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Challenges in Performance of Food Safety Management Systems: A Case of Fish Processing Companies in Tanzania

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ABSTRACT

This study provides insight for food safety (FS) performance in light of the current performance of core FS management system (FSMS) activities and context riskiness of these systems to identify the opportunities for improvement of the FSMS. A FSMS diagnostic instrument was applied to assess the performance levels of FSMS activities regarding context riskiness and FS performance in 14 fish processing companies in Tanzania. Two clusters (cluster I and II) with average FSMS (level 2) operating under moderate-risk context (score 2) were identified. Overall, cluster I had better (score 3) FS performance than cluster II (score 2 to 3). However, a majority of the fish companies need further improvement of their FSMS and reduction of context riskiness to assure good FS performance. The FSMS activity levels could be improved through hygienic design of equipment and facilities, strict raw material control, proper follow-up of critical control point analysis, developing specific sanitation procedures and company-specific sampling design and measuring plans, independent validation of preventive measures, and establishing comprehensive documentation and record-keeping systems. The risk level of the context could be reduced through automation of production processes (such as filleting, packaging, and sanitation) to restrict people's interference, recruitment of permanent high-skilled technological staff, and setting requirements on product use (storage and distribution conditions) on customers. However, such intervention measures for improvement could be taken in phases, starting with less expensive ones (such as sanitation procedures) that can be implemented in the short term to more expensive interventions (setting up assurance activities) to be adopted in the long term. These measures are essential for fish processing companies to move toward FSMS that are more effective.

Although the fish industry is the largest food-exporting sector in Tanzania, it is still experiencing export rejections and restrictions of its products due to failures to meet export market requirements *(15, 31, 38, 51)*. Frequent changes in agricultural health standards, legal and retailer demands, along with increased public awareness on food safety (FS), pose significant challenges to the food companies in developing countries to meet export market requirements *(28, 39, 57)*. Food quality and safety standards influence the international competitiveness of exporting developing countries, especially the high-value agricultural and food products *(1, 28, 29)*, including fish. Apart from meeting conflicting demands of the export market (such as regulation, microbiological criteria, chemical standards, and inspection), exporting countries also comply with private codes of practice (such as voluntary quality assurance [QA] standards) and other forms of supply chain governance *(2, 18, 19, 28)*.

In many exporting developing countries, including Tanzania, FS control is emphasized in export products more than in domestically consumed products *(1, 28, 44)*. In Tanzania, for example, implementation of hazard analysis critical control point (HACCP) principles is only mandatory for exporting sectors such as fish *(58, 59)*. Various dedicated control measures (for example, specific fish transporting trucks and improved fish landing sites) and different internationally acknowledged QA standards and guidelines have been implemented in the FS management systems (FSMS) along the fish supply chain. These efforts have indeed improved the quality of fish and fishery products *(1, 42)*. However, European Union (EU)–approved processing units in Tanzania still have difficulties in maintaining acceptable product quality and safety over time *(31, 38)*. Exported fish and fish products in Africa are still rejected, and companies often receive notifications due to failures to meet food quality (e.g., labeling and packaging) and safety requirements, such as cold chain, microbiological, and chemical standards *(3, 14, 45, 52)*. Moreover, previous studies stated that the performance of quality management systems and FSMS implemented in fish companies is not yet satisfactory *(42, 49, 59)*.

Access to food export markets largely depends on the capacity of food companies to upgrade their levels of

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conformity with export market requirements *(31)*. Compliance with FS and agricultural health standards of importing countries require specific actions and efforts by individual producers and processors to implement the requirements into their quality management system, of which FS management is a specific component. However, lack of insight in the performance of implemented FSMS of fish processing companies impedes such efforts. The objective of this study was to provide insight into the FS performance in light of the current performance of core FSMS (control and assurance) activities and context riskiness of these systems to identify opportunities for improvement in implemented systems in the Tanzanian fish industry. Previously, principles of new diagnostic tools that support food business operators gaining insight into the actual performance of their FSMS have been discussed *(25, 26, 32, 35)*. This study applied a FSMS diagnostic instrument to assess the performance of FSMS in 14 fish processing companies in Tanzania.

MATERIALS AND METHODS

Characteristics of participating fish processing companies. The FSMS–diagnostic instrument (FSMS-DI) assessment was conducted in 14 companies: 3 large (>249 employees), 10 medium (50 to 249 employees), and 1 small (10 to 49 employees). These establishments were certified by the EU to export fish and fishery products to the EU. They all used Codex Alimentarius prerequisite programs and HACCP guidelines to design their FSMS, which comply with EU legislative requirements. In addition to these guidelines, for their system design three companies used the QA standard International Organization for Standardization (ISO) 9001 *(23)*, nine used the ISO 22000 (four of them were certified) *(22)*, and seven companies used the British Retail Consortium (BRC) standard (five of them were certified) *(6)*.

