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Food allergen labelling: "May contain" evidence from Malaysia

3 Abstract

Food allergen labelling is mandatory and regulated whilst precautionary allergen labelling (PAL) 4 5 remains voluntary in most countries. It is the aim of this study to identify the food allergens declared 6 in food products sold in a developing country and to what extent food allergens and PAL are 7 emphasised in the products. A total of 505 food and beverages (snacks, baked goods, confectionary, 8 baby food, condiments & jams, beverages, powder & paste, instant food, chilled & frozen food and 9 canned food) were evaluated in Malaysia. Soybean represents the largest group of food allergen declared in labels, followed by wheat and milk products. Thirteen variations of contains statement 10 11 were found with 'Contains [allergen(s)]' being the most common (55.02%). There were 22 different 12 types of 'may contain' statements with 'May contain traces of [allergen(s)]' being the most common 13 advice labelling used (55.41%). Different font type or emphasis such as brackets (51.57%) and bold 14 font (33.86%) were used to inform consumers about presence of allergens. The national regulations 15 on food allergen labelling are then critically contrasted with other Asian countries and the EU 16 Regulation No. 1169/2011, which represents one of the most stringent food regulations in the world. Improving current allergen labelling limitations and practices would be of great benefit to consumers 17 18 to prevent risk of food hypersensitivity. 19 20 Keywords: allergen regulation; food allergy; food safety; precautionary allergen labelling 21 22 Highlights 23 24 Most surveyed food products in Malaysia declared the presence of food allergens according to -25 the national regulations 26 -Ambiguous and contradictory statements could be further improved to avoid confusion 27 Baby food and confectionaries demonstrated examples of good allergen labelling practices -28 -Reiterates the need for clearer guidance in Malaysia's food allergen labelling regulations 29 30 Introduction 31 Food allergy is an adverse immune reaction that occurs upon exposure to specific food and the 32 reactions can range from mild (e.g. rash, itchy sensation) to severe (e.g. anaphylaxis) (Moore, 33 Stewart, & deShazo, 2017). Food allergy affects up to 6% of children and 4% of adults in the global 34 population (Boye, 2012) and is on the rise throughout Asia (Pang et al., 2017). The prevalence of food allergy is estimated to be 5 - 10% among infants (Matsuo, Yokooji, & Taogoshi, 2015) and 1.5 -35 3% among school-aged children and adults in Japan (Urisu et al., 2014), 4 – 5% of Singaporean 36 37 schoolchildren (Lee, Chew, & Goh, 1997) and 6.25% (out of 656) children in Thailand (Santadusit,

38 Atthapaisalsarudee, & Vichyanond, 2005). Eight foods – cereals containing gluten, egg, milk, soy,

39 peanuts, tree nuts, fish and shellfish contribute to 90% of food allergic reactions (Bush & Hefle,

40 1996).

41

Yadav and Naidu (2015) reported a higher sensitisation towards egg white and cow's milk in children 42 43 less than 2 years in Malaysia whilst prawn was the most common food allergen in children up to 12 44 years (Gendeh, Mujahid, Murad, & Rizal, 2004) and in adults with allergic rhinitis (Wan Majdiah, Nurul 45 Khaiza, Suzina, Che Maraina, & Norr Suryani, 2016). Malaysia is unique as the population comprises 46 of three main ethnic groups (Malay, Chinese and Indians) and a few minority groups, each with their 47 own dietary practices. Although locals share some common dishes i.e. rice, meat products, fish and 48 vegetables, each ethnic groups has their own typical dishes and ingredients, dietary habits and 49 restrictions (Fournier et al., 2016). One of the best way to avoid food allergic reactions is to avoid the 50 trigger food. Education and understanding food labels are crucial to individuals with food allergies 51 (Lanser, Wright, Orgel, Vickery, & Fleischer, 2015). In order to protect consumers, regulations are in 52 place in Malaysia where the quidelines for allergen labelling in Malaysia are according to Food Regulations (1985). Food allergens to be declared include cereal containing gluten (including wheat, 53 54 rye, barley and oat), nut and nut products including peanut and soybean, fish and fish product, milk 55 and milk product (including lactose) and egg and egg product (MOH, n.d.). Precautionary allergen

