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Creators	Soon, Jan Mei and Wahab, Ikarastika Rahayu Abdul

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Global food recalls and alerts associated with labelling errors and its contributory factors

Abstract

Background: Food recalls and alerts associated with undeclared allergens and other forms of labelling errors are on the rise. Besides undeclared allergens, other mislabelling such as undeclared ingredients, providing wrong shelf-life, wrong or lack of storage instructions also pose significant health consequences to consumers. Hence, by identifying the causes of labelling errors, this would facilitate preventative and mitigating strategies in food supply chain. The aim of this study is twofold. First, the study aims to identify the affected food and drink categories, types of allergen, and other labelling issues and associated labelling errors. Second, it aims to identify the causes or contributory factors of labelling errors.

Scope and approach: This study reviews food recall, withdrawals, and alerts of five official food safety websites (Canadian Food Inspection Agency, Food Standards Australia New Zealand, UK Food Standards Agency, US Department of Agriculture Food Safety Inspection Service and US Food and Drug Administration) from 2011 – 2020.

Key findings and conclusions: A total of 2,470 food recalls and alerts linked to labelling errors were identified. Undeclared allergens were identified as the most common type of recall. Among the 2301 recalls and alerts associated with food allergens, 3,100 undeclared allergens were reported of which milk (26.55%), gluten (13.16%) and tree nuts (11.52%) were recorded as the top three contributors. Food products most affected by undeclared, incorrect or missing information associated with food allergens were baked goods (18.65%), ready-to-eat meals / heat and serve (11.10%) and confectionary (10.87%). There were alerts and recalls associated with undeclared ingredients (n=67), wrong expiry dates (n=36), undeclared ingredients & allergens (n=26), and other labelling issues such as incorrect claims or wrong usage / storage instructions (n=40). Most labelling errors remain unknown or un-reported. Where known or suspected causes were reported, packaging and printing error, supply chain failures, product formulation and ingredient change, cross contact and process failure / manufacturing error were recorded as contributory factors. The root cause of labelling error remains underreported or unknown and should be documented clearly and/or investigated further.

Highlights

- Labelling errors were divided into undeclared allergens, incorrect information, missing information, and illegible print.
- Milk, gluten, tree nuts, eggs, and soy were identified as the main undeclared food allergens.
- Baked goods, ready-to-eat/heat-and-serve and confectionary were the food categories with the highest number of undeclared allergens.
- Most labelling errors were due to un-reported or unknown causes; hence the contributory factors were not identified.
- Other reported known or suspected causes include packaging and printing error, supply chain failures, product formulation and cross contact.

41

42 **Keywords:** allergens; cross contact; food recall; ingredient change; labelling error; packaging error;
43 product formulation; supply chain failure

44

45 **Introduction**

46 Food labelling is essential to help consumers to make healthier and safer food choices. Food labels
47 allow consumers to make purchasing decisions that minimise (potentially lethal) personal health risk
48 (e.g. in respect of food allergies). They allow consumers to make valid purchasing decisions and they
49 evidenced that the product to be purchased is within its designated shelf life. Labelling also permits
50 purchasing decisions to be aligned with personal beliefs and dietary restrictions (e.g. vegetarian or
51 vegan products, halal, etc.). Finally, labelling permits consumers to select their favoured brands or
52 products and allows people to plan how and when to use it. Regulations are in place globally to
53 protect consumers. The Codex Alimentarius (Food Code) is a set of international food standards and
54 guidelines including food allergen labelling that is used as a key reference by 186 countries
55 worldwide. Codex Alimentarius recommends the declaration of 8 foods and ingredients known to
56 cause hypersensitivity (FAO/WHO, 1991) on food packaging. Furthermore, in the UK, it has one of
57 the strictest food allergen labelling requirements in the world, including Natasha’s Law (whereby
58 food businesses must include full ingredients labelling on pre-packaged foods for direct sale) that
59 came into force in October 2021 (FSA, 2021a). It is currently mandatory that food labels declare 14
60 food allergens in the UK (FSA, 2021b) and EU (EU 1169/2011). Even so, despite these stringent legal
61 requirements, it remains the case that annually in the UK, thousands of individuals suffer from
62 serious allergic reactions to food that they have purchased and consumed (FARE, 2021; Marchisotto
63 et al., 2017;). Food allergen labelling regulatory frameworks differ according to different countries.
64 For example, US Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) identified
65 eight foods as major food allergens (egg, fish, milk, peanut, shellfish, soy, tree nuts, wheat). Sesame
66 was added to the main allergen labelling list through the passing of the Food Allergy Safety,
67 Treatment, Education and Research (FASTER) Act on 23 April 2021 and will become effective on 1
68 January 2023 (US FDA, 2021). The priority allergens in Canada are crustacean, egg, fish, milk, peanut,
69 soy, tree nuts, wheat and triticale, sulphites, molluscs, mustard and sesame (Government of Canada,
70 2020). The Food Standards Code in Australia and New Zealand requires suppliers to declare the
71 following food allergens (egg, fish, lupin, milk, peanut, sesame, shellfish, soy, tree nuts and wheat)
72 when present (FSANZ, 2020a). In UK, 14 allergens are required to be declared including celery,
73 cereals containing gluten, crustacean, egg, fish, lupin, milk, mollusc, mustard, peanut, sesame, soy,
74 sulphite and tree nuts (FSA, 2021b).

