



Department  
for Business  
Innovation & Skills

**CONSULTATION ON ENFORCING  
THE REGULATION ON COSMETIC  
PRODUCTS (EC) NO. 1223/2009**

MARCH 2013

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## **Consultation on the Enforcement of the Regulation (EC) No.1223/2009 on Cosmetic Products (recast)**

This consultation is relevant to stakeholders who are involved in the manufacture, distribution and importation of cosmetics which fall within the scope of Regulation (EC) No 1223/2009 on Cosmetic Products (Recast) ("Regulation (EC) 1223/2009"). It is also relevant to those involved in the enforcement of Regulation (EC) 1223/2009, which applies in its entirety from 11 July 2013. Consumers may also be interested in the consultation as it concerns the enforcement of Regulation (EC) 1223/2009, which relates to the safety of cosmetic products made available on the market.

Regulation (EC) 1223/2009 replaces Directive 76/768/EEC, which is implemented in the United Kingdom by the Cosmetic Products (Safety) Regulations 2008 (the 2008 Regulations). Regulation (EC) 1223/2009 lists restricted and banned substances, and provides positive lists of preservatives, colorants and UV filters. These provisions are largely unchanged from Directive 76/768/EEC. In addition, Regulation (EC) 1223/2009 clarifies the role of a 'responsible person' and a distributor in ensuring compliance with the relevant obligations, requires all cosmetic products to be notified to the European Commission rather than to national authorities and more clearly describes the product information file. It also introduces a concept of Serious Undesirable Effects, which have to be reported, and defines nanomaterials, which also have to be reported.

Regulation (EC) 1223/2009 is directly applicable in all Member States, meaning that no domestic regulation is required in order for the obligations to have effect. However, domestic regulation is needed in order to enforce Regulation (EC) 1223/2009, in relation to offences and penalties. Regulation (EC) 1223/2009 also requires Member States to provide additional labelling rules for non pre-packaged goods.

This consultation is therefore primarily about the enforcement of Regulation (EC) 1223/2009 within the United Kingdom and the penalties for breaching it. It is not about the content of Regulation (EC) 1223/2009.

Issued: **15 March 2013**

Respond by: **15 May 2013**

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Electronics, Materials, Chemicals & Product Regulation  
Department for Business, Innovation & Skills  
4<sup>th</sup> Floor Orchard 1  
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## 2. Executive Summary

We are consulting on draft Cosmetic Products Enforcement Regulations 2013 (“Enforcement Regulations”) which provide for the enforcement of European Regulation (EC) No 1223/2009 on Cosmetic Products. They apply in respect of all cosmetic products that are made available on the EU market after 11 July 2013.

The Enforcement Regulations create enforcement powers, offences and penalties within the United Kingdom, as obliged under the EU Regulation.

The offences, penalties and enforcement provisions of these draft Regulations are similar to those in the Cosmetic Products (Safety) Regulations 2008, which they replace, and the Consumer Protection Act 1987. However, it has been necessary to expand the offences and penalties to reflect the broader scope of the EU Regulation.

In addition, some updates to penalties and enforcement powers have been made in order to reflect developments in the wider regulatory context, and the Government’s policy in relation to safeguards for powers of entry. Key changes to penalties include increasing the maximum levels of fine from £5,000 to £20,000 for some offences, and a doubling of the maximum imprisonment sentence on indictment for the most serious offences to 12 months. This reflects the current levels of penalties in the UK’s General Product Safety Regulations 2005 which covers consumer goods and therefore provides consistency.

Another key change relates to the powers of an enforcement officer to enter premises in order to ascertain whether there has been compliance with the regulations. Powers of entry no longer extend to premises used wholly or mainly as a private dwelling. Also before entering the premises, an enforcement officer must give reasonable notice unless this notice would reasonably be supposed to defeat the purposes of entry. These measures reflect the Government’s position on safeguards for powers to enter premises.

