REPUBLIC OF GHANA

2011
ANNUAL REPORT

FOOD AND DRUGS BOARD

.....Working for your safety

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FIGURES

TABLES

ACRONYMS AND ABBREVIATIONS

ADRs	-	Adverse Drug Reactions
CEPS	-	Customs Excise and Preventive Service
CID	-	Criminal Investigation Department
CMS	-	Central Medical Stores
EMEA	-	European Medicine Agency
FDB	-	Food and Drugs Board
FDL	-	Food and Drugs Law
FSMU	-	Food Safety Management Unit
FPMSU	-	Food Post Market Surveillance Unit
FPIU	-	Food Premises Inspection Unit
GAIN	-	Global Alliance for Improved Nutrition
GAP	-	Good Agricultural Practice
GCMS	-	Ghana Customs Management System
GCNet	-	Ghana Community Network Limited
GCP	-	Good Cold Store Practices
GCP	-	Good Clinical Practice
GHP	-	Good Hygiene Practice
GM	-	Genetically Modified
GMP	-	Good Manufacturing Practices
GWP	-	Good Warehouse Practice
HACCP	-	Hazard Analysis and Critical Control Point

IECD	-	Import and Export Control Department
ICT	-	International Competitive Tender
ISO	-	International Standard Organization
ISOP	-	International Society of Pharmacovigilance
KNUST	-	Kwame Nkrumah University of Science and Technology
NCB	-	National Competitive Bidding
NFFA	-	National Food Fortification Alliance
NMCP	-	National Malarial Control Programme
PNDC	-	Provisional National Defence Council
PNDCL	-	Provisional National Defence Council Law
PRMIS	-	Projects, Research and Management Information System
QAMSA	-	Quality of Anti-malarial Survey Assessment
TAC	-	Technical Advisory Committee
TACSM	-	Technical Advisory Committee for Safety Monitoring
MOFA	-	Ministry of Food and Agriculture
U.K	-	United Kingdom
USI	-	Universal Salt Iodation
USP	-	United State Pharmacopeia
WHO	-	World Health Organization
WAHO	-	West Africa Health Organization

EXECUTIVE SUMMARY

The year 2011 saw the continuation of work to consolidate the institutional framework for the establishment of the Food and Drugs Board (FDB) as a Government regulatory body responsible for the control of the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemical substances under the Food and Drugs Law 1992 (PNDCL 305B) and its amendment Act 523, 1996. The passage of Tobacco Control Bill and the revision of the Food and Drugs Law are still pending at the Parliament. Other policies and guidelines aimed at strengthening the FDB to deliver on its mandate were put in place. These included the guidelines and documents for food and drugs activities and the mandated fee schedule. An inventory of other policies and guidelines already developed, which have implications for the operations of the FDB were initiated and steps were taken to review them.

During the year, a range of activities including consumer awareness programmes, and Good Manufacturing Practices (GMP) training programmes were outlined to support industry and to protect public health and safety.

Applications for the registration of drugs, food, cosmetics, household chemical substance, medical devices and premises inspections increased significantly during the year. Post market functions increased significantly especially on Herbal Medicinal products, which have grave consequences on public health and its implications for healthcare delivery. There was an improvement in the operations of the Zonal Offices over the previous year. The FDB continued its regulatory control of the exportation of palm oil to the European Union. Three new regional offices were created to enhance the regulatory functions of the FDB. The regions are Cape Coast, Koforidua, Wa regional office, respectively. The Human Resource Unit was elevated to a special unit directly reporting to the Chief Executive Officer.

1. INTRODUCTION

This report covers the activities of the Food and Drugs Board performed during the year 2011.

The Food and Drugs Board was established by the Food and Drugs Law, 1992 (PNDCL 305B). This law has since been amended by the Food and Drugs (Amendment) Act 523, 1996 to provide for the fortification of salt to alleviate nutritional deficiencies, and to bring the provision of the law in conformity with the 1992 constitution of the Republic of Ghana.

1.1 Background of Food and Drugs Board

Before 1990, the control of drugs and the practice of pharmacy profession were under the Pharmacy and Drugs Act (Act 64), 1961. In 1990, the Provisional National Defence Council (PNDC) passed the Narcotics Drugs Control, Enforcement and Sanctions Law (PNDCL 236). This law established the Narcotics Control Board to deal with the rising incidence of drug abuse in the country and threatening dimensions that illicit drug dealing had taken internationally.

In 1992, the PNDC separated the control of drugs other than narcotics from the practice of Pharmacy.

The Food and Drugs Law, 1992 (PNDCL 305B) was then enacted to control the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemical substances. The Pharmacy Act 489 was subsequently passed in 1994 to establish the Pharmacy Council to control the practice of the Pharmacy profession and the registration of Pharmacists. Although the Food and Drugs Law was passed as far back as 1992, it was not until 26th August 1997 that the first Board was inaugurated.

The Food and Drugs Board is under the control and supervision of the Minister responsible for Health.

1.2 Functions of the Food and Drugs Board

The functions of the FDB as spelt out by law (PNDCL 305B) are as follows:

The Board shall advise the Minister of Health on all matters relating to the administration and implementation of the Law.

Without prejudice to the above, the Board shall

- *advise the Minister on measures for the protection of the health of consumers;*
- *in co-operation with the Ghana Standards Board, ensure adequate and effective standards for food and drugs;*
- *monitor through the District Assemblies and other agencies of state compliance with this Law;*
- *advise the Minister on the preparation of effective regulation for the full implementation of the provisions of the Law;*
- *perform the functions assigned to it under this law*

1.3 Mandate

The Food and Drugs Law of 1992 (PNDCL 305B), which established the Food and Drugs Board, put the control, the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemicals under the purview of the FDB with respect to ensuring their safety, quality and efficacy.

1.4 Vision

The vision of the Food and Drugs Board is to become a centre of excellence in food and drug regulatory affairs on the African continent.

1.5 Mission Statement and Goals

The Food and Drugs Board aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy, and quality for all food, drugs, cosmetics, household chemical substances and medical devices (hereinafter referred to as products) locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the law regulating food and drugs in force in Ghana.

To realize this mission, the Food and Drugs Board has set for itself the following goals:

The FDB shall:

- *Advise the Minister of Health on measures to protect the health of the consumer.*
- *Recruit qualified staff and ensure their training, development and maintenance for optimal productivity and quality service delivery.*
- *Ensure that Legislative Instruments are passed for the laws and guidance of its clients.*
- *Develop and implement a well-researched communications strategy to promote the functions of the Food and Drugs Board and matters relating to the health of the consumer under the Food and Drugs Board's contributions to safety and efficacy.*
- *Ensure that product information and advertisement are not misleading or deceptive nor contain references to diseases for which advertisement is prohibited.*
- *Ensure that all local manufacturers of products are licensed and that their operations conform to current codes of Good Manufacturing Practices (GMP).*
- *Ensure that all products locally manufactured, imported, and/or exported are registered to assure their safety, quality and efficacy.*
- *Collaborate with other governmental and non-governmental bodies, the district and municipal assemblies to enable optimal performance of its functions.*
- *Undertake research and analysis to enable the fulfilment of its obligations to the nation.*
- *Develop an organizational structure with financial, information technology and human resource facilities that encourage selfdevelopment, responsibility and empowerment of staff to meet the functions of the Food and Drugs Board.*
- *Have well branded, comprehensive, distinctive and high quality operations throughout the nation.*
- *Establish, maintain, monitor and update standards of products.*