75

76 Food recalls associated with undeclared allergens were identified as the most common cause of
77 recalls and withdrawals globally (Potter et al., 2012; Sheridan et al., 2020; Soon et al., 2020; Spatz,
78 2018). Food Standards Australia and New Zealand (FSANZ) reported that between 2010-2019,
79 undeclared allergens accounted for 40% of the total food recalls (FSANZ, 2019). Similarly, undeclared
80 allergens were the leading cause of food recalls in the United States (Friedlander, 2020; Spatz, 2018).
81 The number of undeclared allergens in Rapid Alert System for Food and Feed (RASFF) notifications
82 had also increased in the past years (Soon et al., 2020; Yeung & Robert, 2018). Previous studies
83 revealed that between one to four undeclared allergens were detected in food products (Blom et al.,
84 2018; Remington et al., 2015; Shelver et al., 2021). Elevated levels of allergens such as milk and
85 gluten were also found in food products declared as milk-free or gluten-free (Bedford et al., 2017;
86 Bianco et al., 2022; de la Barca et al., 2021). Labelling errors resulting in food allergens exposure
87 impose considerably high healthcare and economic costs for food allergic and intolerant patients.

88

89 Food recalls associated with other forms of labelling errors had been reported due to undeclared
90 meat species and ingredients, incorrect information such as wrong shelf life, and missing information
91 (FSA 2020; FSANZ, 2020b; US FDA, 2019; USDA FSIS, 2020). Undeclared poultry and meat species
92 were found in processed meat products. For example, Kane and Hellberg (2016) reported 21% (out
93 of 48 samples) of meat and poultry samples contain additional undeclared meat species. Meanwhile
94 a study by Chuah et al. (2016) revealed 78% of meat and poultry products contain false declaration
95 of species and/or presence of undeclared meat species. Undeclared species in food products cause
96 consumers to lose confidence and trust in supply chain as consumers are not getting what they paid
97 for, and consumption of some animal species are forbidden due to religious beliefs. Incorrect
98 information such as using 'best before' instead of 'use by' for high risk perishable foods in regions
99 where perishable foods are considered unsafe after the 'use by date' in the EU and products must
100 not be marketed after the date (Regulation EU 1169/2011). Providing the wrong extended expiry
101 date (when the product had expired) can pose food safety issues to consumers.

102

103 Previous studies on food recalls, outbreaks and incidents associated with microbiological (Dada et
104 al., 2021; Qiu et al., 2021; Somorin et al., 2020), chemical (Pigłowski et al., 2019), allergen (Bucchini
105 et al., 2016; Padua et al., 2018), physical hazards (Djekic et al., 2017), food products (D' Amico et al.,
106 2018; Caldeira et al., 2021) and food contact materials (De Leo, 2020) had been conducted.

107 However, studies on food recalls associated with labelling issues remain under-reported. The aim of
108 this study is to analyse recalls or alerts in official food alerts, allergy alerts or food recall sites related

109 to labelling issues between 2011 to 2020. The secondary aim of the study is to identify the causes or
110 contributory factors of labelling errors.

