EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS (SAFETY) REGULATIONS 2008

No. 1284

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

2. Description

2.1 The Cosmetic Products (Safety) Regulations 2008 (the Regulations) implement three Commission Directives: 2007/22/EC (OJ No. L 101 of 18.4.2007 page 11), 2007/53/EC (OJ No. L 226 of 30.8.2007 page 19) and 2007/54/EC (OJ No. L 226 of 30.8.2007 page 21), all of which amend 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 the use of certain substances in cosmetics and imposing restrictions on the use of others.

2.2 Directive 2007/22/EC requires that the daily bioavailable intake of iodine from cosmetic products should not exceed 20% of the recommended daily intake and bans the use of Iodopropynyl Butylcarbamate (IPBC) in oral hygiene and lip care products. It also reduces the concentrations of IBPCs allowed in other products (particularly those for young children). The provisions apply to all goods placed on the market from 18 October 2008 and all non-compliant products must not be sold or disposed of to the final consumer after 18 April 2009.

2.3 Directive 2007/53/EC introduces a labelling requirement for toothpaste containing 0.1% to 0.15% fluoride in respect of use by children of 6 years and younger. The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, (now the Scientific Committee on Consumer Products) is of the opinion that if the sole source of fluoride exposure is toothpaste containing fluoride between 1000 to 1500 parts per million, there is a minimal concern that children under the age of six will develop fluorosis, provided that such toothpaste is used as recommended. Substances numbered 26-43, and 47 and 56 in Schedule 4 of the Regulations must carry safety warnings and Schedule 4 has been amended accordingly. The labelling requirement applies from 19 January 2009.

2.4 Directive 2007/54/EC adds a number of substances, numbered 1244-1328 to the list of banned ingredients in Schedule 3 of the Regulations, as part of the Commission's strategy on hair dyes to ensure that only safe substances are used in finished hair dye products. It also deletes four substances from the list of conditionally permitted substances in Schedule 4 of the main Cosmetics Regulations and moves them to Schedule 3 of those Regulations, banning

them from use. The provisions must apply from 18 June 2008 – the date the Regulations will come into force.

2.5 The Regulations consolidate the previous 9 separate technical changes made to the Cosmetic Safety Regulations 2004 by previous amending Regulations. They also simplify the wording of the Regulations and bring the extensive annexes listing substances which are restricted or banned for use in cosmetics into line with those in the Directive. The Directive is due to be turned into a Regulation of the European Parliament and of the Council within three years. Negotiations are currently underway to recast the Directive into a Regulation. Agreement on this is likely to happen around the end of 2008. Member States will then have three years to adapt to its requirements. Consolidation of the Regulations is necessary now to clarify the currently applicable regulations for manufacturers, distributors and enforcement authorities.

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), apart from the provisions on animal testing (see below), and regulation 26, which are made under section 2(2) of the European Communities Act 1972.

4.2 The 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 Directives 2007/22/EC, 2007/53/EC and 2007/54/EC are Commission Directives and have not been subject to Parliamentary Scrutiny.

4.7 A Transposition Note is attached to this Memorandum.

5. Territorial Extent and Application

5.1 Consumer safety of goods is a reserved matter and therefore the Regulations will apply to the whole of the United Kingdom.

6. European Convention on Human Rights

6.1 As the Regulations are subject to the negative resolution procedure and do 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 7 March -5 May 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/file45185.pdf

7.2 Three substantive sets of responses have been received and the views expressed taken into account during the necessary changes to the draft Regulations.

8. Impact

8.1 A Regulatory 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

Summary: Intervention & Options

Department /Agency:	Title:	
Department for Business, Enterprise & Regulatory Reform	**Impact Assessment of the Cosmetic Products (Safety) Regulations 2008**	
Stage: Full	**Version:** Final	**Date:** 12 May 2008
Related Publications:		

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?

