Title:

Amendment to the EU Cosmetics Directive

IA No:

Lead department or agency:

Department for Business, Innovation and Skills (BIS)

Other departments or agencies:

Impact Assessment (IA)

Date: 01/01/2011

Stage: Final

Source of intervention: EU

Type of measure: Secondary legislation

Contact for enquiries:

Summary: Intervention and Options

RPC: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
Positive	Unquant	£0.3-2.6m	No	NA

What is the problem under consideration? Why is government intervention necessary?

Under the EU Cosmetics Directive, an ingredient which is judged to pose a risk to human health may be prohibited or its use subject to certain restrictions and conditions. Over time, amendments to the Directive may be required when technical progress results in the better understanding of risks in existing products or the development of new ingredients and products, some of which, on the basis of scientific evidence, may not be deemed safe for consumers. A further amendment to the EU Directive is necessary at the present time to reflect the findings of a safety assessment of hair dyes carried out by the Science Committee on Consumer Safety (SCCS).

What are the policy objectives and the intended effects?

The SCCS safety assessment found no conclusive evidence that one substance used in the manufacture of cosmetic products - o-aminophenol - can be considered safe. Accordingly, to protect consumer health, it is proposed that this substance should be prohibited under an amended EU Cosmetics Directive.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The Department has considered two options:

Option 0: Do nothing
Option 1: Implement the amended EU Directive.

The preferred option is Option 1. This is because the UK is required by EU law to implement this legislation and runs the risk of infraction proceedings should it not do so.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent)			**Traded:** N/A		**Non-traded:** N/A

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: _____ Date: 8/12/2011

URN 11/1109 Ver. 3.0

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £0.3m	**High:** £2.6m	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Unquantifiable	Unquantifiable	**£0.3m**
High	Unquantifiable	Unquantifiable	**£2.6m**
Best Estimate	Unquantifiable	Unquantifiable	

Description and scale of key monetised costs by 'main affected groups'

Costs incurred relate to the development, manufacture, marketing and labelling of reformulated hair dye products which do not contain the prohibited ingredient o-aminophenol. The above estimates are based on previous independent economic analysis on the costs and benefits of the entire EU Cosmetics Directive and are thus very likely to be overestimates of the costs of complying with the technical amendments. There are no costs to business or public authorities in terms of enforcement.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Unquantifiable	Unquantifiable	**Unquantifiable**
High	Unquantifiable	Unquantifiable	**Unquantifiable**
Best Estimate	Unquantifiable	Unquantifiable	Unquantifiable

Description and scale of key monetised benefits by 'main affected groups'

Business benefits could include increased sales associated with greater access to global markets and EU markets and increased competitiveness through further technological progress and innovation. These have not been quantified in this impact assessment

Other key non-monetised benefits by 'main affected groups'

There are likely to be additional consumer and business benefits including greater consumer trust and satisfaction, and safer products and reductions in incidents involving hair dye products.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Many of the costs and benefits associated with compliance with the proposed technical amendments will already have been realised since firms have been aware for a long time that o-aminophenol was likely to be prohibited and taken steps to develop new products which do not contain it. Limitations associated with methodological approach used in this impact assessment mean that compliance costs are very likely to have been overestimated. Total costs largely assumed to be one-off transition costs.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0.3-2.6b	Benefits: Positive	Net: Positive	No	NA

Evidence Base (for summary sheets)

Problem under consideration

The EU Cosmetic Directives ensures that cosmetic products in the EU are safe by specifying which chemical ingredients for use in cosmetic products are allowed, prohibited or permitted subject to particular restrictions.

Over time, technical amendments to the Directive may be required[1]. There may be two reasons for this. First, further technological innovation in the industry has taken place resulting in the development and commercialisation of new or reformulated cosmetic products. Secondly, ongoing scientific research and assessments by the European Commission's Scientific Committee on Consumer Safety (SCC) brings about a better understanding of the health risks associated with the use of certain substances.

The hair dyes strategy

Serious human health concerns have been raised over the use of certain chemical substances in hair dye products. In light of these concerns, the cosmetics industry and the European Commission launched a strategy to regulate the use of hair dye substances within the EU. Together with the European Commission's Scientific Committee on Consumer Safety (SCCS), they have been assessing the safety of these specific substances for their genotoxicity and mutagenicity whilst provisionally permitting the use of the chemicals (until 31 December 2011).

On 22nd June 2010, the SCCS published its opinion on the use of a particular chemical substance used in the manufacture of hair dyes, o-aminophenol[2]. In it, the SCCS stated that on the basis of available data, o-aminophenol could not be considered a safe ingredient for use in hair dye products and should therefore be added to the list of prohibited substances under Annex II of the EU Cosmetics Directive.

Separately, the SCCS also stated that certain hair dye substances that were only provisionally authorised should be categorised under Annex III of the EU Directive. This Annex covers the list of substances that cosmetic products can only contain subject to the necessary conditions and restrictions included.