111

112 **Scope and Approach**

113 A systematic search and review of food recall, withdrawals and alerts was conducted. Table 1 lists
114 the official food safety websites used to collate the information from 2011 – 2020. This timeframe
115 was selected as Potter (2012), FSANZ (2019) and Soon et al. (2020) had conducted reviews of
116 product recalls and undeclared allergens in the previous decade. Data from official websites were
117 used as the websites provide credible, detailed, and accurate records of food recalls and alerts. Food
118 alerts, public health alerts and allergy alerts that resulted in product recalls were also included in the
119 search. A food alert is issued when an incident has occurred and may result in serious public health
120 issue resulting in immediate action such as product recall. An allergy alert is issued when the allergy
121 information on food label is incorrect or missing and the foods need to be recalled (FSA, 2020; FSS,
122 n.d.). The same recall affecting multiple products (e.g. bakery, confectionary, appetisers) were
123 counted once and only the most affected food product category was documented. Table 2 shows
124 the type of data collected. The details of the labelling error were reviewed and categorised into
125 types of labelling error i.e. undeclared allergen, undeclared ingredients, illegible print, incorrect
126 information and missing information. If the cause or potential cause of errors were reported, these
127 were collated and categorised into nine types of known/suspected causes or contributory factors i.e.
128 cross contact, mislabelling, packaging error, printing error/artwork, process error/manufacturing
129 error, product formulation & ingredient change, supplier change, supplier’s ingredient and others
130 (e.g. employee error, fraud, lack of knowledge, miscommunication). The contributory factors were
131 classified using terms from US FDA and FSIS recalls, Bucchini et al. (2016) and Gendel and Zhu (2013).
132 Where further information was unavailable, the suspected cause was categorised as un-reported or
133 unknown. All data were extracted and transferred to Microsoft Excel. Data were screened to ensure
134 repeated records were not duplicated including identification of withdrawal of recall
135 announcements and amendments (Potter et al., 2012). Both the first and second author carried out
136 random search validation with the original websites and triangulated the data with journal articles,
137 company websites and media to ensure accurate data were recorded. Chord diagram provided by
138 Flourish (<https://public.flourish.studio/visualisation/7570555/>) was used to link the
139 known/suspected causes and contributory factors of labelling errors to food and drink categories.

140

141 Insert Table 1 here

142

143 Insert Table 2 here

144

145 **Results**

146 **Product recalls and alerts associated with labelling errors**

147 2,470 product recalls and alerts associated with labelling errors were documented. This was divided
148 into incorrect, missing or undeclared allergen information (93.16%), undeclared or incorrect
149 ingredient information (besides allergen information) (2.71%), expiry date (1.46%), incorrect
150 information for both ingredients and allergens (1.05%) and other labelling issues such as incorrect
151 claims or identified as RTE when it's raw or missing nutrition facts (1.62%).

152

153 **Labelling errors associated with allergens**

154 A total of 2,301 recalls linked to allergens were identified. Undeclared allergens were identified as
155 the most common cause of recall. 3,100 undeclared, incorrect, or missing information associated
156 with food allergens were reported between 2011 – 2020. The number of recalls associated with
157 labelling errors (n=2,301) were lower compared to the number of undeclared food allergens
158 (n=3,100) since some foods contain two or more undeclared food allergens,. Milk (26.55%) received
159 the highest number of reported recalls or alerts followed by gluten (13.16%), tree nuts (11.52%),
160 eggs (11.42%) and soybean (11.03%) (Figure 1). Where identified, tree nuts such as almond
161 (32.21%), walnut (16.25%) and cashew nut (10.36%) were the main tree nut allergens. There was 92
162 (3.99%) recalls where food and drink products contained more than three food allergens. Bakery
163 products (18.65%), ready-to-eat meals / heat and serve (11.10%), confectionary (10.87%), savoury
164 snacks (5.42%) and appetisers / sides (5.32%) were the most frequently reported food products with
165 undeclared allergens (Figure 2).

166

167 Insert Figure 1 here

168

169 Insert Figure 2 here

170 The main type of labelling error was undeclared allergen (94.91%), followed by incorrect information
171 (4.61%), missing information (0.39%) and illegible print (0.09%) (Table 3). Incorrect information
172 includes incidents of declaring food products as free-from or low in certain food allergens e.g.
173 'gluten-free', 'dairy free', 'egg free', 'vegan' or even statement like 'product is free from all 14 food
174 allergens' but the food products were found to contain the advertised free-from allergen. There
175 were also reports of ambiguous labelling e.g. labelled as gluten free in the front-of pack labelling, but
176 declared gluten in the ingredient list or stated Vitamin A (partially derived from fish oil) in

177 Supplement Facts section, but then stated ‘Contains no common food allergens’. Among the type of
178 incorrect information, printing or artwork error was a recurring theme. Food allergens were not
179 emphasised correctly (e.g. not in bold font) or not declared in English in the UK, where it is
180 mandatory to emphasise allergenic ingredients in the ingredient list by using bold font, contrasting
181 colours or by underlining them (FSA, 2017). Missing information includes absence of advisory
182 allergen labelling, ingredient list or lack of label. Although advisory allergen labelling is voluntary
183 worldwide, some food businesses decide to recall their products when they realised the information
184 were missing. Illegible print such as blurred ingredients and allergen labelling in print makes it
185 difficult to read the statements.

