THE UNITED REPUBLIC OF TANZANIA

NATIONAL AUDIT OFFICE

PERFORMANCE AUDIT ON THE MANAGEMENT OF FOOD INSPECTION AND SURVEILLANCE AT PROCESSING PLANTS AND AT PORTS OF ENTRY

THE MINISTRY OF HEALTH AND SOCIAL WELFARE AND TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)

A REPORT OF THE CONTROLLER AND AUDITOR GENERAL OF THE UNITED REPUBLIC OF TANZANIA

MARCH, 2014

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NATIONAL AUDIT OFFICE

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To be a centre of excellence in public sector auditing

Mission

To provide efficient audit services, in order to enhance accountability and value for money in the collection and usage of public resources

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In providing quality service, NAO shall be guided by the following Core Values:

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To be an impartial entity, which offers services to our clients in an unbiased manner

We aim to have our own resources in order to maintain our independence and fair status

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We are striving to produce high quality audit services based on best practices

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PREFACE

The Public Audit Act No. 11 of 2008, Section 28 authorizes the Controller and Auditor General to carry out Performance Audit (Value-for-Money Audit) for the purposes of establishing the economy, efficiency and effectiveness of any expenditure or use of resources in the MDAs, LGAs and Public Authorities and other Bodies which involves enquiring, examining, investigating and reporting, as deemed necessary under the circumstances.

I have the honour to submit to His Excellency the President of the United Republic of Tanzania, Dr. Jakaya Mrisho Kikwete and through him to Parliament the Performance Audit Report on the Management of Inspection and Surveillance at Food Processing Plants and Ports of Entry in Tanzania.

The report contains conclusions and recommendations that have focused mainly on the inspection of food at processing plants as well as at the ports of entry. The audit covered planning, execution as well as monitoring and evaluation of food inspections and surveillance in order to determine whether the TFDA was conducting and managing risk based inspection and surveillance of food processing plants and at the ports of entry so as to minimise unsafe food and protect consumers' health during the fiscal years of 2009/10 to 2011/13.

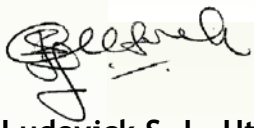
The managements of the Ministry of Health and Social Welfare (MoHSW) and the Tanzania Food and Drugs Authority (TFDA) have been given the opportunity to scrutinize the factual contents of the report and come up with comments on it. I wish to acknowledge that the discussions with the audited entities have been very useful and constructive in achieving the objectives of the audit.

My office intends to carry out a follow-up at an appropriate time regarding actions taken by the audited entities in relation to the recommendations in this report.

In completion of the assignment, the office subjected the report to a critical review by the following experts namely, Dr. Martin E. Kimanya, (Senior Lecturer at The Nelson Mandela African Institution

of Science and Technology) and Professor B. P Tiisekwa (Dean, Faculty of Agriculture, Sokoine University) who came up with useful inputs on improving this report.

This report has been prepared by Mr. Nyanda Leonard Mabuga (Team Leader), Mr. Darius Cosmas and Mr. Andrew Kazembe (Team Members) under the supervision and guidance of Mr. George C. Haule – Assistant Auditor General and Ms. Wendy W. Massoy – Deputy Auditor General. I would like to thank my staff for their devotion and committment in the preparation of this report. My thanks should also be extended to the audited entities for their fruitful interaction and cooperation with my office.



Ludovick S. L. Utouh
Controller and Auditor General,
March, 2014

ACRONYMS AND ABBREVIATIONS

DFS	-	Directorate of Food Safety
DG	-	Director General
FAO	-	Food and Agriculture Organization
HACCP	-	Hazard Analysis and Critical Control Points
ICD	-	Inland Container Depots
IEC	-	International Electro-technical Commission
ISO	-	International Standards Organization
LGAs	-	Local Government Authorities
M&E	-	Monitoring and Evaluation
MAB	-	Ministerial Advisory Board
MDAs	-	Ministries, Departments and Agencies
MIS	-	Management Information System
MLDF	-	Ministry of Livestock Development and Fisheries
MNRT	-	Ministry of Natural Resources and Tourism
MoHSW	-	Ministry of Health and Social Welfare
NAOT	-	National Audit Office of Tanzania
PMO - RALG	-	Prime Mister's Office - Regional Authorities and Local Government
QMS	-	Quality Management System
SOP	-	Standard Operating Procedures
TAEC	-	Tanzania Atomic Energy Commission
TASA	-	TFDA Annual Performance Staff Appraisal
TBS	-	Tanzania Bureau of Standards
TFDA	-	Tanzania Food and Drug Authority

TFDCA	-	Tanzania Food, Drugs and Cosmetics Act
TRA	-	Tanzania Revenue Authority
WHO	-	World Health Organisation
ZOLGAC	-	Zone and Local Government Authority Coordinator

EXECUTIVE SUMMARY

The task of ensuring that food imported and domestically produced is safe for human consumption falls under the mandate of Tanzania Food and Drugs Authority (TFDA). If the food sector remained unchecked and uncontrolled it could be a major cause of the spread of diseases and even resulting into deaths.

There has been public outcry over the existence of food products not suitable for human consumption. That was exemplified by the pilot study conducted by TFDA on the assessment of food-borne diseases conducted in Dodoma, Singida and Manyara regions which showed that there had been incidences of deaths resulting from unsafe food affecting over 1,000 people. This becomes important that the TFDA conduct its food inspection activities in an efficient and effective manner.

The main objective of the audit was to determine whether the Tanzania Food and Drugs Authority fulfil its mission of safeguarding the quality of food in the country.

The audit covered mainly inspection activities during a 4-year period i.e. from 2009/10 to 2012/13.

NAOT used three main methods for data collections in undertaking this audit. Interviews and documents were examined at TFDA headquarters and at zone offices, Ministry of Health and Social Welfare and at TRA. Observations through a number of physical visits were made to 21 food processing plants and five entry points located at four zones of TFDA.

Main Audit Findings

Inappropriate Planning for Food Inspections

The audit team found out that TFDA inspection plans were not addressing key features with regards to required inspection frequency,

number of inspectors, mode of supervision, and performance management monitoring.

For instance plans did not have the number of inspections to be conducted in a particular period of the year, coverage, the desired inspection frequency. Other factors such as re-inspecting food processing plants with serious violations and scheduling inspections in response to consumers' complaints were also not reflected on such plans. Neither did the plans set the inspection milestones/ targets expected nor indicate when inspections were expected to be conducted.

Furthermore, it was noted that TFDA did not prioritize its food inspection to processing plants of high risk by reasons that it was conflicting with the role of collecting fees and charges to self-finance its activities.

The following were the major causes for the inappropriate planning for food inspections at both Processing Plants and Ports of Entry:

- Risk analyses were not carried out to establish the compliance/ performance profile of both the processing plants and licensed importers of food products in the country;
- Inadequate use of Risk-Based Inspection guidelines during the planning of individual inspections;
- The management of TFDA has not yet issued any guidance/ directives to guide its inspectors on how they can make use of different guidelines (issued by ISO, FAO and in-house guidelines) present to-date;
- Inadequate coordination between inspectors, risk assessors, zone offices, planning unit/department etc. during the planning stage of food inspections; and
- Inspectors were not trained on how to conduct risk-based inspections.

Inadequate Conduct of Food Inspections

At Processing Plants

The audit found out that TFDA did not manage to conduct its inspections to all processing plants. It was noted that 3 out of 5 TFDA

zones inspected less than two-thirds of the processing plants in their respective zones. Furthermore, TFDA failed to establish whether all high risk food processing plants were among the two-thirds processing plants covered in their inspections.

The audit noted factors contributing to inadequate coverage of inspections at processing plants include:

- Unclear understanding of the types of inspections to be conducted;
- Inadequate planning for the food inspections;
- Inadequate usage of present food inspection resources (human capital, funding and inspection tools); and

At Ports of Entry

The Audit review of the Inspection Reports prepared by Food Inspectors stationed at the Ports of Entry showed that TFDA was not prioritizing its inspections to high-risk food products. This means that all food consignments whether risky or not were given equal weights by TFDA inspectors which made the inspections less thorough.

As a result, unexamined food consignments went through the ports of entry.

Insufficient Application of Available Options to Secure Corrections of Non Complaincy

It was noted that despite the fact that there were non compliance among processing plants and importers, TFDA has not kept records of those non compliances. Moreover, it was acknowledged by TFDA officials that without more incentive to improve compliance, those processing plants run a higher risk of producing food products unfit for human consumption that should not enter the food supply chain.

The analysis of numbers of inspections, revealing neither violations nor insignificant violations, resulting in fines, number of violations issued and other kinds of punitive actions taken by TFDA could not be established because of the (1) Inadequate record keeping and (2) inadequate format of inspection report which failed to capture the above mentioned information.

Furthermore, it was noted that because of poor record keeping and failure to capture critical data necessary for enforcing food safety in the country, TFDA rarely:

a) takes progressively stronger enforcement action against repeat violators, when warranted;
b) distinguishes between serious violations and minor mistakes on its non compliance records; and
c) provides sufficient guidance on what actions to take in specific circumstances. As a result, plants have repeatedly violated the same regulations with little or no consequence.

Inadequate use of the Inspection Reports

The audit noted that inspectors prepared Inspection Memorandum for each individual inspection and later on recorded the main observations and recommendations in a form of directives in the Inspection Register.

Further analysis of the two sets of inspection reports showed that they have the following weaknesses:

- *Inspection memoranda* do not allow inspectors to comment on the previous inspection directives given to the owner of the processing plants
- *Inspection registers* do not show the number of previously implemented or non-implemented directives to be considered for future inspection

Unscrutinised Food Inspection Reports from LGAs

The audit found out that TFDA zone offices were not scrutinizing food inspection reports submitted by LGAs for detection of deficiencies contrary to the requirements set in the Guidelines for Effective Operations of Zone Offices.

The reviewed annual reports from all five zone offices showed that all zones did not scrutinize the received food inspection reports from LGAs. The Central Zone and Southern Highlands were the only exception which attempted to include information from LGAs.

Inadequate Monitoring and Evaluation of Food Inspection Activities

The interviews with TFDA Officials from Headquarters pointed out that there were no monitoring and evaluation exercises carried-out to assess the performance of food inspection activities both at Processing Plants and Ports of Entry.

It was also noted that failure to monitor performance of inspection activities against the set inspection targets denied TFDA an opportunity to establish whether they are performing well or lagging behind the specific objectives established for the year.

It was also revealed that there is only one Monitoring and Evaluation Indicator specifically for the Food Inspection activities carried out by Food Inspectors. This indicator is aimed at measuring the percentages of the registered premises that have been inspected.

Furthermore, it was observed that the available indicator is focusing on measuring output only (output indicator). This means that TFDA has not developed any outcome indicators which are necessary for assessing the short- and long-term goals and outcomes.

Overall Audit Conclusion

The overall conclusion of this audit work is that the Tanzania Foods and Drugs Authority has not adequately fulfilled its objectives to control safety and quality of food in the country by conducting and managing food inspection. This is due to the fact that Food Inspections both at Processing Plants and at Ports of Entry was not properly planned, no clear targets were set, strategies for those inspections were not well defined and ultimately the actual inspections were not addressing key risk factors which might lead to food-borne diseases.

Similarly, TFDA inspection efforts were unclear and it was not possible for TFDA to establish the level of compliance and performance among Food Processors and Importers.

Audit Recommendations

The following are the recommendations to the Ministry of Health and Social Welfare and Tanzania Food and Drugs Authority:
Tanzania Foods and Drugs Authority should:

1. Carry out the performance profiling of Food Processing Plants and Food Importers in order to establish the compliance level of each of them and use that information as the basis of planning for inspection or re-inspection;

2. Ensure that all zone offices and ports of entry are developing inspection plans based on risk factors and use them as the basis for guiding their inspections;

3. Establish performance measures for food inspection activities, including policy governing risk assessments, timing, work scheduling etc.

4. Ensure that application of sanctions during the inspection is done as per the stipulated laws and regulations, and periodically assess the effectiveness of the applied sanctions;

5. Monitoring and Evaluation indicators for the Food Inspection activities both at Processing Plants and Ports of Entry are formulated and agreed upon; and periodical Monitoring and Evaluation of Inspection activities are carried-out and the results are used as the basis for improvements; and

6. All inspection reports from its zone offices as well as LGAs are thoroughly reviewed and scrutinized to determine any deficiencies and provide feedback to the concerned officials for corrective actions and further improvements;

Ministry of Health and Social Welfare should ensure that:

1. Food Safety Inspections in the country are properly coordinated, harmonized and all stakeholders are working closely together;

2. A general report showing the status of food safety in the country as a result of Food Inspections conducted by different Government Departments is annually compiled and used as the

basis for improving food inspection activities and ultimately food safety; and

3. Data and information regarding food safety are shared among different Government Departments and are used as the inputs for food inspections.

CHAPTER ONE

INTRODUCTION

1.1 Background

A healthy food industry is expected to provide safe and nutritious foods for the communities and entire country in general. At the same time if the sector remained unchecked and uncontrolled it could be a major cause of the spread of diseases resulting in human sufferings in terms of death and loss of time spent on taking care of those who are ill.

The task of ensuring that imported food and domestically produced ones are safe for human consumption fall under the mandate of Tanzania Food and Drugs Authority (TFDA). To exercise its mandate, TFDA conducts inspections of food products, food premises and practices related to export and import of food.

1.2 Motivation

The audit was motivated by the following factors:

There has been public outcry on the existence of food products which were not suitable for human consumption. Some of the recent examples were cases of infant milk, unsuitable meat coming from unsafe slaughtering houses and abattoirs, as well as the recent imported fish recall. Moreover, in recent days Tanzanians have witnessed a number of food consignments impounded at different markets for being unfit for human consumption.

The World Health Organization (WHO) on its *ten facts* about food safety connoted that more than 200 diseases in the world are spread through food[1]. About 75% of the new infectious diseases affecting humans over the past 10 years were caused by bacteria, viruses and other pathogens that were associated with animal and animal products. According to WHO report, millions of people fall ill every year as a result of eating unsafe food. Diarrhoeal diseases alone kill an estimated 1.5 million children affected by contaminated food.

[1] According to World Food Organization (WHO)

WHO estimated that up to one-third of the populations of developed countries are affected by food borne illnesses each year, and the problem is likely to be even more widespread in developing countries.

The food borne illness represents a huge loss for the individuals as well as for the whole society. It affects the productivity of the people all over the world, Tanzanians being one of them, by preventing them to fully discharge their daily economic activities. It also hampers the ability of the Government to reach strategic development goals, both for the society and the country as a whole.

Food Inspection is one of the most important tools for TFDA to reassure itself and ensure that the food in the country is safe and is of high quality. Hence, it is important that the Tanzania Food and Drugs Authority conducts its duties in an efficient and effective way.

The National Audit Office of Tanzania has therefore decided to conduct a performance audit in this area with the view of addressing the concerns raised.

1.3 Audit Design

1.3.1 Audit Objective

The main objective of the audit was to determine whether Tanzania Food and Drugs Authority fulfils its objectives to control safety and quality of food in the country by conducting and managing food inspections.
The specific audit objectives were to determine whether:

- TFDA has risk-based plan(s) for the inspection and surveillance of food processing plants and ports of entry; and rationally allocate resources to areas of greater risk for unsafe food;

- TFDA conducts risk based inspection and surveillance of food processing plants and at the ports of entry so as to minimise availability of unsafe food in the market and protect consumers' health; and

- TFDA conducts periodical monitoring and evaluation of food

inspection and surveillance conducted at the ports of entry and food processing plants and use that information to improve the conduct of inspections.

1.3.2 Scope of the Audit

This audit covers Tanzania Food and Drugs Authority which is under the Ministry of Health and Social Welfare. Within TFDA, an audit was conducted on the Food Inspection and Surveillance programme and focused on the planning, implementation, monitoring and evaluation of food inspections and surveillance at the processing plants and ports of entry.