The Scientific Committee which examines cosmetic safety has pronounced on three areas where existing cosmetics may cause harm to consumers. This has resulted in three technical Directives regulating the uses of certain substances in certain products. Government intervention is necessary to translate the requirements of the technical directives into UK law. The Regulations implement the three new technical Directives and consolidate the 9 previous technical amendments implemented since the coming into force of the Cosmetic Products (Safety) Regulations 2004.

What are the policy objectives and the intended effects?

The measures overall conform to UK policy on consumer safety to protect public health. The Regulations consolidate a much revised text and simplify life for users of the regulations. The three new technical amendments which contribute to consumer safety, (detailed on the assessment sheets below), address the current market failure where consumers fail to appreciate the health risks of products, and should have a positive effect on health, although marginal, in reducing various allergic reactions, and the incidence of fluorosis.

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

(i)- to consolidate the Regulations

(ii)- to implement the three directives separately

(iii)- to do nothing

The existing regulations have had 9 amendments to the annexes, making them difficult to follow. The 3 new Directives would add further complications. The preferred option is to consolidate all the changes to bring them up to date and to bring the technical Annexes into line with the Directive. (see policy options below).

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The Commission published on 5 February 2008 a draft Regulation to replace the existing Directive, the implementation period for which is 3 years. All aspects will be reviewed.

Ministerial Sign-off For consultation 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:

Gareth Thomas

Date: 13th May 2008

Summary: Analysis & Evidence

Policy Option:	Description:

COSTS

ANNUAL COSTS	
One-off	Yr
£ 1,000,000	
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups' These are rough estimated costs based on anecdotal evidence and relate to the toothpaste labelling requirement, and IBPC ban which will require some product reformulation (details in costs and benefits below). We would hope for further information to result from the consultation.

Total Cost (PV) **£ 1,000,000**

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

BENEFITS

ANNUAL BENEFITS	
One-off	Yr
£ 0	
Average Annual Benefit	
£ 0	

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

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, particularly from the reduction of risk of children developing fluorosis. Companies will also benefit marginally from the continuing equality of market requirements across the EEA.

Key Assumptions/Sensitivities/Risks That these minor changes to requirements for some products will have a positive benefit on general health

Price Base	Time Period	**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?	18/6/2008 and
Which organisation(s) will enforce the policy?	Trading
What is the total annual cost of enforcement for these	£ 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	£ -
What is the value of changes in greenhouse gas emissions?	£ -
Will the proposal have a significant impact on competition?	Yes/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 -
Increase £ 0	Decreas £ 0	**Net**	**£** 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 primary aim of the Cosmetic Products (Safety) Regulations 2004 (as amended) is to protect public health by requiring cosmetic products to meet the provisions of the Regulations, including restricting the use of certain cosmetic ingredients, and secondly for EEA market harmonisation.

The Cosmetic Products (Safety) Regulations 2008 will implement three EC technical Directives on the safety of cosmetics. The Regulations will replace the Cosmetic Products (Safety) Regulations 2004 and be introduced using powers in the Consumer Protection Act 1987 (the 1987 Act), and the European Communities Act 1972. The opportunity has also been taken to simplify where possible the wording of the 2004 Regulations and bring the extensive annexes which list substances which are restricted or banned for use in cosmetics into line with those of the Directive.

The Scientific Committee on Consumer Products (SCCP) previously the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (the SCCNFP), has a remit to examine substances used in cosmetics and make recommendations to the Commission and Member States.
It has certain continuing commitments (as in the hair dyes strategy), and examines specific ad hoc examples where concerns about the use of particular substances have been raised. The deliberations of the SCCP have given rise to 48 technical amendments to the Directive since it came into force.

Policy Options

The three 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.

Three options were considered. The existing regulations have had 9 amendments, (arising from 13 technical Directive amendments) to the annexes, (some 100 pages of chemical listings, banning or restricting substances completely or in certain uses), and this makes it very difficult to follow.

The first option is to do nothing. The do nothing option would have resulted in potentially dangerous products perhaps remaining on the UK market. Most manufacturers would however have had to make the changes in order for their products to remain on the market in the rest of Europe. This option would also have led to infraction proceedings by the Commission.

