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Confusion in Design and Facilities of Layout Plan: GMP Requirements

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Abstract: The effectiveness of the food safety system is influenced by design and facilities layout. The purpose of this study is to identify the confusion over design and facilities requirement in food premise on GMP MS 1514:2009 requirements among industries, consultants and authorities. Among the aspects discussed regarding design and facilities are location, design and layout, floors, walls, doors and windows. The methodology used is through questionnaires involving 96 respondents and respectively, 32 from each group. The confusions are grouped into low, medium and high based on the method established. The results show there were confusion in the requirements of design and facilities regarding location, design and layout, floors, walls, doors and windows. There were significant confusions in meeting the requirements of the design and facilities among industries, consultants and authorities. The authorities are found to contribute to the highest confusion followed by industries and consultants. The causes of confusion over design and facilities to industries, consultants and authorities have been discussed. Among the possible factors that contribute to confusion are lack of experiences, availability of technical guideline and reference documents, training effectiveness and understanding of the requirements. The confusion that occurs affects the level of hygiene and food safety as well as harm consumers.

Key words: Food safety system, GMP, HACCP, technical, effectiveness, hygiene

INTRODUCTION

The development of GMP (Good Manufacturing Practices) and HACCP (Hazard Analysis Critical Control Point) in Malaysia refers to MS 1514: 2009 and MS 1480: Department Standard Malaysia (2007). Issues related to this are inconsistencies and confusion of food safety system requirements by the standards mentioned in the development and implementation of the GMP and HACCP systems (Losito *et al*., 2011) which negatively impact industry practices. Mukantwali *et al*. (2013) found that infrastructure which includes insufficient processing rooms, cross-contamination and errors in design layouts and equipment are some of the technical obstacles in the implementation of HACCP. Issues of design and facilities were also reported in the states of the Western Balkans through an audit report on the layout plan (8.6%) and cross-contamination (8.9%) (Djekic *et al*., 2011). Domenech *et al*. (2011) reported that number of non-conformities were high over design and infrastructure in SMEs premises.

However, no detailed studies have been carried out on the problem or confusion related to structural design and facilities in Malaysia. Most of the studies conducted in Malaysia on GMP requirements were related to personnel hygiene and cleaning and sanitation (Soon and Baines, 2012; Tan *et al*., 2013; Saad *et al*., 2013 and Sani and Siow, 2014). There was a studied has been carried out in Malaysia in relation to design aspects over Malaysian SME industries (Hasnan *et al*., 2014). However, the study did not precisely discuss on the design aspects, instead of the effect and obstacles of Malaysian SMEs to fulfil the design requirements (Panisello and Quantick, 2001). Therefore, this study aims to identify the aspects of the confusion that occur related to the design and facilities from the perspective of the industry, consultants and authorities, so that, measures of improvement can be made.

MATERIALS AND METHODS

The selection of respondents: The study is done by involving 3 parties namely the industry, consultants and authority directly involved with the implementation of GMP in the Klang Valley. Industry respondents are selected from the HACCP team and knowledgeable about GMP. One of the respondents selected from the industry usually holds the position as coordinator of HACCP. Selection of consultants is made through individuals or companies which provide consultancy and training

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Table 1: Confusion questionnaires

Code	Aspect	Question
G2	Location	Needs control actions including evacuating the premise in the event of flooding or uncontrolled pest
G12	Design/layout	The layout plan requires a dressing room to control the contamination or cross-contamination caused by food handlers
G14	Design/layout	Application and practice of cleanliness, facilities and equipment in areas with high levels of cleanliness must be different with a low level of hygiene
G18	Floor	The floor surface must be flat without the appropriate gradient allowed in food processing premises
G23	Wall	The curve between the walls and the floor (curving) is not needed in food processing plant
G32	Door	Untreated wooden door is not allowed in food premises
G38	Window	Window installation needs to be constructed to reduce the accumulation of dirt, permit easy cleaning and prevent the entry of insects

Table 2: Confusion Score Index (CSI) of food safety scheme certification

Fq. of answer	Score (%)	Confusion	Results
True> false	75-100	Low	Appropriate
True = false	50-74	Medium	Marginal
True<false	0-49	High	Unsafe

Nor *et al.* (2016)

services on GMP. In the meantime, the selection of authorities is done from certification bodies mainly from the government sector which provides certification for GMP as they are given the authority to oversee the matter given to them by the government of Malaysia.