Rationale for intervention

Following the conclusions of the latest assessment by the SCCS on various hair dye substances, further technical amendments to the EU Cosmetics Directive are required to ensure that EU consumers continue to be protected from cosmetic products which could pose a risk to their health.

The new Directive (2011/59/EU) amends the Cosmetic Products Directive by including a number of substances that were only provisionally authorised into Part 1 of Annex III to the Directive. This Annex covers the list of substances that cosmetic products can only contain subject to the necessary conditions and restrictions included. One substance, o-aminophenol, is also added to Annex II and prohibited from use in cosmetic products.

Scope of impact

It is not possible to ascertain precisely the number of UK hair dye manufacturing firms which would be affected by the proposed technical amendments to the EU Cosmetics Directive. This is due to the poor availability of official statistics and industry data on the number of hair dye manufacturing firms active in the UK and information on how many of these firms have used, or continue to use, o-aminophenol in their hair dye products. To collect such information would be a resource intensive and time-consuming exercise as it would require examining company records going back several years. This is because

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[1] The Directive is "*old approach*" in nature with the detailed requirements set out in the annexes to the Directive. Old approach is the pre-Single Market legislative technique used in the EEC to harmonise legislation. The technical requirements were written into the body of the Directive (or the annexes) and required constant amendment to take account of state of the art development and new knowledge.

[2] SCCS (2010) *Opinion on o-Aminophenol*
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_025.pdf

many firms stopped using o-aminophenol in their hair dye products as far back as 2003 when it first became apparent that use of this chemical ingredient would likely be prohibited at some future date.

However, for the reasons set out below, we believe the actual figure is likely to be relatively small.

First, while we have not been able to find official statistics or industry data on the number of hair dye manufacturing firms in the UK we have found officials statistics published by the Office for National Statistics (ONS) on the wider perfumes and toilet preparations manufacturing industry. According to the ONS this wider industry comprised approximately 336 firms in 2009, generating approximately £714m in Gross Value Added and employing around 16,000 people. This would suggest that the number of UK firms engaged in hair dye manufacturing is relatively small.

Secondly, not all UK hair dye manufacturing firms are likely to have used o-aminophenol in their products. This is because, according to industry evidence, o-aminophenol was not widely used by the industry as other chemical ingredients were available which were comparatively more effective.

Policy objective

The policy objective is to ensure that only safe substances can be used in cosmetics thereby protecting consumers whilst allowing businesses to continue using a wide range of substances to bring innovative products to market thereby supporting growth in the UK industry. The amending Directive makes permanent the provisional allowances that end on 31 December and is welcomed by the UK industry.

Description of options considered

Option 0 - Do Nothing (de minimus)

The UK Government is required to implement the required technical amendments to the EU Cosmetics Directive so a 'do nothing' option is not viable.

The UK Government could leave industry to self-regulate, for example by adopting a voluntary code of practice. However, it is possible that under such a solution, some UK hair dye manufacturing firms that are still using o-aminophenol may continue to do so. This may hinder UK industry in terms of hampering further innovation in the form of the development of new hair dye products and leaves open the risk of consumers being harmed by products containing and could lead to reduce sales and market share in the EU as consumers across all Member States including the UK switch to alternative hair dye products offered by their competitors which do not contain o-aminophenol.

Under this option, there is the continued risk of consumers in the UK being harmed by hair dye products which still contain this chemical ingredient.

In addition, the existing UK Regulations, the Cosmetic Products (Safety) Regulations 2008 which remain extant would deny the cosmetics companies the opportunity of using the permitted substances that were previously only provisionally allowed.

Option 1 - Implement the amended EU Directive

In view of the risks and costs outlined above, the preferred option is to transpose the Directive into UK law by making an Statutory Instrument to amend the existing Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) using the powers available under the Consumer Protection Act 1987.

The following analysis on the potential costs and benefits is deemed proportionate given the relatively small number of UK firms falling under the scope of the proposed technical amendments and the limited availability of relevant industry data and analysis on the impact of EU cosmetics regulation on UK industry. A fuller analysis could be conducted however the collection of the necessary additional information would be a resource intensive and time-consuming exercise.

Under Option 1, UK firms would incur costs developing, manufacturing, marketing and labelling hair dye products which do not contain o-aminophenol. Many firms in the UK have already reformulated their products in a way which is compliant with the new Directive and so incurred these costs.

There are two possible explanations for this. First, there was little industry support for o-aminophenol when the EU hair dye strategy was launched in 2003, with a strong likelihood that it would be prohibited at some point in the future under a new Cosmetic Directive. Accordingly, many UK firms have taken voluntary pre-emptive action to reformulate their hair dye products before proposals to prohibit o-aminophenol were formally brought forward. A second possible reason why much of industry has already moved away from using o-aminophenol in hair dye products is that it is not particularly effective compared to other chemical ingredients which are available.