186

187 Insert Table 3 here

188

189 **Known/suspected causes or contributory factors for undeclared allergens**

190 Based on the 2,301 labelling errors, we further categorised the reported and/or suspected causes
191 and contributory factors for food allergens. Un-reported or unknown causes account for 66.28% of
192 the labelling errors. Packaging error (15.86%), supplier’s ingredients (5.74%), printing error (3.52%),
193 product formulation and ingredient change (4.56%), cross contact (2.48%), change in supplier
194 (0.43%) and process failure / manufacturing error (0.26%) were other known or suspected causes for
195 undeclared allergens. An additional category for ‘others’ (0.87%) including miscommunication, lack
196 of knowledge, employee error, fraud and supply chain error were documented. Among the known /
197 suspected causes, packaging error (n=365) (please refer to turquoise arcs in Figure 3) commonly
198 occurred in RTE meals / heat and serve (20%), bakery (12.33%) and confectionary (11.51%).
199 Supplier’s ingredients (yellow arcs) were identified as another main contributory factor in similar
200 food categories such as baked goods (15.91%), confectionary (13.64%) and RTE meals / heat and
201 serve (8.33%) (Figure 3).

202

203 Insert Figure 3 here

204

205 **Labelling errors associated with ingredients**

206 Incorrect ingredient information and undeclared ingredients were reported in various food and drink
207 categories (n=67) especially in raw/cured and/or fermented meat and fish (35.82%), appetisers/sides
208 (11.94%) and frozen meat and poultry-based products (10.45%). Undeclared ingredients include
209 other meat and poultry species such as pork, beef, sheep, turkey, and chicken; preservatives such as
210 sodium benzoate and sodium nitrite and flavour and sensory enhancer such as aspartame, colouring,

211 and monosodium glutamate. Incorrect information was identified in 8.95% of the food and drink
212 products and the rest were due to undeclared ingredients. Examples of incorrect ingredient
213 information include incorrect serving sizes, labelled as zero sugar when it contains sugar and
214 exceeding marked alcohol content. The known or suspected causes for incorrect information include
215 process failure / manufacturing error. For example, alcoholic beverages with exceeded marked
216 alcohol due to secondary fermentation were linked to process failure. The cause for undeclared
217 ingredients were largely un-reported or unknown (61.19%). Known or suspected causes associated
218 with undeclared ingredients were packaging error (16.42%), printing error (1.49%), ingredient
219 change or product formulation (4.48%), supplier's ingredient (1.49%), change in supplier (1.49%) and
220 others (4.48%).

221

222

223 **Other forms of labelling issues**

224 Wrong expiry dates were notified in 36 food and drink products with both chilled, raw prepared
225 meat and poultry (22.22%) and raw/cured and/or fermented foods (19.44%) being the most
226 prevalent. All labelling errors associated with wrong expiry dates were identified in Australia, New
227 Zealand, and UK official sites, where foods cannot be legally sold after the use by date as they may
228 pose health or safety risk (FSA, 2021c; FSANZ, 2021a). Incorrect use by dates, for example food
229 product was labelled as '12 February 2022' instead of '12 February 2020' or labelled as Feb 2016
230 instead of Jan 2016 were found in 31 recalls while incorrect best before dates were associated with
231 five food recalls.

232

233 Other labelling issues such as providing incorrect information (60%) and missing information (40%)
234 were found in 40 food and drink products. Wrong information such as inaccurate usage or
235 consumption advice, incorrect cooking instructions, incorrectly bear USDA Mark of Inspection (when
236 the company was not authorised to use the logo), incorrectly identified as RTE, and making false 'no
237 antibiotics' claim were notified. Missing information includes missing cooking instructions, storage
238 instruction or safe handling instructions, missing list of ingredients, nutrition facts, establishment
239 number or USDA mark of inspection. There were also recalls where combination of undeclared
240 ingredients & allergens (n=26) were found.

