



Ref. CP.CE-057TER-2006

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Brussels, 21 December 2006

Attention Notice No 62

Dear Sir,

Major Food Allergen Labelling for Wines, Distilled Spirits and Malt Beverages

The European Spirits Organisation - CEPS is the representative body for the spirits industry at the European level. Its membership comprises 38 national associations representing the industry in 29 countries, as well as a group of leading spirits producing companies.

As indicated in our submission of 28 September 2005 concerning a range of alcoholic beverages labelling and advertising issues, inclusive of allergens, raised in the Alcohol and Tobacco Tax and Trade Bureau (TTB) Notice No 41 published 29.4.05, the issue of major food allergen labelling for alcoholic beverages is of importance for the European Spirits Industry. The European Spirits Organisation - CEPS therefore welcomes the further opportunity provided by the TTB to comment on this issue and specifically on the proposed procedures and labelling requirements contained in its Notice No 62 published on 26.7. 06.

For ease of reference, we have divided our comments into separate parts, one concerning the proposed procedures and the other concerning the labelling requirements including the particular questions posed by TTB. Our respective responses are attached.

As stated before, CEPS strongly supports the regulatory cooperation between Europe and the United States as one of the ways to secure a fair, consistent and non-discriminatory international trade environment for our industry. In this context, CEPS would emphasise the continuing importance of on-going consultation with the industry on the issue of major food allergen labelling.

TTB Notice 62 published 26.7.06 re Major Food Allergen Labelling for alcoholic beverages Notice of proposed rulemaking (NPRM)

PROCEDURES

CEPS notes that the proposed regulations contain three exceptions from major food allergen labelling, two of which are provided within the definition of “major food allergen”. The third is an exemption through a TTB petition process.

Without going into the specific detail of the TTB rationale and procedures for seeking exemption, CEPS is limiting its comments to focus on the desirability of harmonised action between national governments on this important issue. The benefits of such a concerted approach are to ensure consistency in the global marketplace and to minimise duplication of effort in terms of scientific research and associated expense. It would also mean that it should become increasingly more straightforward to put regulations in place.

As the TTB may already be aware, the process of securing exemptions from allergen labelling for certain food products within the European Community is well under way. CEPS takes this opportunity therefore to briefly share its experience in addressing this issue within the EU and to suggest that it would be pragmatic and positively constructive if the TTB on behalf of the United States government would go down a similar route.

CEPS experience in the EU

- The key question for the industry was whether or not distilled spirits fell within the scope of the sectors that might need to petition for an exemption from allergen labelling in the EU. In the event, it was necessary to go through the formal channels of seeking an exemption in order to obtain legal certainty.
- Prior to the first 2004 deadline of the European Commission (DG Sanco), CEPS formally submitted a request for an exemption from the requirement to label allergenic ingredients in respect of cereals, milk derived products and nuts used before distillation in the production of spirit drinks. The 3 dossiers sought to substantiate the industry request that the Commission grant a provisional derogation from the labelling requirement because the potentially allergenic raw materials were not found in the final product.
- Commission Directive 2005/26/EC published in the Official Journal L 75/33 on 22.3.2005 duly granted the industry a provisional derogation on this basis.
- In August this year, CEPS submitted 3 further dossiers to the EU Commission to request a definitive exemption from allergen labelling in respect of cereals, nuts and whey used as raw materials (before distillation) in the production of distillates used to make spirit drinks and other products.
- The EU Commission (DG Sanco) has referred these dossiers to the European Food Safety Authority (EFSA) for scrutiny. An EFSA Opinion on each of them will be required within 12 months, following which the Commission will evaluate the EFSA view and, assuming it is favourable, grant a definitive exemption for the potentially allergenic raw materials when used for the production of distillates.
- It is hoped that the significant research undertaken by the Scotch Whisky Research Institute (SWRI) on behalf of CEPS to substantiate the EU industry requests for definitive exemptions

will convince EFSA and the Commission that definitive exemptions from allergen labelling can safely be granted because the potentially allergenic proteins are not found in the final product. It should be noted that this research sought to include as broad a geographical coverage as possible and the samples tested therefore also included US whiskies.