The Enforcement Regulations also contain one provision specific to the making available of cosmetics. This is regulation 5, which sets out the labelling requirements for cosmetic products which are not pre-packaged or are pre-packaged at the point of sale. There is a question in this consultation which covers this matter. The rest of the questions focus on offences, penalties and enforcement powers proposed.

Because the scope of the Enforcement Regulations is relatively limited, and the enforcement regime proposed is broadly compatible with the existing regulation, the period of this consultation is two months. Responses are requested by **15 May 2013**.

All the responses to this consultation will be considered carefully. A Government Response to this consultation will be issued followed by the laying of the Enforcement Regulations to come into force on 11 July 2013.

The Regulations cover the whole of the United Kingdom. The Department may, in accordance with the Code of Practice on Access to Government Information, make available, on public request, individual responses. Could you please state whether parts of your responses are confidential (although please be aware we may not be able to guarantee confidentiality).

A regulatory impact assessment has not been produced for the Enforcement Regulations as this instrument has a negligible impact on the costs of business.

**The consultations questions are listed below for ease of reference so that consultees can get an overview of what information is sought and can refer to them swiftly.**

Question 1: Do you foresee any particular problems that the labelling requirement set out in regulation 5 could bring to your business?

Question 2: Do you agree with the scope of the proposed criminal offences created by the Enforcement Regulations?

Question 3: Do you consider that the proposed penalties outlined in this consultation are appropriate ?

Question 4: Do you agree with the proposals to accord rights of appeal against a written notice?

Question 5: Do you consider that compensation orders, remediation orders, recovery of expenses of enforcement and forfeiture measures are appropriate?

The Overall Regulations

Question 6: Do you consider that the proposed Enforcement Regulations as a whole are effective and proportionate?

### 3. How to respond

When responding please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents by selecting the appropriate interest group on the consultation form and, where applicable, how the views of members were assembled.

The consultation response form is available electronically on the consultation page: <https://www.gov.uk/government/consultations/enforcing-the-ec-regulation-on-cosmetic-products> (until the consultation closes). The form can be submitted by email or by letter to:

Tony Eden-Brown  
Electronics, Materials, Chemicals & Product Regulation  
Department for Business, Innovation & Skills  
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1 Victoria Street  
London SW1H 0ET

Tel: 020 7215 0360

Email: [cosmeticregs@bis.gsi.gov.uk](mailto:cosmeticregs@bis.gsi.gov.uk)

A list of those organisations and individuals consulted is in Annex II. We would welcome suggestions of others who may wish to be involved in this consultation process.

You may make printed copies of this document without seeking permission.

Other versions of the document in Braille, other languages or audio-cassette are available on request.

### 4. Confidentiality & Data Protection

Information provided in response to this consultation, including personal information, may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want information, including personal data that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

## 5. Help with queries

Questions about the policy issues raised in the document can be addressed to:

Tony Eden-Brown  
Chemicals & Product Regulation  
Department for Business, Innovation & Skills  
4<sup>th</sup> Floor  
Orchard 1  
1Victoria Street  
London  
SW1H 0ET

0207 215 0360

The consultation principles are in Annex I

## 6. The proposals

The Enforcement Regulations provide for the enforcement of Regulation (EC) 1223/2009. A regulatory impact assessment has not been produced for this instrument as it has a negligible impact on the costs of business.

Regulation (EC) 1223/2009 is applicable from 11 July 2013 (subject to two exceptions, which are already applicable). It also imposes some obligations on cosmetic products notified under Directive 76/768/EEC. Further details on this Regulation can be found on the attached link <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF>

### **Part 1 of the Enforcement Regulations**

This is largely definitional. It sets the Secretary of State as a competent authority for all of Regulation (EC) 1223/2009. The enforcement authority is also a competent authority for the purposes of certain Articles in Regulation (EC) 1223/2009. The Enforcement Authority is defined in regulation 3, and includes Local Authority Trading Standards Services (LATSS) and its Northern Ireland equivalents.

