



Notification Number: 2010/372/F

## Draft law aimed at suspending the sale of bisphenol A-based infants' feeding bottles.

Date received : 29/06/2010

End of Standstill : Closed

### Message

Message 002

Communication from the Commission - SG(2010) D/51532

Directive 98/34/EC

Translation of the message 001

Notification: 2010/0372/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 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: 201001532.EN)

#### 1. Structured Information Line

MSG 002 IND 2010 0372 F EN 29-06-2010 F NOTIF

#### 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

MM. Yvon Collin, Jean-Michel Baylet, Michel Charasse, François Fortassin, Mme Françoise Laborde, MM.

Jacques Mézard, Jean Milhau, Robert Tropéano et Raymond Vall

Sénat - Palais du Luxembourg - 15 rue de Vaugirard - 75291 Paris cedex 06

Tél. 01 42 34 20 00-Fax 0142 34 26 77



[www.senat.fr](http://www.senat.fr)

#### 4. Notification Number

2010/0372/F - C70A

#### 5. Title

Draft law aimed at suspending the sale of bisphenol A-based infants' feeding bottles.

#### 6. Products Concerned

Bisphenol A-based infants' feeding bottles

#### 7. Notification Under Another Act

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#### 8. Main Content

The draft law suspends the manufacture, import, export and placing on the market, either in return for payment or free of charge, of bisphenol A-based infants' feeding bottles until the Agence française de sécurité sanitaire des produits de santé adopts a reasoned opinion reauthorising these operations.

In the two months following the publication by the Institut national de la santé et de la recherche médicale by its collective expert opinion on endocrine disrupters and no later than 1 January 2001, a report laying out the measures already taken and the measures planned to reduce human exposure to these products sent by the Government to the Parliament.

Keywords: infants' feeding bottle, bisphenol, manufacture, import, endocrine disrupter

#### 9. Brief Statement of Grounds

Bisphenol A is a chemical product used for the manufacture of plastic for infants' feeding bottles. It has been the subject of numerous studies. On 20 October 2009 the Agence française de sécurité sanitaire des aliments (Afssa) took on the task of analysing a toxicity study on the development of the nervous system in rats and other data recently published on the toxic effects of bisphenol A. In its opinion of 29 January 2010, Afssa revealed that the studies conducted in accordance with international standard have so far not objected to the doses to which the consumer is exposed with regards to health risks. However, these studies refer to alert signals following in utero and postnatal exposure to doses less than the tolerable daily intake (TDI). Afssa concluded that if these alert signals were caused by the oestrogenic activity of the bisphenol A, it was therefore fundamental to understand the mechanisms of action of this substance by offering new methods for assessing the risks associated with very low

doses of bisphenol A. Afssa recommends the continuation of expertise in this field.

In its last opinion relating to the exposure of the French population to bisphenol A dated 7 June 2010, Afssa considers "that it would be desirable to keep human exposure to bisphenol A as low as possible, particularly for the most susceptible consumers". It also reiterates that "industrialists must be mobilised in order to develop substitutes for BPA for use in food".

Consequently, measures have been taken to suspend infant's feeding bottles manufactured from BPA until new data is obtained from the Afssa and the Agence européenne de sécurité alimentaire (Aesa) by way of precaution.



#### 10. Reference Documents - Basic Texts

Reference texts: Substitute products exist made of polycarbonate obtained from BPA:

- Poly ether sulphone manufactured with bisphenol S,
- Polypropylene.

These two substitutes must satisfy the requirements of Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004.

#### 11. Invocation of the Emergency Procedure

Yes

#### 12. Grounds for the Emergency

Article 9 (7) of the Directive laying down a procedure for the provision of information allows a Member State to refrain from deferring the adoption of technical regulations, but instead to proceed with their immediate adoption for urgent reasons relating to a serious and unforeseeable situation relating to the protection of human health, etc. The opinions of Afssa sent by the French authorities based on the present notification highlight the possibility of a potential harmful effect on the health of the most susceptible group of the population, that being young infants. These conclusions are corroborated by a study of the Technical University of Denmark, sent by the Danish authorities based on its notification 2010/0294/DK.

#### 13. Confidentiality

No

#### 14. Fiscal measures

No

#### 15. Impact assessment

Yes

#### 16. TBT and SPS aspects

TBT relevance

No - The draft is not a technical regulation or a conformity assessment.

SPS relevance

No - The draft is not a sanitary or phytosanitary measure.

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

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sent to :

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  
.

European Free Trade Association  
Mr. Robert Murphy

AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARI Comisión Interministerial para la Ordena  
M<sup>a</sup> Luisa Aguilar Zambalamberri

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



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Denis Colfer