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The Practice and Perception of Precautionary Allergen Labelling by the Australasian Food Manufacturing Industry

The food industry's practice and perception of precautionary allergen labelling

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Abstract

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Abstract

Background

The precautionary allergen labelling (PAL) and Voluntary Incidental Trace Allergen Labelling (VITAL®) tools were designed by industry to assist consumers with selecting safe foods for consumption. However, a sizeable proportion of food products bear no label and it

is unclear whether these products are free from allergens and therefore safe to consume or have simply not undergone a risk assessment and therefore remain unlabelled for that reason.

Objective

To assess the prevalence of unlabelled products that have undergone a risk assessment process and to examine the factors influencing industry's uptake of the VITAL® process.

Methods

A web-based questionnaire was distributed to Australasian food and grocery manufacturers.

Results

One hundred and thirty seven Australasian manufacturers were contacted and 59 questionnaires were returned (response rate: 43%). The respondents represented 454 different manufacturing sites. Manufacturers reported that 23% (95% CI 19-28) of products (n = 102/434) that had been through the VITAL® risk assessment process had no PAL statement on the label. 34% (95% CI 30-38), (n = 204/600) of products that had undergone another (non-VITAL®) risk assessment process had no PAL statement. In examining the factors that influenced industry's uptake of the VITAL® process, 25 manufacturers reported on factors that influenced the uptake of the VITAL® process, 76% (CI 95% 55-91) reported that VITAL® was an effective tool because it was based on science; 52% (CI 95% 31-72) reported that it was too time-consuming and 36% (CI 95% 18-57) identified a concern with it not being endorsed by the government.

Conclusion and clinical relevance

Currently we estimate that at least 30% of products may have been through a risk assessment process and yet bear no PAL statement on the label. Permissive labelling could be incorporated onto these products if they have been assessed to be safe for consumption.

Keywords

Permissive labelling, precautionary allergen labelling (PAL), Voluntary Incidental Trace Allergen Labelling (VITAL), food allergy

Introduction

Currently there is no cure for food allergy, therefore food allergic consumers rely on accurate and useful information on food labels to assist them when choosing safe foods. Despite industry's best efforts to provide accurate and useful information on food product labels, consumers and health care providers question the effectiveness of precautionary allergen labelling (PAL); 65% of consumers surveyed reported that they often ignore certain PAL statements [1-3].

This current confusion regarding the effectiveness of PAL is not only seen by Australasian consumers and health care providers but also in most western and some developing nations where processed food is - or is becoming - prevalent [4-6]. The status quo of PAL as a non-standardised and voluntary practice may have contributed to this current confusion, yet the Australian manufacturing industry has led the way by being the first to set an industry standard around PAL with the introduction of the Voluntary Incidental Trace Allergen Labelling (VITAL®).

VITAL® was developed by the Allergen Bureau and launched in 2007. It is a not for profit organisation funded by the food industry to develop and acquire information regarding the management of food allergen risks [7]. VITAL® is a risk assessment tool that enables manufacturers to evaluate the allergen risk contributed by raw materials and the manufacturing environment and to determine whether a food product should carry a PAL statement based upon reference doses. These doses are defined milligrams of protein in which the manufacturer will calculate the action levels based on product consumption. Reference doses are based on the thresholds of individuals in the representative population. These have been defined as Eliciting Dose 01 or ED01 (predicted to cause a reaction in 1% of the allergic population) and Eliciting Dose 05 or ED05 (predicted to cause a reaction in 5% of the allergic population).

VITAL® action levels are calculated *using* reference doses and are based on a combination of both ED01and ED05 depending on sufficient data availability [8] . If a product in the VITAL® program contains a concentration of allergen above a company's defined action level, then this particular product carries the PAL statement "may be present" which is the only statement that can be used with VITAL®. If the concentration of allergen in the product is lower than the company's defined action level, it does not require a PAL statement. VITAL® action levels are based on scientific evidence from reference doses derived from clinical testing [9].

A major limitation of the VITAL® process is that products that have fallen below the defined action level (and are thus considered to be safe for consumption by food allergic consumers) bear no information on their labels that alert consumers to this difference. Therefore, it is unclear whether these products contain trivial amounts of allergens and are safe to consume or whether they have simply not undergone a risk assessment and remain untested and therefore unlabelled [3].