Diagnosis of performance level of FSMS activities, FS performance, and context riskiness. The FSMS-DI was used to diagnose performance of core control and assurance activities in fish companies. The FSMS-DI enables systematic analysis and assessment of a company's specific FSMS separate from the QA standards and/or guidelines used to design the system *(32, 35, 36)*. The FSMS-DI is composed of three parts, including assessment of (i) performance of core FSMS (control and assurance) activities, (ii) FS performance, and (iii) context riskiness *(33)* as the major elements. The context riskiness is characterized by ambiguity (due to lack of understanding of underlying mechanisms), uncertainty (due to lack of information), and vulnerability (due to sensitivity of microbial hazards) situations, which complicate decision making in the control and assurance activities *(35)*.

Part 1 involved sets of indicators that represent core control (such as design of preventive measures, design of intervention processes, monitoring system design, and actual operation of control strategies) *(32)*. It also included core assurance activities (including setting system requirements, validation, verification, documentation, and a record-keeping system) *(36)*. Each control or assurance activity indicator consisted of a grid with a description of four different performance levels including low (score 0), basic (score 1), average (score 2), and advanced (score 3). A low level indicates that an activity is not possible/applicable in the given production circumstances (such as physical intervention processes in the manufacture of raw fish fillets), is not done (such as standards and tolerances or calibration), or information is not known. The basic level for control activities is typified by the use of experience, general knowledge, ad hoc analysis, incomplete, not standardized, unstable, and regularly problems. For assurance activities, the basic level is characterized by being problem driven, only checking, scarcely reported, and no independent opinions. The average level for control activities is characterized by being based on expert (supplier) knowledge, use of (sector, legislative) guidelines, best practices, standardized, and sometimes having problems. For assurance activities, the average level corresponds with active, additional analysis, regular reporting, and expert support. The advanced level means that the control or assurance activity is characterized by use of specific information, scientific knowledge, critical analysis, procedural methods, systematic activities, and independent positions *(32, 33, 35, 36)*.

Part 2 involved indicators for the assessment of FS performance (such as external and internal FS performance indicators) of the system *(26)*. Likewise, for the FS performance indicators, four levels were described: not applied (score 0), poor (score 1), moderate (score 2), and good (score 3) *(26)*. Level 0 (no indication of FS performance) refers to absent, not present, and not conducted, showing, for instance, the absence of FSMS evaluation and lack of insight in actual microbial and hygiene performance of the system *(25, 26)*. Level 1 (poor FS performance) is associated with aspects such as ad hoc sampling, minimal criteria used for FSMS evaluation, and having various FS problems within the FSMS. Level 2 (moderate FS performance) represented regular sampling, several criteria used for FSMS evaluation, and having restricted FS problems mainly due to one (restricted) type of problem in the FSMS. Level 3 (good FS performance) pertains to a systematic evaluation of the FSMS using specific criteria and having no safety problems *(26)*.

Part 3 comprised a set of indicators that represent four crucial FSMS context factors, such as product, process, organizational, and chain environment characteristics. For each context indicator, three situations were described, corresponding with a low- (score 1), moderate- (score 2), and high-risk (score 3) situation indicating levels of riskiness for decision making in FSMS activities *(35)*. The criteria underlying riskiness are ambiguity, uncertainty, and vulnerability *(35)*. The description for low-, moderate-, and high-risk situations for product and process characteristics refers to low, potential, and high likelihood of contamination, growth, and survival of pathogens. For organizational characteristics, low, moderate, and high-risk situations represent supportive, constrained/restricted, and lack of administrative conditions to support appropriate decision making in the FSMS. Concerning chain environment characteristics low-, moderate-, and high-risk situations correspond to low, restricted, and high dependability on other chain actors, resulting in a more vulnerable decision-making situation *(33, 35)*. The FSMS diagnosis involved an in-depth face-to-face interview with the responsible QA personnel accompanied with document analysis and onsite visits to the production floor to confirm the assessment (2 to 3 h). The assessment tool contained closed-ended questions.

Data analysis. The FSMS diagnosis resulted into a list of 58 scores for each fish processing company analyzed. Overall mean scores were calculated and transformed to assigned overall scores to obtain a first indication about FSMS performance, FS output, and context riskiness. For the indicators of core FSMS activities and FS performance, if the average level is between 0 and 1.2, an assigned score of 1 is defined. If the average level is between 1.3 and 1.7, an assigned score of 1 to 2 is attributed. If the average level is between 1.8 and 2.2, an assigned score of 2 is defined. If the average level is between 2.3 and 2.7, an assigned score of 2 to