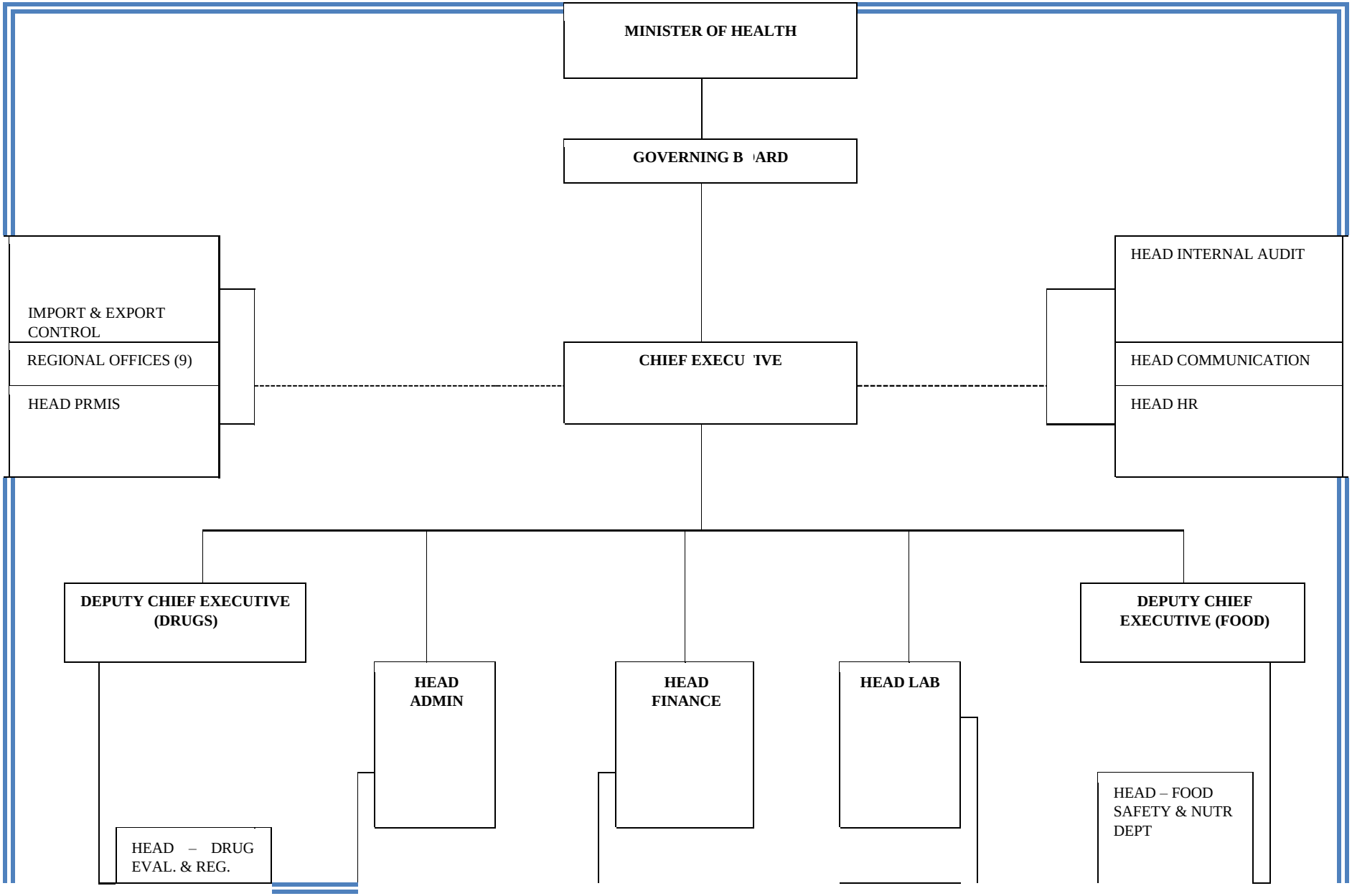
1.6 The Governing Board

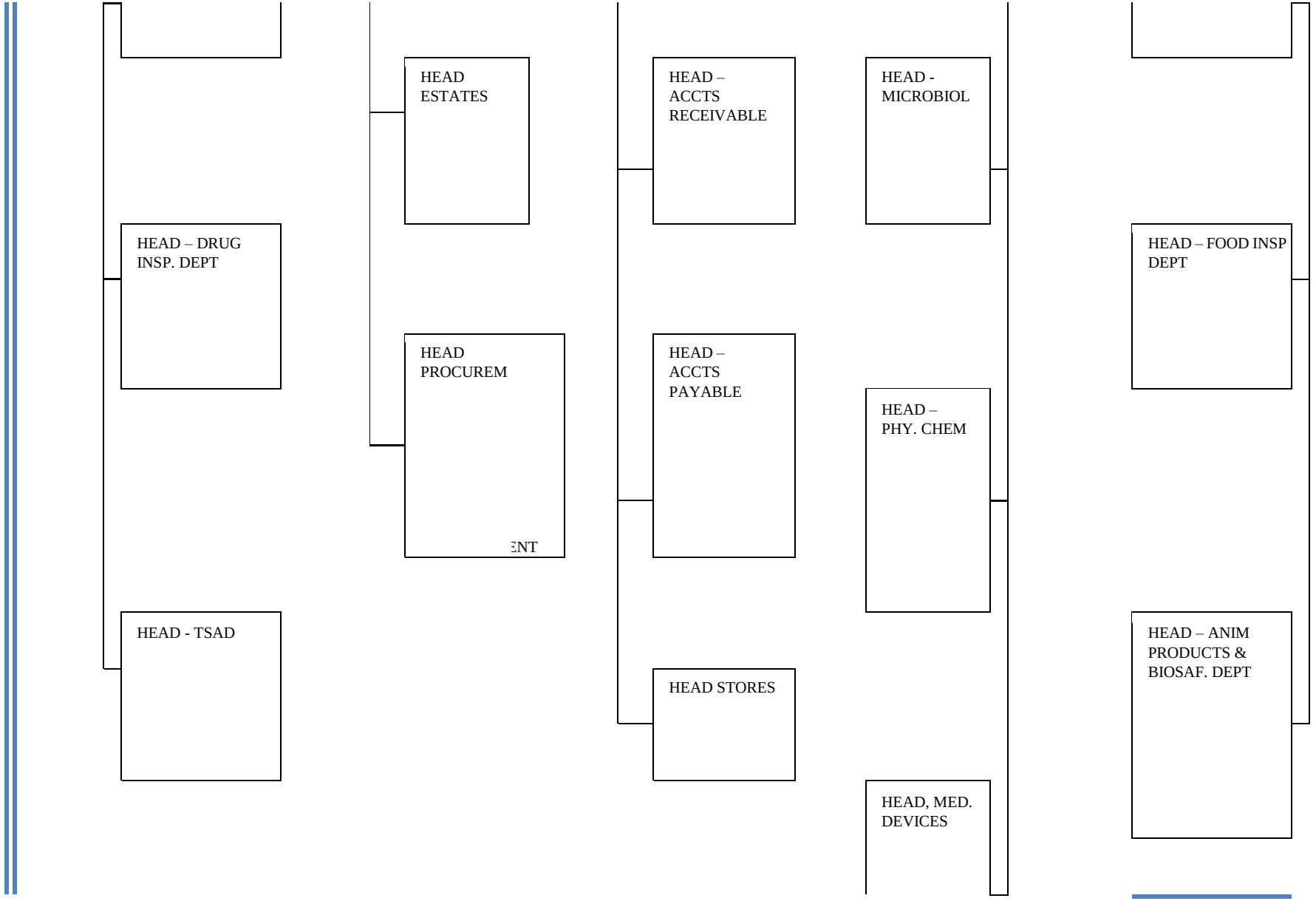
The Food and Drugs Law 1992 (PNDCL 305B) and Food and Drugs Amendment Act 523, 1996 provide for a management structure spear-headed by a Governing Board appointed by the President of the Republic of Ghana. The Chief Executive of the FDB is Dr Stephen Kwabena Opuni and the current Governing Board members are;

1. Mr T.C Corquaye	Chairman, Government Representative.
2. Dr Stephen K. Opuni	Chief Executive, Food and Drugs Board
3. Mr J.A. Pwanmang	Environmental Protection Agency
4. Mr Joseph Nyoagbe	Registrar, Pharmacy Council
5. Dr Paa Nii Johnson	Director, Food Research Institute
6. Mr Alfred Yeboa Tetebo	Fisheries Dept., Ministry of Food and Agriculture
7. Dr. Bashiru Boi Kikimoto	Veterinary Services
8. To be nominated	Crop Services, MOFA
9. Dr George Ben Crentsil	Executive Director, Ghana Standards Board.
10. Prof. Kwaku Tano-Debrah	Dept. of Nutrition & food Science University of Ghana
11. Ms Grace Issahaque.	Representative, Attorney General's Department.
12. Dr Poku Adusei	Representative, Medical and Dental Council
13. Mrs C. Ribeiro	Consumer Representative
14. Mr Kenneth Danso	Ghana Association of Traditional Healers

1.7 The Organisational Structure

The current organogram of the FDB is indicated on page 5.


MINISTER OF HEALTH
GOVERNING B ARD
IMPORT & EXPORT CONTROL
REGIONAL OFFICES (9)
HEAD PRMIS
CHIEF EXECU IVE
HEAD INTERNAL AUDIT
HEAD COMMUNICATION
HEAD HR
DEPUTY CHIEF EXECUTIVE (DRUGS)
HEAD ADMIN
HEAD FINANCE
HEAD LAB
DEPUTY CHIEF EXECUTIVE (FOOD)
HEAD – DRUG EVAL. & REG.
HEAD – FOOD SAFETY & NUTR DEPT


HEAD – DRUG INSP. DEPT
HEAD - TSAD
HEAD ESTATES
HEAD PROCUREM
ENT
HEAD – ACCTS RECEIVABLE
HEAD – ACCTS PAYABLE
HEAD STORES
HEAD - MICROBIOL
HEAD – PHY. CHEM
HEAD, MED. DEVICES
HEAD – FOOD INSP DEPT
HEAD – ANIM PRODUCTS & BIOSAF. DEPT

In summary, the FDB as a national regulatory body has the responsibility for the regulatory control of manufacture, import, export, distribution, advertisement and product information for food, drugs, cosmetics, medical devices and household chemical Substances. This is a very critical role, as misbranding, substandard and/or counterfeit, as well as unsubstantiated product information has very grave consequences on public health and serious implications for healthcare delivery. The FDB, since August 1997, has been pursuing various specific objectives to address issues on regulatory control of products as stated above.

The ensuing sections deal with the summaries of achievements in 2011.

2.0 DRUGS DIVISION

The Drug Division contributes to the attainment of the functions of the Food and Drugs Board for safeguarding public health by ensuring that all medicines on the market meet appropriate standards of safety, efficacy, and quality. These functions are carry out by evaluating all information submitted in the registration dossiers, pre-registration inspection, and drug quality analysis reports.

The Division also evaluates and registers veterinary medicines to promote and protect animal health and to ensure safe animal products for human consumption.

2.1 Drug Evaluation and Registration Department

The Drug Evaluation and Registration Department of the Food and Drugs Board is made up of the following operational units:

- Medicine and Vaccines Evaluation and Registration Unit
- Cosmetic, Household Chemicals and Medical Devices Unit

2.1.1 Medicine Evaluation and Registration Unit

The main functions of Medicine Evaluation and Registration Unit are:

- Registration of Medicinal products and issuance of certificates:
  The Assessment of applications for the registration of medicines and vaccines products involves the following:
- Evaluation of dossiers submitted for registration to ensure that application forms are properly completed and the requisite information and certificates are duly submitted.
- Ensuring that information provided on packages and package inserts are correct and adequate to enable the FDB take the appropriate decision.
- Maintenance of SIAMED database (WHO application software for medicines registration).
- To conduct product application reviews.

During the year under review, 502 product applications were submitted to the Medicines Evaluation and Registration Unit. This total number was made up of 410 imported allopathic drugs (human), 68 locally manufactured allopathic drugs (humans) and 24 imported allopathic drugs for veterinary use. 656 applications were submitted for product re-registration. This figure was made up of 539 imported allopathic drugs for humans, 8 veterinary applications, and 109 locally manufactured allopathic drugs (humans). Table 1 and 2 give the summaries of applications received for registration and re-registration, respectively, during the year under review.

Table 1: Summary of applications received and registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Allopathic Drugs (Human)	410	68	361	27
Veterinary Drugs	24	-	30	-
Vaccines	-	-	-	-
Total	**434**	**68**	**391**	**27**

Source: Medicine Evaluation and Registration Unit, 2011

Table 2: Summary of applications received for re-registration

Product Type	**Applications Received**		**Number Re-registered**	
	Foreign	Local	Foreign	Local
Allopathic Drugs (Human)	539	109	393	40
Veterinary Drugs	8	-	16	-
Vaccines	-	-	-	-
Total	**547**	**109**	**409**	**40**

Source: Medicines Evaluation and Registration Unit, 2011.

2.1.1.1 Product Registration and Document Reviews

In 2011, eight (8) dossier evaluations and four (4) product registration meetings were held. The following are the details of the documentation, which were evaluated at the dossier evaluation meetings**.**

Table 3: Product Registration and Document reviews

TYPE OF DOCUMENT	**NUMBER EVALUATED**
Imported and local Allopathic Drug Registration (for Human)	331
Allopathic drugs additional documentation	541
Imported allopathic medicines registration (veterinary)	-
Total	**872**

Source: Medicine Evaluation and Registration Unit, 2011

2.1.2 Cosmetics, Medical Devices and Household Chemical Substance Unit

The principal functions of the Unit are:

- Evaluation of documents related to all cosmetics, medical devices and household chemicals substances.
- Registration of cosmetic products, medical devices and household chemical substances.

During the year under review, a total number of five hundred and fifty-four (554) applications were submitted for registration. Out of the total number of applications received, two hundred and eighty-nine (289) applications were for cosmetics, ninety-nine (99) were for household chemical substances and One hundred and sixty-six (166) applications for medical devices, respectively. The Unit was able to approve one hundred and forty-three (143) cosmetics products and deferred (146), due to unavailability of laboratory results, whilst eighty-one (81) household Chemicals were given approval and eighty-five (85) were deferred. Eighty-two (82) Medical Devices were approved.

