

Unintended allergens in prepacked foods with and without precautionary allergen labelling: preliminary data relative to some recalled food types

S. Giammarioli*, A. Pastorelli, C. Boniglia, P. Stacchini and M. Silano

Department of Food Safety, Nutrition and Veterinary Public Health, Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy; stefania.giammarioli@iss.it

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RESEARCH ARTICLE

Abstract

Several food producers use precautionary allergen labelling (PAL) to alert consumers to the possible unintended presence of allergens in food products. In the vast majority of countries, the use of PAL is not regulated by legislation; its application is voluntary and does not represent a defined risk that can be communicated to consumers and other stakeholders. Some surveys examined, at the same time, the same product categories with and without PAL to verify the correspondence between label and presence/absence of allergen contamination but no similar studies have been carried out in Italy. On the basis of two recent recalls due to the presence of undeclared casein and soy in fruit candies and wheat flours respectively, we collected 34 samples (17 with PAL and 17 without) belonging to these categories of products. The analyses were performed by ELISA using two commercial kits that target casein and soy trypsin inhibitor respectively. Overall, 11.8% of the samples were contaminated, however the contamination was found only in the wheat samples. The percentage of contaminated wheat products is almost the same in samples with and without PAL, and equal to 25.0% (2/8) and 28.6% (2/7) respectively. The obtained results highlight that in most of the examined foods with PAL (15/17) allergen contamination was not detected and that the absence of PAL does not imply a food is certainly safe for consumption by allergic individuals (contamination 2/17). These data are preliminary and an increase in the sample size and categories examined is necessary to better clarify the current situation of the Italian market. At the same time, global efforts to define threshold levels of allergens are essential to provide a risk-based approach to PAL, and to furnish public health guidance to food industry.

Keywords: unintended allergens, precautionary statements, candies, wheat flours

1. Introduction

The Regulation (EU) No 1169/2011 (European Parliament and Council, 2011) establishes that the declaration of any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances is mandatory, both for prepacked and for non-prepacked foods. While the requirements for the labelling of allergenic ingredients are clearly defined in the legislation, such clarity does not exist around allergens that might be present due to cross-contamination during food production (Ward *et al.*, 2010).

Many food producers use precautionary allergen labelling (PAL) (such as 'may contain', 'may contain traces', 'shared

equipment', etc.), to alert consumers to the possible unintended presence of allergens in the products despite the best efforts to avoid cross contact in the production facility (Dunn Galvin *et al.*, 2015; Remington *et al.*, 2015). Good allergen management practice dictates that PAL should be applied following a risk assessment, which establishes that there is a real likelihood that a significant but unavoidable amount of allergen cross-contamination would occur (Ward *et al.*, 2010).

Nevertheless, in the vast majority of countries, the use of PAL is not regulated by legislation; its application is voluntary and does not represent a defined risk that can be communicated to consumers and other stakeholders (Allen *et al.*, 2014). In effect, in absence of a specific guidance,

many manufacturers have adopted extremely conservative practices, choosing to label products precautionary in case they cannot guarantee full absence of allergens, even if the chance of contamination and/or the potential health impact are negligible (Spanjesberg *et al.*, 2010; Ward *et al.*, 2010). Furthermore, it is suspected that some manufacturers use PAL as an alternative to allergen risk management, rather than as a means to communicate the actual risk of cross-contamination (Allen *et al.*, 2014).

The consequence of the widespread use of PAL, it is different depending on the attitudes of allergic consumers. It can lead on one side a significant restriction on the number of foods deemed potentially safe, with a negative impact on quality of life and an increased risk of nutrition deficiencies. On the other hand, to a loss of credibility and reduced observance by consumers (Allen *et al.*, 2014; Crevel *et al.*, 2014; Dunn Galvin *et al.*, 2015; Hattersley *et al.*, 2014). Clearly, health professionals charged with advising the allergic consumer are faced with the same issues as the consumer when interpreting the current situation (Allen *et al.*, 2014).

Several surveys have been conducted to assess the presence of many allergens in different food categories, bearing or not advisory statements that are summarised in recent reviews (Allen and Taylor, 2018; Do *et al.*, 2018; Graham and Eingenmann, 2018). Some of these studies examined, at the same time, the same product categories with and without PAL to verify the correspondence between label and presence/absence of allergen contamination. These last surveys were performed in USA, Australia and in some EU countries (Food Safety Authority of Ireland, 2011; Ford *et al.*, 2010; Hirst, 2014; López-Calleja *et al.*, 2014; Khuda *et al.*, 2016a,b; López-Calleja *et al.*, 2015; Pele *et al.*, 2007; Spanjersberg *et al.*, 2010). In Italy, in the framework of the 'Regional Integrated Plan for Food Safety', surveys were performed to assess the presence of undeclared allergens in foods without PAL (Barbaro *et al.*, 2014; Bianchi *et al.*, 2016; Decastelli *et al.*, 2012), but no studies were carried out on the presence of allergens in products bearing precautionary statements.

