

THE COSMETIC PRODUCTS (SAFETY) REGULATIONS 2004

Consultation response for the consultation beginning on 21 April 2004 and ending on 15 July 2004.

1. Introduction and background

The Cosmetic Products (Safety) Regulations 2004 implement three EC Directives on the safety of cosmetics, namely 2003/15/EC (7th Amendment), 2003/83/EC (30th Amendment) and 2003/80/EC (31st Amendment). The Regulations have been made using powers in the Consumer Protection Act 1987 and the European Communities Act 1972. The Regulations also consolidate the Cosmetic Products (Safety) Regulations 2003.

The 1987 Act enables the Secretary of State to make Regulations in order to reasonably secure that consumers are protected from unsafe goods. The 1972 Act provides powers to introduce measures such as labelling and marking requirements set out in EC Directives for which the necessary powers are not provided under the 1987 Act.

There is widespread public concern over the issue of animal testing and we believe that these proposals represent a positive step towards a permanent prohibition on animal testing for cosmetics. The Directive, and thus the Regulations, will also improve the level of consumer information..

2. Consultation

On 21 April, the Government launched a formal consultation on the proposed Regulations. The consultation document was sent to over 200 individuals and organisations and was also available on the DTI website. We also spoke directly to a number of small cosmetics manufacturers of which we were aware, to determine what the burdens on them might be. Although our initial findings were that the new requirements would not pose a particular burden on the small businesses we spoke to – in some cases these were individuals making cosmetics at home - respondents to the consultation took a different view (see Comments made).

The main proposals of the draft Regulations were to:

- i) prohibit the marketing of cosmetic products tested on animals and prohibit animal testing;
- ii) prohibit the use of category 1 & 2 Carcinogens, Mutagens and Substances toxic to Reproduction (CMRs) in cosmetics and allow category 3 CMRs only if they have been evaluated as safe for use;
- iii) create a date of minimum durability to be marked on most cosmetic products;

- iv) require the 26 most common fragrance/perfume ingredients, which can cause allergy, to be listed on the ingredient list on cosmetic products;
- v) require certain information on cosmetic products to be held by manufacturers and be made available to the public if requested (without prejudice to commercial secrecy and intellectual property rights);
- vi) require a specific product safety assessment to be undertaken on cosmetics intended for children under the age of 3 and for products intended for external intimate hygiene; and
- vii) add, delete or amend certain substances in the Schedules to the Regulations via the 30th Amendment.

3. Responses received

The Department received 12 responses. These were from:

The Cosmetic, Toiletry & Perfumery Association Ltd (CTPA)
Aromatherapy Trade Council (ATC)
British Toy & Hobby Association (BTHA)
LACORS (Local Authorities Coordinators of Regulatory Services)
Adams, Wilson & Associates Ltd (AW)
The Body Shop
BUAV (the British Union for the Abolition of Vivisection)
Hampshire County Council – Property, Business and Regulatory Services
Small cosmetics manufacturer (SME)
Home Office, Animals Scientific Procedures Division
Royal Pharmaceutical Society of Great Britain (no comments)
The Royal Environmental Health Institute of Scotland (no comments)

4. Comments made

The consultation document posed a number of general questions for consultees.

- 1. Do consultees, particularly those whose trade includes the manufacture, importation or sale of cosmetics believe that the proposed Regulations will have a significant impact on competition or profitability?**

The CTPA did not believe that the Regulations would have a significant effect on competition in the long term. However, whilst all companies are affected by restrictions on ingredients resulting in enforced reformulation, smaller companies in particular are affected disproportionately by short implementation dates, and allowances for the sell-through of products need to be as long as reasonably possible.

AW commented that any change to the Cosmetics Directive has a significant impact on industry. Each proposed change requires that every formulation is reviewed for compliance and appropriate action has to be taken. Time spent ensuring that current products remain compliant with new requirements means that less time is spent developing competitive and innovative products, and this may affect the growth of businesses.

LACORS felt that the changes were fairly burdensome on small businesses, particularly those with a low throughput. However, neither the Body Shop nor the one SME who responded to the consultation felt that the proposed regulations would have a significant impact on competition or profitability.

The ATC were particularly concerned about the impact the proposed Regulations would have on SMEs, as the cost of labelling and packaging represents a much higher than usual proportion of their production costs. They felt that those operating on tight margins might even be forced out of business by the increased costs. Additionally, they thought there would be significant costs in analysing each product formulation for the 26 fragrance allergens.

2. If you are a small or medium-sized enterprise, what costs or other burdens are associated with the introduction of the Regulations?

AW estimate that since the introduction of the 7th Amendment, 10% of the development costs of SMEs have been spent ensuring that products comply with the new Regulations. This is an on-going cost as new requirements are additional to existing ones rather than replacing them.

LACORS thought that it would be difficult for some businesses because significant re-packaging would be required. This might affect SMEs disproportionately. This view was shared by Hampshire County Council who said that the craft/specialist low volume sector can find the compliance regime a real struggle.

The ATC also felt that re-packaging and design would be a major burden on SMEs and might change the look of the product to such an extent that it might even be necessary for them to spend money re-marketing the 'new look' product if they were not to lose regular customers.