Table 4 and Figure 2 respectively, show the number of products received and registered during the year under review.

Table 4: Summary of types of products received and registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Cosmetics	289	17	143	24
Household Chemicals	99	14	81	1
Medical Devices	166	1	82	-
Total	**554**	**32**	**306**	**25**

Source: Cosmetics, Medical Device and Household Chemical Substance Unit, 2011.

2.2 Herbal Medicine Department

The Herbal Medicine Unit was elevated to the status of a Department in April 2010.

The main functions of the Herbal Medicine Department are:

- Registration, processing and evaluation of all herbal medicine applications and food supplements.
- Evaluation of toxicological and clinical information as well as therapeutic data submitted from Centre for Scientific Research into Plant Medicine, Mampong-Akuapim, Noguchi Memorial Institute for Medical Research, Legon-Accra, Faculty of Pharmacy, Kwame Nkrumah University of Science and Technology (KNUST) -Kumasi, and Department of Pharmacology, Korle-Bu Teaching Hospital
- Issuance of product registration number, which is valid for one (1) year in case of locally manufactured products and three (3) years for imported herbal drugs.

During the year under review, a total number of four hundred and twenty-nine (429) herbal medicine applications were received including re-registration applications and one hundred and seventy-six (176) were approved.

A total number of two hundred and seventeen (217) food supplement applications were received and two hundred and three (203) food supplements approved including 11 applications from the previous year.

Table 5: Summary of herbal products received and registered

	Applications Received		**Number Registered**	
	Foreign	Local	Foreign	Local
Herbal Products for Registration	3	231	6	91
Herbal Products for Re-registration	35	160	41	38
Food Supplement	138	-	149	-
Food Supplement for Re-registration	79		54	
Total	**255**	**391**	**250**	**129**

Registration Activities, 2011

2.3 Safety Monitoring Department

The Safety Monitoring Unit was upgraded to the status of a Department in April 2010 with the following objectives:

- Strengthen the science that supports safety and monitoring of products as used in everyday practice to identify previously unrecognized or changes in the patterns of the risk profile.
- Assess regulatory information relating to product safety in order to determine what action, if necessary, to improve safe use of products and make recommendations on product label amendments, product withdrawals and change in the category of distribution of medicines.
- Provide healthcare professionals and the general public with access to clear and timely risk-benefit information for products.
- Maintain contact with international regulatory bodies working in pharmacovigilance and exchange information on drug safety.
- Ensure that all clinical trials conducted in Ghana are in accordance to the Good Clinical Practice and the Helsinki Declaration to ensure the protection and right of human subjects.

The functions of the Department are supported by three (3) specialized Units, namely: Signal Management and Communication Unit, Clinical Trials Assessment Unit and Research and Risk Management Unit.

2.3.1 Signal Management and Communication Unit

Functions:

- Maintain national Drug Safety Database
- Commit reports to the WHO vigiflow database
- Acknowledge receipt of Adverse drug report (ADR) / Adverse Events following Immunisation (AEFI) reports and provide feedback to reporters
- Communicate safety information to healthcare professionals through Dear Doctor / Healthcare professional letters
- Communicate safety information to healthcare professionals and the general public through publications (safety newsletter, website information, media articles, e-mails etc.)
- Coordinate Technical Advisory Committee (TAC) for safety monitoring meetings

- Identify areas for training and provide training for healthcare professionals and public awareness

2.3.2 Clinical Trials Assessment Unit

The Unit evaluates clinical trial applications with support from the Drug Evaluation and Registration Department with the following functions:

- Correspondence with PIs, Sponsors, etc.
- Collate and categorize serious adverse events (SAEs) from clinical trials
- Maintain clinical trials database
- Maintain Database of Serious Adverse Events
- Liaise with Drugs Inspectorate Department to conduct Good Clinical Practice Inspections
- Coordinate TAC clinical trial meetings

2.3.3 Research and Risk Management Unit

The Unit collaborates with public health programmes with the following functions:

- Collaborate with the pharmaceutical industry regarding safety related to marketed products
- Evaluate pharmacovigilance plans and periodic safety update reports submitted by pharmaceutical industry.
- Conduct pharmacovigilance inspections
- Develop proposals for activities and projects
- Carry out impact analysis of the Safety Monitoring activities.

During the year under review, four (4) Technical Advisory Committee meeting were held and fourteen (14) sensitization lectures were conducted.

The summaries of activities conducted in 2011 are summarized in table 6.

Table 6: Summary of activities conducted by Safety Monitoring Department

Activities	Number
ADR Reports Received	326
Number of spontaneous AEFI reports	28
Number of reports committed into vigiflow	474
Number of AEFI reports from active surveillance during yellow fever campaign	726

Number of institutions trained	10
Increased in quality and number of SAE reporting	1,356
Training of investigators and study team on GCP regulatory requirement	46

Source: Safety Monitoring Activities, 2011

2.3.5 Training/Workshop

The Department provided training for three and hundred forty-two (342) institution and four thousand, six hundred and fifteen (4,615) teams of eight (8).

2.3.6 Conferences and Meeting

The Department organised and participated in the following conferences and meetings:

- Hosted the 33rd Annual meeting of National Centres Participating in the WHO Programme for International Drug Monitoring Meeting from 31st October to 3rd November 2010.
- Participated in the 10th International Society of Pharmacovigilance (ISoP) meeting held from the 3rd to 6th November 2010
- A member of staff participated in the Good Clinical Practice (GCP) inspectors training course in London.
- A member of staff participated in the training on Practical Guide for Pharmacovigilance: Clinical Trials and Post marketing in South Africa held from the 11th-13th August 2010.
- 2 members of staff participated in the West Africa Health Organisation (WAHO) workshop to review and strengthen the implementation of National Pharmacovigilance systems in Economic Community of West Africa States (ECOWAS).

2.3.6 Safety Communications

During the year under review, the Department dealt with the following Safety Communications:

1. An alert relating to the sale and distribution of unregistered Vit. K3 Injection, which was distributed to healthcare institutions. Healthcare professionals nationwide were informed about the risks associated with the use of Vit. K3 and to avoid the use of the product.

2. Review of the safety of Metamizole sodium: communication of the Technical Advisory Committee (TAC) of Safety Monitoring recommendation on the use of metamizole sodium.
3. Restrictions on the use of over-the-counter cold and cough preparations in children: follow-up to an earlier communication and the recommendation that these products should not be used in children less than 5 years of age.
4. Suspension of Marketing Authorisation of Rosiglitazone containing Anti-diabetes medicines: issued to all healthcare professionals.
5. Safety information on sibutramine: recommendation by European Medicine Agency (EMEA) to suspend this product and United State, Food and Drugs Administration's (FDA) recommendation to amend the label to include the risk associated with the use of the product in patients with cardiovascular events.

2.4 Drug Inspectorate Department

The Drug Inspectorate Department of the Food and Drugs Board is made up of the following operational units:

- Premises Inspection Unit
- Post-Market Surveillance Unit/Task Force
- Industrial Support Service/Operational Research

The Department's main activities include pre-licensing and post licensing inspections of pharmaceutical, herbal, cosmetic and household chemical substances manufacturing industries. The Department also conducts inspection of local and overseas drug manufacturing facilities to verify compliance to Good Manufacturing Practice (GMP).

2.4.1 Drug Premises Inspection Unit

The principal functions of Drug Premises Inspection Unit are:

- To conduct routine, announced, unannounced Good Manufacturing Practice (GMP) audit inspections in all local licensed pharmaceutical manufacturing facilities for the production of allopathic and herbal drugs, cosmetics and household chemical substances.
- To conduct pre-licensing inspections for new applicants and evaluation of block plans of new manufacturing facilities.
- To conduct site verification inspections in foreign pharmaceutical manufacturing plants in line with GMP Audit inspections for pharmaceutical companies that carry out business in Ghana.
- To conduct industry production capacity monitoring and control of extemporaneous preparations.

The Unit was able to conduct routine audit inspections in 25 manufacturing companies that were registered and generally, the findings of the inspections indicated improvement in Good Manufacturing Practice. Figure 3 shows the routine inspections conducted in local allopathic, herbal, and cosmetics manufacturing plants.

2.4.1.1 External GMP Audit Inspections

Overseas GMP audit inspections of Pharmaceutical Companies carrying out business in Ghana were carried out during the period under review. In all, 25 pharmaceutical manufacturing facilities were inspected and all were found to be GMP compliant.

2.4.2 Industrial Support Services Unit

The Unit supports the activities of the Premises Inspection Unit and the Post Market Surveillance Unit of the Drug Inspectorate Department. The Unit supports these Units by capturing and managing qualitative and quantitative data together with operational guidelines of the Department. The Unit also monitors medicine adverts. A total of 238 applications were vetted within the year 2011, 216 were approved, 5 were suspended because product registration has expired, 2 were rejected and 8 were deferred.

2.4.3 Drug Post Market Surveillance Unit

The Unit monitors registered drugs, cosmetics, household chemical and medical substances that have been given marketing authorisation or otherwise that are in distribution on the Ghanaian market and is of right quality, safe and efficacious. The Unit therefore undertakes the following activities:

- Inspection of storage facilities.
- General and targeted market surveillance (conduction of product quality monitoring).
- Collaboration with Pharmacy Council to monitor quality of products on the Ghanaian market.
- Supervision of safe disposal of expired, unwholesome and confiscated products.
- Destination inspection in liaison with the Import and Export Control Department.
- Undertake investigations into consumer and other complaints.
- Undertake random sample products for analysis.

2.4.4 Enforcement Activities of the Department

In 2011, the task force of the FDB embarked on various swoops to check on non- compliant medicinal products from the Ghanaian Market. The outcome of the operation was that many medicinal products were found to contain no active pharmaceutical ingredients whiles others were found to contain either wrong active ingredients that are harmful to human health or were not registered at all with the FDB and that their quality, safety and efficacy could not be ascertained.

The following regulatory actions were taken against the perpetrators, an administrative fine was imposed, products were seized and destroyed and the company's facility closed down.