The TFDA conducts various kinds of inspections namely; investigative, follow-up, special, routine and audit inspections. However, the main focus of this audit was on the routine food inspection which is dominant and regular.

The inspection of foods is carried out by five TFDA Zone Offices. The five zones are: Eastern, Southern, Central, Northern, and Lake Zones.

The audit covers mainly inspection activities during a 4-year period i.e. from 2009/10 to 2012/13.

1.3.3 Audit Criteria

The assessment of this audit was done basing on the following criteria.

Risk-Based Planning

According to the *Risk Based Food Inspection Guidelines (2009), TFDA* is required to categorize all food processing plants and ports of entry according to risk and prioritize its inspections on those risk category. The same guidelines requires that the frequency of inspection to be higher to the food processing plants and food importers who deemed to be more risky.

The International Standards Organisation (ISO) 9001:2008 on quality management systems requires the Food inspector to prepare inspection plan(s) that stipulates the intended inspection coverage,

timing, required resources for inspections, reporting the results of inspection and monitoring the performance of inspections.

Furthermore, TFDA is required to ensure that inspectors are well qualified and carry-out their inspections in accordance with the stated rules and procedures. This is according to *the ISO/IEC 17020:1998(E) and the TFDA Compliance and Enforcement Policy, 2006*.

Execution of Inspections Work

The *Compliance and Enforcement Policy (2006) and the Risk Based Food Inspection Guidelines (2009), requires* TFDA inspections to focus on foods or processes that have high risk and are likely to cause food-borne diseases if left uncontrolled. The same guidelines also require TFDA food inspectors to prepare and submit to their supervisors an inspection report within seven days after the completion of the actual inspection.

The *Tanzania Food, Drugs and Cosmetics Act* (2003) requires the TFDA to sanction all defaulters who have been found to either import or produce unsafe food. The sanctions to be taken include seizure, forfeiture, destruction of the products at the owner's cost and prosecution of owners to courts of law.

Monitoring, Evaluation and Performance Reporting

The *International Standards Organisation (ISO) ISO/IEC 17020:1998(E)* requires that TFDA should have documented procedures for dealing with feedback and corrective action whenever discrepancies are detected in the performance of inspections. In addition, TFDA has to maintain an up-to-date record system of inspection results conducted at food processing plants and food importers. Moreover, TFDA management is required to review and record the quality of its inspections annually.

1.4 Methods Used to Implement the Audit

In undertaking the audit, several key documents were examined. They included the Tanzania Food, Drugs and Cosmetics Act, 2003, TFDA Strategic Plan, Business Plans, Work Plans and Budget, Action Plan

2009/10 – 2012-2013, Zone Annual Reports, Inspection Memorandums, Inspection Registers, ISO 9001:2008 on Quality Management Systems, Inspection Reports, TFDA Risk Based Food Inspection Guidelines, TFDA Training Policy and TFDA Compliance and Enforcement Policy (2006) and other kinds of reports and documents from the TFDA. A comprehensive list of reviewed documents is given in Appendix Two.

Interviews involving large number of stakeholders involved in the administration of the Food Inspection and Surveillance programme were conducted. The interviewees were representatives from the Ministry of Health and Social Welfare, Directors, Managers and Staff at Central and Zonal levels within Tanzania Food and Drugs Authority. Other interviewed stakeholders were TFDA Inspectors, TRA officials, Food importers and owners of food processing plants. The list of interviewees is provided in Appendix Two. The interviews made use of three main audit questions and sub-questions as outlined in Appendix One.

For the purpose of establishing whether food inspectors did follow the inspection procedures when inspecting processing plants; the audit team was accompanied with food inspectors when visiting processing plants in four TFDA zone offices. In total, 21 processing plants were visited by the audit team. These were processing plants dealing with products like bread, meat, dairy products, cooking oil etc. A comprehensive list of all visited processing plants is given in Appendix Two.

For the Ports of Entry, the audit team visited five ports of entry namely, Dar es Salaam Port (its 4 ICD out of existing 10 ICD), Mwalimu J.K. Nyerere International Airport, Horohoro, Namanga and Sirali Border posts.

1.5 Data Validation Process

The Ministry of Health and Social Welfare and Tanzania Food and Drugs Authority, which are directly concerned with this report, were given the opportunity to go through the draft report and comment on the figures and information being presented. They confirmed on the accuracy of the figures used and information being presented in

the audit report.

Furthermore, the information was crosschecked and discussed with experts in the field of Food Safety Management to ensure validation of the information obtained.

1.6 Structure of the Report

This report is presented in five chapters as follows:

Chapter 1 covers background to the audit, audit motivation, audit design (which includes objective and scope of the audit, methods used for implementing the audit) and assessment criteria used during the audit. It also provides details on the data validation process.

Chapter 2 gives an account of the audit area; it narrates the mandate of TFDA to carry out food inspections and surveillance at processing plants as well as ports of entry, strategic objectives of TFDA, sources of financing and key processes used for food inspection.

Chapter 3 provides the main findings of the audit. The findings have been presented under three main sections namely, risk based planning, conducting and monitoring and evaluation of inspection activities

Chapter 4 provides the conclusion of the audit; and

Chapter 5 presents the audit recommendations.

CHAPTER TWO

SYSTEM USED BY TFDA FOR MANAGING FOOD INSPECTIONS

2.1 Introduction

This chapter deals with issues regarding the existing system used by TFDA for managing food inspections and surveillance at processing plants and ports of entry in Tanzania. It covers food control actors, the mandate of the TFDA to carry out food inspections, TFDA main activities, strategic objectives of TFDA, sources of financing, TFDA success over the last ten years, key stakeholders in food inspections and key processes for food inspection.

2.2 Food Control Actors In Tanzania

Ensuring the safety of food for consumer protection comprises of various aspects and activities that make up the national food safety and control system. Therefore, Tanzania has a number of legislations which independently give mandate to different institutions over food safety and control; such institutions conducts inspections and laboratory services separately. The national food control system is comprised of different pieces of legislation along the food chain, inspection systems, analytical services and administration of the control system by different players.

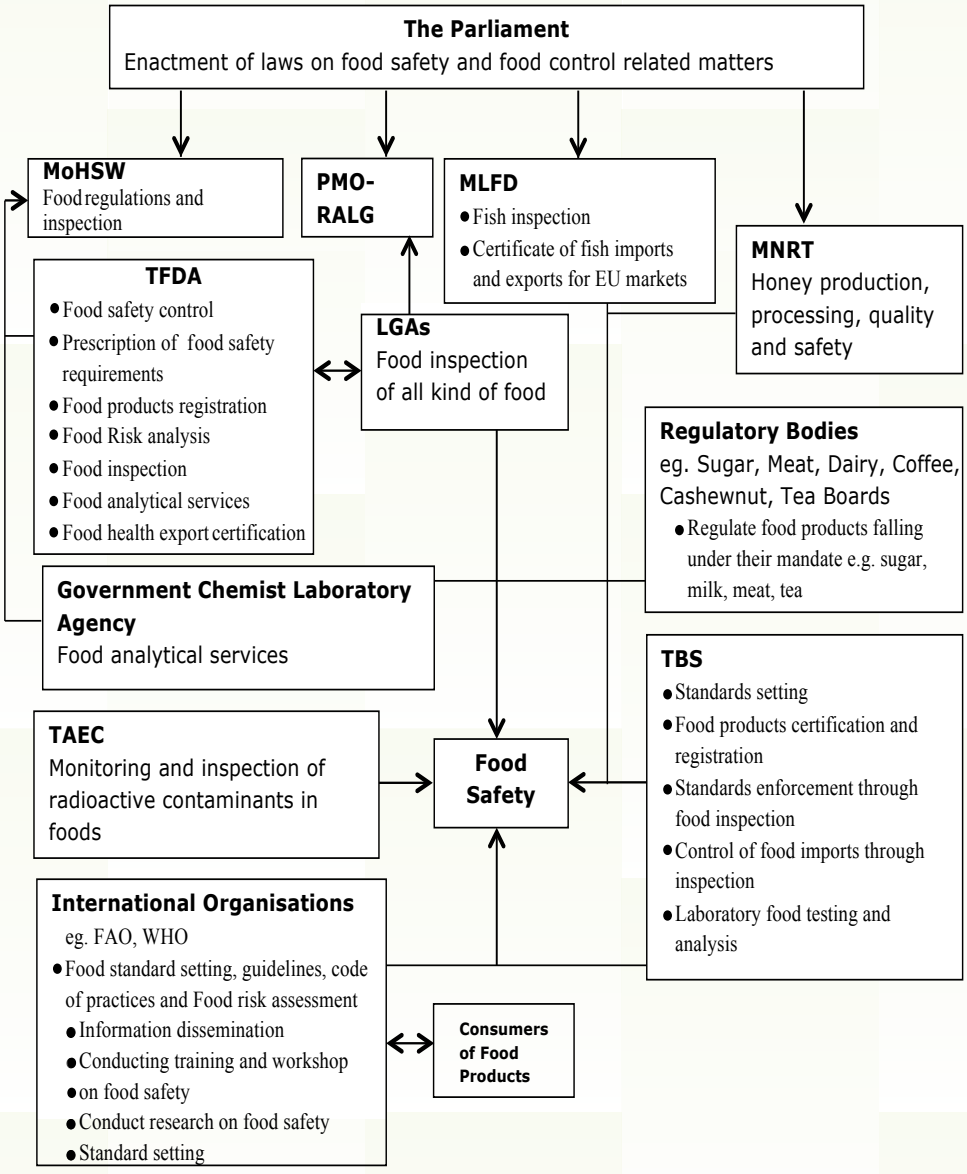


Figure 2.1: Food Control System in Tanzania

2.3 Legal Mandate

TFDA has been empowered under Section 5 of the Tanzania Food, Drugs and Cosmetics Act, No. 1 of 2003 to regulate all matters relating to quality and safety of all kind of food.

Moreover, the Public Health Act of 2009[2] has given mandate to Local Government Authorities (LGAs) to ensure that all premises registered for food manufacturing maintain and adhere to the prescribed public health standards throughout the duration of their registration. This has been the basis for inspection by LGAs to verify as to whether the prescribed health standards have been adhered to or not.

At the Ports of Entry, imported food consignments should be inspected or examined by the Food Inspectors before being removed out of the customs area to ensure that they meet food safety requirements[3]. This also forms the basis of food inspection at the ports of entry.

2.4 TFDA Main Activities

According to section 5(1)(a) of the Tanzania Food, Drugs and Cosmetics Act of 2003, TFDA is responsible for regulating and controlling the quality, safety and efficiency of food, drugs, cosmetics and medical devices. Through enforcement of the Act, TFDA protects and promotes public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices.

Specifically, TFDA is responsible for:

- regulating the manufacturing, importation, distribution and sell of food, drugs, cosmetics and medical devices;
- inspecting food, drugs, cosmetics and medical devices processing plants, premises and selling outlets in ensuring that they observe the set requirements for safety;
- prescribing standards of quality in respect of products manufactured or intended to be manufactured or imported into or exported from in the country;
- assessing, approving and registering products manufactured within or imported into, and intended for use in the country;
- examining, granting, issuing, suspending, cancelling and revoking certificates and licences or permits issued in respect of the products regulated by the authority;

[2] Section 141 of the Public Health Act

[3] Regulation 7(1) of the same regulation states that "No imported food shall be removed out of the customs area before it is inspected or examined, as the case may and certified as fit for human consumption in writings by an inspector".

- providing the public with unbiased information on products regulated by the authority; and
- promoting rational use of drugs, medical devices and herbal drug.

Therefore, this audit is focusing on the inspection of food at the processing plants and ports of entry as one among the core businesses of TFDA with regards to the management of quality of food safety in the country.

2.5 Strategic Goals and Objectives of TFDA's Food Inspections

The TFDA Strategic Plan (2008/09 - 2012/13) set two Strategic goals relating to food safety namely:

- the rate of food not meeting quality and safety standards was to be reduced by 50% by June, 2013; and
- Inspecting 90% of food consignments going through the ports of entry and 70% of registered food premises and identifying the percentage of unregistered premises by June, 2013.

On monitoring and evaluation of TFDA functions including Food inspections and surveillance, the Authority had planned to ensure that M&E framework was developed and implemented by June 2013.

2.6 TFDA's Sources of Finance

The TFDA funds its activities from collections of fees, contributions from the central government for TFDA employees' salaries as well as collections from Development Partners and TFDA stakeholders.

The total amount of funds spent on the Food Inspections and Surveillance by TFDA is shown in Table 2.1 below. Both the budgeted amount and the actual expenditure increased by more than 182% between the last three financial years, 2009/10 – 2012/13. This increase of the total funding can possibly be explained by the increasing number of food processing plants as well as the rising amount of imported foods during this period.

Table 2.1: Budget and Actual Expenditure of the TFDA on Food Inspection for the Period 2010/11-2012/13

Financial year	Budgeted amount (Tshs. Million)	Actual expenditure (Tshs. Million)	Number of		Number of Food Inspectors	
			Food Processing Plants	Ports of Entry	Food Processing Plants	Ports Of Entry
2009/10	102	92	679	32	10	0
2010/11	110	100	1327	32	29	3
2011/12	122	122	1545	32	29	3
2012/13	287	267	1589	32	30	3

Source: *TFDA Medium Term Expenditure Framework (2009/10 - 2012/13)*

2.7 Organization Structure of TFDA

Generally, TFDA functions are coordinated under four directorates, the Directorates of Business Support, Medicine and Cosmetics, Food Safety, and Laboratory Services.

The Directorate of Food Safety is the one which has got the responsibility of conducting Food Inspections and Surveillance at Processing Plants and Ports of Entry. Within this directorate, there are three sections namely; Food Inspection and Enforcement, Food Evaluation and Registration and Food Risk Analysis.

The responsibilities of the Sections under the Directorate of Food Safety are interdependent. Zone Offices also report to the Director of Food Safety through the Zone and Local Government Authority Coordinator (ZOLGAC) for technical issues but for administrative matters they report directly to Director General.

The Directorate of Business Support is responsible for monitoring and evaluating the performance of all TFDA activities including Food Inspections and Surveillance.

2.8 Relationship between the Ministry and TFDA

Tanzania Foods and Drugs Authority (TFDA) is a government agency under the Ministry of Health and Social Welfare, established for the

purpose of regulating and controlling safety and quality of medicines, cosmetics, food and medical devices. TFDA was established after the amalgamation of the Pharmacy Board and the National Food Control Commission which were brought about by the enactment of the Tanzania Food, Drugs and Cosmetics Act of 2003.

The Ministry of Health and Social Welfare is charged with the responsibility of overseeing all issues regarding health in the country including Food Safety. Therefore, TFDA reports back to the MoHSW on issues regarding Food Safety in the country. As such TFDA Director General's reports to the Permanent Secretary of the Ministry of Health and Social Welfare who subsequently reports to the Minister of Health and Social Welfare.

The oversight role of the Permanent Secretary to TFDA is a shared responsibility with the Ministerial Advisory Board (MAB). The function of the ministerial advisory boards is generally to advise the Minister on the following matters: the development and maintenance of a strategic framework, the objectives of the TFDA, the acceptability of the Chief Executive Officer's plans and associated budgets, the setting of priorities and annual performance targets for TFDA, the TFDA's annual reports and accounts, the evaluation of the TFDA's performance, and any other matter provided for in the Tanzania Food, Drugs and Cosmetics Act of 2003.

2.9 Key processes of Food Inspections and Surveillance

2.9.1 Planning for the Food Inspections and Surveillance

Planning for food inspection is a fundamental requirement by the quality management system as laid out in ISO 9001:2008. The standards require that the outputs from one process to be the inputs for the other. The sole responsibility over planning for TFDA activities was vested to the Planning Unit. But, the Planning Unit had to be fed by the reports from food inspectors and food analysis to be able to establish the risk category of Processing Plants and Ports of Entry. The plans are supposed to set priorities and frequency of inspection having considered that TFDA could not have the required capacity to conduct inspections in the entire food industry in the country.