56 57

58 At the global level, Codex stated that the 8 common food allergens shall be declared (Codex, 1985). 59 As different countries vary in their dietary habits, different countries applied different regulations 60 across the world e.g. the Food Allergen Labelling and Consumer Protection Act of 2004 (US FDA 2016), Regulation (EU) No. 1169/2011 (EU Regulation No. 1169/2011) and Standard 1.2.3 -61 62 Mandatory Warning and Advisory Statements and Declarations (FSANZ, 2014). Although food allergen 63 labelling is mandatory and regulated, precautionary allergen labelling (PAL) remains voluntary (Gendel, 2012) with the exception of Argentina (Argentina Food Code, 2010), Japan (Akiyama, Imai, 64 & Ebisawa, 2011), Switzerland (Federal Department Affairs, 2005) and South Africa (Department of 65 66 Health, Government of South Africa, 2010) where PAL is regulated or prohibited. These had triggered a number of studies on allergen frequencies and language used such as those conducted in France 67 68 (Battisti et al., 2016) and U.S. (Pieretti, Chung, Pacenza, Slotkin, & Sicherer, 2009). 69 70 Studies on consumers' attitudes towards food allergen labelling too been carried out in developed

71 nations. Marchisotto *et al.* (2017) reported that consumers in U.S. and Canada have poor

labelling (PAL) remains voluntary in Malaysia.

- vunderstanding of PAL and falsely believing that PAL was required by law. Marra *et al.* (2017) found
- that Canadian consumers preferred the use of standardised PAL and safety symbols on food labelling.
- 74 Consumers in South Korea recommended that the font size, shape, colour and location of food allergy
- information on labels need improvement (Choi & Choi, 2016). Meanwhile, Mfueni *et al.* (2018)
- conducted a study in Malawi and found that the country's food allergen labelling was the least

- demanding compared to other international regulations. Although all surveyed products complied with
- the nation's food allergen labelling requirement, none of the locally manufactured products
- r9 emphasised food allergens (e.g. bold, italic, different font size) or PAL. Mfueni's study is a positive
- 80 step forward for developing countries but data from many Asia countries, including Malaysia are still
- 81 lacking. There is also a perception that food allergy prevalence is low in this region (Shek & Lee,
- 2006). Thus, it is the aim of this study to identify the food allergens declared in food products sold in
- 83 Malaysia and to what extent food allergens and PAL are emphasised in the products.
- 84

85 Methodology

- Commercially processed and packaged food products' were evaluated for allergen and precautionary
 allergen labelling. Eight recent agricultural or biotechnology graduates were recruited as surveyors for
- 88 data collection. Graduates received online training by the researcher and instructions were sent to all
- 89 surveyors by email. The study was conducted between May August 2017. Each surveyor was
- assigned to one food category. This helps to reduce collecting data from the same item. The food
- 91 categories include snacks (n=78), baked goods (19), confectionary (62), baby food (41), condiments
- and sauces (69) and jams and spreads (21), beverages (56), powder and paste (21), instant food
- 93 (52), chilled & frozen food (52) and canned food (34). Instant food is defined as convenient food
- 94 products that could be eaten readily or prepared using minimal time and ingredients (Karl, Moore, &
- Eastman, 1986). Each surveyor surveyed the food items from different parts of Peninsular Malaysia
- 96 i.e. North (Penang), West (Perak, Selangor and Melaka), South (Johor) and East (Kelantan). During
- 97 the market analysis, surveyor identified the product name, list of ingredients and details of advisory
- 98 labels (if any). Two digital photographs were taken for each product. Data were sent to the
- researcher for reviewing. Each product was verified to ensure the data entered for the product and

100 the accompanying photos are correct (Pieretti *et al.*, 2009). Surveyors were contacted to clarify any

- blurry photographs. The photographs were evaluated and items such as name of product, list of
- 102 ingredients, allergens declaration in the list, contains statement, precautionary allergen label (PAL)
- and font type were documented. Data from each label were entered into Excel sheet according to
- 104 food category. The ingredient list was checked for declaration of allergens such as gluten, tree nuts,
- peanuts, soybean, fish, milk and eggs. This is according to the guidelines for allergen labelling in
- Malaysia (Malaysia Food Regulations, 1985 This study also looks at labels that declare crustaceans
 and molluscs, as shellfish allergy is prevalent in Malaysia (Gendeh *et al.*, 2004; Wan Majdiah *et al.*,
- 108 2016). Multiple food products also provided information about other food allergens that are not
- 109 regulated in Malaysia (i.e. celery, lupin, mustard, sesame seed and sulphites) and these were also
- 110 documented. In food labels with 'Contains' or PAL statements, the description of the statement and
- 111 type of food allergen declared were noted. The font type i.e. bold, italic, contrasting colour,
- highlighted, enlarged font or others such as asterisk to demonstrate the presence of food allergens in
- 113 list of ingredients, contains statement or PAL were recorded. Labels were further determined for
- ambiguous or contradictory statements and examples of good allergen labelling practices. Food