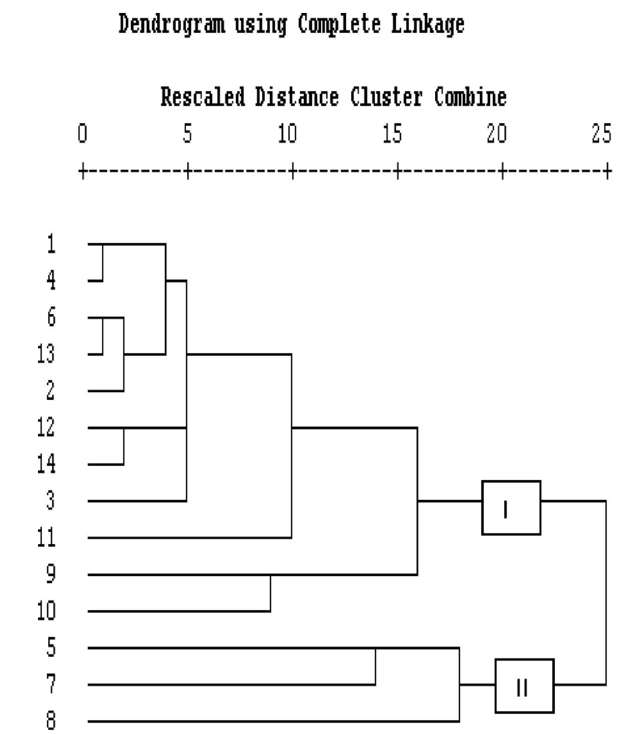


FIGURE 1. *A dendrogram showing the clusters obtained by hierarchical cluster analysis using risk scores of context factor, performance scores of control and assurance activities, and FS indicators. I represents cluster I and the associated numbers indicate list of companies. II represents cluster II and associated numbers indicate list of companies.*

3 is given. Finally, if the average level is between 2.8 and 3.0, an assigned score of 3 is attributed *(26, 33, 53)*. For the indicators of context factors, if the average risk level is between 1 and 1.2, a score of 1 is assigned. If the average risk-level score is between 1.3 and 1.7, a score of 1 to 2 is assigned. If the average risk level is between 1.8 and 2.2, a score of 2 is assigned. If the average risk level is between 2.3 and 2.7, a score of 2 to 3 is assigned. Finally, if the risk level is between 2.8 and 3.0, a score of 3 is assigned *(33)*.

Statistical analysis. A hierarchical cluster analysis SPSS (Version 16.0 for Windows, SPSS Inc., Chicago, IL) with the furthest neighbor method and squared Euclidean distance were applied to provide insight into the differences in context riskiness, FSMS performance, and FS output between the companies. Then statistical analysis by use of Kruskal-Wallis nonparametric H test was performed to compare the mean scores of indicators of FS performance, FSMS activities, and context riskiness between the clusters. The statistical significance was established at $P < 0.05$ level. Hierarchical cluster analysis is suitable to group cases into homogeneous subgroups based on measured characteristics.

RESULTS AND DISCUSSION

Overall context riskiness, FSMS, and FS performance. The overall principle behind the FSMS-DI is that companies operating in a high-risk context (score 3) require a more advanced FSMS (level 3) to achieve a good FS performance (level 3), whereas in a lower-risk context, more simple systems may be sufficient *(33, 35)*. Hierarchical cluster analysis produced two clusters, clusters I and II, which contained 11 and 3 fish processing companies, respectively (Fig. 1). Cluster I had better FS performance (score 3) than cluster II (score 2 to 3; Table 1). However, both clusters had an average FSMS (score 2; Table 2) operating under a medium-risk context (score 2; Table 3). Thus, according to the basic principle of FSMS-DI, a good FS performance (score 3) was anticipated, which has been also reflected in the FSMS-DI (FS score 2 to 3 or 3). Nevertheless, an in-depth analysis of the FSMS activities, FS performance, and context riskiness are imperative to identify the opportunities for improvement of current FSMS in fish processing companies.

TABLE 1. *Frequency analysis of individual scores and statistical analysis of mean scores of indicators of FS performance in each cluster of fish processing companies*

FS performance indicators	Frequency of individual scores of all 14 companies[a]				Mean (assigned scores) of the two clusters[b]		P value[c]
	0	1	2	3	I (11)	II (3)	
External FS performance assessment							
FSMS evaluation	0	3	0	11	2.6 (2–3)	2.3 (2–3)	0.585
Seriousness of remarks of FSMS evaluation	0	0	4	10	2.7 (2–3)	2.7 (2–3)	0.843
Microbiological FS complaints by customers	1	0	2	11	**2.9 (3)**[d]	**1.7 (1–2)**	**0.030**
Hygiene-related complaints by customers	1	0	3	10	2.7 (2–3)	2.0 (2)	0.630
Internal FS performance assessment							
Product sampling to confirm microbiological performance	0	0	2	12	2.9 (3)	2.7 (2–3)	0.305
Judgment criteria	0	1	3	10	2.8 (3)	2.0 (2)	0.077
Hygiene and pathogen nonconformities	0	0	5	9	2.6 (2–3)	2.7 (2–3)	0.925
Overall FS performance					2.8 (3)	2.3 (2–3)	0.128

[a] Number of companies in each score indicating FS performance: 0, not applied; 1, poor; 2, moderate; 3, good.
[b] Mean scores with associated assigned scores of each indicator for each cluster.
[c] P value for Kruskal Wallis nonparametric H test to compare the scores of FS performance, FSMS activities, and context riskiness between the clusters.
[d] Bolded mean scores indicate significant differences ($P < 0.05$) between the clusters.