The Centre for Food and Allergy Research (CFAR) is a Centre of Research Excellence in Paediatric Food Allergy that is funded by the Australian National Health and Medical Research Council. In November 2014, CFAR organised a roundtable discussion which included major stakeholders with an interest in PAL. These stakeholders included researchers, government representatives, health and industry professionals and consumers [1].

The key points of the roundtable discussion form the aims of this study. They were:

1. To assess the prevalence of unlabelled products that have used a risk assessment process (RAP)
2. To examine factors influencing industry's uptake of the VITAL® process [1, 10].

Methods

During the months of April to May 2016, a web-based questionnaire was designed and distributed via email to 137 Australasian food and grocery manufacturers. These are businesses in the food industry that are involved in manufacturing, supplying or selling products that could potentially contain food allergens. They are current members of the Australian Food and Grocery Council (AFGC) and the Allergen Bureau. These respective organisations are industry funded and represent the majority of manufacturers throughout Australasia. The organisations distributed the questionnaire to all their members.

The members received two reminder emails during those months. Participants were asked that they only report their business in Australasia and that the survey be directed to the most appropriate person within their business. Ethics was granted by the Royal Children's Hospital in Melbourne, Australia (HREC: 36029 A).

Statistical methods

Results were entered into a data sheet. Data was presented as observed proportions and 95% confidence intervals were calculated in *Stata (Stata Corp 2011. Stata Statistical Software Release 12 College Station TX: StataCorp),* assuming a binomial distribution. Missing responses were excluded from analysis. The total numbers therefore differ for some responses. For the analysis of the benefits and challenges of using VITAL® , the responses of "agree" and "strongly agree" were first combined and then the proportion of the combined responses and the 95% confidence interval were calculated.

Results

Demographics

One hundred and thirty seven Australasian manufacturers were contacted via industry funded organisations (the Australian Food and Grocery Council: n = 107; and the Allergen Bureau: n = 30). Of the 59 questionnaires returned (response rate: 43%), respondents were from companies that employed < 50 (20%), < 100 (9.0%), < 200 (9.0%), 200-1000 (26%) and >1000 staff (36%). The respondents represented 454 different manufacturing sites throughout

Australasia with Victoria, New South Wales and Queensland being the main reporting sites. Of the total manufacturing sites (n=46), 78% were finished product manufacturers.

Of the products processed by manufacturers who responded, the most common were cereal products at 18% (n = 851), milk products/dishes at 16% (n = 749), savoury sauces at 9% (n = 430) and meat, poultry and game products/dishes at 7% (n = 313) (Table 1).

Allergen management

Hazard Analysis and Critical Control Point (HACCP) is a management system in which food safety is addressed. This process is currently not a legal requirement in Australasia. The HACCP objective is analysis and control of biological, chemical and physical hazards from raw material production, procurement and handling. It also examines the manufacturing process from distribution and consumption of the finished product. The use of HACCP was reported by 98% of manufacturers (n = 45); 100% reported providing training to their staff in the management of allergens and 98% reported that allergens were included in their food safety plan. The food safety plan is a document indicating how a food business will control the safety hazards associated with their food handling activities. Certain high risk food businesses are required to have food safety programs.

Allergen testing/food recall

26 manufacturers reported which types of allergens were tested for in incoming products (in raw ingredients delivered to the manufacturing site prior to the manufacturing process taking place). The most common allergens tested for were cereals containing gluten at 58%; wheat, cow's milk at 50%; and soya at 46% (figure 1A). When testing incoming ingredients, two approaches were predominantly used: external testing (53%) and internal Enzyme Linked Immunosorbent Assay (ELISA) testing at their manufacturing site (50%). These approaches are not mutually exclusive. 34 manufacturers reported which types of allergens were tested for in the finished product (with "finished product" referring to the ingredients that have undergone the manufacturing process but have not yet reached the distribution phase). The most common items tested were cereals containing gluten (66%), cow's milk (53%), wheat (50%), tree nuts (41%) and eggs (35%) (Figure 1B). When testing the ingredients of finished products, two approaches were predominantly used: performing ELISA at their

manufacturing site (63%) or having the test conducted externally (43%). These groups are not mutually exclusive.

