



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 29 May 2008 (02.06)
(OR. es)**

9772/08

**SAN 99
DENLEG 56**

NOTE

from: Spanish delegation
to: Council

Subject: EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS
COUNCIL MEETING ON 9 AND 10 JUNE 2008

**European dimension of problems arising from coeliac disease: Spanish
government plan to assist gluten-intolerant people: need to amend European
legislation**

– Information from the Spanish delegation
(under other business)

Delegations will find attached a note from the Spanish delegation on the above subject, for the
Employment, Social Policy, Health and Consumer Affairs Council meeting on 9 and 10 June 2008.

**EUROPEAN DIMENSION OF PROBLEMS ARISING FROM COELIAC DISEASE:
SPANISH GOVERNMENT PLAN TO ASSIST GLUTEN-INTOLERANT PEOPLE:
NEED TO AMEND EUROPEAN LEGISLATION**

1. EUROPEAN DIMENSION OF PROBLEMS ARISING FROM COELIAC DISEASE

Coeliac disease is a permanent intolerance to gluten prolamines, found in wheat, triticale, rye, barley and oat flours. Although the disease does not need any pharmacological or other treatment, it poses a significant public health problem, as controlling it requires sufferers to follow a lifelong strict gluten-free diet. This means that they have to scrutinise very closely the labelling of the foodstuffs which they purchase and consume, both those specially processed to meet their dietary needs and conventional foodstuffs for ordinary use. However, thorough scrutiny of labelling does not suffice to ensure that coeliac sufferers are protected. Some ordinary foodstuffs, while free from gluten when properly constituted, may still contain it and current EU legislation does not provide any guarantee that it will be indicated in all cases.

A lack of conclusive scientific data has also entailed considerable delay in adopting international standards governing such products. For instance, the matter has been under discussion for over ten years in the *FAO/WHO Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses*, without it being possible to reach unanimous agreement.

Persistent controversy among the international scientific community over the setting of foodstuffs gluten levels effectively protecting coeliac sufferers has prompted clinicians to play very safe as regards the foodstuffs they recommend, under the precautionary principle.

On top of those difficulties, laboratory analysis methods for detecting gluten in foodstuffs were until recently subject to sensitivity and specificity limitations which hampered monitoring. Progress here has considerably tightened up checks on foodstuffs for coeliac sufferers.

However, there are still problems in diagnosing the disease. It is a widely accepted fact that our figures on the incidence and prevalence of coeliac disease in Europe fall well short of the true rates.

Coeliac disease therefore poses an objectively tractable public health problem which should be addressed by Member States' health authorities and, in seeking to bring added value, by the European Union itself.

2. SPANISH GOVERNMENT PLAN TO ASSIST GLUTEN-INTOLERANT PEOPLE

In view of the above situation and of pressing calls by the coeliac community to the Ministry of Health and Consumer Affairs, the Spanish government recently approved a plan to assist gluten-intolerant people, covering various measures and proposed improvements to help resolve the problems caused by coeliac disease in sufferers' lives, including the following:

- improvements in detection (diagnosis) and in care for coeliac sufferers;
- tighter specific checks throughout the food chain;
- establishment of more specific and more sensitive foodstuffs analysis methods;
- encouragement of analytical and clinical research;
- introduction of a specific legal framework covering indications of the presence or absence of gluten in foodstuffs labelling.

On this last point, in the absence of any specific international standards and in view of the inadequacy of current Community labelling legislation for these purposes, we have drawn up a draft royal decree, laying down a safety level (20 ppm of gluten) and specific rules on labelling and claims, in order to bring greater food safety and legal security, both for business and for sufferers. This in essence provides some additional safeguards as regards manufacture, marketing and labelling of both special and ordinary foodstuffs, with a view to protecting the health of gluten-intolerant people.

Spain certainly welcomes the initial harmonisation work already embarked upon by the European Commission and will adjust its draft as necessary. However, there can be no overlooking the time it may take to complete that work; this may be inconsistent with the swift, effective response sought from health policy-makers. Nor should it be forgotten that the scientific basis for some of the rules to be established, presenting products with up to 100 ppm of gluten as "suitable for coeliac sufferers", still remain, to say the least, highly controversial among the international scientific community.

We are also concerned at the failure to address some aspects regarding the adventitious presence of gluten in conventional products, on the grounds that current Community provisions already deal with that problem, whereas those provisions in practice prove inadequate for the purpose.

3. NEED TO AMEND EUROPEAN LEGISLATION

The Community labelling provisions, requiring detailed indication of all ingredients present in foodstuffs (Directives 2000/13/EC and 2003/89/EC), have had some effects not originally foreseen by the legislature. In the absence of any rules on precise limits for gluten, many firms have opted to indicate its accidental presence as a precaution, so as not to risk infringing the legislation and possibly being held liable. Such precautionary labelling indications (of the "may contain" kind) deter coeliac sufferers from consuming the product and reduce their scope for choice in assembling a varied diet, when they could safely consume it if the gluten content does not exceed the safety level set.

What is more, such indications (of the presence of gluten in the product) do not follow any clearly established rule; their inclusion in labelling is entirely voluntary, so that a product potentially harmful to coeliac sufferers may legally be marketed without any warning at all.

A scenario more conducive to food safety, with product labelling systematically warning of potential gluten contamination, would still not be very desirable in purely nutritional terms, as safety would be upheld by eliminating from coeliac sufferers' diet any "naturally gluten-free" foodstuff potentially contaminated, regardless of whether any such contamination had been detected and at what level. The upshot would undeniably be overall dietary impoverishment for coeliac sufferers, whose options would be narrowed down to special foodstuffs.

There is thus a need to press ahead in regulating such situations so as to ensure the highest possible level of protection for the people concerned. Nor does business stand to lose from this, since the security afforded coeliac sufferers by full information on the presence of gluten in products would considerably swell the ranks of potential customers.

Clearly, the prospective Community provisions on dietary products would resolve many, but not all, of the potential problems posed by foodstuffs for the coeliac community, problems which would not be properly dealt with if it were attempted to resolve them merely by indication of ingredients under Directive 2000/13/EC, as this would leave unresolved the problem of adventitious contamination of conventional foodstuffs.