Activities	Outcome	Remarks
Foreign GMP Audit	25	Twenty-four companies were found to be GMP compliant.
Routine Audit of local Pharmaceutical Plants	28	One company had relocated to a new premises and was thus setting up the other had suspended production
Routine Audit of local Herbal Manufacturing Plants	28	Some Companies did not avail themselves for inspection. Some conducting renovation, relocation etc.
Routine Audit of local Cosmetics, H.C and M.D Manufacturing Plant	13	Four companies could not be contacted because they had either close down or changed premises
Monitoring of utilization of controlled substances	10	One company was affected by recent floods, three companies could not be audited because of lack of logistics on scheduled dates
Pre-Licence Inspection of Local Pharmaceutical Manufacturing Plants	2	All companies had been inspected and recommended for approval
Pre-Licence Inspection of Local Herbal medicines Manufacturing Plants	19	All companies had been inspected and recommendations made to them for implementation. Eleven companies has been recommended for approval
Pre-Licence Inspection of Cosmetics, H.C and M.D	12	All companies had been inspected and recommended for approval

Activities	Outcome	Remarks
Warehouse Inspection	42	Some companies relocated without informing the FDB and could not be located, others had suspended importation.
Product Quality Monitoring	39	Monitoring of companies and products are on-going
Safe Disposal	36	The company is yet to contact AMA to arrange for disposal site
Investigations	15	Some investigations have been referred to regional offices for follow-up actions, others are pending court cases while the rest are on-going

Consumer Education	16	Council of state, Parliamentary select committee. National Security, BNI and Police, General Public, 10 religious institutions
Collaborations	2	Interpol Anti-counterfeiting initiative FDB, USP and UNIDO
National Exhibitions	3	
Raids	48	Okaishie, Agbogbloshie, Ashiaman, Lapas etc

Table 7: Summary of task force activities

Origin of Drug Sample / Name of Facility	Medicine Name	Name of Manufacturer	Country of Origin	Activity	Overall Conclusion/outcome
Darose Pharmacy Royal Pharmacy Adepa Pharmacy Sarkuff Pharmacy Biakoye Pharmacy	Ventolin Evohaler and Syrup (Allen & Handburys)	Allen & Hanburys	UK	Products seized from identified shops dealing in the suspected article. Product being distributed by Ernest Chemist, Royal Dach Pharmacy and Inter Pharmacy	Seized products disposed off safely.
VicDoris Pharm.	CIPRO-DOR 500mg	Shijazhuang Pharm group.	China	Product not registered with FDB Company tasked to recall the products from the market and recalled products were safely disposed off.	Company initiate steps to register product. Seized products disposed off safely Administrative fine imposed on company.
	CLAVU-DOR 625mg TABS	Shandong Reyoung Pharms.	China		
Okaishie Market	Ghandour Cosmetics-elitis, lune d'ete, lomani and cigar natural spray	Source of beauty cosmetics co. ltd.		Products seized from identified shops dealing in the suspected article.	Seized products disposed off safely.
Kintampo Municipal Hospital	Artine (Artemether Lumefantrine tablets)	Ambica Pharma sale, Mumbai	India	Products seized and samples submitted for laboratory analysis	Product is not registered, seized product disposed off safely.
Vitamin K^3 injectionkemin 3				Product not registered with the FDB. Product seized and disposed off safely.	Administrative charge imposed.
Meilun Company Limited Ghana	Hou Ji Ling capsules, Su Gang Ning capsules Tummycare capsules wet tissue (men) wet tissue (women) Aloe Sanitary Napkin refreshing wet wipe	Meilun Company	China	Products disposed off safely after establishing that the products were not registered. Samples submitted for complete laboratory analysis Closure of facility.	Opening of Facility after company furnished the FDB with supporting document to prove separation of residence from the operating facility and also taken steps to bring the facility into compliance. Company initiate moves to register products administrative fine.
Accra Metropolis	Sex Enhancing Drugs (Aphrodisiacs) 1. Black superman 2. Beautiful penis augments	Unknown	China	Series of swoop conducted to cause seizure and apprehension of dealers where applicable. Arrested dealers were arraigned before the court, samples submitted to the FDB laboratory for	Seized products disposed off safely. Arrested dealers arraigned before court. Public education exercise via press release by FDB Investigation on-going.

	3. Big penis 4. African iron rod 5. Great penis 6. Black butterfly-1200mg 7. Lonely Girl 8. Max-Hero 9. Sex Lovewarrior 10. Good Man 11. Bed War 12. Magic Man 13. Aphrodisiac Milk 14. Jaguar Power 15. Gerrmany Kim fox 16. Playboy Bunny girl			analysis. Result indicated that the products contains lead, etc.	

Source: Task force activities, 2010

2.5 Tobacco and Substance of Abuse Department

The Tobacco and Substance of Abuse Department has the mandate to control tobacco, licit narcotic drugs, psychotropic substances and chemical precursors in Ghana. Under its mandate, the Department regulates the importation and use of these substances by means of a permit system and other regulatory functions. The importing companies have to furnish the FDB with advice of receipt, annual returns, and the requisitions for the ensuing year. The FDB also receives multilateral chemical reporting notification forms for endorsement in connection with the importation and control of precursors. The FDB also sends quarterly and annual returns on the use and importation of narcotics and psychotropic substances to the International Narcotics Control Board (INCB) in Vienna.

In 2011, the Department vetted and issued 67 import permits for controlled substances. 62 advice of receipt were received. 84 returns on utilised controlled substances were monitored. 41 export authorisations endorsed and confirmed. Export authorisation was received before consignments reached the country.

Multilateral Chemical Reporting Notification endorsed in 2011 was 20.

3 FOOD DIVISION

The Food Division contributes to the achievement of the goals of the Food and Drugs Board for safeguarding public health by ensuring that all food products on the market meet appropriate standards of safety and quality through pre-marketing assessment of food safety and quality. This is achieved by evaluating all samples submitted in the registration process, premises inspection, and meeting labelling requirements.

The Food Division is also mandated to undertake inspection of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify compliance to Good Manufacturing Practices. In addition, the Division ensures that all imported and locally produced food products are of good quality and wholesome.

The activities of the Food Division are carried out by Food Safety and Nutrition Department, Food Inspectorate Department and Animal Products and Biosafety Department and these are supported by eight (8) operational units.

3.1 Food Evaluation and Registration Department

The Food Evaluation and Registration Department is made up of the following operational Units:

- Food Evaluation Unit
- Food Registration Unit

3.1.1 Food Evaluation and Registration Unit

The principal functions of the Unit include:

- Vetting of food product applications and samples for evaluation.
- Evaluation of food products.
- Registration of food products.
- Maintenance of food product register
- Verification/vetting of permit applications.
- Shelf life monitoring of food products.

- Review of labelling and promotional materials.
- Processing of permits.
- Client Services support.

In 2011, a total number of 1,976 applications were considered for registration. Out of this number, 947 representing 47.93% were registered. New software for product evaluation was installed for the Department in April 2011.

Table 8: Summary of food products submitted and registered

ACTIVITY	2011
1.Applications	1976
2. Product registration	947
3. Registration meetings	17
4.Client service enquiries	3,677 attended to 1,727 enquiries (4000+)
*Water (applications received)	764

Source: Food Registration Activities, 2011.

3.1 Group Registration

An evaluation was carried out from the Game Discount World Ghana Limited, Batlantic Merchants Limited and Imexco Ghana Limited under the Group Registration exercise at the premises of the companies.

3.2 Food Inspectorate Department

The Food Inspectorate Department is one of the three Departments making up the Food Division of the FDB. The responsibilities of the Department are performed by three Units, namely Food Post-Market Surveillance Unit (FPMSU), Food Premises Inspection Unit (FPIU) and Industrial Support Services Unit (ISSU).

3.2.1 Food Post-Market Surveillance Unit

The major functions of the Unit are:

- Inspection of dry food storage facilities (Food Warehouse) to ensure their compliance to Good Warehouse Practice (GWP) as a guarantee for the safe storage of food products.
- Investigate into consumer complaints and related issues.
- Monitoring of practices employed in the retail of pre-packaged food to safeguard public health and safety.
- Vetting and approval of food product advertisement applications.
- Training of stakeholders in relevant areas of the Food Law.
- Enforce compliance to Breast Feeding Code.

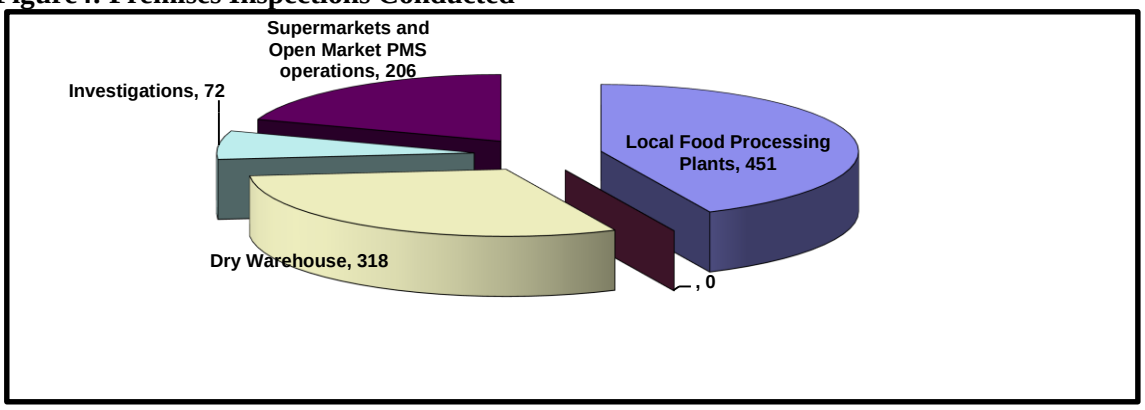
3.2.2 Food Premises Inspection Unit

The Food Premises Inspection Unit (FPIU) carries out the following functions to support the activities of the Food Division:

- Inspection of food processing facilities to assess compliance to current codes of GMP, Good Hygiene Practice (GHP), and other food safety management systems as a guarantee for the production of safe and quality food products.
- Conduct investigation into consumer complaints.

During the year under review, 1,103 types of inspections were conducted covering Local Food Processing Plants, investigation into consumer complaints, Dry Warehouse, Annual pre-Christmas inspections, and Supermarkets and retail outlets. Figure 7 indicates the summary of frequency of inspections conducted in 2011 at the various food plants.

Figure4: Premises Inspections Conducted



Source: 2011 Food Premises Inspection Activities

Based on the outcome of the inspections and other non-compliances noted, the Unit included a training activity in its programme. In consequence, the Unit organised training in GMP and Food Safety management System based on the Principles of Hazard Analysis and Critical Control Point (HACCP) for Quality Assurance Officers of local Alcoholic Beverage Producing Companies.

In the course of 2011, the Department embarked on eleven (11) swoops on Re-branded "Heinz" Corned Beef, Fake J.H Henkes Schnapps, Alilinka Fruit flavoured Drinks, Fake Sultana Rice, Rebranding of JH Henkes schnapps, extending the expiry dates if expired products. All the products were seized and destroyed.

3.2.3 Industrial Support Services Unit

The Unit provides the following functions to support the Food Division:

- Provision of technical support to the food industry through training and implementation of food safety and quality management systems.
- Control of export of palm oil to the European Union.
- Implementation of GAIN project on fortification of wheat flour and vegetable oil with micronutrients.
- Implementation of Universal Salt Iodation (USI) programme

3.2.3.1 Food Industry Audit

To assess adherence to GMP and other food safety management systems, the Unit conducted ten (10) GMP audits, twelve (12) Palm oil pack-house audits, eighteen (18) Needs assessments and two (2) HACCP audits were conducted throughout the year.