45 manufacturers reported on the implementation of a food recall with 29% of food recalls reported to be due to the presence of an unlabelled food allergen.

Gluten free label claims

The use of gluten free label claims was reported by 63% of manufacturers (27 of 43). Of those who responded to further questions on gluten free labelling (n = 26), 62% reported that every batch was tested for gluten. *Two approaches* were predominantly used by manufacturers: ELISA (62%) or having the test conducted externally (54%). These groups are not mutually exclusive.

Precautionary allergen labelling

Precautionary allergen labelling (PAL) was reported to be used by 74% of manufacturers (n = 43). Of the 30 manufacturers that reported the specific allergen that received a PAL statement, cereals labelled for gluten and tree nuts were most common (57% each) followed by peanut (53%), soy (50%) and sesame (50%). The most common types of PAL statements used by industry were “may contain traces of” at 27%, “may contain” at 27% and “may be present” at 23%.

The most common types of risk assessment processes used by industry to determine if PAL was required (n=32) were a combination of both VITAL® and internal company processes (63%), only internal company processes (28%) and only VITAL® (9%).

The benefits and challenges of using VITAL®

The benefits of using the VITAL® risk assessment process were reported by 25 respondents: 83% (CI 95% 59-83) agreed or strongly agreed with the statement: “It allows you to save the assumption as part of the risk assessment process”. (The VITAL® calculator has the function for manufacturers to “save the assumption” and come back to the risk assessment at a later stage. This is helpful for manufacturers particularly where a product may contain multiple ingredients.) 76% (95% CI 55-91) agreed or strongly agreed with the statement: “VITAL® is

based on scientific evidence" and 75% (95% CI 55-91) agreed or strongly agreed with the statement: "VITAL® assists us for allergen cross contact".

The challenges of using the VITAL® risk assessment process were reported by 25 respondents as follows: "It is too time-consuming" - 52% (95% CI 31-72) agreed or strongly agreed; "the government has not endorsed the use of VITAL®" - 36% (95% CI 18-57) agreed or strongly agreed; and "our manufacturing plant is too complex" - 40% (95%CI 21-61) agreed or strongly agreed (Figure 2A & B).

Unlabelled products

Manufacturers reported that 1034 different products from various categories had undergone a risk assessment process. Of these, 42% (95% CI 39-45) (n = 434) had been through the VITAL® risk assessment process *of which* 77% (95%CI 72-80) (n = 332) *carried* VITAL's® statement: "may be present", whereas 23% (95% CI 19-28) (n = 102) had no statement. In contrast, 58% (95% CI 55-61) (n = 600) had been through another risk assessment process *of which* 66% (95%CI 62-70) (n = 396) *carried* a PAL statement, whereas 34% (95% CI 30-38) (n = 204) contained no statement at all. Of those products that had been reported to have undergone a risk assessment (n=1034), 30% (95%CI 27-32) bear no PAL statement on the label (Figure 3, Table 2).

Discussion

This is the first Australasian study to examine food manufacturing industry practice with regards to the management of food allergy testing and labelling. It has a global interest due to the international attention regarding the VITAL® process. The study shows that although the use of HACCP is not currently a legal requirement in Australasia, industry is endeavouring to reduce the risk of cross contact by providing training to all staff in the management of food allergy. The study also shows that of responders, 41 to 60% of industry (depending on the food allergen) actually reported performing analytical testing on the incoming ingredients or the finished products.

The result of this study shows that within a supermarket setting, 30% of products (when combining both VITAL® & PAL) have undergone a risk assessment process but have no label on their products.

In regards to the perceived benefits of PAL, industry regarded VITAL® as an effective tool which was based on science. In contrast, the major reported challenges that may have impeded industry's uptake of the VITAL® process were the perceptions that it was too time-consuming (which may result in a loss of production), that VITAL® was not endorsed by any government agency and the complex nature of the responders' manufacturing plant (which may be due to the modern manufacturing process).