- products with good allergen labelling practices were identified based on provision of allergen names
- in plain English (e.g. casein [milk]), source of generic ingredients such as oil, flour or starch were
- provided (Pieretti et al., 2009) and provision of symbols (such as an asterisk) to indicate if an allergen
- 118 was present or not (Cornelisse-Vermaat, Voordouw, Yiakoumaki, Theodoridis, & Frewer, 2008).

119 **Results and Discussion**

120 Food allergen labelling of food products sold in Malaysia

121 Labels from 505 food and drink products were assessed. 474 food products declared food allergens in 122 their ingredient lists or contains statement. These declarations exclude the allergens listed as part of 123 PAL. Twenty-two variations of PAL were found in 29.3% of the products. All food products' labelling 124 (99.58%) declared food allergens according to the national food allergen labelling regulations with the exception of one chicken product and dry bean curd sheets product. The chicken product labelled 125 126 ISP in its ingredient list. This may cause confusion and particularly pose a risk to soybean allergic 127 individuals if the acronym is 'isolated soy protein'. Similarly, the dry bean curd sheets product did not state (soy) or Contains soy in the label. Figure 1 shows the number and types of food allergens 128 129 declared in the products' ingredient list and/or contains statement (none of the allergens listed in PAL 130 are included). Soybean represents the largest group of food allergen declared, followed by wheat and milk products (Figure 1). Soybeans were mostly declared in condiments and sauces (17.83%), 131 confectionary (15.12%) and chilled and frozen products (13.18%). It represents the most common 132 133 food allergen due to the use of soy lecithin. Battisti et al. (2017) similarly reported that soybeans 134 were found in 20% of the surveyed products due the addition of soy lecithin. Snacks (19.81%), 135 instant food (17.87%) and confectionary (13.53%) were the top three food categories containing wheat while confectionary (20.69%%), beverages (20.20%) and baby food (18.72%) were found to 136 contain the highest amount of milk. Tree nuts such as hazelnuts, almonds, cashews and walnuts were 137 138 declared in bread, confectionary, beverages and instant food. Baby food contains the highest number 139 of fish product especially docosahexaenoic acid (DHA) derived from fish oil. Meanwhile egg protein 140 was declared across all food categories except baby food and beverages. Condiments & sauces and 141 chilled & frozen food represent the food categories with the highest number of shellfish products. 142 Other types of cereal in particular barley and oats were found in instant food products. Sixty-nine food products declared 'other' food allergens (e.g. mustard, sesame, sulphites, celery). . 143 144

In France, 73% of the food products (out of 17,309) were found to contain at least one allergen in 145 146 their ingredients list. The most commonly declared allergen were milk, gluten and egg (Battisti et al., 147 2017) while in Australia, Zurzolo et al. (2013a) found that the most common allergens were wheat, soy and milk. Food allergen labels are crucial to inform consumers about the presence of the trigger 148 149 food. One notable example that demonstrates the importance of food allergen labelling was when the 150 Beijing Organising Committee for the Olympic and Paralympic Games passed a specific regulation on food allergen labelling which remained effective until the end of the games. The regulations requires 151 152 that a specific list of allergens be clearly labelled on pre-packaged foods and restaurant foods

- 153 supplied to participants and attendees (Li *et al.*, 2009). Today, the 8 major food allergens are
- included in the mandatory regulation in China (Gendel, 2012).
- 155
- 156 Insert Figure 1 here
- 157

158 Contains statement

159 Two hundred and nine (44.09%) had both 'Contains' statements and allergens listed in the ingredient 160 list. There were 13 variations of contains statement with 'Contains [allergen(s)]' being the most 161 common (55.02%), followed by 'Contains ingredients from [allergen(s)]' (14.83%) and 'This product contains [allergen(s)]' (9.56%) (Table 1). Snacks (20.57%), instant food (14.83%) and condiments & 162 sauces (13.40%) were the top three food categories with contains statement. In the beverages 163 164 category, there was a declaration stating 'No added coffee bean substitutes such as barley, corn or 165 other cereals'. In addition to targeting allergens such as barley or other gluten containing cereal, this statement informs customers that the coffee bean used in the product are genuine and not replaced 166 or mixed with other low-cost or hazardous alternatives. Coffee bean is categorised as a high-price 167 commodity and is vulnerable to adulteration with cheaper roasted grains. Sources of allergens such 168 169 as roasted soybean, wheat middlings, rye, barley and triticale (Toci et al., 2016) can be added to 170 coffee blends hence posing a threat to individual sensitive to cereal containing gluten or soybean. 171 172 Insert Table 1 here 173 174