#### ***Labelling requirements***

Draft regulation 5 sets out the labelling requirements for cosmetic products which are:

- not pre-packaged;
- pre-packaged at the point of sale at the purchaser's request; or
- pre-packaged for immediate sale.

These requirements are included to meet the obligation found in Article 19(4) of Regulation (EC) 1223/2009 and are intended to be consistent with the requirements found in the 2008 Regulations.

**Question 1: Do you foresee any particular problems that the labelling requirement set out in regulation 5 could bring to your business?**

**Part 2 of the draft Regulations: Offences, Penalties, Enforcement**

Part 2 creates offences, penalties, and enforcement powers for Regulation (EC) 1223/2009. The offences, penalties and enforcement provisions of these draft Regulations are broadly similar to those in the 2008 Regulations and the Consumer Protection Act 1987. However, it has been necessary to expand the offences and penalties to reflect the broader scope of Regulation (EC) 1223/2009.

In addition, some updates to penalties and enforcement powers have been made in order to take into account the wider regulatory context. This includes the General Product Safety Regulations 2005, and EU Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (“RAMS”) which contains some enforcement powers which are directly applicable in the United Kingdom. Regard has also been had to the Government’s position on safeguards for powers of entry, which has been reflected both in the Protection of Freedoms Act 2012 and the consultation on the proposed forthcoming <sup>1</sup>Consumer Rights Bill.

***Market surveillance and enforcement powers***

Under draft regulation 6, enforcement authorities are obliged to carry out market surveillance duties and, where necessary, are given the powers to act outside of their areas. Draft regulation 7 set out the powers they may exercise in the pursuit of these obligations.

***Written notice of enforcement measures***

Draft regulation 8 requires an enforcement authority to provide written notice to the responsible person or the distributor when requiring certain measures to be taken under Articles 25, 26 and 27 of Regulation (EC) 1223/2009. Articles 25 (non-compliance by the responsible person) and 26 (non-compliance by distributors) of Regulation (EC) 1223/2009 give powers to require a responsible person or distributor to take corrective actions in relation to non-compliant products, including requiring the withdrawal or recall of products. Article 27 (safeguard clause) provides a power to require similar actions for products that comply with Article 25(1), but could present a serious risk to human health. It should be noted that under Article 4 of Regulation (EC) 1223/2009 the responsible person may be a manufacturer, an importer or a distributor, depending on the circumstances.

The written notice must satisfy the good administrative practice requirements found in Article 28 of Regulation (EC) 1223/2009. Regulation 8 also sets out how the written notice may be served, including by email.

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<sup>1</sup> Department for Business, Innovations and Skills, March 2012, <http://www.bis.gov.uk/Consultations/consultation-on-consumer-law-enforcement-powers>

### **Authorisation and notification**

Draft regulation 9 requires enforcement authorities to obtain the authorisation of the Secretary of State before taking any action against a cosmetic product, where the authority ascertains, or has reasonable grounds for concern, that it could present a serious risk to human health in accordance with Article 27 (safeguard clause) of Regulation (EC) 1223/2009. Draft regulation 10 requires an enforcement authority to immediately notify the Secretary of State of any action taken by it, for onward transmission to the European Commission (ie the RAPEX system).

### **Offences**

Draft regulation 12 stipulates that it is an offence for a person to contravene certain provisions of Regulation (EC) 1223/2009. These provisions are listed in Schedule 3 of the Enforcement Regulations. It also makes it an offence to obstruct, knowingly mislead or fail to cooperate with a person acting in the execution or enforcement of Regulation (EC) 1223/2009.

### **Question 2 : Do you agree with the scope of the proposed criminal offences created by the Enforcement Regulations?**

### **Penalties**

Draft regulation 13 sets out the penalties that apply when certain provisions of Regulation (EC) 1223/2009 and regulation 12 are breached. Breaches of certain Articles are triable either way (which means they can be tried as either indictable or summary offences), whereas others can only be tried as summary offences.

