission and other players throughout the process.

"… [T]he prohibition of animal testing for this purpose is of keen interest to the European Parliament and the general public." (Schuman, 2002 [DG Enterprise])

Assessment of public opinion across Europe on cosmetics testing has not been undertaken since the amendment was passed, but the European Commission's Eurobarometer 225 survey in 2005 found that:

"82% of EU citizens uphold our duty to protect the rights of animals whatever the cost."

Indications are that public opinion is consistent over time. According to a UK poll conducted by Opinion Research Business in 2004 on behalf of the British Union for the Abolition of Vivisection, 79 per cent of people said they would be likely to switch to a brand that was not tested on animals if they discovered that their existing brand was tested on animals (BUAV, 2010), an indication of similar concern to that found in 1996.

Political Impetus

Members of the European Parliament who were most active in pushing for the 7th Amendment made it clear that their support (and that of the Parliament) was based on an ethical position regarding the relative values of improved cosmetics and animal suffering. For them, the issue was not availability of alternatives but an evaluation of harm-benefit that favoured ending animal tests.

Chris Davies MEP: ***"For too long the cosmetics industry has dragged its feet and refused to make the commitment necessary to develop alternatives to animal testing. Now the law will be clear. Bathroom shelves are already packed with shampoos, deodorants and face creams, and we do not need any more if the price to be paid is continuing animal suffering."*** *(The Independent,* 2002*)*

Dagmar Roth-Behrendt MEP: ***"Most people would agree that we have enough kinds of lipsticks, soaps and perfumes. We don't need to torture hundreds of thousands of animals to get these cosmetics."*** (*New Scientist*, 2002)

Philip Whitehead MEP: ***"The parliament wants to put an end to cosmetic testing and there are times when members of the parliament vote with their consciences, especially on big issues such as this one, and that is what happened. … This proposal puts animal welfare above human vanity, but never above human health."*** (*Daily Mail,* 2002)

MEPs in the current Parliament have yet to consider this issue, but it is to be expected that many will take a similar view.

Harm-Benefit

Since the 7th Amendment was passed, the EU has reviewed the legal basis for all animal experiments. The current (and anticipated final) version of the forthcoming EU Directive on the protection of animals used for scientific purposes states:

"… [A]nimals should always be treated as sentient creatures and their use in procedures should be restricted to areas which ***may ultimately benefit human or animal health****, or the environment."* (Recital 10, emphasis added)

In addition, it states:

"It is also essential to ensure both on moral and scientific grounds that each use of animals is carefully evaluated on the scientific or educational validity, usefulness and relevance of the expected result of that use." (Recital 38)

It also mandates:

"… a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress, ***is justified by the expected outcome****, taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment."* (Article 37, emphasis added) (Council of the European Union, 2010)

Because the testing of cosmetics and cosmetics ingredients within the EU is already illegal, it will not be assessed directly in this new ethical review. On the basis of the principles outlined above, however, animal testing for cosmetics would appear very unlikely to pass the harm-benefit test (the practice of the UK, which already has a "cost-benefit", test not to issue licences for work on cosmetics ingredients or products supports this view). Given the existence of thousands of safe, approved cosmetics ingredients, no benefit to human health arises from testing of cosmetics for human health endpoints, and public and political opinion has already concluded that other benefits are unjustified by the harm. Postponement of the deadline for a complete marketing ban therefore appears inconsistent with the principles of the new directive.

Availability of Alternatives in 2013

At this time, the European Commission is compiling the report on anticipated availability of alternatives, on which the Commission's decision will be based. Draft versions of the report (European Commission, 2010) indicate that it is currently expected to say that alternatives for all endpoints will not be available, although further contributions from stakeholders may change this before finalisation. Nevertheless, it appears reasonable to conclude that alternatives will not be validated for all endpoints and the current regulator, the Scientific Committee on Consumer Safety has already made clear its view that it does not expect to be able to make an assessment of the safety of cosmetics ingredients without the use of animal tests or validated alternatives after 2013.

"The SCCS is of the opinion that evaluation of the systemic risk via repeated dose toxicity testing is a key element in evaluating the safety of new and existing cosmetic ingredients. If these data are lacking in a new cosmetic ingredient submission to the SCCS, it is considered not feasible to perform risk assessment of the compound under consideration." (SCCS, 2009)

"[T]he majority of the existing alternative methods is only suitable for hazard identification of cosmetic ingredients and do not give information on potency. Thus, a full human health risk assessment cannot be performed." *(Ibid)*

Many experts consider that combinations of alternative methods by 2013 or shortly thereafter will provide sufficient information for regulatory decisions to be made. Even if this is not the case, however, benefits of maintaining the deadline to stimulate the earliest possible development of alternatives must be balanced against the actual consequences of an inability to conduct full safety assessment, which will not be a threat to human health but restrictions on the availability of new ingredients for cosmetics sold in the EU.