In examining labelled and unlabelled products, the study shows 434 products underwent a VITAL® assessment only. Of these, 77% were distributed with a PAL statement. 600 products underwent another risk assessment; 66% of these were distributed with a PAL statement. The other products that underwent either the VITAL® or other risk assessment process were distributed with no PAL statement (Figure 3).

Of food products from manufacturers who reported using VITAL® as the risk assessment process, the majority of foods were labelled with a PAL statement.

Possible explanations for this may be that industry does perform the risk assessment but may still have complications with *particulate* contamination. Alternatively they may be applying an overabundance of caution due *to the uncertainties related to information from suppliers about unintended allergen presence.*

The strengths of the study were an equal balance between small and large manufacturing sites and that our respondents represent 454 different manufacturing sites throughout Australasia. We therefore believe that this study represents industry's current practice in regards to PAL. A limitation to the study was that we relied on each manufacturing plant to have the survey completed by the most appropriate person within their plant. We tried to *reduce* this limitation by asking the industry funded organisations with which we collaborated to contact each manufacturing site and ask that only the most suitable person complete the survey. In addition, RAP is such a complex and specialised area that it is unlikely that anyone without extensive knowledge of food safety risk review and food labelling would have undertaken the

task of completing the survey. A further limitation was that the overall response rate was 43%. It is possible that responders who were more engaged with manufacturing risk assessment processes were more likely to respond, which may impair the generalisability of the findings across the whole food manufacturing sector.

In this study, 74% of manufacturers used PAL. This high prevalence may have public health implications, as Marchisotto et al. (2016) showed in their study regarding the global perceptions of food allergen labelling. In this study, the author examined the attitudes of consumers regarding food labelling in 16 countries. It demonstrated that consumers may develop their own risk assessment based on PAL labels and appear to trust PAL labels to provide an estimate of reaction risk [11]. This trust in PAL may come without the consumer's knowledge that PAL is voluntary, unregulated and not endorsed by any government agency. We have also previously shown that consumers grade the level of perceived risk based on the wording of the precautionary statements [3].

Despite the high prevalence of products that have gone through the VITAL® process and carry a PAL statement, this study has shown that a number of products from specific categories have undergone a risk assessment process and have no PAL statement. Are we to assume that they are safe for the food allergic consumer?

Recently experts have suggested that food labelling should also identify safe and suitable foods for allergy affected individuals, not just the foods which should be avoided (ie those with precautionary labelling). This was termed "permissive labelling". Permissive labelling could be used to indicate those products that have been through a risk assessment process and bear no PAL statement [1]. However, it would take further investigation into these products *to examine the frequency and level of unintended allergen presence* , if any, and for all stakeholders to agree that food products that bear no label are safe and suitable for consumption by people with food allergies. Nevertheless, permissive labelling would help to decrease the uncertainty surrounding industry's current labelling practices. The current labelling practices have been shown by DunnGalvin et al. (2015) to have contributed to an increase in stress and anxiety and a reduction in the quality of life for food allergic consumers [12].

All stakeholders have a role to play in ensuring that food labelling, particularly PAL, is clearly understood by consumers. A possible way forward with this may be to introduce a policy where the use of the VITAL® process or its equivalent becomes mandatory. This would ensure that only one risk assessment process is used and only one PAL statement, rather than the plethora of statements that are currently in use. Although the current uptake of the VITAL® process by the Australasian manufacturing industry has been slow, if the concerns that we have highlighted within this study are addressed, this may increase industry's uptake of VITAL®.

Conclusion

The use of precautionary allergen labelling is prevalent within the food manufacturing industry. Currently there are numerous food products that have undergone a risk assessment process and bear no PAL statement on the label. Permissive labelling could be incorporated onto these products if further investigation finds these products to be safe for consumption. There is an urgent need for the standardisation of PAL. The VITAL® process could lead the way, but for this to occur, remaining issues raised by industry need to be addressed.

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Conflict of interest

The authors declare that there are no relevant competing interests.