175

176 May contain statement

177 Out of the 505 food products, 29.3% had a 'may contain' labelling. There were 22 variations of may contain statements (Table 2). 'May contain traces of [allergen)(s)]' was the most common advice 178 labelling used (55.41%). Other variations such as 'processed in a facility that also processes 179 180 [allergen(s)]' occurred in 4.05% of the products whilst labelling containing 'Manufactured on 181 equipment' or 'Manufactured in a facility' that also processes products containing [allergen(s)] were 182 found in 4.73% of the items. Snacks (21.62%), confectionary (19.59%) and powder and paste (18.24%) were the food items with the highest usage of precautionary allergen labelling. Pieretti et 183 184 al. (2009) reported that chocolate candy, cookies and baking mixes were reported with the highest 185 frequency of advisory allergen labelling in US while a study by Zurzolo et al. (2013a) found that 96% (out of 128) of various processed samples were found to contain label declaring 'may be present' or 186 187 'may contain' some of the most common food allergens (e.g. peanuts, tree nuts, egg, milk, soy). 188 Further analyses revealed that only 7% of the samples had detectable levels of peanuts. However, 189 these 7% samples still posed a risk to consumers with peanut allergy (Zurzolo et al., 2013a).

190

191 Insert Table 2 here

192

Allergens were categorised into 10 categories (gluten, tree nut, peanut, soy, fish, milk, egg,

194 crustaceans, mollusc and others [e.g. celery, sesame, mustard]). A total of 469 allergens were found 195 listed under the may contain statement. Milk was the most frequently labelled allergen in the PAL 196 statement (14.93%), followed by peanuts (14.71%) and tree nuts (14.07%). Precautionary statement 197 for milk was found mostly in powder and paste product (3.62%), while 'may contain' peanuts and tree nuts were most frequently declared in snacks (4.26%) and instant food (4.05%). 22.97% of 198 199 labels advised at least 2 types of allergens may be present in the product. There was one item 200 (0.68%) under the powder and paste category that labelled it may contain traces of 8 allergens i.e. (cereal containing gluten, egg, fish, crustacean, molluscs, milk, peanut and tree nuts). 4.73% of 201 202 products from snacks, powder and paste, instant food and chilled products respectively advised that 7 203 allergens may be present in their products. Similarly, 4.73% of products from snacks, condiments and sauces, instant food and powder and paste may contain at least 6 types of allergens. In 'others' 204 205 allergen category listed under PAL, sesame (48.83%), celery (23.26%), mustard (23.26%), sulphite 206 (2.32%) and legume (2.32%) may be present. Sesame were mostly labelled in snacks (23.36%), 207 confectionary (11.63%) and condiments and sauces (6.98%). Sesame seeds are often used as 208 garnish in confectionary products, snacks such as crackers and chip and oriental cuisines (Chen, Wu, & Deng, 2015). Sesame allergy is increasingly reported in developed countries including US, Australia, 209 210 a number of EU countries, Israel and Japan (Gangur, Kelly, & Navuluri, 2005) and is one of the most common seed allergy (Li et al., 2017). In this study, celery and mustard were found mostly in powder 211 and paste category. Both allergens are spices and are widely used in seasonings and flavourings 212

213 (Chen *et al.*, 2015). Spice allergy affects between 4 – 13 individuals out of 10,000 adults globally

(Chen & Bahna, 2011). Although the allergens labelled under the others category are not specified
 under Malaysia Food Regulations 1985, sesame, celery, mustard and sulphites are required by EU
 Regulations.