The SME commented that it would take time and effort to find the information needed on essential oils and to change labels and reprint them, or even to change the size of labels because of the need to include extra information.

3. Are there any consequences of these Regulations which we have not anticipated?

Although the ATC were concerned that the Regulations were in direct contravention of the new European Chemicals Strategy (REACH), because REACH would require testing chemicals on animals, this is an issue of which DTI is well aware and it is

party to the discussions which are taking place. The ATC was also concerned that if there was insufficient time to comply with the Regulations, less reputable companies would not bother to comply. They were also concerned that the enforcement authorities were under-resourced for enforcement of the Regulations. This was not, however, a concern raised by LACORS.

The Home Office commented on the issue of marketing in the EU products which had been tested on animals, either because they were not classed as cosmetics in those countries or because those countries required such products to be tested on animals. They also raised the issue of potential conflict with REACH.

AW commented that a number of medium-sized enterprises which had been running successfully for many years in the UK had closed as they were unable to compete with non-EU based organisations. If the latter did not achieve regulatory compliance in the same way as the UK companies did there could be a significant adverse effect on consumer safety.

4. Do you consider this consultation exercise to be an effective means of disseminating information to those affected by the changes? How else could the DTI ensure these Regulations are implemented effectively?

The CTPA takes the view that this method of consultation is effective for the trade association and its members.

The ATC thought the consultation was an effective way of disseminating information but considered it was too late to consult companies (the consultation began in April 2004) if they were to comply with the proposals by March 2005.

The Body Shop considered the consultation to be effective except for companies (such as themselves) which were not members of trade associations or which were not large enough to employ someone to deal with regulatory affairs. However, they did not have a solution to the problem and recognised that the issue was not confined to cosmetics legislation.

AW said they had come across a number of safety assessors and cosmetics manufacturers in significant positions in the industry who had not heard about the consultation. They therefore thought DTI should consider emailing companies to give them advance warning of consultations, even though they appreciated that this would be an onerous task for DTI.

The SME did not think that the consultation was an effective way to disseminate information as DTI would not be aware of all the people in the cosmetics field who would need to know about the changes.

5. Will the proposed Regulations contribute to safer cosmetics being available and will the labelling requirements help consumers decide which cosmetics they should buy?

The CTPA did not think that the 7th Amendment to the Cosmetics Directive, transposed by the new Regulations, would make any significant difference to consumer safety. For the vast majority of consumers it would make no difference to their purchasing decisions. However, they did welcome the attempt to tighten up on misleading claims relating to animal testing.

AW thought that where products were fully compliant with the 2003 Cosmetics Regulations, the new Regulations would not significantly improve consumer safety. They also doubted whether the new information requirements would be of great value to most consumers. There could be an overload of information on pack labels which could lead to confusion and even to usage instructions or cautionary statements being missed. However, they felt that the listing of specified fragrance substances should assist dermatologists and some of their patients. Moreover, the additional labelling requirements should help enforcement officers identify non-complying products.

The ATC believed that most consumers would be delighted to know that a product had not been tested on animals. As regards the labelling of sensitisers, they thought this would mean little to those who had not visited a dermatologist and identified their sensitisers. However, they thought it could lead to products labelled as sensitisers being avoided by consumers and eventually being removed from the market. This would mean less choice for consumers even though there was no issue for most people in relation to sensitisation from cosmetic products.

As regards durability, they thought most consumers would be aware that products do not have an indefinite shelf-life but that labelling them to ensure that they were used at their best and before they could harm the consumer must improve consumer safety. On balance, they thought that the Regulations would make little difference to most consumers in helping them to decide which cosmetics to buy, unless they had specialist knowledge. They felt that consumer safety in the aromatherapy industry could be compromised if insufficient time were given to comply with the Regulations and small suppliers simply ignored them.

The Body Shop did not think that the Regulations would contribute to the availability of safer cosmetic products. They thought consumers might find the new information on product labels helped them to make purchasing decisions but that was only likely to be relevant for a well-informed and motivated minority.

The BUAV thought that the prohibition on animal testing would not endanger the safety of cosmetics. They also thought that the prohibition would have very little detrimental impact on innovation. However, they did not think that the Regulations did enough to ensure that consumers had the information they required about animal testing as they did not require that cosmetics which *had* been tested on animals were labelled to that effect.

The SME hoped that the Regulations would contribute to safer cosmetics being available and that the labelling requirements would help consumers as long as they were willing to get educated in this respect.

Other comments

There were many detailed comments from those who replied to the consultation and which concerned specific parts of the Regulations. There were also several requests for a guidance note to the Regulations to be provided as soon as possible. This will be available in due course.

Publication of the 2004 Cosmetics Regulations

These have been published as The Cosmetic Products (Safety) Regulations 2004, Statutory Instrument 2004 no. 2152. Due to a technical error the open book and open jar symbols were omitted from the main Statutory Instrument and have been published in The Cosmetic Products (Safety) (Amendment) Regulations 2004, Statutory Instrument 2004 no. 2361. This will be issued free of charge to all known recipients of the principal Regulations.

The Regulations are available from The Stationery Office:

<http://www.tso.co.uk/bookshop> .

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