Cosmetics Directive and REACH

Regulation 1906/2007 on the Registration, Evaluation, Authorisation and Restriction of Chemicals will lead to a significant increase in regulatory animal testing in the EU, with authoritative estimates ranging between 9 and 54 million animals in total (*Nature*, 2010). While REACH promotes the use of alternatives wherever possible, its basic framework mandates animal tests, (including for many endpoints which are also required to meet the requirements of the Cosmetics Regulation [see table below]), and it contains no active mechanism to stimulate or enhance the development of alternatives. The necessity for alternatives is therefore even greater in the period of REACH implementation, and the impetus for alternatives development provided by the 2013 deadline is of more significance than ever at this time.

REACH Toxicity Endpoint (Cosmetics Relevant)	Status of Validated Replacement Alternatives
Acute toxicity	Full replacement not available
Skin corrosivity	Validated replacement method
Skin irritation	Validated replacement method
Eye irritation	Partial replacement methods
Skin sensitisation	Not expected by 2013
28/90 day repeat dose	Not expected by 2013
Genotoxicity/mutagenicity	Partial replacement methods
Reproductive toxicity*	Not expected by 2013
Chronic toxicity (12 months)*	Not expected by 2013
Toxicokinetics*	Not expected by 2013
Carcinogenicity*	Not expected by 2013

Marketing ban in 2009
Marketing ban in 2013

* Not always required for cosmetics ingredients

Development of Alternatives

The deadlines established by the 7th Amendment have stimulated considerable activity in the development of alternatives and can be considered very successful as policy mechanisms for promoting scientific innovation and focussed research, both by industry and European institutions. Most recently, in 2009, the European Commission and European Cosmetics Association announced a €50m fund for research on systemic toxicity (European Commission, 2009), addressing the endpoints to be banned in 2013. The table below illustrates a selection of activity co-ordinated at European level since the 7th Amendment and does not include the activities of individual companies, laboratories, researchers and member states or any activity out with the EU. (Deadlines set by earlier amendments also provided impetus for development of alternatives before the 7th Amendment.)

Toxicity Endpoint	2009 Ban	2013 Ban	Commission Activity	Industry Activity
Acute toxicity	Y		Acute-Tox EPAA*	EPAA
Skin corrosivity	Y		Method already validated	
Skin irritation	Y		EPAA	EPAA
Eye irritation/corrosion	Y			Colipa*
Dermal absorption	Y		Method already validated	
Skin sensitisation		Y	Sens-it-iv	Colipa
28/90 day repeat dose Chronic toxicity (12 months)*		Y	Predictomics	Colipa
Genotoxicity/mutagenicity		Y	CarcinoGENOMICS, Comics	Colipa
Reproductive toxicity*		Y	ReProtect, EPAA	EPAA
Photo-induced toxicity		Y	Method already validated	
Toxicokinetics*		Y	ESNATS	
Carcinogenicity*		Y	CarcinoGENOMICS	
General, including Integrated Testing Strategies			OSIRIS, AXLR8, OpenTox, ESNATS, EPAA	EPAA

"… [I]t can be expected that the process of developing … alternative methods will demand innovative techniques, generate technological progress and result in an overall increase of knowledge, opening new doors for science and business. Therefore, today's investment in research can represent a competitive advantage for Europe in the future."

European Commission, *Alternative Testing Strategies Progress Report 2009*

*****EPAA: European Partnership for Alternative Approaches to Animal Testing
Colipa: The European Cosmetics Association

Implications of Postponement

If the availability of validated alternative methods is permitted to be the sole determinant of EU policy, postponement of the 7th Amendment marketing ban appears very likely. The 7th Amendment was, however, the culmination of a long political process which was driven by a fundamental ethical calculation that the value of new cosmetics ingredients was outweighed by the harm caused to animals in their testing. Since the amendment was passed, the political institutions of the EU have endorsed and enshrined the principle of harm-benefit in the new directive 8869/10, and there is no evidence to suggest that the European public (or their elected political representatives) have altered their ethical position. Given the existence of thousands of substances already approved as safe for use as cosmetics ingredients, no significant negative consequences to European industry or the European public arise from retention of the deadline. Postponement of the ban is therefore likely to be unpopular with the European public and lead to disenchantment with the political system. In addition, the deadlines of the Directive have driven industry and EU level research on alternatives, with positive effects including scientific innovation, competitive advantages and reduction of animal use for cosmetics and other safety testing (including REACH). If the 2013 deadline is postponed, motivation to develop alternative tests is significantly reduced, and in difficult economic times, reduction of investment is a genuine risk.

References

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