2.9.2 Implementing Food Inspections and Surveillance Plans

According to the requirements of ISO 9001:2008, the outputs (plans) from the Planning Unit are used by food inspectors in conducting food inspections. The inspectors are supposed to conduct inspection activities to prioritised Food Processing Plants and Ports of Entry. The frequency of inspection should focus on such processing plants and imported Food Products which had been identified in the plans to be of high risk.

2.9.3 Reporting the Results of Food Inspections and Surveillance

In response to TFDA's Standard Operating Procedures (SOP's), food inspectors are required to prepare and submit inspection reports. Such reports are regarded as one of the monitoring tools used by the Planning Unit as well as TFDA's Management review of the conduct of inspection to which the reports were submitted.

Inspectors had to prepare and submit reports to their Zone Managers. From Zone Offices such reports are to be compiled and submitted to ZOLGAC on monthly, quarterly and annual basis. ZOLGAC had to subsequently submit such reports to the management for the scrutiny and detection of weaknesses and provide recommendations for corrective measures.

2.9.4 Sanctioning the Defaulters

According to TFDA Compliance and Enforcement Policy, TFDA is responsible for nationwide compliance with food safety standards and enforcement of legislative and regulatory requirements through food inspections conducted across a variety of regulated food products. The fundamental objective of food inspection is to ensure that food processors and manufacturers together with food exporters and importers are in conformity with the legislative and regulatory requirements set in the *Tanzania Food, Drugs and Cosmetics Act* and its regulations.

It is in the interest of any regulatory authority that appropriate interventions[4] as stipulated in the Act, regulations, and the TFDA Compliance and Enforcement Policy of 2006, and TFDA guidelines are strictly applied to non-compliance in order for TFDA to achieve its objective of protecting the health of food consumers.

Such interventions may be undertaken independently, concurrently or sequentially with other actions, if the circumstances warrant. It is the responsibility of a regulatory body to train its inspectors on issues regarding food safety, at what time and circumstance should these interventions be maintained. If food inspectors do not apply these interventions appropriately the entire purpose of food inspection to compel food producers and importers to observe the requirement to safety would be defeated.

2.9.5 Monitoring, Evaluating and Reporting on Performance of Food Inspections

According to the ISO 9001:2008 an entity is required to apply suitable methods for monitoring. These methods shall demonstrate the ability of the processes to achieve planned results and when planned results are not achieved, correction and corrective actions ought to be taken, as appropriate.

In the course of implementing its plans, it is crucial for any entity to be able to monitor and evaluate implementation of its work plans and programs. Monitoring and Evaluation[5] provide information about the entity's strategic plan and business plan's progress and target accomplishment.

The TFDA manual for monitoring and evaluation shouldered monitoring and evaluation responsibility to the Directorate of Business Support. This includes planning, executing and reporting on the results of Monitoring and Evaluation. The Strategic Plan requires that the

[4] Appropriate interventions include forfeiture following seizure or prosecution, injunction, prosecution, public warning or public advisory, refusal or suspension of licence, regulatory stop sale, seizure and detention, suspension or cancellation of marketing authorization or product licence, and warning letters.

[5] Monitoring and Evaluation (M&E) system is a means for assessing organizational efficiency, effectiveness, relevance and sustainability. Its purpose is to promote accountability and transparency to TFDA stakeholders.

results of Monitoring be reported quarterly while that of Evaluation be reported at the Mid of the implementation of the Strategic Plan and at its end.

2.10 TFDA's Success Over the Last Ten Years

The Audit Team noted the efforts TFDA is undertaking to safeguard the quality of food in the country despite a lot of challenges associated with the execution of its responsibilities including but not limited to:

- Attaining the centre of excellency for Food Safety in the East and Southern part of Africa
- Accreditation of Food Safety Laboratory by the International Atomic Energy Agency
- Attaining ISO 17025 Certificate
- Since 2003 to 2013 TFDA has received total of 11,689 food products applications for registration out of which 5,918 products were registered;
- From 2005 to 2013 TFDA has granted 19,925 permit to import food in the country and 1,321 applications where denied. Similarly the Authority granted 2,115 export permit of food from Tanzania and denied 21 applications;
- In 2006 TFDA established the Eastern Zone for the purpose of taking the services closer to its customers; and the authority has proceeded to establish five zone offices whereby all the regions in country have been assigned under a specific zone office;
- The authority managed to increase its employees from 62 to 182 in 2003/04-2013 which also include food inspectors and for that it managed to have its own employees (food inspectors) stationed at some of the ports of entry used for importing and exporting of food products;
- The Authority was awarded the best managed institution award in the country among ministries, departments and government agencies in 2010;
- To have conducted a research on mycotoxins in cereals that

helps in regulating food safety in the country.

Despite huge successes made by TFDA since its establishment, the audit team noted there is room for further improvements on the way TFDA is conducting food inspections. Those areas are pointed out in the finding chapter.

CHAPTER THREE

AUDIT FINDINGS

3.1 Preamble

This chapter presents the findings of the audit that addresses the audit objective and its three sub-objectives described in chapter one, covering status on the following:

- Planning for Food Inspections at Processing Plants and Ports of Entry;
- Conducting Food Inspections; and
- Monitoring, Evaluating and Reporting on Performance of Food Inspections.

3.2 Planning for Food Inspections

According to FAO Risk-Based Inspection Manual, authorities are supposed to plan for the Food Inspections. They need to plan and control the inspectors, decide on the nature and type of inspections to be carried-out, inspection scheduling and supervision of inspectors to maximize their productivity and to reduce the risk of dishonest behaviour. The same have been stated in the TFDA Risk-Based Inspection Guidelines (2009).

The following were the main issues observed during the audit:

3.2.1 Addressing Key Features for the Risk-Based Inspections Plans

TFDA was supposed to prepare risk-based inspection plans which addresses all key features including; required number of inspections to be made in a particular period of the year, number of inspectors, mode of supervision and ways and means to be used to manage and monitor for performance and productivity of the inspection techniques as well as inspectors.

The audit found out that TFDA had inspection plans which did not address key features for the risk-based inspection. This was noted through the reviewed inspections action plans developed by each Zone Office.

The sections below provide the analysis of the key features which were not included in the risk-based inspection plans.

Number of Inspections to be made

The Business Plans did not set the inspection milestones/targets expected to be attained in a particular period of the year. Similarly, the reviewed plans showed that they were lacking the set time frames as to when inspections were expected to be conducted and to which particular processing plants or ports of entry.

Moreover, the 20 reviewed action plans from all five zone offices showed that the plans did not have the number of inspections to be made in a particular period of the year, the extent of coverage, the desired inspection frequency and other factors such as re-inspecting food processing plants with serious violations or scheduling inspections in response to consumers' complaints.

The only information which was included in the developed action plans were regions to be visited during the inspections, budget set for the inspections (amount of money for inspection visits) and type of inspection to be conducted, mainly audit inspection.

Further analysis on the adequacy of the register of processing plants revealed that, there is no assurance that all facilities required to be licensed or registered have actually been filed and recorded in TFDA Register provided that the register is the original source document for the inspection census.

Zone managers acknowledged that the starting point for control is the inspection census i.e. a complete and current listing of all food processing plants subject to inspection.

Furthermore, the Audit review of the Food Inspections Guidelines showed that the issue of inspection frequency is left to the judgement of the zone offices; the Zone Manager needs to weigh the costs of inspection against the risks of insufficient numbers of inspections. This means that the Zone Manager needs to consider (and continuously reconsider) such factors as:

- the number and seriousness of violations found on previous inspections;
- the extent to which food safety goals are being achieved as a result of the inspection program; and
- the nature and extent of consumers' complaints.

The interview with Zone Managers, ZOLGAC and officials from Planning Unit within TFDA when trying to establish the reasons for the identified weaknesses in the inspection plans commented that it was an oversight which had to be rectified on subsequent plans by the concerned officials under the Planning Unit.

Number of Inspectors Needed

The audit noted that TFDA has a defined system used for allocating inspectors for inspection of processing plants and ports of entry, but the system was found to have a number of deficiencies.
In that aspect, the officials acknowledged that the plans were prepared without considering factors such as

- the number of inspectors needed to conduct an inspection program
- the number of inspections to be made and the length of time it takes to make an inspection of the desired quality.

Moreover, it was noted that there is no set time frames which define how long it should take to make an inspection of a particular processing plant or imported food consignments. The TFDA officials acknowledged those factors such as what needs to be inspected, how it should be inspected, the number of items to be inspected at a given facility, and the conditions encountered during an inspection were rarely considered when developing the inspection plans.

Supervising the Inspectors

Supervision of food inspectors was another area not reflected in the inspection plans developed by TFDA zone offices. The interviews with Zone Managers revealed that certain types of inspection activities like Food Inspection may lead inspectors to corruption. This is due, in part, to the "fieldwork" nature of inspection, the "one on one" relationship between the inspector and the inspected part, and the potential for significant cost to correct violations disclosed by inspection.

Therefore, the 20 reviewed action plans did not reflect and address the risk of corruption by ensuring that Zone Offices sets and adopts a plan which would be used to supervise the inspection activities that are likely to reduce the potential for corruption and guarantee the desired quality of the inspection.

Zone Managers pointed out that the main effects of not having a clearly stipulated supervision plan include failure to:

- confidently ascertain the quality of the inspection results;
- fairly promote/reward and commensurate some inspectors that have shown outstanding performance;
- have a system of rotating inspectors among the inspected processing plants; and
- identify inspectors who need to undergo periodic refresher courses designed to encourage professional attitudes and maintain quality of the inspections.

Managing and Monitoring for Performance and Productivity

The reviewed inspection plans were silent on the issue of managing and monitoring for results of inspections. The review noted that TFDA has not planned for the performance objectives of the inspections (in terms of both results and inspectors productivity), developed indicators to measure performance, schedule specific inspections (monitoring visits), monitor performance against the objectives, and institute corrective actions when performance lags behind the specific objectives established for the year.

Furthermore, it was also noted that lack of area coverage, milestone and timing has made monitoring of inspection activities to be difficult and unrealistic for the management on quarterly and on midyear basis.

3.2.2 Prioritisation of Food Safety in Inspection

The audit office made an analysis on the level of prioritization of inspections to the food processing plants and port of entry which were of high risk and required more frequent inspections.

Table 3.1 below provides the analysis of the relationship of the identified high risk food products, identified high risk processing plants and the frequency of inspections conducted at the processing plants for the financial year 2012/13.

Table 3.1: Names of Foods and Number of High Risk Processing Plants (2012/13)

List of identified high risk food product	Number of identified high risk-processing plants	Frequency of Inspection (*High*, *medium*, *low*)
Meat and Meat Processing Products	13	Not stated
Milk and Milk Products	11	Not stated
Fish and Fish Products	10	Not stated

Source: TFDA's Database of High-Risk Food Products

Table 3.1 shows that even though TFDA has identified high risk food products and processing plants based on the nature of the products they produced; this was not reflected in the action plans used for the inspections. The action plans were silent on the matter of frequency of inspections to be conducted to those high-risk processing plants and imported high risk food product in that aspect both processing plants (high, medium or low risk) were given equal weight during the inspections.

Furthermore, it was noted that TFDA Zone Offices have not set any frequency for the inspections and it was only stated in general terms that inspections would cover all processing plants in the vicinity. This was found to be contrary to the guidelines for risk-based inspections which required Zone Managers to identify High-Risk Processing Plants and set frequency for inspections.

The list below shows the identified high-risk products for which there was no prioritisation done for inspections in 2012/13.

a) Dairy products and analogues
b) Meat and meat products, including poultry and game
c) Fish and fish products including molluscs, crustaceans and echinoderms
d) Eggs and Egg Products
e) Spices, soups, sauces, salads and protein products
f) Processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera), seaweeds, and nuts and seeds
g) Ready-to-eat savores
h) Composite Foods
i) Portable water

The above list shows that even though TFDA has identified high risk food products and categorized them, this categorization was not reflected in the action plans prepared for the inspections of imported food products. The action plans were silent on the matter of frequency of inspections to be conducted to those high-risk food products and that all imported food products (high, medium or low risk) were given equal weights during the inspections.

Furthermore, it was observed that neither the guidelines for importation and exportation of food products nor the Standard Operating Procedures provided directives to the inspectors on the need for frequent inspections to high risk food products.

Generally, it was noted that because of the failure of TFDA to establish performance profile of processing plants (plants of high risk likely to

produce unfit food for human consumption) it has led its inspectors into attempting to conduct inspections to all processing plants in a particular zone office.

As such TFDA was running into a risk of failing to prioritize its inspection to the high risk food processing plants and imported foodstuff. This demonstrates a failure to strictly adhere to Risk-Based Inspections Guidelines and not making use of its advantages.

3.2.3 Factors Contributing to the Inappropriate Planning for Food Inspection

The account above demonstrated challenges in planning for food inspections. The following were the major causes for the inappropriate planning for food inspections at Processing Plants and Ports of Entry:

- Risk analyses that failed to establish the compliance/ performance profile of both the processing plants and licensed importers of food products in the country;
- Inadequate use of Risk-Based Inspection guidelines during the planning of individual inspections;
- The management of TFDA has not yet issued any guidance/ directives to guide its inspectors on how they can make use of different guidelines present to-date;
- Inadequate coordination between inspectors, risk assessors, zone offices, planning unit/department etc. during the planning stage of food inspections; and
- Most of the Inspectors were not trained on how to conduct risk-based inspections.

These causes are discussed in more details in the following sections:

Unconducted Risk Analysis of Processing Plants and Imported Foods

According to the TFDA's Risk-Based Inspection Guidelines (2009) and the FAO's Risk-Based Inspection Manual, TFDA was supposed to carry-out risk assessment of both Processing Plants and Ports of Entry and use those information as the basis for planning and allocating

resources for the food inspections.

The interviews with food inspectors from Zone Offices revealed that no risk analysis was done from Zone Office which would have helped them in planning for risk based inspection. Similarly, the audit team noted that there were no planning documents from zone offices to verify as to whether risk analysis was made and that food processing plants and ports of entry have been classified and ranked in accordance to the level of risks they pose.

The following risk factors were not considered by the TFDA:

- Results of epidemiological surveillance by Health Authorities in Tanzania;
- Product and producers' history, particularly a record of non compliance or consumer complaints; and
- Frequency of non compliance with regulations by food processing operations that result in unsafe foods.

Despite the fact that such information is stated in the inspection guidelines and was supposed to guide the planning part of the inspections, it was not considered.

During the discussion with TFDA inspectors and zone managers it was noted that the memorandum of inspections and inspection registers would have been the two important documents used to assess the compliance of processing plants inspected, determine their risk category and set the frequency of inspection.

This analysis would have been a potential factor for processing plants performance profiling and subsequently in establishing high risk food processing plants and as such a key tool for planning.
One of the reasons cited by TFDA for not considering risk factors was that the knowledge on risk assessment among its inspectors is still minimal and they need to work on it. Secondly, the staff who are working on risk unit are few and it is hard for them to cover all issues which the authority is dealing with.

Inadequate use of the Risk-Based Inspection Guidelines

The audit noted that TFDA inspectors were not planning their food inspections for the processing plants and imported food products as per the Risk-Based Inspection Guidelines.

The inspectors were instead using guidelines for application and registration of pre-packaged foods which does not provide clear guidance on how to identify risk factors and take them into account during the planning of their inspections.

Non issuance of directives by TFDA Headquarters

TFDA has got a number of guidelines to be used by inspectors and zone offices while discharging their responsibilities. These guidelines include:

a) Risk-Based Inspection guidelines,
b) Guidelines for application and registration of pre-packaged food,
c) Guidelines for TFDA delegated functions to LGAs,
d) Guidelines for conducting audit inspections,
e) TFDA compliance and Enforcement Policy,
f) Guidelines for Importation and Exportation of food products,
g) Guidelines for Investigation and Control of Food-Borne Diseases,
h) Guidelines for Registration and Licensing of Food Premises, and
i) Standard Operating Procedures for Inspections

Therefore, it was expected that TFDA would communicate these guidelines to its zone offices and give directives to food inspectors on how to apply them when conducting food inspections at processing plants and ports of entry.