The following offences are triable either way:

- An offence under regulation 12(1) that arises from breaching any of the following Articles of Regulation (EC) 1223/2009:
  - Article 3 (Safety);
  - Article 5 (Obligations of responsible person);
  - Article 6 (Obligations of distributors)
  - Article 7 (Identification within the supply chain);
  - Article 10 (Safety assessment);
  - Article 14 (Restrictions for substances listed in the Annexes of the Regulation);
  - Article 15 (Substances classified as CMR substances)
  - Article 18 (Animal testing);
  - Article 19 (Labelling);
  - Article 20 (Product claims);
  - Article 23 (Communication of serious undesirable effects);

- An offence under regulation 12(3) or to fail to comply with requirements made by an enforcement authority acting under Articles 25, 26 or 27 of Regulation (EC) 1223/2009.

Where a person is convicted of an offence that is triable either way, they will be liable:

- on summary conviction to a fine not exceeding the statutory maximum (currently £5,000 in England, Wales and Northern Ireland, or £10,000 in Scotland) or to imprisonment not exceeding three months, or to both;
- on conviction on indictment to a fine not exceeding £20,000, or to imprisonment not exceeding twelve months, or to both.

The following offences can only be tried as summary offences:

- An offence under regulation 12(1) that arises from by breaching any of the following Articles of Regulation (EC) 1223/2009:
  - Article 11 (Product information file requirements);
  - Article 13 (Notification requirements);
  - Article 16 (Notification of Nanomaterials);
  - Article 21 (Access to information for the public);
  - Article 24 (Information on substances);
- An offence under regulation 12(2) for obstructing, knowingly misleading or failing to cooperate with a person acting in the execution or enforcement of Regulation (EC) 1223/2009.

If a person is convicted of a summary offence under regulation 12(1), they will be liable to a fine not exceeding level 5 on the standard scale (which is currently £5,000), or to imprisonment not exceeding three months, or to both. If a person is convicted of a summary offence under regulation 12(2) they will be liable to fine not exceeding level 5 on the standard scale.

The Government considers it appropriate to introduce indictable fines of more than £5,000, in order for the penalty to carry sufficient weight, given the aim of the Regulation (EC) 1223/2009 is to protect human health. It is important to point out that all offences may still be tried on a summary basis. The Government proposes to limit the maximum fine for convictions on indictment to £20,000. It also proposes to increase maximum terms of imprisonment for convictions on indictment to a term not exceeding twelve months. These changes are proposed in order to align with the penalties set out in regulation 20 in the General Product Safety Regulations 2005 which covers consumer goods. The Government considers it important to have a consistent approach to the penalty regime in these areas. Article 37 of Regulation (EC) 1223/2009, which relates to penalties, sets out the requirement to provide for effective, proportionate and dissuasive sanctions.

**Question 3:** Do you consider that the proposed penalties outlined in this consultation are appropriate ?

### ***Right of Appeal against the written notice***

Draft regulation 14 (1) states that a responsible person, distributor, or other person who has an interest in the cosmetic product in which the notice is issued has the right to make an application to the appropriate court for an order to vary, or set aside the written notice issued by an enforcement authority. This is similar to the ability to appeal a suspension notice which currently exists under the 2008 Regulations.

Draft regulation 15 sets out the appropriate courts for an appeal.

**Question 4: Do you agree with the proposals to accord rights of appeal against a written notice?**

### ***Compensation Orders, Remediation, Recovery of Expenses and Forfeiture***

Draft regulation 16 enables a compensation order to be made when an enforcement authority takes, or requires a responsible person or distributor to take, certain measures in circumstances where no contravention of Regulation (EC) 1223/2009 has occurred or is likely to occur. The enforcement authority may be liable to pay compensation to any person who has an interest in the cosmetic product in relation to any loss or damage caused. Any disputed question as to right or amount of compensation will be determined by arbitration. A similar provision to this currently applies under the 2008 Regulation.

