



Notification Number: 2008/45/E

## **Draft Royal Decree laying down certain additional guarantees for the manufacture, marketing and labelling of foodstuffs intended to protect persons having a gluten intolerance.**

Date received : 01/02/2008  
End of Standstill : Closed  
Issue of comments by : Commission, Hungary, United Kingdom  
Issue of detailed opinion by : Austria, Belgium, Commission, Finland, France  
Postponement : Yes

### Message

Message 002

Communication from the Commission - SG(2008) D/50221  
Directive 98/34/EC  
Translation of the message 001  
Notification: 2008/0045/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: 200800221.EN)

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

MSG 002 IND 2008 0045 E EN 01-02-2008 E NOTIF

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

E

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

SUBDIRECCIÓN GENERAL PARA ASUNTOS INDUSTRIALES, ENERGÉTICOS, DE TRANSPORTES Y COMUNICACIONES Y DE MEDIO AMBIENTE. DIRECCIÓN GENERAL DE COORDINACIÓN DEL MERCADO INTERIOR Y OTRAS POLÍTICAS COMUNITARIAS. SECRETARIA DE ESTADO PARA LA UNIÓN EUROPEA. MINISTERIO DE ASUNTOS EXTERIORES Y DE COOPERACION. C/ SERRANO GARBACHE, 26 – 4ª PLANTA - MADRID 28071. TELÉFONO: 91.379.84.64. Y 91.379.83.87 FAX: 91.479.84.01



### 3. Originating Department

SUBDIRECCIÓN GENERAL DE GESTIÓN DE RIESGOS ALIMENTARIOS. AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARIA Y NUTRICIÓN

### 4. Notification Number

2008/45/E – C60A

### 5. Title

Draft Royal Decree laying down certain additional guarantees for the manufacture, marketing and labelling of foodstuffs intended to protect persons having a gluten intolerance.

### 6. Products Concerned

Foodstuffs.

### 7. Notification Under Another Act

A) Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (Official Gazette L 109 of 6 May 2000, page 29).

D) Other Directive or Regulation:

- Directive 89/398/EEC of the Council of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.
- Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs.

### 8. Main Content

The draft consists of a preamble, eight articles, a transitional provision, a repealing provision, three final provisions and an annex.

Article 1 establishes the object of the draft.

Article 2 defines specific terms for the purposes of that regulated by the Royal Decree.

Article 3 determines the conditions for the composition and quality of foodstuffs, whether dietetic or not, in particular those intended for coeliacs.

Article 4 includes the labelling conditions which must be met by the products regulated by this draft Royal Decree.

Article 5 specifies the obligations of the operators of foodstuff companies, both those of a general and those of a specific nature appertaining to manufacturers of gluten-free foodstuffs.

Article 6 lays down the necessary communication to the competent authorities of information on the time of marketing the products.

Article 7 lays down the principles which must be adhered to by the analysis methods to be respected in the carrying out of the analyses used for the detection of gluten.

Article 8 lays down the penalty system.

The sole additional provision lays down a period for the revision of the level of gluten contents fixed in the articles of the draft.

The sole transitional provision lays down a period for the marketing of products which do not comply with that laid down in the draft.

The first final provision contains the legal authorisation for the standard.

The second final provision lays down the entry into force of the standard.



The Annex includes the pictogram expressing the absence of gluten in the foodstuffs containing it.

### 9. Brief Statement of Grounds

This is a standard having a framework and purpose based on health, given that it establishes food safety guarantees for coeliacs in laying down a safety threshold for gluten in products likely to contain it in a natural, voluntary or accidental manner in their composition, and lays down, on the basis of that established in Community legislation in the field of labelling, measures in order that the coeliac community consequently has the necessary information available to them.

The standard arises from the provisions of Community Law in force in the field of foodstuffs intended for particular nutritional uses (89/398/EC) and on the labelling, presentation and advertising of foodstuffs (Directives 2000/13/EC and 2003/089/EC; Regulation EU 1924/2006), implementing that which has not been harmonised by these laws and remains at the initiative of the national authorities of the Member States.

In accordance with the provisions of the above paragraph, the standard shall not lay down new obligations in the field of labelling for the economic operators, nor bring “ex novo” any element which may prove discriminatory or affect the free movement of goods within the European Economic Area. On the other hand, in laying down a threshold for the gluten content in foodstuffs intended to be marketed as particularly intended for the coeliac community and/or claiming the absence of this substance, it incorporates an essential legal certainty for fair business practice.

See also: “reason for the urgency”.

### 10. Reference Documents - Basic Texts

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### 11. Invocation of the Emergency Procedure

YES

### 12. Grounds for the Emergency

As indicated in the preamble and in the justificatory report of the draft, coeliac disease is a permanent intolerance to the gluten prolamins present in wheat, rye, barley, oat and triticale flours. There is no treatment for this disease, but its control may be mastered if the persons suffering from it keep a diet strictly free of gluten for their entire lives. This diet does not cure the disease, but achieves the complete clinical normalisation of the sufferer and prevents complications in the short, medium and long-term.

The Spanish health authorities have recently been under pressure from the national associations of persons affected by the disease. Their criticisms and the call for immediate action on behalf of the Spanish authorities, which they believe should not be delayed, come from two directions, on the one hand, from the health and legal perspective, and on the other, from the economic perspective.

In the first of these directions, the coeliac sufferers’ associations are calling for, and the Spanish authorities are taking on, that a reference limit or level for gluten in foodstuffs be urgently established, which would give rise, on the one hand, to a health guarantee for sufferers who, in this way, may have it clear, for the purposes of purchasing products from the food market, which foodstuffs may be considered suitable for them to eat and which not.

Inseparable from this, and vice versa, is the right of the industrial sector manufacturing foodstuffs to count on a specific threshold which brings with it the necessary legal certainty to determine when it may be stated that a foodstuff is suitable or not for the coeliac community. In this direction, it must also be taken into account that Community provisions which have increased, to the benefit of consumers, the obligations to state in detail all the ingredients of foodstuffs on labelling and in advertising (in particular Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003), have not produced any exceptional undesired effects for the legislator. Effectively, faced with absence in the regulation of precise gluten limits, companies shall feel



inclined to declare that these may possibly be present, so as not to run the risk of non-compliance with this legislation and of possibly being liable. These precautionary statements on labelling discourage coeliacs from consuming the product and reduce their opportunities to choose and form a varied diet.

From an economic perspective, the situation coeliac sufferers have to endure cannot continue, who, in addition to seeing their purchasing options limited faced with the insecurity arising from the non-existence of clear and demanding labelling standards, are obliged to purchase products specifically intended for them which are always significantly more expensive. The measures contained in the accompanying Royal Decree shall enable coeliac sufferers to obtain a much wider range of foodstuffs at a cost equal to that paid by the rest of the population. These measures, which should already have been adopted, cannot wait any longer. Consumer associations are demanding that they be immediately adopted, and the Spanish authorities, which share their concerns, understand that there are sufficient reasons, as already explained, which justify the urgent processing of the Royal Decree.

**13. Confidentiality**

No

**14. Fiscal measures**

No

**15. Impact assessment**

No

**16. TBT and SPS aspects**

TBT and SPS aspects

TBT aspects - A) NO

SPS Aspects – B)

II) The tenor of this draft is, essentially, the same as that of a standard, guidelines or international recommendation.

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