According to one firm in the UK cosmetics industry, the one-off cost of reformulating hair dye products away from o-aminophenol was in the region of £5,000. However, this figure cannot be used to estimate the total cost to the UK Cosmetics Industry of implementing the proposed technical amendments. This is because one-off and ongoing compliance costs are likely to vary across firms and depend on a range of factors such as the availability of alternative products, the extent to which existing manufacturing processes need to be reconfigured by an individual firm, and the additional labelling and marketing that may be required.

Work by RPA[3] based on a survey of a small sample of firms in the UK Cosmetics industry concluded that the total costs of complying with all aspects of the Cosmetics Directive was between 0.1 and 1% of turnover for around 70% of responding firms. If RPA's findings were applied to total UK domestic and export sales of hair dyes, which in 2009 were roughly in the region of £260m[4], this would imply total costs of approximately £0.3-£2.6m. We are unable to use the RPA's methodological approach to break this figure down into one-off and ongoing costs.

However, there are significant uncertainties around what the actual cost to UK cosmetics firms of complying with these technical amendments and it is very likely that the true cost figure lies towards the lower end of this range. There are two reasons for this. First, the costs of complying with specific technical amendments are likely to be lower than the cost of complying with all aspects of the Cosmetics Directive. Second, these technical amendments will not impact on all businesses in the UK Cosmetics Industry but rather a smaller, indeterminable number of firms involved in the manufacture of hair dyes and using o-aminophenol in their products. On this basis, £0.3m is our best estimate of the approximate cost to UK hair dye manufacturing firms of implementing the proposed technical amendments.

There are also likely to be some monitoring and enforcement costs incurred by Local Trading Standards Authorities. These costs, which are not quantified here because of the disproportionate effort that would be required, are likely to be relatively small given on the grounds that many UK hair dye manufacturing firms have moved away from using o-aminophenol, some as far back as 2003.

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[3] RPA (2007) *Impact of EU Regulation on the EU Cosmetics Industry*. The report can be accessed at: http://www.rpaltd.co.uk/documents/J574Cosmetics2.pdf

[4] The hair dye manufacture sub-sector has been proxied in this analysis by SIC 204217001 (Hair preparations excluding shampoo, perm wave and hair straighteners-lacquers. Using Prodcom statistics published by the Office for National Statistics, total domestic and export sales totalled around £260m in 2009

Drawing on the 2007 RPA study, the main economic benefits are likely to include greater consumer trust and satisfaction regarding the use of cosmetic products and increased competitiveness (possibly through further technological progress and innovation) in the industry. Given the relatively small number of firms falling under the scope of the proposed technical amendments and the disproportionate effort required to monetise consumer benefits, the potential economic benefits achievable have not been quantified here.

Competition assessment

We have considered the potential impact of the technical amendments on competition. After screening, it has been deemed that no significant adverse impact on competition is anticipated

Small firms impact test

As this is a European measure, it falls outside the scope of the microbusiness exemptions rule whereby no new regulation should impact on firms less than 10 employees and start ups.

However, having considered the potential impact of the technical amendments on smaller firms, it has been deemed that smaller firms would not be disproportionately adversely affected. This is based on survey findings from the 2007 RPA study which found that for all small firms, the total costs of complying with the EU Cosmetics Directive were less than 1% of annual turnover.

Statutory equality duties

We have considered the potential impact of the technical amendments on race, disability and gender equality and deemed that there will not be a major impact upon minority groups in terms of numbers affected or the seriousness of the likely impact, or both.

Wider impacts

Other specific impact tests have been considered including Health, Environment, Greenhouse Gas Emissions, Human Rights, the Justice System, Rural Proofing and Sustainable Development. Again after initial screening, it has been deemed that the proposed technical amendments are not expected to have any significant impact.

Risks and assumptions

There are no risks associated with the Government's preferred option on the basis that the Cosmetics industry has already aligned its manufacturing processes to account for the technical adaptation in the Directive.

Direct costs and benefits to business calculations (following OIOO methodology):

This is a European measure and is out of scope for OIOO.

Summary and preferred option with description of implementation plan.

The amending Directive is required to be implemented by 3 January 2012. We propose to do this by the Cosmetic Products (Safety) (Amendment) Regulations 2011. UK industry supports the approach proposed by the Government.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review]; In line with other EU legislation, it is expected that the PIR would take place with the standard 3-5 year timeframe. The timing of such a review, and the nature of the review itself, would be influenced by the European Commission
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] The objective is to review the effective implementation of the proposed technical amendments. The proposed technical amendments aim to ensure that all hair dye products used by consumers are safe.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] The form that the review will take is not clear at this time but will like involve some survey of UK hair dye manufacturing firms to ascertain that they are complying with the proposed technical amendments
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] The review will use the do nothing option detailed in the impact assessment as a baseline against which the impact of the proposed technical amendments on businesses and consumers can be measured.
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] The review will evaluate whether all UK hair dye manufacturing firms are complying with the proposed technical amendments, namely that they are not using the chemical ingredient o-aminophenol in the manufacture of their hair dye products.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] Monitoring of UK hair dye manufacturing firms to ensure that they are complying with the proposed technical amendments will be conducted by Local Trading Standards Authorities.