Development of confusion level: The development of the level of confusion is based on the percentage of correct or incorrect answers from the questionnaire responses. The percentage values used to assess the level of understanding on HACCP knowledge in the questionnaire are 'Appropriate', 'Medium' and 'Unsafe' (Wallace *et al.*, 2005). However, there is no percentage scale range given. For the purpose of the study, the range of percentage is done through the risk-based method of food premise grading systems used in the Arab Union Nations (Al-Kandari and Jukes, 2011). The grading is based on the following percentage A: 100-90, B: C: 89-75, 74-60, D: 59-45 and E: 44-30. The percentage is then used to set the level of confusion from the respondent feedbacks on the questionnaires as shown in Table 1 and 2.

Pre-test: Pre-test was performed on 10% of the respondents from the total sample population involving the industry, consultants and authorities to ensure clarity, understanding and finalise the content of the questionnaire. The sample concerned was no longer used in the actual study. The results of the pre-test were analyzed to determine the reliability of the alpha coefficient (0.8).

Sampling and data collection: The determination of sample size is based on the equation with the approximate ratio formula accuracy 0.07 at 95% confidence levels (Daniel, 1999). The number of samples (N) is 96 respondents which was then divided into 3 groups, namely industry, consultants and authorities with 32 respondents per group. Industry respondents were selected from companies that have been certified with GMP/HACCP certification from MOH, DVS and SIRIM. Consultants were selected through a list of registration consulting firms in the Klang Valley or known private consultants. However, the auditors were selected from a list of MOH, DVS and SIRIM personnel. The questionnaire were circulated to respondents via. email, postal mail and closed contacts and by hand. Respondents were given a period of 2 months to complete the questionnaire before being grouped and coded for analysis.

Statistical analysis: The analytical methods used are descriptive analysis, frequency analysis, cross tabulation and ANOVA. Frequency analysis is used to determine the percentage of confusion with in the group. Cross-tabulation was conducted to obtain a percentage of total confusion between the group and descriptive analysis aimed to get the value of the mean and standard deviation in the group to determine the cause of the highest incidents of confusion. In the meantime, ANOVA was done to determine the differences between the groups with significant confusion fixed at the value of $p<0.05$.

RESULTS AND DISCUSSION

Location: The results in Table 3 have shown only 68% of respondents agreed to evacuate to safer place in case of flooding and uncontrolled pest. Industries have shown the highest percentage (93.8%) and authorities scored the lowest value (46.9%). Min value 2.40±0.61 of authorities is the lowest value given the correct answers and it was a significant different among the groups with $p<0.05$. The level of confusion regarding this and the rest of the topics discussed is referred to Table 1-3.

The industry is certainly more aware of the need to transfer their industry to a safer location based on their experiences with the real problems and consequences that might occur in residential areas. However, authorities did not experience any difficulties with the location of the

Table 3: Results of confusion over design and facilities

Question/respondent	Uncertain-1 (%)	Not agree-2 (%)	Agree-3 (%)	Mean±SD	p-values within group
G2					
Industry	3.1	3.1	93.8	2.91±0.39	0.002
Consultant	6.3	28.1	65.5	2.60±0.61	
Authority	6.3	46.9	46.9	2.41±0.61	
Total	5.2	26.0	68.8	2.63±0.58	
G12					
Industry	0.0	3.1	96.9	2.97±0.18	0.000
Consultant	0.0	3.1	96.9	2.97±0.18	
Authority	0.0	50.0	50.0	2.50±0.51	
Total	0.0	18.8	81.3	2.81±0.39	
G14					
Industry	12.5	15.6	71.9	2.59±0.71	0.010
Consultant	0.0	3.1	96.9	2.97±0.18	
Authority	0.0	31.3	68.8	2.69±0.47	
Total	4.2	16.7	79.2	2.75±0.52	
G18					
Industry	0.0	53.1	46.0	2.47±0.51	0.021
Consultant	15.6	59.4	25.0	2.09±0.64	
Authority	3.1	93.8	3.1	2.00±0.25	
Total	6.3	68.8	25.0	2.19±0.53	
G23					
Industry	3.1	90.6	6.3	2.03±0.31	0.021
Consultant	12.5	75.0	12.5	2.00±0.51	
Authority	6.3	56.3	37.5	2.31±0.59	
Total	7.3	74.0	18.8	2.11±0.50	
G32					
Industry	0.0	100.0	0.0	2.00±0.00	0.001
Consultant	9.4	87.5	3.1	1.94±0.35	
Authority	3.1	65.6	31.3	2.28±0.52	
Total	4.2	84.4	11.5	2.07±0.39	
G38					
Industry	0.0	34.4	65.6	2.66±0.48	0.002
Consultant	3.1	9.4	87.5	2.84±0.45	
Authority	0.0	0.0	100.0	3.00±0.00	
Total	1.0	14.6	84.4	2.83±0.40	

