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To the attention of:

Director
Regulations and Procedures Division
Alcohol and Tobacco Tax and Trade Bureau
P.O. Box 14412
Washington
DC 20044-4412
United States

Brussels, 20 December 2006

Dear Madame,
Dear Sir,

Re: **Notice No. 62**
Major Food Allergen Labelling for Wines, Distilled Spirits and Malt Beverages

Founded in 1958 and based in Brussels, The Brewers of Europe is the voice of the European brewing industry to the European institutions and international organizations. Current members are the national brewers' associations of 22 European countries, representing more than ninety percent of the beer produced in the EU25.

We are grateful to the Alcohol and Tobacco Tax and Trade Bureau to be able to comment the advance notice of proposed rulemaking with regard to the above mentioned subject.

Please find hereafter The Brewers of Europe comments.

Yours sincerely,

Mr. de Looz-Corswarem
Secretary General

Annex: Comments

The Brewers of Europe comments to the

Notice of proposed rulemaking on major food allergen labelling for wines, distilled spirits and malt beverages

Preliminary remarks

Beer is food

Beer is a natural agricultural product with a long tradition. For a long time beer was considered as “liquid bread”. Both beer and bread - have a common history and come from the same natural raw materials: cereals, yeast and water.

Beer should be as much as possible subject to the general food labelling and advertising requirements. This enhances the consumer’s understanding. Where justified, though, derogations to general rules should be allowed.

Consumers

The Brewers of Europe are supportive of labelling that is meaningful and helpful to the consumer. Too much information is likely to reduce intelligibility of the label and be unhelpful to the consumer. Hence, prioritization on what information must be given on the label is necessary. Basic descriptive information and that necessary to protect consumer health such as information on allergens must have priority.

Allergen labelling

1. What would be the cost associated with mandatory allergen labelling to the industry and, ultimately, the consumer?

Each change in legislation implies costs for the industry. These vary according to the size of the operator. The costs of labelling changes may be minimised by:

- ensuring a sufficient time period to adjust to the new rules: i.e. implementation date to be set 24 to 36 months from the entry into force of the legislation;
- allowing beers labelled until the implementation date to be sold while stocks last;

and

- wherever possible, ensuring that all essential labelling changes are introduced at the same time to minimise the number of label/can changes that are needed and avoiding wastage of packaging materials.

2. Does the proposed rule adversely impact small businesses?

The cost of a label design change per unit of beer packaged is higher for a smaller operator because of lower throughput.

An additional mandatory label mention requires a review of all declarations found on the label in order that they remain legible to the consumer. Consequently, there might be a need to rethink the lay-out and design of labels, possibly requiring larger labels in order to fit the mandatory statements. This could involve significant costs for the industry, which might be more difficult to bear by small & medium sized enterprises.

3. Is there ways in which the proposed regulations can be modified to reduce the regulatory burdens and associated costs imposed on the industry?

The cost to Industry would be reduced if the same rules were to be adopted in different jurisdictions.

The primary aim of the proposed rule-making is to protect the consumer and ensure that beer labels provide information about the major types of allergen which, when present above scientifically determined harmful levels, can pose a significant threat to consumer health. Hence, the mandatory mention on the label should be restricted to the above mentioned category of allergens and:

- not be broadened to general ingredient labelling;
- and
- not encompass products “derived” from major food allergens which may never pose a threat for consumers with allergies - such as isinglass.