The second option is to implement the the three Directives separately. This option would have, apart from the need for three separate consultations, resulted in yet further complications in the Annexes.

The third option is to consolidate the Regulation including the changes arising from the current new technical Directives. This means that companies and regulators have a clean sheet to work with. Additionally the current form of the annexes differs from their form in the Directive. The Regulations align the Annexes. This is important as over the next three years the existing Directive will be replaced by a Commission Regulation and it will be necessary for all stakeholders to work from the same script in order to avoid errors of omission or unintended consequences.

The three new Technical Directives

The first two are specific concerns.

Following an Opinion by the SCCP the Regulations implement Commission Directive 2007/22/EC (OJ No. L 101 of 18.4.2007 page 11). The SCCP considered that the daily bioavailable intake of iodine from cosmetic products should not exceed 20% of the recommended total daily intake. Because of exposure to iodine from Iodopropynyl Butylcarbamate (IPBC), the directive continues the ban of the use of IPBC in oral hygiene and lip care products, and also reduces the concentrations of IBPCs allowed in other products. The provisions apply to all goods placed on the market from 18 October 2008 and all non-compliant products must not be sold or disposed of to the final consumer after 18 April 2009.

The Regulations also implement Commission Directive 2007/53/EC (OJ No. L 226 of 30.8.2007 page 19). Directive 2007/53/EC introduces a labelling requirement for toothpaste containing 0.1% to 0.15% fluoride in respect of use by children of 6 years and younger. The SCCP is of the opinion that if the sole source of fluoride exposure is toothpaste containing fluoride between 1000 to 1500 parts per million, there is a minimal concern that children under the age of six will develop fluorosis, provided that such toothpaste is used as recommended. Reference numbers 26-43, and 47 and 56 of Schedule 4 of the main Cosmetic Products (Safety) Regulations 2004 will be amended accordingly. The provisions shall apply from 19 January 2009.

The third is a result of the on-going "hair dye strategy", the terms of which are set out below.

(1) Following the publication of a scientific study in 2001, entitled "Use of permanent hair dyes and bladder cancer risk", the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (the SCCNFP) concluded that the potential risks were of concern. It recommended that the Commission takes further steps to control the use of hair dye chemicals.

(2) The SCCNFP recommended further an overall safety assessment strategy for hair dyes including the requirements for testing hair dye cosmetic ingredients for their potential genotoxicity/mutagenicity.

(3) Following the opinions of the SCCNFP, the Commission together with Member States and stakeholders agreed on an overall strategy to regulate hair dyes according to which, the industry was required to submit the files with scientific data on hair dyes to be evaluated by the SCCNFP.

(4) As a first step for the implementation of the strategy it was decided to give priority to permanent hair dye substances for which no explicit interest was expressed during the public consultation in defence of their use in hair dyes. Those substances should therefore be banned.

A number of substances that have been used in hair dyes have already been eliminated. Commission Directive 2007/54/EC (OJ No. L 226 of 30.8.2007 page 21) adds a further number of substances, numbered 1244-1328 to the list of banned ingredients, as part of the strategy on hair dyes to ensure that only safe substances are used on finished hair dye products. It also deletes four substances from the general entries in Schedule 4 of the main Cosmetics Regulations (items allowed subject to restriction) and moves them to Schedule 3 (part 1) of those Regulations, banned list). The provisions must apply from 18 June 2008.

The costs of the proposals are largely limited or already undertaken and are not likely to attract high levels of political or media interest.

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 in some cases 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 within the EEA.

There is also a benefit to producers, distributors, regulators and other users of the regulations arising from consolidation of the Regulations.

Costs

Impact on producers

a) Directive 2007/22/EC bans the use of Iodopropynyl Butylcarbamate (IPBC) in oral hygiene and lip care products. It also reduces the concentrations of IBPCs allowed in other products. The provisions apply to all goods placed on the market from 18 October 2008 and all non-compliant products must not be sold or disposed of to the final consumer after 18 April 2009.