3.2.3.2 Sampling and Screening of all palm oil samples intended for export

Curbing the adulteration of palm oil with Sudan dyes to facilitate export and for consumer protection, the unit was able to screen palm oil as and when application is received. One hundred and twenty-two (122) samples of palm oil intended for export were screened and found to be free of Sudan dye.

3.2.3.3 Management of Food Alert

During the year under review, one food alert on groundnut paste was received and investigated.

3.2.3.4 Universal Salt Iodation Programme (USI)

The objective of the programme is to achieve 90% household consumption of iodated salt in Ghana. To monitor each of the three police checks points monthly and monitor salt sold on the markets and issue permits for the transport of raw salt. During the period under review, the Unit made visited 24 checkpoints, 14 markets in Greater Accra to monitor the iodation status of salt sold and 127 permits were issued for non-iodated salt within the country and 973 certificates of Manufacture and Free Sale were issued for the transport of salt outside the country.

3.2.3.5 National Food Fortification Alliance (NFFA)

The Ghana National Fortification Programme aims at reducing the prevalence of micronutrient deficiencies among vulnerable and at risk populations. The principal activity is to monitor and sample producers of wheat flour and vegetable oil for quantitative laboratory analysis of vitamin A and iron. In 2011, three hundred (300) samples were received.

3.2.3.6 Supervision on unwholesome Food Destructions Operations

In 2011, 59 applications were received, fifty-one (51) mandatory and 6 voluntary, fiftysix (56) destruction supervised, one (1) awaiting confirmation destruction date from applicant.

3.3 Food Safety Management Department

The Food Safety Management Department (FSMD) is under the Food Division which has two units namely;

- Food Service Establishment Inspection Unit (FSEIU)
- Public Education and Food Borne Disease Surveillance Unit (PEFDSU) Functions of the Department includes:
- The Registration and Inspection of Restaurants, Food Joints, Street-Vended Food, Catering Facilities and Caterers.
- Maintenance of liaison with the Ministry of Local Government and Rural Development (MLGRD) to ensure dissemination of Food Safety at the District Level and the Safety of the School Feeding Programme Menu.
- Development of Food Safety Guidelines to guide the Out-of –Home Service Operators.
- Maintenance of liaison with Port Health Authority and Environmental Health Officials to regulate Street-Vended Foods and Import/ Export of ethnic food at port of entry/ exit.
- Collection and maintenance of data on foodborne related illnesses for consideration in Public Health Strategic Plan.
- Plan and conduct Consumer Awareness Campaign and Education Programmes on Food Safety Issues.
- Introduction of Hazard Analysis and Critical Control Points (HACCP) Food Safety Management System in the Hospitality Industry.
- Management of the Food Alert System INFOSAN for exchange of Food Safety alert notification.

3.3.1 The registration and inspection of Food Service Establishment

- Introduced the Food Hygiene Permit (FHP) Concept to **273** Food Service Establishments.
- **162** out of the **273** informed facilities purchased the FHP application form.
- Education of Food Service Establishment operators on the need to acquire Food Hygiene Permit (FHP).
- A total of **135** facilities that applied for the FHP, were inspected and offered Technical Assistance.
- **103** facilities were issued with Food Hygiene Permit as against 53 in 2010.

3.3.2 STREET FOOD VENDORS

- Collaborated with MMDA's and inspected the vending and preparation sites of **118** street food vendors in the Accra Metropolis, Tema and Ashaiman Municipalities.
- This served as a pilot study for the street food vendors licensing programme.

3.3.3 TRAINING

- **364** food handlers from (**33**) facilities were trained in Food Safety and Hygiene.
- Trained 268 (90%) Caterers under the Ghana School Feeding Programme(GSFP) in the Greater Accra Region
- Training manuals sent electronically to all Regional Heads for the replication of this training in all regions

3.3.4 Developed a training Manual.

- Developed Educational Materials;

❖ Fliers (5000 copies)

- – 'Food Safety Cautions'
- - 'A Guide to Safer Food'

❖ Posters (5000 copies)

- -'Hygiene of Food Preparation and Sale Points'
- 'Bad Practice and Habits',

- -‘Washing/Cleaning of Utensils’
- ‘5 Keys to Safer Food’

3.3.5 DATA COLLECTION

- Forms for data collection of food poisoning outbreaks.
- Database on food poisoning outbreaks created.

3.3.6 OUTBREAKS &INTERVENTIONS

- Cholera-Accra
- Leaflet on cholera prevention was developed, printed and over 900 copies were distributed during the cholera outbreak (first quarter of the year) .
- Educational Campaign on cholera prevention was done at five(5) major lorry stations in five(5) languages(Twi, Hausa, Ga, Fante and English
- Food poisoning at Ledzokuku Krowo Municipal Assembly Southern Cluster of Schools.
- An eight member committee instituted to certify and monitor the activities of food vendors in the school.
- All the food vendors were educated on basic Food Hygiene.
- EHO and Monitoring team trained.
- ‘Food Vendors Monitoring Form (Basic Schools)’ developed for use in the schools.

3.4 Animal Products and Biosafety Department

The Department was created in August 2007 to ensure the safety of foods of animal origin (meat, poultry, fish, milk and honey), animal feed and to regulate genetically modified (GM) foods/feeds imported into Ghana. The Department comprises three units;

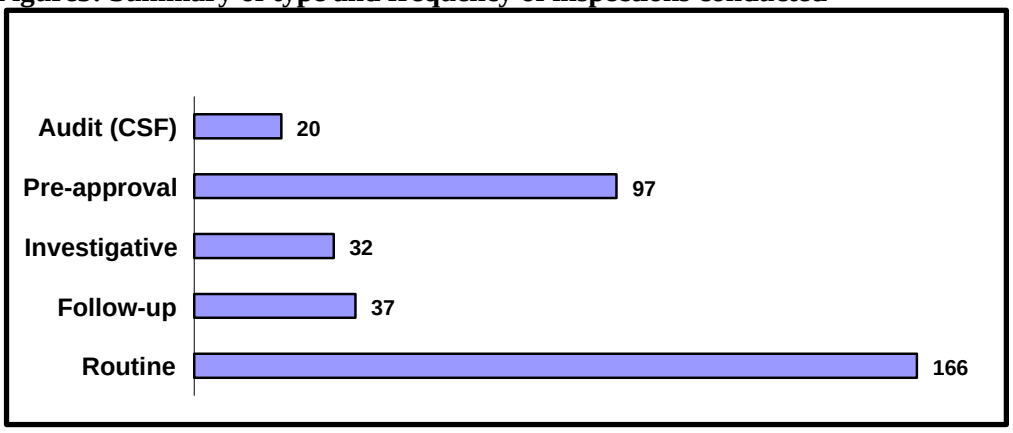
- Animal Products Unit (APU)
- Feed Safety Unit (FSU), and Biosafety Unit (BU)

The functions of the Department include:

- Inspection of cold storage facilities to ensure Good Cold Storage Practices (GCSPs).
- Inspection of Feed mills to ensure Good Manufacturing Practices (GMPs).
- Technical Evaluation of Genetically Modified (GM) Foods/Feed
- Inspection of feed establishments (feed/fish milling, facilities/drying platforms) to ensure Good Feed Handling and Manufacturing Practices (GFHMPs)
- Organisation of training workshops on GCSPs and GMPs for meat and feed industries.
- Consumer education on safety of products of animal origin.

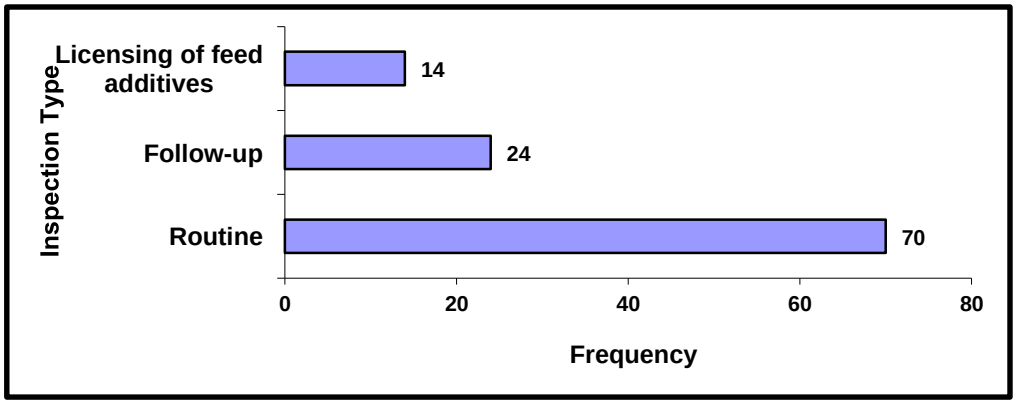
In 2011, the types of inspections the Department conducted are shown in figure 5 and figure 6, respectively.

Figure5: Summary of type and frequency of inspections conducted



Source: 2011 Inspections of Animal and Biosafety Activities.

Figure6: Summary of Feed Mills Premises Inspections conducted



Source: 2011 Inspections of Animal and Biosafety Activities.

The main non-conformances observed during these inspections included:

- Non- calibration of weighing scales
- Lack of pest control programmes
- Lack of proper documentation
- Poorly maintained ancillary facilities
- Lack/expired medical certificates

Steps were taken to help the companies to address all the non-compliances observed.

3.3.1 Biosafety Unit

Two members of staff of the Department attended the second GenØk sub-regional Biosafety course- Hazard Identification and Risk Assessment in Norway. Since their return a series of in-house presentations on the knowledge acquired at the program has been going on.

During the period of review, 15 training programmes were conducted for the Food Division with the aim of deepening awareness on Biosafety within the Division, which covered major topics in Genetically Modified Foods. In addition to the in-house training programmes, other staff members like National Service personnel and attachment staff also benefited from the topics the Unit treated.

3.3.1.1 Capacity Building

During the year under review,

- Three members of the Department attended a Stewardship Awareness Creation workshop organised by Africa Biosafety Network of Expertise (ABNE).
- Two officers received training on Biosafety Clearing house organized by Ministry of Environment Science and Technology.
- One Officer attended International food data conference organized by institute of food research, UK, FAO.
- Two officers had a Biosafety Internship Program with the South Africa regulatory authority.
- One member of the Department attended a one-month course in China on Feed Safety

4.0 Import and Export Control Department

The Import and Export Control Department (IECD) is mandated to regulate the importation and exportation of food, drugs, cosmetics, household chemical substances, and medical devices in accordance with the PNDC Law 305B. The activities of the Department are concentrated at the various entry routes to the Country.