Draft regulation 17 enables a court to require a person to remedy a matter for which they have been convicted. This remedy can be required in addition to, or instead of, any penalty. Draft regulation 18 enables a court to require a person who has committed an offence to reimburse the enforcement authority for reasonably incurred enforcement costs.

Draft regulations 19 and 20 provide that where there is a breach of Article 3 (Safety) of Regulation (EC) 1223/2009, the enforcement authority can apply to the appropriate court for forfeiture of the cosmetic product. This continues the approach found in the 2008 Regulations.

**Question 5: Do you consider that the compensation orders, remediation orders, recovery of expenses of enforcement and forfeiture measures are appropriate?**

### **Schedule 2 of the Enforcement Regulations – Testing of cosmetic products, Powers of entry, Powers to inspect, seize and detain cosmetic products**

#### ***Testing of cosmetic products***

Draft paragraph 1 of Schedule 2 provides that an enforcement authority may purchase a cosmetic product in order to test it to ascertain whether or not the requirements of Regulation (EC) 1223/2009 have been complied with. Draft paragraph 1 also allows, a person from whom the cosmetic product was purchased or seized, who is a party to the proceedings, or who has an interest in the cosmetic product in question, to ask to carry out their own testing. This is a continuation of the testing procedures under the 2008 Regulations.

### ***Power to enter premises***

Draft paragraph 3 of Schedule 2 sets out the power of an enforcement authority officer to enter premises in order to ascertain whether there has been compliance with Regulation (EC) 1223/2009, or the Enforcement Regulations.

However, the Government considers it important to have in place safeguards concerning the power to enter premises. Therefore draft paragraph 3 does not include a power to enter premises which are used wholly or mainly as a private dwelling. Before entering the premises, an officer must give reasonable notice, unless giving such notice would reasonably be supposed to defeat the purposes of entry. This strikes a balance between enabling an enforcement authority officer to undertake spot checks and still needing a clear reason not to give notice. Furthermore, entry should be at a reasonable hour.

In drafting the proposed powers of entry provisions, we have taken into account the requirements of the Protection of Freedoms Act 2012 and the proposals outlined in the Government's consultation in March 2012 on consolidating and modernising consumer law enforcement powers which proposed setting out the powers as a generic set and enhancing safeguards to their use. The aim is for these measures to be taken forward in the proposed forthcoming Consumer Rights Bill.

### **Power to inspect, seize, and detain cosmetic products**

Draft paragraph 4 sets out the powers an officer of an enforcement authority has to inspect, seize and detain cosmetic products in order to ascertain whether Regulation (EC) 1223/2009 or the Enforcement Regulations have been complied with. These are broadly in line with the powers available under the 2008 Regulations, although some modifications have been made to take into account changes in the broader regulatory context, including RAMS.

### **Warrants**

Under the current 2008 Regulations, a Justice of the Peace can issue a warrant to an enforcement officer to enter any premises for the purposes of enforcing the Regulations, providing there are reasonable grounds to do so. Paragraph 5 of the draft Enforcement Regulations largely replicates these warrant powers.

### **The Overall Regulations**

Question 6: Do you consider that the proposed Enforcement Regulations as a whole are effective and proportionate?

## 7. Consultation questions

### Draft Regulation 5: Labelling Requirements

**Question 1: Do you foresee any particular problems that the labelling requirement set out in regulation [5] could bring to your business?**

### Draft Regulation 12: Offences

**Question 2: Do you agree with the scope of the proposed criminal offences created by the Enforcement Regulations?**

### Draft Regulation 13: Penalties

**Question 3: Do you consider that the proposed penalties outlined in this consultation are appropriate?**

### Draft Regulation 14: Appeal Rights Against a Written Notice

**Question 4: Do you agree with the proposals to accord rights of appeal against a written notice?**

**Draft Regulations 16 (Compensation Orders), 17 (Remediation Orders), 18 (Recovery of Expenses of Enforcement), 19 (Forfeiture:England and Wales), and 20 (Forfeiture:Scotland)**