TABLE 2. *Frequency analysis of individual scores and statistical analysis of mean scores of indicators of FSMS activities in each cluster of fish processing companies*

Indicators of FSMS activities	Frequency of individual scores of all 14 companies[a]				Mean (assigned scores) of the two clusters[b]		*P* value[c]
	0	1	2	3	I (11)	II (3)	
Design of preventive measures							
Sophistication of hygienic design	0	0	11	3	2.3 (2–3)	2.0 (2)	0.325
Adequacy cooling facilities	0	0	1	13	3.0 (3)	2.7 (2–3)	0.056
Specificity sanitation programme	0	0	3	11	**2.9 (3)**[d]	**2.3 (2–3)**	**0.038**
Extent of personal hygiene requirements	0	0	4	10	2.6 (2–3)	3.0 (3)	0.234
Sophistication of raw material control	0	0	8	6	2.6 (2–3)	2.0 (2)	0.103
Adequacy product specific preventive measures	0	0	2	12	2.9 (3)	2.7 (2–3)	0.305
Design of intervention processes							
Adequacy physical intervention equipment	14	0	0	0	0 (0)	0 (0)	1.0
Adequacy packaging intervention equipment	9	0	3	2	**0.4 (1)**	**2.7 (2–3)**	**0.005**
Specificity maintenance program	0	2	4	8	**2.7 (2–3)**	**1.3 (1–2)**	**0.009**
Adequacy intervention method	13	0	0	1	0 (0)	1.0 (1)	0.056
Design of monitoring system							
Appropriateness of CCP analysis	0	1	7	6	2.4 (2–3)	2.3 (2–3)	0.794
Appropriateness of limits and tolerances	0	0	4	10	2.7 (2–3)	2.7 (2–3)	0.843
Adequacy of analytical methods	0	0	4	10	2.7 (2–3)	2.7 (2–3)	0.843
Adequacy of measuring equipment	0	0	6	8	**2.7 (2–3)**	**2.0 (2)**	**0.030**
Specificity calibration programme	0	0	2	12	2.9 (3)	2.7 (2–3)	0.305
Specificity of sampling design and measuring plan	0	1	11	2	2.1 (2)	2.0 (2)	0.745
Extent of corrective actions	0	0	2	12	2.8 (3)	3.0 (3)	0.442
Actual operation of control strategies							
Actual availability of procedures	0	0	12	2	2.2 (2)	2.0 (2)	0.442
Compliance to procedures	0	0	7	7	2.5 (2–3)	2.7 (2–3)	0.543
Hygienic performance equipment and facilities	0	0	4	10	2.7 (2–3)	2.7 (2–3)	0.843
Actual cooling capacity	0	0	1	13	3.0 (3)	2.7 (2–3)	0.056
Capability physical intervention equipment	14	0	0	0	0 (0)	0 (0)	1.0
Capability packaging intervention equipment	9	0	1	4	**0.6 (1)**	**2.7 (2–3)**	**0.021**
Measuring equipment performance	0	0	1	13	2.9 (3)	3.0 (3)	0.602
Analytical equipment performance	0	0	0	14	3.0 (3)	3.0 (3)	1.0
Assurance activities							
Sophistication translating external requirements	0	3	5	6	**2.6 (2–3)**	**1.0 (1)**	**0.006**
Extent of systematic use of feedback information	0	0	2	12	2.9 (3)	2.7 (2–3)	0.305
Sophistication validation preventive measures	1	1	4	8	2.6 (2–3)	1.7 (1–2)	0.256
Sophistication validation intervention systems	10	1	1	2	**0.1 (0)**	**2.7 (2–3)**	**0.001**
Sophistication validation monitoring systems	1	0	5	8	2.0 (2)	1.7 (1–2)	0.215
Extent verifying people-related performance	0	1	8	5	2.2 (2)	2.7 (2–3)	0.215

TABLE 2. *Continued*

Indicators of FSMS activities	Frequency of individual scores of all 14 companies[a]				Mean (assigned scores) of the two clusters[b]		P value[c]
	0	1	2	3	I (11)	II (3)	
Extent verifying equipment and methods performance	0	1	5	8	2.6 (2–3)	2.3 (2–3)	0.478
Appropriateness documentation	0	0	7	7	2.5 (2–3)	2.7 (2–3)	0.530
Appropriateness record keeping	0	0	10	4	2.4 (2–3)	2.0 (2)	0.234
Overall FSMS performance					2.1 (2)	2.1 (2)	0.697

[a] Number of companies in each score indicating performance levels of FSMS activities: 0, not applied; 1, basic; 2, average; 3, advanced.
[b] Mean scores with associated assigned scores of each indicator for each cluster.
[c] P value for Kruskal Wallis nonparametric H test to compare the mean scores of FS performance, FSMS activities, and context riskiness between the clusters.
[d] Bolded mean scores indicate significant differences ($P < 0.05$) between the clusters.