The interviews with Food Inspectors from four TFDA zone offices and five Ports of Entry revealed that they were not aware of the existence of the risk-based inspection guidelines but they were aware of the existence of guidelines for application and registration of food products. They commented that the Authority had not issued

directives to inform and guide them on how to use and differentiate the objectives and applications of each of the two guidelines.

Inadequate coordination during the planning stage

Inadequate coordination among inspectors, food risk assessors, Zone Managers and Planning Unit during the planning of inspection was another factor which contributed to the existence of inadequate planning of inspections.

This was the case because:

- The results from the Risk Analysis Unit (Risk Analysis Report) would have been useful to the inspectors and the Planning Unit in planning for risk based inspection. The Risk Analysis Report (output) from the Risk Analysis Department was to be used as inputs by both the Planning Unit and food inspectors in planning for their inspection. That was a chain of input-output relation described in ISO 9001:2008 on quality management system which states that the outputs from one Department are supposed to be inputs to the other.

- Similarly, it was also noted that the Planning Unit had not used any input from the Risk Analysis Unit in planning for food inspection. The Risk Analysis Unit had not used inspection memorandum, reports or registers in establishing the risk category for food processing plants and for imported food products. Further analysis revealed that there were no food inspectors who used food analysis reports in conducting food inspection.

Most of the Inspectors were not trained on how to conduct Risk-Based Inspections

Another factor which was pointed out by TFDA officials as one of the contributory factors for the inadequate planning of food inspections is insufficient knowledge on issues regarding risk-based inspections. The analysis was made by the audit team to establish the number of inspectors who were trained on risk based inspections and even those who have an access to the risk-based inspection guidelines.

Out of 18 inspectors interviewed from four TFDA zone offices and five ports of entry only two had been trained on risk based food inspection. This is despite the fact that TFDA was expecting them to conduct inspections based on major risk factors but the authority did not prepare them to do so. The same was confirmed by the reviewed TFDA's Annual Training Reports for the period 2009/10 to 2012/13.

When inquired for the reasons why the inspectors were not exposed to issues related to the technicalities of risk-based inspections, the Human Resources Department commented that TFDA had not conducted Training Needs Assessment of its Inspectors, so it was stated that it was not easy for TFDA to understand their training needs. Furthermore, Officials from the Human Resources Department indicated that at the end of year 2013, TFDA had conducted training needs of its staff and now the plans are underway to implement the Training Program which was developed as a result of the needs assessment exercise. That was stated as the main reason for the TFDA not having staff that were trained on risk-based inspections.

Moreover, the Audit review of training reports made by auditors revealed that in 2010 TFDA conducted training on how to conduct risk-based inspections. The training was funded by Food and Agriculture Organisation (FAO) and it was not clear why those 16 Food Inspectors were not part of the officials of TFDA who attended that training.

3.3 Conducting Food Inspections at Processing Plants

3.3.1 Coverage of the Planned Inspections

According to the TFDA Strategic Plan and Risk-Based Inspection Guidelines, TFDA is required to conduct all planned inspections to Processing Plants. The same guidelines provide for an opportunity to conduct emergency or ad-hoc inspections in case there is a need.

The review of annual action plans prepared by Zone Offices showed that there were no set milestones determining the number of processing plants to be inspected per year, the estimated time for the inspection to be conducted and even the resources to be used for

the particular inspection.

The interview with TFDA Inspectors and Zone Managers revealed that TFDA in zone offices supposed to inspect all processing plants at least once every year. Therefore, they concluded that if a particular zone has 135 processing plants then all of them ought to be inspected every year.

Table 3.2 provides the analysis of the number of inspections carried out per annum against the number of planned inspections (this is similar to the number of registered processing plants in a particular vicinity).

Table 3.2: Percentage of Processing Plants Inspected per Annum (2012/13)

Zone	Number of Planned Inspections	Number of Inspections conducted	Percentage Inspected (%)
Northern	100	90	90
Eastern	200	285	143
Southern	40	77	193
Central	50	26	52
Lake	80	38	48

***Source**: TASA and Zone offices annual reports (2012/13)*

Table 3.2 shows that two zones surpassed the number of planned inspections to be conducted while the other three zones failed to inspect all processing plants in their localities. The data also shows that in Lake Zone, the inspection coverage is below fifty percent. This means that almost half of the processing plants in that zone were not inspected despite the fact that TFDA had planned to inspect them.

Further analysis to check whether there is any rotation when conducting inspection on the following year revealed that there is no rotation on which processing plants had to be covered. Currently, the Zone offices still stick with conducting inspections to all processing plants even though that goal was not managed in the previous year.

It was also commented by TFDA officials that there is a risk for some of the high risk processing plants to remain un-inspected for a number of years because the current system did not allow for proper goal and target setting for the inspections of processing plants.

Another consequence pointed out for the inability to inspect food processing of which some produce high risk food products was that, the entire population could be subjected to the risks of diseases associated with such products in case those uninspected plants violate food safety.

Inspection Visits to LGAs

The same situation was also observed on the inspection visits supposed to be made by TFDA inspectors to LGAs in their respective zones. In this aspect, zones did not stipulate the number of visits to be made within their jurisdictions.

Table 3.3 below depicts the details regarding the number of present councils in each zone and actual number of councils visited for inspecting various issues regarding Food Safety in the Financial Year 2012/13.

Table 3.3: Percentages LGAs inspected by TFDA inspectors for the financial year 2012/13

Zone	Number of LGAs in a particular zone	Number of LGAs Inspected	Percentage Inspected (%)
Southern	32	27	84
Eastern	33	27	82
Northern	29	23	79
Lake	44	33	75
Central	24	10	42

***Source**: Zone Offices Annual Reports (2012/13)*

Table 3.3 shows that four zones managed to cover more than two-third of the LGAs in their areas while Central Zone covered less than half of the LGAs. This means that more than half of the LGAs in

that zone were not inspected despite the fact that TFDA had that intention of inspecting them.

3.3.2 Inspections were not conducted to High Risk Food Processing Plants

The TFDA's Risk-Based Inspection Guidelines as well as the FAO's Risk-Based Inspection Manual require Food Inspections to be prioritized to the high risk food processing plants in order to drive up levels of compliance and make appropriate use of present resources for food inspections.

The audit found out that TFDA did not prioritize its inspections based on the risk posed by particular processing plants. The basis for deciding which processing plant is to be inspected or not is not clearly stipulated. Currently the ambition is to cover all processing plants falling within the jurisdiction of a particular zone regardless of the risk they pose.

One of the noted reasons for non prioritisations of inspections was that there is a conflicting requirement where TFDA is required to collect fees and charges so as to be able to finance the exercise using its own funds. Therefore, the issue of maximum result with regard to collection of fees and charges may compromise the issue of prioritizing and inspecting high risk food processing plants only since inspecting all processing plants contributes to maximization of collectable fees.

However, the interviews with Food Inspectors confirmed that TFDA was unable to conduct food inspection to all food processing plants and could not ascertain as to whether un-inspected food processing plants were of high risk or not. This is despite the fact that the Guidelines for Application and Registration of Pre-Packaged Food Products listed food products which are of high, medium and low risks.

The Audit team managed to establish that despite the fact that TFDA zone Offices carried-out inspections randomly (covering both high, medium and low risk processing plants) the inspections were not able

to cover all high risk processing plants in all five zones of TFDA. This is as depicted in Table 3.4.

Table 3.4: Number of High Risk Processing Plants covered during the Inspections (2012/13)

Zone	Number of Processing Plants Inspected	Number of High Risk-Processing Plants	Number of High Risk-Processing Plants covered during the Inspection
Northern	90	8	Not established
Eastern	285	12	Not established
Southern	77	2	Not established
Central	26	2	Not established
Lake	38	10	Not established

***Source**: Zone Offices Annual Reports (2012/13)*

Table 3.4 above shows that there is no evidence to show that the inspections conducted by TFDA to the processing plants covered processing plants which were at high risk to produce food unfit for human consumption. This also shows that the inspections were conducted without taking into account the need to categorize processing plants based on risks they pose

When inquiring more on the reasons for not categorizing processing plants based on risks they pose and then plan inspections accordingly, the following reasons were cited by TFDA officials:

- Insufficient use of the risk-based inspection guidelines during the inspections,
- Limited use of inspection database which would assist inspectors to identify areas of high risks (focus areas), and
- Shortfalls in establishing performance profile of individual processing plants in the particular zones.

3.3.3 Factors contributing to the inadequate coverage of Inspection at Processing Plants

Further inquiry of the main factors which contributed to the inadequate coverage of food inspections at processing plants the

following factors were pointed out through the interviews with TFDA officials as well as from reviewed plans, inspection reports and guidelines:

- Unclear understanding of the types of inspections to be conducted
- Inadequate planning for the food inspections
- Inadequate usage of present food inspection resources (both human capacity, funding and inspection tools)
- Inspection checklists were not addressing crucial issues regarding food inspections

These factors are further elaborated below:

Unclear understanding of the types of inspections to be conducted

Through the interviews with Zone Managers and TFDA inspectors it was noted that TFDA zone offices were unclear as to whether they were supposed to conduct audit inspections only or both audit and routine inspections.

The Northern and Lake zones revealed that they were to conduct food audit inspections because LGAs had been granted the power through TFDA's Guidelines for Delegated Functions to LGAs to conduct routine inspections. Officials from the Eastern and Central zones had different views and revealed that they were supposed to conduct both routine (risk based inspections) and audit inspection.

Furthermore, the misunderstanding on whether to or not conduct routine inspection to food processing plants was noted when reviewing the Guideline for TFDA Delegated Functions to LGAs of 2007.

At the same time it was noted that the TFDA Guidelines for Effective Operations of Zone Offices in the country did not indicate as to whether zone offices were to conduct risk based routine inspection.

The TFDA inspectors pointed out that the misunderstanding of the type of inspections contributed to the inadequate coverage since some of the inspections to be conducted were left out.

Inadequate planning for the food inspections

Another factor for the inadequate coverage of inspections at food processing plants disclosed by TFDA Officials both at Headquarters and Zones offices is the inadequate planning for the inspections.

It was acknowledged that most of the challenges faced were as a result of failure to assess risks among processing plants and plan inspections based on the identified risks. Similarly, it also came out of the discussions with planning officials within TFDA that the set goal of inspecting all processing plants at particular zones was not realistic taking into account the present available resources in terms of time, human capacity, inspection tools and budgetary allocations for the inspections.

Inadequate usage of present food inspection resources

Another factor pointed out by interviewee from TFDA which contributed to the inadequate coverage of inspection at food processing plants was the inadequate usage of present food inspections resources. These were resources such as Human resources (mainly inspectors), inspection tools and the funds set aside for food inspection activities.

The following is the analysis of the three mentioned resources used by TFDA while conducting inspections.

Usage of Food Inspectors

To establish to what extent is TFDA making efficient use of its inspectors, the audit team computed the ratio of the number of inspections conducted per inspector. This was computed for all five zone offices and then the comparison was made. The analysis is as pointed out in Table 3.5.

Table 3.5: Ratio of the number of inspections per inspector in Zone Offices (2012/13)

Zone	Number of Planned Processing Plants to be Inspected	Number of Processing Plants Inspected	Number of Inspectors	Ratio of number of Processing Plants Inspected per Inspector
Northern	100	90	3	30
Eastern	200	285	9	32
Southern	40	77	1	77
Central	50	26	1	26
Lake	80	38	2	19

***Source**: Inspection Reports from Zone Offices (2012/13)*

Analysis from Table 3.5 shows that there is a huge difference in the ratio of the number of inspections conducted per inspector in zone offices. The noted difference is ranging from 19 to 77 inspections per inspector.

This means that the number of inspections performed by inspectors from Southern Zone is four times higher than that of inspectors from Lake Zone. On the other hand the remaining zones are delivering around 30 inspections per inspector per annum.

Further analysis to check whether TFDA has established the standard number of inspections which could be performed by one inspector within a year showed that TFDA has not established that one. In that aspect, it was acknowledged during the interviews that TFDA cannot measure the performance of its inspectors and has got no basis for allocating its inspectors.

Non-availability of sufficient inspection tools

The analysis of the availability of inspection tools to the zone offices was made by assessing the availability of inspection tools against the required inspection tools (as stated in the Appendix 9 of the TFDA's Risk-Based Inspection Guidelines).

It was found out that all five zone offices lacked the required inspection tools. Out of 50 inspection tools needed to be used by inspectors while conducting food inspections in Zone Offices there were none at all.

This is despite the fact that the Risk-Based Inspection Guidelines have clearly indicated the required necessary tools for the inspections. The list of missing inspection tools are shown on Appendix Three of this report.

Furthermore, from our physical observations during the inspections, the audit team noticed that TFDA food inspectors had no inspection tools of their own. It was also noted that to some extent inspectors depended on the tools which were availed to them by the owners of the inspected processing plants. Using tools availed by owners compromises the results due to uncertainty of the calibrations and can easily lead to a conflict of interest situation.

Budgeting or funding for the inspections at the Processing Plants

Interviews with the Planning Officers, Zone Managers and Inspectors pointed out that the budget for inspections at processing plants is set under the DG's Office and then it is distributed quarterly to individual Zone Offices.

Furthermore, it was noted that there is no specific budget for food inspection distributed at Zone Offices. The distributed one encompasses other areas of inspections such as drugs, cosmetics and medical devices. This has made inspections for different items i.e. food, cosmetics, drugs and medical devices to compete against one another on the available distributed of the little resources.

Similarly, the audit team failed to get the exact budget set aside for the inspections of food processing plants and imported food products for each of the five TFDA Zone Offices.

However, the audit offices decided to analyse the extent/level of distribution of the budgeted funds set for the inspection of food, drugs, cosmetics and medical devices due to the fact that TFDA is

using large part of the funds for the inspections of processing plants. Table 3.6 shows the ratio of the amount of funds budgeted for the inspection activities of the food processing plants and the number of processing plants in each of the five Zone Offices of TFDA.

Table 3.6: Amount of Funds Budgeted for the Inspection of Food Processing Plants for the Financial Year 2012/2013

Zone	Amount of funds budgeted for inspection activities (TShs.)	Total Number of Food Processing Plants	Ratio of the amount of funds per number of Processing Plants (TShs./Plant)
Northern	60,750,000	143	424,825
Eastern	55,520,000	303	183,234
Southern	51,350,000	463	110,907
Central	27,167,000	42	646,833
Lake	60,750,000	167	363,772

Source: *2012/13 TFDA's Financial Records and Importation Reports*

The above analysis shows that there is great variation of the way TFDA is allocating funds for inspection activities. It shows that the Central Zone was allocated almost six times of the amount of funds for each processing plant than Southern Zone which has got more than ten times the number of processing plants as compared to the central zone.

The huge difference in resource allocations can be explained by a number of factors, one of them being the number of inspections done on other areas such as Pharmacies, Shops etc.

The other reason is the lack of properly defined factors to be considered while setting aside budget for inspection activities performed by TFDA Zone Offices.

Inspection checklists were not addressing crucial issues

The reviewed inspection checklists used by TFDA inspectors while inspecting processing plants were found to include seven main items which are checked by inspectors. Those main items include: Location/Site, Building/Construction, Water Supply, Raw Materials,

Processing and Equipment, Sanitation and Hygiene, and Records.

Furthermore, the review of the same checklists showed that when premises scored a certain range of points, then they can either be deemed to qualify for registration and license/permit or may qualify for registration and licensing with conditions of improvements for future.

Based on that analysis, the audit noted the following weaknesses on the checklists for the inspections of processing plants:

- The first two items that are assessed during the inspections of processing plants, are not directly linked to the issue of the quality of the food products. These items were *location/ siting* and *building/construction*. This means that on average 25 percent of the marks were allocated to issues which were not directly affecting the quality of the food product; and
- Secondly, the allocation of marks showed that the checklist aimed at assessing newly established food processing plants for registration and licensing instead of the already registered plants. Moreover, it was established that these checklists were also intended to cater for the registered processing plants.