The prohibition of use of sodium iodate and colorant CI45425 are believed likely to have little or no effect as they are understood to be hardly, if at all used. The restrictions on use of IBPC for products for children under 3 will have an impact, partly in terms of labelling, but more importantly in that they require the reformulation of some products where IBPC is an ingredient in products for children under three years of age – notably wipes. The consultation has not brought out further detail, but to off-set these costs there is a reasonable time to allow compliance. Anecdotal evidence leads to a very rough cost estimate of £900,000. Companies have had to reformulate a large number of products, but we understand these (large) manufacturers have mainly completed this process in anticipation of the coming into force of these measures.

b) Directive 2007/53/EC introduces a labelling requirement for toothpaste containing 0.1% to 0.15% fluoride in respect of use by children of 6 years and younger. The provisions shall apply from 19 January 2009. There will be some cost to industry in terms of labelling redesign, (estimated at around £500 per item). Industry costs due to this measure may be reduced by periodic re-labelling for other purposes, and an estimate of £100,000.

c) Directive 2007/54/EC adds a number of substances to the list of banned ingredients for hair dyes. It also deletes four other substances from the allowed but restricted list and adds them to the list of banned substances. The provisions must apply from 18 June 2008. The proposed ban is for substances that are not currently used by manufacturers and this Directive will not impose additional costs in the composition of hair dyes made in the UK.

Impact on the public sector

The Cosmetic Products (Safety) Regulations 2004 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 them.

Impact on distributors and retailers

The distribution chain will have to dispose of products containing banned ingredients or out of date packaging by the appropriate dates, but the deadlines for implementation are reasonable and should have minimal impact.

(ii) Implementation of the three Directives separately

Would have attracted identical costs to option (i), without the benefit of consolidated Annexes to the Regulations.
The annexes are complicated, and with 16 Directive amendments there is now a real risk that they are misread by stakeholders; manufacturers, safety assessors, importers, distributors, retailers, trading standards.

(iii)- to do nothing

Costs

Impact on consumers

Potentially dangerous substances could and probably would remain in the market, as there would be no legal means to remove them.

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 exist for them.

Impact on the public sector

The Commission would take infraction proceedings against the UK Government and Trading Standards would be unable to take potentially dangerous products off the market.

Impact on distributors and retailers

Would find themselves in a grey area of uncertainty.

Background

The cosmetics industry is truly international, which can be seen from the flow of trade. There are approximately 150 major companies in the UK involved in the manufacture/importing of cosmetic products. The UK cosmetics market was worth around 10 billion euros at retail prices in 2006, of which approx 50% is manufactured in the UK. Around 50% of cosmetics manufactured in the UK are exported annually. It has not been possible to extract figures for these particular markets affected by these Directives, as a particular product may or may not contain the chemical being restricted. However the UK market for toothpastes is estimated at £350 million per year.

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 2004 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.

Impact on competition

All the Directives will apply in all Member States of the EU and the countries that are members of the EEA, and affects all goods placed on the market in the EEA.

Small Firms are not believed to be involved in the product sectors affected by the changes to the Regulations.

Given the particular nature of their usage, one of the purposes of the consultation is to establish further information about the impact of the Directive on the costs to manufacturers of these products.

Consultation Within Government

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

Public Consultation

Because of the need to bring the amendment on IBPCs into force by 18 June 2008, an 8 week consultation was held for the implementation of the Cosmetic Products (Safety) Regulations 2008.
Key stakeholders, (manufacturers) were already well aware of the proposals and we are aware that most have already taken steps to comply with the range of proposals.

Key stakeholders such as the Cosmetics, Toiletries and Perfumery Association and those who have responded to consultations to previous amendments to the Cosmetic Regulations and publishing the consultation on the DTI website were contacted directly. Three substantive sets of responses have been received and the views expressed taken into account during the necessary changes to the draft Regulations.