**Question 5: Do you consider that compensation orders, remediation orders, recovery of expenses of enforcement and forfeiture measures are appropriate?**

### The Overall Regulations

**Question 6: Do you consider that the proposed Enforcement Regulations as a whole are effective and proportionate?**

## 8. What happens next?

This consultation is necessary to enable the United Kingdom to make the new legislation required to implement the requirements of Regulation (EC) 1223/2009. A response to this consultation will be made and following the date of this issue, the Enforcement Regulations will be laid in Parliament to come into force on 11 July 2013. The Government's Response Document will be placed on the BIS website, with paper copies of the summary of responses made available on request.

## **Annex I: Consultation principles**

The principles that Government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.

<http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf>

### **Comments or complaints on the conduct of this consultation**

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted, please write to:

John Conway,  
BIS Consultation Co-ordinator,  
1 Victoria Street,  
London  
SW1H 0ET

Telephone John on 020 7215 6402  
or e-mail to: [john.conway@bis.gsi.gov.uk](mailto:john.conway@bis.gsi.gov.uk)

However if you wish to comment on the specific policy proposals you should contact the policy lead. (Please see Section 5 for the contact details).

## **Annex II List of Individuals/Organisations consulted**

Consumer Focus

Consumer Council for Northern Ireland

Convention of Scottish Local Authorities

Dept Trade Enterprise and Investment (Northern Ireland)

Essex Trading Standards

National Trading Standards Board

Product Safety Focus Group

The Cosmetic, Toiletry and Perfumery Association

The Guild of Craft Soap & Toiletry Makers

Trading Standards Institute

## **Annex III - Consultation on Enforcing the Regulation on Cosmetic Products (EC) No. 1223/2009: Response Form**

Name:

Organisation (if applicable):

Address:

The Department may, in accordance with the Code of Practice on Access to Government Information, make available, on public request, individual responses.

The closing date for this consultation is **15 May 2013**.

Please return completed form to:

Tony Eden-Brown  
Chemicals & Product Regulation  
Department for Business, Innovation & Skills  
4th Floor  
Orchard 1  
1 Victoria Street  
London SW1H 0ET

Tel: 020 7215 0360

Email: [cosmeticregs@bis.gsi.gov.uk](mailto:cosmeticregs@bis.gsi.gov.uk)

We would like respondents to tick a box from a list of options that best describes them at a respondent. This allows views to be presented by group type.

	Business representative organisation/trade body
	Central government
	Charity or social enterprise
	Individual
	Large business (over 250 staff)
	Legal representative
	Local Government
	Medium business (50 to 250 staff)
	Micro business (up to 9 staff)
	Small business (10 to 49 staff)
	Trade union or staff association
	Other (please describe)

Question1 : Do you foresee any particular problems that the labelling requirement set out in regulation 5 could bring to your business?

Comments:

Question 2: Do you agree with the scope of the proposed criminal offences created by the Enforcement Regulations?

Comments:

Question 3: Do you consider that the proposed penalties outlined in this consultation are appropriate?

Comments:

Question 4: Do you agree with the proposals to accord rights of appeal against a written notice?

Comments:

Question 5: Do you consider that compensation orders, remediation orders, recovery of expenses of enforcement and forfeiture measures are appropriate?

Comments:

Question 6: Do you consider that the proposed Enforcement Regulations as a whole are effective and proportionate?

Comments:

**Do you have any other comments that might aid the consultation process as a whole?**

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Thank you for your views on this consultation. However, as part of the BIS wider customer survey plans, we would appreciate your views on below.

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below.

Please acknowledge this reply

At BIS we carry out our research on many different topics and consultations. As your views are valuable to us, would it be okay if we were to contact you again from time to time either for research or to send through consultation documents?

Yes

No

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