3.4 Conducting Food Inspections at Ports of Entry

3.4.1 Inspections were not conducted to all high risk food products

The TFDA and FAO Risk-Based Inspections Guidelines have stipulated that for the TFDA to get the maximum results there is a need to prioritize its inspection to high-risk food products.

The review of the Inspection Reports prepared by Food Inspectors stationed at the Ports of Entry showed that TFDA was inspecting every food consignment which went through the ports of entry. This means that all food consignments whether risky or non risk were given the equal weight by inspectors.

However, it was found out that non-examined food consignments went through the ports of entry. This is exemplified by the situation the auditors came across at the Dar es Salaam Port. The audit found that not every food consignment that went through the port was inspected before its removal from the customs area.

Furthermore, the audit team reviewed Data Sheet of Imported Food Consignment from "One Stop Centre" at Dar es Salaam Port and found out that there were food consignments released while uninspected. This was contrary to the mandatory requirement of inspecting every consignment going through the port of entry.

The 2012 Data Sheet of Imported Food Consignment showed that 90% of 311 food consignments were not inspected for more than a year despite being conditionally released by Tanzania Revenue Authority (TRA). This is shown on Figure 3.1.

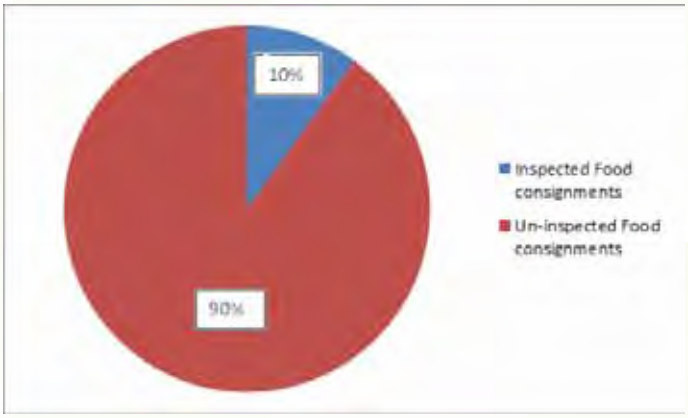


Figure 3.1: Amount of Inspected and Uninspected Food Consignment at Dar es Salaam Port

***Source**: Data Sheet of Imported Food Consignment from "One Stop Centre" at Dar es Salaam Port*

Furthermore, the other two major factors that contributed to non inspection of high risk food products at Ports of Entry include:

a) Uninspected "Small consignments" going through the ports of entry; and

b) Unregistered food products going through the ports of entry unexamined.

Uninspected "Small consignments" going through the Ports of Entry

The audit found out that food consignments termed as "SMALL CONSIGNMENTS" were going through ports of entry without import permits and without being inspected by TFDA. TFDA food inspectors at ports of entry acknowledged that there were food consignments being treated as small consignments and as such needed not to be accompanied with import permit.

The audit office failed to get any document which provides the guidance to the Inspectors on how they can categorize food consignments as small or else. The responsibility for decision-making as to whether the food consignment was classified as small or else was left to the hands of Food Inspectors at the Port of Entry and they lacked guidance on the matter.

Table 3.7 provides an example of four importers who imported an average of 150 Cartons per entry of one type of imported food product i.e. Blue Band and it was termed as small consignment.

Table 3.7: Food Importers whose food consignments were classified as "Small Consignment"

Name of food Importer	Date Imported	Type of food imported	Cartons of imported food (Cartons@12kg)
Importer 1	01.12.2010	Blue Band	150
Importer 1	30.11.2010	Blue Band	150
Importer 1	24.11.2010	Blue Band	50
Importer 2	01.12.2010	Blue Band	150
Importer 3	23.11.2011	Blue Band	100
Importer 3	29.11.2011	Blue Band	200
Importer 4	18.10.2010	Blue Band	104

Source: *Monthly Inspection Reports from the Ports of Entry (2010 - 2012)*

From Table 3.7, in a span of seven (7) days Importer 1 imported a total of 350 cartons of blue band, equivalent to 4,200 kg and they were not inspected by the Food Inspectors only for the reasons that the importer was importing "small consignments". The same situation can be seen on Importer 3 who through the same method managed to import 300 cartons (equivalent to 3,600 kg) of blue band in the country without being inspected by TFDA.

Therefore, in total the four importers imported about 25,200 kg of blue band as small consignments which were not subjected to inspection.

Through the interviews with the Inspectors it was noted that all food products imported in the country ought to be inspected and some importers are using different techniques including splitting of the consignments in small quantities with an intention of avoiding inspections. It was further acknowledged that this system puts the consumers at risk particularly when TFDA is not certain with the quality of those food products. This is particularly the case since food import control law and regulations do not allow this practice as it is known that there is no amount of unsafe food that cannot cause diseases or death to consumers.

Unregistered Food Products going through the Ports of Entry

The audit found out that there were unregistered food products going through ports of entry without being inspected by TFDA inspectors. This was verified through randomly sampled monthly inspection reports (records of inspection) from Ports of Entry, to which 161 items of food consignments were imported.

The information from the monthly inspection reports of the food products imported were compared against registered food products data base from TFDA headquarters. The outcome of that comparison was that about 35% of unregistered imported food products went through the Ports of Entry contrary to TFDA Act and its regulations (for Importation and Exportation of Food Products) which required unregistered goods to either be destroyed or returned to the country

of origin. This situation is demonstrated in Figure 3.2.

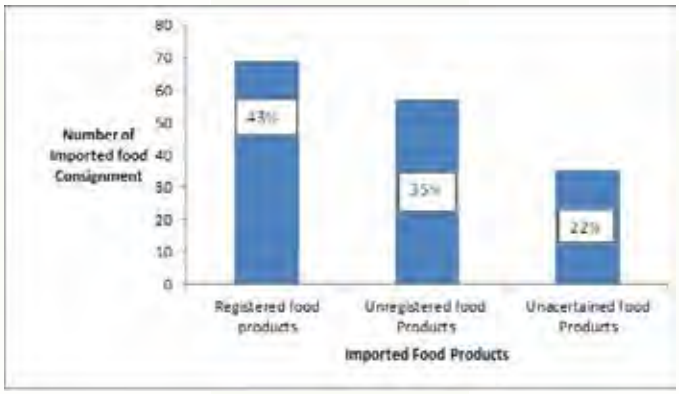


Figure 3.2: Registered, Unregistered and Unascertained Imported Food Products through Ports of Entry

***Source**: Monthly Inspection Reports from Ports of Entry (2012/13)*

However, the audit team could not ascertain as to whether the 35 food products which made about 22% of those food products were registered or not. This was simply because they were recorded not in their common names but in general names making it difficult for a third party to identify those products. These were products such as Chocolate, Chilli Sauce, Assorted food products, Juice, Assorted drinks, Biscuits and Spices.

3.4.2 Reasons for inadequate inspections of Imported Food Products at the Ports of Entry

The audit noted a number of reasons which contributed to the unsatisfactory inspection of imported goods at the ports of entry. These reasons include:

- Inadequate records or information of imported food products;
- Inadequate monitoring of inspection activities carried out at the Ports of entry;
- Non-prioritization of the inspections of imported foods;
- Inadequate planning for food inspections at the Ports of Entry; and
- Inadequate usage of present inspection resources.

The details of the above mentioned reasons for inadequate food inspections at the ports of entry are provided below.

Inadequate records or information of imported food products

During the interviews with TFDA inspectors at the ports of entry and review of inspection reports, it was found that TFDA food inspectors at the ports of entry were conducting inspections of imported food products without having the required records (Cargo Manifest) of the type and quantity of food imported in the country.

Through the interviews it was also noted that inspectors were operating/inspecting products based on the information brought to them at that particular day by food importers or their agents. It was acknowledged that the inspection was ad-hoc since it was not really based on solid records and hence unplanned.

The review of the Importation and Exportation Regulations (2006) and the Standard Operating Procedures for Inspections of Imported Food Products at the port of entry showed that TFDA ought to have sought the list of imported food consignments either from the food importer or Tanzania Revenue Authority.

The audit review found out that inspectors were just waiting until the food products had arrived at the Port of Entry.

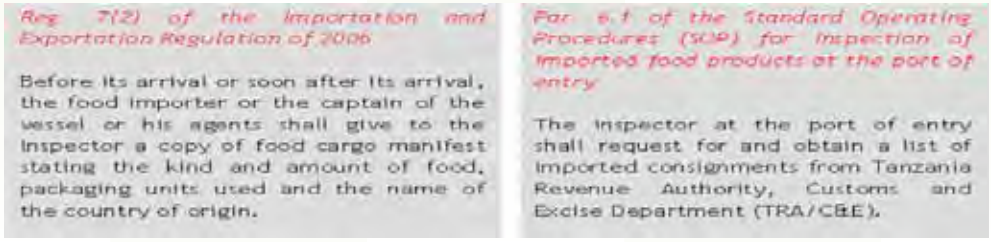
The audit noted that this is one of the factors which contribute to the inadequate inspection of the imported goods since inspectors were not able to plan in advance for the inspections. This was because they were not even aware of the nature and quantity of expected food products to be imported in order for them to be able to plan accordingly for the inspections.

Officials from TRA pointed out that those importation data were normally submitted to them at least two weeks before the products arrival date.

On the other hand, another reason which contributes to lack of importation records was the contradiction arising from the two guiding documents i.e. the Importation and Exportation Regulations (2006) and the Standard Operating Procedures for Inspections of Imported Food Products at the port of entry. Those two documents provide contradicting guidance to the inspectors on where they can get the importation records.

The exhibit below provides the narration of the contradiction arising from the two documents mentioned above.

Exhibit 3.1: Contradicting statements from the two Guiding Documents



***Source**: Importation and Exportation Regulation of 2006 and SOP for Inspection of Imported Food Products.*

It is clearly seen under the Regulations above, the Inspector is expected to recieve the information from either the food importer or the captain of the vessel while under the procedures, the Inspector is expected to request for and obtain the information from TRA, Customs and Exercise Department hence the contradiction of the two.

Inadequate Monitoring of Inspection Activities at the Ports of entry

The fourth reason for the inadequate food inspections at Ports of Entry was the inadequate monitoring of inspection activities. The audit found that there were hardly any evidence to suggest the existence of monitoring of inspection activities.

The inspectors acknowledged that it was hard to detect any corrective measures without having a thorough review of the procedures for food inspections at the Ports of Entry. Furthermore, they noted that

deficiencies of unregistered food products entering the country and uninspected food consignments would have been picked up easily during the monitoring exercise and then effect appropriate corrective measures.

TFDA pointed out a number of reasons which contributed to weak monitoring of inspection activities at Ports of Entry. These include (1) insufficient number of skilled staff to carry-out this kind of exercise (2) lack of clearly defined performance goals and monitoring indicators that would guide those who would be carrying-out the inspections (3) non-existence of procedures for monitoring food inspection activities at Ports of Entry.

Non-prioritization of the inspections of imported food

The audit found out that the TFDA does not have a risk-based model to determine the nature and type of inspections of the imported food products to be performed. This was observed in all three visited ports of entry.

The interviews with Food Inspectors in three ports of entry visited, showed that the decision to choose imported food products for further examination upon arrival at a port of entry is based on an assessment of risk indicators by TFDA inspector at the border.

Furthermore, the audit noted that TFDA had not linked its food inspections at the Ports of Entry with the nature of risks posed by imported food products in the respective ports of entry. It was also observed that the inspections plans did not focus on those imported food products which were perceived to be of high risk.

Inadequate Usage of Present Food Inspection Resources

A third factor pointed out by TFDA officials which contributes to the inadequate inspection of imported food products at Ports of Entry was the inadequate usage of present food inspections resources. These were resources such as Human resources (mainly inspectors) and funds set aside for food inspection activities.

Usage of Food Inspectors

The audit noted that TFDA had not established to what extent it was making efficient use of its inspectors. This was the case since TFDA did not establish the standard number of food inspections that could be carried out by a single inspector in a port of entry per year.

Since that information is lacking, inspectors were just allocated to different Ports of Entry without taking into account the size of workload of particular port. It was the expectation of the audit office that factors such as the estimated quantity of imported food products would be used as the basis for allocating inspectors and other resources for inspection purposes.

Factors Contributing for the Inadequate Budgeting for Inspection Activities

Inadequate funds allocation for the inspection of imported food products at the ports of entry and at the Processing plants was due to the following:

- Despite the fact that food inspection is one of the core activities of TFDA, there is no specific budget set aside for this core activity. The budget for implementing the inspection activities is tied up with other activities and during the utilization, the resources can be allocated anywhere. The inspection activity has to compete with other core activities within TFDA during the resource utilization;

- Zone and Ports of Entry Offices for TFDA did not prepare the analysis of the resources required for the whole cycle of food inspection i.e. starting from planning stage up to the re-inspection/follow-up and making sure that it is shared among other departments within TFDA to come up with participatory TFDA Budget which addresses the needs of all core activities; and

- It was also noted that the actual function of budgeting for Food Inspection is left to Planning and Budgeting Officers

who do not have adequate information on the actual/specific needs of inspectors.

3.5 The Level of Application of Sanctions

3.5.1 Insufficient Application of Available Options to Secure Corrections of Non-Compliance

The audit team reviewed 65 Inspection Memoranda, 5 Inspection Registers and visited 21 food processing plants to assess the level of application of sanctions to defaulters. The reviews indicated that Processing Plants have been violating food safety regulations and were issued with non-compliance records by TFDA.

Furthermore, it was noted that despite the fact that there are non compliance among processing plants and importers, TFDA has not kept records of those non complaints. Moreover, it was acknowledged by TFDA officials that without more incentive to improve compliance, those processing plants run a higher risk of providing food products for human consumption that should not enter the food supply chain.

For all inspected plants that do not meet regulatory food safety requirements, TFDA established the following five enforcement actions:

- **Non Compliance Record**: Inspectors cite violations of regulations by issuing non compliance records. When inspectors identify repeat violations, they link the non compliance records in TFDA' mission critical monitoring system, the Public Health Information System (PHIS). As soon as the inspectors identify a trend in violations, they may inform the TFDA Zonal office, which determines if more aggressive enforcement action should be taken.

- **Regulatory Control Action**: In conjunction with issuing non compliance records, an inspector can take regulatory control actions by retaining the product, rejecting equipment or facilities, slowing or stopping the production line, or refusing to allow plants to process the defective product until the plant takes immediate corrective action.

- **Warning**: This is a warning notice issued by TFDA Zonal offices.

It notifies a plant that, although the violations do not pose an imminent threat to public health, TFDA may either withhold the marks of inspection or suspend the plant, unless the plant responds to TFDA within 7 working days to demonstrate how it has or will achieve compliance.

- **Suspension**: During a suspension, plants cease production. TFDA Zonal offices withdraw inspectors from their duties and inform the public of the cause of the suspension through TFDA's website and other media. The length of suspension is determined by how long it takes the plant to fix the problem.

- **Prosecution:** The TFDA Zonal Manager may file a case before the court of law seeking a redress.

The analysis of numbers of inspections, revealing either no violations or insignificant violations, resulting in fines, number of violations issued and other kinds of punitive actions taken by TFDA could not be established because of the (1) improper record keeping and (2) inadequate format of inspection reports which failed to capture the above mentioned information.
Furthermore, it was noted that most of the processing plants issued with non compliance were repeating the same kind of violation or not rectifying the identified non-compliance.

The same was confirmed through the interviews with different TFDA officials who acknowledged that TFDA's enforcements through inspections and surveillance do not deter food processing plants from becoming frequent violators of food safety regulations.

Through the interviews with those officials, it was noted that because of poor record keeping and failure to capture critical data necessary for enforcing food safety in the country, TFDA rarely:

d) takes progressively stronger enforcement action against repeat violators, when warranted;
e) distinguishes between serious violations and minor mistakes on its non compliance records; and
f) provides sufficient guidance on what actions to take in specific circumstances. As a result, plants have repeatedly violated the same regulations with little or no consequence.