industry because they cannot always be at the location proposed as well as do not suffer the consequences of wrong placements. Most of the authoritie's respondents disagreed with moving out of factories to other, safer areas due to the cost incurred.

Design and layout: Table 3 have shown only 81.3% of respondents agreed to provide changing rooms in the premise plant layout (G12). Industries and consultants have shown the highest percentage (96.9%) and authorities scored the lowest value (50.0%). Min value 2.50±0.51 of authorities is the lowest value given the correct answers if compared to other groups of respondents. A significant different has been identified among the groups ($p<0.05$) for providing of changing room among the groups. According to Ministry of Health of Malaysia (2010) changing room is important infrastructure to be provided as a prevention area to control contamination by food handlers. Meanwhile, results for G14 have shown 79.2% of respondents agreed over the different practice is required for different areas. Consultants is the highest percentage (96.9%) and authorities scored the lowest value (68.80%). Min value 2.69±0.47 of authorities is the lowest value given the correct answers and the results were significantly different ($p<0.05$) among the groups. The level of cleanliness area in plant layout is divided into 4 zones which one of them is high clean zone (Cramer, 2003). The aims of this area to control all hazards and protecting equipment and facilities from exposed to contaminated working environment and maintaining the positive pressure. With all the explanations it means the practice of hygiene must follow the area where we research.

The confusion of authorities over this issue might be due to lack of technical knowledge and effective GMP training. GMP training needs to be more specific to clarify the requirements of the process and research procedures according to the zone assigned to control all forms of food contamination whether biological, chemical or physical. The authorities may view that high costs is required to prepare all facilities to the appropriate level of cleanliness and risk area. Previous research reported that the cost is the main obstacles in the infrastructure involving food premises (Fotopoulos *et al*., 2011; Ragasa *et al*., 2011; Macheka *et al*., 2013).

Floor: In response to floor surface (G18) Table 3 have shown 68.8% of respondents disagreed over floor must have appropriate gradient. Authorities have shown the highest percentage (93.8%) of correct answers and authorities scored the lowest value (53.1%). Min value 2.47±0.51 of industries is the lowest value given the correct answers compared to the rest of groups. Significant different has been identified over this issue between the groups. Floor surfaces should be flat for food premises with an appropriate gradient to avoid stagnant water from accumulating and becoming a breeding ground for microorganisms (Moerman, 2010). Floor surfaces must have a slope with an estimated 1-2% (Lelieveld *et al*., 2005).

The confusion of industries over the floor requirements perhaps due to lack of criteria and specification about the technical requirements on design and facilities. Without the technical requirements industries, consultants and authorities have no guideline to construct and build the premise as standard needs and eventually lead to inconsistencies among them.

Wall: In terms of wall, 74.0% of respondents in Table 3 agreed no need to have curve between floor and wall (G23). Industries scored the highest percentage (90.6%) of correct answers and authorities scored the lowest value (56.3%). Min value 2.31±0.59 of authorities is the lowest value given the correct answers and was observed significant different among the groups. Ministry of Health of Malaysia (2010) joint between floor and wall must have a curve or no 90° angels.