Diagnosis of performance of FSMS activities. In general, both clusters had FSMS activities performing at an average level (Table 2). However, the clusters scored 2 to 3 or 3 (advanced level) in several control (14 of 25) and assurance (3 of 9) activities (Table 2). All analyzed fish companies manufactured fresh and raw frozen fish products; hence, no (score 0) physical intervention equipment (equipment that applies physical processes, such as heating and drying) and intervention methods (e.g., fermentation) are applied to inactivate or eliminate microorganisms to acceptable levels. Furthermore, the sampling design and measuring plans were based on the fishery sector guidelines, not tested in a company-specific situation (score 2). In addition, the procedures, which were mostly paper based, were partly available on location and kept up-to-date on an ad hoc basis (score 2). The EU inspectors in 2011 in the Tanzanian fish industry found that some fish companies lacked procedures or instructions on how to use chlorine test kits and proper product storage in the cold store *(15)*. Procedures guide workers through their production and sanitation activities, preventing poor decision making *(5, 34)*.

For preventive measure design, a significant difference ($P < 0.05$) between clusters was only observed in specificity of sanitation programs. Cluster I had more significantly advanced specific sanitation programs (scored 3) than cluster II (score 2 to 3). However, not statistically significant, cluster II scored 2 (average level) in hygienic design of equipment and facilities and raw material control (Table 2), which, respectively, shows that critical equipment, such as cooling facilities, comply with specific hygiene requirements (but not tested in the company production situation) and the major quality checks on raw materials were mainly on size and sensory attributes. The EU mission in Tanzania in 2006 reported inadequate design in facilities and the absence of hand washing basins and appropriate soap in some of the inspected fish companies *(14, 15)*. A study in Nigerian seafood processing plants also observed the use of inappropriate equipment and cooling facilities *(46)*. Unhygienically designed equipment and facilities are implicated with microbiological cross-contamination in the fish industry *(17, 55)*. This present study observed that some of the analyzed companies have installed bells, which ring every 30 min to remind personnel to wash and disinfect their hands (including processing equipment, e.g., knives) in a chlorine dip (5 ppm). Otherwise, a section supervisor reminds workers at a certain determined time interval to wash their hands and processing equipment. Periodic washing and sanitization of equipment prevent accumulation of dirt and microorganisms, which could contaminate the products, on the equipment, tables, and hands of the personnel. Furthermore, every section has specific cleanliness personnel, who regularly perform cleaning.

For intervention processes design, a significant difference ($P < 0.05$) between the clusters was observed in adequacy of packaging intervention equipment and specificity of maintenance programs (Table 2). Cluster I had basic (score 1) packaging intervention equipment and advanced maintenance and calibration programs (score 2 to 3). Cluster I companies packaged their products in

TABLE 3. *Frequency analysis of individual scores and statistical analysis of mean scores of indicators of context factors in each cluster of fish processing companies*

Indicators of context factors	Frequency of individual scores of all 14 companies[a]			Mean (assigned scores) of the two clusters[b]		P value[c]
	1	2	3	I (11)	II (3)	
Product and process characteristics						
Risk of raw materials	0	0	14	3.0 (3)	3.0 (3)	1.0
Risk of product group(s)	0	5	9	2.6 (2–3)	2.7 (2–3)	0.925
Safety contribution of packaging concept	0	13	1	2.0 (2)	2.3 (2–3)	0.056
Extent of intervention steps	0	1	13	2.9 (3)	3.0 (3)	0.602
Degree of production process changes	1	7	6	2.3 (2–3)	2.7 (2–3)	0.338
Rate product/process design changes	9	4	1	1.6 (1–2)	1.0 (1)	0.167
Organization characteristics						
Presence of technological staff	6	8	0	1.6 (1–2)	1.3 (1–2)	0.365
Variability of workforce composition	5	8	1	1.7 (1–2)	1.7 (1–2)	0.929
Sufficiency of operator's competences	8	6	0	1.5 (1–2)	1.3 (1–2)	0.717
Extent of management commitment	11	3	0	1.2 (1)	1.3 (1–2)	0.585
Degree of employee involvement	5	7	2	1.8 (2)	1.7 (1–2)	0.798
Level of formalization	10	3	1	**1.2 (1)**[d]	**2.0 (2)**	**0.077**
Sufficiency of information system	10	4	0	1.3 (1–2)	1.3 (1–2)	0.843
Chain characteristics						
Safety contribution in chain position	2	11	1	1.8 (2)	2.3 (2–3)	0.103
Power in supplier relationships	13	1	0	1.0 (1)	1.3 (1–2)	0.056
Authority in customer relationships	5	8	1	1.7 (1–2)	1.7 (1–2)	0.658
Severity of stakeholder requirements	1	9	4	2.3 (2–3)	2.0 (2)	0.407
Overall context riskiness				1.9 (2)	1.9 (2)	0.815

[a] Number of companies in each score indicating risk levels of the context: 1, low; 2, medium; 3, high.
[b] Mean scores with associated assigned scores of each indicator for each cluster.
[c] P value for Kruskal Wallis nonparametric H test to compare the context riskiness between the clusters.
[d] Bolded mean scores indicate significant differences ($P < 0.05$) between the clusters.

