COMMENTS FROM THE EUROPEAN COMMUNITIES RELATING TO NOTIFICATION

G/TBT/N/USA/205

MAJOR FOOD ALLERGEN LABELLING FOR WINES, DISTILLED SPIRITS AND MALT BEVERAGES

The European Communities (EC) welcomes the opportunity to comment on the above-mentioned notification of the United States.

1. In general terms, the EC notes that the proposed USA Regulation is in line with the relevant Community legislation that foresees a mandatory labelling of allergens while providing for the possibility of derogations in accordance with the below-mentioned procedure. Although the content of the proposed Regulation does not seem to raise any particular problem from a substance point of view, the EC regrets that it does not give any indication on the time that the rules will be implemented (entry into force, transitional period for industry). Given that the EU legislation provides for a similar regime as the USA covering the same allergenic substances, it would certainly be preferable to seek some coherence in terms of timetable and scientific evidence in order to avoid causing unnecessary burdens to traders. Moreover, it would be important that the USA provides the EC with further details on the date of the effective application of the proposed rules.

2. Concerning labelling of allergens and in particular the ongoing procedure for exemptions and the related timeframe, the EC would like to remind the US authorities that the situation in the EU stands as follows:

   Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended by Directive 2003/89/EC, establishes a list of ingredients or substances liable to cause allergies or intolerances that must always appear in the ingredients list on foodstuffs labels; it is obligatory to mention allergens in alcoholic beverages on their labels.

   These provisions have been fully implemented in the EU since 25 November 2005.

   However, it is possible that some ingredients or substances, derived from allergens, are not likely to be a risk for allergic people. Therefore, the labelling Directive provides for the possibility of granting, initially, provisional derogations for allergen derivatives in order to allow industry to finalise the undertaken studies required for a permanent derogation.

   In accordance with a procedure established in Directive 2000/13/EC, provisional labelling exemptions for certain ingredients or substances were granted by the Commission Directive 2005/26/EC, which establishes a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC, on basis of information provided by the applicants and following an EFSA opinion. As regards alcoholic beverages the relevant exemptions refer to:

   1. cereals used in distillates for spirits,
   2. lysozym (produced from eggs) in wine,

3. albumin (produced from eggs) used as fining agent in wine and cider,
4. fish gelatine or Isinglass used as fining agent in beer, cider and wine,
5. whey used in distillates for spirits,
6. milk (casein)products used as fining agents in cider and wines,
7. nuts used in distillates for spirits, and
8. nuts (almonds, walnuts) used (as flavour) in spirits.

These provisional exemptions are granted until 25 November 2007.

Applicants interested in obtaining a permanent labelling exemption were obliged to submit their request before 31 August 2006 along with the scientific studies establishing that the products concerned are not likely to trigger allergic reaction in sensitive individuals and can be definitely excluded from the list of allergens that must be labelled.

The Commission consulted the EFSA on the received submissions.

After an EFSA opinion has been issued and after consultation of the Standing Committee on the Food Chain and Animal Health, the Commission will adopt a legislative act that should come into effect on 25 November 2007 at the latest. For those products which will be excluded from Annex IIIa beyond 25 November 2007, the situation will remain unchanged regarding the labelling requirement. Other products will have to be labelled after a transitional period allowing manufacturers to take all necessary steps to comply with the new labelling requirement.

The EC would like to invite the authorities of the United States to take the above concerns into account.

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