217

218 Companies can further specify the type of legumes that may be present. For example, a canned food 219 product labelled that it was manufactured in a factory that also processed products containing 220 legumes. Although peanuts and soybeans are classified as legumes, specifying the type of legume will 221 be helpful to consumers. Other products such as yeast was labelled as 'Packed in a facility that 222 processes peanuts, wheat, gluten, soy, milk solids and yeast' under the instant food category. 223 Coconut and seeds were also listed in the advisory labelling of chilled and frozen goods such as pastry 224 and flatbread. In this case, specifying the seeds (e.g. sesame seeds) would be helpful for consumers. 225 Although seeds (except sesame seed) are not mandatory in EU or most countries' regulated labelling, 226 there had been recent report of allergic reactions to pumpkin seeds (Valverde-Monge, Bartolome,

- 227 Custa-Herranz, & De las Heras, 2017).
- 228

229 Thirty-nine percent of products (total n= 17,309) surveyed in France (Battisti *et al.*, 2017), 17% 230 products (total n = 20,241) in U.S. (Pieretti *et al.*, 2009) and 65% (total n = 1,355) of products in 231 Australia (Zurzolo et al., 2013b) had precautionary statements. The 3 most popular forms of PAL used 232 in U.S. are 'may contain [allergen', manufactured on shared equipment with [allergen] and 233 'manufactured in the same facility with [allergen] (Taylor et al., 2007). Forty percent of the surveyed 234 consumers in U.S. and Canada purchased food with PAL (Marchisotto et al., 2017). This represents a 235 worrying trend as Hefle et al. (2007) and Mills, Wang and Kattan (2016) also found that consumers with food allergy are increasingly ignoring PAL and take risks with food products. The purpose of may 236 237 contain or PAL statements is to inform consumers of unintentional presence of allergens if they were 238 to consume a given product. However, excessive usage of PAL without appropriate risk assessment 239 can result in proliferation of multiple PAL statements. As a result, consumers develop 'label fatigue' over time and may also choose to disregard PAL statements if they did not develop allergic reactions 240 241 after consuming products with advisory labelling (Soon & Manning, 2017). Studies had found that allergic individuals who ignored PAL went on to develop allergic reactions to food products cross 242 243 contaminated with food allergens (Sheth et al., 2008; 2010). A number of studies detected food 244 allergens in food products with PAL statement and those with no food allergens disclosed on the 245 label. For example, Khuda et al. (2016) detected soy protein in 25% of bakery samples with no PAL 246 and 19% of the samples which had a precautionary statement (n=284). Peanuts were detected in 25% of 'may contain' and 'present in environment' food labelling, while 11% of the samples where 247 248 peanut was not disclosed were also tested positive (Pele, Brohee, Anklam & Van Hengel, 2007). In a separate study, Remington et al. (2015) predicted that food products with PAL or no allergen 249 declaration can contain concentration of allergen that causes a reaction in > 1% of the allergic 250 251 population. PAL should be substantiated by a documented formal risk assessment and strategies such

- as harmonisation of PALs or reducing the variations of PAL (Ben-Shoshan *et al.*, 2012), addressing
- the inconsistent usage of PAL and communicate risks to consumers (Soon & Manning, 2017). Zurzolo
- *et al.* (2017) suggested innovative ways such as using "may be present" symbol to represent a low
- 255 level of cross contamination, toll free number to find out more information about the product or
- 256 mobile phone application to scan the barcode of the food product and receive instant information of
- the ingredients.

259 **Font**

The interface design used to differentiate allergens in the ingredient list, contain and may contain 260 261 statements vary among the 474 food items. Less than half of the products (43.46%) used 254 262 different interfaces in combination or individually. Bold font (33.86%), brackets (51.57%), capital 263 letters (8.66%) and other forms (5.91%) were used to inform consumers about the presence of 264 allergens. One product used italic font, 2.36% were found with different font sizes and 1.18% with 265 different colour or a lighter background. 1.97% products used an asterisk e.g. vitamins* to inform 266 consumers that the vitamins *contain soybean oil. Similarly, an asterisk was presented in preservative 267 (sulphur dioxide)* to declare that the product *contains preservative as sulphite in some fruits. These are examples of good allergen labelling practices where the manufacturers or packers provided clear 268 269 and thorough information of the product's contents. The typefaces comply with Regulation No. 12 270 (Sub-regulation 4) of Malaysia Food Regulations (1985), where the statement of ingredients are not 271 smaller than 4 point lettering and legible. Mfueni et al. (2018) also reported that imported food 272 products in Malawi also used different emphasis (e.g. bold, italics, enlarged font or contrasting colour)

