EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT No. 2) REGULATIONS 2008 No. 2566

1. This explanatory memorandum has been prepared by the Department of Business, Enterprise and Regulatory Reform and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 The Regulations implement Commission Directive 2008/42/EC (OJ No. L 093 of 4.4.2008 pages 13-23), (as amended by the corrigendum published in OJ No 136 of 24.5.2008 page 52) which amends Council Directive 76/768/EC (OJ L 262, 27.9.1976 p. 169) on the approximation of the laws of the Member States relating to cosmetic products (the Principal Directive). The Principal Directive protects public health by prohibiting certain substances in cosmetics and imposing restrictions on the use of others. The Principal Directive was implemented via the Cosmetic Products (Safety) Regulations 2008 (S.I. 2008/1284) (the Principal Regulations).

2.2 Directive 2008/42/EC amends the Principal Directive by restricting the levels of certain sensitising substances used as fragrance ingredients.

2.3 The provisions of the Directive apply from 4 April 2009 and products which fail to comply with this amendment may not be sold or otherwise disposed of to a final consumer after 4 October 2009.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Background

4.1 These Regulations are made under section 11 of the Consumer Protection Act 1987 (safety regulations).

4.2 The Principal Directive requires Member States to ban or restrict the use of certain substances in cosmetic products. It also severely limits the use of animal testing of cosmetic products and their ingredients. On 20 June 2005 the DTI submitted a scrutiny EM (9068/05) on a "Report from the Commission to the Council and the European Parliament on the Development, Validation & Legal Acceptancy of alternative methods to animal tests in the field of Cosmetics (2004)". The Commons European Scrutiny Committee considered it not legally or politically important and cleared it (Report 1, Sess

05-06). The Lords Select Committee on the EU did not report on it (Progress of Scrutiny, 27/6/05, Sess 05/06).

4.4 The Department of Trade & Industry submitted an Explanatory Memorandum on the Opinion of the Commission relating to Directive 2003/15/EC: Explanatory Memorandum 11451/02 on 30/9/02 relating to an "Opinion of the Commission pursuant to Article 251 (2), third sub-paragraph point (c) of the EC Treaty on the European Parliament's amendments to the Council's Common Position regarding the proposal for a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to Cosmetic Products".

4.5 The Commons European Scrutiny Committee considered it legally and politically important and cleared it (Report 38, Item 23741, Sess 01/02). The Lords Select Committee on the EU cleared it in Sub-Committee D on 29/1/03 (Progress of Scrutiny, 03/02/03, Sess 02/03).

4.6 Directive 2008/42/EC, is a Commission Directive and has not been subject to Parliamentary Scrutiny.

4.7 A Transposition Note is attached to this Memorandum.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom as consumer safety aspects of goods are a reserved/excepted matter.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 A consultation exercise on draft regulations to implement the Directive was conducted from 13 August – 20 September 2008. The consultation document was also sent to other interested parties published on the BERR website at:

http://www.berr.gov.uk/files/file47401.pdf

7.2 There was one response to the consultation which suggested the insertion of additional information in the Statutory Instrument.

8. Impact

8.1 An Impact Assessment is attached to this memorandum.

9. Contact

Tony Eden-Brown at the Consumer and Competition Policy Directorate, Department for Business, Enterprise & Regulatory Reform, tel: 020 7215 0360 or e-mail: tony.edenbrown@berr.gsi.gov.uk can answer any queries regarding the instrument.

DEPARTMENT FOR BUSINESS, ENTERPRISE & REGULATORY REFORM
30th September 2008

Summary: Intervention & Options

Department /Agency:	Title:	
Department for Business, Enterprise & Regulatory Reform	**Impact Assessment of the Cosmetic Products (Safety) (Amendment No2) Regulations 2008**	
Stage: Final	**Version:** 1	**Date:** 29 September 2008
Related Publications:		

Available to view or download at:

http://www.ialibrary.berr.gov.uk

Contact for enquiries: Tony Eden-Brown **Telephone:** 020 7215 0360

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

Commission Directive 2008/42/EC, on the advice of the Scientific Committee on Consumer Products (SCCP), identifies some potentially sensitising fragrance substances used in cosmetic products. It indicates these should be both restricted overall and/or labelled when they reach potentially sensitising levels. Whilst products on the UK market are believed to fall within these levels, Government intervention is necessary to transpose the Directive into UK law in order to warn consumers as they might not otherwise appreciate the potential health risks of these products, leading to a market failure

What are the policy objectives and the intended effects?

The measures overall conform to UK policy on consumer safety to protect public health. The new technical amendment will contribute to consumer safety and may have a positive effect on health, although marginal.

What policy options have been considered? Please justify any preferred option.

