



Notification Number: 2009/588/E

## DRAFT ROYAL DECREE REGULATING ANIMAL HEALTH PRODUCTS.

Date received : 30/10/2009

End of Standstill : 01/02/2010

### Message

Message 002

Communication from the Commission - SG(2009) D/52567

Directive 98/34/EC

Translation of the message 001

Notification: 2009/0588/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: 200902567.EN)

#### 1. Structured Information Line

MSG 002 IND 2009 0588 E EN 01-02-2010 30-10-2009 E NOTIF 01-02-2010

#### 2. Member State

E

3.a. SUBDIRECCIÓN GENERAL DE ASUNTOS INDUSTRIALES, ENERGÉTICOS, DE TRANSPORTES Y COMUNICACIONES Y DE MEDIO AMBIENTE - DIRECCIÓN GENERAL DE COORDINACIÓN DEL MERCADO INTERIOR Y OTRAS POLÍTICAS COMUNITARIAS - SECRETARÍA DE ESTADO DE ASUNTOS EUROPEOS - MINISTERIO DE ASUNTOS EXTERIORES, C/SERRANO GALVACHE, 26 PLANTA 4ª, TORRE SUR DESPACHO 04-51. MADRID 28071. TELEPHONE +34 (91) 379.84.64 - +34 (91) 379.83.98 FAX: +34 (91) 379.84.01 E-MAIL: d83-189@ue.mae.es

3.b. MINISTERIO DE MEDIO AMBIENTE, Y MEDIO RURAL Y MARINO. DIRECCIÓN GENERAL DE RECURSOS AGRÍCOLAS Y GANADEROS

#### 4. Notification Number

2009/0588/E – C30A



## **5. Title**

DRAFT ROYAL DECREE REGULATING ANIMAL HEALTH PRODUCTS.

## **6. Products Concerned**

ANIMAL HEALTH PRODUCTS (INCLUDING ANIMAL HEALTH MATERIALS AND TOOLS FOR THEIR APPLICATION).

## **7. Notification Under Another Act**

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## **8. Main Content**

THE PURPOSE OF THE DRAFT ROYAL DECREE IS TO REGULATE THE AUTHORISATION, MARKETING AND USE OF ANIMAL HEALTH PRODUCTS, INCLUDING ANIMAL HEALTH MATERIALS AND TOOLS INTENDED FOR THE SPECIFIC APPLICATION OF ANIMAL HEALTH PRODUCTS. IT LAYS DOWN GENERAL REGULATIONS FOR THE CONTROL OF CERTAIN ANIMAL HEALTH PRODUCTS AND THE CONFIDENTIALITY AND PROTECTION OF INFORMATION, RULES FOR THE AUTHORISATION OR RESPONSIBLE DECLARATION OF MARKETING AND FOR MANUFACTURING ENTITIES, AND FOR THE SUPERVISION, SUSPENSION, MODIFICATION OR REVOCATION OF AUTHORISATIONS.

## **9. Brief Statement of Grounds**

ADVANCEMENTS IN VETERINARY PRACTICE AND NEW OPERATING PRIORITIES BROUGHT ABOUT BY THE CATTLE HEALTH SITUATION MAKE IT NECESSARY TO UPDATE AND UNIFY LEGAL REGULATIONS DATING BACK TO 1981 (ROYAL DECREE 163/1981 OF 23 JANUARY).

MEANWHILE, DIRECTIVE 2006/123/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 12 DECEMBER 2006 ON SERVICES IN THE INTERNAL MARKET REQUIRES THAT THE AFOREMENTIONED ROYAL DECREE BE REPEALED, ONCE THE EXISTING PROCEDURES AND AUTHORISATIONS RELATED TO CATTLE AND AGRICULTURE HAVE BEEN ANALYSED. TO THIS END, THE NEW REGULATIONS LAY DOWN AS A GENERAL RULE THE SUBMISSION OF A MANGIERIAL DECLARATION FOR THE MARKETING OF THE PRODUCTS, EXCEPT IN THE CASE OF REAGENTS FOR DIAGNOSING DIFFERENT ANIMAL DISEASES, WHICH IS SUBJECT TO PRIOR AUTHORISATION FOR REASONS OF ANIMAL HEALTH AND PUBLIC SAFETY (IMPERATIVE REASONS ENVISAGED IN THE DIRECTIVE) GIVEN ITS FUNDAMENTAL IMPORTANCE FOR THE DETECTION OF DISEASES, INCLUDING THOSE OF A ZOONOTIC NATURE (MAY BE TRANSMITTED TO HUMANS).

## **10. Reference Documents - Basic Texts**

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## **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**

-

**16. TBT and SPS aspects**

TBT ASPECTS

B) THIS DOCUMENT IS NOT A REGULATION THAT MUST BE REPORTED WITHIN THE FRAMEWORK OF THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE.

SPS ASPECTS

B) THIS IS NOT A SANITARY OR PHYTOSANITARY REGULATION WITHIN THE FRAMEWORK OF THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES.

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