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	No	No
Small Firms Impact Test	No	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	No
Disability Equality	No	No
Gender Equality	No	No
Human Rights	No	No
Rural Proofing	No	No

Annexes

This Transposition Note shows how directives 76/768/EEC, 2007/22/EC, 2007/53 EC, and 2007/54/EC have been implemented. Directive 76/768/EEC has recently been amended by Directives 2007/22/EC, 2007/53 EC, and 2007/54/EC. The first table below shows how Directive 76/768/EEC as a whole has been implemented. Three further tables show how Directives 2007/22/EC, 2007/53 EC, and 2007/54/EC have specifically been implemented.

The Department for Business, Enterprise & Regulatory Reform has lead responsibility for implementation of Directives 76/768/EEC, 2007/22/EC, 2007/53 EC, and 2007/54/EC.

Directive 76/768/EEC

Directive 76/768/EEC (OJ L262 27.7.1976, p.169) on the approximation of the laws of the Member States relating to cosmetic products was previously implemented by the Cosmetic Products (Safety) Regulations 2004 (SI 2004/2152) ("the 2004 Regulations"), as amended from time to time. **The Cosmetic Products (Safety) Regulations 2008** ("the 2008 Regulations") will revoke and replace the 2004 Regulations. Directive 76/768/EEC will therefore now be implemented by way of the 2008 Regulations. The 2008 Regulations also implement directives 2007/22/EC, 2007/53 EC, and 2007/54/EC.

These Regulations do more than is necessary to implement the Directive in the following area:

Regulation 12(4). This provision sets out labelling requirements in cases where certain cosmetics are supplied in component form and need to be mixed together by the consumer before use. The requirement has been in UK legislation since at least 1996. We have retained this section of the Regulations as we believe this is important for consumer safety.

The table below shows how Directive 76/768/EEC has been implemented by reference to the relevant parts of the 2008 Regulations.

Directive 76/768/EEC

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1(1)	Defines "cosmetic product"	3	
1(2)	Reference to illustrative list of cosmetic products	Not implemented (as list is illustrative only)	
1(3)	Excludes substances listed in Annex V from the scope of the Directive, but permits Member States to take measures in relation to those measures. Annex V only contains one entry (strontium and its compounds with certain exceptions).	Not implemented (as Member States are permitted to take measures in relation to the excluded substances).	
2 (first paragraph)	Provides that cosmetic products	4(1)	

	placed on the market in the Community must not cause damage to human health		
2 (second paragraph)	Provision of warnings does not excuse non-compliance with Article 2	4(3)	
3	General requirement that Member States ensure that only cosmetic products which conform to the Directive may be placed on the market.	The regulations as a whole implement this provision.	
4(1)(a)	Prohibits marketing of cosmetic products containing substances listed in Annex II	5(1)(a) which cross-refers to Schedule 3	
4(1)(b)	Prohibits marketing of cosmetic products containing substances listed in Annex III Part I	6 which cross-refers to Schedule 4	
4(1)(c)	Prohibits use of colouring agents other than those listed in Annex IV, Part I	7(1)(a) prohibits use of colouring agents (except cosmetic products intended solely to colour hair) except those listed in schedule 5	
4(1)(d)	Prohibits use of colouring agents (except cosmetic products intended solely to colour hair) listed in Annex IV Part I used outside the conditions laid down	7(1)(b) prohibits use of colouring agents (except cosmetic products intended solely to colour hair) listed in schedule 5 unless they meet certain conditions	
4(1)(e)	Prohibits use of preservatives other than those listed in Annex VI Part I	8(a) which prohibits preservatives not listed in Schedule 6	
4(1)(f)	Prohibits use of preservatives listed in Annex VI Part I outside the conditions specified	8(b),(c) which prohibits use of preservatives in Schedule 6 unless they meet the requirements specified in Part I of that schedule.	
4(1)(g)	Prohibits use of UV filters other than those listed in Annex VII Part I	9(a) prohibits use of UV filters not listed in Schedule 7	