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386 Table 1: The number of reported foods manufactured by 46 manufacturers

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Product type	Number of products manufactured	Percentage
Cereals and cereal products*	851	18.6
Milk products and dishes	749	16.4
Savoury sauces and condiments	430	9.4
Cereal based products and dishes#	414	9
Meat, poultry, game products and dishes	313	6.8
Egg products & dishes	247	5.4
Special dietary foods	236	5.1
Confectionery & cereal/nut/fruit/seed bars	235	5.1
Snack foods	203	4.4
Vegetable products & dishes		

	151	3.3
Soup	147	3.2
Seed & nut products	148	3.2
Fish products & dishes	105	2.3
Seafood products & dishes	103	2.2
Legume & pulse products & dishes	91	1.9
Infant formula & foods	74	1.6
Dairy & meat substitutes	68	1.4
Total	4565	100

388 ** Includes bread, rice, noodles, pasta and breakfast cereals;*

389 *# Includes sweet biscuits, savoury biscuits, cake, sweet pastry, savoury pastry, pizza,*
390 *sandwiches and burgers.*

391

392 Table 2: Comparison of the Risk Assessment Process (RAP)* and outcomes for
393 each specific food product type

394 **comparison is presented as the percentage of finished products with and without a PAL statement*

395

Food product	PAL	Type of RAP	PAL Label	No PAL label
Cereal products	241	VITAL®	30	100%
		Other	211	47%	53%
Milk products	194	VITAL®	100	-	-
			94	73%	27%

						396
		Other				
Cereal base products	200	VITAL®	180	100%		
		Other	20	100%		
Meat, poultry, game products & dishes	4	VITAL®	4	100%		
		Other	0			
Savoury sauces & condiments	260	VITAL®	110	34%	66%	
		Other	150	100%		
Snack foods	96	VITAL®	10	20%	80%	
		Other	86	66%	34%	
Egg products & dishes	2	VITAL®	2	100%		
		Other	0			
Special dietary food	100	VITAL®	0			
		Other	100	-	-	
Confectionery & cereal/nut/fruit/seed bars	6	VITAL®	6	100%		
		Other	0			
Vegetable products & dishes	8	VITAL®	0			
		Other	8	100%		
Seed/nut products & dishes	24	VITAL®	2	100%		
		Other	20	100%		
Soups	16	VITAL®	10	100%		
		Other	6	100%		
Fish products & dishes^	0	VITAL®	0			
		Other	0			
Seafood products & dishes^	0	VITAL®	0			
		Other	0			
Legume/pulse products & dishes	3	VITAL®	0			
		Other	3	100%		
Infant formula & foods	50	VITAL®	50	90%	10%	
		Other	0			
Dairy/meat substitutes#	73	VITAL®	0			
		Other	43	-	-	

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398 ^ *No foods in these categories were reported to have undergone any risk assessment process.*

399 *# Numbers do not add up due to participant error.*

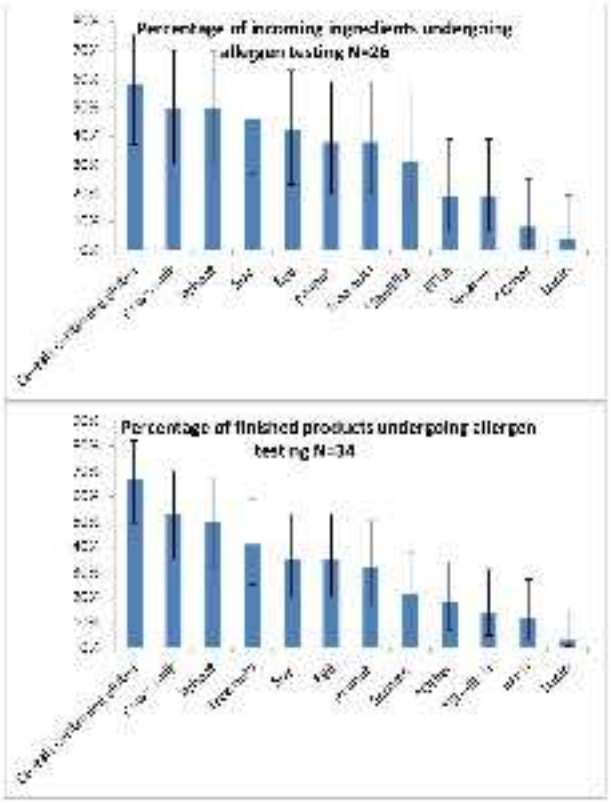

Figure 1A & B: Manufacturer practice when testing incoming ingredients and finished product