- 273 on the list of ingredients
- 274

275 FALCPA (2004) provided manufacturers with two options to label food allergens i.e. to include the 276 name of the food source in parenthesis (e.g. Ingredients: whey (milk), eggs) if the name of the food 277 source of the major allergen does not appear elsewhere in the list of ingredients or manufacturers 278 can use 'Contains [allergens] immediately after or adjacent to the list of ingredient. EU Regulation No 279 1169/2011 mandate that food allergens on the regulatory list is to be emphasised e.g. using bold, 280 italics, highlighted or underlined font to identify them if used as ingredients in a pre-packaged food. 281 Recent changes to the EU Food Information for Consumers Regulation (EU FIC) Regulation No. 282 1169/2011 stated that allergy boxes such as 'Contains [allergens]' is no longer allowed. The 283 regulation however permits the usage of icons or symbols to indicate the presence of allergens as 284 long as it is with accompanied words or numbers to ensure uniform consumer understanding (FSA, 285 2015). Previous research in EU reported customers facing difficulty when reading information on label particularly in terms of font sizes being too small, colour contrast of label, visibility problems when 286 287 reading glossy materials (Cornelisse-Vermaat et al., 2008). Dutch customers also liked the usage of symbols on the package to indicate if an allergen was present or not. However, they prefer textual 288 289 allergen information to be included in addition to symbols (Cornelisse-Vermaat et al., 2008). This was 290 prior to the change in the EU FIC regulation.

291

292 Consumers in South Korea were concerned about the font size of the food allergen information and

293 considered them too small to be noticeable (Choi & Choi, 2016). Regulations in South Korea specified

that the font size should be bigger than 12 points. The location of the allergic information, which

appears below the nutrition information, was also barely noticeable (Choi & Choi, 2016). Cornelisse-

Vermaat *et al.* (2008) reported that participants perceived the readability of the label (font size andcontrast) could be improved.

298

299 Ambiguous declaration

There were 199 ambiguous labelling found in the food products where sources of ingredients were unknown. Categorically, this can be divided into source of oil or shortening (26.13%), type of flour or starch (18.09%) and others (e.g. emulsifier, thickener, source of lecithin, conditioner, hydrolysed or textured vegetable protein, spices, breadcrumbs and flavourings) (55.78%). Maltodextrin were excluded in this study. Although Food Regulations 1985 did not mention maltodextrin, EC 1169/2011 stated that wheat-based maltodextrin, wheat-based glucose syrup and wheat-based dextrose are exempted from food allergen labelling.

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308 Chilled and frozen food recorded the highest number of ambiguous labels (28.64%). 25% of the 309 labels did not specify the type of oil or shortening used, 50% of the labels did not state the source of 310 flour used (e.g. high protein flour, starch) and 23.42% could further provide information about the 311 source of lecithin, spices, flavours, binders and emulsifier. A chicken nugget product labelled ISP in its 312 ingredient list. Assuming that ISP is isolated soy protein, not stating the full product name may put soybean allergic individuals at risk. This was reported by Mittag et al. (2004) who found that patients 313 314 were allergic to dietary product containing soy protein isolate. Beverages recorded 15.07% 315 ambiguous labels and could further improved the labelling by providing the source of oil (15.38%) 316 and other ingredients (19.82%). Most products only provided generic terms such as hydrogenated 317 vegetable oil or fat, malt, malt extract powder, emulsifier, thickener and conditioner. In beverages, cereals used to make alcoholic distillates are exempted from food allergen labelling. Although 318 319 maltodextrin was excluded in this study, some baby formula products demonstrated good allergen 320 labelling practices and also listed the sources of maltodextrin (e.g. from corn or potato starch). 321

About 14% of snacks' labels were confusing. Generic terms were found in 19.23% of oil (e.g. cooking 322 323 oil, vegetable oil, vegetable fat and popping oil), 22.22% of flour and 9.01% of other ingredients (hydrolysed vegetable protein, emulsifier). The term popping oil was found in a popcorn product. 324 325 Food manufacturers used the generic term 'vegetable oil' as the type of oil used in production may 326 change due to supply issues. However, there are several widely used oil that are derived from plants 327 commonly known as food allergen e.g. peanut, soy (Crevel, Kerkhoff, & Koning, 2000) and sesame. 328 In fully refined oil, protein are almost completely removed and do not present risk of allergic reactions in the majority of susceptible individuals (Blom et al., 2017; Crevel et al., 2000). The amount of 329 330 protein in refined peanut oil is estimated at 0.1 – 0.3 µg/ml (Olszewski et al., 21998; Ramazzotti et 331 al., 2008) and refined soy oil is 0.32 µq/ml (Errahali et al., 2002). Sesame oil is commonly used 332 directly without refining for culinary purposes (Olasunkanmi, Omolayo, & Olusegun, 2017) and had

been reported to cause hypersensitivity in susceptible individuals (Gangur *et al.*, 2005). Crude oils are estimated to be between $3 - 13 \mu g/g$ (Crevel *et al.*, 2000).