The activities of the Department cover the Tema Port, Kotoka International Airport (KIA), and the head office, for the issuance of electronic permits through the GCNet System. The operational areas of the Department include various freight stations and carrier terminals at the KIA as well as container terminals, freight stations, sheds and wharf sites at the Tema Port. The details are listed below: **Head Office**

1. Electronic Permit System-Office

Tema

2. Main Port (Wharf Sites and Sheds)
3. Tema Container Terminal (TCT)
4. Maersk Container Terminal (MCT)
5. Africa Coastal Services (ACS) Terminal
6. Tema Bonded Terminal (TBT)
7. Golden Jubilee Terminal (GJT)
8. Container Freight Station (SDV, DHL,CONSHIP, Maersk)
9. SCAN Station

KIA Office

1. DHL warehouse
2. Courier Dome
3. Aviance warehouse

The Department also perform an oversight responsibility over the Takoradi Harbour and Elubo duty post under Takoradi Zonal office and Aflao duty post, under the Ho Regional Office.

The main functions of the Department are:

- Receiving and processing import permits electronically.
- Inspection of regulated products at the ports and duty posts
- Identification and streamlining of all permits and registration issues before regulated products are released to importers.
- Verification of international documents accompanying regulated products of imports and exports.
- Compilation of Data on regulated imports and exports at the various entry points.
- Gather intelligence on smugglers and investigate sources of fake regulated products.
- Education of stakeholders (importers and exporters) of regulated products on the FDB's requirements for importation and exportation of the regulated products.

4.1 Issuance of Permits

The Permit (GCNet) Unit of the Department received a total of 18,122 permit applications in 2011. The details are indicated below;

Table 9: Permit Applications received by the Permit (GCNet) Unit

PERMIT CATEGORY	NUMBER OF PERMITS	REMARKS
Applications	18,122	From Agents/importers
Provisionally approved	7,313	Products duly registered and valid
Rejected	2,337	Mostly unregistered products, others to be sent to different MDAs
Processed narcotics	133	

4.2 Inspections/Clearances

Inspections/clearances of imported food and drugs products carried out by the Department, at both the Tema Port and the KIA during the year is indicated in table 10.

Table 10: Clearances/Inspections via Electronic Permit System

Month	Clearances/Inspections Made						
	Food	**Drugs**	**Household chemical substances**	**Cosmetics**	**Medical Devices**	**Tobacco**	**Total**
January	393	166	26	42	46	2	**675**
February	513	181	37	33	59	3	**826**
March	465	178	35	42	51	2	**773**
April	487	222	43	25	32	3	**812**
May	356	141	28	36	38	3	**602**
June	487	151	54	30	57	1	**780**
July	370	200	40	24	30	2	**666**
August	350	140	25	30	35	2	**582**
September	400	160	50	33	55	3	**701**
October	390	210	50	36	34	3	**723**
November	440	170	30	40	38	4	**722**
December	520	196	60	41	60	3	**880**
TOTAL	**5,171**	**2,115**	**478**	**412**	**535**	**31**	**8,742**

Source: 2011 Import and Export Control Activities

4.3 KIA Unit Operations

A total of 3,002 inspections were conducted at the KIA for the period under review. Inspections of samples of products brought into the country via courier were also conducted within the period under review. The monthly breakdowns of the inspections conducted are shown in table 11.

Table 11: Clearances/Inspections carried out during the year at KIA

MONTH	NUMBER OF INSPECTIONS	INSPECTIONS AT COURIER
January	96	115
February	50	188
March	46	235
April	247	60
May	223	46
June	267	74
July	152	62
August	185	55
September	176	41
October	161	57
November	183	55
December	186	42
Total	**1,972**	**1,030**

Source: 2011 KIA Unit Operations

4.4 Cargo Tracking

The Pre-inspection Monitoring Unit of the Department were stalled for a period as a result of the malfunction of the GCNet system at the Tema Office.

4.5 Patrols at the Terminals

The Tema Office of the Department patrols the port daily to identify reefer vessels that have berthed at the wharf sites. Information gathered during the patrol is passed on to the team that inspects the reefer vessels. The various container terminals are also patrolled to identify specific containers for inspection.

4.6 Inspection of Reefer Containers and Vessels

During the period under review, a total of nine hundred and sixty one (961) reefer containers inspected. A total of one hundred and fifty-seven (157) reefer vessel inspections were carried out at the Tema port. The products were mainly frozen fish, chicken and fish meal. All consignments inspected were wholesome expect fish that was carried by M/V Sally Reefer part of which had gone bad due to leakage of water into one of the lower hatches. The receiver declined to receive it. It was thus re-exported. This took place in the first quarter.

4.7 Detention Unwholesome Food Destructions

During the 2011 operational year, the Department supervised destruction of several products including;

- 306 consignments/products were detained. 188 were food consignments/products whilst 124 were drugs, cosmetics, medical devices, household chemical substances.
- Most of the products were detained pending completion of registration/renewal of registration whilst others were detained pending correction of labelling.
- Others were detained for thorough inspection and sorting.
- All detentions were referred to the appropriate departments/regional offices.

The details are outlined in the table below:

Product Category	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**	**Total**
Food	62	45	22	59	188
Drugs, Cosmetics, Medical Devices, Household Chem. Subs.	48	32	16	28	124
Total	110	77	32	87	306

4.8 Unwholesome Food Destructions

During the 2011 operational year, the department supervised destruction of several products including;

- Twenty-eight (28) metric tonnes of frozen chicken backs imported by Nasachy Trading/Kuffour Kwame Limited which were found to be unwholesome at Tema port.
- Twenty-five (25) 20-footer containers of Pomo and Gino tomato paste imported by Primex Ghana Limited onboard a vessel that got burnt during voyage.

- Assorted local food products that were rejected when exported to Germany. The products included smoked fish, groundnut paste, groundnut oil, palm oil, ground pepper etc.
- Eighty-six (86) 50kg bags of rice found to be unwholesome at Customs bonded warehouse T258.
- One thousand five hundred and forty-five (1545) cartons of turkey tails, which were concealed behind some frozen chicken backs, consigned Monitak Enterprise/Kusi Atta Monic.
- The destruction exercises were carried out at the Kpone landfill site.

4.9 Coordination of Other Points of Entry/Exit

The Head of Department went on a three-day working visit to the Takoradi Zonal office and Elubo post to assess the level of importation/exportation made through those routes as well as the support that the Takoradi office will require to adequately control imports and exports. The Takoradi office has since had quite a significant increase in revenue generated from control of imports and exports. As a follow-up, the Department in conjunction with PRMIS Department will hold a training program for the Takoradi office in 2011.

5.0 Quality Control Laboratory Department

The Quality Control Laboratory provides laboratory services in the form of quality evaluation of Food, Drugs, Cosmetics and Chemical Substances. The Laboratory plays the role of determining the quality of these products, thereby enabling the FDB to take regulatory decisions. The laboratory performs chemical, physical and microbial analysis of chemical and herbal drugs. The quality parameters employed are as established in standard compendia indicated in schedule IV of the Food and Drugs Law (PNDCL 305B). The Department also supports both internal and external clients by providing reliable analytical and advisory services. The functions of the Quality Control laboratory are carried out by three main Units namely:

- Physicochemical Unit
- Microbiological Unit and
- Medical Devices Unit

5.1 Physicochemical Unit

The Physicochemical Unit undertakes quality investigation by considering physical and chemical properties of the products. The products the Unit handles are mainly food and food related products, drugs (allopathic, herbal and veterinary), cosmetics and household chemical substances.

The Unit accepts samples from Drug Registration Department, Food Safety and Nutrition Department, Inspectorate Departments, Post-Market Surveillance Units, Port Offices and Zonal Offices. The Unit also receives samples from external organisations for analysis, such as Criminal Investigation Department (CID) of the Ghana Police Service, Custom Excise and Preventive Service (CEPS), Central Medical Stores (CMS) of Ghana Health Services, and the Pharmacy Board of Sierra Leone.

5.2 Microbiology Unit

The Microbiological Unit undertakes microbiological testing of samples including food and food products, water, non-alcoholic beverages, drugs, cosmetics, and herbal preparations.

The analytical tests include the determination of aerobic plate count, yeast, mould count, and coliform count. The determination of faecal streptococcus, pseudomonas as well as the detection and enumeration of pathogenic and toxigenic microbes such as Salmonella, Staphylococcus aureus, Escherichia coli, Clostridium perfringens, and Bacillus cereus in food, water, drug and cosmetic samples are some of the functions the Unit perform.

5.3 Medical Devices Unit

The Medical Devices Unit of the Quality Control Laboratory started operation in June 2004 following successful installation of the following equipment from Valendor, Sweden:

- Four Station Air Inflation Tester
- Electric Hole Tester

- Water Leakage Tester
- Tensile Testing Machine and Cutting Press
- Water Vacuum Bowl and Vacuum Bowl for package seal
- Aging Oven
- Mandrel and Digital Gauge and others

5.4 Extent of Performance and Achievements in Product Testing

The Department received a total of two thousand, eight hundred and fifteen (2,815) samples for quality evaluation for the year under review. This represents a decrease of four hundred and four (404) in comparison with the number of samples received in the previous year 2010 (3,219). These were made up of allopathic drugs (35.8%), cosmetics (7.3%), household chemical substances (4.5%), food (22.0%), herbal drugs (18.7%), medical devices (11.2%) and veterinary drugs (0.4%). Table 12 gives the summary of product categories received for the various analytical tests.

Table 12: Summary of product categories received and analysed

Sample Category	Received	Analysed	Pending	Passed	Failed
Allopathic Drugs	1007	904	103	815	89
Herbal Drugs	525	487	38	272	215
Veterinary Drugs	12	12	-	9	3
Food	620	620	-	486	134
Cosmetics	207	196	11	188	8
Household Chemical Substance	127	120	7	115	5
Medical Devices	317	316	1	308	8
Total	**2,815**	**2,655**	**160**	**2,193**	**462**

Source: 2011 Laboratory Analysis

5.5 Projects Executed

In 2011, the third round of the United State Pharmacopeia quality Monitoring (USP/FDB PQM) Anti-Malaria project was completed. Four Hundred samples of antimalarial preparations were sampled from all the five (5) sentinel sites of the Food and Drugs Board for minilab screening. Eight (80) of these samples were sent to the Food and Drugs Board

laboratory in Accra for confirmatory testing. This includes all samples that failed minilab screening and ten per cent (10%) of passed samples. The Food and Drugs Board took the appropriate regulatory actions and sanctions against the Marketing Authorisation holders and various drug distribution outlets where products with quality defects were found.

5.6 Chemical, and other laboratory Consumables

The Department took delivery of its requisition for the year 2011 in the month of December.

5.7 Equipment

All the new equipment which was ordered for the Microbiology and Physicochemical Units was delivered in the month of December, 2011 and it will be installed and qualified in the first quarter of 2012.

5.8 Training/Workshop Activities

The Department continued with its In-house training programmes as part of its preparation towards ISO 17025 accreditation, Thirty One (31) Standard Operating
Procedures (SOP) covering the Laboratory Services Department scope of accreditation i.e.