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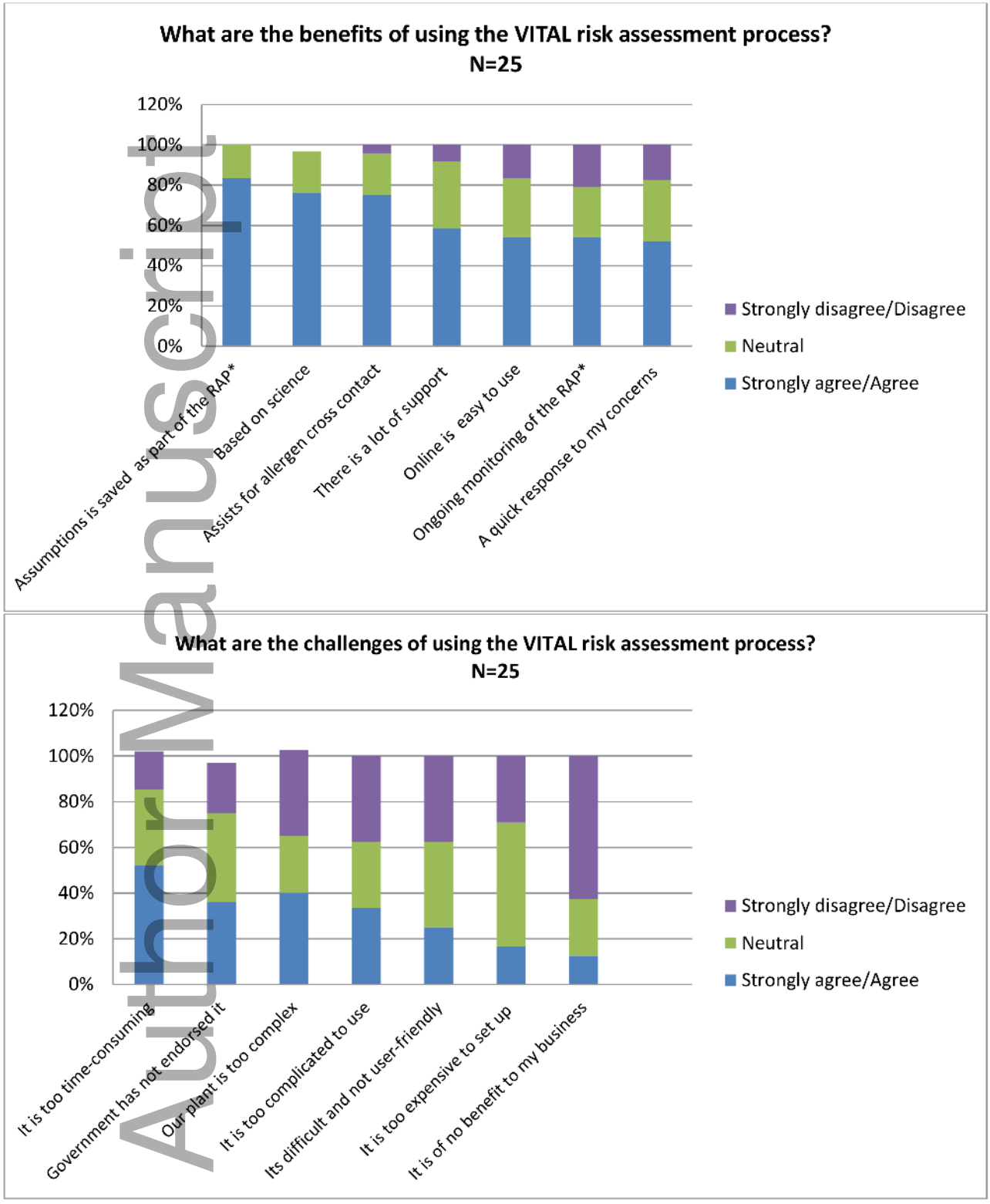