Styrofoam and waxed boxes with plastic lining to prevent microbiological contamination. However, these packaging methods could not reduce or inactivate microorganisms, including pathogens. Cluster II companies used dedicated packaging intervention equipment (e.g., vacuum packaging) for the fish industry, the packaging conditions and equipment specifically designed and tested for company production circumstances (score 2 to 3). Moreover, cluster II had basic maintenance and calibration programs (score 1), denoting maintenance/calibration initiated by problems, but no clear instructions about frequency and were not well documented. This is in alignment with EU audit reports, which revealed poor maintenance of the processing floor *(14),* damaged doors of cold stores, a broken ceiling of the salt store, and a rusted ice machine and knife sharpeners *(15)* in Tanzanian fish exporting companies.

For monitoring system design, a significant difference ($P < 0.05$) was observed in adequacy of measuring equipment (Table 2). Cluster I had an average-advanced performance (score 2 to 3) in measuring equipment, while cluster II portrayed an average level (score 2). The rest of indicators of monitoring system design scored 2 to 3 or 3 for both clusters, indicating that they are based on scientific evidence and have been tested and adapted for the company specific production situation. For the actual operation of core control strategies, the difference ($P < 0.05$) between clusters was observed in capability of packaging intervention equipment. Cluster I indicated a basic level (score 1) owing to unstable packaging processes, major variations, and lack of control charts, while cluster II showed an average-advanced level (score 2 to 3) because they have stable packaging processes, with minor variations, and use control charts, although not systematically interpreted. Similarly, poor packaging processes of seafood were observed in Nigerian companies *(46).*

For assurance activities, the significant differences ($P < 0.05$) between the clusters were noted in translating external requirements into internal FSMS requirements and validation of intervention systems (Table 2). Cluster I had an average-advanced level (score 2 to 3), whereas cluster II had a basic level (score 1) in translation of external requirements into internal FSMS requirements. This, respectively, demonstrates that cluster I was more proactive in translating external requirements than cluster II, which was more reactive. Previous studies narrated that fish companies in Tanzania translate external requirements into their systems as a response to FS problems or as demanded by the export market and competent authority *(15, 16).* In general, fish exporters and local authorities have adopted a reactive strategy toward sanitary and phytosanitary standards compliance *(40, 41).* For instance, fish companies in African countries, including Mauritius, have adopted private

QA standards, such as BRC, to meet the demands of their customers *(40)*. Similarly, fish exporting companies in Tanzania have extensively implemented HACCP to meet export market demands *(19, 30, 56)*.

Moreover, 9 of 10 companies in cluster I did not apply intervention processes; thus, the validation of intervention systems scored 0. On the contrary, all companies in cluster II used vacuum packaging equipment; the effectiveness was independently validated based on an expert's opinion on regular basis and after system modification (score 2 to 3). Although not statistically significant ($P = 0.256$), cluster I had an average-advanced level (score 2 to 3) in validation of preventive measures, whereas cluster II had a basic-average level (score 1 to 2). This implies that validation of preventive measures in cluster I was based on historical knowledge and judged by the staff working in the system; whereas in cluster II, it was carried out systematically by independent experts using scientific knowledge on a regular basis. A scientific evidence-based, systematic, and independent validation of effectiveness of preventive measures will result in an effective FSMS *(36)*. In addition, fish companies had structured and partly automated documentation; however, access to external sources was not formalized. Also, verification of procedures and compliance were based on independent analysis of procedures and records on a regular basis. A study in the United States found that 35% of respondents have never carried out validation of their control systems in their plants *(20)*. Furthermore, previous studies observed poor documentation and record-keeping systems in fish processing plants in Tanzania *(14, 15)* and aquaculture farms in Uganda *(4)*.