The aim of this study is to collect analytical data about the prevalence of unintended allergens in prepacked products sold in the Italian market and to compare the results relative to products with and without PAL. This paper reports preliminary data on some food categories.

2. Materials and methods

Based on two recent recalls due to the presence of undeclared casein and soy in fruit candies and wheat flours respectively, we collected 34 samples belonging to these categories of products from 8 different supermarkets and 1 cafeteria in Rome and neighbouring countries. Nineteen

samples of candies of 12 different manufacturers (9 with PAL and 10 without) were analysed for the presence of casein and 15 samples of wheat (*Triticum aestivum* or *Triticum durum*) flours and semolina of 13 manufacturers (8 with PAL and 7 without) for soy. The analyses were performed in duplicate on each sample by enzyme linked immunosorbent assay (ELISA) using two commercial kits: EAE017096 Casein high sensitive and EAE010096 Soy, both from Euroclone that target casein and soy trypsin inhibitor (STI), respectively.

The instructions attached to the kit were followed with the exception of the number of plate washes that were increased from three to four. In particular 0.5 g of sample, pulverised finely in the case of candies, was extracted with 10 ml of extraction buffer at 60 °C for 15 min, centrifuged and filtrated. 100 µl of the extract were used for the immunoassay. The reliability of the two kits was preliminarily evaluated verifying the main validation parameters reported by the manufacturer. The limits of quantification (LOQs) declared (0.2 mg/kg for casein and 40 µg/kg for STI) were verified on replicate blank samples of candies and wheat flours and calculated as optical density mean + 10 standard deviation. For STI the LOQ it was equal to the declared one, whereas for casein it was slightly higher (around to 0.5 mg/kg). Repeatability and recovery were evaluated on the same blank samples spiked with casein or STI. The performance obtained with spiked samples at 0.5 mg/kg for casein and 40 µg/kg for STI correspond to the requirements established in the European Standard EN 15633-1 (European Committee for Standardisation, 2009) and in the guidelines for validation of ELISA methods (Abbott *et al.*, 2010). In particular, the relative standard deviation for repeatability was less than 20% and the recovery within the range of 80-120%. The above-mentioned values (0.5 mg/kg and 40 µg/kg) were used as cut-off for the presence/absence of the allergens.

3. Results

The results relative to candies are shown in Table 1. Nineteen different type of candies were analysed: 8 products containing fruit juices or fruit preparations, 2 anise candies containing anise extract or flavour, 4 mint candies containing mint flavour or peppermint essential oil, 4 herb candies containing flavours and/or essential oils and/or herbal extracts, 1 liquorice candy containing liquorice paste. The preparations contain also sugar, glucose syrup, or dextrose in different proportion and combination together with other ingredients (such as citric acid, guar gum, pectin, tartaric acid, etc.). In the nine products with PAL, two different sentences are used in the label: 'may contain traces of milk' in five products and 'manufactured in a facility that also uses milk' in the other four. In all the samples analysed, with or without PAL, the casein was found less than 0.5 mg/kg.

Table 1. Casein content (mg/kg) in candies, with and without precautionary allergen labelling (PAL), examined.