PHASE 1

- HPLC (Assay and related Substances)
- UV (Identification and Assay)
- Dissolution of oral solid dosage forms
- Water determination by Karl Fisher
- Titrimetry (Aqueous and non-aqueous)
- PH
- Identification by FT-IR

PHASE 2

- GC (Assay and related Substances)
- AAS (metals-Asay and limit Tests)
- GS-MS
- Pharmaceutical Microbiology has been developed and staff trained in the use of these procedures. The following under listed training programme and workshops were attended.

- Training course on the determination of Pesticide Residues in Food products at the National Food institute, Copenhagen Denmark, 21st March-7th April 2011.
- Two staff members were attached to the World Health Organisation (WHO) prequalified laboratories in Kenya and Tanzania from the 20th June to 1st July 2011.
- Practical attachment in Bioequivalence studies at Accutest Laboratories, India, 18th-25th June 2011.
- Training workshops on the practical measurements of uncertainties in testing laboratories at FMHACA-Ethiopia, 18th-20th July, 2011.
- Attachment at the USP Laboratories for visiting scientists. July-October, 2011
- 3rd Regional Thematic Working group meeting in Conakry, Guinea which was organised by United National Industrial Development Organization (UNIDO) from the 17th-19th October, 2011. The objective of the meeting was to harmonize Microbiological and chemical methods for the West African Sub-region.
- Southern African Development Committee Meeting in Mauritius from the 14th18th November, 2011. The purpose of the meeting was for the discussion of the results of the Proficiency Trail Test for Microbiological Analysis of Drinking (potable) water in Africa in which the Microbiology Unit of Food and Drugs Board participated.
- Interregional seminar for quality control laboratories involved in the World Health Organisation (WHO) prequalification programme in Amman, Jordan 2124 November 2011. The Programme was part of the activities of WHO to support laboratories involved in its prequalification programme.

5.9 Recommendation

Two (2) analysts from the Physicochemical Unit (food) should be sent to Campden University's Food Research Centre in the United Kingdom for a two (2) week training programme in Mycotoxin analysis of Food products with special reference to Aflatoxins and Ochratoxins. This will enable the Laboratory Services Department to build enough capacity to conduct full mycotoxin analysis in 2012.

6. Zonal Operations

The FDB operates Regional and Zonal Offices as part of its decentralization programme. This is to fulfil its mandate of regulating food, drugs, cosmetics, household chemical substances and medical devices to ensure its quality, safety and efficacy. In 2011, the FDB operated 9 Regional Offices that are indicated below.

- Kumasi Regional Office, responsible for Ashanti region.
- Tamale Regional Office, responsible for Northern region.
- Sunyani Regional Office, responsible for Brong Ahafo region.
- Bolgatanga Regional Office, responsible for Upper East
- Wa Regional Office, responsible for Upper West regions.
- Takoradi Regional Office, responsible for Western Region
- Cape Coast Regional Office, responsible for Central Region.
- Koforidua Regional Office, responsible for Eastern Region.
- Ho Regional Office, responsible Volta regions.

Generally, the activities of the Regional Offices which are mainly operational cover the following areas:

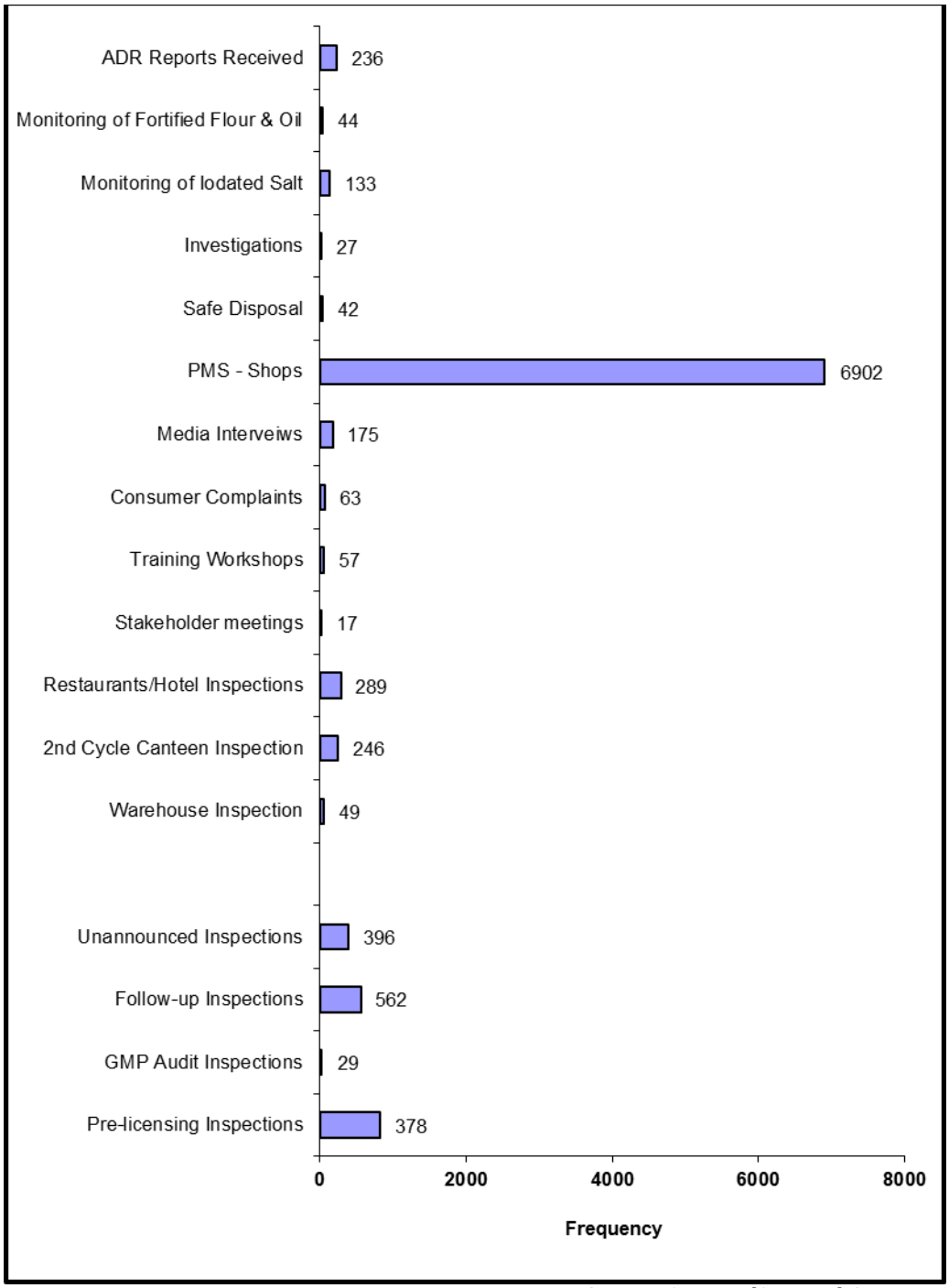
- Premises inspections.
- Carry out post-market surveillance exercise.
- Advert monitoring function
- Embark on consumer awareness and education programmes.
- Organise stakeholders meeting.
- Organise sensitization programmes, seminars, workshops, and training for all stakeholders in the food and drug industry.
- Investigate consumer complaint protocols to deal with consumer issues.
- Sale and assisting manufacturers, producers and importers in the registration of regulated products.

Most of the internally generated funds of the Regional Offices come from the activities of sale of registration forms, advertisement forms, advertising fees, destination inspection fees, destruction fees, and product registration fees.

6.1 Extent of Performance and Achievements of Regional Operations

Most of the activities during the year under review centred on pre-licensing inspection of small-scale food producers. The post-market surveillance function was to ensure that expired drugs and food products, unregistered drugs and food, as well as unwholesome food, which were sold to innocent consumers, were taken off from the shops. Meetings, seminars/workshops with stakeholders and media interviews and programmes were some of the prominent activities. Figure 12 shows the combined summary of activities performed by the Zonal/Regional Offices.

Figure 7: Extent of Performance of Zonal/Regional Operations.



Source: 2011 Zonal/Regional Operations

7. Administration

The Administration Department of the Food and Drugs Board supports the services of the various technical Departments of the FDB. The Department provides services in the areas of general management and administration (which includes administrative support to all Divisions and Departments), transport management, estates management and security, and procurement management.

7.1 Transport

Transportation plays a pivotal role in the running of any organisation. The Transport Unit was established in April 2009 and was headed by a Transport Officer.

The activities for the period are as follows:

- Implementation of transport management system.
- Improved the use of forms and logbooks by vehicles operators and users for better data collection.
- Assessment of vehicles performance using key performance indicators (KPI's).
- Record keeping and data collection has improved through the use of logbooks and other forms including computer software.
- Improved fuel consumption.
- Organization of training for Transport Management Unit staff.
- Improve the use of transport management tools such as the use of Vehicle log books, trip authority forms, planned preventive maintenance (PPM) etc.
- Routine Vehicle checks.
- Assessment of vehicle performance using the key performance indicators.
- Periodic TMU meetings.
- Insurance and renewal of Road-worthiness of all vehicles.
- Accident-free year due to improved supervision and training on road safety.

7.2. Estates

Within the year under review, a number of activities were conducted, especially in the maintenance of estates due to the increasing numbers of staff, both permanent and National Service persons.

There has not been any significant development with regard to the estates of the Food and Drugs Board. However,

- Major work was done on the construction and completion of our new head Office and laboratory building and is due to be completed by March, 2012
- Acquisition of land for the construction of the Tema Port Office
- Acquisition of land for the construction of permanent residence for the CEO.
- General repairs and maintenance of the estate has improved throughout all the offices of the Food and Drugs Board.
- Improved functioning of plant and equipment.

7.3 Procurement Unit

The Procurement Unit was established to ensure that internationally accepted standard procedures are followed in all the FDB procurement activities. This was done within the context of a national procurement code, Public Procurement Act 663 enacted in 2003. The main objective of the FDB procurement processes was to establish a system of procurement that is transparent, competitive, accountability and fairness.

The act sets out the legislative framework for public procurement in Ghana and defines official rules for the acquisition of Goods, Works and Services.

Activities carried out in the year 2011

- Fifteen (15) additional pick-ups were procured to boost operational activities
- Four (4) small capacity engine vehicles were procured for port operational activities
- Two (2) 30-Seater capacity buses were procured for the transportation of staff to and from work.
- Laboratory chemicals, reagents, microbiology media and glassware's were procured to ensure the smooth running of the quality control laboratory.

- Modern laboratory equipment were procured to boost the capacity of the quality control laboratory in accordance with ISO 17025 requirement.