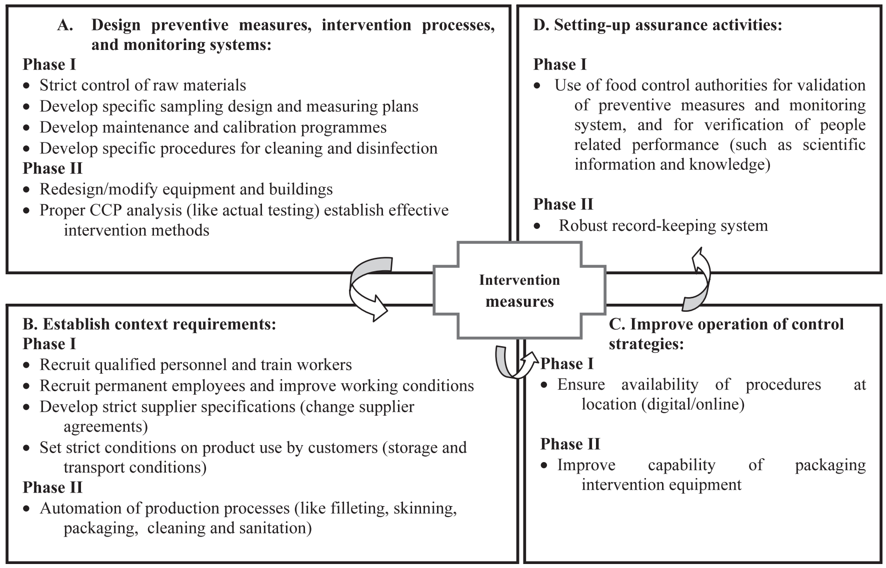
Diagnosis of FS performance. Table 1 illustrates that clusters II and I, respectively, scored 2 to 3 and 3, indicating good FS performance. Both clusters indicated a comprehensive external and internal FSMS performance assessment. Several accredited third parties, including the Tanzania Food and Drugs Authority, Tanzania Bureau of Standards, EU, and auditors for specific QA standards (e.g., BRC and ISO 22000), inspect fish companies. A significant difference ($P < 0.05$) between the clusters was observed in one indicator of external FSMS performance, the microbiological FS complaints by customers. Although cluster I companies had never received microbiological FS complaints (score 3), cluster II received and recorded various complaints. No significant difference ($P > 0.05$) in indicators of internal FSMS performance were observed; however, companies in cluster II used legal (e.g., Tanzania and the EU) microbiological criteria and specifications from external parties (e.g., customers and sector organizations) to judge their microbiological results (score 2). Cluster I companies applied additional specifications established in their internal guidelines (score 3). Applying more criteria to interpret microbiological results gives a more accurate indication of the microbiological performance of the FSMS *(26)*.

Diagnosis of riskiness of FSMS context. Table 3 shows that there was no significant difference ($P > 0.05$) between the clusters in the overall context riskiness as all companies were operating in moderate-risk context (overall score 2). Generally, most companies indicated high-risk level (score 3) in raw materials (14 of 14), extent of intervention steps (13 of 14), and final product groups (9 of 14). This implies that raw materials, such as fresh fish, were associated with high initial microbiological levels (including pathogens) and required special storage conditions (such as chilling/icing to <4°C); final product groups had high water activity, and production process did not involve intervention steps to reduce microbiological contamination to acceptable levels. Previous studies found that fish from tropical waters had high microbiological counts on their skins and gills (10^3 to 10^6 CFU/cm^2) compared with coldwater fish ((10^2 to 10^4 CFU/cm^2) *(21, 43)*. Moreover, pH (7.0) and water activity (0.98) of fish meat provide optimum conditions for bacterial growth *(43)*.

For organizational characteristics (Table 3), the level of formalization (the degree to which organization's procedures, rules, personnel requirements, and information systems are written down and enforced) in cluster I was significantly ($P < 0.05$) higher (score 1) than in cluster II (score 2). Although cluster I had procedures for every activity, in cluster II, procedures were restricted (limited) to crucial processes typically related to the FSMS. However, both clusters indicated low-moderate risk (score 1 to 2) organizational characteristics, which correspond to supportive conditions for decision making in safety tasks. This shows that fish companies had sufficient operators' competence, high management commitment, and well-established information systems to support decisions in the FSMS. On the contrary, previous studies reported lack of knowledge and skills for Nigerian seafood processors *(46, 47)* and workers in Ugandan aquaculture farms *(4)*. In addition, studies in Belgian poultry *(53)*, Japanese dairy *(54)*, and Spanish meat *(48)* processing plants observed inadequate information systems. Likewise, poor operators' competence and restricted employee involvement and workforce composition have been reported in a Vietnamese fish company *(43)*. Workforce composition refers to the typical variation of composition of people involved in a respective representative production unit or company *(35)*.

