



Notification Number: 2015/295/E

## Draft royal decree regulating cosmetic products

Date received : 12/06/2015  
End of Standstill : 14/09/2015 ( 14/12/2015)  
Issue of detailed opinion by : Commission

### Message

Message 002

Communication from the Commission - TRIS/(2015) 01743  
Directive 98/34/EC  
Translation of the message 001  
Notification: 2015/0295/E

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201501743.EN)

#### 1. Structured Information Line

MSG 002 IND 2015 0295 E EN 12-06-2015 E NOTIF

#### 2. Member State

E

#### 3. Department Responsible

Subdirección General de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y Medio Ambiente.

Dirección General de Coordinación de Políticas Comunes y de Asuntos Generales de la Unión Europea.  
Secretaría de Estado para la Unión Europea.

Ministerio de Asuntos Exteriores y de Cooperación.

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### 3. Originating Department

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### 4. Notification Number

2015/0295/E - C00P

### 5. Title

Draft royal decree regulating cosmetic products

### 6. Products Concerned

Cosmetic products.

### 7. Notification Under Another Act

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### 8. Main Content

This draft consists of eight chapters divided into 24 articles, plus four additional provisions, a sole transitional provision, a sole repealing provision and four final provisions. It has an annex relating to the requirements for undertaking cosmetic product manufacturing and importing activities.

The purpose of this royal decree is to regulate the supplementary provisions which the Member States must set in accordance with the provisions of Regulation (EC) No 1223/2009 on cosmetic products, applicable in full since 11 July 2013. Another purpose is to update and harmonise the current regulations on cosmetic products and, specifically, to define the legal framework for the manufacture, import and placement on the market of cosmetic products, and to set out the provisions to strengthen the coordinating role of the Spanish Agency of Medicines and Health Products as a national authority in the field of cosmetic products.

### 9. Brief Statement of Grounds

The primary objective of this royal decree is to regulate, within the Spanish legal system, the aspects that, in the directly applicable European regulation, are conferred to the mandate of the Member States, as well as the others related to the sector whose national regulation requires updating in order to adapt it to the current economic situation or the new legal regulations in the field, e.g. the responsible declaration of cosmetic product manufacturing and import activities.

Thus, this royal decree, like the European standard that it supplements, aims to simplify the procedures and rationalise the terminology, reducing the administrative burden and ambiguities, as well as to strengthen certain elements of the regulatory framework for cosmetics, such as market control, in order to ensure a high level of protection for human health.

### 10. Reference Documents - Basic Texts



No basic text(s) available.

**11. Invocation of the Emergency Procedure**

No

**12. Grounds for the Emergency**

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**13. Confidentiality**

No

**14. Fiscal measures**

No

**15. Impact assessment**

Yes

**16. TBT and SPS aspects**

TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft has no significant impact on international trade.

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European Commission

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