ID	Product	PAL	Ingredients	Casein (mg/kg)
1	fruit-filled candies	no	sugar, glucose syrup, fruit juices, citric acid, guar gum, flavours	<0.5
2	fruit candies	no	dextrose, sugar, glucose syrup, fruit juices, citric acid, flavours	<0.5
3	lemon candies	no	sugar, glucose syrup, citric acid, flavours, plant extracts, colorants	<0.5
4	fruit-filled candies	manufactured in a facility that also uses milk	sugar, glucose syrup, fruit juices, citric acid, palm oils, guar gum, flavours	<0.5
5	citrus fruits candies	may contain traces of milk	sugar, glucose syrup, concentrated fruit juices, citric acid, orange essential oil, natural lemon flavour	<0.5
6	citrus fruits candies	manufactured in a facility that also uses milk	glucose syrup, sugar, citric acid, juice and orange pulp, flavours	<0.5
7	fruit-filled candies	no	sugar, glucose syrup, fruit preparation, pectin, citric acid, sodium citrate, natural flavours	<0.5
8	orange soft candies	no	sugar, maltodextrin, tartaric acid, rice starch, flavours, arabic gum, ascorbic acid, carnauba wax	<0.5
9	anise candies	manufactured in a facility that also uses milk	sugar, glucose syrup, flavours	<0.5
10	anise candies	no	glucose syrup, sugar, flavours, anise extract	<0.5
11	mint candies	may contain traces of milk	glucose syrup, sugar, natural mint flavour	<0.5
12	mint candies	manufactured in a facility that also uses milk	sugar, glucose syrup, flavours	<0.5
13	mint soft candies	no	sugar, glucose syrup, modified starches, natural flavourings (mint, anise), maltodextrin, arabic gum, liquorice extract, menthol, starch, carnauba wax	<0.5
14	mint candies	no	glucose syrup, sugar, peppermint essential oil	<0.5
15	Chinese rhu-barb sweets	no	sugar, glucose syrup, natural flavours	<0.5
16	menthol and eucalyptus candies	may contain traces of milk	glucose syrup, sugar, caramelised sugar, menthol, eucalyptus essential oil, natural flavours	<0.5
17	herbs candies	may contain traces of milk	sugar, glucose syrup, herbal plant extracts, liquorice extract, natural mint flavour, aromas	<0.5
18	herbs candies	may contain traces of milk	isomalt, sucralose, acesulfame k, polydextrose, flavours, herbal extracts, colorant	<0.5
19	liquorice candies	no	glucose-fructose syrup, sugar, liquorice paste, flavours	<0.5

In Table 2, the 15 samples analysed for the presence of soy are reported: 7 wheat flours with different content of ashes and proteins, 5 semolina including 2 baby foods, 2 durum wheat flours and 1 flour mix for cakes containing wheat flour and starch. The same precautionary label 'may contain traces of soy' is used in eight of these products. The presence of STI was found in 3 wheat flours and 1 semolina (2 with PAL and 2 without) in a range of 58-705 µg/kg of STI.

4. Discussion and conclusions

Thirty-four samples were analysed, 17 with PAL and 17 without. Overall, 11.8% of the samples were contaminated, however the contamination was found only in the wheat flour samples (4/15; 26.7%). The percentage of contaminated wheat products is almost the same in samples with and

without PAL, and equal to 25.0% (2/8) and 28.6% (2/7) respectively.

In Table 3, the main surveys reporting the prevalence of contaminated samples for milk and soy in different products, with and/or without PAL, are reported.

Not all studies examined both types of products, in particular 2 surveys (Crotty and Taylor, 2010; Zurzolo *et al.*, 2013) considered only products with PAL and 2 surveys only products without PAL (Bianchi *et al.*, 2016; Canadian Food Inspection Agency, 2014). With the exception of dark chocolate, the overall data showed that for milk the percentage of positive samples is extremely variable (0-42%) for products with PAL, while in products without PAL a low prevalence of contamination was found (2-3%). In particular, two of these surveys reported data about candies:

Table 2. Soy trypsin inhibitor (STI) content ($\mu\text{g}/\text{kg}$) of wheat flour samples, with and without precautionary allergen labelling (PAL), examined.

ID	Product	PAL	Ingredients ¹	STI ($\mu\text{g}/\text{kg}$)
1	semolina	no	durum wheat flour	<40
2	Tuscan semolina	may contain traces of soy	durum wheat flour	<40
3	semolina	no	durum wheat flour	265
4	baby food – wheat semolina	no	durum wheat flour, durum wheat flour diastase treated, minerals, vitamins	<40
5	baby food – biological wheat semolina	no	durum wheat flour, vitamin B1	<40
6	durum wheat flour	may contain traces of soy	durum wheat flour	<40
7	durum wheat flour	may contain traces of soy	durum wheat flour	<40
8	whole flour	no	wheat flour, type 0	<40
9	wheat flour for pizza	no	wheat flour, type 00	505
10	wheat flour	may contain traces of soy	wheat flour, type 0	<40
11	wheat flour	may contain traces of soy	wheat flour, type 00	705
12	wheat flour	may contain traces of soy	wheat flour, type 00	<40
13	wheat flour	may contain traces of soy	wheat flour, type 00	<40
14	wheat flour	may contain traces of soy	wheat flour, type 00	58
15	flour mix for cakes	no	wheat flour, type 00, wheat starch	<40

¹ Type 0: ashes max. 0.55 g – proteins min. 9.00 g/100 g dry matter; Type 00: ashes max 0.65 g – proteins min. 11.00 g/100 g dry matter.