For chain characteristics (which represent safety contribution in chain position, extent of power in supplier relationship, degree of authority in customer relationship, and severity of stakeholder requirements), there were no significant differences ($P > 0.05$) between clusters in indicator scores (Table 3). The majority of fish companies (13 of 14) scored 1 in supplier relationships (indicating low-risk level) because they developed product specifications and audited the FSMS of their suppliers. Some companies provided supplier guarantee, advice, and training in good handling practices. In addition, both clusters revealed moderate to high authority in customer relationships (score 1 to 2). Hence, fish companies could discuss product usage with major customers (not final consumers) and could influence their quality management systems and FSMS (Table 3), which shows less dependence on chain actors that support the decision-making process *(35)*. A recent study in Vietnamese fish industry observed that fish companies had

FIGURE 2. *Proposed intervention measures for improvement of FSMS.*



restricted influence on their export customers *(43)*. Cluster I encountered severe stakeholders' requirements (e.g., government, retailers, and consumers); apart from legislative requirements, they had to meet additional demands (such as BRC and Eco-labels), which could be similar or different (score 2 to 3). Although cluster II companies received strict demands, they were similar for all stakeholders (score 2). Likewise, a Vietnamese fish company had to meet additional QA requirements, which were different from each customer *(43)*. Serving different export markets may cause food companies to maintain several HACCP plans, even though they deal with one process and product *(8, 27, 50)*. This situation could result in several CCP, complicating CCP monitoring activities and ending in ineffective HACCP plans.

Usefulness of the FSMS diagnostic instrument. Apart from official inspections, the diagnostic tools used in this study can serve as useful instruments for fish companies to assess their system in a broad perspective and separate from the QA guidelines/standards used to identify opportunities for improvement in their FSMS or in their context. In this case, it can serve as basis for identification of preventive measures (as cooling facilities, sanitation programs, and raw material control) to progress toward more advanced system levels and measures to reduce the context riskiness (employee involvement, formalization, and customer relationships). It can further serve as a preliminary internal auditing instrument before third-party inspections (e.g., national and EU). Also, this diagnostic instrument can be used by the fishery sector to diagnose groups of companies in more vulnerable situations that would require support in designing and evaluating their systems. At the government level, the food control authorities could use this diagnostic tool to improve their auditing protocols.

Intervention measures for improvement of more effective FSMS. Fish companies need to improve their FSMS to high levels and reduce the context riskiness to assure good FS performance. FSMS activities, which need improvement, include hygienic design of equipment and facilities, raw material control maintenance and calibration programs, CCP/CP analysis, procedures, sampling design and measuring plan, translation of external requirements into internal FSMS requirements, validation of preventive measures, documentation, and record-keeping systems. For context characteristics, the factors that contribute to high-risk levels include intervention steps, safety contribution of packaging concept, degree of production process changes, lack of technological staff, variability in workforce composition (temporary operators), employee involvement, and severity in stakeholder requirements. For the fish companies to develop toward effective FSMS, intervention measures could be taken in phases, starting with less expensive ones that can be implemented in the short term to more expensive interventions to be adopted in the long term (Fig. 2). Therefore, fish companies could start by improving the design of preventive measures, intervention processes, and monitoring systems; followed by establishing context requirements, then improving operation of control strategies and setting up assurance activities.

The first phase for the design of preventive measures, intervention processes, and monitoring systems could include the development of specific sanitation procedures (such as equipment, production zones, cooling facilities, and toilets), sampling design and measuring plans, maintenance/calibration programs of intervention equipment, and strict control of raw materials *(11, 13, 26)*. For monitoring purposes, periodic evaluation of microbiological quality of raw materials from all suppliers is essential to establish the sources of raw materials with high microbial hazards. Also, it would enable fish companies to identify the microbiological performance of suppliers. A different level of control could be practiced for various suppliers to reduce the risk of accepting poor-quality raw materials. In addition, the food control authorities (National Fish Quality Control Laboratory, Tanzania Bureau of Standards, and Tanzania Food and Drugs Authority) could perform validation and verification of preventive strategies. For the context characteristics, the risk levels could be lowered in the first phase by training of employees and recruiting trained and skilled personnel on permanent basis, change in supplier specifications, and developing specific requirements on product use by major customers, which could reduce unpredictable product storage, transport, and use. Inadequate handling (such as time-temperature abuse and contamination) of fish products along the supply chain may contribute to proliferation of spoilage and pathogenic microorganisms *(9, 55)*. These are critical measures for the fish processing companies, because no intervention strategies have been applied to reduce or eliminate microorganisms to acceptable levels *(33)*.

The expensive intervention measures for the preventive strategies and monitoring system in the second phase include modification of equipment and buildings *(11, 13, 26)* and implementation of HACCP/CCP analysis *(10, 24)*. For the context riskiness, fish companies could automate their production processes, such as filleting, skinning, packaging, and cleaning and sanitation, to reduce people interference and the risk of microbiological contamination. For assurance activities, fish companies could set system requirements (such as proactive translation of external assurance requirements from legislation or branch demands into the requirements of companies' FSMS) and establish robust documentation and record-keeping systems. A robust system of record keeping will demonstrate whether procedures are precisely and consistently followed; it is also vital for verification and certification *(7, 12, 13)*, as well as traceability purposes *(37, 42)*. For the operation of control strategies, companies could improve the capability of packaging intervention equipment, particularly, the vacuum packaging. The proposed intervention measures are necessary for fish processing companies to move toward FSMS that are more effective and guarantee product safety.

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