241

242 **Discussion**

243 Our findings are in line with previous studies where labelling error is the predominant cause for
244 recall. Bucchini et al. (2016), reported between 42-90% of food recalls were explained as 'Not

245 indicated on the label' while Potter et al. (2012) stated mislabelling is consistently listed as one of
246 the top three causes of recall in food industry (Potter et al. 2012). This study reveals the high rates of
247 labelling errors leading to global food recalls and withdrawals.

248

249 Milk, gluten, soy, eggs, and tree nuts were identified as the main undeclared food allergens in this
250 study encompassing Australia and New Zealand, Canada, US, and UK. Similarly, previous studies
251 identified that milk, egg, tree nuts and wheat represented the most common undeclared food
252 allergens in North America food recalls (Bucchini et al., 2016; Malyukova et al., 2012), undeclared
253 milk, gluten, and egg were reported in Australia and New Zealand (Bucchini et al., 2016; Sheridan et
254 al., 2020) and European Union (Bucchini et al., 2016; Padua et al., 2019). The high rates of
255 undeclared allergens were also supported by study of food products imported from Mainland China
256 where samples contained detectable milk, egg and wheat residues at VITAL® Action Level Two and
257 Precautionary Allergen Labelling [PAL] is recommended for such products (Yee et al., 2021). The
258 Voluntary Incidental Trace Allergen Labelling (VITAL®) is a voluntary guidance. It provides a
259 standardised science-based risk assessment process and is highly useful for food industry to assess
260 the impact of allergen cross contact and determine if precautionary statements are required (Taylor
261 et al., 2018; VITAL Allergen Bureau, n.d.) In Blom et al. (2018), patients were followed-up for a year
262 and were asked to report accidental allergic reaction and to send the culprit food products for
263 testing. Cow's milk, peanut and tree nuts were detected in food products that did not declare the
264 allergen on ingredient lists resulting in accidental food allergic reactions among the patients. 37%
265 (n=51) of the products analysed contained 1 to 4 allergens that were not declared in the ingredient
266 list. Although it was not reported in Blom et al. (2018), we suspect that the affected food products
267 were not recalled. In a separate study, up to 23% of food samples (n=1125) were found to contain
268 between 2.5 – 6,471 ppm milk in food products with Precautionary Allergen Labelling (PAL), posing
269 potential health consequences if food allergic consumers were to ignore PAL (Manny et al., 2021).

270

271 Baked goods, RTE meals/heat & serve, confectionary, savoury snacks and appetisers/sides were the
272 most common food categories affected by undeclared allergens. These foods are characterised by
273 heterogeneity of raw materials and ingredients and are highly processed foods (Slimani et al., 2009).
274 Studies revealed that bakery products, snacks and candies were the most recalled categories due to
275 undeclared allergens (Do et al., 2018; Gendel & Zhu, 2013). In non-pre-packed bakery items, milk
276 was detected in 31/73 of baked products advertised as 'cow's milk-free' (Trendelenburg et al. 2015),
277 egg and soy were found in 22/363 and 71/284 bakery samples (Khuda et al., 2016a, b). Milk, gluten,
278 egg, and soy were often used as sub-ingredients in product formulation mix. For example, this study

279 revealed hidden allergens in sub-ingredients such as gluten in soy sauce, egg in egg wash glaze, and
280 soy lecithin in releasing agent. Food labelling can be misleading especially if labels contain unfamiliar
281 ingredient names or derivatives of food allergen (Puglisi & Frieri, 2007). Using proteins such as
282 albumin, lecithin, sodium caseinate and whey and not declaring its common name was another
283 cause for undeclared food allergens. It is a requirement in most food allergen labelling regulations to
284 declare food allergen in simple, plain English terms to ensure clear and uniform understanding
285 (FALCPA, 2004; FSA, 2017; FSANZ, 2021b; Government of Canada, 2018).

286

287 Processed meat and poultry products were identified as the main food categories affected by
288 undeclared species. This reiterates previous studies where undeclared species in processed meat
289 continue to be identified in commercial products. Shehata et al. (2019) found 14% (n=100) of
290 sausage products sold in Canada contained >1% undeclared species, while 20.83% (n=48) of ground
291 meat products sold in US were mislabelled (Kane & Hellberg, 2016) and one fifth of meat samples
292 tested in the UK contained species not listed on the label (Mackay, 2018).