If the directive were not implemented in full, UK consumers might be exposed to potentially sensitising substances. The Commission would also be highly likely to take infraction proceedings against the UK if we failed to implement it. In addition exporters would have to comply with the requirements as part of their business operation.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The overall Regulations will be reviewed when the European Regulation (which is a recast of the existing Directive) comes into force in around 3 years time.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

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 Minister:

Malcolm Wicks

Date: 2nd October 2008

Summary: Analysis & Evidence

Policy Option: (i)	Description: full implementation

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' The requirement is intended to ensure there are no significant levels of potentially sensitising fragrances in cosmetics, without notifying consumers.
One-off (Transition) **Yrs**		
£ 0		
Average Annual Cost (excluding one-off)		
£ 0	**Total Cost** (PV)	**£ 0**

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

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**		
£ 0		
Average Annual Benefit (excluding one-off)		
£ 0	**Total Benefit** (PV)	**£ 0**

Other **key non-monetised benefits** by 'main affected groups' There may be a marginal positive impact on public health over time. Companies will also benefit marginally from the continuing equality of market requirements across the EEA.

Key Assumptions/Sensitivities/Risks That the vast majority of cosmetics products manufactured in, or imported into the UK already fall within these requirements.

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£ 0**

What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	4/4/2009
Which organisation(s) will enforce the policy?	Trading Standards
What is the total annual cost of enforcement for these organisations?	£ N/A
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£ 0
What is the value of changes in greenhouse gas emissions?	£ 0
Will the proposal have a significant impact on competition?	No

Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large **0**
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease £ 0 **Net Impact** **£** 0

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

EVIDENCE BASE

Overview

The Scientific Committee on Cosmetic Products considers that, on the basis of the International Fragrance Association (IFRA) code of practice, a number of substances have been correctly identified as sensitising fragrance compounds, which might cause allergic reactions in consumers. It considered that the overall levels of these substances should be limited in cosmetics.

For a further five substances identified, but which are allowed and used also in foodstuffs, it has indicated there should be a labelling requirement and in some cases an overall limit should be applied.

The Directive also corrects a previous error concerning Peru balsam, now allowing Peru balsam extract and distillate, whilst retaining the ban on the crude form of the substance.

The IFRA guidelines, which their members must follow, and which the majority of the industry already abides by voluntarily, mean that with few exceptions, the implementation of the Directive via these Regulations would have no impact on either products on the market or manufacturing practices. It is most likely to impinge if at all on imports from outside the EU. Any costs on UK businesses are therefore likely to be very limited and are not likely to attract high levels of political or media interest.

The provisions will apply from 4 April 2009, and products containing higher than the prescribed levels must not be disposed of to the final consumer after 4 October 2009.

The Cosmetic Products (Safety) Regulations 2008, the overriding Regulation which this technical change amends lists some thousands of substances which may not be used in cosmetics and sets limits for many others. Technical changes are frequent as the SCCP continues to evaluate substances over which there are concerns.

Policy Options

The new amendments arise from opinions of the SCCP, and are solely technical in nature. The Directives are consistent with UK policy and practice on these issues. They guarantee a high level of consumer safety by restricting the use of certain ingredients, and allow conformity to market harmonisation objectives.

There were two options:

1. To fully implement the Directives, which will allow enforcement agencies (Trading Standards) to remove potentially dangerous products from the market, and ensure that products on the market are as safe as scientific knowledge allows, whilst harmonising the internal market for such products.

2. The do nothing option would leave an area of concern in that known sensitising agents could be placed on the market and Trading Standards would not have the means to address the issue. It would also almost certainly lead to infraction proceedings by the Commission.

Benefits and Costs of Options

(i)- to do nothing

Costs

Impact on producers

Most manufacturers would anyhow have to conform to the new Directives in order to export to the rest of the EU, so the vast majority of costs, if any, would still exist for them.

Impact on the public sector

The Commission would be highly likely to take infraction proceedings against the UK Government, and Trading Standards would not have the legal means to remove from the market a product containing higher and significant levels of the various prohibited or restricted substances.

Impact on distributors and retailers

Distributors and retailers would find themselves in a grey area of legal uncertainty regarding the appropriate levels of the substances, which this Directive addresses.

Benefits and Costs of Options

(ii)- to fully implement the provisions of the Directives

Benefits

Impact on consumers

The overriding consideration of the Directive is the safety of consumers, and these amendments will improve consumer protection. The Directive will impact equally across the particular sectors of industry affected and will be implemented in all Member States. Consumers will have a marginally safer choice of product.

Impact on producers

There will be some marginal benefit to manufacturers in being sure that their products can be sold without problems throughout the EEA.

Costs

Impact on producers

It is important to stress at the outset that it is difficult to quantify the costs on producers of implementing this proposals due to non-availability of data. It is not believed by industry sources that costs will be incurred as the vast majority of cosmetic manufacturers are already following the IFRA guidelines, which are either identical to, or stricter than the requirements in the Directive.

Impact on the public sector

The Cosmetic Products (Safety) Regulations 2008 are enforced by local authorities' trading standards departments. It is the responsibility of the manufacturers of cosmetic products made in the EU or importers of finished cosmetic products to ensure that products comply with the Regulations.
Trading Standards will have to enforce these additional requirements which are marginal in terms of the total list of banned product components. There are no reasons to believe these additions to the Regulations will have any substantive impact on their enforcement burdens.