Indeed, The Brewers of Europe are of the opinion that it would be misleading to the consumer if beers produced with the aid of isinglass finings had to be labelled as “contains: fish”. Clearly, this is factually incorrect. Moreover, there is an overwhelming body of evidence that isinglass used as a clarifying agent in the production of beer is unlikely to cause an adverse allergenic reaction in fish allergic individuals. This was recognised by the European Food Safety Authority¹ and led to a temporary exemption² from EU allergen labelling rules. Meanwhile, both the European isinglass manufacturers and brewers funded an extensive research programme designed to further investigate the allergenic potential of isinglass when used as a beer processing aid. The scientific work included several studies on the allergenic status of isinglass using accepted methodologies and also methodologies developed specifically for the planned studies. A key element of the plan involved a DBPCFC (double blind placebo controlled food challenge) study. The protocol for the DBPCFC study was drafted by the leading experts in this area (The Food Allergen Research and Resource Programme, Lincoln Nebraska) and involved exposure to

¹ See EFSA opinion

http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda_opinions/755.Par.0001.File.dat/02.opinionisinglass1.pdf

² See Commission Directive 2005/26/EC

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_075/l_07520050322en00330034.pdf

extremely high levels of isinglass. The results from the food challenges have been submitted to the European Food Safety Authority (EFSA) for assessment. It is the opinion of the allergen experts at FARRP that ingestion of isinglass does not present a risk to fish allergic individuals. The European Commission will base its decision on whether isinglass should be permanently exempt from allergen labelling on the EFSA opinion. This decision has to be taken by mid-November 2007.

A TTB recognition of EU exemptions would avoid another exemption procedure and provide industry with legal certainty, while ensuring a high level of protection to consumers.

4. The proposed rule allows the industry members a great deal of flexibility in the placement of mandatory allergen labelling statements. Does this flexibility reduce the costs of compliance? Would this flexibility interfere with the consumer's ability to locate the allergen declaration? Alternatively, should TTB mandate specific placement, type size, and presentation requirements for these labelling statements in addition to the requirements already applicable to all mandatory information on alcohol beverage labels?

The EU Directive states that the name of any major food allergen defined must be declared and that the indication shall comprise the word "contains" if ingredient listing is not applied. The term "contains" is not necessary when the ingredient is already included under its specific name in the voluntary list of ingredients or in the name under which the beverage is sold. There is no need for double labelling and, according to the experience obtained in Europe, this meets consumers' expectations.

The Brewers of Europe are of the opinion that prescription should be targeted only to information which is intended to protect the consumer's health and safety, and to basic descriptive information. However, practical considerations such as use of label space, letter size or colours, should be subject only to the general requirement of clarity, comprehensibility and legibility.

5. Do the proposed rules provide adequate information to consumers about the use of fining or processing agents? Should processing or fining agents be subject to a different labelling requirement, for example, a 'processed with' labelling statement instead of a 'contains:' labelling statement? Would requiring a distinction between primary ingredients and fining and processing agents be informative to the consumer or would it mislead consumers? Would distinct labelling for processing and fining agents allow industry members to impart more specific information about the use of processing and fining aids?

The EU Directive states that the name of any substance listed, except those benefiting from an exemption, must be declared and that the indication shall comprise the word "contains" if ingredient listing is not applied.

This wording, although misleading as beer actually no longer contains e.g. wheat, nevertheless appears to meet the information expectations of those suffering from coeliac disease.

The Brewers of Europe see no need to apply a distinct information mention according to the major allergen being a primary ingredient or a processing/fining agent. This distinction is not made for non-alcoholic foods. Hence, instead of providing the consumer with valuable information, it might lead to confusion. The question that should be applied to raw materials, additives, derived products or processing aids is whether the material present in the product is allergenic? If a material is not allergenic, it is misleading to the consumer to label it as being such.

6. Should mandatory allergen labelling statements for alcoholic beverages disclose the specific species of fish, or is it sufficient to merely label the allergen as 'fish', as TTB proposes?

The Brewers of Europe fully support the argumentation put forward by TTB for not requiring the specific species of fish to be labelled.

7. How much time does industry require to comply with mandatory food allergen labelling requirements? What delayed effective date would reduce the regulatory burdens on affected industry members and at the same time ensure the protection of consumers?

As stated before, the implementation date should be set 24 to 36 months after the date of entry into force of the legislation. In addition, beers labelled until the implementation date should be allowed to be sold on the market as long as stocks last.

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