TFDA Rarely Takes Progressively Stronger Enforcement Action against Repeat Violators

It was noted that the practice provided no room for determining the number of non compliance records repeated at the plants. Furthermore, inspectors pointed out that this practice provides loopholes for the processing plants to repeat the same serious violations with little or no consequence.

However, TFDA Officials stated that as long as a plant was making progress in correcting violations and there was no immediate public health risk, TFDA officials did not feel the need to pursue progressively stronger enforcement action.

TFDA Does Not Always Distinguish Between Serious Violations and Minor Violations

TFDA does not distinguish between violations that pose a higher risk to public safety from those that do not. Food safety non compliance records range from a plant's inaccurate internal records to severe rodent infestation on the kill floor, fecal matter, or contaminated ready to eat products.

Due to the range of non compliance records, TFDA should provide guidance to inspectors on classifying non compliance records so that TFDA can identify patterns of severe violations more easily. Without distinguishing between minor and serious violations, TFDA would need to read the description of each non compliance record to identify the processing plants with history of severe violations.

TFDA Does Not Provide Sufficient Guidance on What Action to Take in Specific Circumstances

TFDA has not issued regulations or policies on when to initiate stronger enforcement action for repeat violations. There are no quantifiable criteria explaining when actions such as suspensions or Notices of Intended Enforcement should be issued. However, TFDA directives do not quantify how many violations constitute "multiple

or recurring non-compliance;" nor mandate when to suspend a plant. Although the authority stated that the frequency of violations over a specific timeframe is important in determining when to take stronger enforcement action, TFDA's guidance does not define frequency or specify time frames. Without more specific criteria, inspectors and officials have the option not to pursue even the most serious violations. TFDA officials may also choose different courses of action, leading to plants being treated inconsistently.

3.6 Reporting on the results of inspection

The TFDA's Risk-Based Inspection Guidelines of 2009 requires the inspectors to report on the results of inspection by preparing and submitting the inspection report within seven days to their supervisor. The same guidelines provided for the format of the inspection report.

The audit team reviewed the inspection reports to assess the quantity and nature of deficiencies disclosed by inspections as well as the timelines of those reports.

3.6.1 Adequacy of the inspection reports

The audit noted that inspectors prepared Inspection Memorandum for each individual inspection and later on the main observations and recommendations (in the form of directives) are recorded in the Inspection Register.

Further analysis of the two sets of inspection reports showed the following weaknesses:

- *Inspection memoranda* do not allow inspectors to comment on the previous inspection directives given to the owner of the processing plants
- *Inspection registers* do not show the number of previously implemented or non-implemented directives to be considered for future inspection

Inspection memoranda did not allow inspector to comment on the previous inspection directives

The TFDA's Risk-Based Inspection Guidelines requires the inspectors to scrutinize and comment on the extent to which the previously issued inspection directives or recommendations have been implemented. It was also observed that food inspectors had to carry with them the inspection memorandum from the previous inspection.

The audit review of the format of the inspection memorandum and a number of inspection memoranda showed that their formats did not provide an opportunity for the inspectors to comment on the level of implementation or non-implementation of previously issued recommendations/directives.

The inspectors noted that through the current format of the inspection memorandum it is not possible to show the performance trend of individual processing plants and every inspection is regarded as a new one.

Inspection registers do not show the number of previously implemented or non-implemented directives

According to 5 Inspection Registers reviewed, it was noted that TFDA was not keeping any records regarding the implemented and/or non-implemented directives. Therefore, it was not easy for the auditors to establish the level of implementation of the directives.

Furthermore, the interviewed TFDA officials acknowledged that such information could guide food inspectors on the areas of concentrations during the inspections as well as be basis for increasing the level of enforcement and penalties for the repeat offenders.

3.6.2 Coordination of reporting and feedback

The quarterly progress reports (which include inspection results) are submitted to TFDA Headquarters for further analysis and compilation. This is done through Zone and Local Government Coordinator

(ZOLGAC).

The interviews with ZOLGAC, Zone Managers, Inspectors and MQM pointed out that reporting of the inspection results and feedback mechanism on the conducted food inspection was not adequately functioning and coordinated. It was pointed out that inspections reports from zone offices have been late submitted. This made it hard for the TFDA Headquarters to compile, scrutinise and subsequently suggest for correction as the case may be.

Similarly, it was pointed out by officials from TFDA Headquarters that due to that situation of not receiving the inspection reports on time, it was not possible for the TFDA Headquarters to provide any meaningful feedback and further guidance on the conducted inspections.

Further analysis on the reasons for delayed submission of the inspection reports by some Zone Offices showed that Zone offices were not preparing separate inspection reports as required by the Risk-Based Inspection Guidelines.

The interviewed Zone Managers pointed out that issues regarding the inspections of processing plants were reflected in monthly, quarterly, midyear and annual reports as one of the activities conducted by zone offices at a particular period.

Furthermore, TFDA Management commented that they have already started to take some actions to address delayed submission of quarterly progress reports by (1) asking all zone managers to submit those reports timely; and (2) discuss and deliberate on those reports in the Management every second week of the month.

3.6.3 Unscrutinised Food Inspection Reports from LGAs

The guidelines for the effective operations of zone offices required zone offices to scrutinise inspection reports submitted by LGAs.

The audit found out that TFDA zone offices were not scrutinizing food inspection reports submitted to them quarterly by LGAs, for

detection of deficiencies contrary to the requirements set in by the Guidelines for Effective Operations of Zone Offices.

The reviewed Annual Reports from all five zone offices showed that all zones did not scrutinize the food inspection reports received from LGAs with exception of the Central zone which attempted to include information from LGAs. Furthermore, it was observed by Officials from TFDA that by lacking such kind of information on Food Inspections reports made by LGAs hinders the ability of TFDA to evaluate the performance of LGAs and eventually limits TFDA ability to suggest ways for improving the conduct of food inspections done by LGAs.

Further review of the Annual Reports from TFDA zone offices showed the amount of money collected from fees which amounted to 60%[6] of collection from the conduct of inspection done by LGAS at a particular period but did not include the deficiencies detected during the inspection.

3.7 Coordination with Other Government Departments

According to Section 5(2)(f) of TFDA Act, TFDA is supposed to work with other government departments in order to achieve its set objective of conducting food inspections at the processing plants and ports of entry.

These Other Government Departments include; Tanzania Revenue Authority, Tanzania Bureau of Standards, Fair Trade Competition, Local Government Authorities, Meat and Milk Board, Sugar Board, Ministry of Livestock and Fisheries etc.

The review of TFDA annual performance reports and the interviews with officials from TFDA and the above mentioned government departments showed that the coordination between TFDA and other government departments was inadequate. This was evidenced by the following four factors:

- Non sharing of statistical data pertaining to food inspections;

[6] This is the inspection fee collected by LGAs. 40% of the fees is retained by LGA and the remaining 60% is remitted to TFDA

- Unclearly defined reporting relationships;
- Non sharing of food inspection results; and
- Un-harmonised inspection activities at the ports of entry.

3.7.1 Non-sharing of data

According to Risk-Based Food Inspection Manual (FAO, 2008), it has been pointed out that the national authorities have the responsibility of protecting public health by reducing the risk of food-borne disease and providing food safety education and information to consumers and the food industry.

The government authorities were expected to share various statistical data and other guidance on how to handle various issues pertaining to food inspections. These are information such as quantity of food imported in the country, number of registered and licensed food processing plants and importers, performance records of processing plants and importers etc.,

The audit noted that TFDA has not instituted any mechanism which would assist its inspectors to make use of information from other government institutions. The information such as the quantity of food to be imported from other countries were not sought from TRA, the up-to date list of processing plants registered by BRELA, licensed importers as registered by TRA and the intelligence information on the performance of various processing plants and importers were not sought from respective developments.

The Inspectors from TFDA observed, that failure to make use of the information affects the planning of the Food Inspections at both levels at the processing plants as well as at ports of entry. That made the inspection lack a focal point and ineffective.

3.7.2 Unclear defined reporting relationship

The audit found that despite of the fact that Health Officers (food inspectors) from the MoHSW are also conducting Food Inspections and prepare Food Inspection Reports, those reports were not shared by TFDA.

The Interviews with the Officials from the Public Health Department of the MoHSW stated that it is hard to share their reports with TFDA since they are the parent ministry and TFDA was expected to provide that information. On the other hands, the officials agreed that lack of clearly reporting and information sharing mechanism hinders the ability of the government to enforce the TFDA Act and in that aspect minimize the food-borne diseases in the country.

As a result the Public Health Department of the MoHSW and TFDA operated as separate entities despite the fact that both of them belong to the same Ministry.

The reasons pointed out for this situation include:

- Absence of regular meetings between TFDA and Public Health Department of the Ministry of Health and Social Welfare to discuss issues regarding food inspections which is part of the public health; and
- Improper defined reporting mechanism of the results of food inspections conducted by the MoHSW to TFDA.

3.7.3 Non-sharing of Food Inspection Results

A number of Government Departments were also carrying-out food inspections in various areas. These include the Ministry of Health and Social Welfare through the Public Health Department, Local Government Authority and TFDA themselves.

During the audit it was noted that despite the fact that the above mentioned government departments were doing almost the same kind of work and they have one ultimate goal of maintaining food safety in the country, they were not sharing the results of their inspections.

Through the interviews with officials from the Ministry of Health and Social Welfare and TFDA, it was pointed out that there were three reasons which necessitate the need for those government departments to work together.

These include:

- each department has got no capacity (staff and fund) to cover the whole country without the support of other departments;
- there is a dependence on each other in terms of technical know-how of Food Inspections; and
- there was a need of aggregating the inspection results of the entire country in order to get the overall picture on the performance on food safety.

The details of the type of inspections conducted by different government departments and reports produced are as provided in Table 3.8.

Table 3.8: Types of Inspections Conducted by Different Government Departments

Government Department	Number of Ports of Entry	Processing Plants and other food premises	Focus area of conducted inspections	Main content of the report
MoHSW	20	-	• Public Health • End product verification	Public Health issues with small component of Food inspections
TFDA	5	1589	• Food Processing Inspections • End product verification	Food Inspection
LGAs	4	Many	• Public Health • Food Processing Inspections • End product verification	Food Inspection
No defined entity	3	-	-	

Source: *Inspection Reports from MoHSW, TFDA and LGAs (2012/13)*

Table 3.8 shows that different Government Departments were involved in Food Inspections. It also shows that their inspections are focusing on three main areas namely, Public Health, Food Processing Inspections and end product verification.

The same table also shows that there are some Ports of Entry which are covered by none of the three Government Departments which implies that food products imported through these three Ports of Entry are admitted in the country uninspected. It was also noted that all government departments need to share information and coordinate their inspections more adequately for the purpose of avoiding duplication of efforts.

Furthermore, knowing the fact that different government departments came up with food inspection reports, the audit checked with TFDA to establish whether they got them or not. It was found out that TFDA was lacking information from other key players such as the MoHSW and LGAs for the conducted food inspections.

The interviews with the MOHSW's officials revealed that the reports from the Ports of Entry were collected, compiled and eventually submitted to the Permanent Secretary of the MoHSW. But they acknowledged that those reports were not shared with TFDA because of lack of clearly defined mechanism for sharing food inspections reports.

On the other hand food inspection reports from LGAs, TFDA zone offices confirmed that a substantial number of LGAs were not submitting reports on the conducted food inspections in their respective jurisdictions. The details of the extent are as provided in Table 3.9.

Table 3.9: Analysis of number of reports prepared by LGAs and those submitted to TFDA (2009/10 2012/13)

Zone	Number of Councils	Number of Required Reports Monthly	Number Submitted Reports	Percentage Submitted (%)
Northern	22	88	30	34
Central	26	104	8	1
Eastern	16	64	40	63
Lake	24	96	4	4
Southern	12	48	32	67

***Source**: Submitted reports from LGAs to Zones*

The data in Table 3.9 shows that a substantial number of councils were not submitting food inspection reports to TFDA. Only 29% (equivalent to 114) of inspections reports were submitted to TFDA out of the required 400 reports.

Therefore, the main consequences for partial submission of inspection reports include:

- Difficulty in getting the real picture or situation of the food safety in the country since some of the information were not analyzed and compiled together; and
- Lack of room for TFDA to scrutinize those inspection reports and ultimately limiting the ability of TFDA to suggest ways of improving food inspections at the council level.

3.7.4 Un-harmonised Inspection Activities at the Ports of Entry

In every port of entry visited by the audit team, it was found out that food inspectors from both the Ministry of Health and Social Welfare and those from TFDA were conducting food inspection. The MoHSW's inspectors were conducting food inspection as per the Public Health Act of 2009 alongside TFDA food inspectors.

The Audit team also noted that at certain times food inspectors from the Ministry complemented TFDA food inspectors, and vice versa, in case of absence of any of those inspectors.

On the other hand, the audit office failed to establish the demarcation between TFDA and the MoHSW over the conduct of food inspection. Both of them were conducting similar kind of inspection (*see Table 3.8*). This was also indicated by the officials from the Public Health Department of the MoHSW. They noted that despite food inspection being one of the activities of TFDA there was no demarcations in relation to food inspection among different actors. Repetitive food inspections by various regulatory organs can result in unecessarily bothering the food importers/manufacturers and lead to increase cost of doing business in the country.

In that aspect, they observed that the entire food inspection management in the country is not harmonised and properly coordinated.

3.8 Monitoring and Evaluation of Food Inspection Activities

3.8.1 Inadequate Monitoring and Evaluation of Food Inspection Activities

According to TFDA Strategic Plans[7], the Planning Unit was supposed to conduct periodical monitoring and evaluation of the inspection activities conducted by TFDA Food Inspectors stationed at its five zone offices.

The interviews with TFDA Officials from Headquarters pointed out that there is no monitoring and evaluation exercises carried-out to assess the performance of food inspection activities both at Processing Plants and Ports of Entry.

It was also noted that failure to monitor performance of inspection activities against the set inspection targets denied TFDA an opportunity to establish whether they are performing well or lagging behind the specific objectives established for the year.

3.8.2 Inadequate Monitoring and Evaluation Indicators for Food Inspection

According to the requirements of ISO 9001:2008 on quality management system, managing for inspection results requires the TFDA to establish performance objectives, develop indicators to measure performance, prepare an annual work plan, and schedule specific inspections, monitor performance against the objectives, and act when performance lags behind the specific objectives established for the particular year.

[7] For the period 2008/9 – 2011/12 (the former) and 2012/13 – 2014/15 (the current)

The interviews with TFDA officials mainly from MQM and Planning Unit which are responsible for carrying out audit and monitoring and evaluation of TFDA's activities revealed that there is only one Monitoring and Evaluation Indicators specifically for the Food Inspection activities carried out by Food Inspectors. This indicator is aimed at measuring the percentages of the registered premises that have been inspected.

Furthermore, it was observed that the only available one indicator is focusing on measuring the output only (output indicator). This means that TFDA has not developed any outcome indicators which are necessary for assessing the short- and long-term goals and outcome. Furthermore, when inquired more on whether they understand the importance and impact of the performance indicators, the officials acknowledged that without a means for measuring the results achieved by the inspection it becomes very difficult to determine whether TFDA has achieved their goals of deterring specific food related hazards and risks leading to improved public health, safety, and welfare.

3.8.3 Performance Evaluation of Food Inspections

Despite the fact that TFDA was lacking performance indicators for its inspection activities, the audit office decided to check the performance of TFDA by using the following indicators as pointed out in the FAO manual for food inspection:

- Number of inspections;
- Number of food-borne illness outbreaks; and
- Number of consumer complaints.

The analyses of the above three performance indicators are as detailed in Table 3.10.

Table 3.10: Number of Food-Borne Diseases and Consumer Complaints Received by TFDA for the period 2009/10 – 2012/13

Financial Year	Total Number of Processing Plants Inspected	Number of food-borne illness outbreaks	Number of Consumer Complaints
2009/10	484	307	None
2010/11	499	271	18
2011/12	560	243	4
2012/13	516	213	13

Source: *Report on the assessment of food borne illness- pilot study in the three regions of Dodoma, Manyara and Singida (2009/10 - 2012/13)*

Table 3.10 shows that there are some cases of food-borne illness outbreaks in the country recorded for the last four years. The presented data shows that the problem is relatively constant and there is no sign of huge improvements so to say.