293

294

295 Packaging and printing error /artwork

296 Packaging error has been identified as a cause for undeclared allergens and ingredients. This is
297 consistent with the findings from Gendel and Zhu (2013) where large number of recalls were caused
298 by failures in label control. In our study, incidences of packaging error occurred when the wrong
299 package or label was used, wrong product was used, comingling of labels and food occurred, and
300 lack of label cross checking. If food production uses multiple similar packaging, operators may
301 mistakenly use the wrong packaging. This could be due to complacency or lack of training and label
302 review (Ridler, 2021). This study also revealed that inadequate label review has led to employees
303 using labels produced earlier on the same day or placing the wrong film onto labelling machine.
304 Another potential cause for mislabelling error is labelling food products for export. Certain foods for
305 export require an over-sticker on the ingredient list and if the product has not been relabelled
306 correctly or exported with incorrect allergen information, this could result in international food
307 recall (Ridler, 2021).

308

309 Kumar and Budin (2006) reported that inspection of food processors found 50% of food producers
310 did not have any label cross-checking system in place. The lack of label review may have contributed
311 to using the wrong labels. Ridler (2021) suggested implementing a start-up validation process to
312 confirm the product, packaging / label, and other requirements before commencing the production

313 run. Food label and artwork creation is a lengthy and complex process and goes through an iterative
314 loop of designs, revisions, approval, reproduction, and print (Vazquez et al., 2003). The iterative
315 process and revisions of artwork may leave room for error, especially when regulations changed, and
316 terminologies are updated. Whinnett (2021) discussed some of the common challenges associated
317 with artwork creation and management. Errors in artwork design could potentially be caused by
318 data errors due to copy and paste, misalignment of specification and artwork versions, artworks
319 being managed through disparate systems, availability of cross functional production information
320 and handling of artwork design by cross functional teams.

321

322 Cross contact

323 Cross contact is the unintentional incorporation of food allergen into a food and can occur at any
324 stages of the food supply chain i.e. at farm level to catering services (Do et al., 2018). Cross contact
325 as a reported cause for undeclared allergens was noticeably small in this study. Cross contact was
326 identified as the root cause of 7.1% of allergen recalls (n=732) (Gendel and Zhu, 2013) and between
327 0-17% of recalls were linked to cross contact in production (Bucchini et al., 2016). Milk, gluten, and
328 peanut were the main allergens reported in cross contact incidences in this study and involved foods
329 such as bakery, confectionary and snacks. The nature and physical state of the allergenic food matrix
330 e.g. gluten in the form of flour and use of milk powder enables the allergen to spread easily (Galan-
331 Malo et al., 2019). Milk powder also contains 8 – 10 times more protein than liquid milk (Diaz-Amigo,
332 2010). Although the use of peanut paste reduces the spread of allergenic dust compared to crushed
333 peanut or peanut meal, however, it poses a challenge in cleaning (Stone & Yeung, 2010). Similarly,
334 the removal of heterogeneously distributed pieces of allergen materials such as peanut or tree nuts
335 are also difficult (Roder et al., 2008). Cross contact can result from ineffective allergen control
336 programme such as inadequate cleaning of shared processing and packaging equipment, improper
337 production scheduling resulting in allergenic proteins carried over into next product, lack of physical
338 separation, cross contact from airborne dust and aerosols carrying allergenic protein due to handling
339 and cleaning techniques e.g. sieving and use of compressed air for cleaning and lack of allergen-
340 specific validation and verification procedures (Jackson et al., 2008). Food allergen can also be
341 present due to cross contact in the raw material and ingredient supply chains (Spanjersberg et al.,
342 2009). Undeclared ingredients including meat species could also be caused by cross contamination
343 of animal species in processed meat. According to Chung & Hellberg (2020), this is due to incomplete
344 cleaning of grinding equipment leading to cross contamination of animal species.

345

346 Supply chain failures

347 Although supply chain failures are categorised as ‘external’ types of error and include operational
348 errors caused by suppliers such as missing or incorrect labelling of ingredients (Jia & Evans, 2021),
349 cross contact, switching to alternative ingredients without informing their clients; the causes for
350 supply chain failures are similar to those listed in Figure 3. If an ingredient supplier fails to label all
351 food allergens correctly, it will be difficult for the food manufacturer to declare them correctly.
352 Hence supplier control and effective risk communication of ingredient status across the supply chain
353 are important (Crevel et al., 2010). However, food manufacturers also play a significant role in
354 obtaining and assessing food allergen risks from their suppliers (Jia & Evans, 2021). Supply chain
355 failures have serious consequences as the ingredients may have been sent to different
356 manufacturers or co-packers and could result in multiple nationwide or even international recalls.

