



Notification Number: 2009/513/F

## **Decision of the Director General of the French Food Safety Agency of xx xxx 2009 amending the decision of 22 September 2008 relating to good practice in the manufacture of veterinary medicinal products.**

Date received : 24/09/2009

End of Standstill : 28/12/2009

### **Message**

Message 002

Communication from the Commission - SG(2009) D/52218

Directive 98/34/EC

Translation of the message 001

Notification: 2009/0513/F

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 késéset - 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: 200902218.EN)

#### **1. Structured Information Line**

MSG 002 IND 2009 0513 F EN 28-12-2009 24-09-2009 F NOTIF 28-12-2009

#### **2. Member State**

F

#### **3. Department Responsible**

Délégué interministériel aux normes – SQUALPI – Bâtiment Le Bervil - 12, rue Villiot – 75572 PARIS Cedex 12  
d9834.france@finances.gouv.fr

tél : 01 53 44 98 24 – fax : 01 53 44 98 88

#### **3. Originating Department**

Agence française de sécurité sanitaire des aliments  
27-31 Avenue du Général Leclerc



94701 MAISONS-ALFORT Cedex  
mf.guillemer@afssa.fr  
tél : 02 99 94 78 53 – Fax : 02 99 94 78 99

#### **4. Notification Number**

2009/0513/F - C30A

#### **5. Title**

Decision of the Director General of the French Food Safety Agency of xx xxx 2009 amending the decision of 22 September 2008 relating to good practice in the manufacture of veterinary medicinal products.

#### **6. Products Concerned**

Veterinary medicinal products

Establishments manufacturing or importing veterinary medicinal products.

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

a) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 laying down a Community code relating to veterinary medicinal products amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 on the labelling and presentation of foodstuffs (JO L 311 of 28 November 2001 p.1 and JO L 336 of 30 April 2004 p 58),

b) Commission Directive 91/412/EEC of 23 July 1991, laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (JO L 228 of 17 August 1991 p.70),

#### **8. Main Content**

This new Decision enables the transposition into national law of the European provisions implementing Article 51 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 amended establishing a Community code on veterinary medicinal products, of Article 3 of Commission Directive 91/142/EC of the Commission of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products and published in Volume 4 "EU guidelines of good manufacturing practices for medicinal products for human use and veterinary use", Eudralex "the rules governing medicinal products in the European Union".

This draft standard amends and completes the provisions of the Decision, previously notified under Number 2008/0226/F, of the Director General of the French Food Safety Agency of 22 September 2008 relating to good manufacturing practice for veterinary medicinal products by the amendment of Annex Number 1 published in March 2009 and the addition of a new guideline Number 20 published by the European Commission in March 2008.

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

It involves updating the standard reference base for good practice with the recently published changes.

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

a) This decision completes the statutory provision relating to good practice opposable to establishments manufacturing or importing veterinary medicinal products and their conditions of authorisation and operation.

b) Articles L. 5142-3 of the Public Health Code, statutory part.



**11. Invocation of the Emergency Procedure**

NO

**12. Grounds for the Emergency**

-

**13. Confidentiality**

NO

**14. Fiscal measures**

NO

**15. Impact assessment**

-

**16. TBT and SPS aspects**

TBT aspect

a) YES

SPS aspect

a) NO

i) The draft is not a sanitary or phytosanitary measure, in the sense of Annex A of the SPS Agreement.

Catherine Day  
Secrétaire général  
Commission européenne

Point de contact Directive 98/34  
Fax: (32-2) 296 76 60  
email: dir83-189-central@ec.europa.eu

-----  
sent to :

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1  
Frau MARKL Iris

European Free Trade Association

.

Työ- ja elinkeinoministeriö



Ms. Leila Vilhunen

Malta standards Authority  
Sarah Jane Meli

Kommerskollegium  
Ms Gunnel Fälth

Slovenian Institute for Standardization SIST  
Mrs Vesna Stazisar

Office of standards, metrology & Testing Kralikova Dana  
.

Bundesministerium für Wirtschaft und Technologie (Referat EB2)  
Frau Kathrin Lettgen

Représentation Permanente de la France  
.

Ministerio dell'industria  
Sr. CASTIGLIONI Enrico

Ministry of Economy Dept for Economic Regulations  
Mrs Barbara H. Kozłowska

Ministry of Economy and Commerce Division for Internal Market  
Catalina Groza

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1  
Frau Brigitte WIKGOLM

Représentation Permanente de la Belgique auprès de l'Union européenne  
.

Ministerio de Asuntos Exteriores y Coop. DG de Coordinación del Mercado Interior  
Juan Carlos Calvo Huerta

Min. of Economic Affairs & Communication  
Mr. Karl Stern

Délégation Interministérielle aux Normes  
Mme PORTOU-DUPIN

Min. of Industry, Energy & Technology  
Mr K. Polychronidis

CU N Lovseth Hanne Leen  
.

Ministerie van Financiën Belastingdienst - Douane Noord / CDIU  
De Heer IJ.G. van der Heide



Instituto Português da Qualidade  
Sra Eng<sup>a</sup>. Anete Freitas

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1  
Franz BORTH

Institut Belge de Normalisation  
Mme F. Hombert

EU internal market coordination (Ministry of Economics)  
Mr. Dainis Matulis

BELNotif (Qualité et Sécurité) SPF Economie, PME, Classes moyennes, Energ  
M. Paul Caruso

Cyprus org. for the promotion of quality Ministry of Commerce, Industry & Tourism  
M. Antonis Ioannou

ELOT  
Mrs. Tzoulou Afroditi

NSAI  
Mr Tony Losty

Lithuanian Standards Board  
Daiva Lesickiene

Undersecretariat of Foreign Trade General Directorate of Standardisation  
Mr Mehmet COMERT

Czech Office for Standards, Metrology and testing  
Mrs Lucie Ruzickova

Erhvervs- og Byggestyrelsen/Danish Enterprise & Construction Authority  
Bjarne Bang Christensen

EFTA Surveillance Authority  
Mr. Gunnar Thor PETURSSON

Ministero dello sviluppo economico Dip.to Impresa e Internazionalizzazione  
Sr. CASTIGLIONI Enrico

Department for Business, Innov. & Skills  
Mr Philip Plumb

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1  
Ida CSISZAR

State Agency for Metrological and Technical Surveillance  
Violetta Veleva



SL

.

CU FL-Amt für Handel und Transport (TPMN)  
Dipl. Ing. FH Thomas Näf

Hungarian Notification Centre Ministry of National Development and Eco  
Mr Zsolt Fazekas

Institut luxembourgeois de la normalisat (ILNAS)  
Mr Manuel Turmes

Service de l' Energie de l' Etat  
M. Miguel Borges

Représentation Permanente du Luxembourg

.

Office of standards, metrology & Testing Director of the department of European I  
Mrs Kvetoslava STEINLOVA

-----  
sent to :

European Free Trade Association

.

Työ- ja elinkeinoministeriö  
Ms. Leila Vilhunen

Malta standards Authority  
Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market  
Catalina Groza

CU N Lovseth Hanne Leen

.

NSAI  
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation  
Mr Mehmet COMERT

EFTA Surveillance Authority  
Mr. Gunnar Thor PETURSSON



Représentation Permanente du Royaume-Uni

.

Department for Business, Innov. & Skills  
Mr Philip Plumb

State Agency for Metrological and Technical Surveillance  
Violetta Veleva

SL

.

Hungarian Notification Centre Ministry of National Development and Eco  
Mr Zsolt Fazekas

Représentation Permanente de l'Irlande  
Denis Colfer