Figure 2A & B: Industry's perspective of the benefits and challenges of using VITAL®

** RAP: Risk Assessment Process*

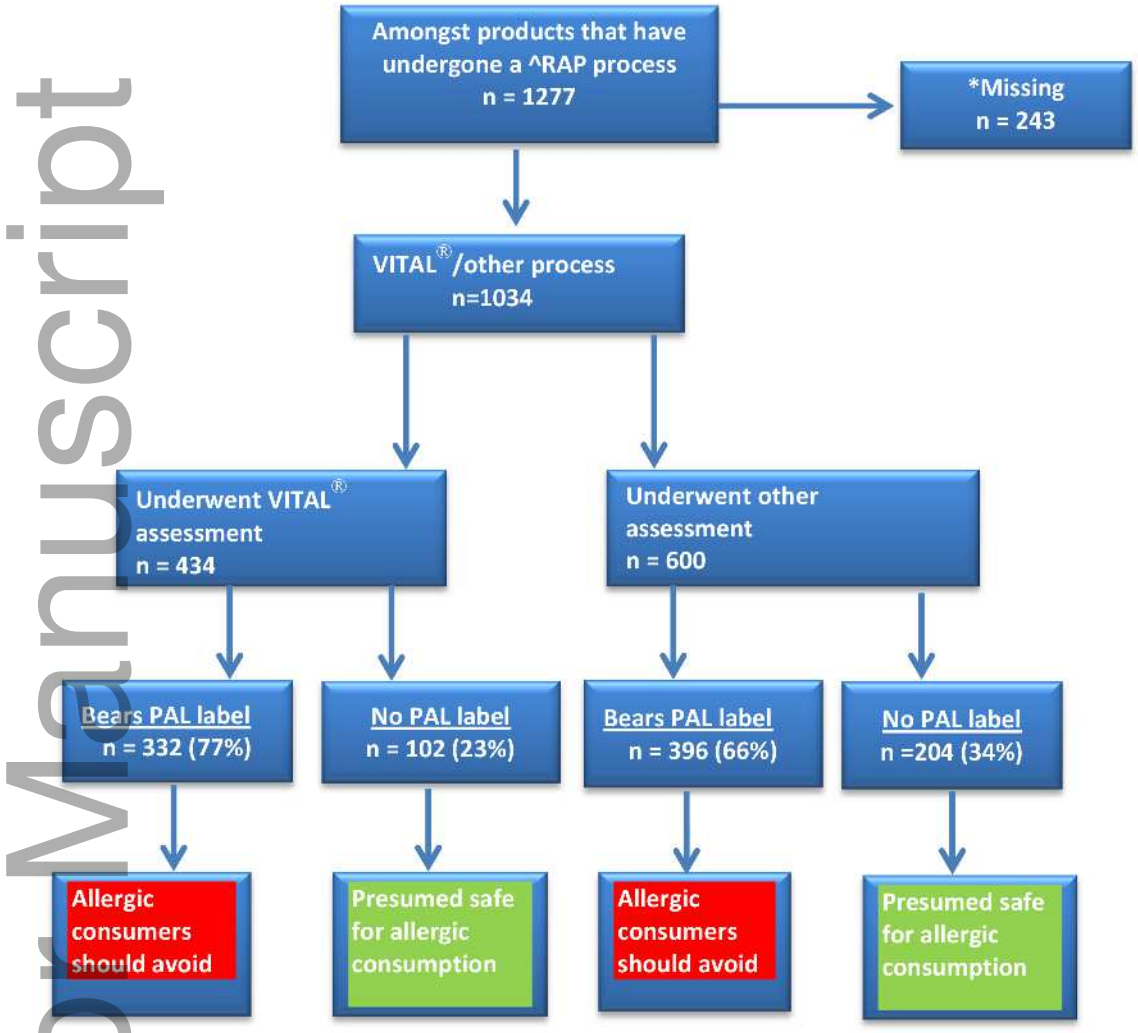

Figure 3: Comparison of Risk Assessment Processes and the percentage of finished products with and without a Precautionary Allergen Labelling (PAL) statement.^ Risk Assessment Process. *No information was provided on what type of risk assessment process these products underwent.

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