3.9 Following Up on Inspection Results

The TFDA Risk-based Inspection Guidelines of TFDA requires the inspectors to make follow-up actions in order to assess the actions taken by managements of the processing plants to correct deficiencies disclosed by the inspection process.

Re-inspections of processing plants

The review of the inspection memorandums from all five TFDA Zone offices pointed out that TFDA inspectors were notifying processing plants' owners on time of the deficiencies disclosed by inspection. This was mainly done within seven days after the inspection have been completed.

Further analysis made to verify whether processing plants' owners were correcting the deficiencies promptly showed that was not the case. The interviews with TFDA inspectors revealed that the main method for verifying the level of corrections made was through conducting re-inspection of the processing plants.

The review of inspection reports showed that TFDA was not carrying-out re-inspections to those processing plants revealing significant violations. According to inspectors, failure to re-inspect those processing plants is undermining the achievement of underlying goals of inspection.

The main reasons pointed out for not re-inspecting all processing plants which were found to have significant violations include:

- The plans did not have any element of follow-up hence it was not possible for the inspectors to engage themselves on re-inspections,
- Failure to make use of inspection memoranda and registers which could guide inspectors on identifying Processing Plants which were supposed to be re-inspected, and
- Non-recording of processing plants which were seen to have repetitive violations of food safety laws and regulations.

Fines and Penalties Imposed to Defaulters

Another important follow-up measure or effective enforcement tool on the inspection results was through imposition of fines to all processing plants and implementation of other forms of penalties to defaulters.

The interview with TFDA Legal Department's Officials revealed that TFDA was not imposing fines to compounding offences done by Food Processing Plants and Food Importers as per TFDA's Fees and Charges regulation.

This was because the regulation did not provide for the amount to be charged in relation to a particular offence. This is despite the fact that the regulations have been in place for more than seven (7) years i.e. from 2006 up to 2013.

Further discussions with TFDA Legal Officials revealed that currently TFDA is finalizing the document which will specify the amounts to be charged in relation to a particular offence.

This means that repetitive offenders were not fined despite committing frequent offences. This provided an incentive for them to repeat the same. This has been the case in all five Zone Offices where the inspection register showed that the same owners have been committing the same kind of violations no severe action have been taken.

In assessing the inspection process, the audit team noted that inadequate use of the records from the Inspection Register contributed to this problem. When inspectors conduct the inspections they either carry with them the inspection memorandum of the previous inspection (this was the case for Central and Lake Zones) or do not go with any reference documents (for the case of other zones). In that aspect, inspectors failed to have a track record of the facility owner and therefore, previous violations could not be identified and were hence treated like the first violation.

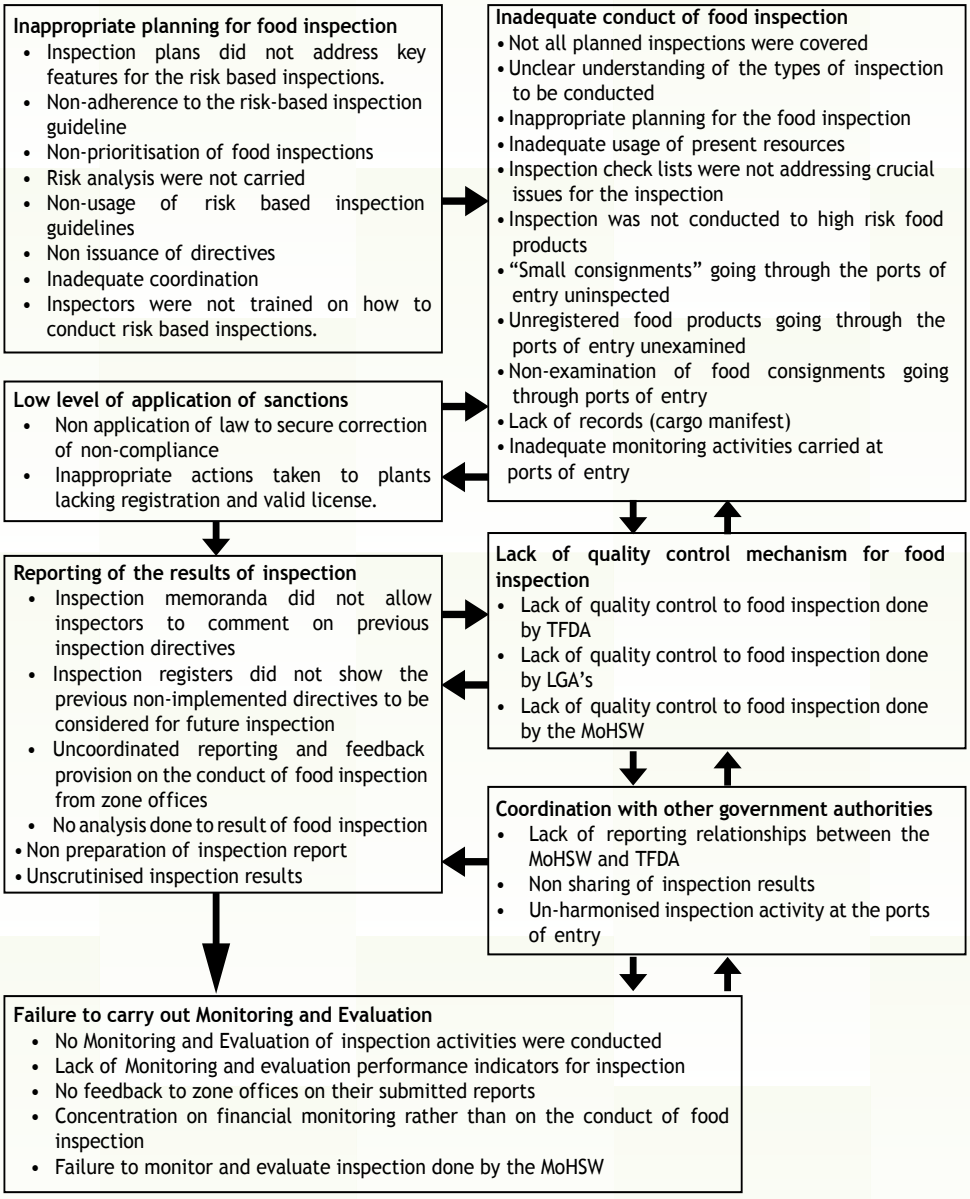
While the TFDA officials acknowledged having in place an Inspection register where the track records of each processing plants is kept, it was rarely referred to by inspectors when planning for the inspections.

The interviews with the owners of the processing plants revealed that TFDA have not instituted a proper mechanism for administering the collection of fines and there is no proper follow-up on the matter.

The TFDA officials on the other hand observed that since there are no consequences to the delay of paying fines, owners were not bothered as they had no incentives to pay such fines on time.

3.10 Summary of Findings

The graph below summarises the shortcomings by showing relationship between the mentioned aspects



CHAPTER FOUR

CONCLUSIONS OF THE AUDIT

4.1 Overall Conclusion

The overall conclusion of this audit work is that Tanzania Foods and Drugs Authority has not adequately fulfilled its objectives to control safety and quality of food in the country by conducting and managing food inspection. This is due to the fact that Food Inspections both at Processing Plants and Ports of Entry were not adequate since they were not properly planned, no clear targets were set, strategies for those inspections were not well defined and ultimately the actual inspections were not addressing key risk factors which would lead to the food-borne diseases.

Similarly, TFDA inspection efforts were unclear and it was not possible for TFDA to systematically establish the level of compliance and performance among Food Processors and Importers. This led to its failure to measure the effectiveness of its food inspections and in that sense failed to reassure the general public on their effectiveness to curb the risk posed by domestically produced as well as that imported food.

4.2 Specific Conclusions

4.2.1 Unsatisfactory Planning for Food Inspections

The planning for food inspections at Ports of Entry and Food Processing Plants is not based on risk factors. All Food Processing Plants and Imported Food Products are given equal priority in inspection despite the fact that some of them are more risky in terms of health and environment hazards than others.

Failure to prioritize its food inspection based on risk-factors to a great extent hampered the effectiveness of TFDA to conduct thorough and high quality food inspections to fewer but very risky Food Processing Plants and Imported Food Products. Due to poor planning TFDA has failed to allocate resources, inspectors, inspection tools and funds for inspection, in a rational manner.

4.2.2 TFDA Does Not Conduct Risk-Based Inspection

Tanzania Foods and Drugs Authority has failed to conduct risks based inspections and surveillance of Food Processing Plants and at the Ports of Entry so as to optimize resources utilization and minimise availability of unsafe food and protect consumers' health.

The inspections failed to cover all the areas, particularly high risk food processing plants and imported food products is properly as prescribed by various guidelines issued by TFDA. This was due to the TFDA attempt to inspect all processing plants and imported goods without having a clearly defined risk based procedure which would have helped to focus and expand the coverage as well as to improve the quality of inspection results.

Regarding the application of sanctions, TFDA' enforcement system allows progressive actions against repeat violators, but TFDA rarely pursues stronger actions. The processing plants and food importers have little incentive to improve their processes since there are no substantial consequences for repeatedly violating food safety regulations. It is critical that owners of processing plants and food importers work towards preventing violations from occurring in the first place because recurring severe violations may jeopardize public health. By helping food processing plants and food importers move towards this goal, TFDA can improve its assurance that the nation's commercial supply of food is safe and wholesome.

4.2.3 Inadequate Monitoring and Evaluation System for Food Inspections

The Monitoring and Evaluation System for Food Inspections at both Processing Plants and Ports of Entry is not functioning. Even though, the Tanzania Foods and Drugs Authority has different Departments and Units charged with the duty of conducting Monitoring and Evaluation, that has not been done

TFDA was not conducting periodical monitoring and evaluation of the conducted food inspection and surveillance at the Ports of Entry

and Food Processing Plants and in that aspect it has failed to use the information resulting from Monitoring and Evaluation exercise to improve the conduct of the inspections.

However, the M&E system is not working and this is due to the failure to develop suitable indicators for measuring the performance of inspection activities. TFDA failed to establish the basis not only of measuring the performance of inspection methods but also the performance of individual inspectors. This has denied TFDA the opportunity to learn and improve its performance.

The dysfunctional Monitoring and Evaluation have provided a loophole for some food inspection deficiencies to go unnoticed and uncorrected both at Processing Plants and at Ports of Entry. Those deficiencies are but not limited to (1) non submission of reports from LGAs (2) the lack of clarity among Zone Offices whether to conduct audit inspection or both audit and routine inspections (3) inappropriate actions taken to repetitive non-complying food processing plants (4) consignments going through Ports of entry un-inspected (5) un-registered food products going through ports of entry.

All the above deficiencies would have been detected and dealt with if TFDA Monitoring and Evaluation system were functioning well.

Furthermore, the problem of Monitoring and Evaluation of Inspection activities is also reflected in the work done by the Ministry of Health and Social Welfare who have not conducted any Monitoring and Evaluation work to assess the performance of TFDA in the Food Inspection arena.

CHAPTER FIVE

RECOMMENDATIONS

5.1 Preamble

The audit findings and conclusion point out that there are weaknesses in the management of inspections of Food Processing Plants and Imported Food Products in the country. The weaknesses were noted on all three audited parameters, namely: planning of inspections, conducting the inspections and Monitoring and Evaluation of inspections both at Processing Plants and Ports of Entry.

This chapter therefore, contains recommendations to the Ministry of Health and Social Welfare and the Tanzania Foods and Drugs Authority on what should be done to improve the situation.

The audit office believes that these recommendations need to be fully implemented for the inspections of Food Processing Plants and Imported Food Products to be managed properly so as to ensure the presence of the 3Es of Economy, Efficiency and Effectiveness in the use of the public resources.

5.2 Planning for Food Inspections

Tanzania Foods and Drugs Authority should:

1. Carry out the performance profiling of Food Processing Plants and Food Importers in order to establish the compliance level of each of them and use those information as the basis of planning for inspection or re-inspection;

2. Ensure that all zone offices and ports of entry are developing inspection plans based on risk factors and use them as the basis for guiding their inspections; and

3. Establish performance measures for food inspection activities, including a clear policy governing such critical factors as risk assessments, timing, work scheduling etc.

5.3 Executing Food Inspections

Tanzania Foods and Drugs Authority should:

1. Establish procedures to further prioritize and ensure timely completion of inspections of high risk processing plants and imported food products;

2. Establish a system for capturing food importation data including the importer or agent, quantity, type of food imported, actual or expected delivery date, port of entry to which the consignment intends to go through etc., which would help the TFDA inspectors to plan for their inspections and carry-out thorough inspection work; and

3. Increase efforts to provide coordinated real-time access to data among government departments and obtain training on how to use that data to perform necessary analytics to monitor performance, including activities such as inspections and response to public complaint.

5.4 Application of Sanctions

Tanzania Foods and Drugs Authority should:

1. ensure that application of sanctions during the inspection is done as per the stipulated laws and regulations, and periodically assess the effectiveness of the applied sanctions;

2. Develop a strategy to take progressively stronger enforcement actions against plants with serious and repetitive violations, and develop criteria and procedures to classify all severe food safety non compliants; and

3. Modify existing criteria to create standardized suspensions and Notices of Intended Enforcement that should be applied, as well as define the frequency and specify the timeframes when violations would lead to such enforcement actions.

5.5 Monitoring and Evaluation of Inspection Activities

Tanzania Foods and Drugs Authority should ensure that:

1. Monitoring and Evaluation indicators for the Food Inspection activities both at Processing Plants and Ports of Entry are formulated and agreed upon; and periodical Monitoring and Evaluation of Inspection activities are carried-out and the results are used as the basis for improvements; and

2. All inspection reports from its zone offices as well as LGAs are thoroughly reviewed and scrutinized to determine any deficiencies and provide feedback to the concerned officials for corrective actions and further improvements;

5.6 Recommendations to the Ministry of Health and Social Welfare

Ministry of Health and Social Welfare should ensure that:

4. Food Safety Inspections in the country are properly coordinated, harmonized and all stakeholders are working closely together;

5. A general report showing the status of food safety in the country as a result of Food Inspections conducted by different Government Departments is annually compiled and used as the basis for improving food inspection activities and ultimately food safety; and

6. Data and information regarding food safety are shared among different Government Departments and are used as the inputs for food inspections.

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14. ISO 9001:2008. *International Standards Organization 9001. on Quality Management Systems. Fourth edition*

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16. Food and Agriculture Organization of the United Nations. *Risk-Based Food Inspection Manual*. 2008.

17. Food and Agriculture Organization of the United Nations and World Health Organization. *Guidelines for Food Import Control Systems*. Adopted in 2003, revised in 2006.

APPENDICES

Appendix One: Audit Questions and Sub audit Questions

Audit Question 1: Did TFDA had risk-based plan(s) for the inspection and surveillance of food processing plants and ports of entry; and rationally allocate resources to areas of greater risk for unsafe food?

Sub-questions1.1	Did TFDA establish a plan that set milestones and timeliness for conducting food inspection and surveillance?
Sub-questions1.2	Did the plan identify coverage, timing, and set the monitoring process of the conduct of inspectors?
Sub-questions1.3	Did TFDA identify the risk category of food processing plants and ports of entry for the purposes of developing risk based plans and list them in a risk register?
Sub-questions 1.4	Did TFDA prioritize these risks with respect to high-risk food processing plants and ports of entry?
Sub-questions 1.5	Did TFDA develop an inspection and surveillance plan according to prioritized risk category subject to the approved financial and human resources?
Sub-questions 1.6	Did TFDA allocate its resources to the highest risked food processing plants and ports of entry or food importers?
Sub-questions 1.7	Did TFDA develop a training policy to train its inspectors on how to conduct risk-based inspections?
Sub-questions 1.8	Did TFDA train its inspectors on how to conduct risk based food inspection?