Table 3. Surveys on the presence of unintended milk and soy in foods with and without precautionary allergen labelling (PAL).

Survey	Food	Allergen	% (positive samples / total samples)	
			With PAL	Without PAL
Ford <i>et al.</i> , 2010 USA	baking mixes, chocolate and non-chocolate candies, cookies, salty snacks, cold cereals, etc.	milk	10.2% (6/59)	3.0% (4/134)
Crotty and Taylor, 2010 USA	baked goods/mixes, chocolate and non-chocolate candies, cereals, frozen desserts, instant meals, etc.	milk	42.0% (34/81)	–
Spanjersberg <i>et al.</i> , 2010 Netherlands	dark chocolate	milk	100% (3/3)	100% (10/10)
Zurzolo <i>et al.</i> , 2013 Australia	chocolates, breakfast cereals, muesli bar, savoury biscuits, sweet biscuits	milk	0.0% (0/123)	–
Hirst, 2014 UK	ready meals, confectionery, cereals and cereal products, chilled and frozen desserts, snacks, yogurt, meat, etc.	milk	6.1% (29/474)	2.1% (10/474)
Bianchi <i>et al.</i> , 2016 Italy	meat products, bakery products, infant foods, etc.	milk	–	2.0% (16/791)
Food Safety Authority 2011 Ireland	baby foods, biscuits, breads, cakes, cereals, ready meals, etc.	soy	3.3% (1/30)	4.7% (5/106)
CFIA, 2014 Canada ¹	flours, baked goods, baking mixes, breads, cookies, etc.	soy	–	44.1% (171/388)
Khuda <i>et al.</i> , 2016 USA ²	bakery (bread, cookies, cakes, pastry, etc.)	soy	13.7% (10/73)	15.2% (32/211)
	snack (chips, crackers, bar, popcorn, etc.)	soy	19.2% (14/73)	24.2% (51/211)
			9.0% (7/78)	6.1% (12/196)
			9.0% (7/78)	10.7% (21/196)

¹ CFIA = Canadian Food Inspection Agency.

² Two different ELISA kits were used in the study.

in the study of Ford *et al.* (2010) no samples contained milk residues (0/11 candies) as in our case; instead in the study of Crotty and Taylor (2010) 17% of samples (1/6) with a precautionary statement contained milk residues.

Regarding soy, the percentage of contaminated samples without precautionary statements is much higher (5-44%) than those found in products with PAL (3-19%). Only the survey carried out in Canada (Canadian Food Inspection Agency, 2014) gives specific data on flour contamination prevalence, that correspond to 54% of the samples without PAL examined. In addition, a study carried out by Remington *et al.* (2013) showed that a high percentage of wheat flours were contaminated (62.8%; 22/35), but it does not provide information on the presence/absence of PAL. Data obtained in our study confirm that soy contamination in wheat flours has a relatively high prevalence, probably due to co-mingling of soy with wheat during harvest, transport, and storage (Do *et al.*, 2018; Khuda *et al.*, 2016b; Remington *et al.*, 2013).

The results presented in this paper are obviously preliminary: it is necessary to increase the sample size, evaluate more than one lot for each sample (heterogeneous allergen distribution can result in variable results between lots or within a lot), and sampling more food categories.

Nevertheless, this study is the first carried out in Italy that provides a snapshot, even if limited, on the correspondence between presence/absence of PAL and contamination.

In conclusion, the obtained results, together with literature data, show that the presence of undeclared allergens in foods labelled with PAL is extremely variable, depending on geographic differences, selected food categories, choice of allergen detection methodology, etc., (Allen *et al.*, 2018; Do *et al.*, 2018; Graham and Eingemann, 2018), and it does not necessarily represent a health risk (Graham and Eingemann, 2018). On the other hand, the analyses performed on products without PAL, highlight that the absence of precautionary statements does not imply a food is certainly safe for consumption by allergic individuals.

The Authors agreed with the opinion expressed in recent reviews (Allen *et al.*, 2018; Graham and Eingemann, 2018) that, although further systematic surveys of foods with and without PAL could help to clarify the current situation, global efforts to define threshold levels of allergens are essential to provide a risk-based approach to PAL, and to furnish public health guidance to food industry. Without the adoption of Reference Doses by public health authorities, the food industry appears to have difficulty in adopting a risk-based approach to PAL, preventing further progress in the protection of allergic consumers.

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