335

A total 34 discrepancies (difference between ingredient list and contains statement) were found in all 336 337 food categories except baby food and powder and paste products. In nine food products, food 338 allergens were listed in the ingredients but not included in the contain statement. For example, a 339 wafer product has wheat, soybean and milk listed as ingredients but only declared 'Contains wheat 340 and milk'. Meanwhile the other 25 products declared allergens in the contain statement although 341 these were not listed in the ingredients. In a codfish snack, soybean was declared in the allergen 342 advice as: 'Contains wheat, soy product and seafood'. Although fish meat and wheat flour were declared in both ingredient list and contain statement, soybean was not. Both snacks and chilled & 343 344 frozen food recorded 23.53% of the discrepancies.

- A cracker product labelled wheat and milk in the ingredient list, but also declared the following "This
- product contains wheat and is manufactured in a facility that may process products that contain
- celery, peanuts, tree nuts, sesame, dairy and soy'. Only wheat was declared in the contain
- 348 statement, while the precautionary statement stated that it may contain milk. The declaration of milk
- in both the ingredient list and the advisory list may create confusion among consumers. Similarly, a
- 350 coated peanut product declared wheat and peanuts in the ingredient list but also stated 'this product
- 351 contains other tree nuts' in the contain statement. Furthermore, the product's PAL was repeated
- twice 'Produced in a facility that also produces gluten (wheat) and peanuts. May contain gluten
- 353 (wheat) and peanuts'. Although wheat and peanuts were declared in the ingredients list, the advisory
- labelling informed consumers that the product may contain wheat and peanuts. Fourteen food
- products repeated the advisory labelling. For example, in the snack category, the repetition was as
- 356 follow: 'This product is produced in a facility that also produces peanuts, tree nuts and gluten. May
- contain peanuts, tree nuts and gluten'. Confectionary products such as nut coated chocolate werelabelled as 'May contain traces of other nuts. Allergen info: Made by equipment that also processes
- 359 products that contain peanuts, tree nuts, sesame and cereals that contain gluten'.
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- Ambiguous and contradictory labelling may cause confusion among consumers. The discrepancy
 between the allergens declared in the ingredients list and contains statement or allergy information
 may be a possible disadvantage as consumers may rely only the contain statement and ignore other
- potential allergens listed in the ingredients (Ben-Shoshan *et al.*, 2012). Statements that are vague are
- inappropriate for consumers to assess risk accurately (Pape, 2009). Food labels serve as the interface
- between consumers and the pre-consumption food system (i.e. farm to point of sale). Tonkin, Well,
- Coveney, Meyer & Wilson (2016) named this a vulnerability point as correct labelling and awareness
 from consumers will mitigate potential risks such as consumption of undeclared or unintentional
- from consumers will mitigate potential risks such as consumption of undeclared or unintentional
- 375 presence of food allergens.
- 376

377 Good allergen labelling practices

378 The following food categories demonstrated good allergen practices (Table 3). This is in addition to 379 meeting the requirements of Malaysia's Food Regulations 1985. Baby and young children food 380 category which consists of infant formula and cereal-based foods for infants and young children has the highest number of good allergen labelling practices. Ingredients list contain simple food allergen 381 382 name adjacent to jargons such as lactose (milk), whey (milk), emulsifier (soy lecithin) and docosahexaenoic acid (fish oil). Young babies are at higher risk to foodborne diseases (Worsfold, 383 1996) hence baby food manufacturers have to be extra vigilant in ensuring quality of the raw 384 385 materials, processing and safety of baby food (Featherstone, 2016). Baby food in Malaysia is guided 386 by Food Regulations (1985) in Part VIII Standards and particular labelling requirements for food. In 387 addition to adopting good hygienic practices whilst handling milk, parents and carers should pay attention to reading and understanding baby and young children's food labels. Confectionaries came 388 in second with 52 good allergen labelling practices. Noteworthy examples include listing the source of 389 390 oil (which also contains source of emulsifier) and colouring (tartrazine). Tartrazine (E102) is one of 391 the six food colours linked to hyperactivity in children (Bateman et al., 2004; McCann et al., 2007). In 392 EU, food and drinks that contain tartrazine, sunset yellow, quinolone yellow, carmoisine, allura red and ponceau 4R must carry the warning 'may have an adverse effect on activity and attention in 393 394 children' (EC Regulation No 1333/2008, 2008; Oplatowska-Stachowiak, & Elliott, 2017). Shek and Lee (2006) reported that labelling of foods manufactured or packaged in Asia needs to be improved. By 395 396 improving some of the current limitations in the surveyed products and using the examples of good allergen labelling practices, Malaysia's food manufacturers, packers and importers will be able to 397 398 benchmark against other stricter and comprehensive food allergen labelling regulations.

