EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT) REGULATIONS 2008

2008 No. 2173

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.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 The Regulations implement Commission Directive 2008/14/EC (OJ No. L 042 of 16.2.2008 pages 43-44) 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 2008/14/EC amends the Principal Directive by setting a maximum limit for glyoxal in cosmetic products.

2.3 The provisions of the Directive apply from 16 November 2008 and products which fail to comply with this amendment may not be sold or otherwise disposed of to a final consumer after 16 February 2009.

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

3.1 As well as implementing the Directive, these Regulations also correct errors in the Principal Regulations identified by the JCSI in their 23rd Report of 2007/8. As indicated on the headnote, copies of the Regulations will be supplied free of charge to all known purchasers of the Principal Regulations.

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 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 2008/14/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 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 1 July - 11 August 2008. The consultation document was sent to manufacturers, trade associations, consumer groups, individuals and other interested parties. The consultation document was also published on the BERR website at:

http://www.berr.gov.uk/files/file46883.pdf

7.2 There were no responses to the consultation.

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
14th August 2008

Summary: Intervention & Options

Department /Agency:	Title:	
Department for Business, Enterprise & Regulatory Reform	**Impact Assessment of the Cosmetic Products (Safety) (Amendment) Regulations 2008**	
Stage:	**Version:** Final	**Date:** 11 August 2008
Related Publications: (OJ No. L 042 of 16.2.2008 pages 43-44).		

Available to view or download at:

http://www.berr.gov.uk/consultations/open-consultations/index.html

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

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

Commission Directive 2008/14/EC, following the advice of the Scientific Committee on Consumer Products (SCCP), clarifies the limit for the presence of glyoxal in cosmetic products as a trace substance only. Transposition of this Directive into UK law will ensure that consumers are not exposed to a higher level of glyoxal which is suspected to be a mutagenic substance. Government intervention is necessary, as consumers may not be aware of the potential health risks of the products, leading to a market failure due to information asymmetry.

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 (detailed on the assessment sheets below) and should have a positive effect on health, although marginal.

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

(i)- to implement the directive in full

(ii)- to do nothing

There is nothing to justify non implementation of the Directive in full. Exporters would need to fulfil the obligations anyway, and UK consumers might be exposed to a potentially mutagenic substance, which they should not. The Commission would also take infraction proceedings against the UK.

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.

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: 14th August 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 glyoxal left in a cosmetic after manufacture. The only foreseeable costs would be in quality control measures which should already be in place.
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 will 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 substance is not present in existing products manufactured or imported into the UK.

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?	16/11/2008
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?	£ -
What is the value of changes in greenhouse gas emissions?	£ -
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 (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

EVIDENCE BASE

Overview

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) stated in its opinion of 25 September 2001 that substances classified pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must not be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as carcinogenic, mutagenic or toxic for reproduction, of category 3, and substances with similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.

Following an Opinion by the SCCP the Regulations will implement Commission Directive 2008/14/EC (OJ No. L 042 of 16.2.2008 pages 43-44). The SCCP considered that glyoxal, although a category 3 CMR (carcinogenic, mutagenic or toxic to reproduction), was safe to include in products as long as it was in a concentration of no more than 100 parts per million. The provisions apply to all goods placed on the market from 16 November 2008 and all non-compliant products must not be sold or disposed of to the final consumer after 16 February 2009.

Glyoxal is an intermediary substance which might be used in the preparation of a range of other substances, but would not be added in its own right. Essentially the Directive clarifies the limits for the presence of glyoxal as a trace substance only. Manufacturers who use glyoxal as an intermediary substance will have to ensure they respect this limit. However it is unlikely that it is widely used in the first place.

Any costs will be very limited and the Regulations are not likely to attract high levels of political or media interest.

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 with market harmonisation objectives.

There are two options:

1. To fully implement the Directives, which would 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. Do nothing. As glyoxal is not allowed within the current Directive it should not be present in products at the moment. The do nothing option would leave a grey area of uncertainty which this Directive addresses. It would also lead to infraction proceedings by the Commission.

Benefits and Costs of Options

(i)- 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

It is important to stress at the onset that it was difficult to quantify the costs on producers of implementing this proposals due to non-availability of data. The only foreseeable costs would be in quality control measures which should already be in place. 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

Glyoxal is classified as a CMR and is therefore prohibited as an ingredient in a cosmetic products; however, its use as an intermediate chemical and complete reaction during the manufacturing stage should mean there is no glyoxal remaining in the cosmetic. To ensure the public is protected from any unreacted glyoxal in a cosmetic product, a prescribed residual safe level of 100 mg/kg has been set. This should not require the reformulation of any products and, in any case, manufacturers should already be monitoring cosmetic products using glyoxal as an intermediate chemical to ensure no glyoxal is present as part of their quality control processes.

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 glyoxal than 100ppm. However there should be no impact given that there should not be any such products on the market in the first place.

(ii)- to do nothing

Costs

Impact on producers

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

Impact on the public sector

The Commission would take infraction proceedings against the UK Government, and Trading Standards would have more difficulty in proving a product containing a higher level of glyoxal than 100ppm should be taken off the market.

Impact on distributors and retailers

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

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) Regulations 2008 apply a specific restriction for a particular substance.

Impact on competition

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.

Impact on small firms

No costs are being imposed on small firms. 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 will be any impact on small firms, because nobody should currently be producing products containing glyoxal.

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 Executive have been consulted about these proposals during the consultation exercise.

Public consultation

This is an EU Directive and there is a requirement to adopt the amendment by 16 August 2008. Therefore, the Government has conducted a six week consultation, to which there have been no responses. So far, we have been consulting informally with the key stakeholders and they are aware that this Directive was on the way. We are aware that most will have already taken steps to comply if necessary.

Key stakeholders such as the Cosmetics, Toiletries and Perfumery Association, and those who have responded to consultations to previous amendments to the Cosmetic Regulations have been contacted directly. The consultation was published on the BERR website. No responses have been received.

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

Annexes

Transposition Note for Directive 2008/14/EC

This Transposition Table shows how the Department has implemented *Commission Directive **2008/14/EC** of 15 February 2008**,** amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress* (OJ L 042, 16.02.2008, p.43-44).("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 2008/14/EC.

The table below shows how Directive 2007/14/EC has been implemented.

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1	**Amends the list in Part 1 of Annex III of Directive 76/768/EEC (substances which cosmetic products must no contain except subject to the restrictions and conditions laid down) by restricting the maximum level of a substance, glyoxal, allowed in a cosmetic product.**	**Regulation 2 amends Part 1 of Schedule 4 to the Principal Regulations.**	

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Date 14th August 2008