4(1)(h)	Prohibits use of UV filters listed in Annex VI Part I outside the limits specified	9(b) prohibits use of UV filters listed in Schedule 7 unless they meet the requirements set out in columns (c), (d) and (e) of Part I of that schedule	
4(2)	General exemption for presence of trace quantities of prohibited substances	5(2)	
4a (1)(a)	Prohibits the marketing of cosmetic products where the final formulation in order to meet the requirements of the directive has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level	10(1)(a)	
4a (1)(b)	Prohibits the marketing of cosmetic products containing ingredients, which have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level.	10(1)(b)	
4a (1)(c)	Prohibits the performance of animal testing of finished cosmetic products in order to meet the requirements of this directive	11	
4a (1)(d)	Prohibits animal testing on ingredients or combinations of ingredients in order	10(2)	

	to meet the requirements of this directive no later than the date on which such tests are required to be replaced by one or more validated alternative methods listed in Annex IX to the Directive or Annex V to directive 67/548/EEC.		
4a(2)	Imposes obligations on the Commission.	No need to implement.	
4a(3)	Inserts definitions for: "finished cosmetic product" and "prototype"	3	
4b (first sentence)	Provides for the prohibition of the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1-3 under Annex I to Directive 67/548/EEC.	The Commission adopted Directive 2003/15/EC to add these substances to Annex II of the Cosmetic Products Directive and so this is implemented in Schedule 3.	
4b (final sentence)	Provides exemption in respect of substances classified as category 3 where the SCCP[1] has decided they are acceptable for use.	Not implemented - no substances yet approved.	
5(a)	Permits marketing of cosmetic products containing substances listed in Annex III, Part 2 subject to specified conditions up to the dates specified in column g).	6 which prohibits the supply of any substance listed in Schedule 4 unless specified requirements are met.	
5(b)	Permits marketing of colouring agents listed in Annex IV Part 2 subject to specified conditions and until the dates given. Annex IV Part 2 is empty.	No need to implement – Annex IV Part 2 is empty.	
5(c)	Permits marketing of	No need to implement	

[1] Scientific Committee on Cosmetic Products.

	preservatives listed in Annex VI, Part 2 subject to specified conditions and until the dates given in column f). Annex VI Part 2 is empty.	– Annex VI Part 2 is empty.	
5(d)	Permits the marketing of UV filters listed in Annex VII Part 2 subject to specified conditions and until the dates specified. Annex VII Part 2 is empty.	No need to implement – Annex VII Part 2 is empty.	
5a	Imposes obligation on Commission	Not necessary to implement	
6.1 (a)-(f)	Provides that cosmetic products may only be marketed if the container and packaging indicate specified information (set out under 6.1(a)-(f) below).	12	
6.1(a)	Name or style and registered address of manufacturer or person responsible for marketing the product	12(1)(a)	
6.1(b)	Nominal content at time of packaging	Weights and Measures Act 1985 section 21, Schedule 6, paragraph 15 (as substituted by the Weights and Measures (Cosmetic Products) Order 1994, (SI 1994/1884, article 2).	
6.1(c) (apart from final paragraph)	Date of minimum durability (save where the minimum durability exceeds 30 months)	12(1)(b)	
6.1(c) (final paragraph)	Where the minimum durability exceeds 30 months there shall be an indication of the time after opening for which the product can be used without causing harm to the consumer (this is to be indicated by way	12(b), final paragraph which refers to the symbol (open jar) contained in schedule 9, Part 2	

	of the open jar symbol introduced into Annex VIIIa of the Directive by directive 2003/80/EC		
6.1(d)	Particular precautions for use	12(1)(c)	
6.1(e)	Batch number	12(1)(d)	
6.1(f)	The function of the product	12(1)(e)	
6.1(g)	Provides that cosmetic products may only be marketed if the packaging displays a list of ingredients	12(2)	
6.1 (last 2 paragraphs)	Provisions permitting use of labels or leaflets instead of on the packaging itself in certain circumstances	13(3)-(6)	
6.2	Covers labelling of products which are not packaged prior to sale	13(1),(2)	
6.3	Prohibits misleading labelling, advertising and other forms of statement	Consumer Protection from Unfair Trading Regulations 2008, regulation 3.	
6 - Final paragraph	Regulates claims about animal testing on product labels and packaging	14	
7.1	Member States may not prohibit or restrict free-movement of goods which comply with the directive (subject to 7.2-7.3)	No need to implement	
7.2	Member States may require certain information to be provided in the national language	12(3)	
7.3	Permits Member States to require certain information on substances used in cosmetic products to be made available for the purposes of medical treatment	19	
7a.1	Requires manufacturers to ensure that certain	16(1)(a)-(i)	