357

358 Failure to update label due to product reformulation or ingredient change is another cause for
359 undeclared allergen. The failures were mostly associated with lack of communication between
360 supplier – manufacturer – label design. Examples include failure of manufacturer to inform labelling
361 department of the ingredient change; manufacturer submitted the change to the labelling
362 department but the change was not made; company reformulated and updated the labelling but
363 employees incorrectly used the old formulation for production. Lack of knowledge or awareness
364 about changes in food labelling regulations for different regions where the product is to be sold can
365 also cause issues of mislabelling (Ridler, 2021).

366

367 Although most incidents were unintentional, it is possible that some of the causes for undeclared
368 allergens and ingredients were linked to fraud. For example, soy and almond proteins were
369 intentionally added to dairy products while gluten containing cereal and soy were added to coffee
370 products as they were cheaper ingredients and could cause serious consequences to public health
371 (de Moura Ribeiro et al., 2017; Visciano & Schirone, 2021).

372

373 **Unknown or un-reported causes of labelling errors**

374 Most of the reported labelling errors in the review did not specify the actual or suspected cause. .
375 The actual cause for the error was either not reported, unknown or potentially not investigated
376 further. The unknown incidents in this study could be deliberate or unintentional and potentially
377 caused by other factors as shown in Figure 3 or simply due to human error and lack of verification
378 (Kowalska et al., 2018). The huge number of unknown causes of labelling error is a cause for
379 concern. We suggest using the US FDA and FSIS sites as excellent examples of reporting the causes
380 for labelling errors. Both sites provide some of the most comprehensive information on the cause or

381 factors contributing to mislabelling and recall. It is suggested that the root cause of labelling errors
382 should be documented and/or investigated to prevent similar incidents.

383

384

385 **Limitations**

386 The Rapid Alert System for Food and Feed (RASFF) was not included as the site was undergoing site
387 maintenance during the review. RASFF was reviewed in numerous previous studies. Not all sites
388 have a complete list of food recalls from 2011 – 2020. Only official and publicly available sites in
389 English language were included and therefore relevant sites in other languages were missed. The
390 high number of recalls from the official sites should not be negatively regarded as poor
391 manufacturing practices and allergen control, but potentially due to better surveillance and
392 reporting systems. Some food and drink categories were not detailed in the official sites, and the
393 products were categorised based on the descriptions provided. This study did not include an analysis
394 on the evolution or changes to food labelling regulations. It is likely that legislative changes affected
395 labels and could result in labelling errors especially when food labels were not updated accordingly.
396 It is also complex, lengthy, and resource-consuming to conduct a full investigation for each recall
397 hence, most recalls or alerts did not include the suspected or actual cause for the labelling error. A
398 large proportion of contributory factors for undeclared allergens and ingredients were unknown,
399 and the causes could be accidental, or deliberate and are potentially linked to other root causes such
400 as human error and lack of verification. Root cause analysis such as those conducted by Soon et al.
401 (2020) will provide the agri-food industry with better information on how to prevent such incidences
402 from recurring.

403 **Conclusion**

404 This study identified the known/suspected causes and contributory factors associated with labelling
405 errors. Food recalls caused by undeclared allergens, ingredients, or labelling issues were recorded
406 across 28 food and drink categories. Highly processed foods such as baked goods, RTE meals / heat
407 & serve, confectionary, savoury snacks and appetisers/sides recorded the highest number of
408 undeclared allergens. Milk, gluten, soy, eggs, and tree nuts were the top five undeclared allergens.
409 Undeclared ingredients such as other meat and poultry species, preservatives and flavour and
410 sensory enhancer were also recorded. The main type of labelling error is undeclared allergen,
411 incorrect information, missing information, and illegible print. Most labelling errors were due to un-
412 reported or unknown causes; hence the contributory factors were not identified. Among the known
413 or suspected causes, packaging error, supplier's ingredients and production formulation & ingredient
414 changes were the main contributory factors. The root causes of labelling errors remain under-

415 reported or unknown and should be documented and/or investigated further to prevent similar
416 incidents.

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