399

400 Insert Table 3 here

401

402 Food allergen labelling regulations

403 Table 4 compares Malaysia's food allergen labelling regulations against Codex, other Asian countries

404 and the EU. The Codex Alimentarius Commission Committee on Food Labelling has listed the major

405 food allergens and ingredients known to cause hypersensitivity (Codex, 1985). Countries use Codex's 406 list as a national benchmark to define and establish their own country's allergen list based on dietary habits and geographical regions. Malaysia Food Regulations (1985) requires the declaration of cereal 407 408 containing gluten, eggs, fish, milk, peanuts, soybeans and tree nuts. Indonesia shares a similar list to 409 Codex with the exception of sulphites (> 100 ppm). Japan, South Korea and member countries of the 410 EU are interesting examples demonstrating specific allergens vary by countries and reflect differences 411 in dietary preferences and culture. For example, buckwheat is an important allergen in Japan and 412 Korea (Akiyama et al., 2011; Han, Kim, & Ahn, 2012) as is the case of celery, mustard, sesame, lupin 413 and mollusc which have been identified as significant allergens in European countries (Tsabouri,

- 414 Feketea, & Nikolaou, 2017).
- 415

416 In Thailand, allergen information for pre-packaged foods were required since 2014 based on

417 Notification No. 367 (Royal Thai Government Gazette, 2014). This was based on Surojanametakul *et*

418 *al.* (2012) study that reported one third of Thai commercial food products contained undeclared

allergens greater than 10 ppm. Thailand's food labelling had evolved over the years and now

420 contributes to international food labelling policies (Rimpeekool *et al.*, 2015). The Agri-Food and

421 Veterinary Authority of Singapore does not encourage the use of precautionary allergen labelling such

422 as "May contain" to declare the presence of allergens or substances known to cause hypersensitivity.

423 Food traders who use PAL may be required to provide justification to customers if concerns were

raised regarding potential food allergens in the products (AVA, 2017).

- 425
- 426
- 427

428 Insert Table 4 here

429

430 Crustaceans are listed as major allergens in most countries listed in Table 4. It is not specify in
431 Malaysia's listing of foods causing hypersensitivity. However, studies found that prawn was the most

common food allergen in children up to 12 years (Gendeh *et al.*, 2004) and in adults with allergic

433 rhinitis in Malaysia (Wan Majdiah *et al.*, 2016). Similarly, other neighbouring countries reported

434 shellfish allergy in Thailand (Lao-araya & Trakultivakorn, 2012), Philippines (Shek *et al.*, 2010),

435 Singapore (Chiang *et al.*, 2007) and China (Chen, Hu, Allen, Ho, & Li, 2011; Chen *et al.*, 2012). This

reiterates the need for clearer guidance in Malaysia's food allergen labelling regulations.

437

438 Conclusion

439 Successful avoidance of food allergens rely on accurate and clear food labelling. Although more than

440 99% of the surveyed food products' labelling declared the presence of food allergens according to the

local regulations, there still exists multiple cases of missing, ambiguous and contradictory statements

442 in the labels. On a more positive side, some food categories demonstrated good allergen labelling

- 443 practices that could be emulated by other food manufacturers and packers. At this time, there
- 444 remains extensive work in determining food allergy prevalence and levels of undeclared allergens in
- 445 Malaysia. Studies on consumers' attitudes and purchasing habits of food products with allergens and
- 446 PAL can be used to identify the needs of consumers. Improving current allergen labelling regulations
- and practices would be of great benefit to consumers to prevent risk of food hypersensitivity.
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