	product information is available to "Competent Authorities".		
7a.1(d)	Sets out a list of what should be included in the heath assessment	16(2)	
7a.1 (final paragraph)	Information supplied under 7a.1 (a) and (f) shall be made available to the public	16(3), (4)	
7a.2	Provisions relating to assessment procedures	16(2)	
7a.3	Covers language requirement for information provided under 7a.1	16(6)	
7a.4	Notification of place of manufacture or importation of products	17	
7a.5	Designation of "Competent Authorities"	15(3)	
8	Requires Commission to take specified action	No need to implement	
8a.1	Permits Member States to authorise use of products not listed under the directive subject to certain specified conditions	20	
8a.2	Requires Member States send text of any authorisation to the Commission	No need to implement	
8a.3	Member States may request inclusion of further substances (authorised under 8a.1) in lists under the directive	No need to implement	
9 to 11	Administrative provisions	No need to implement	
12.1	Permits Member States to introduce temporary measures to prohibit products complying with the Directive where they think the product represents a hazard	No need to implement	

	to health		
12.2-3	Imposes requirements on the Commission	No need to implement	
13	Imposes further requirements on Member States taking action under 12.1	No need to implement	
14	Implementation and Coming into force provisions for the Directive as a whole	Coming into force section of the regulations (with regard to the latest amendments to the Directive)	

Directive 2007/22/EC

Directive 2007/22/EC (O.J. L101, 18.4.2007, p.11) amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes IV and VI thereto to technical progress has been implemented by the following parts of the Cosmetic Products (Safety) Regulations 2008.

These parts of the 2008 Regulations do not go beyond what is necessary to implement Directive 2007/22/EC, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Annex IV by deleting a substance and amends Annex VI by deleting the reference to one substance and amending the entry for another.	Regulation 2(2) and 2(3), Schedules 5 and 6	
2	Prohibits placing on the market of non-compliant cosmetic products from 18 October 2008 and sale or disposal to final consumer of these cosmetic products after 18 April 2009.	Regulation 2(4)	
3	Implementing measures to be adopted and published by 18 January 2008.	Coming into force provisions	
4-5	Administrative	No need to	

	provisions	implement.	

Directive 2007/53/EC

Directive 2007/53/EC (O.J. L226 30.8.2007, p.19) amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annex III thereto to technical progress, as amended by a Corrigendum(O.J. L22 25.1.2008, p.21) has been implemented by the following parts of the Cosmetic Products (Safety) Regulations 2008.

These parts of the 2008 Regulations do not go beyond what is necessary to implement Directive 2007/53/EC, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Annex III by adding text after certain entries	Regulation 2(1) and Schedule 4, entries 26 to 43, 47 and 56.	
2	Implementing measures to be adopted and published by 19 June 2008 and applied from 19 March 2009	Regulation 2(1) and coming into force section.	
3-4	Administrative provisions	No need to implement.	

Directive 2007/54/EC

Directive 2007/54/EC (O.J. L226 30.8.2007, p.21) amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annexes II and III thereto to technical progress, as amended by a Corrigendum(O.J. L258 4.10.2007, p.44) has been implemented by the following parts of the Cosmetic Products (Safety) Regulations 2008.

These parts of the 2008 Regulations do not go beyond what is necessary to implement Directive 2007/54/EC, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Annexes II and III and VI to the Directive by adding, deleting or amending entries.	Schedules 3 and 4	
2	Implementing measures to be adopted and published by 18 March 2008 and applied from 18 June 2008	Coming into force section	
2-4	Administrative provisions	No need to implement	

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