This results have shown inconsistencies of authorities in interpreting the standard requirements. Misinterpretation of standard requirements among authorities will be followed by industries and consultant to wrongly set up the facilities. The study through photo taking by Jali *et al*. (2016) also shown some confusions by industries in relation to curve between floor and wall. The need of curving is important in GMP plant layout in order to permit easy cleaning and preventing stagnant water. As stagnant water will be a suitable place for the growth of microorganism mainly listeria monocytogenes (Moerman, 2010). Various materials can be used for building the curve such as epoxy cement and pieces of stainless steel plates. The size of the curve must be about 1 inch radius or more (Schmidt and Erickson, 2014).

Door: With regard to doors (G32) in Table 3, 84.4.0% of respondents disagreed about the use of untreated wooden door. Industries got the highest percentage (100%) of correct answers and authorities scored the lowest value (65.6.3%). Min value 2.28±0.52 of authorities is the lowest value given the correct answers. The criteria to be considered for the selection of door material is a smooth surface, resistant to moisture, permit easy cleaning and sanitizing (USDA/NCD & CS 1997; MS 1415: Department of Standard Malaysia (2009). Compared to other material types such as PU panels or stainless steel door, wooden doors will decay especially when frequently exposed to water as the results of cleaning or handling of research processes.

The confusion of authorities over the material of doors in premise plant layout need more attention due to it will be followed by industries and consultant upon designing the facilities. This confusion has been found significantly different ($p<0.05$) among the groups of respondents. The approval of premise and plan layout for implementing HACCP is responsibility of authorities like Ministry of Health of Malaysia and certification bodies. If they are doing the wrong decision therefore the industries and consultants will follow the result of audit like it was true even though it was wrong.

Window: For window construction (G38), the results have shown 84.4% of respondents agreed on the installation of window constructed to reduce the accumulation of dirt, permit easy cleaning and prevent the entry of insects. Authorities scored the highest percentage (100%) of correct answers and industries scored the lowest value (65.6.3%). Min value 2.66±0.48 of industries is the lowest value given the correct answers. In this aspect, significant different ($p<0.050$) was also occurred between the groups.

Window installation has flaws because of their likelihood of being broken, dust collection caused by the ledge formed, negative pressure in production areas as the windows open and the entry of dust. It is not suitable for the construction of new food premise plants to have windows installed for the reasons discussed (Lelieveld *et al*., 2005; Meorman, 2010; Schmidt and Erickson, 2014). However, if windows are needed to be installed there are some approaches that may be applied such as having 2 layers of glass, tinted glass and the use of polycarbonate glass to stop them from breaking. Jali *et al*. (2016) also reported that some industries still used single layer glass in construction of window in theirs industry. The confusion of industries over this issue perhaps due to there is no clear explanation of window installation in MS 1514:2009 and no guideline available.

Table 4 has shown the overall results of confusion over design and facilities between industry, consultant and authorities. There were 5 low, 2 medium and 0 high confusions among the groups of respondents. Respondents of authorities (4) was the one who highly contributed to confusion over design and facilities requirements and followed by industries (3) and consultants (0).

Table 4: Overall results of confusion towards design and facilities

		Confusion score			Group			
Code	Aspect	L	M	H	I	C	A	Significant ($p<0.05$)
G2	Location	✓					✓	✓
G12	Design/layout	✓					✓	✓
G14	Design/layout	✓			✓			✓
G18	Floor		✓		✓			✓
G23	Wall		✓				✓	✓
G32	Door	✓					✓	✓
G38	Window	✓			✓			✓
Total		5	2	0	3	0	4	

L: Low; M: Medium; H: High; I: Industry; C: Consultant; A: Authority

CONCLUSION

Confusion amongst industries, consultants and authorities can be categorized into several issues, namely building materials, layout research procedures and the characteristics of building internal infrastructure. The authorities are found to contribute to the highest confusion followed by industries and consultants. As a few topics related to design and facilities discussed it was observed that the consultants have a very good knowledge on it. However, authorities require more training on the standard requirements and auditing practice. As a conclusion, perhaps causes of confusion were due to the lack of technical knowledge, the absence of supporting documents to guide in meeting MS 1514: Department of Standard Malaysia (2009) lack of experience and effectiveness training. The preparation of the guidelines as a supporting document is useful to assist practitioners in complying with design and facilities of MS 1514:2009 more efficiently.

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