- Meantime, following consultation on draft best-practice guidance on avoiding cross-contamination and using appropriate advisory labelling, the UK Food Standards Agency (FSA) has published the final version of its voluntary Guidance on Allergen Management and Consumer Information. This confirms, among other advice, that “cereals used in distillates for spirits are unlikely to trigger allergic reactions in allergic people or intolerance in those with coeliac disease”. This advice is in line with the information provided by the UK Coeliac Society which states, in its “Questions and Answers” (2003, under heading “Food, Drink and Ingredients”, second page, middle column - enclosed -) that yes those suffering from coeliac disease can drink all spirits.

Application of the EU experience to the US

- CEPS’ investment and work in seeking the exemption referred to for distillates was undertaken on behalf of the EU spirits industry and by extension the global spirits industry. No third-country producer has sought separate exemption for their products within the EU. Accordingly, distilled spirits produced in the USA are benefiting from the provisional derogation granted in response to CEPS’ request and will equally benefit from a definitive derogation, if and when it is hopefully granted.
- The US spirits industry through its representative organisation, the Distilled Spirits Council of the United States (DISCUS) is in turn coordinating a response to TTB on Notice No 62 on behalf of both US and third-country distilled products. In this connection, CEPS believes that as provisional derogations have been granted in the EU on the basis of CEPS’ initial research, and as EFSA and DG Sanco are assessing CEPS’ 3 final dossiers, it would make sense in terms of saving duplication, expense and time for DISCUS to use this same scientific material when petitioning TTB for an exemption for distillates from allergen labelling.
- CEPS also wants to draw TTB’s attention to significant points in its EU experience:
 - (1) If a potentially allergenic raw material is used in the production process and the potential allergens are shown to be no longer present in the final product by appropriate methods of analysis, a means should be provided for the industry (or an individual party) to prove this and, furthermore, while doing so, they should be given temporary exemption.
 - (2) There is a real need to be careful not to include allergen labelling when allergens do not exist in the final product because failure to do so would de-sensitise consumers to allergen statements on labels. For instance, in the case of a consumer who suffers from coeliac disease and who has safely drunk whisky or another cereal-based spirit drink in the past, if he/she is suddenly informed by a label at a later date that the product contains allergens, he/she may think that in some cases he/she is not affected by the potential allergen. The consumer may then look at allergen warnings on other products and assume that these too can be safely taken when in fact they could be potentially harmful.

LABELLING REQUIREMENTS: CEPS response to TTB questions

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

And

Question 4 – The proposed rule allows industry members a great deal of flexibility in the placement of mandatory allergen labelling statements. Et seq.

As previously stated in the comments that we submitted on 28 September 2005 in response to TTB Notice n° 41, a separate allergen labelling declaration should only be required if any allergen present in the final product is not identified in the product name or elsewhere on the label. Also, it follows that, if the product name on the label of an alcohol beverage container indicates that an allergen is present in the product, it should be sufficient for the allergen to appear in the product name.

Question 5 – Do the proposed rules provide adequate information to consumers about the use of fining or processing agents? Et seq.

Fining or processions agents should be dealt with in the same way as other allergenic ingredients. The determinant for a necessary label declaration should be whether an allergen is present in the final product. A consistent approach with the EU is desirable.

Question 7 – How much time does industry require to comply with mandatory food allergen labelling requirements? Et seq.

As TTB may be aware, the European Commission's procedures for allergen labelling exemptions were divided into two different steps. First, the industry was invited to submit its requests for temporary exemptions and then, for those that were granted temporary derogation, further time was given to allow the preparation of more comprehensive dossiers for seeking definitive exemptions. Many such dossiers have been submitted and the EFSA opinions for the definitive exemptions are still awaited. The period of time between the initial 2003 legislation and the final legislation ensuring a definitive exemption for allergens labelling will be about 4 years.

Thereafter, adequate time should be allowed for products that are denied exemption to bring their labels into compliance with the allergen labelling regulations, as is understood will happen in the EU.

Thank you again for the opportunity to comment on the TTB Notice 62 on Allergen Labelling and we very much hope that our comments outlined above will be taken into consideration.

Yours sincerely,



Jamie Fortescue
Director General

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