Audit Question 2: Did TFDA conduct risk based inspection and surveillance of food processing plants and the ports of entry so as to minimise unsafe food and protect consumers' health

Sub-questions 2.1	Did TFDA inspect food processing plants which are at high risk to produce unsafe/unfit food stuff for human consumption frequently?
Sub-questions 2.2	Did TFDA record the particulars of every inspection and put them in a register for the establishment of the food importer and food processing plant performance profile?
Sub-questions 2.3	Did TFDA determine whether all food processing plants were registered and operated under a valid licence given by the authority?

Sub-questions 2.4	Did TFDA food inspectors examine and certify every food consignment before it was removed from the customs area?
Sub-questions 2.5	Did TFDA determine whether all food importers who carried on the business of importing food for the last three years were registered and had a valid import permit?
Sub-questions 2.6	Did TFDA apply the sanctions according to legislation to food processing plants and food importers that did not comply with or violated the legislation?

Audit Question 3:TFDA conducts periodical monitoring and evaluation of the exercise of conducted food inspection and surveillance at the ports of entry and food processing plants and use that information to improve the conduct of inspections

Sub-questions 3.1	Did TFDA food inspectors prepare and submit inspection reports that identified risky food processing plants and food importers, weakness of their inspection and suggested ways to resolve the problem of unfit foodstuff to their supervisors in a timely manner from the day of actual inspection?
Sub-questions 3.2	Did TFDA identify trends in the reports submitted by its inspectors to be used in risk based plans?
Sub-questions 3.3	Did TFDA identify risks and issues from inspections reports to be used in planning and executing its inspection?
Sub-questions 3.4	Did TFDA plan and take action following the recommendations identified in inspection reports?
Sub-questions 3.5	Did TFDA have a documented procedure to assess and evaluate the performance of its inspectors?
Sub-questions 3.6	Did TFDA improve the performance of its inspectors and record the results or recommendations of its review?
Sub-questions 3.7	Did TFDA review the annual inspection performance for future improvement at regular[1] intervals?
Sub-questions 3.8	Did TFDA cooperate with any-body or Institution having functions similar to those related to food?

Appendix Two: Methods of Data Collection

Various methods of gathering data and information such as documentary review, interviews and physical observation were employed in the conduct of this audit.

a) Interviews

A number of interviews were conducted at TFDA HQ, Zone Offices, Port of Entry and Ministry of Health and Social Welfare. The aim of those interviews was to gather information and confirm or provide further clarification from the documents reviewed.

Tanzania Foods and Drugs Authority:	Director of Food Safety, Manager of Inspection and Enforcement, Manager of Risk Analysis, Registration Manager, Head of Unit - Quality Management Systems, Head of Planning, Head of Human Resources, Internal Auditor, 4 Zone Managers, ZOLGAC and 8 Food Inspectors.
Ministry of Health and Social Welfare:	Director of Public Health, Health Officer In-charge – Julius Nyerere International Airport and Health Officers (Food inspectors) at the ports of entry
TRA:	Custom officers In-charge at Ports of Entry
Others:	Owners and workers of visited food processing plants and Agents of food importers at ICDs

b) Document Review

Various documents were reviewed in order to get a comprehensive, relevant and reliable picture on whether TFDA was conducting risk based inspection and surveillance of food products at the points of entry and processing

plants.

Documents which were reviewed include but not limited to:

Planning Documents:	TFDA Strategic Plan (2009/10 – 2012-2013), TFDA Business Plans (2009/10 – 2011/12), TFDA Work Plan and Budget (2009/10 – 2011/12) and TFDA Action Plan 2009/10 – 2011/12;
Performance Reports:	Zone Annual Reports for the period 2009/10 – 2011/12, Inspection Memorandums, TASA of food inspectors, Inspection Registers and Inspection Reports;
Guidelines:	ISO 9001:2008 on Quality Management Systems, TFDA Risk Based Food Inspection Guidelines Rev. No. 1, 2009, TFDA Guidelines for Importation and Exportation of Food, Rev. 3 of November 201, TFDA Guidelines for Application and Registration of Pre-packaged Food in Tanzania Rev. 3 of May 2012, TFDA Guidelines for Registration and Licensing of Food Premises Rev. 3 of November 2011, TFDA Guidelines for conducting audit inspections first ed. July 2008, TFDA Guidelines for Effective Operations of Zone Offices, Guidelines for TFDA Delegated Powers to LGAs of 2007, TFDA Manual for Conducting Monitoring and Evaluation of August 2013, TFDA Report Writing Guidelines of 2008 as amended in 2012.
Legislations:	Tanzania Food, Drugs and Cosmetics Act, 2003
Regulations:	Tanzania Food, Drugs and Cosmetics *(Importation and Exportation of Food)* Regulations of 2006 and Tanzania Food, Drugs and Cosmetics (*Fees and Charges) Regulations* of 2006 as amended in 2011
Policy Document:	TFDA Training Policy and TFDA Compliance and Enforcement Policy 2006.

c) Observations

For the purpose of establishing whether food inspectors did follow guidelines when conducting food inspection at the processing plants; the audit team accompanied food inspectors when conducting inspections.

d) Field/Site visits

The Audit team carried out field visits to TFDA zone offices together with ports of entry to which TFDA food inspectors were stationed. The purpose was to ascertain how food inspection was conducted to the food products which were imported in the country.

The visits were also intended to gather more information to substantiate the information obtained from TFDA Headquarters and Zone Offices and to observe the operations on the ground.

The audit team visited five ports of entry namely, Dar es Salaam Port, Mwalimu J.K. Nyerere International Airport, Horohoro Border, Namanga Border, Sirari Border. Furthermore, the audit team also visited four (ICDs) which are part of the Dar es Salaam Port. These ICDs include: AMI, AZAM and Tanzania Railway Haulage.

Similarly, the audit team visited the following processing plants from four TFDA Zones:

Eastern Zone:	Royal Oven Bakery, Four Flowers Bakery, Rosette Bakery, Real Taste Bakers, Flonester Bakery and Unnamed[8] & Bakery – Kimara
Northern Zone:	Happy Sausage Co Ltd, Arusha Meat Co Ltd, Meat King, International Daily Milk-Arusha and Kilitan Poultry
Lake Zone:	Vicfish, Kuku Poa, Raha Oil Ltd, Bakers Den Ltd and Warsame Bakery
Central Zone:	Cetawico, A-sante Water, Kisasa Supplies, Tanzania Meat Company and Flying Chef

[8] Unnamed is actually its real registered name

Appendix Three: Laws and Regulations Governing Food Safety in Tanzania

Institution/Organisation	Responsibilities	Governing Laws
Ministry of Health and Social Welfare	Food import inspection at ports of entry	The Public Health Act, Act No. 12 of 2009
Pime Minister's Office Regional Administration and Local Government (LGAs)	Food inspection at processing plants, food outlets, restaurants	The Local Government laws (Miscellaneous • Amendment) Act, Act No. 13 of 2006 • The Public Health Act, Act No. 12 of 2009
Ministry of Fisheries and Livestock Development	• Fish inspection • Certificate of fish exports	Fisheries Act, No. 22 of 2003
Ministry of Natural Resources and Tourism	Honey quality and safety production, processing	The Beekeeping Act, No. 15 of 2002
Tanzania Food and Drugs Authority	• Food standard setting • Food products registration • Food safety control • Food inspection • Food export certification	Tanzania Food, Drugs and Cosmetics Act, No. 1 2003
Government Chemist Laboratory Agency	Food analytical services	The industrial and Consumer chemicals (Management and Control) Act No. 3 of 2003
Tanzania Atomic Energy Commission	Monitoring and inspection of radioactive contaminants in foods	Atomic Energy Act, Act No. 7 of 2003
Tanzania Bureau of Standards	• Standards setting • Food products certification and registration • Standards enforcement through food inspection • Control of food imports through inspection • Laboratory food testing and analysis	The Standards Act, No. 2 of 2009 (Revised)
Regulatory Bodies • Sugar Board, Meat Board, Dairy Board, Coffee Board, Cashewnut Board, Tea Board	Regulate food products falling under their mandate e.g. sugar, milk, meat, tea	• Sugar Industry Act, Act No 26 of 2001 • Coffee Industry Act, Act No 23 of 2001 • Cashewnut Board Act, Act No. 18 2009 • Tea Act, Act No. 3 of 1997 • The Dairy Industry Act, Act No. 8 of 2004 • Meat Industry Act, Act No. 10 2006

Appendix Four: List of Inspection/Sampling tools

1. *Common tools* e.g. pliers, spoons, screwdrivers, can/case opener and knife are useful for opening shipping containers, cutting bags and scooping out food products.

2. *Hand held flashlight*: A bright flashlight is useful when working in an area with a limited amount of light and explosion proof flashlight is used when working in dusty areas e.g. flour mills.

3. *Scissors:* are used for cutting cloth containers or as tweezers to handle bag cuttings.

4. *Dippers:* used to collect samples of liquids such as milk.

5. *Dry borer tube:* used for flour, dried milk products used for bacteriological sampling.

6. *Special probe:* used for dried grains such as wheat and maize.

7. *Conical shaped metal probe*: often referred to as "bag thief" is used for sampling bags of grain, coffee beans and spice.

8. *Special probes or Triers:* are used for butter and cheese.

9. *Boot or Flour trier:* used for sampling elevator boots (bottoms) in large flour mill or bakery.

10. *Disposable Plastic spoons and pipettes:* for aseptic sampling for bacteriological analysis.

11. *Rubber or latex surgical gloves:* used to permit handling without adding bacteria to the sample.

12. *Metal screen and a collecting pan*: used for checking bulk grains for insects, rodent faeces, and other foreign material (dockage).

13. *Wire mesh and screen*: is used for sifting flour for insects, with collecting pan and cover.
14. *Thermometer:* used to check ambient temperature and food temperature.

15. *Ultraviolet light:* for examination of urine strains.

16. *Dissecting kit:* includes useful tools for measuring, cutting and collecting food samples if necessary.

17. *Isopropyl alcohol or ethyl alcohol:* for disinfecting sampling tools.

18. *pH Indicator* (pH and Chlorine test papers) to check product pH and chlorine residues

19. *Malachute green solution* for determining the presence of sulfur dioxide in comminuted or ground meat

20. *Moisturemeter* for Moisture Content

21. *Sealing wax* for container sealing

22. *Lactometer* for measuring specific gravity of Milk

23. *Phosphatase kit* for phosphate testing

24. *Weighing balance* for weight measurement

25. *Iodine test solution* for Iodine test

26. *Spatula* for sample holding

27. *Hand refractometer* for measuring Total Soluble Solids (TSS)

28. *Testing equipment* for the presence of ammonia, hydrogen sulphide and peroxidise

29. *Camera for taking* photographs.

30. *Hatchet or chisel* for use on frozen eggs. For dried eggs, a suitable grain trier may be used

31. *Sheet metal shears* for shearing of metal

32. *Tweezers* are used in holding back rodent stained bagging material and for sampling suspected rodent contaminated food material that may be underneath the stained area.

33. *A sewing kit* with bag for sewing.

34. *Needle and twine* to sew up the sampled area of a cloth bag.

35. *Tape measures* for length measurement.

36. *Towels* (Paper and cloth towels)

37. *Hammers and chisels* for opening containers

38. *Field hygrometer* for measuring humidity

39. *Pocket hand lens* (large hand held magnifying glass) for identifying small insects, rodent excreta, pellets etc, as such.

40. *Grain sample divider*

41. *Bags* (Paper and Plastic bags) for holding dry samples

42. *Glass jars* for holding samples

43. *Flour slick:* Is very often used in bakeries or other establishments using milled flours. It is used to spread a portion of flour out in such a way as to cause insects to become visible. It can also be used to scrape caked product from inside of mixers, conveyors, etc to sample the material which may contain live insects.

44. *Simple paint brush:* when moistened can be used to pick up insects without crushing them.

45. *A multipurpose sharp pointed* instrument used in pinning back the cut away portion of bag to permit the use of two hands for collecting the sample.

46. Sanitizing solution for sanitation e.g. hand washing etc

47. *Writing materials* (pens, pencils, notebooks, etc) for note taking

48. *Protective clothing* (overalls, overcoat, masks, head cover-hard hat/ paper hat) to prevent the inspector from contaminating the sample or sampling facilities

49. *Scalpel and spare blade* used for cutting away bagging material to expose possible rodent urine stained product underneath.

50. *Rapid test Kit box:* A set of apparatus for rapid qualitative test of food samples

Appendix Five: List of Recommendations and TFDA's Response

1.	Carry out the performance profiling of food processing plants and food importers in order to establish the compliance level of each of them and use those information as a basis of planning for inspection or pre- inspection;	Agreed.
2.	Ensure that all zone offices and ports of entry are developing inspection plans based on risk factors and use them as basis for guiding their inspections.	Agreed. Inspection plans will be improved taking into account the risk factors.
3.	Establish performance measures for food inspection activities, including a clear policy governing such critical factors as risk assessments, timing, work scheduling etc.	Agreed. Performance measures for food inspection activities are established in the business plan. Performance targets will be set on quarterly basis.
4.	Establish procedure to prioritize and further set frequency to ensure timely completion of inspections of high risk processing plants and imported food products.	Agreed. This is being implemented now, however, both low and high risk products are required to be inspected, the only difference is the frequency of inspection.
5.	Establish a system for capturing food importation data including the imported or agent, quantity, type of food imported, actual or expected delivery date, port of entry to which the consignment intends to go through etc., which would help the TFDA inspectors to plan for their inspections and carryout thorough inspection work.	Agreed, However, Import and export certification and tracking system is being reviewed.
6.	Increase efforts to provide coordinated real time access to data among government departments and obtain training on how to use that data to perform necessary analytics to monitor performance, including activities such as inspections and response to public complaint.	Agreed, Currently a Food Safety policy is being developed. This will provide a framework for a coordinated food safety control system that among other things will establish a mechanism for data sharing.

7.	Ensure that application of sanctions during the inspection is done as per the stipulated laws and regulations, and periodically assess the effectiveness of the applied sanctions.	Agreed Sanctions are being taken through seizure and destruction of unregistered and unfit products. Prosecution and re-exportation of food products.
8.	Develop a strategy to take progressively stronger enforcement actions against plants with serious and repetitive violations, and develop criteria and procedures to classify all severe food safety non compliance ;	Agreed, Stern measures are normally taken to persistent violators including suspension of production and sale of products.
9.	Modify existing criteria to create standardized suspensions and notices of intended enforcement that should be applied, as well as define the frequency and specify the timeframes when violations would lead to such enforcement actions.	Agreed We need to develop guidelines on how to deal with the matter or review the compliance and enforcement policy, 2006.
10.	Monitoring and evaluation indicators for the food inspection activities both at processing plants and ports of entry are formulated and agreed upon; and periodical monitoring and evaluation of inspection activities are carried -out and the results are used as the basis for improvements;	Agreed
11.	All inspection reports from its zone offices as well as LGAs are thoroughly reviewed and scrutinized to determine any deficiencies and provide feedback to the concerned officials for corrective actions and further improvements;	Agreed, Currently quarterly reports from Zone Offices are discussed on quarterly basis during the meeting of the Zone Managers and Directors.

Appendix Six: List of Recommendations and MoHSW's Response

Overall comment:

The Ministry of Health and Social Welfare re-affirm and concurred with reccommendations made by the Audit Team to TFDA of building capacity of Inspectors, update the food safety inspection guidelines including prioritization for high risk processing plants, refining of contradicting guidelines like "importation and exportation regulation (2006) and standard operating procedures for inspection of imported food products at the port of entry", allocating seperate budget for food safety inspection to the zone offices and the rest of the reccommendations.

S/N	Recommendations	Response
1	Food Safety Inspections in the country are properly coordinated, harmonized and all stakeholders are working closely together;	Agreed
2	A general report showing the status of food safety in the country as a result of Food Inspections conducted by different Government Departments is annually compiled and used as the basis for improving food inspection activities and ultimately food safety;	Agreed
3	Data and information regarding food safety are shared among different Government Departments and are used as the inputs for food inspections.	Agreed

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