Impact on distributors and retailers

The distribution chain will have to dispose of products containing a higher level of these substances than indicated by 4 October 2009. However there should be minimal impact given the belief that there are few, if any products on the market outwith the proposed Regulations

Identifying the extent to which the Regulations interact with other legislative provisions

Two legislative provisions are relevant:

- The General Product Safety Regulations 2005 (GPSR) set the general safety requirement of a product by requiring that no producer may place, offer to place on the market, supply, agree to supply, expose or possess a product for supply if the

product is intended for use by consumers unless the product is safe in normal and foreseeable use. Specifically, the GPSR place certain obligations on producers and distributors, including a requirement to provide adequate warnings and instructions for use, and to notify local authorities when they become aware that a product placed on the market/supplied presents a risk to consumers.

- Consumer Protection Act 1987 (the "CPA"); This provides the legal basis for much of the consumer safety legislation introduced in the UK, including the Regulations. Infringement of the Regulations would attract enforcement action either under the CPA or under the GPSR, depending on the circumstances.

Identifying the unique aspects of the Regulations

The Cosmetic Products (Safety) Regulations 2008 specifically ban or limit substances which may be used in cosmetics and set out the steps and requirements manufacturers and importers must meet to place products on the market. The Cosmetic Products (Safety)(Amendment No2) Regulations 2008 specifically restrict the level in cosmetic products of certain substances which are known sensitisers.

Impact on competition

The requirements of the Directive will apply in all Member States of the EU and the countries that are members of the EEA, and affects all cosmetic products placed on the market in the EEA. There is not expected to be an impact on competition in any way.

Impact on small firms

No costs should be imposed on small firms, although it is possible that some may be still using restricted items above the new safety level. However, given that a product must meet the requirements of the Directive to be placed on the market, there is no way to offer small firms a derogation from having to meet the full requirements of the Cosmetic (Safety) Regulations 2008, including this amendment. However, there are no reasons to believe there should be any substantial impact on small firms, because the IFRA standards have been in the public domain since 2000. However, one of the purposes of the consultation was to publicise the Regulations and allow anyone unaware of the incoming Directive time to adjust to the requirements of this Regulation.

Gender, Race, Disability

After initial screening as to the potential impact of this policy/regulation on race, disability and gender equality it has been decided that there will not be an impact upon minority groups in terms of numbers affected or the seriousness of the likely impact, or both.

Consultation within Government

The relevant interested department, the Department of Health, and the Health and Safety Commission have been consulted about these proposals.

Public consultation

This is an EU Directive and there is a requirement to transpose the amendment by 4 October 2008. So far, we have been consulting informally with the key stakeholders and they were well aware that this Directive was on the way. We are aware that most will have already taken any steps to comply with the proposal. A six week consultation concluded 20 September 2008.

Key stakeholders such as the Cosmetics, Toiletries and Perfumery Association, the British Fragrance Association, and those who have responded to consultations to previous amendments to the Cosmetic Regulations were contacted directly. The consultation was published on the BERR website. The sole response received, from the Cosmetics, Toiletries and Perfumery Association, suggested the incorporation of additional information in the Statutory Instrument.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	***Results in Evidence Base?***	***Results annexed?***
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	No	No
Rural Proofing	No	No

Transposition Note for Directive 2008/14/EC

This Transposition Table shows how the Department has implemented *Commission Directive **2008/42/EC** of 3 April 2008**,** amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress* (OJ L 093, 4.4.2008, p.13-23).("the Directive")

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (O.J. L. 262, 27.9.1976, p.169), as last amended by Commission Directive 2008/14/EC (O.J. L. 042. 16.2.2008, p. 43-44), imposes prohibitions and restrictions on the use of specified substances in cosmetic products. It is implemented by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) ("the Principal Regulations").

These Regulations do what is necessary to implement the Directive, by amending the Principal Regulations to include consequential changes to ensure coherence in the area to which they apply. The Department for Business, Enterprise & Regulatory Reform has lead responsibility for implementation of Directives 76/768/EEC and 2008/42/EC.

The table below shows how Directive 2007/42/EC has been implemented.

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1	**Amends the lists: in Annex II (substances which must not form part of the composition of cosmetic products) to allow the use of peru balsam extract and distillate; and Part 1 of Annex III of Directive 76/768/EEC (substances which cosmetic products must not contain except subject to the restrictions and conditions laid down) by amending the restrictions on five substances which are also used in foodstuffs and adding a further 82 substances to the list.**	**Regulation 2c amends Schedule 3 entry 1136 to the Principle Regulations (peru balsam);** **Regulation 2d amends Part 1 of Schedule 4 to the Principal Regulations by deleting entry 68, amending entries 45,72,73,88 and 89, and adding entries 103-184.**	

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