9. Projects, Research and Management Information System (PRMIS) Department

The Projects, Research and Management Information System Unit (PRMIS) was set-up in November 2003 with limited scope to deal with the increasing Food and Drugs Board (FDB) functions and work programmes including its decentralisation programmes with a few human resources. The scope and the capabilities of PRMIS Unit have grown apart from core information technology functions to include monitoring and evaluation functions to effectively manage the growing information needs of the FDB, which necessitated the change in status from a Unit level to a Departmental level in April 2010. This is to ensure an effective management of information and its technologies to maximise improvements in the FDB mission performance.

The mandate of the Department is to provide service and support for all aspects of computerisation including: determination of information technology (IT) policies, information and information management systems, information system environment, and management of hardware and software; to monitor and evaluate programme of work and to generate quarterly performance and annual reports to Management and the Health Ministry; and finally to coordinate and collate project and research reports of the Food and Drugs Board.

In 2010, the PRMIS Department was able to execute about 90% of its programme of work to support regulation. The Department continued hosting the FDB website and deployed the corporate e-mail system across the FDB. The local area networks were enhanced to enable management of groups, network resources and users. The bandwidth of the internet access and connectivity was upgraded from 2mb/256k to 4mb/1mb to enhance fast information search and download. The internet access was also extended to KIA and Tema Offices, respectively, to support import and export control functions under the Ghana TradeNet system. This was to support information search for food and medicines regulation and permit control of the regulated products. A new Untangle software ver. 8.0 was

acquired and installed to enable internet connectivity for over 117 computers and to reduce the incidence of accessing and downloading inappropriate materials, blocking of social networking sites, etc., which reduce productivity. The Zimbra software for corporate e-mailing was upgraded from 32 bit to 64 bit to accommodate FDB corporate e-mail services to the Zonal/Regional Offices. The web portal was re-designed to accommodate new developments in regulation and to allow mobile internet access with the corporate e-mail.

During the year under review, the Department also developed two comprehensive software in-house to support pharmacovigillance activities and Stores Unit, respectively. The FDB acquired new computer hardware systems for distribution to enhance the regulatory functions. The computer hardware systems are as follows: desktop computers – 58, laptops – 4, servers – 1, palm tops – 8, scanners – 23, printers – 10 (ordinary) and – 27 (network).

The year saw the development and installation of knowledge base management system to enable staff to have ready access to FDB's documented base of facts, regulatory information, and operational processes electronically.

9. Support Units under the Chief Executive Office

The Communication Unit, which report directly to the Chief Executive (CE) of the FDB, also perform duties that significantly support the functional activities of the FDB.

9.1 Communications and Public Education Unit

The Unit serves as an interface between the FDB and its stakeholders, which includes the media, the business community, industry and consumers. The Unit arranges for foreign travels, various media programmes particularly with respect to consumer education, and media coverage of the FDB's activities. The Unit also ensures the publication of health alerts and press releases for the information of the public and the international community at large. Assisting in the organisation of swoops with the police and the media is another function of the Unit.

During the year under review, the activities performed under the Communication Unit are as shown in table 15.

Table 14: Activities conducted by the Communication Unit

Area of Activity	**Frequency**	**%**
Media Coverage	30	7.0
Media Interviews	135	31.6
Press Releases, Disclaimers, Notices	40	9.4
Visas Acquired (India, USA, Canada, South Africa, China, Netherlands, Germany, Morocco, Brazil, Norway	84	19.8
Tickets Purchased (India, USA, Canada, Switzerland, Lagos, Italy, Hungary, Singapore, Kenya, Norway)	114	26.7
Travel Insurance	24	5.6
Total	**427**	**100**

Source: 2011 Communication Activities

9.1.0 Collaborative Functions with other Departments.

The Unit played a major role in the successful implementation of the following programmes:

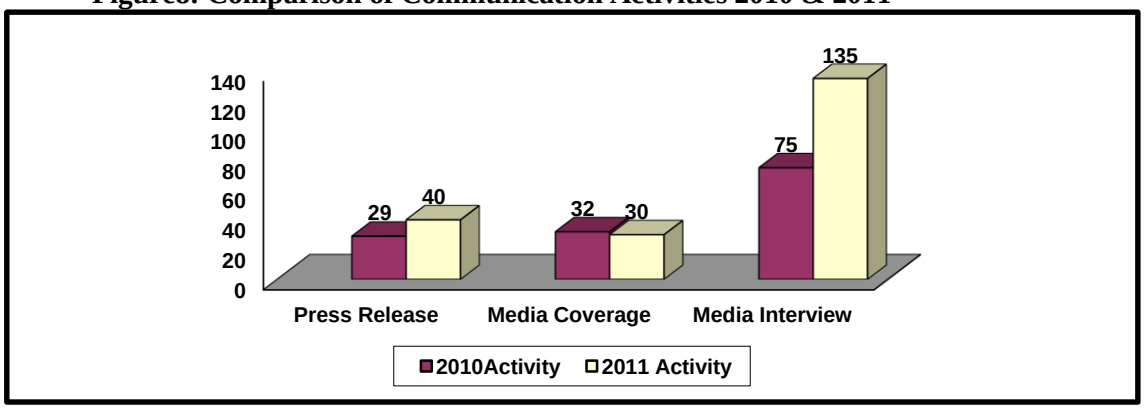
- Stakeholders Validation Workshop to discuss the Situational Analysis Report for Food Safety in the country.
- The World Food Day organized under the theme '**Safe and Adequate Food, Our Quality Responsibility'.**
- Police swoop on producers of wele at the Mallam market production site under unhygienic conditions**.**
- Police raid on unregistered Yafo Yafo and Kingdom Herbal products**.**
- Police swoop at Makola market to arrest sellers of fake rice branded products.
- Training for Sachet water producers.
- Destruction of seized expired, unregistered and unwholesome products.

- Food sensitization Programme for travelers within the country. Inspection of Street Food Vendors within the Accra Metropolis
- Destruction of seized turkey tail.

9.1.1 Some of the major press releases that were issued also include the following;

- Health Alert on Se Menhyia Herbal Products.
- Sale of expired Corned Beef.
- Unregistered products sold by Medimoses Prostate Centre.
- The arrest of 30 unwholesome drug peddlers

Figure8: Comparison of Communication Activities 2010 & 2011



Source: 2010&2011 communication data

9.1.2 Human Resource Unit

During the year under review, the FDB got financial clearance from the Ministry of Finance and Economic Planning to recruit personnel to fill existing vacancies. Fifty (50) Regulatory Officers, five (5) Administrative Officers, eight (8) Administrative Assistants, two (2) Secretaries and ten (10) Drivers totalling 75. Comprising of thirty (30) scientific officers and six (6) administrative Officers. Four (4) resignations with one (1) retiree were recorded.

Table 13: Summary of permanent staff

Employee Categories	Total Staff Strength
Permanent	385

Temporary	37
National Service Personnel	45
Seconded Staff	11
Total	**478**

Source: 2011 Human Resource Data

Activities carried out in the year 2011

- In 2011, 102 staff were promoted.
- Salary anomalies have been normalized. The remaining newly recruitment and promotion arrears will be fully paid by controller and Accountant General's department by the end of February 2012.
- There was a 20% increase in the salary by the government across board, effective 1 January 2011. Government would advise the schedule of payment.
- FDB is in the negotiating process for the market premium to be migrated unto the single spine.
- The grade structure has being completed.

Future Direction

The Food and Drugs Board will continue to confront the challenges presented by the implementation of the Food and Drugs law, 1992 (PNDCL 305B) and its Amendment Act, 1996 (Act 523). In particular, steps will be taken to reinforce the corporate identity of the FDB and reposition management for increased commitment to the mandate of the FDB.
In this regard, the FDB's operational direction for 2012 will focus on the following:

- Completion, furnishing and occupation of Head office complex building.
- Procurement of ten (10) operational vehicles and ten (10) saloon cars to augment the fleet.
- Complete preparations towards single spine migration
- Appointment of legal Officer for FDB
- Complete the review of condition of Service for Staff

- Acquisition of a permanent office accommodation for the Kumasi Regional Office.
- Construction of the Tema Port Office
- Construction of a permanent residence for the CEO.
- Procurement of computers and IT accessories both hard and software
- Procurement of Laboratory chemicals, glassware, microbiology media and equipment
- Recruitment of artisans (electricians and plumbers) to assuage frequent breakdown of facilities.
- The review of the Tobacco Bill will be completed.
- The FDB's condition of service is in its final draft stage.
- The design of Human Resource policy manual is on-going with 40th completion.
- Staff will receive adequate training and development.
- The review of the Food and Drugs law 1996 (PNDCL 305B) to make it more effective and relevant to the needs of the country and its obligations to the international community will be completed.
- Strengthen consumer awareness programmes to ensure public health and safety and consumer confidence.
- Accreditation as per ISO 17025 requirements.

ANNEX A.1

FOOD AND DRUGS BOARD MANAGEMENT TEAM AND ZONAL OFFICES

Strategic Management Team

Chief Executive	Dr Stephen Kwabena Opuni
Head of Drug Division	Mrs Akua Amartey (Acting)
Head of Food Division	Mr J. Odame Darkwah **(**Acting)
Head of Administration	Mr Jones Ofosu **Head of Finance**
	Mr Kwasi Agyei **Head of Quality Control Laboratory**
Mr Karikari Boateng	
Head of PRMIS	Mr Andrews Boadi

Office Addresses

Head Office:

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P O Box CT 2783
Cantonments - Accra, Ghana
Telephone: +233-0302-235100/233200/225502
Fax: +233-0302-229794
URL: http://www.fdbghana.gov.gh
E-mail: fdb@fdbghana.gov.gh

Other Locations

Quality Control Laboratory
Tel: +233-0302-673864

Fax: +233-0302-667095

Port Offices

Airport: Tel: 0302-784653

Elubo: Tel: 03122-22538

Tema: Tel: 0303-213418 **Regional/Zonal**

Offices:

Kumasi
Address: The Regional Officer
Food and Drugs Board
P O Box ST 402, Kumasi.

Location: SIC Building 2nd Floor, Bompata, Kumasi
Tel/Fax: 03220-36070

Takoradi
Address: The Zonal Officer
Food and Drugs Board
P O Box MC 2129, Takoradi.
Location: SSNIT Regional Offices, (near central Police Station)
Tel/fax: 0303-27558

Bolgatanga
Address: The Zonal Officer
Food and Drugs Board
P O Box 612, Bolgatanga.
Location: Regional Administration Building
Tel: 03820-23727
Fax: 03820-24590

Ho
Address: The Zonal Officer
Food and Drugs Board
PMB, Ho
Location: Ghana News Agency Building
Tel: 03620-65529
Fax: 091-28411

Tamale
Address: The Regional Officer
Food and Drugs Board
Tamale
Location: Regional Administration Building
Tel: 03720-24935 Telefax: 032720-24889

Sunyani
Address: The Regional Officer
Food and Drugs Board, Sunyani
Location: Sam Bennet Building, Market Square
Tel: 03520-28791