

Supporting Document 2

International Regulations Table – Proposal P1031

Allergen Labelling Exemptions

Exemptions from allergen and sulphite declarations in various jurisdictions

Jurisdiction	Current exemptions
Codex	Sulphite in concentrations of less than 10 mg/kg is exempted from declaration
Australia New Zealand	<ol style="list-style-type: none"> 1. Cereals containing gluten and their products – must be declared other than where present in standardised beer and spirits 2. Fish and fish products – must be declared except for isinglass derived from swim bladders and used as a clarifying agent in beer and wine 3. Tree nuts – must be declared other than coconut (from <i>Cocos nucifera</i>) 4. Sulphites – added sulphites where equal to or less than 10 mg/kg are exempt from declaration
European Union	<p>Exemptions are listed below the source allergen, and are based on GMP or specified manufacturing processes:</p> <ol style="list-style-type: none"> 1. Cereals containing gluten: <ol style="list-style-type: none"> (a) wheat-based glucose syrups including dextrose; (b) wheat-based maltodextrins; (c) glucose syrups based on barley; (d) cereals [where] used for making distillates or ethyl alcohol of agricultural origins for spirit drinks and other alcoholic beverages. 2. Fish: <ol style="list-style-type: none"> (a) fish gelatine used as carrier for vitamin or carotenoid preparations; (b) fish gelatine or isinglass used as fining agent in beer and wine. 3. Soybeans and products thereof: <ol style="list-style-type: none"> (a) fully refined soybean oil and fat; (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean source; (c) vegetable oil derived phytosterols and phytosterol esters from soybean sources; (d) plant stanol ester produced from vegetable oil sterols from soybean sources. 4. Milk and products thereof (including lactose): <ol style="list-style-type: none"> (a) Whey [where] used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; (b) Lactitol.

Jurisdiction	Current exemptions
	<p>5. Nuts and products thereof: (a) Nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.</p> <p>6. Added sulphites: where less than 10 mg/kg</p>
United States of America	<p>The regulations under the Food and Drug Administration only apply to the listed “major food allergens”¹ and where protein is present.</p> <p>Exemptions include any highly refined oil derived from the major food allergens and any ingredient derived from such highly refined oil; and raw agricultural commodities in their natural state, such as fresh fruits and vegetables. Further exemptions may be obtained via a petition or notification to the US Food and Drug Administration.</p>
Canada	<p>None listed in the regulations. However it is noted the Canadian regulations apply only to the part of the ingredient or component that is responsible for the adverse reaction (e.g. the protein, modified protein or protein fraction).</p> <p>Added sulphites When present as an ingredient sulphites must be listed regardless of amount however, when a ‘contains’ statement (ie for allergen declarations) appears on the label, only added sulphites present at greater than or equal to 10 ppm need to be declared.</p>

References

Codex Alimentarius Commission, 1985. “General Standard for the labelling of Prepackaged Foods Codex Stan 1 – 1985 (rev. 1- 1991)

European Union (2011). “Regulation (EU) No 1169/2011 of the European Parliament and of the Council of October 25 2011” Annex II. Official Journal of the European Union

Health Canada, 2010 “Health Canada’s Modifications to Regulatory Project 1220 – Enhanced labelling for Food Allergens, Gluten sources and Added Sulphites “available at: <http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/proj1220-modifications-eng.php>

US Food and Drug Administration, 2004 “Food Allergen Labeling and Consumer Protection Act of 2004” . Public Law 108-282. Title II, available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/cm106187.htm>

¹ Milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans.