

2022

# NAFDAC ANNUAL REPORT



## Chapter 1

### Historical Background

#### 1.0 Introduction

NAFDAC was established as a parastatal of the Federal Ministry of Health to give a frontal attack to health problems arising from food, drugs, chemicals and other similar regulated products without the inhibition of the civil service setting.

Until 31<sup>st</sup> December, 1992 the responsibility of preventing the hazards arising from unwholesome foods, ineffective, substandard and adulterated drugs, toxic and corrosive cosmetics and chemicals as well as contaminated packaged water was vested on Department of Food and Drugs Administration and Control (FDAC) of the Federal Ministry of Health. However, with the rising incidences of counterfeit and substandard drugs, unwholesome food, etc, as well as the need to overcome bureaucratic bottlenecks of the Ministry, NAFDAC was created to promptly and decisively attend to these challenges.

The National Agency for Food and Drug Administration and Control (NAFDAC), established by Decree No. 15 of 1993 as amended and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004.

The Act mandates the Agency to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Bottled Water, Chemicals and Detergents (known as regulated products).

#### **Vision:**

To be a World Class Regulator that ensures availability of quality and safe Food, Drugs and other regulated products.

#### **Mission**

To protect and promote the public health by instituting an effective and efficient regulatory system that ensures only the right quality Food, Drugs and other regulated products are manufactured, exported, imported, advertised, distributed, sold and used.

#### **Core Values:**

The PRIDE core values of the Agency are:

1. Professionalism
2. Resilience
3. Integrity (Transparency & Good Governance)
4. Dedication & Commitment
5. Excellence

#### **1.1 Brief History of NAFDAC and Organizational Structure**

NAFDAC pioneer Governing Council was inaugurated on 31<sup>st</sup> December, 1992 with Prof. G.E. Osuide as the Director-General. In April 2001, Prof. (Mrs.) D.N. Akunyili (OFR) was appointed the Director-General to replace The Interim Management Committee (IMC). She left the services of NAFDAC in December 2008 following her appointment as a Federal Minister and was replaced by Pharm. (Mrs.) D.I. Amlai as the Acting Director-General until the appointment of Dr. P.B. Orhii (Ph.D, FAS, OON) on the 9<sup>th</sup> of January,

2009. Following the removal of CEOs of Government Agencies by President Muhammadu Buhari (GCFR), Mrs. Yetunde O. Oni assumed office as Acting Director-General in February 2016 until her retirement in September 2017. Mr. A.A. Mogbojuri (FCA) assumed the helm of affairs of the Agency until the appointment of a substantive Director-General, Prof. Mojisola Christianah Adeyeye (Ph.D, FAS) on 3<sup>rd</sup> November 2017.

**The Top Management;** The Top Management Staff of NAFDAC comprises:

Director General - Prof. Mojisola Christianah Adeyeye, PhD, FAS

- Director, Drug Registration and Regulatory Affairs – Dr. Monica Eimunjeze
- Director, Ports Inspection Directorate – Prof. Samson B. Adebayo
- Director, Public Affairs (Office of the Director General) – Dr. Abubakar Jimoh
- Director, North East Zone – Dr. Bukar Usman
- Director, Investigation and Enforcement – Barr. Kingsley Ejiofor
- Director, Drug Evaluation and Research – Pharm. (Mrs.) Ijeoma Nwankwo
- Director, Narcotics and Controlled Substances – Pharm. Edosa Ogbeide
- Director Laboratory Services (Food) – Dr. Charles Nwachukwu
- Director Laboratory Services (Drugs) – Mr. Victor Abiola
- Director, Food Registration and Regulatory Affairs - Mrs. Abayomi Bolaji
- Director, Pharmacovigilance/Post Marketing Surveillance – Pharm. Rametu O. Momodu
- Director Human Resource Management – Mr. Joseph.A. Aina
- Director Agulu Laboratory Services – Pharm. Yedunni Adenuga
- Director North West Zone – Pharm. Dauda Gimba
- Director, Finance and Accounts – Mr. Ayanbenga O. Ayanwande
- Director, Planning, Research and Statistics – Dr. Abimbola Adegboye
- Director South West Zone –Mrs. Roseline Ajayi
- Director Food Safety and Applied Nutrition – Mrs. Eva Edwards
- Director National Vaccine Control Laboratory, Mrs. O.O. Adekunle-Segun
- Director Federal Capital Territory – Mr. Abdulsalam Ozigis
- Director, Lagos State Office – Mr. A.O. Babarinde
- Director South South Zone – Pharm Francis Ononiwu
- Director North Central Zone – Pharm. Shaba Muhammad
- Director Veterinary Medicine and Allied Product – Pharm. Uche Sonny-Afoekelu
- Director, Chemical Evaluation and Research – Dr. Patrick Omakpariola
- Director, Kaduna Laboratory Services, Mr. Sokomi A. Sariel
- Deputy Director i/c, Legal Services - Barr. Mohammad H. Bello
- Deputy Director i/c South East Zone – Mr. Collins Ogedegbe
- Service Units in the Office of Director General:
  - Special Assistant to DG NAFDAC (Abuja) – Mr. Nantim M. Dadi
  - Special Assistant to DG NAFDAC (Lagos) – Dr. Gbenga Fajemirokun

## **1.2 Functions of NAFDAC**

The functions of NAFDAC as provided in the enabling law that establishes it are to:

- Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water, Chemicals and detergents (Regulated Products);

- Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products) and their raw materials as well as their production processes in factories and other establishments;
- Undertake appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products) and establish relevant quality assurance systems, including certification of the production sites and of the regulated products;
- Undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products) and establish relevant quality assurance systems, including certification of the production sites and of the regulated products
- Compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products);
- Undertake the registration of foods, drugs, cosmetics, medical devices bottled water, Chemicals and detergents;
- Control the exportation and issue quality certification of food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export;
- Establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions;
- Pronounce on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis;
- Undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes;
- Grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances;
- Collaborate with National Drug Law Enforcement Agency (NDLEA) in measures to eradicate drug abuse in Nigeria;
- Advise Federal, State and Local Governments, the private sector and other interested bodies regarding the quality, safety and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products);
- Undertake and coordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals
- Issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals
- Compile and publish relevant data resulting from the performance of the functions of the Agency or from other sources;
- Sponsor such national and International conferences as it may consider appropriate;
- Liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency;
- Determining the suitability or otherwise of medicines, drugs, food products, cosmetics, medical devices or chemicals for human and animal use;
- Carry out such activities as are necessary or expedient for the performance of its functions.

### 1.3. NAFDAC Offices and Location

The Agency operates from various offices across the country. These offices consist of:

- **Corporate Headquarters** located at Plot 2032, Olusegun Obasanjo Way, Wuse Zone7, Abuja. In addition to the Director General's office, the head office houses the following Directorates: Pharmacovigilance/Post Marketing Surveillance, Planning, Research & Statistics, Admin & Human Resources Management, Finance & Accounts, the office of Public Affairs and FCT Office.
- **Lagos Operational Office** located at Block D, Plot 2, Isolo Industrial Estate, Oshodi-Apapa Express Way, Lagos
- **Six Zonal Offices** located as follows;
  - North East - NAFDAC Laboratory Complex Biu Road, Maiduguri.
  - North West - Federal Secretariat, Zaria Road, Kaduna.
  - North Central - Federal Secretariat, 6<sup>th</sup> Floor, Room 614, Jos.
  - South East - Federal Secretariat, Independence Layout Enugu.
  - South West - Federal Secretariat, Jericho Ibadan.
  - South South – Federal Secretariat, PH, River State.
- **Thirty-Seven (37) State Offices** located in all States of the Federation and FCT Office.
- **Six Laboratories** at Oshodi - Lagos, Yaba - Lagos, Kaduna, Maiduguri, Port Harcourt, and Agulu - Anambra State. The Work in the Calabar Laboratory has reached an advanced stage.
- **Ports and Land Border offices**, located at Lagos (Tincan, Lilypond and Apapa), Port Harcourt, Warri, Calabar, Seaports, Airports (Murtala Mohammed Lagos, Nnamdi Azikiwe Abuja and Aminu Kano) and Land border posts (Seme, Idiroko, Mfum, Jibiya, Kamba, Illela and Maigatari)
- One Stop Investment Center (OSIC) - NIPC Building Maitama, Abuja.

## **Chapter 2**

### **Strengthening of the Regulatory Framework of NAFDAC**

#### **2.1 WHO Benchmarking**

In November 2017, the management was driven with the passion to Strengthening Nigeria Regulatory System using the WHO Global Benchmarking Tool (GBT) approach.

The Agency conducted its first self-benchmarking evaluation using the WHO-GBT in February 2018. The outcome of the findings placed the Agency on maturity level One (ML1), symbolizing a weak regulatory system with no formal approach embedded on regulatory processes, legal provisions, weak Organization Structure, strategic planning and lack accountability, transparency and communication.

The Management set a 3 year realistic targets to achieve WHO-GBT ML3 rating from 2018 to 2021 and engaged staff of the Agency to strengthen all area of weakness, defined priorities in the regulatory system and ensure corrective actions at all levels.

The Re-benchmarking assessment of the NRA for the National Agency for Food and Drug Administration and Control (NAFDAC) and Pharmacist Council of Nigeria (PCN) took place from 21st – 25th February 2022.

On the 30th of March 2022 upon the critical evaluation of the eight Hundred and Sixty-Eight (868) evidence to review for system strengthening, WHO officially ranked Nigeria's National Regulatory Agencies as Maturity level 3, meaning a Stable, well-functioning and integrated regulatory system and eligible for inclusion into the transitional WHO Listed Authorities (WLA) after additional evaluation of their performance to be globally recognized as meeting WHO and other international standards.

The Agency is now working assiduously towards the Attainment of WHO ML4 and World Listed Authority (WLA) Status. Attainment will enable:

- o Global trade of Nigerian-made pharmaceuticals through collaborative registration with other regulatory agencies
- o Local Pharma manufacturers to be more competitive in AFCTA

#### **2.2 International Organization for Standardization (ISO) 9001:2015: Certification/0 Quality Management System (QMS) Activities**

Having entrenched Quality Management System (QMS) in its operations, Agency received ISO 9001:2015 certification in June 2019.

##### **2.2.1 QMS Gap Assessment for the Zones, LSO and FCT.**

In line with the 2022 Annual QMS Plan approved by the Director general the gap assessment of QMS in the states and zones was conducted by the QMS Steering Committee on the 20<sup>th</sup> -22<sup>nd</sup> of June and 27<sup>th</sup> - 29<sup>th</sup> June ,2022 respectively.

The objectives of this intervention are as follows;

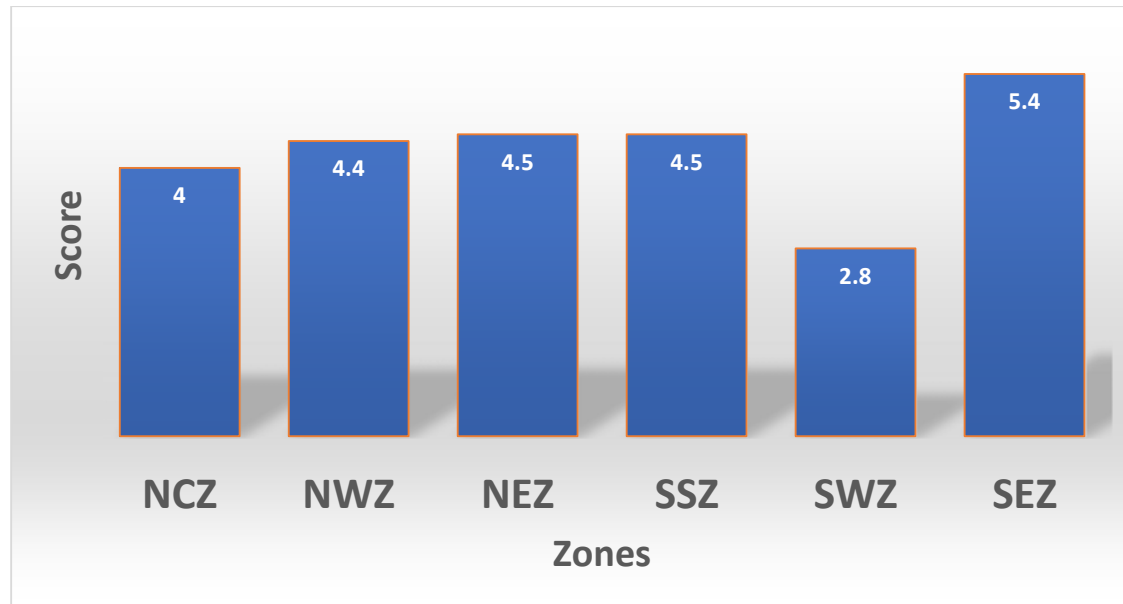
- a. To harmonize implementation of QMS in all NAFDAC formations to facilitate service delivery.
- b. To harmonize operational processes and procedures to ensure reproducible and reliable outcomes
- c. To verify commitment and compliance to QMS at the state and zonal levels.
- d. To verify compliance to cascading of previous QMS trainings of 2018 and 2021 and implementation of requirements.
- e. To mentor and provide support for the QMS teams in the state and zonal offices.

## 2.2.2 Summary findings

The gap assessment tool (Checklist) was developed using the ISO 9001:2015 Standard requirement and NAFDAC procedural requirements as reference guide. The grading matrix was 10 points for 23 questions where each question is 2.3 points

The assessment results revealed that there is QMS presence in the thirty-six (36) states and six (6) zonal offices, however the level of implementation and commitment varied across states and zones.

**Figure 1: Average Score for Zones**



From the objective evidence gathered during the audit and interviews conducted the performance was attributed to the commitment and dedication of the state coordinators and QMS responsible persons in the implementation of Quality management system in their states.

**2.2.3 Training of Members of the Risk Management Team of the Different Directorates on ISO 31000 standard:** Members of the NAFDAC Risk Management Team drawn from the different directorates were trained by DU&T Consulting Ltd, Lagos from 23 – 27 May 2022. The participants met the certification requirement and were awarded Certificates by Cognicert Limited as ISO 31000 Risk Manager.

## 2.2.4 Audits:

- **Conduct of Internal Audit of All Directorates In Abuja and Lagos Formations-** In line with the 2022 QMS work plan, the Members of the Steering Committee audited the QMS processes and operations of the Directorates in Abuja and Lagos respectively to ascertain their conformance to the ISO 9001:2015 Requirements and the integration of the QMS concepts to the processes for effective and efficient service delivery.
- **Conduct of Follow-Up Audit to the April Internal Audit-** A Follow-up audit was conducted from July 26 -30, 2022 to ascertain the adequacy and/or effectiveness of the corrections or corrective actions carried out to address the nonconformance observed during the internal audit.
- **QMS External (Surveillance) Audit-** The QMS Unit of the QMO in conjunction with the External QMS Auditor from AFNOR conducted a recertification audit on NAFDAC Formations in Abuja and Lagos to determine the extent of compliance to the ISO 9001:2015 Standard and to the sustenance of the acquired QMS Certification.

## 2.2.5 Meetings:

- **Meeting to Discuss Report of the April 2021 State/Zonal QMS Training** On the instance of the DG-NAFDAC, the NAFDAC-QM convened a meeting to discuss the recommendations of the April 2022 Zonal QMS Training and the Next Steps towards institutionalizing QMS in these other NAFDAC Formations.
- **2022 Management Review Meeting (MRM)** The MRM held on 7<sup>th</sup> October, 2022 was held via virtual (zoom) platform to harmonizes the findings of the internal audit that needs top management's attention.
- **Steering Committee Meeting to Discuss Key Issues Pertaining to NAFDAC QMS** such as Post MRM activities, internal audit and follow-up report, annual evaluation of Service Providers, customer satisfaction survey, distribution of QMS SOPs to zones/states and QMS budget.

## 2.2.6 QMS Procedures

- **Review of Obsolete QMS Global Procedures:-** During the period under review a total of eleven (11) QMS obsolete Procedures that was due for review were updated by Members of the Steering Committee in conjunction with the relevant Originating Directorates as may be applicable.
- **Development of New Procedures:-** In 2022, three new global SOPs were developed were prepared by relevant directorate/office in conjunction with the QMS Steering Committee Members.
- **Awareness training on the reviewed/newly developed QMS SOPs:-** The members of the Quality team members across the Agency were trained on all the newly developed/reviewed Management SOPs to enable them to deploy these procedures effectively.
- **Distribution of Reviewed/newly developed QMS Global Procedures to the Directorates:-** Following, the directive of the NAFDAC-QM, the Agency-wide Documentation Officer prepared the controlled copies of the reviewed QMS Global SOPs and distributed to all the Directorates in Abuja and Lagos including the Office of the Director General and its Liaison Office in Lagos.

## 2.3 Information and Communication Technology (ICT) Division

The Information Communication Technology (ICT) is a Division under the Director General's Office. The organisational structure of the Division is decentralized with staff in different NAFDAC facilities all over the Agency Formations and headed by Deputy Director (ICT) in NAFDAC Headquarter.

There are three distinctive management level/Subunits in the Division, saddled with the responsibility of providing IT technology support and solutions to all Directorates, Divisions and Units to ensure that all their functions, processes and activities receive required enablement and align with the overall Agency's strategic objectives.

The following are the summary of activities/achievements of ICT Division in the year 2022.

### 2.3.1 IT Infrastructure

#### *Major accomplishments*

- About 405 systems (205 Laptops and 200 desktops with UPS) were procured and distributed to:
  - Directorates
  - Zonal Offices and Laboratories
  - QMS
  - Dossier Review Team
  - Senior officers

- IT Staff

- Preventive maintenance was carried out on 80% of the IT infrastructure in the Agency.
- About 67 faulty systems including desktops, laptops, printers, and UPS making up 90% of the reported faulty systems were fixed.
- Routine quarterly maintenance was carried out successfully on the network infrastructure within this period.
- 1000 license antivirus was deployed via the Enterprise server successfully (License renewed)
- Microsoft Office 365 Enterprise edition – ( 500 License renewed)
- Upgraded 146 computers to a minimum of 4GB RAM and upgraded the Operating System (OS) from Windows 7 to Windows 10 for better efficiency.
- Internet services (LAN and Wireless) provided at Headquarter-Abuja, Corporate Office-Isolo-Lagos, PID- Yaba, Laboratory Service (Drug)-Yaba, Laboratory Service (Food)-Oshodi, Kaduna Laboratory Service – Kaduna, Investigation and Enforcement-Apapa.
- Supported the hosting of over 300 Virtual Meetings using (Zoom and Microsoft Team), thereby saving cost on traveling and other associated risks.

### **2.3.2 Website and Information Security Services:**

#### ***Major Accomplishments***

The website was greatly improved during the reporting year. The site was upgraded with the creation of more sections to enhance the the look and feel. We reviewed the website In-house, and provided some changes. Below is the summary of changes on the website:

- Provision of Web Page Search functionality for key WHO Global Benchmarking Tool (GBT) and Quality Management System (QMS) requirements on the website:
  - Guidelines Search/filter Table
  - Regulations Search/filter table,
  - Clinical Trial Search/filter table
  - 1114 Summary of Product Characteristics (SMPC) Search/filter table.
  - Recall and Alert Search/filter table.
- Analysis of Website usage feedback.
  - 69% cumulatively found website content useful within the year-2022
- Ensure website contents' confidentiality, availability, and integrity through routine updates, backups, and vulnerability analysis.
  - Backup of the website was conducted twice a month translating to twenty-four (24) backups from January – December.
  - A plugin for malware threat vulnerability detection was implemented.
  - 37 website plugins have been updated.
- A total of Hundred & Ten (110) contents were uploaded within the period under review.
- A total of Thirty-Five (35) contents were reviewed and updated within the period under review.

### **2.3.3 Supported IT Systems and Application**

#### ***Major Accomplishments***

- The Sage x3 ERP accounting solution used by the Finance &Account Directorate (F&A) was maintained and supported by ICT Division 100%.

- Accounting software (SAP) ERP has been deployed and 80% completed, F&A staff have been trained on the use and migration is in progress.
- E-permit system support for CER, FSAN, VMAP, R&R, NCS, and PID.
- NAPAMS support services for R&R (Drug) , R&R (Food) , DER, FSAN
- Laboratory Information Management System (LIMS) – Maintained and supported services renewed for Yaba and Isolo laboratories.
- Provided support needed for over 300 video conferences via Zoom and 400 via Microsoft Teams.
- **Agency-Wide Systems:**
  - Email services provided by Galaxy Backbone Plc – 2100 email accounts existing were maintained and managed by the Division and additional 200 new staff accounts were created.
  - 500 licenses of Microsoft 365 renewed and re-activated within the year under review.
  - AHReMs solution was supported by the Division.

### **2.3.4 Project Management**

#### ***Major accomplishments***

**New projects were initiated and some completed.**

- NAFDAC GreenBook - Registered Drug Database
- Dossier Management System (DMS) for R&R (Drug) Directorate.
- eClinical Trials (eCTAP) for Clinical Trials application and monitoring
- Laboratory Information Management System for the laboratories in Oshodi and Yaba.
- ISO 27001 (Information Security Management System – ISMS) and ISO 22301 (Business Continuity Management System – BCMS) certification and accreditation project.
- Service Desk Manage engine for Asset Management

The Division is repositioning itself to achieve more in the year 2023 based on the approved budget and workplan for 2023

## Chapter 3

### 3.0 Offices in Director – General’s office

#### 3.1 Activities of Public Affairs

Public Affairs is one of the offices created by Director-General, Prof. Mojisola Christianah Adeyeye following the restructuring of the Agency under her leadership. It was carved out of former Special Duties Office which later became Special Services, and now Public Affairs.

It is domiciled in the Office of the Director General and headed by a Director with the primary responsibility of projecting the corporate image of NAFDAC, promoting its activities and programs, and serve as an interface with the public. The office has two main units, namely Public Relations and Protocol.

#### *Activities in Brief*

Publicity of NAFDAC activities: This include enforcement, destruction exercises, prosecutions/convictions, workshops, advocacy meetings/visits and town hall/stakeholder’s forum. Some of the activities covered and publicized by the office within the period under review are highlighted below.

##### **1. Meetings, Conference & Training**

- Press Conference on Announcement of NAFDAC’s Attainment of Maturity Level 3 by DG (NAFDAC) at Transcorp Hilton – Abuja on 30<sup>th</sup> March, 2022.
- Commissioning of NAFDAC operational vehicles by Prof. Christianah Adeyeye and assisted by Governing Council Members on 31<sup>st</sup> March, 2022.
- Donation of 74 Android enabled scanners and 3 Barcode Printers to NAFDAC by WHO on 23<sup>rd</sup> March, 2022.
- Review of DG (NAFDAC)’s 4 years scorecard in 2022.
- Handing-over of the seized unregistered Instant Milky (Non-Diary) product by the Nigerian Customs Service to NAFDAC in Karu, Abuja on 28<sup>th</sup> April, 2022.
- Signing of NAFDAC – NYSC MoU for creation NAFDAC Desks in 774 LGAs on 13<sup>th</sup> May, 2022.
- Press conference on Herbal intoxicant in Abuja on 19<sup>th</sup> August, 2022.
- Food Fortification survey training in Abuja on 14 – 16<sup>th</sup> September, 2022.
- Collaboration meeting with NAFDAC and Medicine for Material Venture (MMV) on the 9<sup>th</sup> September, 2022 Lagos
- National Stakeholders Meeting on Reduction of Industrial Trans-fat Acids from Nigerian Food supply on 8<sup>th</sup> September, 2022 Lagos
- Visit of United International Health to the DG NAFDAC to collaborate and assist manufacturers in Nigeria 8<sup>th</sup> September, 2022 Lagos.
- Coverage of FSAN Technical Regulations Meeting on marketing of food and non-alcoholic beverage to children in Lagos.

- Coverage of the Commissioning of NAFDAC's state offices in Kwara and Osun state
- Coverage of the road show in commemoration of World Anti-Microbial Awareness Week (WAAW) 2022 in Lagos.
- Coverage of Ag. DG's meeting with staff on 23<sup>rd</sup> November, 2022.
- Coverage of the Ag. DG at the 3<sup>rd</sup> Breakfast Meeting organized by the African Resource Centre for Excellence in Supply Chain Management in collaboration with the Federal and state Ministry of Health CEO's of Pharmaceutical Companies in Lagos on the 2<sup>nd</sup> December, 2022.
- Coverage of the Meeting of the Ag. DG with the Association of Food, Beverages and Tobacco Employers (AFBTE) at Isolo, Lagos on the 1<sup>st</sup> December, 2022
- Coverage of the Ag. DG at the 2022 National Conference on MSMEs organized in Lagos on the 20<sup>th</sup> December, 2022
- Coverage of meeting with USP on the 20<sup>th</sup> December, 2022.
- Coverage of the Ag. DG at the 12<sup>th</sup> Annual Symposium and Award Ceremony of the Health Writers Association of Nigeria in Lagos on the 20<sup>th</sup> December, 2022.
- Coverage of the sting operation on warehouses of different brands of unregistered and substandard tomato pastes, food seasoning and sardines led by the Ag. DG in Lagos
- Coverage of the unveiling of the first Radio Pharmaceutical PET Tracer Manufacturing Facility in West Africa by the Ag. DG in Lagos on the 12<sup>th</sup> December, 2022
- Coverage of Ag. DG visit to Yaba Lab NAHCO in Lagos on the 19<sup>th</sup> December, 2022
- Coverage of the Ag. DG at an interactive Forum by the Manufacturers Association of Nigeria (MAN) in Ikeja, Lagos

## **2. Destruction, Raids & Enforcement Activities**

The office covered Destruction, Raids & Enforcement Activities conducted by the Agency during the period under review.

## **3. Coverage of Advocacy Visit, Workshop/ Sensitization And Interview**

- Director-General's visit to Arise TV station in Lagos, January, 2022
- Coverage of oversight visit to NAFDAC, Abuja by House of Reps. Committee on Healthcare Services on 24<sup>th</sup> August, 2022.
- AU -3 Steering Group Agenda at Transcorp Hilton Hotel in Abuja on 5- 6<sup>th</sup> September, 2022.
- Coverage of the Courtesy Visit from Pharmaceutical Society of Nigeria to the Ag. DG on the 2<sup>nd</sup> December, 2022 in Abuja.
- Director South – South Zone Courtesy Visit to some security Agencies such as DDS, NDLEA and The Nigeria Police – 12<sup>th</sup> to 13<sup>th</sup> September, 2022.
- Flag off of Media Sensitization Workshop for Nigerian Health Journalists in Abuja on 6<sup>th</sup> December, 2022.
- Coverage of Courtesy Visit of the Director-General (SME) to Ag. Director-General, NAFDAC in Abuja on 7<sup>th</sup> Dec. 2022
- Coverage of the Sensitization Workshop on Regulatory control and Dangers of Bleaching Cream in Lagos on the 14<sup>th</sup> December, 2022.
- Coverage of Ag. DG visit to Yaba Lab NAHCO in Lagos on the 19<sup>th</sup> December, 2022
- Coverage of Sensitization & Awareness Campaign on Aflatoxins in Groundnuts in Kano on 22<sup>nd</sup> December, 2022.

- Publicity: Press Releases in Major National Dailies.

#### **4. Publications**

- NAFDAC News. Quarterly News magazine of NAFDAC activities.
- The Scorecard. A chronicle of activities and achievements of NAFDAC
- Information Brochure

#### **5. Sustained Mass Media Enlightenment Programmes.**

The PR Unit has continued to sustain the following programmes in the media.

- ❖ NAFDAC & YOUR HEALTH TV Programme on TVC and NTA stations – Mondays (6:30pm-7:00pm) and Tuesdays (8:00-8:30pm) respectively.
- ❖ NAFDAC & Your Health Radio programme on the Federal Radio Corporation of Nigeria (FRCN) Network by 4:30pm on Mondays and in 36 states FM stations at different time schedules.
- ❖ Interviews, Special Features and Guest appearances on Radio and TV.
- ❖ Syndicated articles in major national dailies.

#### **6. Increased Visibility in the Digital and New Media, Namely:**

- ❖ Facebook, Twitter, Instagram, YouTube.
- ❖ Regular update of information on the activities of NAFDAC on the Facebook and Twitter
- ❖ Participated and uploaded information on various activities such as:
  - ✓ Event information
  - ✓ Safety information
  - ✓ Photographs
  - ✓ Videos
  - ✓ Customer services
  - ✓ Director-General's presentations and addresses.
- ❖ Increased followership and recognition through stakeholders' engagement and regular updates.

#### **3.1.1 Protocol Unit**

A total number of Sixty (60) international trips comprising of Twenty-Nine (29) GMPs, Fourteen (14) Trainings, workshops and Meetings, Twenty-One (21) Seminars and Summit were proposed to be consummated by 109 officers within the year 2022 but only Thirty-Nine (39) comprising 20 GMPs, Nine Training/Workshops and 10 meetings/summits/seminars were actually consummated by seventy eight (78) staff of the agency.

The Twenty-Five (25) trips that were to be carried out by Thirty-One officers of the Agency could not hold due to withdrawal and postponement of trips by the international counterpart.

**Table 3.1.1.1: Activities of Protocol Unit**

Month	No of Staff	Proposed Programs to Be Attended			No of Staff	Actual Programs to be Attended		
		GMP	Training/ workshop	Meeting/ Seminar/ Summit		GMP	Training/ workshop	Meeting/ Seminar/ Summit
<b>Total</b>	109	29	14	21	78	20	9	10

**3.2 Office of Trade and International Relations (OTIR)****A. Investors/Visitors at One Stop Investment Centre (OSIC – NIPC):**

The following 17 investor visited/called the Desk and was sent the relevant guidelines and asked to visit NAFDAC website or nearest NAFDAC Office for more information: -

**Table 3.2**

S/ N	Date	Name of Enquirer/ Company/ Purpose	Contact (Telephone & E-Mail)	Country	Sector	Mode of Contact	Remarks
1	13/01/2022	Mr. Michael Anusa/ Jetro / Enquiry on facial cleansing foam and registration Procedure.	08033016172	Nigeria	Cosmetics	Interpersonal	Relevant information was given
2	19/01/2022	Mrs. Ifeoma Blessing Benjamin/ No 3 Shettima Ngalada Street, Jikwoyi phase 2/ process of registration of pap.	080391482277	Nigeria	Food	Interpersonal	She was given the relevant guidelines.
3	19/01/2022	Mrs. Ruth Aaron Imodu/ Phase 2 extension down sloping by new living faith Jikwoyi/ Enquiry on registration of cosmetics.	08166800812	Nigeria	Cosmetics	Interpersonal	She was given the relevant guidelines.
4	5/10/2021	Mr. Nwokeafor Ignatius/ Lagos State/ inquiry about the importation of wine.	07083214920	Nigeria	Beverages	Interpersonal	Relevant information was given.
5	3/3/2022	Mr. Kento Matsushita/ of Toyota building 2 <sup>nd</sup> floor, uhuru highly, Lusaka Road Nairobi, kenya/ enquiry on the registration of sanitary towels.	+254 110629804	Kenya	Sanitary towel	Interpersonal	He was given relevant information.
6	3/3/2022	Mr. Kunihiko Takano/ Unicham guld hygienic industries co. ltd, Riyadh Saudi Arabia. / Enquiry about the registration of Sanitary towel.	966 (50)302 8861	Saudi Arabia	Sanitary towel	Interpersonal	He was given relevant information.

			Kinihito- takano@unicharm.co m				
7	3/3/2022	Mr. Makoto Sasaki/ Sumitomo Fudosan Mita Twin building, west wing, Japan/ Enquiry about the registration of Sanitary towel.	81 80 23671910  Makoto- sasaki@unicharm.co m	Japan	Sanitary towel	Interpersonal	He was given relevant information.
8	3/3/2022	Mr. Tsuyoshi Yato of No 28, Ndola Crescent, Wuse Zone 5, Abuja/ Enquiry about the registration of Sanitary towel.	09094329068  <a href="mailto:tyato@cfao.com">tyato@cfao.com</a>	Nigeria	Sanitary towel	Interpersonal	He was given relevant information.
9	3/3/2022	Mr. Pendo Egure/ NIPC/ request for the guideline on the registration of both imported and locally manufactured drugs.	<a href="mailto:pendo.egure@nipc.gov.ng">pendo.egure@nipc.gov.ng</a>	Nigeria	Pharmaceuti cals	Interpersonal	He was given the relevant guideline.
10	3/3/2022	Ms. Adu Modupe/ Small chop express/ enquire about the process of registration of plantain chips and Chin-Chin.	<a href="mailto:adumodupe57@gmail.com">adumodupe57@gmail.com</a>  <a href="http://il.com">il.com</a>	Nigeria	Food	Interpersonal	Relevant information was given.
11	3/3/2022	Mr. Idriss Mouchili/ Coega development corporation ltd South Africa/ enquiry on the registration of sanitary towel.	+27 (0) 836019299  <a href="mailto:Idriss.mouchili@coega.za">Idriss.mouchili@coega.za</a>	South Africa	Sanitary towel	Interpersonal	Relevant information was given.
12	8/3/2022	Mr. Saad Umar Abubakar/ Egyptian Herbal international Trade/ enquiry on drugs, herbal oil and medical devices.	<a href="mailto:saddumab@gmail.com">saddumab@gmail.com</a>  m  08111110370	Egypt	Pharmaceuti cals	Interpersonal	He was given the relevant guidelines.
13	28/3/2022	A team of investors from Germany led by Mr. Olawale Falope/ Blue planet Eco solution/ Enquiry on registration of non- alcoholic sanitizer.	<a href="mailto:info@blueplanetisgr.com">info@blueplanetisgr.com</a>  <a href="http://een.com">een.com</a>  +496940150789  07067116234	Germany	Sanitizer	Interpersonal	Relevant information was given.
14	6/4/2022	Mr. Donald/ Lugbe, FCT, Abuja/ enquire about the process of registration of bread.	07030454953	Nigeria	bread	Interpersonal	He was given relevant information

15	5/5/2022	Mrs. Agatha Manafa/ E 97/98 street, Lungi International Market, Maitama Extension, Abuja/ enquire about bread production.	08130303535  agathananafa@gmail l.com	Nigeria	bread	Interpersonal	Relevant information was given.
16	5/5/2022	Mr. Uchenna Okafor/ Ayamelum L. G. A. Anambra State/ enquire about bread production.	08142976932  Uchetex0202@gmail .com	Nigeria	Bread	Interpersonal	Relevant information was given.
17	25/8/2022	Mr. Uchenna Timothy Dike/ Gwarimpa, FCT Abuja/ enquire about importation and registration of Drugs.	08034065662	Nigeria	Pharmaceuti cal	Interpersonal	Relevant information was given.

### **B. Summary of Activities/ Programs (Meeting, Workshop, Training, Trade Fair, Conference, Exhibition, Business & Investment Forum)**

The Unit participated in Ninety-Four (94) programmes during the period under review. Some of the programmes are listed below.

- Meeting of the inter-ministerial committee on the continuous closure of Nigerian owned businesses in Ghana 12/1/22
- Inauguration of inter-ministerial committee on establishment of cold chain and the Gulf of Guinea trade hub in Calabar, Cross River State 25/1/22.
- Meeting of the sub-committee on Regulatory framework and ease of doing business of the National Trade facilitation committee (NTFC) on the developed work plan between Nigeria and Mexico for the export of Hibiscus 26/1/22 - 2/2/22.
- Hosted the meeting with the Director General Association of Cottage Industrialists of Nigeria (ACIN) 2/2/22
- Participation at the National Biosafety Management Agency review meeting 9-10/2/22
- Participation at the stakeholder's meeting on the establishment of a designated competent Authority for the Administration of the African Continental Free Trade Area (AFCFTA) rules of origin 24/2/22
- Inauguration of the National Quality Council (NQC) by the Secretary to the Government of the Federation (SGF). 7/3/22
- Hosted the meeting with the Pan Africa Competitiveness forum (PACF) 12/4/22.
- Inter-ministerial meeting preparatory to the Nigeria-Canada trade and Investment mission in Ottawa Canada 21/6/22
- Participation at the meeting of selected Stakeholders to consolidate the harmonized Free Trade Agreement (FTA) template 2/8/22

### **C. Presidential Enabling Business Council (PEBEC) M&E Report.**

- The Desk collated and vetted the M&E monthly reports from 36 States including FCT for submission to PEBEC through regular phone calls, text messages and emails to State/Zonal Coordinators and Desk officers to remind them to update and promptly submit their reports.
- Analysis of collated reports from the States to ensure compliance to product registration timelines.

### 3.3 REPORTS FROM THE ZONES

#### 3.3.1 NORTH CENTRAL ZONE

The North Central Zone comprises of six states namely Benue, Nasarawa, Niger, Kogi, Kwara and Plateau States.

#### Highlight of Activities:

The report summarizes the regulatory activities carried out by the States within the zone in the Year under review as highlighted below:

##### 1. Routine Inspections

One Thousand, Two Hundred and Thirty-Three (1,233) routine inspections were carried out in the Zone during the period under review.

##### 2. Sanctions

One Thousand, Four Hundred and Eighty-Two (1,482) sanctions were imposed on various establishments in the Zone during the year under review.

##### 3. Surveillance

Four Thousand, Two Hundred and Forty-Eight (4,248) surveillance were carried out in the Zone during the year under review.

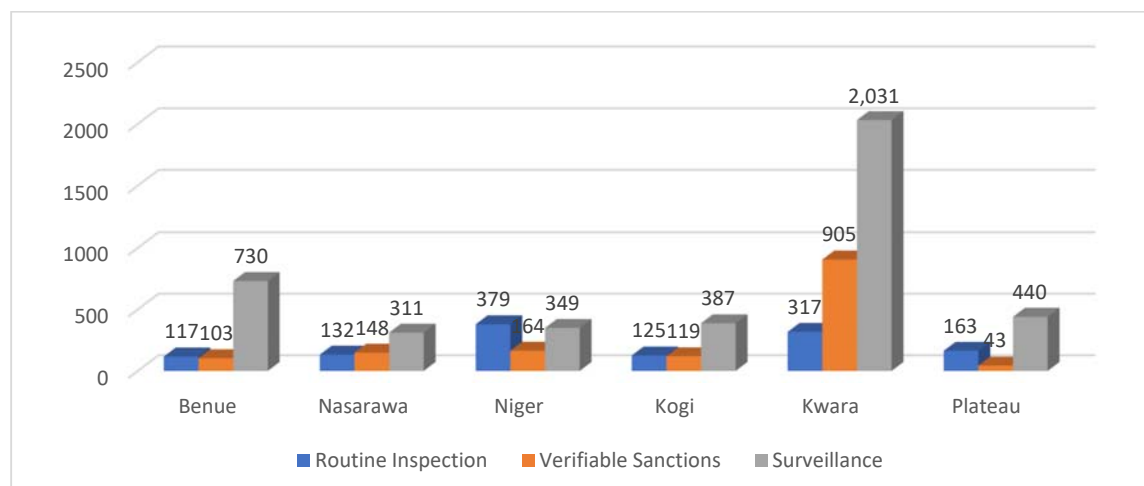
**Table 3.3.1.1: Regulatory Activities in North Central Zone by Directorates**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	DER	21	4	0
2.	CER	7	13	0
3.	R&R	0	75	0
4.	PVPMS	0	1,012	3,766
5.	VMAP	11	6	13
6.	FSAN	1,194	372	469
7.	NCS	0	0	0
8.	Others	0	0	0
	<b>Total</b>	<b>1,233</b>	<b>1,482</b>	<b>4,248</b>

**Table 3.3.1.2: Regulatory Activities in North Central Zone**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	Benue	117	103	730
2.	Nasarawa	132	148	311
3.	Niger	379	164	349
4.	Kogi	125	119	387
5.	Kwara	317	905	2,031
6.	Plateau	163	43	440
	<b>Total</b>	<b>1,233</b>	<b>1,482</b>	<b>4,248</b>

**Figure 3.3.1.1: Regulatory Activities in North Central Zone**



### 3.3.2 NORTH WEST ZONE

The North West zone comprises of seven states namely Jigawa, Kaduna, Kano, Katsina, Kebbi, Sokoto and Zamfara.

#### Highlight of Activities:

The report summarizes the regulatory activities carried out by the States within the zone in the Year under review as highlighted below:

#### 1. Routine Inspections

Four Hundred and Twenty (420) Routine inspections were carried out in the Zone during the period under review.

#### 2. Surveillance

Four Thousand, Four Hundred and Sixty- Three (4,462) Surveillance were carried out in the Zone during the year under review.

#### 3. Sanctions

Nine Hundred and Forty-Seven (947) sanctions were imposed on various establishments in the Zone during the year under review.

#### 4. Other Regulatory Activities

**Table 3.3.2.1: Regulatory Activities in North West Zone by Directorates**

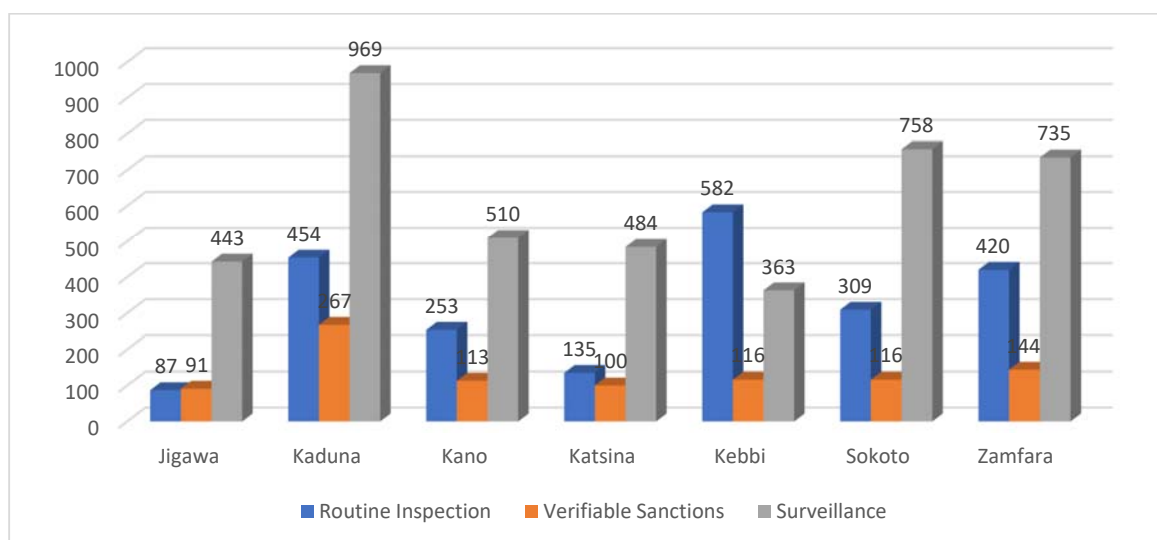
SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	DER	191	107	742	37
2.	CER	2	10	114	20
3.	R&R	0	1	0	52
4.	PVPMS	0	447	2,410	0
5.	VMAP	12	69	560	0
6.	FSAN	186	311	636	49
7.	NCS	30	2	0	0

8.	Others	0	0	0	0
	<b>Total</b>	420	947	4,462	158

**Table 3.3.2.2: Regulatory Activities in North West Zone by States**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	Jigawa	87	91	443	0
2.	Kaduna	454	267	969	66
3.	Kano	253	113	510	61
4.	Katsina	135	100	484	4
5.	Kebbi	582	116	363	7
6.	Sokoto	309	116	758	20
7.	Zamfara	420	144	735	0
	<b>Total</b>	<b>2,240</b>	<b>947</b>	<b>4,262</b>	<b>158</b>

**Figure 3.3.2.1: Regulatory Activities in North West Zone by States**



### 3.3.3 NORTH EAST ZONE

#### Introduction

The Northeast Zone (NEZ) comprises of six (6) states namely, Adamawa, Bauchi, Borno, Gombe, Taraba and Yobe State.

For the past Twelve (13) years, the Zone has been tormented by security challenges. Still some local government areas particularly in Borno, Yobe and Adamawa are not readily accessible due to insurgency.

During the period under review staff were trained on QMS. Five Thousand Five Hundred and Twenty-Six (5,526) regulatory activities i.e., Routine, Sanction and Surveillance were carried out.

Despite the insecurity challenges officers in the zone have not relented in discharging their responsibilities.

### Highlights of Activities

Breakdown of activities carried out during the period under review are highlighted below:

#### 1. Routine Inspections

One Thousand Six Hundred and Sixty-Seven (1,667) Routine inspections were carried out in the Zone during the period under review.

#### 2. Surveillance

Three Thousand, Two Hundred and Forty-Three (3,243) Surveillance were carried out in the Zone during the year under review.

#### 3. Sanctions

Four Hundred and Seventy-One (471) sanctions were imposed on various establishments in the Zone during the year under review.

#### 4. Other Regulatory Activities

Five Thousand, Four Hundred and Fifty (5,450) other regulatory activities such as BMS monitoring, Institutions visited for PVG activity, ADR reports, Consumer complaints, Investigations, Production inspection and renewals were also carried out were also carried out.

#### 5. Number of Approved Products

A total number of Three-Hundred and six products were approved at the zonal approval meeting held in the year, 2022.

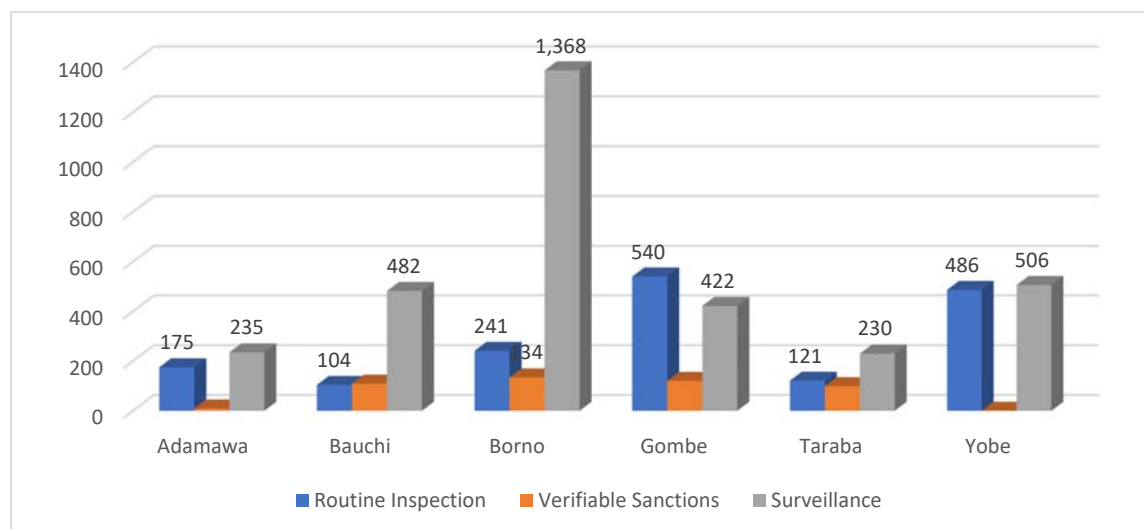
**Table 3.3.3.1: Regulatory Activities in North East Zone by Directorates**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	DER	258	88	287
2.	CER	17	9	1
3.	R&R	0	0	0
4.	PVPMS	152	114	1,814
5.	VMAP	126	28	723
6.	FSAN	1114	232	416
7.	NCS	0	0	0
8.	I&E	0	0	2
	<b>Total</b>	<b>1,667</b>	<b>471</b>	<b>3,243</b>

**Table 3.3.3.2: Regulatory Activities in North East Zone by States**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	Adamawa	175	9	235
2.	Bauchi	104	109	482
3.	Borno	241	134	1,368
4.	Gombe	540	120	422
5.	Taraba	121	99	230
6.	Yobe	486	0	506
	<b>Total</b>	<b>1,667</b>	<b>471</b>	<b>3,243</b>

**Figure 3.3.3.1: Regulatory Activities in North East Zone by States**



**Table 3.3.3.3: Product Registration**

SN	States	No. of Approved products
1.	Adamawa	67
2.	Bauchi	21
3.	Borno	58
4.	Gombe	51
5.	Taraba	64
6.	Yobe	45
	<b>Total</b>	<b>306</b>

## 6. Quality Management System.

The zone has integrated the Quality Management System requirement into its daily activity. Step-down training/awareness for QMS were conducted.

## 7. Collaboration with State Government

There is also an increase in collaboration between the Agency and the State Government in the zone which have led to the inclusion of NAFDAC as a member of the state security council in Borno State. Ministries of Health, Education, and Information on request of NAFDAC were directed to work with NAFDAC in areas of sensitization/awareness creation.

## 8. Meetings

A total number of twenty-nine (29) meetings were conducted in the zone during the period under review. The meetings conducted were as follows.

1. NAFDAC Borno and Yobe have being Participating in Security Forum and Council meetings in their state.
2. Consultative meeting with herbal medicine practitioners.
3. Consultative meeting with ATWAP Officials.
4. Consultative meeting with Officials of pharmaceutical society of Nigeria.
5. Interactive meeting with supermarket operators.

6. Consultative meeting with master bakers.
7. Meeting with Borno State rice and grain dealers' association (Baga road)

**9. Stakeholder Forum:** A total number of nine (9) stakeholders forums were conducted during the period under review.

Some of the the stakeholder's forum conducted are as follows.

1. Cereals /Legumes/Grains dealer's stakeholder's forum in Taraba state
2. Fruit, Vegetable dealers and Vegetable oil dealer's stakeholder's forum in the Taraba state.
3. Stakeholders training on food processing for MSMEs conducted with the support of mercy corps in Borno and Gombe State.
4. Staff/Trainees of IFAD/VCDF section stakeholders of Ministry of Agriculture Taraba state.
5. Tea/Beverages Stakeholders, Taraba state government, Taraba Investment and Properties (TRIP) Ltd, Mambila Beverages Nigeria Ltd and Others.

### 3.3.4 SOUTH WEST ZONE

A total of 2,057 of regulatory activities carried out in the South West Zone from 1<sup>st</sup> January to 31<sup>st</sup> December 2022.

#### Highlights of activities

The states in the South-West Zone carried out various activities during the year under review as highlighted below;

1. Routine Inspection: 1,010 routine inspections were carried out.
2. Surveillance: 184 surveillance activities were carried out.
3. Sanctions: 236 sanction activities were carried out.
4. Production: 824 production inspection were carried out.
5. Renewal: 461 renewal inspection were carried out.

**Table 3.3.4.1: Regulatory Activities in South West Zone by Directorates**

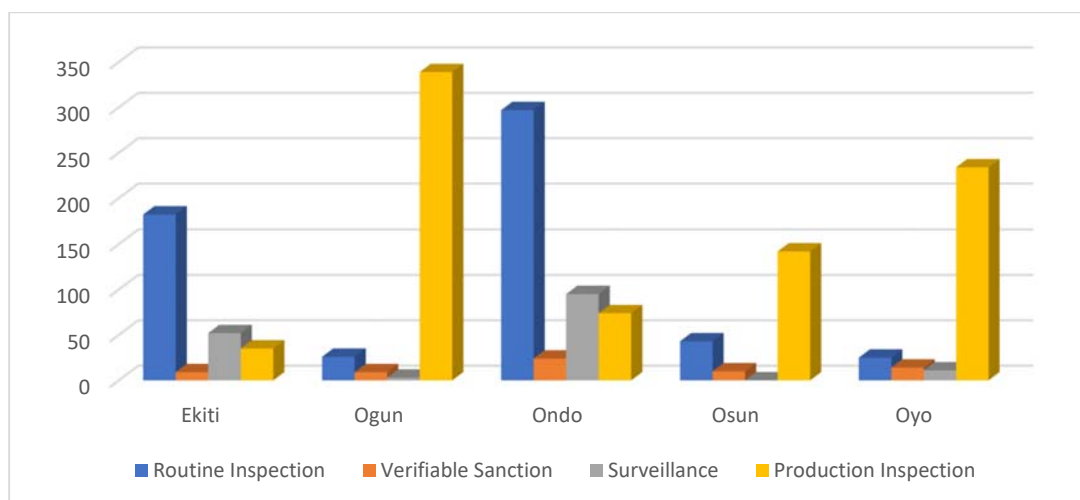
SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	DER	160	11	13	
2.	CER	7	1		
3.	R&R				
4.	PVPMS	206	13	144	
5.	VMAP	2	1	9	
6.	FSAN	635	210	17	
7.	NCS			1	
8.	I&E				
	<b>Total</b>	<b>1010</b>	<b>236</b>	<b>184</b>	

**Table 3.3.4.2: Regulatory Activities in South West Zone by States**

SN	States	Routine Inspection	Verifiable Sanction	Surveillance
1.	Ekiti	200	7	60
2.	Ogun	43	142	4
3.	Ondo	291	34	52
4.	Osun	73	27	45

5.	Oyo	403	26	23
	<b>Total</b>	1010	236	184

**Figure 3.3.4.1: Regulatory Activities in South West Zone by States**



**Table 3.3.4.3. Product Registration**

SN	States	Water Products presented	MSME Products presented	Bread products presented	Cosmetics	Total product presented	Stepped down	Approved
1.	Ekiti	47	30		3	80	6	74
2.	Ogun	130	158	86	8	382	3	379
3.	Ondo	46	73	16	10	145	2	143
4.	Osun	137	49	2	3	191	1	190
5.	Oyo	77	191	65	12	345	1	344
	<b>Total</b>	437	501	169	36	1143	13	1130

### 3.3.5. SOUTH SOUTH ZONE

The number of regulatory activities (routine, sanctions & surveillance) carried out in the Zone for the year 2022 is Two Thousand and Three (2,003)

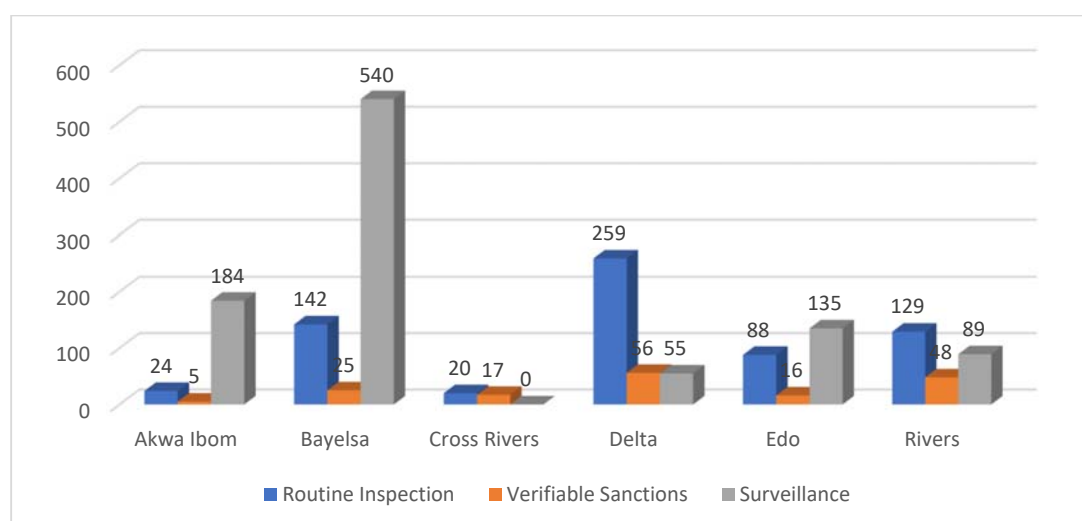
**Table 3.3.5.1: Regulatory Activities in South South Zone by Directorates**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	DER	57	31	64
2.	CER	6	0	0
3.	R&R	0	0	0
4.	PVPMS	261	70	767
5.	VMAP	0	0	1
6.	FSAN	572	107	66
7.	NCS	1	0	0
8.	I&E	0	0	0
	<b>Total</b>	897	208	898

**Table 3.3.5.2: Regulatory Activities in South South Zone by States**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	Akwa Ibom	193	36	202
2.	Bayelsa	120	21	350
3.	Cross Rivers	53	22	41
4.	Delta	89	85	118
5.	Edo	333	42	160
6.	Rivers	109	2	27
	<b>Total</b>	<b>897</b>	<b>208</b>	<b>898</b>

**Figure 3.3.5.1: Regulatory Activities in South South Zone by States**



**Table 3.3.5.3: Product Registration**

SN	States	Total Number of Products presented	Water (Renewal)	Food	Cosmetics	Bread
1.	Zonal Total	1,354	267	789	210	88
2.	Akwa Ibom	701	41	104	53	30
3.	Bayelsa	167	1	5	0	11
4.	Cross Rivers	187	42	8	0	4
5.	Delta	54	71	47	69	0
6.	Edo	17	52	49	52	14
7.	Rivers	228	60	576	36	29

### 3.3.6: SOUTH EAST ZONE

#### 1. Highlight of Activities:

The regulatory activities carried out by the States within the zone in the Month year 2021 are as highlighted below:

- a. **Routine Inspection:** A total number of Five Hundred and Seventy-Nine (**579**) routine activities were carried out within the zone in the year 2022 under review.
- b. **Verifiable Sanction:** A total of Two Hundred and Five (**205**) verifiable sanctions were meted out within the zone in the year under review.
- c. **Surveillance:** A total number of One Thousand and Seventy-Four (**1,074**) surveillance activities were carried out within the zone in the Month under review.

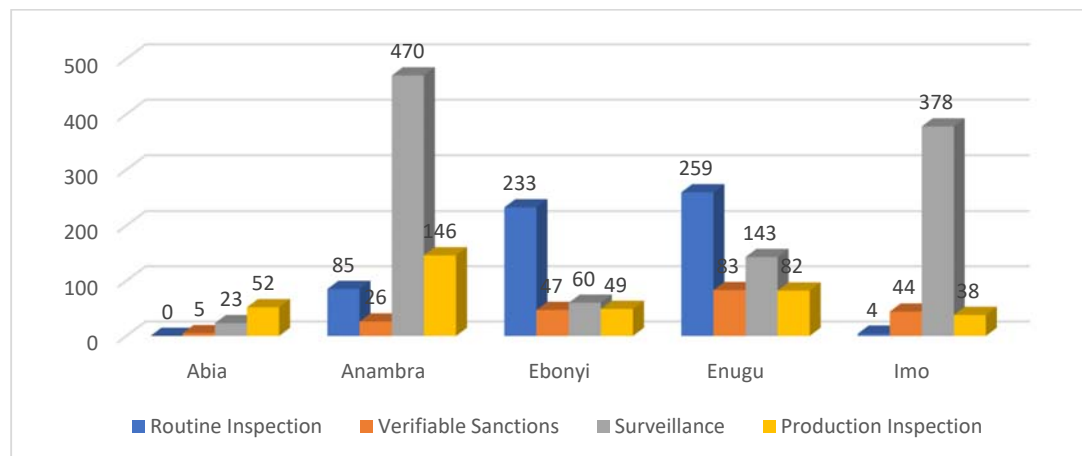
**Table 3.3.6.1: Regulatory Activities in South East Zone by Directorates**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	DER	207	55	196	34
2.	CER	0	0	0	0
3.	R&R	0	0	0	3
4.	PVPMS	46	103	509	0
5.	VMAP	0	0	0	3
6.	FSAN	307	47	369	314
7.	NCS	19	0	0	0
8.	I&E	0	0	0	0
	<b>Total</b>	<b>579</b>	<b>205</b>	<b>1,074</b>	<b>354</b>

**Table 3.3.6.2: Regulatory Activities in South East Zone by States**

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	Abia	0	5	23	52
2.	Anambra	85	26	470	146
3.	Ebonyi	233	47	60	49
4.	Enugu	259	83	143	82
5.	Imo	4	44	378	38
	<b>Total</b>	<b>579</b>	<b>205</b>	<b>1,074</b>	<b>367</b>

**Figure 3.3.6.1: Regulatory Activities in South East Zone by States**



**Table 3.3.6.3. Product Approval in South East Zone by State.**

A total of **Two Hundred and Sixty-Nine (260)** product approvals were given in the year under review.

S/N	Category of Products	Type of Registration	NUMBER of Products Registered by State					Total
			Abia	Anambra	Ebonyi	Enugu	Imo	
1	Bread Products	New Registration	17	0	0	0	0	17
2	Bread Products	Renewal	0	0	0	0	0	0
3	Cosmetics Products	New Registration	0	0	0	3	4	7
4	Cosmetics Products	Renewal	1	1	0	0	0	2
5	MSME Food Products	New Registration	23	39	13	29	24	128
6	MSME Food Products & Packaged Water	Pack Size Extension	0	1	0	0	0	1
7	Bread Products Registered	Pack Size Extension	0	0	0	0	0	0
8	MSME Bread Products	Renewal	0	0	0	0	0	0
9	MSME Food Products	Renewal	4	9	1	0	2	16
10	MSME Water Products	Renewal	21	38	3	15	11	88
11	MSME Water	Factory Extension	0	0	0	0	0	0
12	MSME Food & Water	Factory Relocation	0	0	0	0	0	0
13	MSME Food	Change of Package/Label Design	1	0	0	0	0	1
<b>Total Number of Products Registered</b>			<b>67</b>	<b>88</b>	<b>17</b>	<b>47</b>	<b>41</b>	<b>260</b>

## 2. Meetings:

- The zonal office held monthly approval and pre-approval meetings except in July (due to strike action); all states within the zone joined these meetings.

- There was also a meeting between the State Coordinator and Regulatory officers in the South East Zonal and Enugu State Offices.
- Abia State office held meeting with various stake holders including NAPMED, Tenant Branch Road.
- A meeting was also held between the then DSEZ and state coordinators as well as unit heads in the zone on ways to move the zone forward.

### 3. Stakeholder Forum:

- The SEZ represented the agency in an interagency stakeholder’s forum organized by Nigeria Export Promotion Council (NEPC).
- Advocacy visits was held by Abia state office to key stakeholders; sensitization at Abia State Celebration of SME day in Umuahia and sensitization of NAPMED Tenant Road Branch.
- The Anambra state office held a training for stakeholders on the agency’s regulatory activities.
- On 26th June, 2022, the Zonal office represented the agency is in a programme marking the international day against drug abuse and illicit trafficking held in Enugu in collaboration with NDLEA. The theme of the even was” Addressing drug challenges in Health and Humanitarian Crises.
- The SEZ office also participated in a two (2) day workshop for beneficiaries of women and youth empowerment programme (WYEP) of Agro-Processing, Productivity Enhancement and Livelihood Improvement Supports (APEALS) Project, Enugu State. APEALS project essentially sought to empower these youths in production of MSME products. The programme held between 27th-28th April, 2022 in Enugu.
- The SEZ office also participated and represented the agency in an export clinic organized by Nigerian Export Promotion Council (NEPC) for newly registered non-oil exported which held in Enugu on 29th June, 2022.
- Sensitization of the bakers in Ebonyi State to avoid production of bread without due regulatory process and approval.

### 4. Trainings: Staff of the zone attended various trainings both virtual and physical including:

- GMP training for all regulatory officers
- Step down training on food safety in Dairy sector.
- QMS Officer in the zone successfully participated in QMS Gap Assessment Audit in South East Zonal Office as well as QMS trainings.
- Staff of the zone participated in an FSAN training on market-level food fortification.
- Regulatory officers from each in the zone participated in Truscan training.

### 3.3.7: FEDERAL CAPITAL TERRITORY (FCT) OFFICE

#### Introduction:

The Federal Capital Territory Office has nine (9) Units namely: -

1. Chemical Evaluation and Research (CER)
2. Food Safety and Applied Nutrition (FSAN)
3. Registration and Regulatory Affairs (R&R)
4. Veterinary Medicine and Allied Products (VMAP)
5. Drug Evaluation and Research (DER)

6. Narcotics and Controlled Substances (NCS)
7. Finance and Accounts (F&A)
8. Human Resource Management (HRM)
9. One Stop Shop (OOS) domiciled at the Abuja Enterprise Agency

### Highlight of Activities

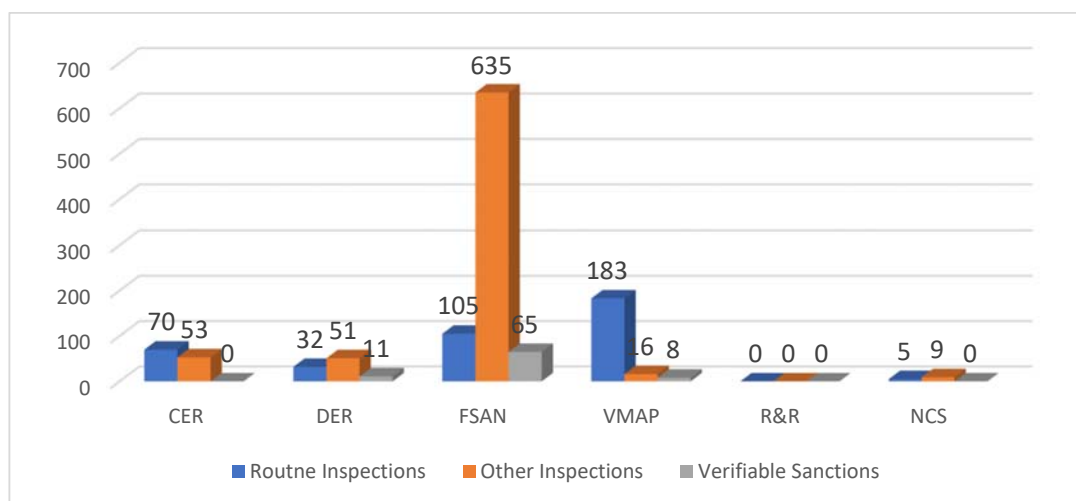
#### 1. Inspections

The FCT Office, through the various inspecting Units-FSAN; DER; CER; VMAP and NCS carried out different types of inspections as highlighted below:

**Table 3.3.7.1: Regulatory Activities of FCT Office in 2022**

SN	Unit	Nos. of Routine Inspection	No of other Inspections	Verifiable Nos. of Sanctions
1	CER	70	53	0
2	DER	32	51	11
3	FSAN	105	635	65
4	VMAP	183	16	8
5	R&R	0	0	0
6	NCS	5	9	0
7	OSS	0	0	0
8	DFCT	0	0	0
9	<b>Total</b>	<b>395</b>	<b>764</b>	<b>84</b>

**Figure 3.3.7.1: Regulatory Activities of FCT Office in 2022**



**Table 3.3.7.1: Summary of activities carried out by Registration and Regulatory Affairs Unit**

S/N	Activities	No. of Activities
1	Counselling of clients	205
2	MSME new registration	142
3	MSME Renewals	134
4	MSME Pack size extension	17
5	MSME Factory Extension	6

6	MSME Factory Relocation	18
7	Number of bread and bakery products registered/Renewed	161
	<b>Total</b>	<b>683</b>

### 3.3.8. LAGOS STATE OFFICE (LSO)

#### Introduction:

Lagos State Office have consolidated in the modest achievements made in the areas of sensitization, awareness campaigns, monitoring, and sectorial meetings, to make further remarkable progress in training of her officers and stakeholders.

The outcome of these awareness, training and sensitization programs have brought a major boost on the number of applications received which is currently on the increase at Lagos State Office.

It has also brought a lot of NAFDAC regulated businesses (micro & small) from the informal sector to the formal sector of the economy, thereby making it easy for NAFDAC regulatory control.

However, the activities for the year under review commenced with the in-house meetings, development and review of the SOPs, Inspections amongst others. Summary of activities are as follows.

#### 1. Highlights of Activities:

Within the period under review, we achieved the following:

##### a. Routine Inspection:

One hundred and two (102) routine inspection were conducted.

##### b. Verifiable Sanctions.

There were only two verifiable sanctions within the period under review.

This could be attributed to the sensitization programs the formation has embarked on. Warning letters were issued because most of them are first offenders.

##### c. Good Hygiene Practice (GHP):

Thirty-nine (39) GHP notifications were issued within the period under review.

##### d. Production Inspections:

Nine hundred and ninety-eight (998) production inspections were conducted within the period under review. Continuous training of stakeholders has brought a major boost on the number of applications received.

##### e. Renewal Inspection:

One hundred and forty-five (145) renewal inspections were conducted.

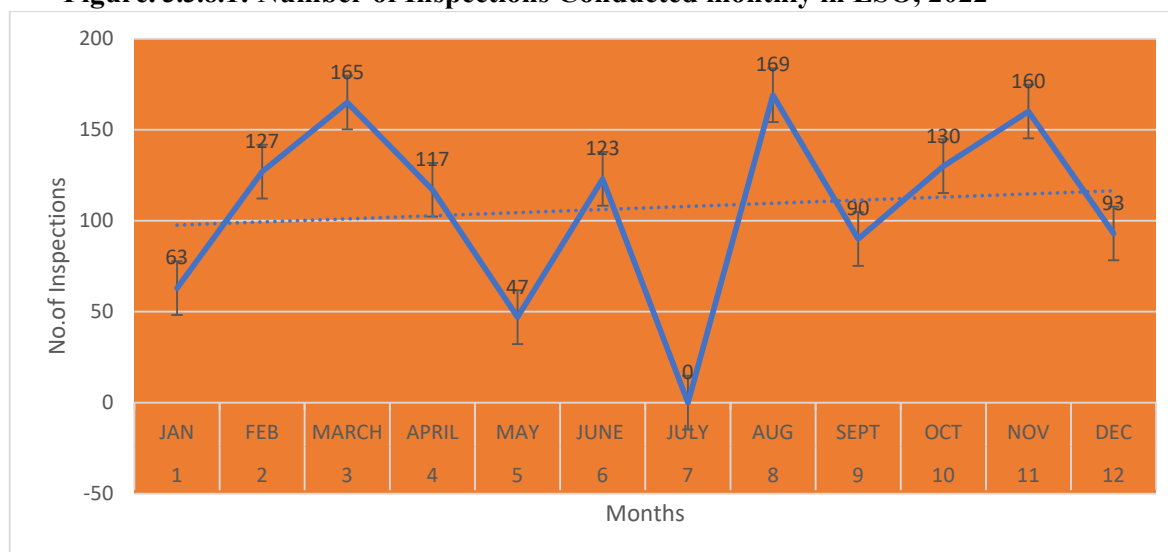
A total of one thousand two hundred and eighty-four (1,284) inspections were conducted in the formation throughout the year.

**Table 3.3.8.1. Summary of Activities of LSO From January to December 2022**

SN	Month	Routine Insp.	Verifiable Sanctions Imposed	Surveillance	GHP Insp. Conducted	Production Inspections	Renewal Inspection	Total
1.	Jan.	-	-	-	-	51	12	63
2.	Feb.	14	-	-	1	87	25	127

3.	March	13	-	-	1	121	30	<b>165</b>
4.	April	32	-	-	-	78	7	<b>117</b>
5.	May	10	-	-	-	37	-	<b>47</b>
6.	June	31	-	-	1	90	1	<b>123</b>
7.	July	<b>Industrial action</b>	<b>Industrial action</b>	<b>Industrial action</b>	<b>Industrial action</b>	<b>Industrial action</b>	<b>Industrial action</b>	<b>Industrial action</b>
8.	Aug.	-	-	-	1	154	14	<b>169</b>
9.	Sept.	-	-	-	6	74	10	<b>90</b>
10	Oct.	-	-	-	3	111	16	<b>130</b>
11	Nov	2	-	-	24	123	11	<b>160</b>
12	Dec	-	-	-	2	72	19	<b>93</b>
	<b>Total</b>	<b>102</b>	<b>0</b>	<b>0</b>	<b>39</b>	<b>998</b>	<b>145</b>	<b>1,284</b>

**Figure. 3.3.8.1: Number of Inspections Conducted monthly in LSO, 2022**



\*The graph showed that the highest inspection conducted was on the month of August 2022. This was because of the continuous sensitization /awareness program constantly carried out at LSO through different media outlets.

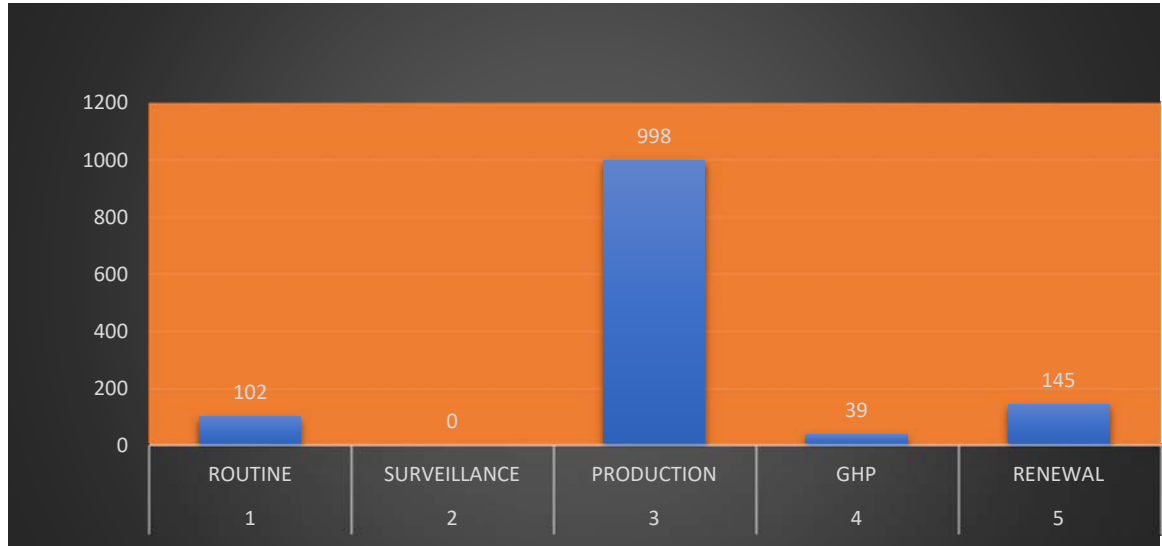
There were no activities on the month of July. This was because of the industrial action embarked by the Agency.

August to December had almost similar records on inspections activities, indicating stability and parity on physical activities.

## **2. At a Glance Type of Inspections Conducted at LSO in the Period Under Review.**

The bar chart below depicts the different kinds of inspection activities carried out by the Lagos State Office during the period under review.

**Figure. 3.3.8.2: Type of Inspections Conducted at LSO 2022.**



The bar chart showed that LSO carried out mostly production inspection, followed by renewal, routine, and GHP inspections respectively.

There was no surveillance conducted within the month under review.

These could be attributed to increased number of applications for production inspection that tends to occupy the time of the fewer officers at the formation.

Lagos State Office were able to carry out a lot of production inspection because of the extra vehicle provided to enable us attend to most of our activities.

**3. Data Extraction.**

Lagos State office (LSO), has continuously and successfully carried out the computerization of over seven thousand (7000) applications submitted at LSO

This will enable safety, easy access, and proper storage of data.

**4. External Sensitization Activities**

The following meetings/ programmes were attended by officers from Lagos State Office (LSO).

- I. Interactive symposium with the regulatory bodies organised by NASSI Lagos chapter held at Ikeja on the 24<sup>th</sup> of March 2022.
- II. Vantage Forum, an annual entrepreneurial advancement initiative organised by the Elevation Church, Lekki held on Saturday, 9<sup>th</sup> April, 2022.
- III. An Audit for strengthening of NAFDAC activities in the Directorate to understudy the processes in line with existing quality management system held on the 25<sup>th</sup> of May 2022.
- IV. Two officers participated in a two-day sensitization programme organised by Lagos West Senatorial district held on the 27<sup>th</sup> – 28<sup>th</sup> of October 2022

**a. Meetings Conducted**

The following inhouse meetings were conducted at Lagos State Office (LSO)

- I. NAFDAC-LSO Sub-Food and Cosmetics Approval meeting for the month of January held on 31<sup>st</sup> of January 2022 at the registration office of LSO.

- II. LSO first meeting of the year 2022 held on the 24<sup>th</sup> of January,2022 at the Laboratory Auditorium, Oshodi
- III. Final Food and Cosmetics Approval meeting for the month of January and February, held on the 4<sup>th</sup> of March 2022 at Oshodi Auditorium.
- IV. NAFDAC-LSO Final-Food and Cosmetics Approval meeting for the month of April held on the 8<sup>th</sup> of April,2022 at Laboratory Auditorium, Oshodi
- V. LSO Final Food and Cosmetics Approval meeting for the month of February, held on the 10<sup>th</sup> of March, 2021, at Oshodi Auditorium.
- VI. Sub-Food and Cosmetics Approval meeting for the month of April held on the 25<sup>th</sup> of May, 2022, at Oshodi Auditorium.
- VII. LSO Sub Food and Cosmetics Approval Meeting for the month of June held on the 12<sup>th</sup> of August 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- VIII. LSO Sub Food and Cosmetics Approval Meeting for the month of August held on the 26<sup>th</sup> of August 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- IX. LSO Final Food and Cosmetics Approval Meeting for the month of June & August held on the 1<sup>st</sup> of September 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- X. LSO Sub Food and Cosmetics Approval Meeting for the month of September held on the 28<sup>th</sup> of September 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- XI. LSO Final Food and Cosmetics Approval Meeting for the month of September held on the 30<sup>th</sup> of September 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- XII. LSO Sub Food and Cosmetics Approval Meeting for the month of October held on the 24<sup>th</sup> of October 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- XIII. LSO Final Food and Cosmetics Approval Meeting for the month of October held on the 31<sup>st</sup> of October 2022, at the Central Laboratory Auditorium Oshodi, Lagos.
- XIV. The LSO sub- Food and Cosmetics approval meetings for the month of November 2022 held on 25<sup>th</sup> of November 2022 at Registration office, Oshodi Lagos.
- XV. The final Food/Cosmetics approval meeting for the month of November held on the 30<sup>th</sup> of Nov, 2022 at Oshodi Laboratory Auditorium Lagos.
- XVI. Sub- Food and Cosmetics approval meeting for the month of December held on 14<sup>th</sup> December 2022 at the registration office, Oshodi, Lagos.
- XVII. The LSO Final Food & Cosmetics Approval meeting for the month of December held on 16<sup>th</sup> December 2022 at the Central Laboratory Auditorium, Oshodi.

## Chapter 4

### Food Safety and Applied Nutrition (FSAN) Directorate

#### 4.0 Overview

The Food Safety and Applied Nutrition (FSAN) Directorate was created in 2013 to bring issues of food safety and nutrition to the forefront of NAFDAC activities. The Directorate Head Office is 2<sup>nd</sup> Floor, NAFDAC Office Complex, Plot 1 Isolo Industrial Estate, Apapa-Oshodi Expressway, Isolo, Lagos.

The FSAN Directorate is mandated to, amongst other things, ensure that:

- 1) Food manufactured, imported, exported, distributed, advertised, sold, and used in Nigeria meet the highest standard of food safety reasonably achievable,
- 2) Food business operations are in line with NAFDAC regulations and with international best practices.
- 3) Consumers are protected from unfair practices, through a fair and effective food, water, and related products regulatory regime.

To achieve the above, the Directorate has put in place a framework to ensure best practices in line with the Agency's Quality Management System. This will also help to align with the Agency's vision to be a leading regulatory Agency in the global arena.

#### 4.1 Structure

The Directorate is headed by a Director, and comprises five (5) Divisions, a Satellite office and the Director's office.

1. Food Inspection, Medium Enterprises & Agricultural Products (FI/ME/AP)
2. Food Evaluation, Food Storage & Quick Service Restaurants (FE/FS/QSR)
3. Packaged Water (PW)
4. Bakery (Bread) and Baked Products (BBP)
5. Food Safety, Codex & Regulations (FS/Codex)
6. FSAN Satellite Office (Abuja) – (FSAN-SO)
7. Director's Office.

#### 4.2 Functions of The Directorate Include:

1. Safeguarding public health through a fair and effective food, water and related products regulatory regime that carries out Good Manufacturing Practice (GMP) inspections of Food and Water establishments, Quick Service Restaurants, Bakeries, etc.
2. Issuance of authorization for importation of bulk food raw materials.
3. Safety evaluation of processed foods, food supplements, water, food additives and related products to ensure they meet the required standards before registration and use.
4. Engaging in regulatory and research programs to inform regulatory decisions and actions on food safety issues including physical, chemical, and biological contaminants in food and related products.
5. Engagement, collaboration, and consultation with relevant stakeholders in the food and nutrition value chain from farm to table in form of industry outreach, consumer education and stakeholders' meetings to provide information.
6. Coordination and promotion of Codex Alimentarius Commission activities, WTO Sanitary and Phytosanitary (SPS) measures, International Food Safety Authorities Network (INFOSAN)

activities, National Food Fortification Programmes, the International Code of Marketing of Breastmilk Substitutes (BMS) and other nutrition programmes.

### 4.3 Regulatory Activities

**Table 4.1: Summary of FSAN Regulatory Activities for Year 2022**

S/N	FSAN ACTIVITIES	OUTCOME	NCZ	NEZ	NWZ	SSZ	SWZ	SEZ	LAGOS	TOTAL
1	Routine Inspections	Satisfactory	1,367	859	856	353	332	237	61	4,065
		Unsatisfactory	726	-	428	193	119	-	65	1,531
2	Special Inspections	Satisfactory	69	65	35	34	10	46	11	270
		Unsatisfactory	3	-	23	16	1	-	-	43
3	GMP Re-assessment	Satisfactory	42	46	28	19	34	10	29	208
		Unsatisfactory	2	1	-	2	-	-	1	6
4	Production Inspection	Satisfactory	492	149	620	533	835	361	576	3,566
		Unsatisfactory	21	9	18	172	7	43	8	278
5	Follow-up Inspection	Satisfactory	73	19	26	12	10	10	97	247
		Unsatisfactory	10	4	15	26	1	-	1	57
6	GMP Re-assessment (Renewal)	Satisfactory	396	123	471	194	556	148	321	2,209
		Unsatisfactory	5	1	9	60	4	-	1	80
7	Inspection of warehouses for Global Listing	Satisfactory	24	22	38	15	20	7	57	183
		Unsatisfactory	1	-	-	1	2	-	3	7
8	Cold Chain Facilities monitoring	Satisfactory	3	2	6	1	10	-	-	22
		Unsatisfactory	-	-	-	-	-	-	-	-
9	No. of Surveillances activities carried out	Compliant	456	624	195	130	37	408	-	1,850
		Non-compliant	169	-	146	60	7	-	-	382
10	No. of compliance directives issued		221	131	442	525	33	296	4	1,652
11	No. of Investigations activities carried out	Concluded	33	227	43	23	3	5	-	334
		Ongoing	19	-	20	11	13	-	2	65
12	Sanctions imposed on companies		579	55	250	115	63	31	-	1,093
13	No. Put on Hold		43	-	76	-	2	2	1	124
14	No. of Hold Removed		93	-	-	-	-	16	-	109
15	No. of Establishments visited for Mop-up		73	6	13	64	6	-	-	162
16	No of Products mopped up		116	19	14	116	-	6	-	271
17	No. of Consumer Complaints received		40	2	10	5	8	2	-	67
18	Number of Consumer Complaints investigated	Concluded	4	-	2	6	3	19	-	34
		Ongoing	8	-	6	-	2	-	-	16

19	No. of Product Alerts received		-	5	4	1	4	2	-	16
20	No. of Institutions visited for annual water monitoring		1	-	-	-	-	-	-	1
21	Breast Milk Substitutes (BMS) Monitoring		14	127	146	-	5	1	-	293
22	No. of Salt Iodization Surveys carried out	Concluded	50	-	-	-	20	-	-	70
		Ongoing	27	-	-	-	-	-	1	28
23	No. of Vitamin A/Premix Survey carried out	Concluded	241	-	-	-	20	-	-	261
		Ongoing	105	-	-	-	-	-	1	106
24	GPS Marking of location		-	-	-	-	-	-	-	-
25	Change of Location		-	-	-	-	2	-	2	4
26	Pack size Extension		-	-	-	-	4	-	1	5
27	cGMP Certification		-	-	-	-	2	-	7	9
28	No. of Sampling Inspection		-	-	-	-	-	-	3	3
29	No. of products sampled for laboratory analysis		-	-	-	-	-	-	-	-
30	Others		7	11	-	-	-	86	9	113
<b>Total</b>			<b>5,533</b>	<b>2,507</b>	<b>3,940</b>	<b>2,687</b>	<b>2,175</b>	<b>1,736</b>	<b>1,262</b>	<b>19,840</b>

Regulatory activities conducted in the period under review covered a wide spectrum and included various types of facility inspection activities (special, production, GMP re-assessment, routine, follow-up, warehouse, surveillance). Below is a summary of inspection activities conducted across the Zones and Lagos for Year 2022.

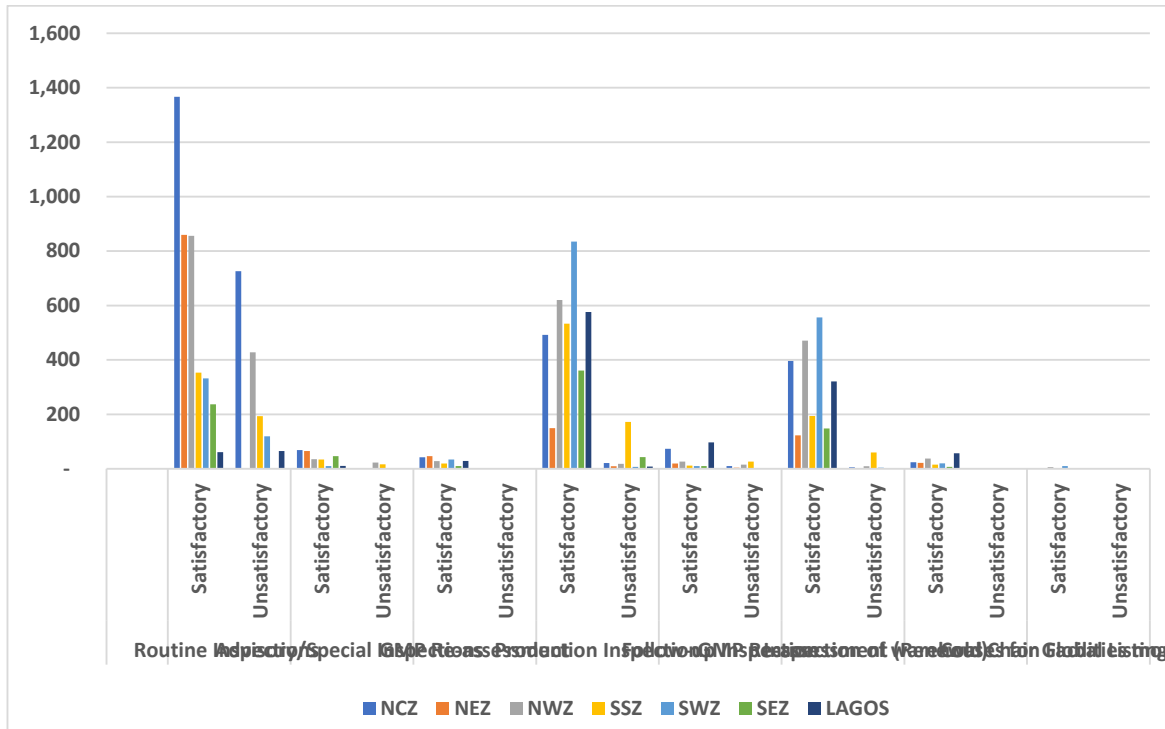
**Table 4.2: Summary of FSAN Inspection Activities For Year 2022**

S/N	FSAN ACTIVITIES	OUTCOME	NCZ	NEZ	NWZ	SSZ	SWZ	SEZ	LAGOS
1	Routine Inspections	Satisfactory	1,367	859	856	353	332	237	61
		Unsatisfactory	726	-	428	193	119	-	65
2	Special Inspections	Satisfactory	69	65	35	34	10	46	11
		Unsatisfactory	3	-	23	16	1	-	-
3	GMP Re-assessment	Satisfactory	42	46	28	19	34	10	29
		Unsatisfactory	2	1	-	2	-	-	1
4	Production Inspection	Satisfactory	492	149	620	533	835	361	576
		Unsatisfactory	21	9	18	172	7	43	8
5	Follow-up Inspection	Satisfactory	73	19	26	12	10	10	97
		Unsatisfactory	10	4	15	26	1	-	1
6	GMP Re-assessment (Renewal)	Satisfactory	396	123	471	194	556	148	321
		Unsatisfactory	5	1	9	60	4	-	1
7		Satisfactory	24	22	38	15	20	7	57

	Inspection of warehouses for Global Listing	Unsatisfactory	1	-	-	1	2	-	3
8	Cold Chain Facilities monitoring	Satisfactory	3	2	6	1	10	-	-
		Unsatisfactory	-	-	-	-	-	-	-

Figure 1 below shows a graphical presentation of the inspection activities conducted in the 6 Zones and Lagos in the period under review.

**Figure 4.1: Zonal Distribution of FSAN Inspection Activities In 2022**



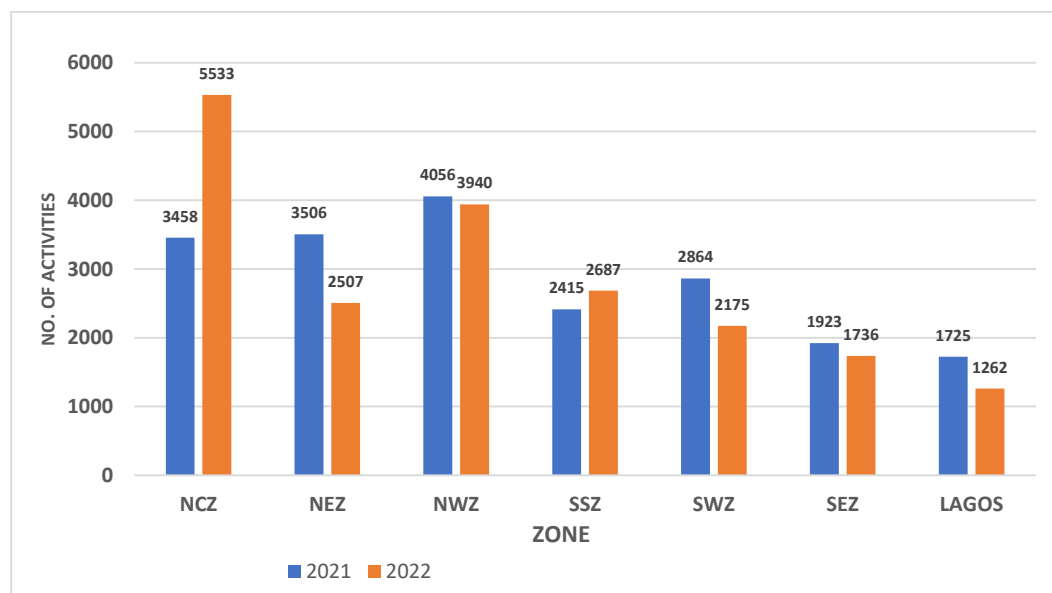
The number of routine (unannounced) inspections with unsatisfactory outcomes are relatively high, generally recording about half of the number of facilities visited. This indicates the critical role of unannounced inspections as a tool for bringing food manufacturers into post registration regulatory compliance with minimum Good Manufacturing Practice (GMP) requirements. The number of production inspections conducted are generally relatively low across the Zones and Lagos in comparison with figures for 2021 and this could be indicative of the pervasive downturn of business and economic activities nationally which also affected the food industry. The lower figures from the North-East Zone (NEZ) and South-East Zone (SEZ) may also be reflective of their peculiar security situations while that of the South-West Zone (SWZ) which are the highest is likely due to the concentration of food manufacturing companies in Ogun State.

**Table 4.3: Comparison of FSAN Regulatory Activities in 2022 With 2021**

ZONES	2021	2022
NCZ	3458	5533
NEZ	3506	2507

NWZ	4056	3940
SSZ	2415	2687
SWZ	2864	2175
SEZ	1923	1736
Lagos	1725	1262

**Figure 4.2: Comparison of FSAN Regulatory Activities In 2022 With 2021**



**Figure 4.2** shows a graphical representation of activities in 2022, compared with 2021 reflecting the general downturn of economic activities.

**Table 4.4: Number of cGMP And GHP Certificates Issued**

No. of Certificates Issued In 2022		Total
cGMP	GHP	
21	7	28

In the year 2022, the Directorate issued twenty-one (21) current Good Manufacturing Practice (cGMP) certificates to indigenous manufacturers and seven (7) Good Hygiene Practice (GHP) certificates to Supermarket Operators upon their request.

## 4.4 Other Activities of FSAN

### 4.4.1 Breast-Milk Substitute (BMS) Code Activities

The FSAN Directorate anchors the activities of the Agency on implementation of the International Code of Marketing of Breast-milk Substitutes (BMS).

In the year under review, the theme for the World Breastfeeding Week was “*Step-up for Breastfeeding: Educate and Support*”. The Directorate participated in the training/advocacy of some health professionals and Civil Society groups on the BMS Code. During the event, there was a public presentation of the National Strategy for the Implementation of the International Code of Marketing of Breast milk Substitutes in Nigeria (2021–2025) as well as other Code Regulatory publications (Training manual on the Code, NAFDAC BMS Code Monitoring Toolkit and Advocacy Briefs).

In line with the role of NAFDAC as the designated authority for BMS Code implementation, and the objectives of the National Strategy for the Implementation of the International Code of Marketing of Breast milk Substitutes in Nigeria, the FSAN Directorate as the Secretariat of NAFDAC BMS activities, anchored the inauguration and inaugural meeting of the re-constituted BMS Technical Committee in collaboration with UNICEF.

#### **4.4.2 Food Fortification with Micronutrients**

The FSAN Directorate, on behalf of the Agency, serves as the Secretariat of the National Fortification Alliance (NFA), a platform of relevant Ministries, Departments and Agencies (MDAs), industry, and development partners where issues on the national food fortification programme are deliberated upon. The NFA meets biannually and the FSAN Directorate successfully coordinated and participated in the two (2) meetings for 2022.

On behalf of the Agency, the FSAN Directorate conducted annual compliance monitoring at the retail/market level in fulfilment of her role in the National Fortification Alliance (NFA). The Directorate successfully organized and anchored the following:

- i. Three (3) day pre-survey training for FSAN field officers for the 2022 food fortification nationwide compliance monitoring from 14<sup>th</sup> to 16<sup>th</sup> September 2022.
- ii. Food fortification compliance monitoring across the 36 States of the country in the week beginning 19<sup>th</sup> September 2022.

#### **4.4.3 CODEX Activities**

The FSAN Directorate anchors the activities of Codex Alimentarius (Joint FAO/WHO Food Standards Programme) for the Agency in the development of international food standards regarding safe food and ensuring fair practices in food trade. The Director General (NAFDAC) is the Chair one of the sub-Committees of the National Codex Committee (NCC) - the National Codex Committee - General Purposes Technical Committee (NCC-GPTC) which prepares Nigeria’s delegates and develops national positions for promoting Nigeria’s interests in the international food standard setting arena. The Directorate successfully hosted relevant Ministries, Departments and Agencies (MDAs) and other members of the NCC to the four (4) NCC-GPTC meetings assigned to NAFDAC for year 2022:

- i. NCC-GPTC Preparatory meeting for the 52<sup>nd</sup> session of Codex Committee on Food Hygiene (CCFH) on 10<sup>th</sup> February 2022.
- ii. NCC-GPTC Preparatory meeting for the 15<sup>th</sup> session of Codex Committee on Contaminants in Foods (CCCF) on 21<sup>st</sup> April 2022.
- iii. NCC-GPTC Preparatory meeting for the 53<sup>rd</sup> session of Codex Committee on Pesticide Residues (CCPR) on 16<sup>th</sup> June 2022.
- iv. NCC-GPTC Preparatory meeting for the 53<sup>rd</sup> session of Codex Committee on Food Hygiene (CCFH) on 15<sup>th</sup> November 2022.

As a key stakeholder in Codex work for Nigeria, the Directorate participated actively in the revision of the NCC Procedural Manual (now in its 4<sup>th</sup> edition) and participated in the under-listed NCC programs to create awareness:

- i. Awareness and advocacy workshop for high level policy and decision makers and public presentation of National Codex Committee (NCC) Procedural Manual on 8th September 2022.
- ii. Training of NCC members on Risk Analysis and the revised Procedural Manual from 19th - 24th September 2022.

#### **4.4.4 Stakeholders Engagement**

Engagement with stakeholders is recognized as an important activity to improve service delivery. In the period under review, the FSAN Directorate engaged her stakeholders in the food, water and bakery sectors, leveraging on the interactions to deliver technical presentations on areas of the Directorate's regulatory activities covering GHP, GMP, newly integrated Inspection module for FSAN on the NAPAMS platform, product labelling and other aspects relevant to their operations.

- i. Engagement with members of the Association of Food, Beverage, and Tobacco Employers (AFBTE).
- ii. Hybrid meeting with members of the National Executive Committee of the Association of Master Bakers and Caterers of Nigeria.
- iii. Engagement and training of stakeholders in the packaged water sector.
- iv. Engagement and training of stakeholders in the bakery (bread) sector.
- v. Training of members of the Association of Table Water Producers (ATWAP).

#### **4.4.5 Regulations and Guidelines**

The Directorate developed the under-listed draft regulations:

- i. Draft Regulations on Restricting the Marketing of Unhealthy Foods and Non-alcoholic Beverages to Children
- ii. Draft Regulations on Malt drinks
- iii. Draft Regulations on Bread

#### **4.4.6 Other Nutrition Programmes**

The FSAN Directorate is engaged in the coordination and implementation of food and nutrition programmes and projects of government in collaboration with relevant Ministries, Departments and Agencies (MDAs), Development Partners (UNICEF, GAIN, Technoserve, Alive and Thrive, Helen Keller International, USAID Advancing Nutrition, Bill and Melinda Gates Foundation, etc.) and relevant non-governmental organizations and civil society organizations.

In the period under review, the Directorate participated actively in several Nutrition programmes and Committees including National Council on Nutrition, National Committee on Food and Nutrition, National Home-Grown School Feeding Programme, Committee on Spirit Drinks Regulation, Micronutrient Deficiency Control (MNDC), National Taskforce on Maternal, Infant and Young Child Nutrition, National Nutrition Technical Working Group (FMOH), ECOWAS Nutrition Forum, National Multisectoral World Breastfeeding Week Celebration Committee, National Technical Committee on the

Code of Marketing of Breast-milk Substitutes, Reproductive, Maternal, Newborn Child, Adolescent and Elderly Health plus Nutrition (RMNCAEH+N) Coordination platform, Front-of-Pack Nutrition Labelling (FOPNL) and Sodium Reduction Programme.

In a bid to contribute to the successful implementation of reducing the consumption of industrially produced trans fatty acids (iTfAs) in line with the REPLACE Action package of the World Health Organization, the FSAN Directorate in collaboration with development partners, Network for Health Equity and Development (NHED) and Trans Fat Free Nigeria Coalition successfully hosted the following workshops:

- i. Pre-Stakeholder's workshop on Reduction of Industrially produced Trans-Fatty Acids (iTfAs) in Nigeria's food supply on 21st June 2022 in Lagos.
- ii. Stakeholder's workshop on Reduction of Industrially produced Trans-Fatty Acids (iTfAs) in Nigeria's food supply on 8<sup>th</sup> September 2022 in Lagos.

#### **4.4.7 Training**

In furtherance of the Management's focus on capacity building for staff, the FSAN Directorate successfully organized and executed capacity building activities for her staff, with a blend of external training and monthly in-house hybrid training for FSAN staff nationwide using identified in-house resource persons. Below is a list of some of the training activities covered in 2022:

- i. Training on Food Safety System Certification 22000 (Clauses 1 – 5). In-house training.
- ii. Training on Food Safety System Certification 22000 (Clauses 6 – 10). In-house training.
- iii. HACCP Refresher course on 6<sup>th</sup> June 2022. (In-house training).
- iv. Food Safety and Value Chain on 6<sup>th</sup> June 2022. (In-house training).
- v. External 2-day virtual training of forty-five (45) FSAN staff to acquire basic Hazard Analysis and Critical Control Points (HACCP) certification from the International HACCP Alliance, USA.
- vi. Cascade training on basic HACCP Principles. In-house training.
- vii. Training on the International Code of Marketing of Breast Milk Substitutes (BMS) in commemoration of the World Breastfeeding Week.
- viii. Training on Food Fortification (methods, types of food vehicles and significance).
- ix. External 2-day virtual training of twenty-eight (28) FSAN staff on Food Fraud/Vulnerability Assessment and Critical Control Points (VACCP).

The FSAN Directorate organized and facilitated the signing of the Memorandum of Understanding (MoU) between NAFDAC and the Danish Veterinary and Food Administration (DVFA) for a Strategic Sector Cooperation (SSC) Project on cooperation in the field of food safety. The MoU Signing Ceremony took place in Lagos in June 2022 with the visiting Danish Team from Denmark. Under this collaboration, eight (8) FSAN staff were trained on different aspects of food safety and management in 2022.

## Chapter 5

### Drug Evaluation and Research (DER) Directorate

#### 5.0 Introduction

The Drug Evaluation and Research (DER) Directorate, under the leadership of Mrs. Ijeoma U. Nwankwo as Director, ensures the promotion and protection of public health in Nigeria by continually improving the quality of clinical research, product evaluation, document review and GMP inspections of manufacturing facilities for drugs, vaccines and other biologics, herbal medicines, nutraceuticals, cosmetics and medical devices. The Directorate is also committed to the development and continued improvement of its Quality Management System (QMS) to ensure a robust and effective Inspectorate that will guarantee quality, safe and efficacious pharmaceuticals including biologics, herbal medicines and nutraceuticals as well as quality cosmetics and medical devices are consumed by the Nigerian public.

The Directorate is structured into the following five Divisions as well as the Director's Office and the QMS Unit:

- Pharma Operations
- Herbal Medicines and Nutraceuticals
- Clinical Trials, Vaccines and Biologics
- Cosmetics and Medical Devices
- Pharmaceutical Compliance

#### 5.1 Summary of Regulatory Activities of the Directorate in 2022

The summary of all regulatory activities carried out nationwide in the year 2022 as they relate to the Divisions in the Directorate is as shown below:

• Clinical Trial, Vaccines & Biologics	-	525
• Herbal Medicines & Nutraceuticals	-	1,350
• Pharma Operations	-	876
• Pharma Compliance	-	1,557
• Cosmetics & Medical Devices	-	2,618
• Quality Management System	-	483
<b>Total</b>	-	<b>7,409</b>

**Table 5.1: Summary of Inspections carried out in 2022.**

S/N	Type of Inspection	Herbal Medicines & Nutraceuticals	Clinical Trials, Vaccines/ Biologics	Drugs	Cosmetics & Medical Devices	Total
1.	Routine Inspection	270	0	26	168	464
2.	Pre-Production Inspection (Drug companies only)	0	0	8	0	8
3.	Special Inspection	12	0	9	13	34

4.	Pre-Registration Inspection	0	0	10	0	<b>10</b>
5.	GMP Re-assessment Inspection	8	0	13	8	<b>29</b>
6.	Production Inspection	110	0	0	201	<b>311</b>
7.	Follow-up Inspection	6		10	18	<b>34</b>
8.	Inspection of Warehouses/Retail Outlets for Global Listing	0	0	0	41	<b>41</b> <b>for both renewal and fresh application</b>
9.	Global Listing Renewal	0	0	0	0	<b>0</b>
10.	Cold Chain Facilities Monitoring for Vaccines & Biologics	0	104	0	0	<b>104</b>
11.	Coding Inspection	0	0	23	0	<b>23</b>
12.	Surveillance Inspection	1		25	1	<b>27</b>
13.	Co-packaging Inspection	0	0	0	0	<b>0</b>
14.	GMP Assessment on change of factory site	0	0	0	1	<b>1</b>
15.	No. of Overseas GMP Inspections carried out	0	0	20	0	<b>20</b>
16.	MAS Coding Inspection	0	0	12	0	<b>12</b>
17.	No. of Investigation /For Cause (GMP & GCP) Inspections Conducted	0		1	0	<b>1</b>
18.	No. of GCP Inspections Conducted	0	3	0	0	<b>3</b>
	<b>Total</b>	<b>407</b>	<b>107</b>	<b>157</b>	<b>451</b>	<b>1,122</b>

**Table 5.2: Sanction Activities carried out by DER in 2022**

<b>Breakdown of Sanction Activities for the Year 2022</b>										
S/N	States	Warning of offenders	Compliance Directives (CDs)	Admin Charges on Offenders	Seizure/ withdrawal/ Mop Up of Products	Destruction of Products	Products Put on Hold	Outfits put on hold	Closure of Outfits	Total
1	Abia	0	0	0	0	0	0	0	0	<b>0</b>
2	Adamawa	0	0	2	0	0	0	0	0	<b>2</b>
3	Akwa-Ibom	0	0	0	0	0	0	0	0	<b>0</b>
4	Anambra	3	19	2	0	0	0	0	0	<b>24</b>
5	Bauchi	2	0	3	8	0	0	0	0	<b>13</b>
6	Benue	0	0	0	0	0	0	0	0	<b>0</b>
7	Borno	0	35	0	0	0	0	0	0	<b>35</b>
8	Bayelsa	0	0	0	0	0	0	0	0	<b>0</b>
9	Cross-river	0	0	0	0	0	0	0	0	<b>0</b>
10	Delta	0	0	0	0	0	0	0	0	<b>0</b>
11	Ebonyi	0	0	0	0	0	0	0	0	<b>0</b>
12	Edo	0	0	0	0	0	0	0	0	<b>0</b>

## Breakdown of Sanction Activities for the Year 2022

S/N	States	Warning of offenders	Compliance Directives (CDs)	Admin Charge s on Offend ers	Seizure/ withdrawa l/ Mop Up of Products	Destructi on of Products	Products Put on Hold	Outfits put on hold	Closure of Outfits	Total
13	Ekiti	0	0	0	0	0	0	0	0	0
14	Enugu	3	1	1	0	0	0	0	0	5
15	Gombe	8	4	2	4	0	0	0	0	18
16	Imo	0	4	0	0	0	0	0	0	4
17	Jigawa	0	0	0	0	0	0	0	0	0
18	Kaduna	4	9	0	8	0	0	0	0	21
19	Kano	1	0	6	5	0	0	0	0	12
20	Katsina	6	0	0	0	0	0	0	0	6
21	Kebbi	9	0	6	11	0	0	0	0	26
22	Kogi	0	0	0	0	0	0	0	0	0
23	Kwara	0	0	1	0	0	0	0	0	1
24	Lagos	1	7	0	0	0	0	0	0	8
25	Nasarawa	0	2	0	1	0	0	0	0	3
26	Niger	0	1	0	0	0	0	0	0	1
27	Ondo	9	3	0	0	0	0	0	0	12
28	Ogun	0	0	2	2	0	0	0	0	4
29	Osun	0	1	0	0	0	0	0	0	1
30	Oyo	0	0	1	0	0	0	4	0	5
31	Plateau	0	2	0	0	0	0	0	0	2
9132	Rivers	0	0	0	0	0	0	0	0	0
33	Sokoto	0	0	0	0	0	0	0	0	0
34	Taraba	0	0	0	0	0	0	0	0	0
35	Yobe	0	3	0	0	0	0	0	0	3
36	Zamfara	0	0	0	1	0	0	0	0	1
37	FCT	0	0	3	0	23	0	3	0	29
<b>Total</b>		<b>46</b>	<b>91</b>	<b>29</b>	<b>42</b>	<b>23</b>	<b>0</b>	<b>7</b>	<b>0</b>	<b>238</b>

### A. Issuance of Authority to Manufacture

Authority to manufacture products on different product lines in pharmaceutical manufacturing facilities was issued to seven (7) companies in 2022.

### B. Issuance of GMP Certificates

GMP Certificates were issued twenty-two (22) pharmaceutical companies whose operations were adjudged to comply with minimum GMP requirements in 2022.

### C. Summary of Inspection Reports

A review of One Thousand and Fifty-Six (1,056) reports of inspections conducted nationwide in 2022 as captured under the relevant product categories listed below:

S/N	Product Category	Number
1.	Drug	132

2.	Herbal & Nutraceuticals	431
3.	Cosmetics & Medical Devices	493
	<b>Total</b>	<b>1,056</b>

#### **D. Regulations, Guidelines and Other Quality Documents**

Twenty-one (21) operational SOPs were revised in the reporting period and these SOPs were approved, made effective by training the relevant personnel and deployed for use of staff. Deployment of relevant QMS forms for effective implementation of the SOPs within the directorate was also done.

One (1) guideline was finalized, approved, made effective through training of DER staff nationwide and the guideline has been hosted on the NAFDAC website.

#### **5.2 Activities of the Divisions**

##### **A. Pharmaceutical Operations Division**

###### **a. Inspections**

###### **i. Preliminary Inspection report review.**

Preliminary Inspection reports of two companies were received. The reports were reviewed, and the observations were shared with the inspectors from the state offices for capacity building.

###### **ii. Pre-Production Inspections**

Pre-Production Inspections were carried out in eight (8) (companies out of which seven (7) companies were found satisfactory while one company was adjudged unsatisfactory. Authority to manufacture pharmaceutical products on the relevant product lines were issued to the compliant companies while the facility that was operating below minimum NAFDAC GMP requirements was directed to raise a Corrective and Preventive Action (CAPA) plan.

###### **iii. Pre-Registration Inspection** was carried out in ten (10) companies All were found to be operating within minimum NAFDAC GMP requirements therefore their products were recommended for registration.

###### **iv. Routine inspections** were conducted in twenty-six (26) pharmaceutical manufacturing facilities nationwide in 2022.

###### **v. On-Site CAPA Effectiveness Verification Inspections:**

Following a satisfactory outcome of review of their CAPA plans, On-Site CAPA Effectiveness Verification Inspections were conducted in ten (10) facilities in 2022. Most of the facilities were seen to have made significant improvement and were operating within minimum GMP requirement and as such their applications were recommended for further processing.

###### **vi. GMP Re-Assessment Inspections** were conducted in thirteen (13) facilities in 2022 out of which twelve (12) facilities were found to be operating in compliance with requirements

###### **b. Review of CAPA Plans**

Forty-four (44) companies submitted electronic copies of their CAPA Plans for review during the reporting period. Ten (10) of the plans were eventually found satisfactory after the permitted rounds of review and these companies were scheduled for inspection.

**c. Review of Factory Designs and Layouts**

Fifty-one (51) companies submitted proposed facility layouts for review. Thirty-six (36) of the layouts were approved while the remaining are at various stages of review.

**d. Sampling of Products for Laboratory Analysis**

Products from eight (8) companies were sampled based on the SOP for Risk-based Sampling of regulated Products for Laboratory Analysis. All the products were recommended for laboratory analysis as they were rated high risk.

**e. Special Inspection**

Following a market surveillance report received on substandard Dexamethasone tablets in Nigeria, the three local companies mentioned in the report were visited. The tablet lines of these companies were placed on HOLD to enable effective investigation to be carried out on the affected product.

**B. Pharmaceutical Compliance Division**

**a. Foreign Facility Verification Applications**

A total number of Five Hundred and twelve (512) applications were received in the reporting period. Four hundred and sixteen (416) facilities were cleared for processing of the registration applications in lieu of foreign GMP Inspection. Some applications which were in process from 2021 were carried over and concluded in 2022.

**b. Issuance of Permit to Import Active Pharmaceutical Ingredient (API)**

A total of Sixty-Five (65) applications were received and processed for issuance of API permit in 2022 but permits were issued to Seventy-three (73) applicants within this period due to some applications that were carried over from 2021.

**c. Monitoring of Overprinting of NAFDAC Registration Number and Affixing MAS Labels**

Thirty-five (35) Companies made requests for over printing of NAFDAC registration number or affixing of Mobile Authentication Service (MAS) labels in 2022 and their requests were all granted after satisfactory monitoring of the activity.

**d. Other Activities**

- i. Participation in the training on inspection module of NAPAMS for integration of GMP inspection processes in the e-registration platform.

**C. Clinical Trial, Vaccines & Biologics Division**

**a. Clinical Trial Applications**

Thirty-eight (38) new clinical trial applications were received during the reporting period out of which twenty-two (22) were approved and sixteen (16) are still undergoing processing.

No applications for renewal of Clinical Trial Authorization were received while all eight (8) applications for protocol amendment received were approved. One (1) application for additional

site for an ongoing trial was received and approved while nine (9) Clinical Trial Progress Reports were also received and reviewed.

**b. Issuance of Import Permit for Investigational Medicinal Products (IMP).**

Twenty-four (24) applications for importation of Investigational Medicinal Products for conduct of clinical trials were received during the reporting period. Nineteen (19) were approved while, four (4) are still undergoing processing.

**c. Review of Clinical Trial Study Reports**

Thirty-two (32) clinical data submissions were received in 2022 out of which Seventeen (17) have been reviewed while review of the remaining are still ongoing.

**d. Cold Chain Storage Facility Inspections**

Good Storage Practice Inspections were conducted in Six (6) cold chain facilities for storage of vaccines and other biologics in Lagos State while a total of ninety-eight (98) of such inspections were conducted in other parts of the country in 2022.

**e. GCP Inspections**

Three (3) scheduled GCP Inspections was conducted within the period under consideration.

**f. Other Activities**

- i. Pre-submission meetings were held with four (4) organizations in 2022 to acquaint the applicants with expectations for submission of their clinical trial applications
- ii. Staff of the Division participated in the following programs held within the year:
  - o BVGH-NAFDAC training on regulatory oversight for Oncology clinical trials in Africa held virtually from 29<sup>th</sup> April 2022 to 24<sup>th</sup> June 2022.
  - o Participation and AVAREF Meeting, 20<sup>th</sup> to 24<sup>th</sup> June 2022 at Addis Ababa.
  - o Basic GCP Inspection training –Online 27<sup>th</sup> July- 11<sup>th</sup> August 2022.
  - o AVAREF Webinar: The DAC Assessment tools for clinical trials, 25<sup>th</sup> August 2022.
  - o Safety Monitoring in Clinical Trial – Kigali 30<sup>th</sup> August -31<sup>st</sup> August 2022.
  - o NAFDAC Green-book training 19<sup>th</sup> -20<sup>th</sup> September 2022.
  - o Clinical data assessment course 13<sup>th</sup> September 2022.
  - o AVAREF Webinar on Monkey pox: Epidemiology and Vaccine strategy – Online 28<sup>th</sup> September 2022

**D. Herbal Medicines & Nutraceuticals Division**

**a. Applications for Inspection of Facilities**

Four hundred and seven (407) applications were received for inspection of herbal medicines facilities nationwide out of which One Hundred and Sixty-One (161) of the applications were received from herbal medicine manufacturing companies in Lagos State in 2022. One hundred and ten (110) of the Lagos applications had satisfactory documentation and were scheduled for inspection.

**b. Review of Inspection reports from NAFDAC States offices**

A total of Ninety-seven reports of inspections conducted by NAFDAC State offices nationwide were received in 2022.

**c. Other Activities**

- i. Two (2) audit exercises were conducted in the Division during the period in view.
- ii. Virtual meetings were held with the African Organization for Standardization's Conformity Assessment Committee (ARSO CACO) on 1st and 24th May 2022 while the 28th ARSO General Assembly was held between 27th June and 1st July 2022 in which the Directorate representative was in attendance.
- iii. NAFDAC GMP Guidelines for Herbal Medicinal Products 2022 was developed in the Division during the period in view and was approved.

**E. Cosmetics and Medical Devices Division**

**a. Production Inspections**

Production Inspections were carried out in two hundred and one (201) companies nationwide

**b. Warehouse/Outlet Inspection for Global Listing of Cosmetics**

Warehouse/outlet inspections for global listing of cosmetic products were carried out in forty-one (41) Supermarkets for Good Hygiene/Good Storage practice

**c. Registration of Medical Devices**

Fifty-one (51) applications for registration of various medical devices such as condom, sanitary pads, sanitizers, lubricants, ultrasound scan gel and test kits were processed out of which twenty-nine (29) were found satisfactory and recommended for registration while thirty-two applications (32) were not recommended.

**d. Risk-based Sampling of Products for Laboratory Analysis**

Four hundred and forty-two (442) cosmetics products were recommended to Drug Registration and Regulatory Directorate for registration based on risk assessment and samples of the products were also sent to the laboratory for retention purposes.

**e. Document Review**

A total of One Hundred and Seventy (170) applications were received from cosmetics & Medical devices manufacturing facilities in Lagos state and One Hundred and Thirty-Eighty (138) GMP inspection reports from different Cosmetics & Medical devices manufacturing facilities were received from Zonal offices across the country. All the reports were reviewed and finalized for further processing.

**F. Quality Management System (QMS) and Other Activities Related To WHO-Global Benchmarking (WHO-GB) of NAFDAC**

- a. The QMS Unit coordinated the participation of the Directorate staff in the following trainings/workshops held within the Agency in 2022:
  - i. All trainings as approved in the Directorate Internal Training Plan.

- ii. Training on WHO Terms of Reference (TOR) for Re-benchmarking assessment of the Agency's regulatory functions by WHO-GB Team.
  - iii. Virtual training on Clinical Trial Protocol Evaluation and Regulation.
  - iv. NAFDAC Drug Information and Greenbook Project training.
  - v. Data Entry Session for NAFDAC Drug Information and Greenbook Project.
  - vi. NAFDAC Train-the-Trainers GMP Training
  - vii. Virtual GCP trainings for NAFDAC staff nationwide.
  - viii. Training on Inspection Module of NAPAMS.
  - ix. Refresher training on Risk categorization and Recategorization of facilities focusing on the PIC/s risk- based inspection model on 4<sup>th</sup> August 2022.
  - x. In-house training on revised SOP for risk-based inspection planning for pharmaceutical manufacturing facilities for DER staff nationwide by the Directorate on 22<sup>nd</sup> August 2022.
  - xi. Basic GMPI virtual training (Batch 1- 2022) conducted by PRS Directorate in collaboration with relevant technical directorates on 5<sup>th</sup> – 16<sup>th</sup> September 2022.
- b.** The QMS Unit conducted the following activities aimed at maintaining the established quality management system in the Directorate during the reporting period:
- i. Development and approval of the Quality Objectives for the Directorate for year 2022.
  - ii. Conduct of the Annual Directorate and Management Review meetings.
  - iii. Conduct of Divisional Self-Assessments and Directorate Internal Audit.
  - iv. Review and approval of all obsolete Directorate operational SOPs
  - v. Distribution of controlled copies of approved operational SOPs and withdrawal of obsolete copies of operational SOPs.
  - vi. Coordination of the conduct of the Divisional Self-Assessments, QMS Internal Audit, follow-up audit, as well as monitoring of closeout of all non-conformances for the Directorate.
  - vii. Participation in Risk Management certification training for NAFDAC Quality Team members.
  - viii. Compiled the Directorate input into the NAFDAC 2022 Management Review Meeting.
  - ix. Participation in the ISO 9001 Recertification Audit of the Agency
- c.** The Unit made the following submissions on behalf of the Directorate within the reporting period:
- i. Submission of the Directorate nominees for the Private Sector Sensitization and Awareness Workshop.
  - ii. Submission of the Directorate Nominees for the USP PQM+ Training on medical devices
  - iii. Compilation and submission of list of recommended companies for third party audit to DG-NAFDAC.
  - iv. Submission of the Directorate Nominee for the NAFDAC Exhibition stand at the 34<sup>th</sup> AGM and Scientific Symposium of West African Postgraduate College of Pharmacists.
  - v. Compilation and submission of the Directorate activities for the quarterly Governing Council meetings.
  - vi. Nomination of DER Participants in the Biomanufacturing Workshop held in South Africa.
  - vii. Submission of recommendation on NAFDAC PIC/S Accession program to DG-NAFDAC.
  - viii. Nomination of the Directorate participant at the 95<sup>th</sup> Annual National Conference of the Pharmaceutical Society of Nigeria.

- d. The following activities related to WHO Global Benchmarking were carried out by the Directorate representative on the GBT Team in 2022:
- i. Development of the Agency's GBT Workplan for 2022.
  - ii. Participation in meeting with the DG on the Performance Evaluation Program (PEP).
  - iii. Participation in the preparation and review of the manuscript for the NAFDAC Maturity Level 3 success story for publication.
  - iv. Provision of technical support to Autorite Ivoirienne de Regulation Pharmaceutique (AIRP), Cote D'Ivoire on the pathway for GBT-assessment.
  - v. Participation in the meeting for the GBT self-assessment for the Lot release (LR) function, as well as other GBT meetings
  - vi. Participation in the WHO training workshop for WHO-GBT assessors held in Istanbul, Turkey.

### **5.3 Meetings**

- a. The Directorate held her annual Directorate meeting & Management Review Meeting at NAFDAC Isolo Auditorium on 16<sup>th</sup> February 2022.
- b. The Directorate staff participated in WHO GBT benchmarking program that assess the Agency's maturity level from 21<sup>st</sup> -25<sup>th</sup> February 2022.
- c. The Directorate held a meeting on 1<sup>st</sup> March 2022 and the highlights of the meeting included requirements for borderline products, review of timelines for GMP Inspection report writing and development of annexures to GMP Guidelines.
- d. Participated in a meeting titled provision of level of implementation of action plan with verifiable data as objective evidence to support QMS submissions in NAFDAC.
- e. The Directorate represented the Agency at the following programs, including making presentations on behalf of the Agency:
  - i. Participation in meeting between the DG-NAFDAC and representatives of Innovative Biotech on Local Vaccine Manufacturing.
  - ii. Presentation on Introductory course for Biologics Development and Manufacturing to the Regulatory Task Force of Partnership for African Vaccine Manufacturing (PAVM).
  - iii. Represented the DG-NAFDAC at the meeting of the Technical Working Group for Vaccine Manufacturing in Nigeria held in Abuja.
  - iv. Represented the DG-NAFDAC at the workshop on Local Vaccines manufacturing in Abuja 25<sup>th</sup> – 26<sup>th</sup> August 2022
  - v. Presentation on NAFDAC Preparedness for Regulation of Vaccine manufacturing at the Technical Session with representatives of KENUP Foundation held in Abuja.
  - vi. Presentation on DER functions and activities at the Induction Program for newly employed staff.

### **5.4 External Training/Workshops:**

Staff of the Directorate participated in the following external training/workshops in 2022:

- i. African Health Summit organized by IQVIA held in Kenya on the 16<sup>th</sup> & 17<sup>th</sup> November 2022.
- ii. One day training program organized by the Code of Conduct Bureau, held at NAFDAC Central Laboratory Complex Auditorium, Oshodi, Lagos on 10<sup>th</sup> February 2022.
- iii. Introductory Course for Biologics Development and Manufacturing organized by International Vaccine Institute (IVI) in S. Korea in July 2022.
- iv. 2022 Introductory Course for Biologics Development and Manufacturing (Online Course) organized by International Vaccine Institute (IVI) S. Korea.
- v. Five weeks online and two weeks in-person session of 2022/2023 AIG Public leaders' program. Participants took part in leadership skill, conceptual framework and practical tool application

- capacity building program in order to improve their competence on effective leadership skill for use in their organizations, department and team operations etc.
- vi. AVAREF Webinar on COVID-19 Boosters overview and SAGE recommendations and Covid-19 Boosters data requirements and regulatory considerations held 12th April 2022.
  - vii. Virtual training on guidance document for Master Data Attributes held on 19th April 2022. This guidance document was used to provide a platform for uniformity on the list of master data attributes the MAHs will be required to share with the Agency for the phased implementation of pharmaceutical traceability in Nigeria.
  - viii. WHO AFRO and EMRO: Sensitization workshop for the dissemination, adoption and adaptation of four AMDF Guidelines on regulation of Medical Devices including in vitro diagnostics held on the 17th and 18th May 2022.
  - ix. Virtual workshop on Documentation Format Requirements and Principles for Assessment for WHO Prequalification and Emergency Use Listing of Vaccines.
  - x. AVAREF webinar on Next Generation COVID-19 vaccines and Covid-19 Therapeutics held on 29 June 2022.
  - xi. Self-paced online training on GMP Manufacturing and Characterization of Vaccines for Human Use organized by the Education Unit of The United States Pharmacopeia (USP). It was 4-hour self-paced training which was followed by a Q&A training session on 30th June 2022.
  - xii. Introductory Course for Standard Practices organized by International Vaccine Institute (IVI) and held in S. Korea in October 2022.
  - xiii. RCORE Advanced training on Clinical Trial held in Ghana from 29th November -10th December 2022.
  - xiv. Impact Summit organised by Xcene Research held in Lagos on 1st & 2nd December 2022.
  - xv. Virtual cGMP Training Marathon for Vaccine Manufacturing: Sustaining a GMP-compliant environment in November 2022.

## Chapter 6

### Drug Registration and Regulatory Affairs (DR&RA) Directorate

#### 6.0 Introduction

The Drug R&R Directorate is one of the Directorates of the Agency, whose functions are anchored on the provisions of the Drugs and Related Products (Registration, Etc) Decree No. 19 of 1993 as amended vis:

- Registration of drugs, cosmetics, medical devices, chemicals, detergents.
- Other functions are as follows:
  - i. Formulating, updating, compiling and periodic review of standard specifications, regulations and guidelines for the production, importation, exportation, sale and distribution of drugs, cosmetics, medical devices and chemicals.
  - ii. Approval and control of advertisement of drugs, cosmetics, medical devices, and chemicals to ensure that advertisements are not exaggerated, deceptive or detrimental to the consumer.
- Monitoring of advertisement to ensure compliance and identify illegal advertisements

#### 6.1 Divisions and Units of the Directorate

The Directorate now has Five (5) Divisions with several Units to enable it carry out its regulatory functions:

1. Drugs Registration Division
2. Biologics, Vaccines and Medical Devices Division (BVM)
3. Drug Adverts Control Division (AC)
4. Animal Health Products and Finished Chemicals (AHFC)
5. Cosmetics Division

**The Director's office** is made up:

- i. Liaison Offices to the Director (LOD Drug)
- ii. Post Registration Documentation /NAFDAC Registered Products Automated Database (PRD/NARPAD)
- iii. Global Listing Office
- iv. Technical Services which comprises:
  - Regulations
  - Quality Management System
  - Dossier Review Team

#### 6.2 Highlights of Activities:

- Participation of Drug R&R Officer at the Virtual Training Program of BIO Ventures for Global Health (BVGH)/NAFDAC: Clinical Trial Protocol Evaluation & Regulation held 31st July, 2022.
- Drug Registration & Regulatory Affairs (Drug R&R) August Monthly Meeting held 9th August 2022.
- Training on Screening of Product Dossiers for Drug R&R Dossier Assessors held 16<sup>th</sup> August, 2022 at NAFDAC Auditorium Isolo, Lagos.
- Step-down Training of all DR&R Regulatory officers on “Science Communication in Theory and Practice” and training on Reviewed SOP on NAPAMS MANAGEMENT held 31st August, 2022 at Drug R&R General Office, Isolo, Lagos.
- Training on Fundamentals & Identification of Features of Critical Process Parameters (CPQ), Certificate of Suitability (CEP) & Batch Manufacturing Report (BMR) for Drug R&R Dossier Assessors held 31st August, 2022 at the NAFDAC Auditorium Isolo, Lagos.
- Training on Fundamentals of Dossier Assessment and Report Writing for Drug R&R Dossier Assessors held 7th September 2022 at the NAFDAC Auditorium Isolo, Lagos.
- Virtual Participation at the Russia-Nigeria Bilateral Trade Relations: Prospects and current opportunities held 12th September 2022.

- Drug R&R September Monthly Meeting held 14th September 2022 at Drug R&R General Office Isolo, Lagos.
- Training on Assessment of Stability Data for Drug R&R Dossier Assessors held 28th September 2022 at NAFDAC Auditorium, Isolo, Lagos.
- Training of all NAFDAC Inspection Officers on NAPAMS Inspection Module held 5<sup>th</sup> October 2022 at NAFDAC Auditorium, Isolo, Lagos.
- Participation at the Made in Nigeria Cosmetics Expo (MINCE) held between 1st to 3rd October 2022 at Oregun, Lagos.
- Drug Registration & Regulatory Affairs (Drug R&R) August Monthly Meeting held 11th October 2022.
- Drug R&R November Monthly Meeting held 8th November 2022 at Drug R&R General Office Isolo, Lagos.
- Step down training on Medical Devices Quality Management System and Regulatory Compliance held from 8<sup>th</sup> to 11<sup>th</sup> November, 2022 at the HOD/BVM office, Isolo, Lagos.
- Training on Analytical Method Validation -Dossier Requirement for Drug R&R Dossier Assessors held 9<sup>th</sup> November 2022 at NAFDAC Auditorium Isolo, Lagos.
- Participation at the UNITAID Industrial Engagement -Presentation on NAFDAC ML3 Journey 10<sup>th</sup> to 12<sup>th</sup> November, 2022 held at Cape Town, South Africa.
- Training on concept of Public Assessment Report for Drug R&R Dossier Assessors held 16<sup>th</sup> November 2022 at NAFDAC Auditorium Isolo, Lagos.
- Participation at the WHO PQ Assessment Meeting held 21<sup>st</sup> to 25<sup>th</sup> November 2022 at Copenhagen, Denmark.
- Participation at the NIPRD/WAPCP Workshop on Local Manufacturing of Active Pharmaceutical Ingredient (API) - Presentation on Regulatory Consideration and Licensing held 29<sup>th</sup> to 30<sup>th</sup> November 2022 at Abuja.
- Participation at the West African Beauty Fair Show Panelists held 29<sup>th</sup> November to 1<sup>st</sup> December 2022.
- Training on Important Aspects to consider during Dossier Review Dissolution Requirement and Where commitments are required for Drug R&R Dossier Assessors held 30<sup>th</sup> November, 2022 at NAFDAC Auditorium Isolo, Lagos.
- Participation at the African Medical Devices Forum (AMDF) Technical Committee Meeting held 6<sup>th</sup> to 7<sup>th</sup> December 2022 in Accra, Ghana.
- Participation at the Evaluation of Medical Products (EMP) Technical Committee Meeting held 6<sup>th</sup> to 7<sup>th</sup> December 2022 in Accra, Ghana.
- Global VAX Vaccine Manufacturing Workshop - Building A Sustainable & Competent African Workforce. Promoting the Quality of Medicines Plus (PQM+) held 6<sup>th</sup> to 9<sup>th</sup> December, 2022 at Cape Town, South Africa.
- Training on Specification, features of Specifications, Dissolution & review of Dossier for Drug R&R Dossier Assessors held 7<sup>th</sup> December, 2022 at NAFDAC Auditorium Isolo, Lagos.
- Participation at the 10th Annual meeting on the Collaborative Registration Procedure held 12<sup>th</sup> to 15<sup>th</sup> December, 2022 at Istanbul, Turkey.

**(A) Drugs Registration Divisions**

The Directorate carried out the registration of regulated products which are summarized below:

The total number of products Drugs and other products registered in 2022 was four thousand and twenty two (4,022):

**Table 6.1: Comparative Analysis of Registered NAFDAC Regulated Products 2021-2022**

NAFDAC regulated products	January - December	
	2021	2022
Drugs and related products	6,779	4,022

This represents a 40.67% decrease over the figures of the same period in year 2021 (Six Thousand, Seven Hundred and Seventy-Nine (6,779) products).

***Drugs and Related Products Registration Divisions***

A total of Four Thousand and Twenty-Two (4,022) drugs, and related products were registered:

**Table 6.2: Summary of the Activities of Drug and Related Products Registration Divisions**

Products		Forms purchased	Completed forms received	Products presented for approval	Products approved	Products rejected
Human drugs	Imported	e-reg	2,529	702	702	0
	Local	e-reg	393	387	356	31
Medical devices	Imported	e-reg	479	276	276	0
	Local	e-reg	74	80	80	0
Vaccines / biologicals	Imported	e-reg	119	63	63	0
	Local	e-reg	0	0	0	0
Cosmetics	Imported	e-reg	0	217	217	0
	Local	e-reg	0	1,228	1,228	0
Herbal drugs	Imported	e-reg	1,103	509	508	1
	Local	e-reg	509	230	230	0
Pesticides	Imported	e-reg	234	247	244	3
	Local	e-reg	109	77	77	0
Veterinary drugs	Imported	e-reg	164	258	258	0
	Local	e-reg	55	72	72	0
Finished Chemical	Imported	e-reg	0	0	0	0
	Local	e-reg	0	0	0	0
<b>Total</b>		$\Sigma$ (e-reg)	-	-	<b>0</b>	-

**(iv) Liaison Office to the Director (Drugs and related products)**

- Four Thousand, One Hundred and Four (4,104) drugs and related products applications were received and sent to the Legal Unit for perusal.
- Seven Thousand, Six Hundred and Eighty-Four (7,684) applications of drugs and related products were processed and sent to relevant Divisions.

**Table 6.3: Comparative Analysis of Post Registration Documentation / NARPAD Activities 2021-2022**

	<b>2021</b>	<b>2022</b>
<b>1. No. of Certificates Prepared</b>	<b>8,924</b>	<b>2,232</b>
<b>Breakdown</b>		
i. Drug	906	189
ii. Cosmetics	817	211
iii. Packaged water	3,377	1,007
iv. Food	1,278	380
v. Medical devices	251	0
vi. Listing food	1,660	472
vii. Pesticides	178	0
viii. Veterinary medicines	123	0
ix. Herbal medicines	234	0
x. Correction & omission	100	18
<b>2. No. of Products keyed in the NARPAD (NAFDAC database)</b>	<b>6,901</b>	<b>3,106</b>
<b>3. No. of Certificates issued</b>	<b>3,029</b>	<b>2,316</b>
i. Drug	673	669
ii. Food	548	450
iii. Cosmetics	382	231
iv. Pesticides	129	54
v. Veterinary drugs	193	116
vi. Biologicals & Vaccines and Medical devices	127	62
vii. Herbal medicines	117	103
viii. Packaged water	771	587

**(vi) Post Registration Documentation / NAFDAC Registered Products Automated Database (PRD)/NARPAD**

This Unit is charged with the responsibility of preparing Registration and Listing Certificates of products that have successfully completed the registration process. It is also charged with the responsibility of keying in registered products into NAFDAC Registered Products Automated Database (NARPAD).

- Two Thousand, Two Hundred and Thirty-Two (2,232) certificates were prepared in the period under review. Breakdown: Drug (189), Cosmetic products (211), packaged water (1,007), Food products (807), Medical devices (57), Herbal (51), Veterinary products (83), Pesticides (68) and correction & omissions (91).
- Three thousand, one hundred and six (3,106) products were keyed into the NAFDAC Registered Products Automated Database (NARPAD).

- Two Thousand, Three Hundred and Sixteen (2,316) Registration and Listing certificates were issued in the period under review. Breakdown: drug (669), food (450), cosmetics (231), pesticides (54), veterinary drugs (116), medical devices and biological & vaccines (62), herbal (103) and water (587).

## Chapter 7

### Food Registration and Regulatory Affairs (FR&RA) Directorate

#### 7.0 Introduction

The Food R&R Directorate is one of the Directorates of the Agency whose functions are anchored on the provisions of the Food, Drugs and Related Products (Registration, etc.) ACT Cap F33 Laws of the Federation of Nigeria (LFN) 2004 viz:

- Registration of food and packaged water. Other functions are as follows:
- Formulating, updating, compiling and periodic review of Regulations and Guidelines for the production, importation, exportation, sale and distribution of food and bottled water
- Approval and control of advertisements of food, and packaged water to ensure that advertisements are not exaggerated, deceptive or detrimental to the consumer.
- Monitoring of advertisements to ensure compliance.

#### 7.1 Divisions and Units of FR&R Directorate

The Directorate comprises the following Divisions and Units:

**1. Food Registration Division (FRD):**

- Unit I (Lagos & Oyo States)
- Unit II (South-South, South-East & Ogun State)
- Unit III (North-Central, North-East, North-West & Other South-West States)

**2. Imported Food and Feeds Division (IF&F):**

- Imported Food Unit I (Europe & America)
- Imported Food Unit II (Asia, Africa & Oceania)
- Feeds (Imported & Made in Nigeria)

**3. Food Regulations Division (FReD)**

- Regulations Unit
- QMS Unit

**4. Advertisements Control Division (AC):**

- Advert Registration Unit
- Advert Monitoring & Control Unit

**5. Packaged Water Division (PWD):**

**6. The Director's Office consists of:**

- Liaison Office of the Director (LOD)
- Global Listing of Supermarket Items & Fast Foods

#### 7.2 Major Achievements and Highlights:

1. The Directorate got a new Director in the person of Mrs. Abayomi Bolaji *mni* in September 2022.

2. All food product applications are now registered via the NAPAMS platform.
3. A team of NAFDAC Technical Committee on Food Regulations reviewed the following eight (8) draft Regulations emanating from the Veterinary Medicines and Allied Products (VMAP) Directorate:
  - i. Food Products Registration Regulations
  - ii. Poultry Starter Feed Regulations
  - iii. Poultry Grower Feed Regulations
  - iv. Poultry Finisher Feed Regulations
  - v. Poultry Layer Feed Regulations
  - vi. Large Ruminant Feed Regulations
  - vii. Catfish Feed Registration Regulations
  - viii. Tilapia Feed Regulations
4. The Water Unit which was hitherto under the Director's office was constituted into a Division in October 2022 and provided with new office space.
5. Engaged in the statutory monthly SUBFDRC and FDRC product approval meetings throughout the year.
6. Internal Audit of the Directorate was held in August 2022.
7. The Directorate held consultative meetings with stakeholders on registration issues.
8. The following trainings were undertaken to strengthen the capacity of staff in 2022:
  - a. Directorate Quality Management System Meetings
  - b. Basic GMP Training Held on 5th & 26th September 2022.
  - c. Vetting of claims on Food Advertisement.
  - d. Training on the drafting of Food Regulations.
  - e. Vetting of Key Parameters in Food labels
  - f. Developing and Reporting Key Performance Indicators.
  - g. Healthy Lifestyle at the Work Place.

### 7.3 Major Challenges:

The functions of the Directorate are hampered by the following significant challenges:

1. The Directorate is grossly short staffed
2. Inadequate office space
3. NAFDAC internet access not available in the Portakabin
4. Inadequate office equipment, e.g. laptops and photocopiers/scanners.

#### Advert Control Division: Dec. 2022

S/No	Products/Activities	Food		Water	Total
		Local	Imp.	Local	
1	No of Applications brought forward				350
	No of Applications received for Advert				92
	Total Number of Applications available for processing				0

			Processed				432
			No.Outstanding				27
2	Products Advert Monitored		Television				112
			Out-Of-Home				229
			Press				4
			Radio				175
			Medical Journal				0
			On-Line				85
3	No. of Adverts Presented for FDRC						415
a	Approved						415
b	Not Approved						0
4	Breakdown of Approved Advert		New Application				400
			Re-validations				17
5	Miscellaneous Service		Approval				0
			Amendment				0
			Payment Advice				450
			Unauthorised/Admin Charge				6
			Consultative Meeting				14
	Admin Charges						0

#### Summary of R&R Food Directorate Activities for the Year 2022

No. of Product Registered			
	Food	Water	Feed
Imported	649	0	48
Made in Nigeria Foods	2082	2467	206
<b>Total</b>	<b>2,731</b>	<b>2,467</b>	<b>254</b>
Remarks	A total of 541 Food products were registered within the period.		

5,452

#### LOD MONTHLY REPORT FOR THE MONTH OF DEC. 2022

Applications	Imported Products	Local Products	
		Food	Water
New Applications	499	1,447	2,098
Renewals	115	552	459
Pack Size Extensions	0	0	0
Additional Variants	0	0	0
Change in Formulation	0	0	0
Global Listing	0	0	0
Applications Processed for Permit	85	0	280
Applications Fully Processed	638	1,888	1,812
Applications Processed with Compliance	0	0	0
Transfer of License	0	0	0
Additional Packaging Material	0	0	0
Additional Source	0	0	0

Change of Name	0	0	0
Change of Agencyship	0	0	0
Change In Label Design	0	0	0
Admin Fine for Late Renewal Issued	0	0	0

Activities of Regulatory Affairs Division (Dec. 2022 )

Activities	Number	
<b>No of Regulations Sold</b>	0	
No of Drafted regulation	In Process	45
	Completed	6
No of Drafted Nigerian Industrial Standards (SON)		3
No of Gazetted Regulations		0
No of Developed SOP's		0
No of Stakeholders meeting		0
No of regulations being considered at Standards and Regulations Committee		83
No of Standards & Reg Comm. Meeting		1
No of Products Vetted	Satisfactory	2
	unsatisfactory	0
No of Meetings/Training attended		14
No of Drafted Guidelines		0
No of Technical/Regulatory inputs made		12
No of Memo treated		9

Activities of Food Registration Division Dec. 2022

S/No	Process	Food (Local)	Food (Imp)	Feed (Imp)	Feed Local	Water	Total
1	No of Application Forms brought forward	0	0	0	0	1590	0
2	Number of application Forms received	0	1041	41	284	2336	497
3	Total Number of application Forms available for processing	#VALUE!	1041	41	284	1229	497
4	Total Number of application Forms Treated	892	932	41	254	1687	361
5	No of Application Forms pending as backlog	0	0	0	0	0	0
6	No of products sent to lab	0	722	40	1	#VALUE!	#VALUE!
7	No of laboratory reports received	667	767	43	160	2512	4149
a	satisfactory	649	767	43	160	2315	3934
b	unsatisfactory*	18	0	0	0	248	3
8	No of Administrative Approval	72	2	0	2	58	8
9	No of Fast Track Approval issued	141	0	0	5	20	16
10	No of Import Permit issued	0	553	25	0	0	578
11	No of GMP reports received	566	636	19	204	2533	3958
a	satisfactory	566	626	19	204	2209	3624
a	unsatisfactory*	0	0	0	0	109	109
12	No of Products Presented for Approval (FDRC)	2154	577	37	217	2671	5656
a	Approved	2154	577	34	217	#VALUE!	#VALUE!

b		Non-Approved*	0	0	0	0	0	0
13	Full Registration		1479	339	20	126	637	2601
14	Listing		325	0	#####	41	1426	#VALUE!
15	Renewal		108	159	7	41	319	634
16	No of Approved Pack Size Extensions		384	0	0	0	6	390
17	No of Approved Change in Agencyship		0	0	0	0	1	1
18	Change in Product Name		70	0	0	0	7	77
19	Change in label design		165	1	0	0	4	170
20	Additional Manufacturing Source		24	11	0	0	9	44
21	Change in Manufacturing Site		18	5	0	0	2	25
22	No of Compliance Directive		884	0	0	0	0	884
23	No of change in packaging design		0	0	0	0	1	1
24	No of additional packaging materials		0	0	0	0	1	1
25	No of change in formulation		0	4	0	0	0	4
26	Promotional labels design		81	0	0	0	0	81
27	Additional Variant		0	65	0	0	0	65
28	Revenue							

## Chapter 8

### Ports Inspection Directorate (PID)

#### 8.0 Introduction:

In the year under review, the Ports Inspection Directorate was responsible for ensuring that NAFDAC regulated products imported into or exported out of Nigeria met requisite standards of safety and right quality. The mandate of the directorate amongst other things embraced the following statutory functions:

- To regulate and control the importation of drug, food, medical devices, cosmetics, detergents, drinks, and bottled water.
- Screening of import documents before the issuance of pre-release stamps.
- To undertake the inspection of imported food, drugs, medical devices, cosmetics, chemicals, detergents, drinks, and bottled water at ports of entry before release.
- To control the exportation of regulated products and issue quality certification for such regulated products.

The activities of the Directorate were carried out by the various Divisions, Ports, land border and Outstation offices.

#### 8.1 Divisions:

There are Six (6) divisions namely:

1. Director's Office Division: This division consists of two mainly units, E-clearance and Intelligence and monitoring.
2. Port Chemical, Cosmetics and Medical Devices Division (CCMD): comprise of two units namely Chemical unit and Cosmetic & medical devices unit.
3. Port Drug Division consist of two units, Drug Endorsement & Sample reception/ Drug store unit.
4. New Technologies/Port Port-Clearance
5. Port Food Division
6. Export Division

#### 8.2 Port Offices:

There are 10 NAFDAC Port offices across the Country. Six (6) Seaports and four (4) Airports. The six (6) seaports offices are in Lagos namely Apapa, Lekki free trade zone, Tincan, Kirikiri Lighter Terminal, Lilypond, Ikorodu and the four (4) airports are Murtala Mohammed International Airport, Lagos, Aminu International Airport, Kano, Nnamdi Azikiwe International Airport, Abuja, and Akanu-Ibiam International Airport, Enugu.

#### 8.3 Outstation Offices:

PID has the following as outstations office; Port-Harcourt, Warri, Calabar, Kaduna, Kano, Abuja, Enugu, Onitsha.

#### 8.4 Land borders:

NAFDAC PID covers the underlisted borders; Idiroko, Seme, Kamba, Jibiya, Maigatari and Illela.

## 8.5 Staff Report

### Staff Strength

PID has a total of two hundred and forty-two (242) staff members in thirteen (13) locations. Below is a Table showing the staff distribution and composition of PID officers across various PID offices and locations.

**Table 8.1: PID Staff Distribution by Office Location 2022**

Location	Lagos	Abuja	Calabar	Warri	Kano	P/H	Enugu	Kamba	Jibiya	Illela	Onitsha	Kaduna	Maigatari	Total
Staff Strength	138	16	7	9	19	25	3	3	5	5	6	3	3	242

### 8.5 Activities Summary

#### A. Transaction Summary

In 2022, the activities of PID involved the processing of port clearance transactions which generated revenue from inspection charges, analysis, and radiation charges as well as administrative approvals and charges imposed on violations. The following are noteworthy:

- A total of **207,866,595.9** quantity in Metric Tons worth **₦15,809,334,985,171.00** was imported in the year under review.
- In the year under review, **57,392 SGD** were treated against **75,648 SGD** treated in the year 2021. It was revealed that **24%** decrease in the number treated in year 2022.
- A total of Two Thousand, Three Hundred and Seventy-Six (**2376**) violations were treated accounting for about 48% decrease to the Four Thousand, Five Hundred and Thirty-One (**4531**) cases reported in 2021.
- Statistics of the reports are shown in Table 3.

**Table 8.2 Transaction Summary Table for 2022**

PID Office Locations	No. of Transactions
Lagos Ports	50,079
Land Borders	420
Outstations	6,893
Director's Office	819
Export	-
<b>Totals</b>	<b>57,392</b>

#### B. Treated SGDs

A total of Fifty thousand and Seventy-Nine (**50,079**) SGDs were treated from Lagos office, four hundred and Twenty (**420**) from Land borders and Six thousand, Eight hundred and Ninety Three (**6,893**) from Outstation offices which

made up a total Fifty Seven thousand, Three hundred and Ninety Three (**57,392**) treated SGDs in the year under review.

**Table 8.3: SGDs Treated in 2022**

Location	SGDs Treated
Lagos Office	50,079
Land borders	420
Outstations	6,893
<b>Total</b>	<b>57,392</b>

### C. Violations

The most reported types of violations in the year under review were non-endorsement (29.5%), Labeling lapses (21%), unapproved pictorial (21%), No CRIA (10%), No permit (10.9%), Importation Above Approved Quantity (1.6%) and mobile authentication service (1%).

Table 10 below gives the statistics report of types of violations.

**Table 8.4: Violation Types**

Violation Types Reported	Total Cases
Change of Source	8
Concealment	8
Importation above Approved Quantity	39
No CRIA	249
Labelling Lapse	521
Expired Certificate	15
No Permit	260
Non-Endorsement	700
Others (Specify in Remark)	6
Unapproved Pictorials	518
Unregistered Pack Size	3
Unregistered Products (Excl. Medicines)	15
Unauthorized labelled packaging materials	2
Unauthorized parallel importation	2
Mobile Authentication service	30
<b>Total</b>	<b>2,376</b>

### D. Quantity of Imported Items

A total of 207,866,595.9 Quantity in Metric Tons and 15,809,334,985,171 Cost Insurance Freight were treated in the year under review.

**Table 8.5: Quantity Metric Ton (MT) and Cost Insurance Freight (CIF)**

Product Class	Quantity (MT)	CIF Value
Agarbatties	87.94	1,192,198,537.63
Agrochemicals	594,187.32	202,318,867,537.52

Autocare	88,455.80	9,182,104,124.20
Baby Foods	8,193.42	15,304,932,311.20
Bakery Wares	2,287.17	45,813,655,435.80
Beverages	172,863.98	688,827,666,241.55
Cereals	23,086.96	4,732,584,473.08
Cereals & Cereal Products	3,243,701.05	609,916,741,489.84
Composite Foods	11,949.90	50,683,543,318.00
Confectionery	26,504.26	14,755,045,773.83
Controlled Solvents	460,594.69	61,406,650,204.46
Cosmetics & Household	1,407.09	1,685,880,992.38
Dairy Products	134,473,044.72	1,275,027,947,033.85
Eggs & Egg Products	0.01	4,055.00
Fats & Oils	660,341.42	652,898,705,290.53
Finished Pharmaceuticals	1,159.90	37,477,104,406.38
Fire Extinguisher	55.21	217,037,110.00
Fish & Fish Products	19,905,250.19	900,033,247,655.99
Food Raw Materials	11,651,462.94	7,039,774,568,288.17
Fruits & Vegetables	3,877.05	22,540,856,980.84
Industrial Chemicals	16,292,352.44	2,829,619,035,957.67
Meat & Meat Products	10,951.97	7,807,156,475.43
Medical Devices	114,794.46	20,505,198,997.79
Nutritional Foodstuff	3,909.98	65,195,502,574.92
Raw Materials	286,966.13	86,986,338,092.00
Ready-To-Eat Savourings	1.02	122,690,534.15
Reagents	21.64	989,169,831.66
Refrigerant Gas	1,205.84	859,341,815.52
Salt	19,001,355.89	790,685,143,701.45
Salts & Spices	18,302.60	125,384,378,410.22
Shoe Polish	100.8	7,654,732.00
Sugar	747,254.00	154,871,250,894.00
Supermarket Items	3,571.67	86,952,300,853.77
Sweeteners	56,768.26	3,087,466,257.29
Vaccines & Biologicals	186.18	1,638,930,202.46
Veterinary Products	341.98	834,084,580.40
<b>Grand Total</b>	<b>207,866,595.89</b>	<b>15,809,334,985,171.00</b>

## E. Divisional/Outstation Reports

### i. Export Activities

- Activities in the Export Division are online which involved review of submitted documentation, Inspection, Laboratory Analysis, and e-certification. These operations are usually carried out in collaboration with relevant Directorates of the Agency and other stakeholders.
- Applications received were One hundred and Six (**106**) with Eighty-eight (**88**) Certificates issued and Two (**2**) Export Approvals given.

- The Agency participated in NESS organized Study Tour of Turkey between February -March 2022 as part of NESS capacity building work plan for 2021.
- The Agency hosted a meeting (Virtual) of stakeholders on facilitating” Processing of Agro-Allied Product for Export” on the 28<sup>th</sup> of April 2022 as part of the PEBEC recommendation at a review meeting.
- The Agency participated in Nigeria Export Promotion Council (NEPC) sensitization session on Domestic Export Warehouse (DEW) held in Lagos, Abuja, Kaduna, and Port Harcourt held from 12<sup>th</sup> -20<sup>th</sup> May 2022.
- The Export Division of the Agency hosted a 2-day meeting between the Central Bank of Nigeria (CBN) and NAFDAC with Service Providers on the Integration of Export e-Licenses and NXP held on 30<sup>th</sup> and 31<sup>st</sup> August 2022 at NAFDAC Yaba Office, Lagos
- The Export Division of the Agency held advocacy visits to the Nigeria Customs Service (NCS) in the major ports in Lagos to strengthen existing collaboration for a more robust and effective regulatory function to ensure that only quality, safe and wholesome products that meets international market requirements are exported from Nigeria: Apapa Port Export Desk 9<sup>th</sup> November 2022, Tincan Command 10<sup>th</sup> November, 2022 and MMIA 16<sup>th</sup> November 2022.
- The Division also participated in a Non- Export Summit Tagged “RT 200 EXPORT” organised by Central Bank of Nigeria (CBN) on the 26<sup>th</sup> November, 2022 in Lagos.

**Table 8.6: Details of Export activities**

Product Group	Applications Received	Weight (MT)	Certificates Issued						
			Combined Certificate of Manufacture and Free Sale	Certificate of Free Sale	Health Certificate	Certificate of Pharmaceutical Product	Export Approval	Export Certificates	Compliance Directive
FOOD (Finished Products)	58	12,173.65	28	1	10	-	1	3	12
FOOD COMMODITIES (processed & semi processed)	2	305.702	-	-	-	-	-	-	1
DRUGS (Finished Pharmaceutical & Cigarettes)	28	106.9097	6	4	-	19	1	-	
COSMETICS	3	4.912	2	1	-	-	-	-	3
CHEMICAL	15	1,136.00	11	1	-	-	-	2	1
<b>TOTALS</b>	<b>106</b>	<b>13,727.18</b>	<b>57</b>	<b>7</b>	<b>10</b>	<b>19</b>	<b>2</b>	<b>5</b>	<b>20</b>
			<i>Total Certificates issued:88</i>			<i>Total Export Approvals: 2</i>			

**Figure 8.1: Export Certificates Issued in the Year 2022**



**b. New Technologies/ Post-Port Clearance Division (NT/PPC)**

The division has two distinct activities namely: Hold assignment and fast track inspection.

**Placement/ Removal of Hold Label Report**

- A total of Seven (7) hold placements and Forty (40) hold removals were carried out in the year under review.

**c. Director’s Office**

In the year under review, the office of the director handling trade portal platform processed One hundred and forty (140) approval of letter of non-objection, Five hundred and Eighteen (518) authorization to open form M, Seventy-Eight (78) approval for Materials for machine trials & Research purposes, Fifty-Three (53) Approval to import donated items by NGO'S and Thirty (30) Approval to import products by Government agencies, multinational organizations and international bodies from their activities. Table 15 gives the detail.

**Table 8.7: Breakdown of Activities by Month.**

Month	Approval of letter of non-objection	Authorization to open form M	Materials for machine trials & Research purposes	Approval to import donated items by NGO'S	Approval to import products by Government agencies, multinational organizations, and international bodies
January	36	119	3	2	15
February	34	115	9	3	6
March	24	57	7	5	1

April	7	38	6	7	1
May	6	25	8	4	1
June	5	27	6	5	0
July	4	12	9	2	1
August	6	24	12	6	1
September	6	19	5	7	0
October	3	19	2	4	0
November	2	31	8	2	2
December	7	32	3	6	2
<b>Total</b>	<b>140</b>	<b>518</b>	<b>78</b>	<b>53</b>	<b>30</b>

#### F. Outstation SGDs Treated

- Outstation offices accounted for a total of Six thousand, eight hundred and Ninety-Two (6,892) SGDs with Port Harcourt accounting for the most treated SGDs and highest revenue generated.
- A total of Five thousand, four hundred and sixty-seven (5,467) SGDs were treated in Port Harcourt, while Kaduna had the least number of SGD.

**Table 8.8: SGDs Treated in PID Outstations for the Year 2022**

Outstations	Kano	Port Harcourt	Ibadan	Abuja	Warri	Enugu	Calabar	Kaduna	Total
<i>SGDs Treated</i>	214	5467	11	835	183	92	89	1	<b>6,892</b>

#### G. Report of Samples for Laboratory Analysis

- A total of 10,038 samples were sent to the Laboratory for analysis while 11,763 samples were received in the year under review.
- A total of 11,743 samples had satisfactory laboratory evaluation while 20 were unsatisfactory.

**Table 8.9: Samples sent for Laboratory Analysis in 2022**

Months	Food	Drug	CCMD
<b>Total Samples Sent</b>	4333	5009	696

**Table 8.10: Analysis report of samples received from the Laboratory.**

Month	Food		Drug		CCMD	
	Passed	Failed	Passed	Failed	Passed	Failed
<b>Total Samples</b>	4043	7	6967	11	733	2

## **8.6 Achievements**

1. Deployment of the Ports Inspection Data Capture and Risk Management System (PIDCARMS) Online System as a web-based, online, fully automated business process application used across all PID formations Nationwide and enables importers conduct documentation and clearance processes from the comfort of the homes and offices, within and outside Nigeria.
2. The decrease in violation cases can be attributed to the management and leadership by blocking some loopholes.
3. Development, deployment, and implementation of electronic invoicing and receipting of all payments at the Ports Inspection Directorate.
4. Improved collaboration between NAFDAC and Nigeria Customs Service which has led to the joint seizure of over 200 containers of fake pharmaceuticals.
5. Expanded PID activities to various bonded terminals and land borders such that NAFDAC commenced operations in Lekki free trade zone.
6. Stakeholders and sectoral groups engagement that has led to improvement in compliance to NAFDAC regulatory requirements and processes.
7. Continuous In-House monthly lectures for all Regulatory and Non-Regulatory staff.
8. Strengthening of the Clean Report of Inspection and Analysis Scheme (CRISA) scheme and the unraveling of sharp practices by importers on imported products.

## Chapter 9

### 9.0 Investigation and Enforcement (I&E) Directorate.

The Investigation & Enforcement Directorate is the arm of NAFDAC, principally responsible for ensuring compliance with the Agency’s mandate on regulatory activities related to Food, Drugs, Cosmetic, and Medical Device etc. It also coordinates the enforcement activities of all other Directorates, zonal and states offices of NAFDAC Nationwide. The Federal Taskforce on Counterfeit and Fake Drugs and Unwholesome Processed Foods is domiciled in the Directorate.

In 2022, the Directorate continued its enforcement activities with more vigour despite a number of challenges. The activities are summarized as follows:

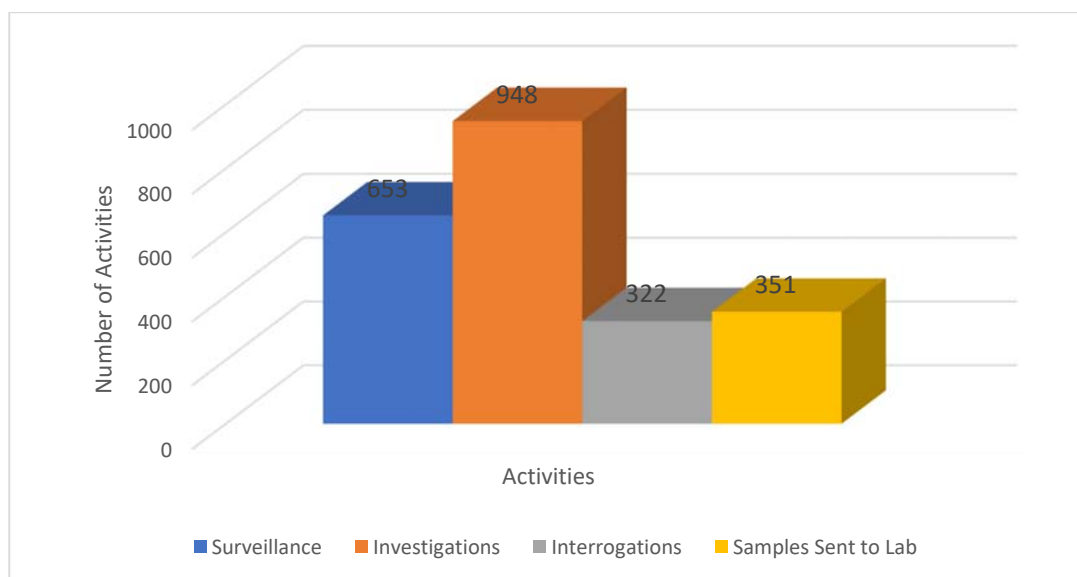
1. **Surveillance:** The Directorate carries out surveillance in order to recognize or monitor threats and prevent/investigate criminal activities. A total of 653 surveillance activities were carried out in 2022.
2. **Investigations:** In order to ascertain the veracity of Cases under investigation, the Directorate examines all materials and available facts before reaching a conclusion; a total of 948 investigations were carried out.
3. **Interrogations:** The Directorate interrogated suspects, interviewed victims and witnesses of crimes related to NAFDAC Enactments. 322 Interrogations and interviews were conducted.
4. **Sampling:** During the process of investigation, all violative NAFDAC Regulated Products were sampled and forwarded to the laboratory for appropriate analysis and pronouncement. A total of 351 investigative samples were forwarded.

The breakdown is as follows:

**Table 9.1: Activities of Investigation and Enforcement Directorate in 2022**

	Surveillance	Investigations	Interrogations	Samples Sent to Lab
January	63	80	37	34
February	60	117	65	18
March	64	105	23	55
April	66	96	30	23
May	46	61	9	55
June	25	40	13	1
July	0	6	0	0
August	51	69	30	38
September	42	62	33	51
October	72	88	40	16
November	89	118	16	36
December	75	106	26	24
<b>Total</b>	<b>653</b>	<b>948</b>	<b>322</b>	<b>351</b>

**Figure 9.1: Activities of Investigation and Enforcement Directorate in 2022**



## 5. Raid on Hawkers of Pharmaceutical Products

Raids are routinely carried out on hawkers of drugs in markets, streets and moving vehicles. The Directorate carried out a total of 16 raids, arrested 63 hawkers, and 283 wares were seized in the year under review.

**Table 9.2: No of Hawkers Arrested**

Month	Raid	Hawkers Arrested	No. of Wares Seized
January	4	20	56
February	3	27	62
March	0	0	0
April	0	0	0
May	3	4	41
June	2	4	33
July	0	0	0
August	1	7	48
September	1	1	18
October	0	0	0
November	0	0	0
December	2	0	25
<b>Total</b>	<b>16</b>	<b>63</b>	<b>283</b>

## 6. Compilation of Case Files

The Directorate in conjunction with the Legal Services Directorate filed Fourteen (14) cases in court. The Agency secured two (2) convictions against counterfeiters at various courts of the Federation. The breakdown is as follows:

**Table 9.3: No of Cases Sent to Legal Unit**

Month	Prosecution	Conviction
January	0	0
February	4	0
March	3	0
April	0	0
May	3	0
June	0	0
July	0	2
August	1	0
September	0	0
October	0	0
November	2	0
December	1	0
Total	14	2

## 7. Destruction of Seized NAFDAC Regulated Products

The Directorate carried out the destruction of Substandard and Falsified Medical Products, Unwholesome Processed Food Products, Unsafe Cosmetics, other Expired and Counterfeit NAFDAC Regulated Products valued at **₦15,814,022.50 in the month of November 2022 in North West Zone.**

## 8. Other Activities

There was appreciable improvement in compliance by stakeholders with relevant Laws and Regulations particularly in the area of registration, due to enforcement activities.

### *12:9 Training*

*I&E Officers were trained in the following:*

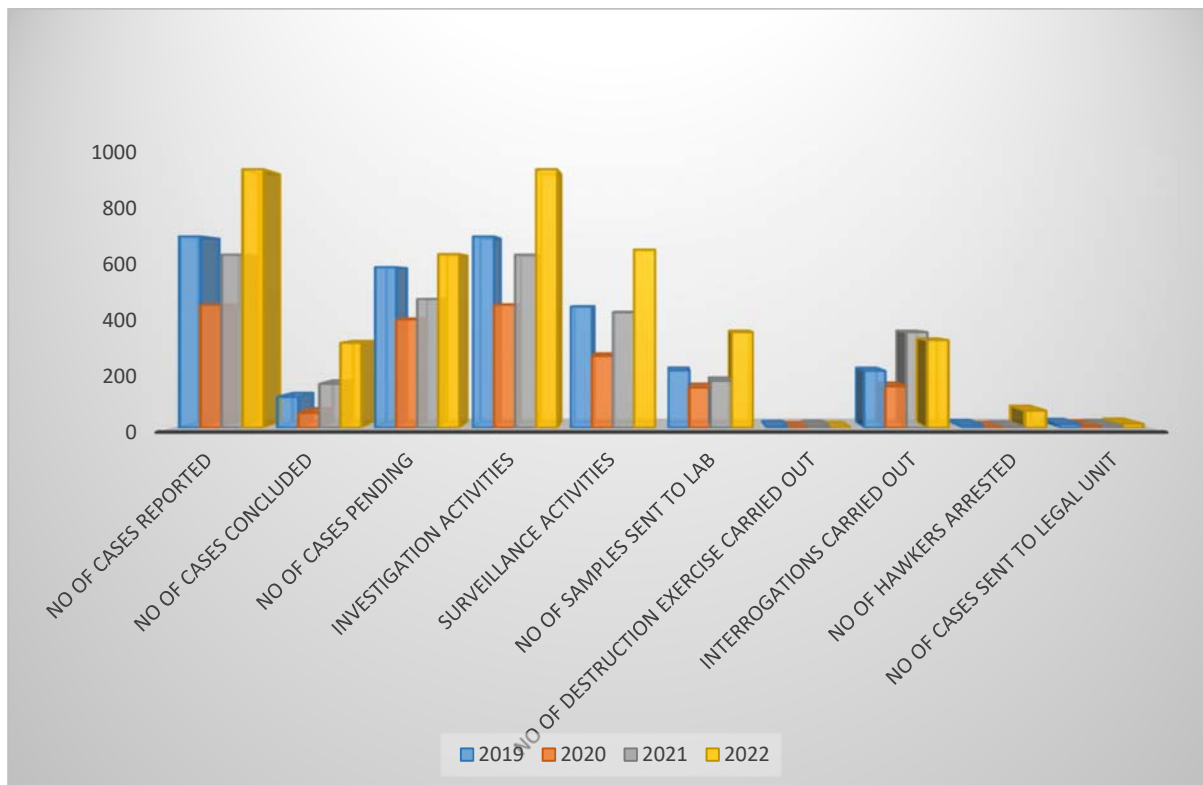
- UNODC Drug Control Exercise Workshop
- Anticorruption and leadership Training
- Medicine Crime Investigation Training
- Training on Intellectual Property, Illicit Goods & Pharmaceutical Crime

**Table 9.4: Summary of Enforcement Activities 2019 – 2022**

	2019	2020	2021	2022
No of Cases Reported	701	452	634	948
No of cases Concluded	113	54	161	312
No of Cases Pending	588	398	473	636
Investigation Activities	701	452	634	948
Surveillance Activities	445	264	424	653
No of Samples Sent to Lab	210	148	172	351
No of Destruction Exercise Carried out	5	0	6	1

Interrogations Carried out	209	152	351	322
No of Hawkers Arrested	9	1	3	63
No of cases sent to legal unit	13	7	9	14
<b>Total</b>	<b>1,951</b>	<b>1,928</b>	<b>2,858</b>	<b>4,248</b>

**Figure 9.2: Chart Showing Major Enforcement Activities for Year 2019, 2020, 2021 and 2022**



## Chapter 10

### Narcotics and Control Substances (NCS) Directorate

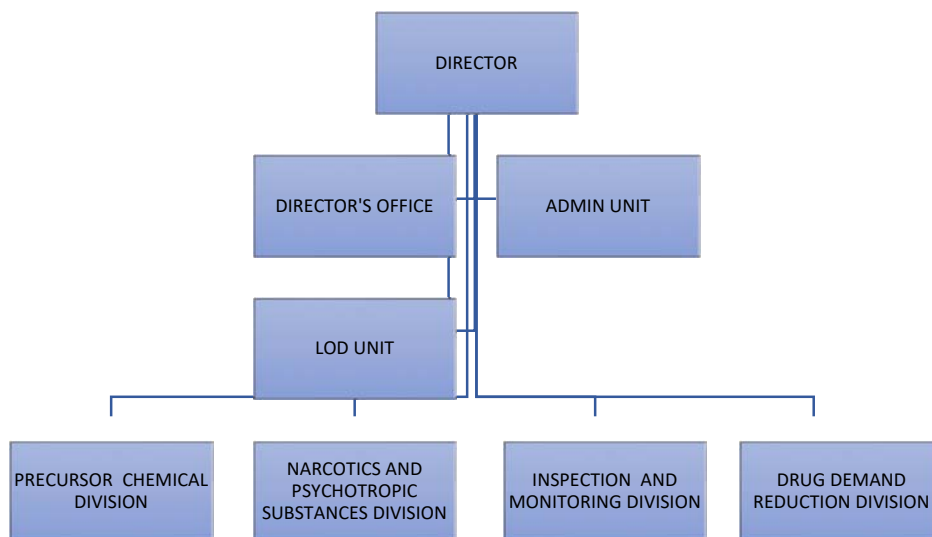
#### 10.0 Introduction

The Directorate is empowered by the NAFDAC Act 2004 to ensure availability of narcotics and other controlled substances for medical and scientific purposes while preventing the diversion to illicit channels and abuse.

The following are the core functions of the Directorate:

- Grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances;
- Collaborate with National Drug Law Enforcement Agency (NDLEA) and other stakeholders, in a bid to eradicate drug abuse in Nigeria;
- Take measures to ensure that the use of narcotic drugs, psychotropic substances are limited to only medical and scientific purposes;
- Coordinate Drug Demand Reduction Activities.
- Grant authorization to health facilities to purchase finished narcotics from central and zonal narcotics stores.
- Audit Warehouses to ensure proper storage, handling and distribution practices.
- Submission of statutory information of returns to the International Narcotics Control Board and ensures Nigeria fulfills its obligations under the three international drug control conventions of the United Nations:
  - **The United Nations Single Convention on Narcotics Drugs (1961)**
  - **The United Nations Convention on Psychotropic Substances (1971)**
  - **The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)**

Figure 10.1 Structure of the Directorate



## **10.2 Staff Strength**

As at 31<sup>st</sup> December, 2022, the staff strength of the Directorate stood at thirty-four (34). During the year in review, five (5) officers were posted to the Directorate, one (1) officer was posted out, one (1) officer resigned and one (1) officer retired from service. Six (6) officers were also promoted.

## **10.3 Programs, Meetings and Projects**

### **A. Launch of International Narcotics Control Board (INCB) annual report**

The Directorate hosted the launch of the International Narcotics Control Board annual report and precursors report 2021 at NAFDAC auditorium, Isolo on 10<sup>th</sup> March, 2022. Staff of the UNODC, NDLEA, Nigerian Customs Services were among the stakeholders who attended the event.

The INCB's primary function is to monitor and promote treaty implementation, provide for a direct working level contact between concerned authorities, and to assist, through its secretariat, real-time exchange of information in the prevention and diversion of controlled substances.

The report captured and summarized the activities coordinated by INCB for the year 2021 across the Globe.

### **B. The Response to Drugs and Related Organised Crime in Nigeria project NGAV16**

Project Closure - NGAV16 - The event held on the 21<sup>st</sup> November, 2022 in Abuja was the formal closure of the project that had run for 10 years. The EU, UN, UNODC, NAFDAC, FMOH, NDLEA, FMOE and others organizations made presentations appreciating the project and highlighting the impact over the years.

Many participants requested for a continuation of such collaboration.

The project gave awards to certain individuals for their efforts. Dr Musa Umar (rtd), Mrs. Edosa Ogbeide (D-NCS) and Mrs Asomugha (DD-NPS) received awards.

The Agency is to continue its regulatory functions as well as implementation of the NDCMP

### **C. National Drug Control Master Plan (NDCMP) TWG**

National Drug Control Master Plan (NDCMP) is a Plan endorsed by the Presidency to combat drug trafficking, drug abuse and diversion of controlled Medicines. The plan which represents the Governments effort towards conceptualizing and developing comprehensive strategic tools and frameworks for addressing multifaceted challenges with drug cultivation, production, trafficking and use in the country, contains four thematic pillars:

- **Supply reduction**
- **Drug demand reduction**
- **Access to drugs for medical purposes**
- **Governance and coordination.**

The NDLEA is championing the establishment of State Drug Control Committee chaired by the First ladies; a number of states have started. NAFDAC is a member of state Drug Control committee (SDCC).

The TWG is considering advocating for Drug Abuse counselling/screening into primary health care

### **D. Quantification of Narcotic Medicines for Medical Use in the Nigeria**

The Federal Government of Nigeria is the sole legitimate source of Schedule 1 Narcotics in Nigeria. There was a hands-on meeting to train stakeholders at the different points of data collection along the supply chain on how to quantify utilization data to inform procurement of Schedule 1 Narcotics at the national level. This was held in Abuja from 6<sup>th</sup> – 7<sup>th</sup> September, 2022.

#### **E. Development of Electronic Tool for Narcotic Medicine Procurement and Utilization**

Part of the recommendations of the Technical Working Group on Access and Control also reiterated in the National Drug Control Master Plan 2021-2025. was to encourage the full digitization of the procurement and handling of Schedule 1 Narcotics to feed into an existing national healthcare database that can be accessed by all relevant parties (NAFDAC, FMOH and healthcare facilities).

The main objective is to improve real time monitoring of these substances, giving access to evidence-based, real-time, logistics data to minimize diversion, ensure accurate estimates when needed and ultimately, for effective decision-making.

As a conclusion to the meeting, it was suggested that the FMOH team review the choice of **Labour Market Information Systems (LMIS)** system for Controlled Medicines and come up with a more appropriate concept paper. Meeting was held in Abuja 8<sup>th</sup> – 9<sup>th</sup> September, 2022.

#### **10.4 Internal Capacity Building**

In order to strengthen regulatory activities, knowledge acquired from workshops and other training activities were cascaded down to other staff. Current regulatory issues and new processes were the regular topics for the capacity building seminar series. A total of thirteen (13) internal capacity building sessions were carried out in 2022.

#### **10.5 Partnerships for Prevention of Dangerous Substances Trafficking Through the Internet.**

Inter-regional workshop on public-private partnership for prevention of dangerous substances trafficking through the internet was held at Grand Rotana Resort, Sharm El Shaeikh, Egypt from 11<sup>th</sup> to 14, September, 2022. The workshop was well attended and Nigeria was represented by NAFDAC, NDLEA, Jumia and My medicine which covered the public and private sector. There were presentation from participants all over the Globe. Nigeria representatives also made their presentation, telling our story. It was resolved at the end of the workshop that there should be strong collaboration between public and private sectors in each country in term of exchange of ideas. And there should also be inter-regional collaboration to curb the menace of drug trafficking through the internet.

#### **10.6 Drug Demand Reduction**

In response to the current situation of drug abuse, the Directorate carried out various targeted sensitization and awareness programs many of them in partnership with CSOs and other relevant MDAs.

The Directorate's drug demand reduction activities in the year under review focused on preventing initial drug use by carrying out education and awareness campaigns in relevant settings such as the family, the community school, faith-based organization and the work place. The Directorate conducted fifteen (15) campaigns in 2022.

#### **10.7 Singapore's Drug Control Innovative Strategies**

Workshop on Singapore's Drug Control- Innovative Strategies employed in Drug Control in Singapore from 25<sup>th</sup> to 28<sup>th</sup> of October, 2022. Multifaceted approach in fighting drug abuse and trafficking among which the use of social media is prominent was discussed. NAFDAC may adopt some of these strategies that well suits our current situations which will further strengthen the fight against Drug abuse in the nation.

### **10.8 Collaboration with Nigerian Army Officers' Wives Association (NAOWA)**

The Directorate collaborated with the Nigerian Army Officers' wives during the end of year gathering organized for the youths themed "STEPPING UP". A drama on Drug Abuse and its consequences was presented by Wale Adenuga Production after which a short lecture was delivered. The campaign took place at the 9 Brigade Nigerian Army Cantonment Ikeja, Lagos on 20<sup>th</sup> December, 2022.

### **10.9 Legalization of Cannabis**

Three MDAs: NAFDAC, NDLEA and the FMOH, unanimously expressed their concern at promoting the legalization of cannabis for licit purposes, based on the prevailing circumstances in the country; while all others present at the meeting were inclined to it. NAFDAC drew the attention of participants to the following keys issues:

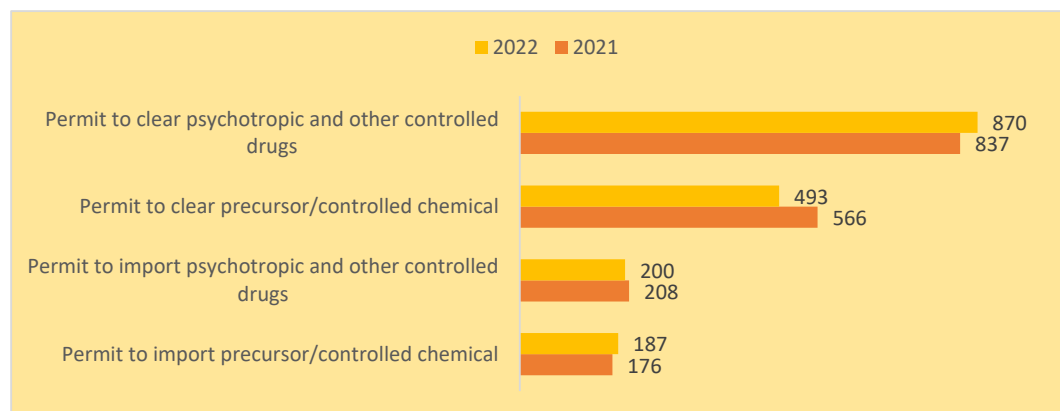
- In Nigeria currently, the cultivation, consumption, handling and possession of cannabis or cannabis related product still remains illegal by law (The Indian Hemp Act, NDLEA Act and Dangerous Drug Act).
- Discussion about regulatory framework can therefore only take place if the provisions of the above extant laws are amended.
- The legalization of cannabis use for nonmedical purposes in some countries represents a challenge to public health and well-being, particularly among young people of such countries. Nigeria should therefore tread on the path of caution.
- Nigeria is already facing security challenges like kidnapping, banditry, terrorism, rape etc. which are exacerbated by drug abuse and misuse; and legalising cannabis may likely compound the situation.
- In some countries where cannabis has been legalized like the USA and Canada, properly regulated medical cannabis programs are in place to tackle any attendant untoward effects.
- The agency advised that going forward; discussions regarding benefits of cannabis should not consider the economic benefits alone but the public health concern as well.
- NAFDAC will reject any attempts to classify medical cannabis as "herbal medicines".
- NAFDAC has not issued any market authorization license for any product containing Cannabis or any of its known derivations or key constituents.

It was concluded that there should be an agency wide round table meeting involving all relevant Directorates to streamline opinions and discuss the issue of cannabis regulation.

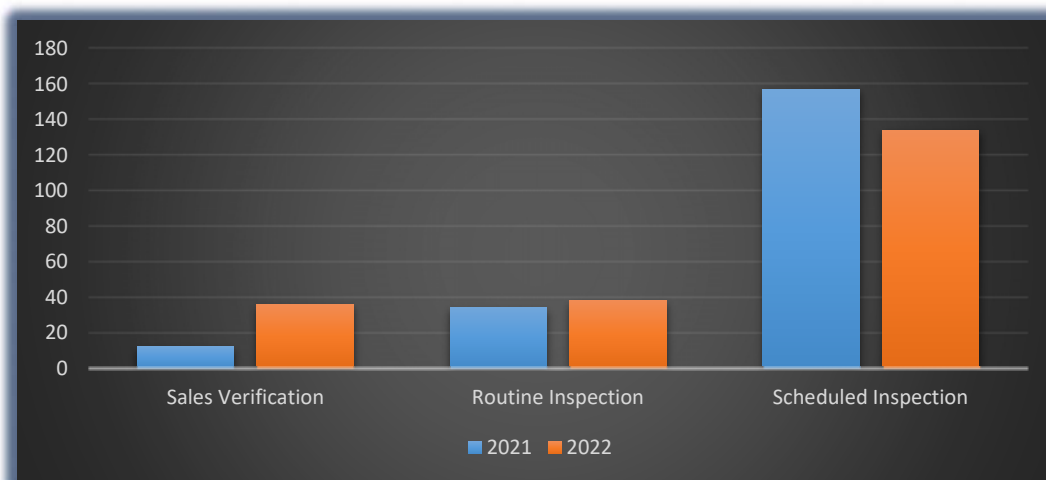
### **10.10 Conclusion**

The Narcotics and Controlled Substances Directorate has remained focused on its key responsibility of ensuring availability of narcotics and other controlled substances for medical and scientific purpose while taking measures to minimize diversion to illicit use and abuse.

## Comparison of NCS Activities of 2021 Against 2022



## Warehouse Inspection for 2021 Against 2022



## Table Summary of the Activities of NCS Directorate in 2022

S/N	Activities	Inspection and Monitoring	Narcotics and Psychotropic Substances	Precursor Chemical
	<b>No. of Applications Received</b>			
8	Schedule Warehouse Inspections	134	-	-
	I. Satisfactory	132	-	-
	II. Unsatisfactory	2	-	-
	II. Inspection not held	-	-	-
9	Routine Warehouse Inspections	38	-	-
	I. Satisfactory	38	-	-
	II. Unsatisfactory	-	-	-
	II. Inspection not held	-	-	-

10	No of outstation inspection Reports Received	64	-	-
	I. Satisfactory	27	-	-
	II. Unsatisfactory	1	-	-
11	Sales Verification	36	-	-
	I. Satisfactory	12	-	-
	II. Unsatisfactory	21	-	-
	II. Verification not held	3	-	-
12	LPO Verification	-	-	-
	I. Satisfactory	-	-	-
	II. Unsatisfactory	-	-	-
13	Hospital Inspections	-	-	-
	I. Satisfactory	-	-	-
	II. Unsatisfactory	-	-	-
	II. Inspection not held	-	-	-
14	Surveillance	-	-	-
15	No of investigations conducted	-	-	-
16	No of investigations conducted (Outstation)	-	-	-
17	Outstation verification report received	12	-	-
18	<b>Total Permits/Authorisations Issued</b>	-	-	-
19	Permit to Import Controlled/Precursor Chemical	-	-	187
20	Permit to Clear Controlled/Precursor Chemical	-	-	493
21	Permit to Import Psychotropic/ other controlled drugs	-	200	-
22	Permit to Clear Psychotropic/ other controlled drugs	-	870	-
23	Authorizations to Import Narcotics ( Bulk and Finished Schedule I Narcotics)	-	4	-
24	Authorizations to Clear Narcotics ( Bulk and Finished Schedule I Narcotics)	-	4	-
25	Authorizations to Purchase finished Narcotics	-	51	-
26	Pre-export Notification	-	81	107
	No of Pre-export Notification objected to	-	3	12
	No of Pre-export Notification non objected	-	78	86
27	No of schools, clinics, markets, NYSC Camps visited	-	-	-
28	Training (In-house/External)	13	13	13
29	Statutory Meeting/ Workshop/Stakeholder Consultative meeting	-	-	-
30	No of Violations	-	8	2

## Chapter 11

### Laboratory Services (Food and Cosmetics)

#### 11.0 Introduction

The Laboratory Services Directorate (Food) performs its activities through enhanced facilities, maintenance and capacity development of personnel in two Laboratories listed below:

- Central Laboratory, Oshodi, Lagos State
- Area Laboratory, Port Harcourt, Rivers State
- Area Laboratory, Calabar

#### 1. Goals

The goals of the Laboratory Services Directorate (Food) are:

- To generate quality and timely test results that meet international standards
- To provide excellent customer service

#### 2. Analytical Performance

The Laboratory Services Directorate (Food) received Fifteen Thousand One Hundred and Ninety (**15,190**) samples in 2022. Seven Hundred and Seventy-Five (**775**) samples were carried over from 2021 bringing it to a total of Fifteen Thousand Nine Hundred and Sixty-Five samples (**15,965**) handled in 2022. Out of these, Fifteen Thousand Five Hundred and Ninety-Seven (**15,597**) samples were analysed which represents **97.7%** output in 2022.

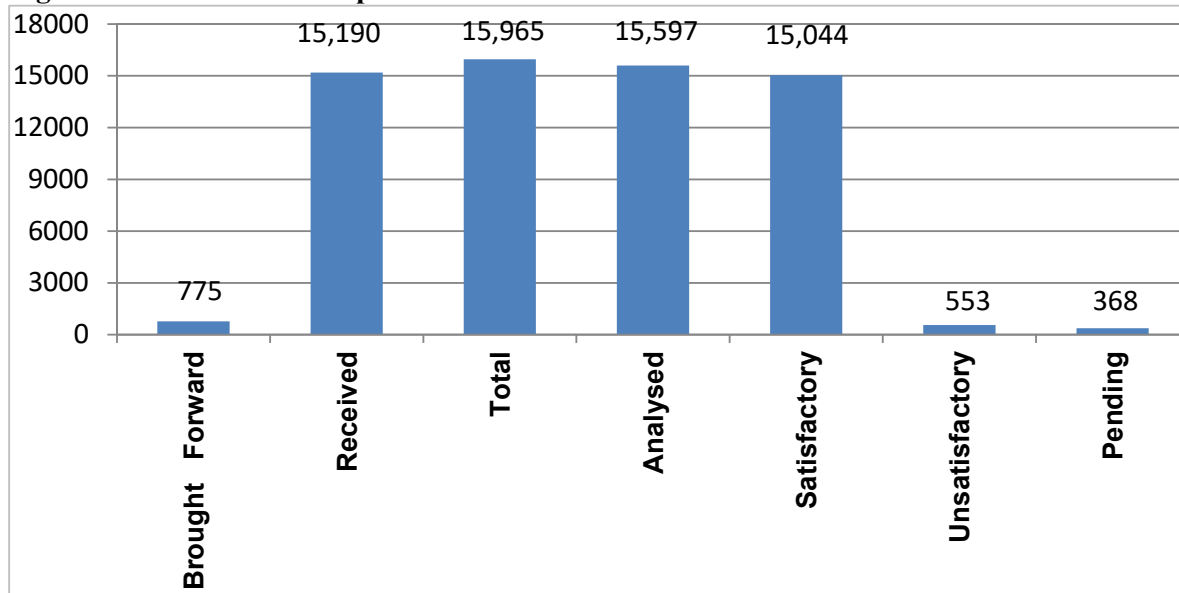
**Table 11.1** below shows the summary of activities for the period under review with profile of samples handled in **Figure 11.1**, while **Figure 11.2** shows percentage of samples analysed. Of the analysed samples, **97%** of the samples were satisfactory as shown in **Figure 11.3**. **Figure 11.4** shows the Individual Laboratory performances. **Table 11.2** represents the samples received according to categories which are illustrated in **Figure 11.5**. The summary of Food samples received according to categories are further illustrated in **Figures 11.6**.

**Table 11.1: Summary of Analytical Performance in the Year 2022**

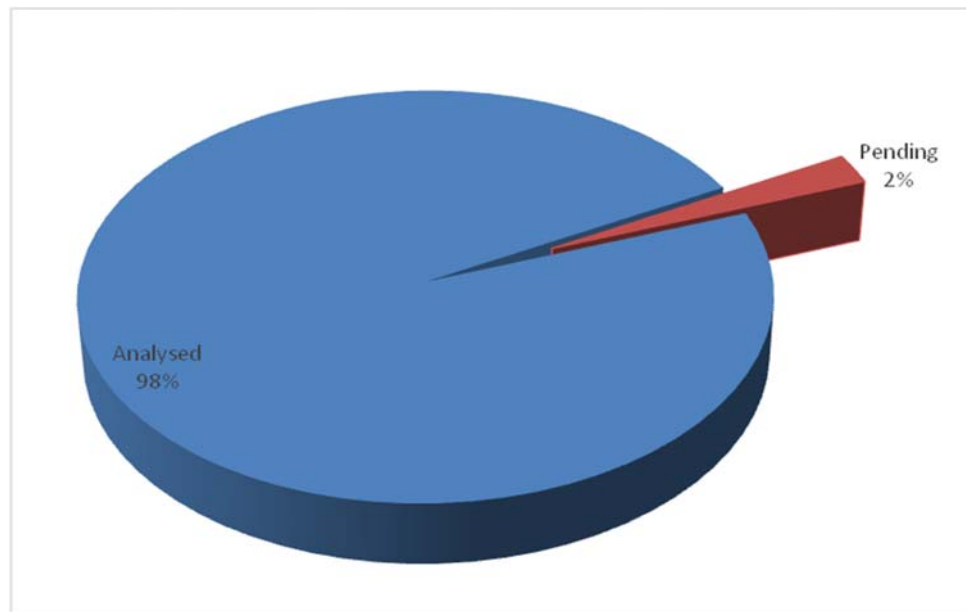
	No. of Samples Brought Forward	No. of Samples Received	Total Number of Samples	No. of Samples Analysed	Number of Satisfactory Samples	Number of Unsatisfactory Samples	No. of Samples Pending	Percentage Performance
Oshodi	625	13,442	14,067	13,699	13,265	434	368	97.4%
P/Harcourt	150	1,748	1,898	1,898	1,779	119	0	100.0%
<b>Total</b>	<b>775</b>	<b>15,190</b>	<b>15,965</b>	<b>15,597</b>	<b>15,044</b>	<b>553</b>	<b>368</b>	<b>97.7%</b>

**Overall Performance = 97.7%**

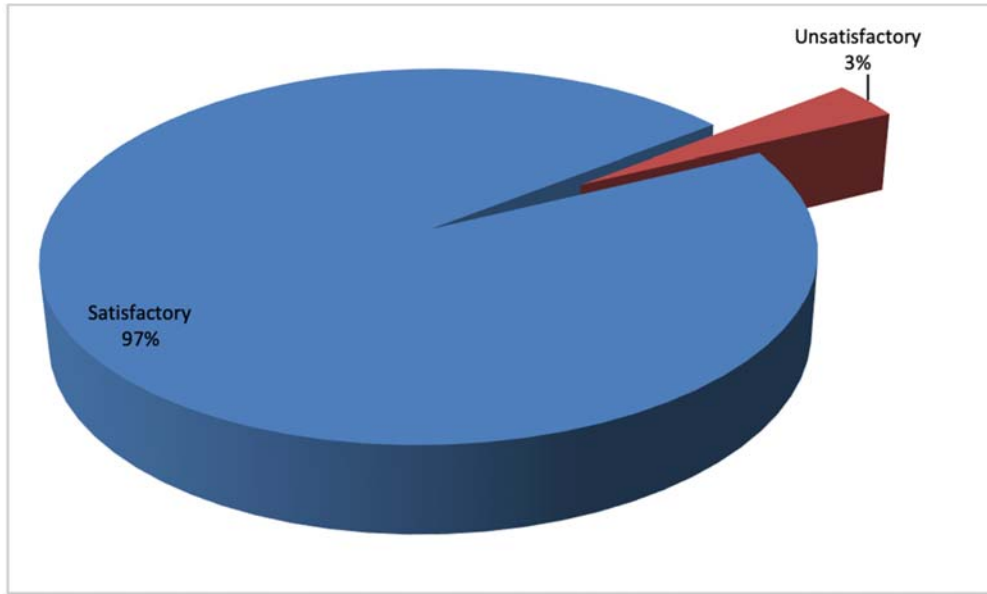
**Figure 11.1: Profile of Samples Handled in the Year 2022**



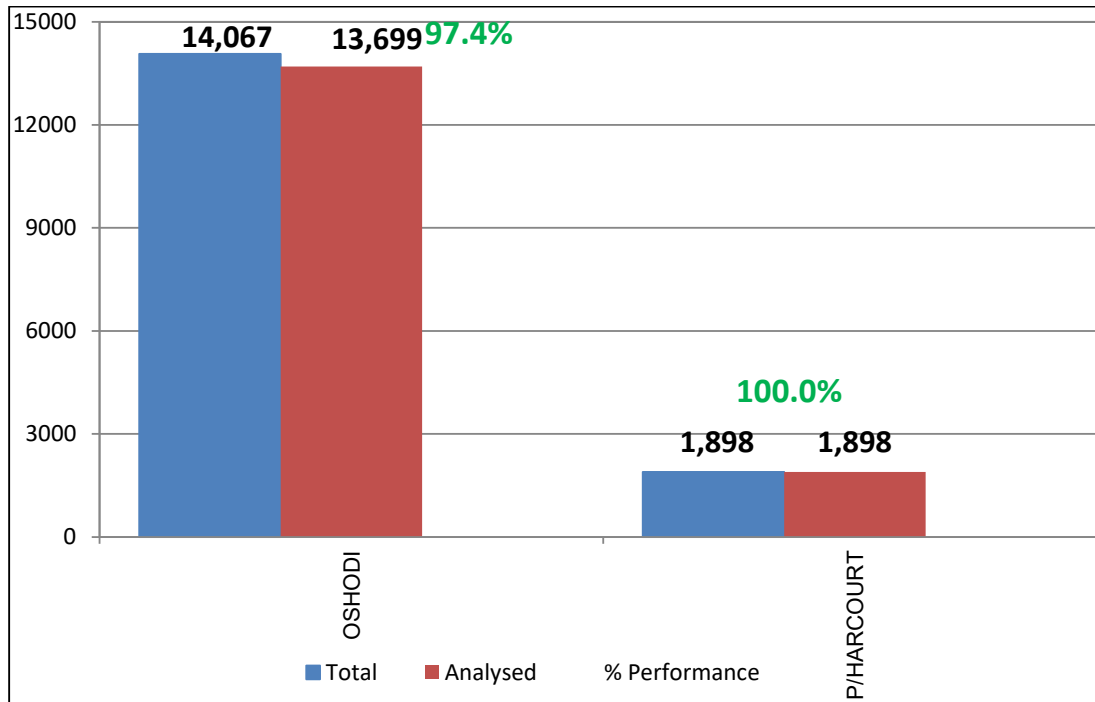
**Figure 11.2: Percentage of Samples Analyzed in 2022**



**Figure 11.3: Percentage of Satisfactory/Unsatisfactory Samples**



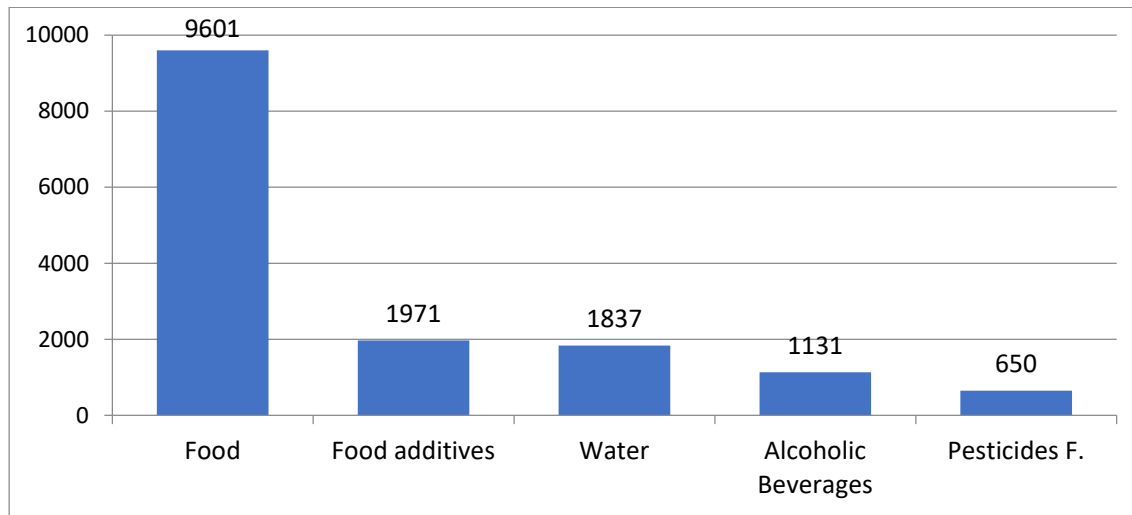
**Figure 11.4: Individual Laboratory Performance**



**Table 11.2: Sample Received According to Categories in 2022**

January- December						
	Registration	Compliance	Investigation	Enforcement	Others	Total
Food	5,409	3,840	206	89	57	9,601
Dairy and Milk Product	180	579	77	2	-	838
Non Dairy Products	10	-	-	-	-	10
Baby and Infants Foods	43	158	-	-	-	201
Fat and Oils	172	337	20	3	-	532
Cereal and Cereals Product	265	809	52	37	-	1,163
Bread	1,331	-	-	-	-	1,331
Tea, Coffee and Cocoa Product	162	237	3	-	-	402
Fruits and Fruits Products	142	37	11	24	-	214
Carbonated Drinks	172	77	3	2	-	254
Meat and Meat Products	117	53	2	5	-	177
Fish and Fish Products	85	380	2	1	-	468
Salt	3	36	2	-	-	41
Seasoning and Flavouring Products	276	431	13	11	1	732
Sugar and Sugar Products	85	123	3	3	-	214
Nut and nut products	166	31	1	-	-	198
Legume and legume products	135	39	1	-	-	175
Egg and egg products	7	8	-	-	-	15
vegetable and vegetable products	4	17	2	-	-	23
root and tuber products	161	70	-	1	1	233
Flavoured Drinks	17	6	-	-	-	23
Ready to Eat	53	-	-	-	-	53
Miscellaneous (Food Samples)	1,823	412	14	-	55	2,304
Food Supplements	-	-	-	-	-	-
Food Additives	93	1,752	-	-	-	1,845
Alcoholic Beverages	807	215	91	15	3	1,131
Water	1,836	-	1	-	-	1,837
Pesticides F.	472	177	1	-	-	650
Animal feeds	-	-	-	-	-	-
Fertilizer	-	-	-	-	-	-
Chemicals	-	126	-	-	-	126
<b>TOTAL</b>	<b>8,617</b>	<b>6,110</b>	<b>299</b>	<b>104</b>	<b>60</b>	<b>15,190</b>

**Figure 11.5: Categories of Samples Received in 2022**



**Figure 11.6: Summary of Food Samples Received According to Categories**



### 3. Trend in Assessment of Regulated Products (2020 - 2022)

57% of samples received for analysis in the Laboratory Services Directorate (Food) were for registration purposes while the compliance samples account for 40% of the samples received compared to previous year which was 66% and 32% respectively.

There was a slight increase in the number of Enforcement samples received in 2022 compared to that of previous years.

**Table 11.3: Trend of Samples Received Based on Purpose of Analysis**

<b>Purpose of analysis</b>	<b>Number of samples 2020</b>	<b>Percentage 2020</b>	<b>Number of samples 2021</b>	<b>Percentage 2021</b>	<b>Number of samples 2022</b>	<b>Percentage 2022</b>
<b>Registration</b>	10,358	67.83%	10,922	65.69%	8,617	56.7%
<b>Compliance</b>	4,499	29.46%	5,256	31.61%	6,110	40.0%
<b>Investigation</b>	390	2.55%	380	2.29%	299	2.0%
<b>Enforcement</b>	22	0.14%	63	0.38%	104	0.7%
<b>Others</b>	1	0.01%	6	0.04%	60	0.4%
<b>Total</b>	<b>15,270</b>		<b>16,627</b>		<b>15,190</b>	

### **3.1 Trend in the Categories of Regulated Products Received in the Directorate**

- Food samples constituted the highest number (9,601; 62.8%) of samples received in the Directorate followed by Water samples (1,837; 12.09%)
- Of the Food samples received, Bread samples constituted the highest (1,331; 24.6%)
- Two hundred and ninety-nine (299) samples were received for investigation purposes with Alcoholic beverages samples constituting the highest percentage (30.4%; 91)
- One hundred and four (104) samples were received for enforcement purposes with cereals and cereals products being the highest (37; 35.6%)

## **4 ISO Accreditation**

### **4.1 ISO 17025:2017 Laboratory Accreditation**

- The Central Laboratory Oshodi was reassessed virtually for ISO 17025:2017 Laboratory accreditation by ANAB (ANSI National Accreditation Board) on the 25<sup>th</sup> November, 2022. Four (4) non-conformances were observed during the audit and corrective actions are being taken.
- The Laboratory currently has thirty-nine (39) scopes accredited.

### **4.2 ISO 9001:2015 Quality Management System**

- The Central Laboratory Oshodi was reassessed by Association Francaise de Normalisation (AFNOR also known as French Standardization Association) on the 3<sup>rd</sup> of November, 2022 towards renewal of the Agency's ISO 9001:2015 QMS accreditation.

## **5. Staff Matters**

○ **Staff Strength:**

Total staff Strength	<b>110</b>
• Port Harcourt	32
• Oshodi Lab	78

**6. Training**

□ **Local Training of Staff**

- i. Overview of FR&R was done on the 23th of March, 2022 by Mr. Nnanna Ibemgbo of Food Registration and Regulatory Directorate for staff of Central Laboratory Oshodi
- ii. Quality Risk Management Training was conducted for NAFDAC Central Laboratory Oshodi Quality risk Management team from 20<sup>th</sup> to 22<sup>nd</sup> of June, 2022 by the Quality Assurance Manager
- iii. Staff of Area Laboratory Port Harcourt participated in a five (5) days local training on Laboratory Information Management System (LIMS) within the Laboratory, from Monday 22<sup>nd</sup> to Friday 26<sup>th</sup> August, 2022.
- iv. There was a five (5) days local training on Laboratory Information Management System (LIMS) conducted by a combined team of Consultant Engineer (Okey Onwnagha), Staff of Central Drug Control Laboratory Yaba (Mr Arinze Ezenweokiki and Mrs Chinwe Ogbuokiri) and a staff of NAFDAC ICT, Abuja (Mr James Alaaga) from Monday 22<sup>nd</sup> to Friday 26<sup>th</sup> August, 2022 for all staff of Area Laboratory Port Harcourt.

□ **International Training**

- i. A staff of Mycotoxin unit of the Central laboratory Oshodi attended a 10 days sponsored training on Method of analysis of food contaminants: Rapid Screening and Confirmatory Techniques at Dubai Central Laboratory, Dubai from 24<sup>th</sup> July 3<sup>rd</sup> August 2022

□ **Industrial Training Students/Interns/NYSC**

A total of One Hundred and Twenty-Six (126) students underwent Industrial training in the Directorate in 2022 while Twenty-Two (22) NYSC corps member and Two (2) interns served the Laboratory Directorate.

○ **FURNITURE**

New sets of furniture were received in the Central Laboratory Complex, Oshodi on the 26<sup>th</sup> of April 2022.

**7. Partnership with Governments and Organisations**

A. **International Atomic Energy Agency (IAEA)**

- The Food Laboratory formations are participating in the current IAEA/AFRA Project; RAF 5084 (Strengthening Food Contaminant Monitoring and Control Systems and Enhancing

Competitiveness of Agricultural Export Using Nuclear and Isotopic Techniques). The Project which began in 2020 is scheduled to last for four (4) Years; 2020- 2024

- Two (2) NAFDAC staff participated in the Regional Meeting on Proficiency Test (PT) and Inter-Laboratory Test/Comparison Studies(ILCs) from 5th - 9th September 2022 at the Department Of Veterinary Technical Services, Harare ,Zimbabwe
- Four (4) NAFDAC staff, one of whom was sponsored under the RAF 5084 project, participated in the Workshop On Africa Food Safety Organised By The National Metrology Institute Of South Africa at the Emperors Palace Conventional Center, Johannesburg South Africa from June 27th July 1st , 2022. The other three (3) participants were sponsored by NAFDAC
- The project supported Mycotoxin, Veterinary Drug Residues and Metal Laboratory Units with NMISA and Progetto Trieste Proficiency Testing Materials

**B. United States Agency for International Development (USAID)**

- Some representatives form USAID visited the NAFDAC Central Laboratory Oshodi on the 31<sup>st</sup> August 2022, towards supporting the Laboratory on testing of micro nutrients in ready - to-use therapeutic foods (RUTF).

**C. Organisation for Prohibition of Chemical Weapons (OPCW)**

- The OPCW supports the Laboratory unit in Central Laboratory Oshodi dedicated for testing of Chemical Weapons.
- The OPCW Laboratory Unit in Oshodi participated in two (2) CWC Chemical Analysis Competency Test (CCACT) during the year; the CCACT 14 received in March and CCACT 15 received in November 2022. The analysis were satisfactorily done, as all spiked chemicals were identified as well as those not indicated. This is due to the adequate provision of all necessary equipment by the Agency.
- The Laboratory unit attended a virtual training on the 17<sup>th</sup> and 18<sup>th</sup> March 2022 with the representatives of the mentoring Laboratory; VERIFIN, Finland.
- The Laboratory unit staff also attended a virtual joint OPCW training with VERIFIN on the 22<sup>nd</sup> and 23<sup>rd</sup> March 2022
- One staff of the unit attended the virtual OPCW Training Workshop on Basic Course on Emergency response to chemical incidents for member states of the economic community of west African States (ECOWAS) on the 7<sup>th</sup> of April 2022
- The Laboratory unit staff also attended a virtual 51<sup>st</sup> Proficiency Test Meeting And CCACT 14 Individual Laboratory meeting with OPCW from 11<sup>th</sup> -15<sup>th</sup> June 2022

## 8. Special Activities

### A. Proficiency Testing/ Certified Reference Material

The Proficiency Testing/ Certified Reference Material Laboratory Unit established in the NAFDAC Central Laboratory Oshodi with support from by UNIDO had conducted a series of PT scheme this year;

- In the first quarter of 2022, the unit conducted the first round of PT scheme was *Iodine in Edible Salt* in March/April 2022 with twenty one (21) participating Laboratories. 70% of the laboratories had a z-score within limit.
- In the third quarter of 2022, a second round of PT scheme; *Total Aflatoxin and Aflatoxin B1 in Corn Meal* was conducted in August 2022 with ten (10) participating Laboratories. An average of 15% had a z-score within limit.
- The unit is currently conducting an Inter Laboratory Comparison (ILC) test with *the National Public Health Reference Laboratory (LNSP) in Côte d'Ivoire* on *Iodine in Edible Salt*. The samples were dispatched in November.
- The Laboratory is also conducting a pilot Inter Laboratory Comparison (ILC) test on Specific gravity in alcoholic beverages, Titratable acidity of drink and Saponification value of Vegetable Oil within the five NAFDAC Food testing Laboratories. The samples were also dispatched in November.

### B. Inter-Laboratory Audit of NAFDAC Laboratories

NAFDAC laboratories Inter-laboratory Audit for Central Laboratory Oshodi was carried out on the 22<sup>nd</sup> – 24<sup>th</sup> August 2022 by auditors from other NAFDAC Laboratories in line with the harmonization of Laboratory documents.

### C. Relocation of Area Laboratory, Port Harcourt to Calabar

In preparation towards the relocation of the Area Laboratory Port Harcourt to Calabar, the Laboratory stopped receiving samples for analysis from various state offices from 10<sup>th</sup> October 2022 to clear up all samples at hand.

The renovation of the Laboratory is almost completed and equipment would soon be transferred from Area Laboratory, Port Harcourt to the Laboratory, as well as the new ones installed.

Consequently, in line with preparation towards the installation of equipment in the Laboratory, the Engineer from Synapses Technologies Limited visited the Calabar Laboratory in November, 2022 for site inspection. The installation of the electrical earthing in the building was observed to be inadequate, which has forestall the installation of new equipment to avoid electrical damage.

**D. Laboratory Information System (LIMS)**

The Central Laboratory Oshodi now has most of their analytical processes operative on the Laboratory Information System (LIMS).

**E. Meetings and Visitations:**

- i. The annual Management Review Meeting held virtually on the 5<sup>th</sup> of October 2022 with the Director General and all Laboratory Services Directors in attendance.
- ii. **Visit to Area Laboratory, Port Harcourt;** The Director Laboratory Services (Food) along with the Director Admin & HR visited the Laboratory on the 21<sup>st</sup> September 2022 to sensitize the staff towards relocation to Calabar.
- iii. **Visit to Calabar Laboratory;** The Director Laboratory Services (Food) along with the Engineering team from Abuja visited the Laboratory on the 30<sup>th</sup> and 31<sup>st</sup> of August, 2022 to inspect the level of work done by the Contractors.
- iv. **Second Total Diet Studies Planning Meeting;** Two staff of the Central Laboratory Oshodi attended the planning meeting towards the commencement of the second TDS at the NAFDAC Office, Isolo on the 19<sup>th</sup> and 20<sup>th</sup> December, 2022.

**F. Activities Of Health Safety And Environment (HSE) Central Laboratory Oshodi For 2022**

**i. HSE Audit**

The NAFDAC Safety Manager conducted a safety audit of the Laboratory on the 8<sup>th</sup> of June 2022. A number of non-conformances were observed, most of which are being addressed, with the exception of those relating to the renovation of the Laboratory complex.

**ii. HSE Training**

- Training for fire drill preparedness, Laboratory Safety and Promoting a Healthy Lifestyle at the Workplace were carried out by NAFDAC Central Laboratory Oshodi HSE team members for CLO staff on the 17<sup>th</sup> February, 2022.
- The NAFDAC Safety Manager conducted a virtual training on HSE SOPs for all HSE Committee members from 2<sup>th</sup> October to 1<sup>st</sup> November 2022

**G. Proficiency Testing**

All Laboratory Units in Central Laboratory Oshodi with accredited scopes participated in Proficiency Testing Schemes and inter-Laboratory testing. Most of the results were satisfactory while the unsatisfactory reports have been addressed.

**9. Constraints**

The major constraints that hampered the efficiency of the Laboratories in 2022 included the following:

- Insufficient staff in the Directorate
- Lack of adequate computers and printers

#### **10. Way Forward**

For continuous improvement in efficiency and services of the Directorate, the following are being recommended;

##### **Staff**

- ✓ The Laboratory is grossly short staffed and currently top heavy with, hence the Laboratory is severely in need of Regulatory Officers I &II, Senior Regulatory Officer as well as Laboratory Assistants to handle analysis of samples

##### **Laboratory Equipment and Consumables**

- ✓ Procurement of reference standards, chemicals, glassware and equipment accessories

##### **Infrastructure**

- ✓ Provision of sufficient computer systems
- ✓ Minor internal renovation of Central Laboratory, Oshodi
- ✓ Proper earthing of the electrical system of the Calabar Laboratory and other pending activities, towards a successful relocation of of Area Laboratory, Port Harcourt, Rivers State to Calabar, Cross River State.

##### **ISO 17025:2017 Laboratory Accreditation**

- ✓ The Directorate would ensure it sustains the accredited scopes in Central Laboratory, Oshodi and hopes to extend the scopes further in 2023.

#### **11. Conclusion**

The Laboratory Services Directorate (Food) achieved much in terms of analyses of samples despite the pertinent challenges. The Directorate successfully sustained the previously accredited analytical scopes in the Central Laboratory Oshodi and hopes to thrive better in 2023.

## Chapter 12

### Laboratory Services Directorate (Drugs)

#### 12.0 Introduction

The Drugs Laboratory Services (LS) Directorate was established by the Director General to enable the Drugs Laboratory to be more prudent and more productive in achieving its mandate and that of the Agency. The Directorate currently has two functional laboratories viz:

- Central Drug Control Laboratory (CDCL), Yaba, Lagos.
- Maiduguri Area Laboratory,

#### (A) Highlights

- 21<sup>st</sup>-25<sup>th</sup> February: GBT assessment
- Uganda FDA visitation to Central Drug Control Laboratory, Yaba from 9<sup>th</sup>-12<sup>th</sup> May,2022
- NIPRID/USP Training: 14<sup>th</sup> June-17<sup>th</sup> June.
- In the period being reported the National Control Laboratory for Vaccines and Biologics was excised from the Directorate.
- In the month of August, a team of officers from CDCL Went to Area Laboratory, Maiduguri to train officers on **Laboratory Information Management System**
- September 30<sup>th</sup>-7 October: Educational visit by Burkina Faso National Regulatory Authority Laboratory Staff
- Within the period under review, there was ISO 9001:2025 Recertification Audit for NAFDAC which started on Tuesday Nov 1<sup>st</sup> 2022. According to the audit Plan, the assessment was on-site, conducted by ANAB external auditor for CDCL on Thursday Nov 3<sup>rd</sup> ,2022.
  - External Auditor: Moussallem Roy  
Outcome: No Non-conformities were identified
- ISO 17025:2017  
Reaccreditation Audit  
Held 21<sup>st</sup>-24<sup>th</sup> November 2022  
  
Auditor; Dr. Pearl Fernandez  
Outcome: No Non-conformance were identified

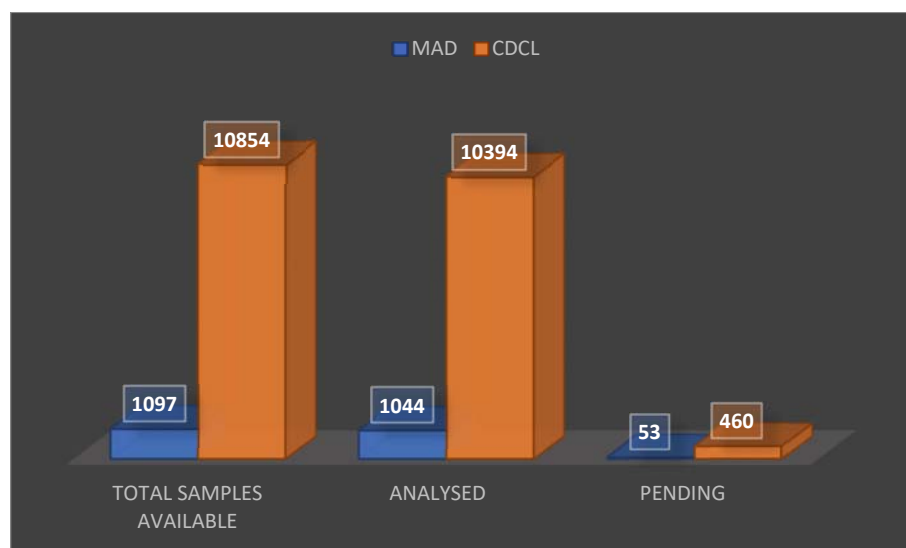
#### (B) Analytical Performance of the Directorate

January 2022– December 2022, Drugs Laboratory Directorate received a total of **11242 samples**. The number of samples brought forward (carried over) from December 2021 was **709**. This implies that a total of **11951** samples were available for analysis during this period. However, from this number (**11951**), a total of **11438 samples** were finally analysed representing **95.71 %**.

**Table 12.1: Summary of Analytical Performance for 2022**

Labs	No. of Samples Brought Forward	No. of Samples Received	Total Number of Samples Available	No. of Samples Analysed	No. of Samples Pending
Mad Area Lab	116	981	1097	1044	53
CDCL	593	10261	10854	10394	460
<b>Total</b>	709	11242	11951	11438	513

**Figure 12.1: Graphical Representation of Analytical Performance for 2022**



The Directorate wish to express her gratitude to the Management and Governing Council of NAFDAC for the support the laboratories have received in the recent past especially in the areas of bulk purchase of chemicals and reagents, consumables, new equipment and vehicles.

## Chapter 13

### Laboratory Services Directorate, Agulu

#### 13.0 Introduction

Laboratory Services Agulu, Anambra State was created as a full-fledged Directorate in January 2020 by the Director-General: Professor Mojisola Adeyeye. The Laboratory serves the South-East and South-South Zones of the country where analysis of Food, Drugs, Cosmetics, Medical Devices and Herbal products are carried out. The Laboratory also receives samples from other Directorates such as ports Inspection, Drug Registration and Regulatory Affairs, Investigation and Enforcement and Pharmacovigilance and Post Market Surveillance.

#### 13.1 Achievements

##### A. Analytical Performance

##### i. Number of Samples Received

The Laboratory received four thousand and six hundred and twenty-six (4,626) samples. Two hundred and thirty-six (236) samples were brought forward from the previous year (2021) bringing to a total sum of four thousand, eight hundred and sixty-two (4,862) samples for analysis within the year under review.

##### ii. Number of Samples Analyzed

Four Thousand, Seven Hundred and Fifty-Four (4,754) samples were analyzed within the year under review. This represents 97.78% productivity. Out of the number analyzed, Four Thousand, One Hundred and Fifty-Four (4,154) samples were analyzed within the timelines. This represents 85.44% of analyzed samples within the timelines

##### iii. Number of Pending Samples

One Hundred and Eight (108) samples were pending within the year under review.

##### iv. Number of Satisfactory and Unsatisfactory Samples

Four Thousand, Five Hundred and Two (4,502) samples were satisfactory while Two Hundred and Fifty-Two (252) were unsatisfactory within the year under review.

##### v. Survey Samples:

- ✓ The Laboratory participated in the edible salt survey. A total of Three Hundred and Eighty-Four edible salt survey samples from the five (5) South-Eastern States and three (3) South-South States within the year under review. The status of the samples is as shown in the table below.

**Table 13.1: Status Edible Salt Survey Samples**

States	No. of Sample Received	Satisfactory	Unsatisfactory
Abia	48	47	1
Anambra	48	47	1
Akwa Ibom	48	48	0
Delta	48	48	0
Enugu	48	48	0
Ebonyi	48	42	6
Imo	48	48	0
Rivers	48	48	0

<b>Total</b>	<b>384</b>	<b>376</b>	<b>8</b>
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- ✓ The Laboratory also participated in the United States Pharmacopoeia (USP)/ NAFDAC drug survey. One Hundred and Sixty-Three (163) drug survey samples were received from Pharmacovigilance and Post-market Surveillance Directorate. The analysis is as shown below.

**Table 13.2: Status of (USP)/ NAFDAC Drug Survey Samples**

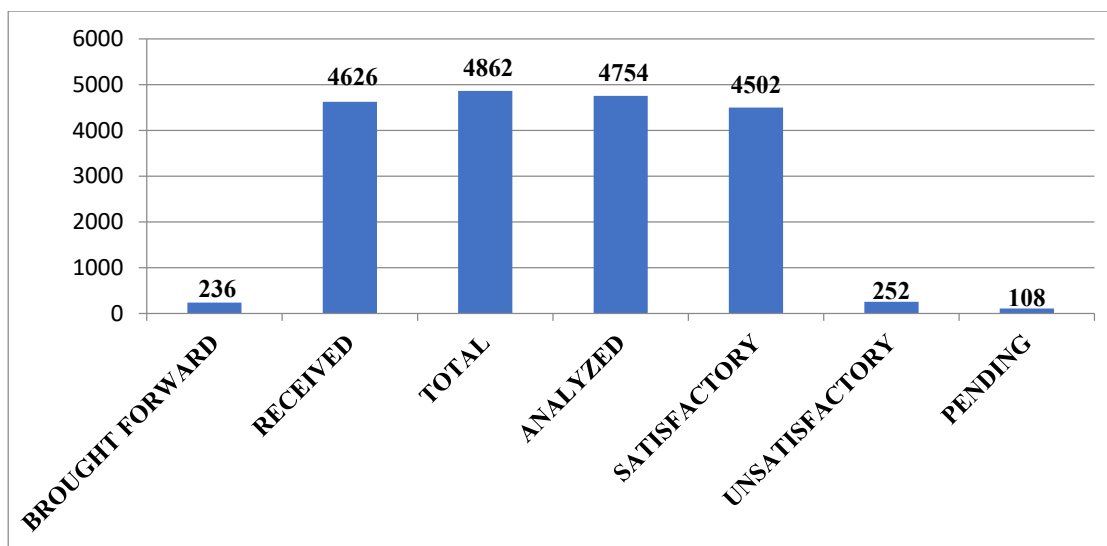
S/N	Name of Sample	No. of Samples Received	Satisfactory	Unsatisfactory
<b>1</b>	Artemether/Lumefantrine Tablets	55	53	2
<b>2</b>	Amoxicillin Capsule	1	0	1
<b>3</b>	Amoxicillin/Clavulanic Acid Tablets	33	24	9
<b>4</b>	Ciprofloxacin Tablets	74	67	7
	<b>Total</b>	<b>163</b>	<b>144</b>	<b>19</b>

Tables 13.1, 13.2 & 13.3, Figures 13.1& 13.22 below show the statistics of the activities within the year under review.

**Table 13.3: Cumulative Summary Report of Analytical Activities for the Year 2022**

<b>Product</b>	<b>No. Samples Brought Forward</b>	<b>No. of Samples Received</b>	<b>cumulative Total</b>	<b>Cumulative total No. of Samples Analysed</b>	<b>Cum % of sample analysed</b>	<b>Samples Analyzed Within Timelines</b>	<b>% of Samples Analyzed within the Timelines</b>	<b>No. of Satisfactory Samples</b>	<b>No. Unsatisfactory sample</b>	<b>No. of Samples Pending</b>
January	236	158	394	244	61.93	156	39.59	232	12	
February		362	756	584	77.25	446	58.99	559	25	
March		353	1109	1068	96.30	820	73.94	1020	48	
April		422	1531	1338	87.39	1078	70.41	1278	60	
May		268	1799	1643	91.33	1374	76.38	1573	70	
June		303	2102	1904	90.58	1625	77.31	1817	87	
July		0	0	0	0.00	0	0	1817	0	
August		569	2671	2424	90.75	2037	76.26	2326	98	
September		517	3188	2920	91.59	2471	77.51	2791	129	
October		733	3,921	3,475	88.63	3,003	76.59	3308	167	
November		368	4,289	4,144	96.62	3,607	84.10	3,922	222	
December		573	4862	4,754	97.78	4,154	85.44	4,502	252	
<b>Total</b>		<b>4626</b>	<b>4,862</b>	<b>4,754</b>	<b>97.78</b>	<b>4,154</b>	<b>85.44</b>	<b>4,502</b>	<b>252</b>	<b>108</b>

**Figure. 13.1 Analytical Activities for the Year 2022**



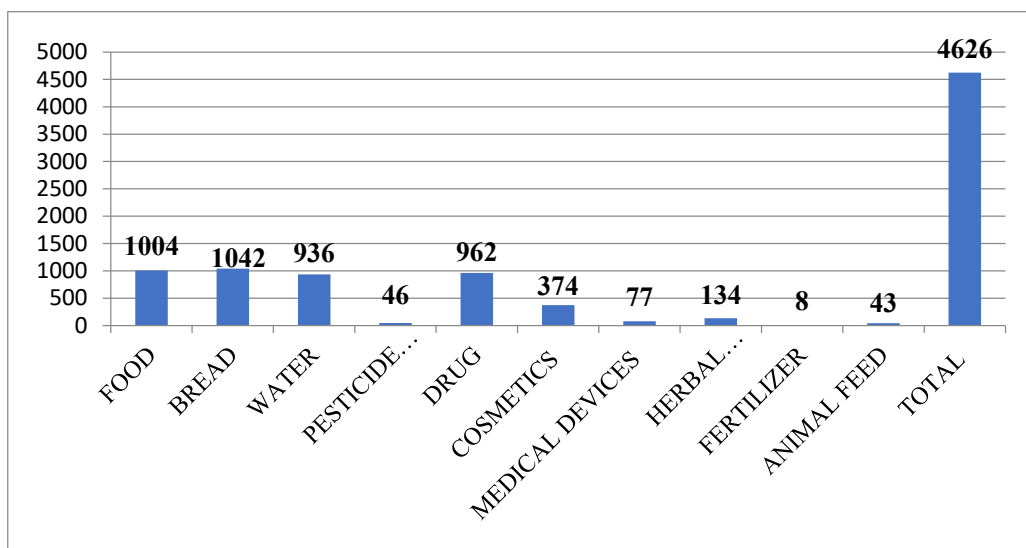
**Table 13.4 Profile of Samples Received for the Year 2022**

Product	Imported	Local		
		MSMEs	Others	Total
Food	30	841	133	1,004
Bread	0	556	486	1,042
Water	0	600	336	936
Pesticide Formulation	42	0	4	46
Drug	831	0	131	962
Cosmetics	4	0	370	374
Medical Devices	71	0	77	77
Herbal Preparation	0	0	134	134
Fertilizer	2	0	6	8
Animal Feed	0	7	36	43
Others (Specify) PT Sample	0	0	0	0
<b>Total</b>	<b>980</b>	<b>2,004</b>	<b>1,642</b>	<b>4,626</b>

**Table 13.5 Sources of Samples Received for the Year 2022**

		Imported			Local						
		Registration	Renewal/ Compliance	Others	MSMEs			Others			Total
Registration	Renewal/ Compliance				Others	Registration	Renewal/ Compliance	Others	Registration	Renewal/ Compliance	
Food		0	30	0	741	110	0	78	9	36	1,004
Bread	Medium	0	0	0	414	143	0	0	0	0	557
	Medium/Large	0	0	0	360	125	0	0	0	0	485
Water	Sachet	0	0	0	389	80	0	0	0	0	469
	Bottle	0	0	0	387	80	0	0	0	0	467
Pesticide Form.		0	42	0	0	0	0	3	0	1	46
Drugs		0	715	4	0	0	0	35	3	205	962
Cosmetics		0	1	3	1	0	0	351	17	1	374
Medical Devices		9	58	4	0	0	0	5	0	1	77
Herbal Preparation		0	0	0	0	0	0	126	0	8	134
Fertilizer		0	2	0	0	0	0	6	0	0	8
Animal Feed		0	0	0	0	0	0	43	0	0	43
Others (Specify)		0	0	0	0	0	0	0	0	0	0
<b>Total</b>		<b>9</b>	<b>848</b>	<b>11</b>	<b>2,292</b>	<b>538</b>	<b>0</b>	<b>647</b>	<b>29</b>	<b>252</b>	<b>4,626</b>

**Figure 13.2: Categorized Quantity of Samples Received in 2022**



### 13.2 Quality Assurance

- i. The year 2022 started with the implementation of the Annual Work plan of the Directorate. The proposed programs were vigorously pursued by the Quality Assurance Unit and over 98% implementation was achieved in all except for staff training.
- ii. More than 80% of equipment were calibrated by an external calibration provider during the year of review.
- iii. Internal audit was carried out according to the 2022 audit protocol. The non-conformances identified were closed except for few that are awaiting management action. Follow up audit was also carried out to ensure that the non-conformances recorded have been closed and, corrective actions put in place were effective.
- iv. Monitoring of accredited scopes and implementation of QMS in all laboratory units continued within the year under review.
- v. The Laboratory participated in Proficiency Tests/Inter-Laboratory Comparisons (PT/ILC) on HPLC, Disintegration, pH, UV, Polarimeter, Dissolution and some Condom test parameters. The results for the UV, Dissolution, HPLC, Disintegration and Condoms tests have been received while the others are being awaited.
- vi. A joint Management Review Meeting (MRM) with other NAFDAC Laboratories was held on 5<sup>th</sup> October 2022. Most of the issues raised at the meeting have been addressed while others are at various stages of implementation. The Directorate was applauded for her excellent performance during the meeting.

### 13.3 Accreditation

The Laboratory was assessed from 5<sup>th</sup> – 7<sup>th</sup> December 2022 by ANSI-ASQ National Accreditation Board (ANAB) via zoom-online for ISO/IEC 17025:2017. The Laboratory underwent scope extension in Food (6), Water (1) and Medical Devices (15). In addition, the re-accreditation of the previous sixteen scopes was done. The outcome was very successful as no non-conformance was recorded.

#### **13.4 Training**

- i. Scheduled and unscheduled trainings were held either online or face-to-face as may be the case and, all were geared toward improving the quality management system of the Agency in compliance to international standards.
- ii. In-house training for staff of Drugs and Food Divisions took place during the year under review.
- iii. All staff took part in the GMP Inspection training conducted by Planning Research and Statistics Directorate,
- iv. Hands-On training on LIMS took place from 11<sup>th</sup> – 12<sup>th</sup> February 2022 at ALSD during the year under review.
- v. Trainings on harmonized SOPs and other Quality Management System documents continued in the year under review.
- vi. The following internal trainings were conducted by Quality Assurance Unit during the year. Training topics included Good Documentation Practice, ISO 9001:2015 Management System, ISO/IEC 17025:2017 Clause by Clause Summary 1 & 2, WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) and other relevant in-house training topics.

#### **13.5 Health Safety and Environment**

Safety Signage including directional signs and energy saving stickers were installed at strategic locations of the Laboratory for staff and visitors to see as reminders and guide. Also, First-Aid Boxes were procured for the Laboratory. Fire extinguishers were also placed in strategic locations around the Laboratory.

#### **13.6 Staff Matters**

As of 31<sup>st</sup> December 2022, the Laboratory has a total of thirty-five (35) staff comprising of twenty-nine (29) senior staff and six (6) junior staff. In addition, there were six (6) Corps members, one (1) Intern Pharmacist, and eleven (11) IT Students.

#### **13.7 Procurement and Renovation**

- i. Equipment procured by the Agency such as p<sup>H</sup> Meters, Thermo-hygrometers, HPLC, GC-MS, GC-FID, AAS. FTIR, Analytical Balances were installed at various units of the laboratory within the year under review.
- ii. Office furniture including laboratory stools were also supplied. Thirty (30) 2HP Split Unit, and one (1) 10 HP air-conditioners were also supplied. Test kits and chemicals were also supplied.
- iii. Renovation works were carried out in the laboratory complex. This included replacement of collapsed water tank, renovation of warehouse, installation of air-extractors and other renovation works in the laboratory complex.

#### **13.8 Conclusion**

The Directorate successfully sustained the previously accredited analytical scopes and got extension in Twenty-Two (22) new Scopes in Food/Water and, Medical Devices. The Directorate is committed to sustaining and exceeding her achievements thereby meeting the

NAFDAC mandate and in accordance with our strategic goals. We also hope that most of the constraints facing the Laboratory will be resolved as soon as possible and staff of the laboratory are motivated more for better performance. The year ended on a good note as our certificate of Accreditation was extended by another one year.

## Chapter 14

### Kaduna Laboratory Services

#### 14.1 Executive Summary

The Kaduna Laboratory Services receives samples from 13 states (Northwest states- Kaduna, Kebbi, Katsina, Kano, Sokoto, Jigawa and Zamfara. North Central states- Niger, Kogi, Benue, Plateau, Nasarawa and Kwara) and the FCT. Occasionally samples come from the Lagos State as well.

The Directorate has worked hard to make sure reports are sent out without delay especially the MSMEs and Bread samples. In 2022, the laboratory had a Document Surveillance Audit with ZERO nonconformance.

The laboratory received a total Of Seven Thousand Nine Hundred and Twenty-Six (7,926) samples. Seven Thousand and Ninety-Five (7,095) samples were locally produced while the remaining Eight Hundred and Thirty-One (831) were foreign samples. From the month of December 2021, six hundred and sixty-three (663) samples were brought forward. The Laboratory then had a total of Eight Thousand Five Hundred and Ninety-Two (8,592) samples as at 25<sup>th</sup> December 2022.

In the year under review Eight Thousand Two Hundred and Twenty-Three (8,223) samples were analysed. Seven Thousand and Ninety-Two (7092) were satisfactory and One Thousand One Hundred and Thirty-One (1,131) were unsatisfactory and Three Hundred and Sixty-Nine (369) sample have been carried over into the year 2023.

The laboratory received investigation samples of green tea imported from Niger Republic to Sokoto state and snuff popularly called **Shake** from Zamfara NAFDAC Office and the analysis are ongoing. PV/PMS Abuja also submitted samples of different brands of cough syrups, paracetamol and ibuprofen suspensions for investigation suspecting containing diethylene glycol (DEG) and Propylene glycol. The analysis in progress, however with little challenge in sourcing for the reference standards for diethylene glycol and propylene glycol.

Apart from registration and routine samples, the laboratory also received investigation samples from Enforcement Directorate and PV/PMS.

**Table 14.1: Summary of Laboratory Analysis for the Year 2022.**

Product type	No of samples brought forward	No of samples received	Total number of samples	No of samples analysed	No. of satisfactory Samples	No of unsatisfactory samples	No of pending samples
Food	265	3701	3966	3800	3328	472	166
Chemistry	203	951	1154	1069	984	85	85
Water	127	2389	2516	2443	1946	497	73
Cosmetics	65	431	496	471	396	75	25
Pesticides Formulation*	03	113 (124)	116 (124)	96 (124)	94 (124)	2	20
Mycotoxin*	0	344 (1072)	344 (1072)	344 (1072)	344 (1072)	0	0
Microbiology*	153	5663	5816	5520	4847	673	296
<b>Total</b>	<b>663</b>	<b>7929</b>	<b>8592</b>	<b>8223</b>	<b>7092</b>	<b>1131</b>	<b>369</b>

#Key: Figures in red (soft copy) show samples that the asterisked\* laboratory acquired from the water, food, chemistry and/or the drug compliance unit. **Key performance indicator (KPI) is 95.71% for the year 2022.**

## ***14.2 Details of Activities***

### **A. Technical**

#### **I. Investigation by Months**

##### **January**

###### ***Gombe***

The Investigation and Enforcement Directorate NAFDAC in conjunction with the Federal Task Force carried out a raid and arrested a suspect who produces, sales and distributes an unregistered Herbal products (with fertility claims). This product is suspected to be toxic and has been submitted in the Laboratory for analysis.

###### ***Kano***

Samples of Parboiled rice and pasta were submitted for investigation.

##### **February**

###### ***Kaduna***

The Investigation and Enforcement Directorate NAFDAC in conjunction with the Federal Task Force submitted unregistered Herbal products for oral intake. These products are suspected to contain Formalin (street name ‘Soak & Die’), which is used in shampoos, disinfectants and antiseptics and not for ingestion.

##### **April**

In view of the recall of some variety of Indomie Instant Noodle packs from Egypt, owing to the order from the Egyptian National Food Safety Authority and the suspension by the Rwandan Food and Drug Authority of importation a variety of Indomie from Kenya. The Laboratory received some varieties of the Indomie noodles in the Nigerian market for test on aflatoxins and pesticide residue and result were satisfactory.

##### **June**

The Kaduna Federal Task Force Investigation and Enforcement acquired from the Nigeria Customs Services, imported, unregistered instant non-diary milk that is being sold and distributed. A compliant was also issued by the Rido/Muslim/Christian/Farmers Interfaith Cooperative Society against the Kaduna Refinery and Petrochemical Company (KRPC) alleging that the operations of KRPC have polluted their water system. Water samples were submitted for analysis and results were unsatisfactory.

##### **August**

###### ***Delta***

The Laboratory received food samples from Delta state office concerning a suspected disease outbreak in Mary Mount College, Boji Boji Owa, Ika North East LGA, Delta State. The water samples were unsatisfactory.

##### **September**

###### ***Fortification Survey***

The 2022 Food Fortification Survey/ Compliance Monitoring for the agency has commence and the Kaduna Laboratory Services has received Two Hundred and Eight-Eight (288) samples each from the following states, Kano, Katsina, Zamfara, Gombe, Bauchi, Sokoto, Taraba, and Kebbi totaling Two Thousand Three Hundred and Four (2,304) samples.

### ***PV/PMS***

The sampling of Artemether/ Lumefantrine tablets was carried out in seven (7) states across the country and a total of one hundred and fourteen (114) samples were submitted for analysis and out of which 12 samples were unsatisfactory.

### ***Sokoto***

The Sokoto State submitted a sample Dambun Masara for analysis. This sample is suspected to have killed seven (7) out of eight (8) persons in one family after they ate the sample for breakfast. No pesticides/insecticides detected from the sample.

### **October**

Samples were submitted for analysis, following the emergence of substance of abuse of particular syrup (CODOLIN SYRUP) by the National Drug Law Enforcement Agency (NDLEA) and the result was unsatisfactory.

### **PV/PMS**

The DG (NAFDAC) directed the urgent sampling of Augmentin 625mg tablets in Abuja to enable the Agency take necessary regulatory actions, this along with brands of Dexamethasone Tablets. The six different batches of the Augmentin analysed were satisfactory while Dexamethasone two were satisfactory and one is unsatisfactory.

### **November**

#### **Federal Task Force/ Investigation and Enforcement Directorate**

Samples of Green Tea, said to have been imported from Niger Republic received from Sokoto State office are unsatisfactory because have not been registered with the Agency.

The Laboratory also received investigation samples Snuff popularly called ‘**shake**’ (smokeless tobacco) from Zamfara state. The product though not registered by the Agency is widely patronized and used as stimulants, aphrodisiacs, analgesic etc. It is undergoing analysis.

#### **Pharmacovigilance and Post Marketing Surveillance (PV/PMS)**

PV/PMS Abuja also submitted samples of different brands of cough syrups, paracetamol and ibuprofen suspensions for investigation suspecting containing diethylene glycol (DEG) and Propylene glycol. The analysis in progress, however with little challenge in sourcing for the reference standards for diethylene glycol and propylene glycol.

### **Zamfara**

The Laboratory also received investigation samples Snuff popularly called ‘**shake**’ (smokeless tobacco) from Zamfara state. The product though not registered by the Agency is widely patronized and used as stimulants, aphrodisiacs, analgesic etc. It is undergoing analysis.

### **December**

The investigation and enforcement directorate (I&E), Kaduna submitted a sample of unregistered powdered milk from the People's Republic of China PRC. It is suspected to have been illegally imported and unregistered.

## **II. Report From Laboratory Units**

### ***a) Food Unit***

The food unit received a total of Three Thousand Seven Hundred and One (3,701) samples, Two Hundred and Sixty-Five (265) samples were brought forward; thus, the unit had a total of three thousand nine hundred and sixty-six(3966) samples. Three Thousand Eight Hundred (3,800) samples were analyzed, out of which Three Thousand Three Hundred and Twenty-Eight (3,328) samples were satisfactory and Four Hundred and Seventy-Two (472) samples were unsatisfactory. One Hundred and Sixty-Six (166) samples have been carried over into the year 2022.

### ***b) Chemistry Unit***

The chemistry unit received a total of Nine Hundred and Fifty-One (951) samples. Two Hundred and Three (203) samples were brought forward, making a total of one thousand and fifty-four (1154) samples. One Thousand and Sixty-Nine (1,069) samples were analyzed, with Nine Hundred And Eighty-Four (984) samples satisfactory and Eighty-Five (85) unsatisfactory. Eighty-five (85) samples were carried over into the year 2022.

### ***c) Water Unit***

The water unit received Two Thousand Three Hundred and Eighty-Nine (2,389) samples. One Hundred and Twenty-Seven (127) samples were brought forward, making a total of Two Thousand Five Hundred and Sixteen (2,516). Two thousand four hundred and forty-three (2443) samples were analyzed, out of which One Thousand Nine Hundred and Forty-Six (1946) samples were satisfactory and Four Hundred and Ninety-Seven (497) samples were unsatisfactory. Seventy-three (73) samples were carried over into the year 2022.

### ***d) Cosmetics Unit***

The Cosmetics Unit Received Four Hundred and Thirty-One (431) samples. Sixty-five (65) were brought forward, making a total of Four Hundred and Ninety-Six (496) samples. Out of the total, Four Hundred Seventy-One (471) samples were analyzed with three hundred and ninety-six (396) samples satisfactory and Seventy-Five (75) samples unsatisfactory. Twenty-five (25) samples have been brought forward to the year 2022.

### ***e) Pesticide Formulation***

The pesticides formulation unit received One Hundred and Thirteen (113) samples. Three (03) samples were brought forward making a total of One Hundred and Sixteen (116) samples. Ninety-six (96) samples were analyzed. Ninety-four (94) samples were satisfactory with two (2) samples unsatisfactory. Twenty (20) samples were brought forward into the year 2022. The laboratory also acquired one hundred and twenty-four samples from other labs and analysed all and all were satisfactory.

### ***f) Mycotoxin Unit***

The mycotoxin unit received a total of Three Hundred and Forty-Four (344) samples and acquired One Thousand and Seventy-Two (1,072) samples. No sample was brought forward.

All samples were analyzed, and all samples were satisfactory. No sample was brought forward into the year 2022.

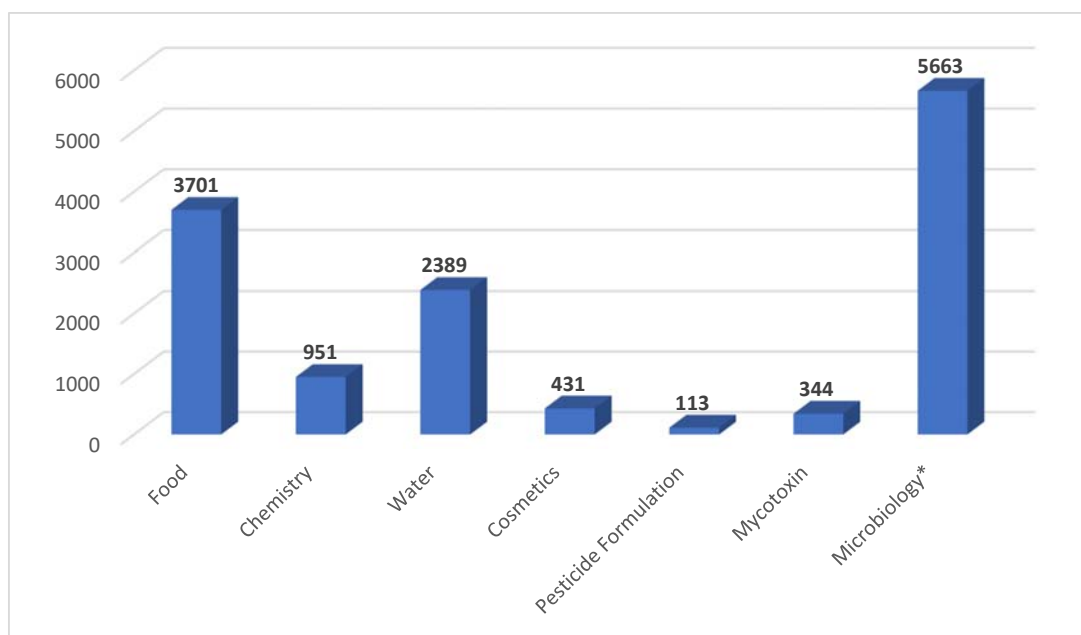
**g) Microbiology Unit**

The microbiology unit acquired samples from various units totalling Five Thousand Six Hundred and Sixty-Three (5,663) samples and brought forward One Hundred and Fifty-Three (153) samples. Total samples for analysis were Five Thousand Eight Hundred and Sixteen (5,816) samples. Five Thousand Five Hundred and Twenty (5,520) samples were analyzed, out of which Four Thousand Eight Hundred and Forty-Seven (4,847) samples were satisfactory and Six Hundred and Seventy-Three (673) were unsatisfactory. Two Hundred and Ninety-Six (296) samples were carried over into the year 2022.

**Table 14.2: Showing the Total Samples Received In 2022**

S/N	Product type	Quantity
1.	Food	3,701
2.	Chemistry	951
3	Water	2,389
4.	Cosmetics	431
5.	Pesticides Formulation	113 (124)
7.	Mycotoxin	344 (1072)
8.	Microbiology*	5,663
	Total	7,926

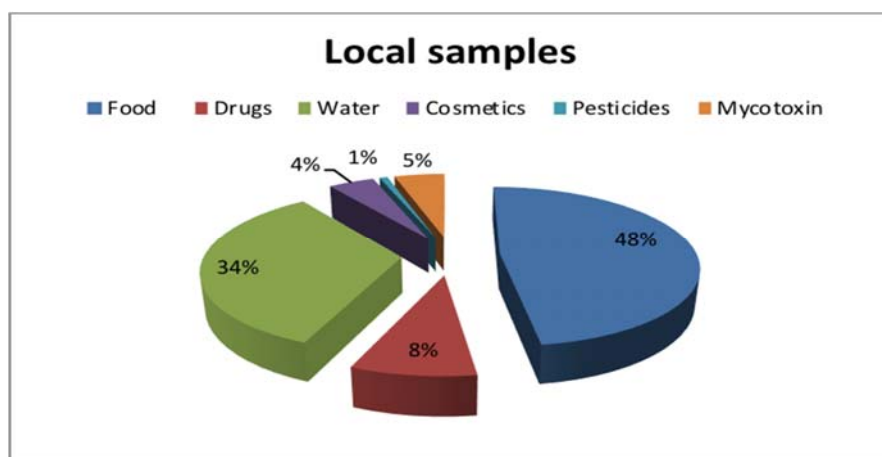
**Figure 14.1: Showing Number of Samples Received in 2022**



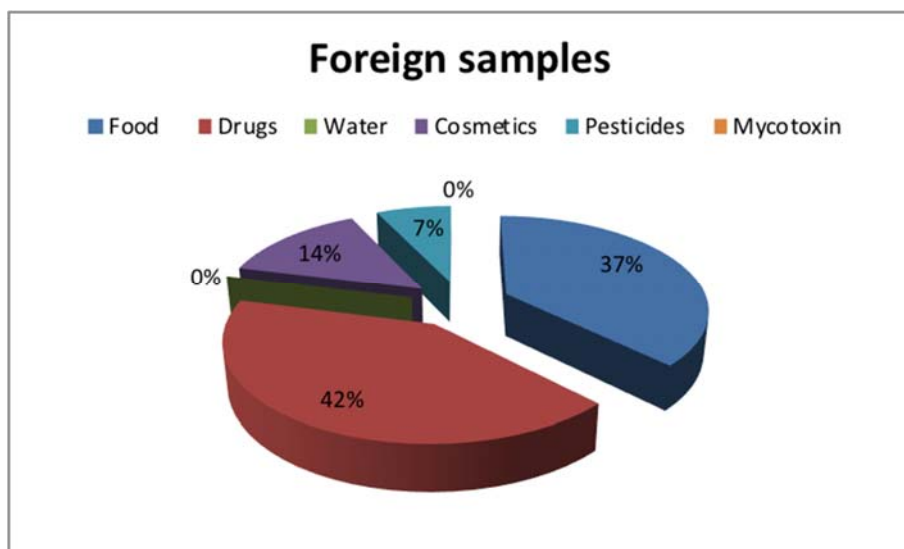
**Table 14.3: Profiles of Local and Foreign Samples Received in 2022**

SN	Product type	Samples received	
		Local	Imported (foreign)
1.	Food	3,387	311
2.	Drugs	606	345
3	Water	2389	0
4.	Cosmetics	315	116
6.	Pesticides	54	59
7.	Mycotoxin	344	0
	<b>Subtotal</b>	<b>7,095</b>	<b>831</b>
		<b>TOTAL</b>	<b>7,926</b>

**Figure 14.2: Local Samples Received for 2022**



**Figure 14.3: Foreign Samples Received for 2022**



**Table 14.4: Pending Sample For 2022**

SN	Laboratory Unit	Number of Samples Pending	Reasons for Pending Samples
1.	Food	166	Awaiting Microbiology reports, and work is ongoing
2.	Chemistry	85	Bulk of samples was received at the end of the year. Work is ongoing
3.	Water	73	Awaiting Microbiology reports, and work is ongoing
4.	Cosmetics	25	Awaiting Microbiology reports, and work is ongoing
5.	Pesticides Formulation	20	Work is on-going
6.	Pesticides Residue	0	-
7.	Mycotoxin	296	-
8.	Microbiology	369	Work is ongoing
9.	Drug Compliance	166	Awaiting Microbiology reports and work is ongoing.

## B. Administrative Unit

### Staff Strength

- Numbers of staff - Seventy (70),
- Corpers - Seven (07)
- Interns - Four (04).

## Chapter 15

### Chemical Evaluation and Research (CER) Directorate

#### 15.0 Introduction

The Chemical Evaluation and Research (CER) Directorate has the mandate to safeguard public health by ensuring that only the right **chemicals** are manufactured, imported, exported, distributed, sold and used in Nigeria.

#### 15.1 Structure of CER

The directorate is structured into 4 divisions. These are:

- I. Chemical Import Control (CIC)
- II. Agrochemicals and Controlled Chemicals Division (AC/CC)
- III. Chemical Monitoring and Risk Assessment (CM&RA)
- IV. Chemical Research and Review (CR&R)

#### 15.2 Functions of CER

- I. Ensure availability of chemicals to bonafide companies through prompt issuance of permits to import and clear Industrial and Restricted Chemicals. The process of obtaining import permits is electronic and can be done on the Nigeria Single Window Portal ([www.trade.gov.ng/nafdac](http://www.trade.gov.ng/nafdac))
- II. Undertake and co-ordinate research programs on the storage, adulteration, distribution and rational use of chemicals
- III. Carry out the Risk Assessment of Chemicals
- IV. Issue Authorizations/Licenses to Chemical Marketers and Manufacturers
- V. Inspect Warehouses for Storage of Chemicals
- VI. Generate relevant reports & statistics on Chemicals
- VII. Investigate breach of regulations on chemicals by companies of individuals
- VIII. Safeguard the health of the populace and environment by ensuring sound chemical management
- IX. Ensure conformity to International Standards for controlled and restricted Chemicals
- X. Conduct surveillance and monitor hazardous and harmful Chemicals in circulation

#### 15.3 Summary of Activities

In 2022, a total of **Twenty-five Thousand, Two Hundred and Forty-Nine (25,249)** regulatory activities were carried out by CER Directorate nationwide. **Twenty Thousand, Eight Hundred and Ninety-eight (20,897)** of these regulatory activities were carried out in Lagos state while **Four Thousand, Three Hundred and Fifty-two (4,352)** CER regulatory activities were recorded in NAFDAC offices in the other states.

A total of **Eight Thousand, Three Hundred and Eighty-Two (8,382)** applications were received for issuance of permits to import general and restricted chemicals, permits to clear

restricted chemicals, Listing as a chemical marketer or chemical manufacturer and inspection of storage facilities for Chemicals.

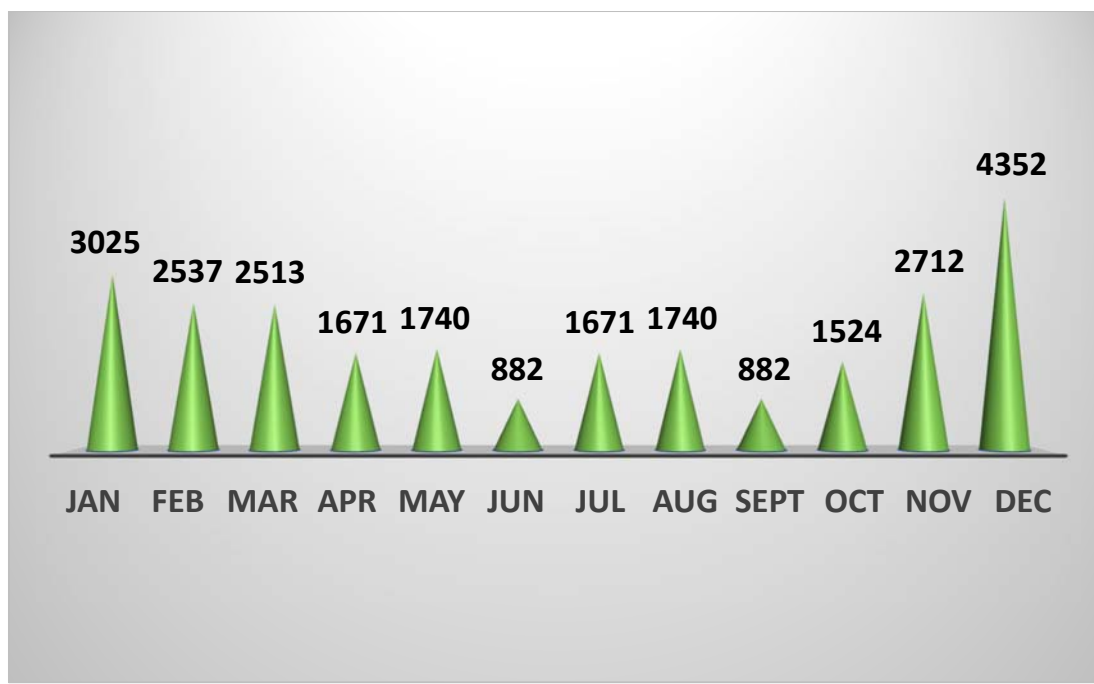
**Three Thousand, Two Hundred and Sixty (3,260)** permits to import were approved for both general and restricted Chemicals while **One Thousand Two Hundred and Seventy-One (1,271)** permits to clear were issued for restricted chemicals. **Six Hundred and Nineteen (619)** facilities were listed as chemical marketers and manufacturers and issued Listing Notifications. A total of **One Thousand, Three Hundred and Eighty-Seven (1,387)** satisfactory inspection activities were carried out in the year under review.

**Two Hundred and Seventy-Eight (278)** routine monitoring inspections were carried out in Lagos. **Five Hundred and Fifty (550)** Compliance Directives were issued for various inadequacies and incomplete documentations.

**Table 15.1: Monthly Activities in CER Directorate**

S/N	TYPE OF ACTIVITIES	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	TOTAL
1	No of applications received for Permit to Import	772	570	518	286	291	210	286	291	210	303	564	895	5196
2	No of applications received for Permit to Clear	106	101	116	128	140	56	128	140	56	96	95	90	1252
3	No of applications received for Warehouse inspection	244	83	107	53	43	16	53	43	16	53	249	205	1165
4	No of applications received for Listing Certificate	157	35	72	48	40	17	48	40	17	50	72	173	769
5	No of applications received for LPO verification	84	64	36	24	27	20	24	27	20	5	32	66	429
6	No of applications received from outstation for permits to import/clear, warehouse inspection, LPO verification and Listing certificates	49	78	68	42	77	21	42	77	21	37	37	64	613
7	No. of applications treated for Permit to import and Listing Certificate	200	116	66	60	73	32	60	73	32	92	498	336	1638
8	No. of applications treated for Permits to Clear	106	101	135	128	140	56	128	140	56	96	95	90	1271
9	No. of applications treated within timeline	152	101	200	106	92	57	106	92	57	188	120	257	1528
10	No. of applications in progress	83	75	82	77	79	30	77	79	30	99	181	160	1052
11	No of E-permits to Import issued	416	468	427	197	198	165	197	198	165	118	100	611	3260
12	No of E-permits to Import issued within timeline	103	117	74	46	21	16	46	21	16	8	100	611	1179
13	No of approved permits to Clear	106	101	135	128	140	56	128	140	56	96	95	90	1271
14	No of approved permits to Clear issued within timeline	106	101	135	128	140	56	128	140	56	96	95	90	1271
15	No. of Listing Notifications issued to Chemical Marketers	81	103	67	28	28	18	28	28	18	46	42	127	614
16	No of Listing Notifications issued to Chemical Manufacturers	0	0	0	0	0	1	0	0	1	0	2	1	5
17	No. of Listing Certificates prepared for DG'S endorsement	0	0	0	0	0	0	0	0	0	0	0	0	0
18	No of inspections conducted (Satisfactory reports)	122	170	156	113	121	16	113	121	16	69	123	247	1387
19	No. of follow - up inspections	0	0	0	0	0	0	0	0	0	1	0	0	1
20	No. of routine monitoring inspections	17	33	22	14	32	3	14	32	3	45	39	24	278
21	No of surveillance inspections	0	0	0	0	0	0	0	0	0	0	0	13	13
22	No. of LPO verification treated	77	61	34	26	25	20	26	25	20	4	19	66	403
23	No. of LPO verification untreated	0	0	0	0	0	0	0	0	0	0	0	0	0
24	No. of Queries/CDs issued	28	42	36	39	17	16	39	17	16	20	152	128	550
25	No. of consultative meetings/seminar and workshop held	13	14	23	0	12	0	0	12	0	0	0	7	81
26	No. of Violations	1	1	2	0	0	0	0	0	0	2	2	1	9
27	No. of Warehouses/Products/Consignments put on Hold	2	2	2	0	4	0	0	4	0	0	0	0	14
28	<b>TOTAL</b>	<b>3,025</b>	<b>2537</b>	<b>2,513</b>	<b>1,671</b>	<b>1740</b>	<b>882</b>	<b>1,671</b>	<b>1740</b>	<b>882</b>	<b>1,524</b>	<b>2712</b>	<b>4352</b>	<b>25249</b>

**Figure 15.1: Monthly Regulatory Activities in CER**



**Table 15.2: Comparative Analysis of Key CER Regulatory Activities 2021-2022**

S/N	Activities	2021	2022
1	Number of Regulatory activities recorded	17,265	25,249
2	Number of Applications received	8,138	8,382
3	Number of Permits to Import issued for General and Restricted Chemicals	3,474	3,260
4	Number of Permits to Clear issued for Restricted chemicals	1,315	1,271
5	Number of Inspections Conducted	1,738	1,387
6	Number of Listing notifications issued to Chemical Marketers	858	619
7	Number of Queries/CDs issued	531	550

The Chemical Evaluation and Research Directorate recorded huge level of success in 2022 despite the six weeks industrial action that hampered our activities across the nation.

A significant higher number of regulatory activities were recorded in 2022 as compared to 2021. The directorate also recorded a significant higher number of queries and compliance

directives. This may be attributed to monitoring exercises carried out in Lagos and outstation offices within the year.

The Directorate also ensured that as much as possible timelines were adhered to while also making the processes easy and seamless for the clientele.

**Table 15.3: Performance Outlook for January – December 2022**

S/N	Activities/Tasks	Actual Performance
1	Processing of Applications for Chemical/Raw Materials Warehouse Treated	100%
2	Processing of applications for Permit to import chemicals within stipulated timelines	92.9%
3	Prompt issuance of Permit to Clear restricted chemicals to marketers within timeline	100%

**Table 15.4: CER Outstation Activities 2022**

S/N	Outstation	Number Of Activities
1	South West	312
2	South East	591
3	South South	881
4	North West	311
5	North East	47
6	North Central	156
7	FCT Abuja	658
	<b>Total</b>	<b>2,956</b>

#### **15.4 Quality Management Systems (QMS) and Internal Trainings**

The CER QMS team organized and conducted trainings and workshops in the year under review. Guidelines and operational procedures were also reviewed. Trainings on Process Safety Management, Domestication of the chemical Weapons convention in Nigeria, NAFDAC Quality Documents, Scheduled Chemicals of Chemical Weapons Convention were conducted for all members of staff of CER.

#### **15.5 Meetings/Workshops**

The Directorate participated in the underlisted meetings/workshops:

1. Executive Program on Chemical Security and Safety Mauritius October 2022
2. Article II Workshop Hague Netherlands November 2022
3. Stakeholder Review and Validation of the Nigeria’s Draft cooling plan organized by the Federal Ministry of Environment 25<sup>th</sup> – 26<sup>th</sup> May, 2022

4. OPCW Advanced course on Chemical Safety and Security Management for member states in the Africa Region
5. Chemical Regulation, Security, Safety, Handling & Storage Meeting with Chemical Dealers in Lagos 1<sup>st</sup> December, 2022
6. Sub Regional Basic Course on Emergency response to Chemical incidents for ECOWAS 14<sup>th</sup> – 18<sup>th</sup> June 2022
7. Project Steering Committee (PSC) meeting of the UNEP Special Program Project 6<sup>th</sup> – 8<sup>th</sup> September 2022
8. Training on the use of International Atomic Energy Agency (IAEA) Intouch+ Platform organised by NAEC, Abuja 6<sup>th</sup> – 7<sup>th</sup> June 2022

### **15.6 Other Regulatory Activities**

1. Preparation of guidelines for Production Inspection of Chemical Manufacturing Facilities in Nigeria and the guidelines for NAFDAC Good Manufacturing Practice for Chemicals and Chemical Products.
2. Organization of a NAFDAC Stakeholder’s Meeting to sensitize players in the Chemical Industries, Manufacturers and End-users on recent developments for the issuance of Listing Certificate, End-User Certificate for Chemicals of security and safety concerns 13<sup>th</sup> April, 2022
3. Organization of an in-house Human Capacity Building Program on key Components of Chemical Monitoring for CER Regulatory Officers.
4. Inspection of Chemical Manufacturing sites and plants in Lagos State for compliance in activities.
5. **Two Hundred and Seventy-Eight (278)** surveillance inspection activities were carried out in the year under review.
6. **Four Hundred and Three (403)** Local Purchase Orders presented by Chemical marketers were verified from the bona-fide end-users.

### **15.7 Challenges**

1. Operational Vehicles
2. Robust Internet Facility
3. Computer Systems
4. Office Furniture
5. Human Capital and Man-power development

## 15.8 Focus

1. Full Deployment of the electronic processing of Permits to clear for restricted Chemicals and Listing of Chemical manufacturers.
2. Enhanced collaboration with International Chemical Control Organizations such as Organization for the Prohibition of Chemical Weapon, Montreal Protocol, Stockholm Convention etc.
3. Continuous sustenance of Quality Management System achievements through Monitoring and Evaluation to ensure continuous improvements.
4. Constant engagement with listed chemical marketers to ensure that they keep to the terms of their listing certificates with the overall objective of ensuring that chemicals do not get into wrong hands who may deploy them for clandestine purposes.
5. Establishment of a Laboratory in collaboration with the Laboratory Services Directorate for Chemicals.
6. Regular engagement with industries and other relevant stakeholders to ensure sound management of chemicals in Nigeria.
7. Continuous collaboration with MDAs like Office of the National Security Adviser (ONSA), Federal Ministry of Environment, Federal Ministry of Agriculture, NESREA, NCS, etc. on matters of common interest; like the issuance of end-user certificate; Mercury as a global pollutant, chemicals interaction with the ozone layer and the ozone depleting substances, chemical weapons etc.
8. Continuous monitoring (through enhanced routine inspections) of chemicals in Industries to check utilization and stock levels and possible diversion for unauthorized purpose; and also monitor disposal practices.

## Chapter 16

### Veterinary Medicines and Allied Products (VMAP) Directorate

#### 16.1 Meetings/Training/Workshops:

The Directorate participated in all her statutory meetings at both local and international levels. All in-house meetings were also attended. In the same vein seminars, training, workshops, and stakeholder meetings were also attended. Most of the meetings were held on a virtual platform. Principal amidst the training/workshops/meetings during the period under review are listed below:

- Ad-hoc committee on banned pesticides meeting on 10th January, 2022
- VMAP Directorate 2022 Retreat held at Equity Resort Ijebu-Ode from 14th-16th January, 2022
- Sub-Approval meeting held on 25th January, 2022
- Training of Kano State officers on inspection of Pesticides and Agrochemicals held on 1st February, 2022
- Meeting with FMARD (Federal Ministry of Agriculture & Rural Development and Japanese organization on the training of NAFDAC officers on applications of HACCP in rice production in Nigeria, held at Lagos State Ministry of Agric Oko-Oba Agege, Lagos on 8th February, 2022
- Virtual meeting between NAFDAC and Committee Linking Europe-Africa-Caribbean-Pacific (COLEACP) Belgium led by DG NAFDAC held on 16th February, 2022
- Virtual meeting on New Codex Project on Food Borne Anti-Microbial Resisitance (AMR) hosted by South Korea Ministry of Drugs, held on 17th February, 2022
- Virtual step-down training for NAFDAC officers in the SEZ & NCZ on overview of survey on Hazard Analysis and Critical Control Point (HACCP) on Rice Milling held on 15th March, 2022.
- Virtual meeting on Antimicrobial Consumption Surveillance with FMARD staff held on 30th March, 2022
- Virtual meeting with Office International des Epizooties (OIE), FMARD on Antimicrobial use of Surveillance held on 30th March 2022.
- Virtual training of officers in West Africa Sub-region on Surveillance of AMR in Food held on 12<sup>th</sup> of April, 2022.
- US Delegation Virtual meeting with Nigerian NAFDAC on International Health Regulations (IHR) Amendments held on 27<sup>th</sup> April, 2022.
- World Food Summit held virtually on the 5<sup>th</sup> and 6<sup>th</sup> May 2022, hosted by the Danish Ministry of Agriculture and Food.
- Physical training of Qualifying Work Force Antimicrobial Resistance for Asia and Africa held at NCDC Abuja between 13<sup>th</sup> – 15<sup>th</sup> July, 2022.
- In-House Capacity Training on Impact of Veterinary Medicine on Human Health held on 17<sup>th</sup> October 2022.
- Courtesy visit to Animal Care Konsult on 10<sup>th</sup> November 2022.

## 16.2 Inspections Conducted

Eight Hundred and Ten (810) inspections were conducted in the year under review.

<b>Inspection</b>	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>	<b>Total</b>
Warehouse	94	16	7	30	147
Permit Monitoring	15	21	0	0	<b>36</b>
Production	6	7	11	2	<b>26</b>
Routine	77	22	18	50	<b>167</b>
Pre-Production	5	0	3	4	<b>12</b>
Pre-Registration	2	0	1	3	<b>6</b>
Follow up	2	0	0	1	<b>3</b>
Cold Chain	7	5	3	1	<b>16</b>
Surveillance	41	30	52	84	<b>207</b>
GMP Assessment	13	3	2	3	<b>21</b>
GMP Inspection	0	0	1	3	<b>4</b>
Listing as Toll miller	2	3	3	0	<b>8</b>
Field Trial	2	3	3	0	<b>8</b>
Advisory	1	0	0	0	<b>1</b>
Investigation	2	0	0	0	<b>2</b>
GMP Risk Categorization	39	16	23	53	<b>131</b>
Farm stead GMP Inspection	0	0	1	0	<b>1</b>
Sampling	0	0	0	1	<b>1</b>
Renewal	0	0	0	6	<b>6</b>
<b>Grand Total</b>					<b>810</b>

## 16.3 e-Licence/Permit/Certificate Issued:

<b>Permit issued/Certificate</b>	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>	<b>Total</b>
Import permits for Animal feeds, Concentrates, Additives, Premixes, and Fish meals.	172	33	20	5	230
Permit to import Active veterinary pharmaceutical ingredients/vaccine for vet use	0	1	0	0	1

Import permits for Bulk Pesticide and Agrochemicals.	14	3	6	4	27
One-Off Permit	3	0	0	2	5
<b>Sub-total</b>					<b>263</b>
<b>Certificate Issued</b>					
Listing as Toll Miller	0	0	1	0	1
Listing license for Agrochemical Marketer	6	2	1	2	11
Authority to Clear	10	4	8	10	32
<b>Sub-total</b>					<b>44</b>
<b>Grand Total</b>					<b>307</b>

#### 16.4 KPI

Measure	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter	Total % Achieved
Applications received and documented within Specified timeline	100%	84%	65%	100%	87.3%
Inspection conducted within specified Timeline	100%	63.24%	53%	73%	72.31
No of permit approved within Specified timeline	90.2%	69.3%	35%	33.3%	34.4%

#### 16.5 Sanction Activity

Type of Sanction	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter	Total
Compliance Directive	19	10	1	38	68
Warning	2	2	7	0	11
Products placed on Hold	2	0	0	1	3
Invitation Letter	0	0	8	0	8
Outfit Placed on Hold	0	0	0	1	1
Closure of Outfit	0	0	0	1	1
<b>Total</b>	<b>23</b>	<b>12</b>	<b>16</b>	<b>41</b>	<b>92</b>

- **Product Registration Samples sent to lab - 145**
- **Summary of Local GMP Inspection Sent to R&R – 68**

## Chapter 17

### Pharmacovigilance and Post Marketing Surveillance (PV/PMS)

#### 17.1 Pharmacovigilance Division

The PV Division is responsible for promoting rational and safe use of medicines by sourcing, collating, analyzing and disseminating information on adverse drug events. The Division has sustained its activities even in the face of the pandemic. The activities of the PV Division within the period under review are hereby summarily presented as follows:

##### A. Individual Case Safety Reports (ICSRs) Management

One of the major functions of NPC is to manage data collected from the individual case safety reports (ICSRs) sent to the NPC via different sources; CIOMS, NPC ADR Forms, e-Reporting and Med Safety App. The reports, irrespective of the source, are transcribed and entered into VigiFlow which can further be transmitted to the VigiBase, the WHO International Drug Safety Monitoring Program database domiciled in Uppsala Monitoring Centre, Sweden after causality assessment. As of 28<sup>th</sup> December, 2022, a total of forty-nine thousand nine hundred and ninety-eight (49,998) ICSR/AEFIs were documented on the Vigiflow.

##### Received Reports

A total number of **Thirteen Thousand Eight-Hundred and Fifty-Five (13,855)** ICSR/AEFIs were received via the various reporting platforms as shown in table below;

**Table 17.1. Number of reports received in 2022**

Means of reporting	2022	Comments
Med Safety App	11,942	Review ongoing
e-Reporting	738	Review ongoing
CIOMS	374	Transcribed and uploaded to Vigiflow
NPC ADR Forms	35	Uploaded to vigiflow
AEFI Forms (NEC)	766	766 uploaded to vigiflow
<b>Total Received</b>	<b>13,855</b>	

##### Update on Manual Data entry to VigiFlow

ADR reports received from Health institutions and Marketing Authorization Holders (MAH) as CIOMs are transcribed and uploaded manually at the NPC into the Vigiflow. Similarly, AEFI reports from NEC are manually uploaded. A total of **One Thousand Two Hundred and Eighty-Two (1,282)** reports were uploaded and eight hundred and fifty (850) have been committed into the VigiBase as shown in the table below:

**Table 2. Manual ICSR/AEFI Data Entry to Vigiflow**

	Number Uploaded	Number Committed to VigiBase	Number Pending Review and Committing
Manual Data Entry ICSRs	5	3	1
Manual Data Entry AEFI	7	5	2
<b>Total</b>	<b>12</b>	<b>8</b>	<b>4</b>

## B. Review of Safety Documents

Ninety (90) Periodic Safety Update Report (PSUR)/[Periodic Benefit risk Evaluation Report (PBRER) and fourteen (14) Risk Management Plan (RMP) were received and reviewed in 2022 as follows:

S/No	Month	No. of PSUR	No. of RMP	Company	Remarks
1.	January 2022	8	1	<ul style="list-style-type: none"> <li>• ASZ</li> <li>• J &amp; J</li> <li>• NOVARTIS</li> <li>• SANOFI</li> <li>• ABBIE</li> <li>• SUN PHARMA</li> </ul>	NPC is continuously monitoring the use of products in clinical practice. PSUR conforms with GVP, 2020.
2.	February 2022	8	1	<ul style="list-style-type: none"> <li>• BAYER</li> <li>• ROCHE</li> <li>• PFIZER</li> <li>• HEALTH-HYGIENE HOME</li> <li>• FENSYL MHP CONSULTING LTD</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
3.	March 2022	5	0	<ul style="list-style-type: none"> <li>• NOVARTIS</li> <li>• GSK</li> <li>• PFIZER</li> <li>• MDS</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
4.	April 2022	7	4	<ul style="list-style-type: none"> <li>• NOVARTIS</li> <li>• BAYER</li> <li>• SANOFI</li> <li>• ASZ</li> <li>• J &amp; J</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
5.	May 2022	5	2	<ul style="list-style-type: none"> <li>• J &amp; J</li> <li>• BAYER</li> <li>• NOVARTIS</li> <li>• ASZ</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
6.	June 2022	5	2	<ul style="list-style-type: none"> <li>• J &amp; J</li> <li>• BAYER</li> <li>• NOVARTIS</li> <li>• ASZ</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
7.	July 2022	0	0		
8.	August 2022	23	1	<ul style="list-style-type: none"> <li>• FENSYL</li> <li>• NOVARTIS</li> <li>• BLOOMS</li> <li>• SANOFI</li> <li>• J &amp; J</li> <li>• MERCK</li> <li>• PFIZER</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
9.	September 2022	13	1	<ul style="list-style-type: none"> <li>• SANDOZ</li> <li>• NOVARTIS</li> <li>• SANOFI</li> <li>• J &amp; J</li> <li>• PFIZER</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
10.	October 2022	3	1	<ul style="list-style-type: none"> <li>• HEALTH-HYGIENE-HOME</li> <li>• PFIZER</li> <li>• SANOFI</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
11.	November 2022	10	1	<ul style="list-style-type: none"> <li>• NOVARTIS</li> <li>• PFIZER</li> <li>• J &amp; J</li> <li>• BAYER</li> <li>• SANOFI</li> </ul>	NPC is continuously monitoring the use of products in clinical practice

12.	December 2022	3	0	<ul style="list-style-type: none"> <li>• EXELTIS</li> <li>• NOVARTIS</li> <li>• PFIZER</li> </ul>	NPC is continuously monitoring the use of products in clinical practice
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### C. Cohort Event Monitoring (CEM) Evaluation Following Covid-19 Vaccination

The National Agency for Food and Drug Administration and Control (NAFDAC) in collaboration with the University of Maryland Baltimore (UMB) through funding from United States Centre for Disease Control and Prevention (US-CDC) is conducting a Cohort Event Monitoring (CEM) Evaluation following COVID-19 vaccination in selected tertiary health facilities and other high volume vaccination centers across the six geopolitical zones of Nigeria. The CEM is a multi-regional prospective cohort evaluation that aims to monitor and ensure COVID-19 vaccine safety in the country.

In view of on-going CEM activity, a causality assessment meeting was held in collaboration with the UMB to assess the AEFI reports that have accrued from the CEM. The meeting held from 10<sup>th</sup> to 12<sup>th</sup> January, 2022. A total of Seven Hundred and Twenty-One (721) reports of AEFIs from CEM were assessed and committed to VigiBase during this meeting.

A data review and validation meeting was held from 21<sup>st</sup> to 23<sup>rd</sup> April, 2022 in Goshen Guest house, Abuja-Keffi express way, Nasarawa State. The review and validation continued in the NAFDAC CHQ in the week of 25<sup>th</sup> to 29<sup>th</sup> April, 2022. A total number of Six Thousand Six Hundred and Thirty-Three (6633) AEFI reports from the CEM were reviewed and validated during this period.

Phase II CEM activities commenced in June 2022 and ran as follows:

- Training of Trainers (ToT) held in Nasarawa State from 6<sup>th</sup> – 7<sup>th</sup> June, 2022
- Training of follow-up personnel held at MGIC office, FCT from 8<sup>th</sup> – 10<sup>th</sup> June, 2022
- State level trainings held in FCT, Enugu, Bauchi, Kano and Edo states from 14<sup>th</sup> – 15<sup>th</sup> June, 2022
- CEM Pilot in FCT, Enugu, Bauchi, Kano and Edo states on 16<sup>th</sup> June, 2022
- CEM Phase II commencement in FCT, Enugu, Bauchi, Kano and Edo states on 20<sup>th</sup> June, 2022

Supervisory visits were carried out by Pharmacovigilance staff in all the CEM sites across the 6 geopolitical zones throughout the year.

### D. WHO-GBT Assessment

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The WHO-GBT assessment of Nigeria national regulatory systems toward attainment of maturity level 3 took place in February 2022. Vigilance Systems (VL), core function of the PV division were assessed on 24<sup>th</sup> February, 2022 in the NAFDAC CHQ Abuja.

### E. Pharmacovigilance Assessment of Health Facilities

NAFDAC in collaboration with the National Agency for the Control of AIDS (NACA) is implementing a number of activities approved under the Global Fund Resilient and Sustainable Systems for Health (GF-RSSH) grant. One of the activities to be implemented under the NAFDAC-NACA GF-RSSH grant is quarterly assessment of pharmacovigilance systems in selected health facilities towards safety monitoring of new medicines used for HIV-AIDS, Tuberculosis and Malaria (ATM) interventions across the country. The main objective of this exercise is to evaluate the level of participation of healthcare institutions across the country in the Pharmacovigilance system and ascertain drug safety problems of new molecules used in HIV-AIDS, Tuberculosis and Malaria in patients using relevant tools. In view of this, PV assessment using the WHO Indicator tools was carried out in six states of the federation and 10 Health facilities were visited in each state

## F. PV/PMS Self-Assessment

As part of on-going implementation of Quality Management Systems according to the requirements of ISO 9001:2015, a self-assessment or internal audit of divisions of the Directorate was conducted on 8<sup>th</sup> and 9<sup>th</sup> March, 2022. The PV Division was assessed on 9<sup>th</sup> March, 2022.

## G. Safety & Immunogenicity of Fractional Doses Of Moderna-Mrna-1273, Oxford/Astrazeneca, and Janssen COVID-19 Vaccines Among Nigerian Adults- A Randomised Non-Inferiority Double Blind Trial (SIFCoVAN Trial)

SIFCoVAN Trial is a multi-site Project conducted under collaboration of NIMR, NIPRD, NPHCDA and NAFDAC. The aim of the trial is to demonstrate a non-inferiority in the immune response and safety of 25% and 50% to the 100% standard doses of licensed COVID-19 vaccines (Moderna-mRNA-1273, Oxford/AstraZeneca and Janssen) and evaluate their safety and tolerability among Nigerians aged 18 - 65. In view of the above, site assessment was conducted at the various sites in the week of 11<sup>th</sup> to 15<sup>th</sup> April, 2022. Teams comprising NIMR, NIPRD, NPHCDA and NAFDAC visited the various sites as follows:

SN	Site	Team	Date
1.	Aminu Kano Teaching Hospital Kano	Pharm (Mrs) Ekama Sabdat (NIMR) (Lead), Dr Kabiru Muhammed (NPHCDA), Dr Muhammed Shehu Busu (NIPRD) Pharm. <b>Bitrus Fraden (NAFDAC)</b>	12 <sup>th</sup> -13 <sup>th</sup> April 2022
2.	Nnamdi Azikiwe University Teaching Hospital Nnewi Anambra State	Prof. Oliver Ezechi (NIMR) (Lead), Dr. Iwalokun Bamidele (NIMR), Dr. Danraka Abubakar (NIPRD), Dr. Agbakwuru Obioha (NPHCDA) and <b>Pharm. Adown Sunday Philip (NAFDAC)</b>	14 <sup>th</sup> -15 <sup>th</sup> April 2022
3.	Delta State University Teaching Hospital Delta State	Dr Iwalokun Bamidele (NIMR), Prof. Henry O. Egharevba (NIPRD), Dr Ofonakara Izu (NPHCDA), Ekpenyong Margaret (NIPRD), <b>Angela Faniyi (NAFDAC)</b>	11 <sup>th</sup> -12 <sup>th</sup> April 2022
4.	NIPRD Abuja FCT	Dr Musa A.Z (NIMR) (Lead), Mrs Ijeoma Nwoha (NPHCDA), Dr Henry Egharevba Omoregia (NIPRD) and <b>Thomas Torkula (NAFDAC)</b>	14 <sup>th</sup> -15 <sup>th</sup> April 2022
5.	NIMR Research Hospital Lagos State	Dr. Olusegun Emiju (NPHCDA) (Lead), Ezenyi Ifeoma (NIPRD), Dr. Salako Abideen (NIMR) and <b>Uchenna Elemuwa (NAFDAC)</b>	13 <sup>th</sup> -14 <sup>th</sup> April 2022

## H. Pharmacovigilance Retreat

The PV retreat held from 23<sup>rd</sup> to 25<sup>th</sup> June 2022. The objectives of the retreat were to understand the basics of research methodology, the basics of data analysis and visualization and to draft out two manuscripts on AEFI due covid-19 vaccines used in Nigeria (with respect to the work done in the AU3S Project).

The topics being worked on for the manuscripts are:

1. **Impact of Med Safety App Use on Adverse Event Reporting in Nigeria**
2. **Trends of COVID 19 AEFIs; a retrospective review using the passive surveillance data reported through the Med Safety App, in the Nigerian National Database" VigiFlow" from March 2021 to May 2022.**

## I. Transitioning To Optimal Paediatric DTG 10mg (TORPEDO) Study

The Transitioning to Optimal Paediatric DTG 10mg (TORPEDO) study commenced in October, 2021 across seven (7) facilities in Nigeria namely: PHC Base Akwa-Ibom, State Specialist Hospital, Sokoto, University of Calabar Teaching Hospital, Jos University Teaching Hospital, Military Hospital, Port Harcourt, Lagos University Teaching Hospital and Federal Medical Centre Makurdi. The enrollment period ended in December 2021, with 180 children enrolled into the study and preliminary analysis of month 1 data shows that 100% of patients interviewed prefer the pDTG regimen to their previous regimen, with no serious adverse effects recorded. NASCP, in collaboration with NAFDAC, conducted

month (6) visit to 7 facilities with the objective to assess the status of the 6 months implementation of the pDTG OR at the site and to review the implementation data submitted with the facility focal persons. This visit took place from 4<sup>th</sup> – 8<sup>th</sup> July, 2022.

#### **J. State Level Trainings of Primary Healthcare Professionals on Electronic Reporting Platforms.**

The National Primary Healthcare Development Agency in collaboration with NAFDAC is training healthcare professionals at the primary level (DSNO, immunization officers) on AEFI electronic reporting portals namely DHIS2 and Med Safety App. TOT is done at the state level then training is cascaded to clusters of LGAs. Several PV/PMS staff attended the trainings which ran throughout the year.

#### **K. QMS Audit**

QMS Audit of PV/PMS Directorate was held on 30<sup>th</sup> November, 2022.

#### **L. Meetings/ Trainings/ Workshops**

##### **1.0 Meetings Attended**

- i. Participated in the Pavia blended training on Pharmacovigilance and TB 17<sup>th</sup> – 20<sup>th</sup> January, 2022
- ii. Workshop for the Review and Finalization of Patent and Proprietary Medicine Vendors (PPMVs) and Community Pharmacists (CPs) Training Manual on The 14<sup>th</sup> and 15<sup>th</sup> of March 2022 at Dennis Hotels, Abuja:
- iii. 2022 World Malaria Day Meeting Held at the National Malaria Elimination Programme Office, Abia House Abuja on 25<sup>th</sup> April 2022:
- iv. Virtual Planning Meeting for 2022 Round of Seasonal Malaria Chemoprevention (SMC) on the 20<sup>th</sup> of April, 2022:
- v. PAVIA Triangle Skype Meeting: Pharmacovigilance in Africa (PAVIA) triangle Skype meeting was held on 3<sup>rd</sup> of August 2022 with Institute of Human Virology of Nigeria (IHVN) and other key partners.
- vi. Sensitization of Stakeholders on National Health Workforce Registry: The Division participated in the sensitization of stakeholders on National Health Workforce Registry on which held at Grand Cubana Hotel, 6, Ebitu Ukiwe Street, Jabi, Abuja on Thursday, 18<sup>th</sup> August, 2022.
- vii. Meeting On Adverse Drug Reaction Incidence in Kwara State: A virtual meeting was held on the 23<sup>rd</sup> of August, 2022 on the Serious Adverse Drug Reaction that resulted in the tragic death of a four (4) year old female who had received SPAQ (Sulphadoxine- Pyrimethamine (SP) and Amodiaquine (AQ)) as part of the Seasonal Malaria Chemoprevention (SMC) Intervention by the National Malaria Elimination Programme (NMEP) on the 28<sup>th</sup> of July 2022. In attendance are representatives of NMEP, University of Ilorin Teaching Hospital, Global Fund, SMEP Kwara state and NAFDAC. The purpose of the meeting was to give updates on the investigation of the Serious ADR, to deliberate over gaps that may have resulted in the unfortunate occurrence and also to discuss next steps moving forward especially as the second cycle of the Intervention was about to commence. NAFDAC stressed the need for a Risk Mitigation Plan to be put in place for SMC as both Sulphadoxine- Pyrimethamine (SP) and Amodiaquine (AQ) are known to have the potential to cause serious ADRs.
- viii. Multisectoral Collaboration Meeting with Ministries, Departments and Agency at Newton Park Hotel Wuse Zone 4, Abuja on 8th September, 2022:
- ix. ADR Reporting in Clinical Trials 5th October, 2022 Virtual Meeting: mandate of AVAREF to include authorization of products in emergencies. In Attendance from NAFDAC: Dr Rametu Momodu (PV/PMS), Dr Ijeoma Nwankwo (DER), Pharm Uchenna Elemuwa (PV/PMS), Dr Beno Yakubu (Clinical Trials, DER), Dr Abiodun Abiola Sadikat (PV/PMS), Pharm Asmau Abubakar (PV/PMS), Mrs Angela Faniyi (PV/PMS).

- x. Meeting of the National Drug Safety Advisory Committee (NDSAC) Held Via Zoom On 12th October, 2022.
- xi. Quarter Three (Q3) International Health Regulation (IHR) Technical Working Group (TWG) Meeting Held at Ajuji Greenwich Hotel, 12<sup>Th</sup>-14<sup>Th</sup> October, 2022
- xii. Engagement Meeting with Sydani Officials at Director's Office PVPMS on November 8<sup>Th</sup> 2022:
- xiii. Strengthening HIV Self-Testing in the Private Sector (SHIPS) 23<sup>rd</sup> November, 2022
- xiv. Pharmacovigilance Training of Programme Pharmacists at Ministry Of Defence Health Implementation Program at Petrus Hotel Area 11 Garki Abuja on 23<sup>rd</sup> June 2022:
- xv. Pavia Blended Learning Step Down Training Held at Goshen Guest House Nasarawa State from 13<sup>Th</sup>-15<sup>Th</sup> July 2022:
- xvi. Adverse Event Following Immunization Module Trainings/Med Safety App:
- xvii. Regulatory Preparation for Lassa Vaccines in Western Africa Held at Fraser Suites Abuja from 24<sup>Th</sup> to 26<sup>Th</sup> October 2022:
- xviii. 7<sup>th</sup> Nigeria Family Planning Conference:

## 2.0 Advocacy Visits Conducted

- i. **Advocacy Visit to Tonia Pharmacy Wuse Zone 4 Carried out on 17<sup>Th</sup> February 2022:** In an effort to improve Pharmacovigilance activities, the officials of Pharmacovigilance and Post Marketing Surveillance (PV/PMS) Directorate paid an Advocacy Visit to Tonia Pharmacy on February 17<sup>th</sup>, 2022. The PV/PMS Directorate officials were Dr Abiodun Abiola Sadikat, Pharm Asmau Abubakar (ACRO PV/PMS) and Ms. Ameyin Oritsemoyowa Ometie (NYSC). The advocacy visit was to strengthen the collaboration between NAFDAC and Tonia Pharmacy to improve the detection and reporting of ADRs and solicit support and assistance towards improving adverse drug reaction reporting to the National Pharmacovigilance Centre (NPC) Abuja by Healthcare Providers and Healthcare Facilities in Abuja.
- ii. **Advocacy Visit to Bakan Gizo Pharmacy Wuse II Carried out on 10<sup>Th</sup> March 2022:** In an effort to improve Pharmacovigilance activities, the officials of Pharmacovigilance and Post Marketing Surveillance (PV/PMS) Directorate paid an Advocacy Visit to Bakan Gizo Pharmacy on March 10<sup>th</sup>, 2022. The PV/PMS Directorate officials were Pharm Asmau Abubakar (ACRO PV/PMS) and Ms. Ameyin Oritsemoyowa Ometie (NYSC). The advocacy visit was organized to strengthen the collaboration between NAFDAC and Bakan Gizo Pharmacy to improve the detection and reporting of ADRs and also solicit support and assistance towards improving adverse drug reaction reporting to the National Pharmacovigilance Centre (NPC) Abuja by Healthcare Providers and Healthcare Facilities in Abuja.

## Food And Drug Information Centre (FDIC)

### A) Recall And Alert Notifications

One hundred and twenty-four (124) notifications were treated from January to December 2022 some of which are as follows;

S/N	Title of Notification	Action Taken
1	Recall of All Drug Products Due to A Lack of Sterility Assurance by Edge Pharma.	DHCP
2	Recall of Nitroglycerin Lingual Spray by Padagis Due to a Possible Defective Delivery System	DHCP
3	Recall of All Drug Products Due to A Lack of Sterility Assurance by Edge Pharma.	Zonal notice

4	Recall of Nitro-glycerine Lingual Spray by Padagis Due to a Possible Defective Delivery System	Zonal notice
5	Recall of Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump by Getinge/Datascope/Maquet.	DHCP
6	Sandoz, Inc. Issues Nationwide Recall of One Lot of Enoxaparin Sodium Injection, USP 40mg/0.4 ml single -dose Due to Temperature Excursion	Zonal Alert DHCP
7	P&G Issues Voluntary Recall of Aerosol Dry Conditioner Spray Products and Aerosol Dry Shampoo Spray Products	DHCP

From January to December 2022, fifty-six (56) DHCPL, twenty-nine (29) zonal notices were disseminated to Healthcare Professional and NAFDAC offices respectively, forty-seven (47) Public alert were sent for upload on NAFDAC website and five (5) state notices were sent to NAFDAC state offices.

**A) Consumer Complaints Handled During the Month Under Review 2022**

Consumer complaints were received from walk-in complaints, DG's Office, the Reforms Unit, PRASCOR, via email and phone calls. A total of twenty-seven (27) consumer complaints were received and investigated by PV/PMS offices January to December 2022.

### C) Rapid Alert System for Food and Feeds (RASFF)

RASFF is Rapid Alert system for Food and feeds. It is a key tool to ensure the cross-border flow of information to swiftly react when risks to public health are detected in the food.

Eighty-one (81) Alert Notification were received from EU, analysed and disseminated within January to December 2022.

S/N	RASFF REF NO	Date Received	Reason for Rejection	Comment
1	2022.0156	10/1/2022	Alert Notification on contaminated Pet food (meat meal) product that was distributed to Nigeria from Netherlands.	Disseminated to the relevant stakeholders and Directorate.
2	2022.0754	8/2/2022	Salmonella spp present/25g in Sesame seeds from Nigeria.	Alert disseminated to relevant MDAs and NAFDAC Directorates PID, FSAN, CER, LAB.
3	2021.5502	8/3/2022	Elevated levels of aflatoxins in ground melon seeds from Nigeria, via Belgium. alert - product originating from Nigeria - aflatoxins (B1 = 31.8; Tot. = 40.0 µg/kg - ppb) in ground melon seeds from Nigeria, via Belgium	According to FBO Marigold Investment, the product that has been sampled at Tropical Food (Retailer in Germany) is part of the same batch that was already recalled following RASFF 2021.0624 and RASFF 2021.0682. A lot of irregularities were identified during the investigation for this earlier RASFF notifications: Marigold Invest was not able to trace the exporter.  2. RASFF contact point desk sent feedback to EU SANTE -RASFF Team.
4	2022.1425	17/3/2022	alert - product distributed to Nigeria - unauthorised substance ethylene oxide (sum of EO and 2-CE expressed as EO: 0.1 mg/kg - ppm) in various semi-finished products for confectionery and ice cream from Italy.	Disseminated
5	2022.1799	25/03/2022	alert - product distributed to Nigeria - foodborne outbreak suspected (Salmonella Typhimurium monophasic) to be caused by chocolate product from Belgium.	Disseminated
6	2022.2090	12/04/2022	Border rejection - product originating from Nigeria - illegal import of bushmeat from Nigeria	Analysed and Information Disseminated to relevant stakeholders in food supply chain.
7	2022.1799	27/4/2022	alert - product distributed to Nigeria - foodborne outbreak suspected (Salmonella Typhimurium monophasic) to be caused by chocolate products from Belgium.	Disseminated
8	2022.2604	4/5/2022	border rejection - product originating from Nigeria - Salmonella (in 1 out of 5 samples /25g) in sesame seeds from Nigeria imported to Spain.	Disseminated
9	2022.2602	4/5/2022	border rejection - product originating from Nigeria - Salmonella (presence /25g) in sesame seeds from Nigeria	Disseminated
10	2022.1015	31/5/2022	Border rejection-Illegal import of bushmeat from Nigeria, via the Netherlands	Disseminated appropriately
11	2022.3275	5/6/2022	border rejection - product originating from Nigeria - Salmonella (present /25g) in sesame seeds from Nigeria	Disseminated all MDAs concerned in food supply chain.
12	2022.1957	12/6/2022	border rejection - product originating from Nigeria - attempt to illegally import bush	

13	2022.2090	14/6/2022	border rejection - product originating from Nigeria - illegal import of bushmeat from Nigeria.	
14	2022.3502	21/6/2022	Alert notification-Traces Of Almond 45:55mg/Kg) In Hazelnut Nougat Spread From Belgium .	
15	2022.4027 -	3/8/2022	alert - product distributed to Nigeria - recall from consumer of vanilla ice cream from France, containing vanilla extract from Madagascar, dispatched from United States, exceeding the MRL for ethylene oxide (between 1.7 and 3.6 mg/kg - ppm).	Alert disseminated to relevant MDAs concerned in food supply chain. <ul style="list-style-type: none"> <li>• EU Rep in Nigeria</li> <li>• Nigerian Agricultural Quarantine Services</li> <li>• Federal Ministry of Agriculture and Rural Development</li> <li>• Nigeria customs services</li> <li>• Fed Min of Trade and Investment.</li> <li>• Africa Centre for control of Aflatoxin.</li> <li>• Nigeria Investment Promotion Commission</li> <li>• Federation of Agric Commodities of Nigeria. (FACAN)</li> <li>• COCA COLA bottling Company.</li> <li>• Nigeria Export Promotion Council</li> <li>• Raw Material Research Development and Agency</li> <li>• NICCIMA</li> <li>• European Union Rep in Nigeria</li> <li>• Central bank of Nigeria</li> <li>• United Nation Development Org.</li> <li>• Food safety steering Committee</li> <li>• Federal Competitive Consumer Protection Council.</li> <li>• CER Directorate</li> <li>• PID NAFDAC</li> <li>• VMAP NAFDAC</li> <li>• Food lab service NAFDAC</li> <li>• FSAN NAFDAC</li> <li>• Sanitary Phyto Sanitary /MSME NAFDAC</li> <li>Nigeria Shippers council.</li> </ul>
16	2022.3502	8/7/2022	Alert notification 2022.3502 on product distributed to Nigeria - traces of almond (45; 55 mg/kg - ppm) in hazelnut nougat chocolate spread from Belgium.	RASFF Notification disseminated to relevant MDAs. memo sent to Lagos for investigation of the trading company.
17	22.3995	8/7/2022	Chlorpyrifos in Hibiscus from Nigeria	memo sent to Lagos for investigation of the trading company.
18	2022.4553	4/8/2022	Salmonella In Sesame Seeds from Nigeria.	RASFF Notification disseminated to relevant MDAs.
19	2022.4582	5/8/2022	Salmonella In Sesame Seeds from Nigeria	memo sent to Lagos for investigation of the trading company.
20	2022.4615	8/8/2022	On Salmonella in Sesame Seed from Nigeria. Presence/26 GR in one of the ten units/25g.	RASFF Notification disseminated to relevant MDAs.
21	2022.4616	8/8/2022	Border rejection notification on Salmonella in sesame seed from Nigeria.	RASFF Notification disseminated to relevant MDAs.
22	2022.4617	8/8/2022	Border rejection notification on Salmonella in sesame seed from Nigeria.	RASFF Notification disseminated to relevant MDAs.
23	2022.4635	9/8/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece.	RASFF Notification disseminated to relevant MDAs.
24	2022.4636	9/8/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece	RASFF Notification disseminated to relevant MDAs.

25	2022.4772	17/8/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece	RASFF Notification disseminated to relevant MDAs.
26	2022.4773	18/8/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece.	RASFF Notification disseminated to relevant MDAs.
28	2022.3995	26/09/2022	Unauthorized subs chlorpyrifos 0.03mg/kg in hibiscus from Nig dispatch via Turkey.	RASFF Notification disseminated to relevant MDAs.
29	2022.5088	28/09/2022	Salmonella in Sesame Seeds from Nigeria	memo sent to Kano for investigation of the trading company.
30	2022.5100	5/10/2022	Salmonella in Sesame Seeds from Nigeria	memo sent to Ogun state office for investigation of the trading company.
31	2022.5099	2/10/2022	Salmonella in Sesame Seeds from Nigeria.	memo sent to Ogun for investigation of the trading company.
32	2022.5125	5/10/2022	Salmonella in Sesame Seeds from Nigeria	memo sent to Lagos for investigation
33	2022.5134	5/10/2022	Salmonella in Sesame Seed from Nigeria. Presence /25g.	memo sent to Lagos for investigation of the trading company.
34	2022.5128	3/10/2022	Salmonella in Sesame seed	memo sent to Lagos for investigation
35	2022.5129	25/9/2022	Border rejection notification on Salmonella in sesame seed from Nigeria.	memo sent to Lagos for investigation
36	2022.5130	5/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria.	memo sent to Lagos for investigation
37	2022.5173	2/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Germany.	memo sent to Lagos for investigation
38	2022.5334	7/10/2022	Border rejection notification on Aflatoxin B1-13.23 µg/kg To 29.8 µg/kg in groundnut from Nigeria exported to Belgium	Memo sent to Lagos for investigation
39	2022.5126	2/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece	memo sent to PVPMS Lagos for investigation. RASFF Notification disseminated to relevant MDAs
40	2022.5124	2/10/2022	Border rejection notification on Salmonella detected in 2 out 5 samples in sesame seed from Nigeria exported to Greece.	RASFF Notification disseminated to relevant MDAs in the food supply chain. Memo to Lagos for investigation.
41	2022.5706	3/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece	memo sent to Kano for investigation.
42	2022.5711	4/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece	Memo to Lagos for investigation.
43	2022.5712	4/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece via Turkey	Memo to Lagos for investigation.
44	2022.5707	4/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria exported to Greece dispatched from Turkey.	Memo to Lagos for investigation. RASFF Notification disseminated to relevant MDAs.
45	2022.5708	3/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria Border rejection notification on Salmonella in sesame seed from Nigeria	RASFF Notification disseminated to relevant MDAs. Memo to Lagos for investigation.
46	2022.5126	28/9/2022	Border rejection notification on Salmonella in sesame seed from Nigeria via turkey	Memo to Lagos for investigation.
47	2022.5020	28/9/2022	Border rejection notification on Salmonella in sesame seed from Nigeria	Memo to kano for investigation.

48	2022.5019	27/9/2022	Border rejection notification on Salmonella in sesame seed from Nigeria. (presence/25g)	Memo to Kano for investigation.
49	2022.4942	25/09/2022	Border rejection notification on Salmonella in sesame seed from Nigeria	RASFF Notification disseminated to relevant MDAs.
50	2022.4941	26/09/2022	Border rejection notification on Salmonella in sesame seed from Nigeria	RASFF Notification disseminated to relevant MDAs.
51	2022.4823	25/09/2022	Border rejection notification on Salmonella in sesame seed from Nigeria	RASFF Notification disseminated to relevant MDAs.
52	2022.5132	5/10/2022	Border rejection notification on Salmonella detected in 2 out of 5 samples in sesame seed from Nigeria exported to Greece.	Memo to Lagos for investigation.
53	2022.5360	3/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria presence/25g.	Memo to Lagos for investigation.
54	2022.5134	5/10/2022	Border rejection notification on Salmonella in sesame seed from Nigeria presence/25g.	RASFF Notification disseminated to relevant MDAs.
55	2022.5221	8/10/2022	Salmonella in Sesame Seeds from Nigeria	memo sent to Kano for investigation of the trading company.
56	2022.6142	20/10/2022	Damaged packaging and incorrect labelling in dry locust beans.	RASFF Notification disseminated to relevant MDAs.
57	2022.6144	20/10/2022	Calabash salt Contaminated with arsenic 19mg/kg and lead 30.6mg/kg.	RASFF Notification disseminated to relevant MDAs.
58	2022,5097	13/10/2022	Salmonella in Sesame Seeds from Nigeria	memo sent to Kano for investigation of the trading company.
59	2022.5087	14/10/2022	Salmonella in Sesame Seeds from Nigeria(presence/25g)	memo sent to Kano for investigation.
60	2022.5090	14/10/2022	Salmonella in Sesame Seeds from Nigeria (presence/25g)	memo sent to Kano for investigation.
61	2022.0882	14/11/2022	Salmonella in sesame seed	Alert disseminated to relevant MDAs.
62	2022.6308	28/10/2022	Crevettes crues surge lees from France distributed to Nigeria	Alert disseminated to relevant MDAs in food supply chain.  Memo sent to Lagos state for investigation.
63	2022.6735	18/11/2022	Salmonella in Sesame Seeds from Nigeria	Alert disseminated to relevant MDAs.
64	2022.6586	16/11/2022	Alcohol in non-alcoholic beverages from Denmark distributed to Nigeria. (Sparkling tea BLA)	Alert disseminated to relevant MDAs.
65	2022.6240	14/11/2022	Salmonella in Sesame Seeds from Nigeria	Alert disseminated to relevant MDAs.
66	2022.5127		Salmonella in Sesame Seed from Nigeria. Presence /25g.	Alert disseminated to relevant MDAs.
67	2022.6737	23/11/2022	Sesame seed from Nigeria with Salmonella	Alert disseminated to relevant MDAs.
68	2022.5126	8/12/2022	Salmonella in sesame seed	Follow up Alert notification disseminated to relevant stakeholders in food supply chain.  Memo to EU Delegate Nigeria requesting exporter details.  Memo sent to Lagos.
69	2022.5334	14/12/2022	Aflatoxins in groundnut exported to Belgium by Infra Source resources Lagos	Alert disseminated to relevant MDAs in food supply chain.  Memo sent to FMOFA  Memo sent to Lagos PVPMS for investigation.
70	2022.7252	16/12/2022	Salmonella in Sesame Seeds from Nigeria	Alert disseminated to relevant MDAs.

71	2022.5934	12/10/2022	Chlorpyrifos in Asparagus distributed to Nigeria from Netherland	Alert disseminated to relevant MDAs in food supply chain.  Memo sent to Lagos PVPMS for investigation.
72	2022.5709	3/10/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain and PVPMS Lagos for Investigation of the trading company.
73	2022.5710	3/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain.
74	2022.5182	3/10/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain.
75	2022.65166	7/9/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain.
76	2022.5184	2/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food distribution chain.
77	2022.5168	1/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain.
78	2022.5131	3/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain.
79	2022.5137	5/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Alert disseminated to relevant MDAs in food supply chain and PVPMS Lagos for Investigation of the trading company.
80	2022.5710	12/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria	Alert disseminated to relevant MDAs in food supply chain and PVPMS Lagos for Investigation of the trading company.
81	2022.6308	20/12/2022	Salmonella in sesame seed presence /25g originating from Nigeria.	Follow up action taken, Spain measure:Special treatment provided for in article 71 of EU Regulation 2017/625: decontamination by heat treatment with IFS accreditation no. ES21/209449 granted by DAkKS and under control of the Spain local Health Authority.

#### **D) Review of Safety Submissions From January to December 2022**

Six (6) Safety submissions were received and reviewed within the period under review.

#### **E) Trainings, Meetings and Workshop**

- Pharma Kalat Musa, Pharm Iyadoo Ikhide and Mrs Abioye Kehinde attended training on Pharmacovigilance at KNCV between 17<sup>th</sup> to 20<sup>th</sup> January 2022.
- Pharm Musa Kalat, Pharm Ikhide Iyadoo and Mrs Ebibi Chioma attended a Training on Green Book-Registered Drug Database System Held from the 3<sup>rd</sup> – 6<sup>th</sup> Of May 2022 at Lagos Travel Inn, Ikeja-Lagos.
- HOD FDIC Pharm Musa Kalat attended TMC meeting at Lagos held from 1<sup>st</sup> – 2<sup>nd</sup> of August 2022
- Mrs Abioye Kehinde, Mrs Okerefor Emmanuella, Mrs Hannatu Odekunle and Mrs Ebibi Chioma facilitated AEFI and MedSaftey training at Plateau, Nasarawa, Anambra, Benue held from 9<sup>th</sup> – 12<sup>th</sup> August TO 15<sup>TH</sup> Aug 2022.
- HOD FDIC Pharm Musa Kalat participated in GMP assessment at Hyenang pharmaceuticals Kaduna held from 17<sup>th</sup> – 18<sup>th</sup> August 2022
- Ms Shifao Bello staff facilitated a training on MedSaftey at River state between 22<sup>nd</sup> to 26<sup>th</sup> August 2022.

- Mrs. Kehinde Abioye and Mrs Hannatu Odekunle facilitated State Specific AEFI training on MedSafety app in Ondo and Jigawa State respectively from 10<sup>th</sup> Oct to 15<sup>th</sup> October 2022.
- Mrs. Emmanuella Okereafor and Mrs. Chioma Ebibi facilitated State Specific AEFI training on MedSafety app in Niger state and Yobe State respectively from 17<sup>th</sup> Oct to 21<sup>st</sup> October 2022.
- HOD FDIC Pharm Musa Kalat and Pharm Iyadoo Ikhide participated in AEFI Cohort Event Monitoring and Supervisory visit to health facilities in Edo state and Kano state respectively from 17<sup>th</sup> Oct to 21<sup>st</sup> October 2022.
- Pharm Musa Kalat participated in anti-corruption and Leadership training at Nassarawa between 26<sup>th</sup> and 27<sup>th</sup> October 2022.
- Pharm Musa Kalat attended Nigeria Health watch (NHW) meeting held 28<sup>th</sup> October 2022.
- Mrs Okereafor Emmanuella and Mrs Abioye Kehinde participated in AEFI Monitoring Supervisory visit to Ekiti and Bauchi state respectively between 13 to 15<sup>th</sup> December 2022

**E) Newsletter:**

The Last Quarter Newsletter of 2021 was disseminated 31<sup>st</sup> March 2022 titled: **New Developments and Activities of the National Pharmacovigilance Centre in the year 2020 and 2021**. First quarter 2022 newsletter titled ``**New developments in Good Distribution Practices of Nigerian drug facilities**'' was disseminated on 25<sup>th</sup> August 2022.

- F) NCSC:** NAFDAC Consumer Safety Club Competition has been revived, proposal for commencement of the activities has been approved and the activities commenced with letters written to zonal coordinators, UBEC and NCSC registered schools informing them of the activities and event taken place in first quarter of 2023.

**Post-Marketing Surveillance**

The division focused on **conducting Good Storage and Distribution Practices (GDP)** Inspections in the distributor/Wholesalers' outlets nationwide and Preparation of GBT. Also, the Division carried out routine and investigative surveillance activities in the open market, retail outlets, pharmaceutical outlets and megastores. Below is a summary of the activities undertaken by Post Marketing Surveillance (PMS Division) from January - December 2022.

**Summary of Routine Surveillance & Investigation Activities Carried Out Within the Period Under Review**

Number of Surveillance carried out	Number of Establishment visited	Number of Product mopped-up	Number of Pharmacy visited for GSDP	Number of GLSI Monitored	Number of Investigation carried out	Number of Sanction carried out	Revenue generated
406	195	90	33	26	25	52	458,790

**The total number of PMS activities Carried out for the year 2022 is 580**

## Summary Report of Good Storage And Distribution Practice (GSDP) Inspection

33 Facilities were inspected for Good Storage and Distribution Practices (GSDP) Inspection in Abuja in the year 2022 under review.

## Global Listing of Supermarket Items (GLSI)

A total of 27 GLSI approvals were received during the period under review.

## Investigative Surveillance

### 1. Investigative Surveillance on imported Tomato concentrates.

Investigative Surveillance activities was carried out on fourteen (14) establishments in February following an information received on the nation-wide sales of banned food items (imported Tomato concentrates) in supermarkets and open markets, a directive was issued by the DD i/c PV/PMS to carry out surveillance within FCT. NAFDAC team of inspectors from PMS Division visited different stores in Abuja. The facilities found to engage in sales of imported tomato concentrates such as tomato ketchups, tomato pastes and tomato plums in retail packs were issued a sanction. The inventory of the imported tomato concentrates was taken and subsequently mopped up for destruction. Company's representatives were advised to familiarize themselves with Nigerian Custom Prohibition List to avoid stocking and sale of violating items on prohibition list in their supermarket. A video of defective Capri Sun that was purchased at H-Medix Pharmacy and Supermarket, no 48 Adetokunbo Ademola Crescent, Wuse 2, Abuja was brought to the notice of PMS division. H-Medix later reported to have returned the affected batch of products to their supplier; SMABIRM Nigeria Limited. Owing to this, a directive was issued by the Deputy Director in charge of PV/PMS to carry out investigative surveillance at SMABIRM Nigeria Limited situated at Shop 7, Daniel Ogbaje Street, Garki II Model Market, Garki, Abuja. The management of SMABIRM Nigeria Limited was issued an invitation letter. Samples of the product seen in the store were taken.

### 2. Report of surveillance on vegetable oil dispensed using fuel dispensing pumps

The DG NAFDAC had directed that D(I&E), D(FCT), D (NWZ) and D(FSAN) meet and discuss the issue of vegetable oil dispensing using fuel dispensing pumps identified in the Kaduna metropolis. The meeting recommendations approved by the DG included countrywide surveillance to be carried out to ensure that the unsafe practice is eliminated.

Following this directive, a team of PV/PMS Officers visited some markets within the FCT metropolis to carry out covert surveillance to identify if the practice of handling/dispensing of vegetable oil via surface tanks connected to dispensing pumps exists in the state. The findings are shown below;

S/N	Date of Visit	Location	Findings
1	21 <sup>st</sup> April 2022	Garki II Model Market, AMAC LGA, Abuja.	The largest Market by Landmass and population in Abuja. It is popularly called the "Monday" market. The market is very big and major in Abuja. It is situated within the metropolis and readily accessed by many people from different areas, even some as far as outside the state. The vegetable oils were dispensed from drums and kegs using a funnel. No fuel dispensing apparatus was found on the site at the time of the visit.
2	21 <sup>st</sup> April 2022	Utako Market, AMAC LGA, Abuja.	Just like every other market in Abuja, the Utako Market creates an atmosphere where buyers and sellers can trade in virtually everything. The good thing about this market is that it is closer to farms where food items are produced, therefore easing off the cost of transportation which could be a major factor in traders offering lower prices. The vegetable oils were dispensed from drums and kegs using a funnel. No fuel dispensing apparatus was found on the site at the time of the visit.

3	21 <sup>st</sup> April 2022	Wuse Market, AMAC LGA, Abuja.	This is the main market in Abuja and is located in Zone 5 of the Wuse District. It is a general market where you can find almost anything; foodstuff, fresh vegetables, meat, clothes, electronics, furniture, phones, rugs and carpets, etc. One good thing about the market is that it is organized and generally clean. The vegetable oils were dispensed from drums and kegs using a funnel. No fuel dispensing apparatus was found on the site at the time of the visit.
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### 3. Investigative Surveillance and Mop-Up of Japata Alcoholic Bitters 100 ml (All Variants) Carried Out In FCT-Abuja.

The result of the Laboratory analysis conducted on samples of Japata Alcoholic bitters collected from the production site and from different market locations after consumer complaints were received and investigated confirmed the samples were found to be laced or to be contaminated with psychoactive substances. The meeting recommendations approved by the DG included countrywide surveillance to be carried out to ensure that the unsafe practice is eliminated. Following this directive, a team of PV/PMS Officers visited some Markets and Motor parks within the FCT metropolis to carry out covert surveillance to identify the samples and stores that sell the affected products. The Team was led by Mrs. Balogun.

The affected products are as follows;

S/N	Product Name	NAFDAC Reg. No
1	Japata Alcoholic Bitters, 15% Alcohol volume x 100ml	08-04671
2	BOP-Daddy Ginger Liquor 30% Alcohol volume/ 200ml	A8-7585L
3	Cork & Shoot Alcoholic Bitters, 18% Alcohol volume, 100ml	A8-7585L
4	One core Alcoholic Bitters Drink, 18% Alcohol volume, 100ml	B1-2486

#### Findings:

S/N	Name	Date of Visit	Personnel Met	Phone Number	Findings
1	The Management Of Utako Ultra-Modern Market, FCT-Abuja.	25 <sup>th</sup> April 2022	Mr. Patrick Yerima	08036024513	They were receptive to the surveillance team. They described the part of the market area where the team would find stores that deal in the sale of alcoholic bitters. They advised the team to come along with a letter next visit to receive the full support of The Management They allowed the team to conduct the surveillance activity. No store contained any of the Alcoholic bitters.
2	Madam Uche Shop Gwagwalada Market, FCT-Abuja.	27 <sup>th</sup> April 2022	Mrs. Uche	09071057302	The store was well ventilated and neat. None of the Alcoholic bitters was found She said she hasn't heard of any of the alcoholic bitters shown to them

3	Uche Best Cosmetic & Variety Store Gwagwalada Market, FCT-Abuja.	27 <sup>th</sup> April 2022	Mr. Mekus	08060128814	The store was well ventilated and neat. None of the Alcoholic bitters was found. He said he hasn't heard of any of the alcoholic bitters shown to them
4	Emvo Skin Remedy Cosmetics & Wine Gwagwalada Market, FCT-Abuja.	27 <sup>th</sup> April 2022	-	08156549612	The store was well ventilated and neat None of the Alcoholic bitters was found. They said they haven't heard of any of the alcoholic bitters shown to them
5	234 Supermarket Gwagwalada Market, FCT-Abuja.	27 <sup>th</sup> April 2022	Mrs. Chinenye	08069419393	The store was well ventilated and neat None of the Alcoholic bitters was found She said they haven't heard of any of the alcoholic bitters shown to them
6	Gwagwalada Motor Park, FCT-Abuja.	27 <sup>th</sup> April 2022	-		The sellers at the park stated that they know Japata bitters but they no longer have them because it was scarce. A particular seller said it was scarce because it's now expensive None of the Alcoholic bitters was found.
7	Utako Motor Park, Jabi, FCT-Abuja.	28 <sup>th</sup> April 2022	-		Some of the sellers at the park stated that they have not heard about any of the alcoholic bitters shown to them. A bottle of Japata bitters was bought from one of the sellers in the park who was later found to have it.

#### 4. A Follow-Up Investigative Surveillance Was Carried Out on AMAC Corner Stone Warehouse (Major Distributor of Chivita Products) Situated At Nyanya.

The first visit was made on the 21<sup>st</sup> January 2022 due to consumer complaint received that the facility distributes and stores their products under unsanitary conditions which was confirmed by NAFDAC team who visited the facility. A compliance directive was issued. Owing to this, a follow-up investigative surveillance was carried out on the 4<sup>th</sup> of February 2022 at the same warehouse. This visit revealed there were still lapses despite the professional guidance given to the manager, this led to the second follow-up which was carried out on the 29<sup>th</sup> of March.

The team discovered that there was improvement such as neatness of the environment, installation of an air-conditioner and fixing of the screened doors. However, there was no standby power source and products were still stacked close to the ceiling.

On the 5<sup>th</sup> of April the DDi/c PVPMS gave the company representatives an ultimatum to either relocate or expand the facility by acquiring two empty shops next to theirs. The Manager chose to acquire the empty stores. Another follow-up investigation was slated for 12<sup>th</sup> May.

On the 13<sup>th</sup> of May the team visited the facility, but the manager was absent at the time of the visit. The team observed that the earlier agreement with the DD was not implemented. The DDi/c met with the company representatives on the 14<sup>th</sup> of May and agreed that the final inspection would be on the 14<sup>th</sup> of June after which failure to fully comply by the facility manager would lead to the closure of the facility by the Agency. A team was to visit the facility on the 14<sup>th</sup> of June.

Sequel to the last findings, the facility was put under regulatory action due to non-conformance observed; the Premises was locked on the 15<sup>th</sup> June 2022 and the CEO was invited to meet with the A/c Director PVPMS. In response, the facility head signed a compliance undertaken with the Agency (NAFDAC) and the facility was unlocked on the 16<sup>th</sup> June, 2022. The whole store house was later

painted and looking healthy, air conditioners are working properly and products are well stocked on a well arrange pallets.

**5. Investigative Surveillance on a case of SF product (Super Lemon Tea with a fraudulent expiry date) procured from a H-Medix Store in Abuja,**

Following the report of an investigation conducted by the FDIC Division, Abuja on a case of SF product (Super Lemon Tea with a fraudulent expiry date) procured from a H-Medix Store in Abuja, and the directive issued by AD (PMS) for a mop up to commence, a team of PMS officers led by Pharm. Walter Udokwelu went to one (1) distribution outlet and four (4) retail outlets within Abuja to carry out the exercise. The details are as follows.

**Name of Product; Super Instant Lemon Tea**  
**Manufacturer; Malindo F&B SDN BHD, China**  
**Authorized Agent; Sam Johnson International LTD, No 15 A/h Lumon Street, Ajao estate, Lagos, Nigeria**  
**NAFDAC Registration Status; Yes (01-9701)**

S/ N	Name of Facility Visited	Location	Personnel Met	Findings (Qty of Defaulting Product Found)
1	H-Medix Wholesale Outlet	No 28, Ademola Adetokunbo Crescent, Wuse 2, Abuja	Mr. Beba Ugeh Manager 09050866982	0
2	H-Medix Retail Store	No 48, Ademola Adetokunbo Crescent, Wuse 2, Abuja	Mrs. Nwosisi Philomena Manager 08064604952)	0
3	H-Medix Retail Store	No 109, 109 Plaza, Ademola Adetokunbo Crescent, Wuse 2, Abuja	Mr. Ejembi, Innocent Manager	17 packs (20 sachets in a pack)
4	Sahad Stores	Plot 1356, Abubarka Tafawa Balewa way, Central business district F.C.T., Abuja.	Mr. bdulkamar Adamu Floor Manager (08060002800)	0
5	Grand Square Stores	270 Mohammedu Buhari way, Central business district F.C.T., Abuja.	Mrs. Ogonna Chukwuma Senior Manager, (08075193021)	0

All defaulting packs of Super Instant Lemon Tea seen at visited sites were mopped up by the PMS team. All personnel met at the various outlets visited were encouraged to also contact their customers and suppliers notifying them of the defaulting product and requesting those who already have the products in their facilities to submit same to NAFDAC formations, nationwide. The management of the H-Medix outlet where seventeen (17) packs of the defaulting product were found, was requested to provide the receipt(s) of purchase, on or before the close of business on Monday, 26/09/2022 to enable further investigations.

**6. Investigative Surveillance on A consumer complaint on NAPTRENE tetracycline**

A consumer complaint on **NAPTRENE tetracycline** was received via social media. Due to the trending video of the drug on the internet, the Director PV/PMS issued a directive that PMS officers should pose as mystery shoppers and visit retail pharmacy/patent stores particularly in rural areas within FCT to ascertain the presence of this drug in the market and purchase samples for laboratory analysis if found. Following this directive, a team of PMS regulatory officers led by Mrs. Abimbola Balogun visited some pharmacy/patent stores in Kpaduma, Kabusa, Galadimawa villages. A total of seventeen (17) patent /pharmacy stores were visited on the 19<sup>th</sup> of September,2022. The product was found in two patent stores in kabusa village.

**Description of the Product Found:**

**Brand name:** NAPTRENE

**Generic name:** Tetracycline

**Manufacturer:** Ningbo Voice Biochemic Co. Ltd,

Address:298, West Zhongshan road, Ningbo, China.

**Importer/marketer:** SPANPHARM Nig. Limitedl

Address:49A, Ogundana Street, off Allen Avenue, Ikeja ,Lagos.

**Description of product and packaging;** secondary package ( yellow colour with red stripes). Product is Red and yellow capsules (10 in each sachet).

Shop Address Found	NAFDAC Reg.No	Mfd Date	Expiry Date	Batch No	Product Description Found
Nicholas U Med patent store, kabusa.	04-5885	09/20	09/23	200924	date markings written on the 3 sachets of capsules found corresponds with the secondary package (carton). NAPTRENE was printed on the sachet purchased.
Medicine store, paseli, kabusa	Sachet: A11-0404 Carton: 20061	Carton: 06/20	carton: 06/23 sachet: 04/23	sachet:C0420007 carton: 200611	Date markings on the sachet differs from that on the carton. The brand name NAPTRENE was not printed on the sachets found in the carton.
Sun -Okoro medical Store	04-5885	09/20	09/23	200924	date markings written on the 24 packets (secondary package) of Naptrene found corresponded with the primary package (sachet). NAPTRENE was printed on all sachets found.

**Places Visited:**

**Kabusa Village, Along Sunnyvale Road, AMAC FCT**

S/N	Name of Patent Store Visited	Date of Visit	Personnel Met/Phone No	FINDINGS
1	Nicholas U Med patent store , Kabusa village.	19/09/22	Mr Nicholas Udeh 08135839168	An external mystery shopper visited the shop and purchased 3 sachets of Naptrene tetracycline. These were the only quantity available in the store at the time of visit.
2	Medicine store ,Paseli -Kabusa village.	19/09/22	-shop attendant	An external mystery shopper visited the shop and purchased 3 sachets of Naptrene tetracycline. These were the only quantity available in the store at the time of visit.
3	Patent Medicine Store, Kabusa.	19/09/22	Shop attendant	Naptrene was not found in the store at the time of visit.
4	Medicine store	19/09/22	Shop attendant	Naptrene was not found in the store at the time of visit.

5	Nicholas U Med patent store , Kabusa village.	21/09/22	Mr Nicholas Udeh 08135839168	Based on the information received from the external mystery shopper, NAFDAC team of Inspectors visited the patent store which was observed to be a retail drug store, small in size and had very few drugs on the shelf at the time of visit. The team lead discussed at length with the store operator who revealed where he purchased just 1 pack = 10 sachets x 10 capsules each) of Naptrene. He cooperated with the Inspectors and led them (on a bike) to the place of purchase within the kabusa village. Unfortunately he could not provide invoice of purchase for Naptrene.
6	Patent Store, opp. Okada park, Kabusa village.	21/09/22	07068000281	The patent store the team was led to was found to be locked at the time of visit. Neighbors informed the team that the store operator was not available that day. A call was place to the number provide but there was no response. On enquiry from the informant, he revealed he has another supplier and promptly led us to the store (Sun- Okoro medical store).
7	Sun -Okoro Medical Pharmacy store, (wholesaler) opp. Payless Plaza, Kabusa.	21/09/22	M.D: Mr Okoro Vitalis, 08067881676 Attendant: Mr chinwe ugwu 081378874	An intern attached to PMS unit posed as a mystery shopper, he was able to purchase a full pack of Naptrene with receipt issued for the purchase (find attached). With this evidence, the team visited the wholesaler drug store immediately. The store has adequate space, quite neat and well equipped with drugs at the time of visit. The shop attendant was on ground. On enquiry, he revealed that the M.D was not available. However, a call was placed to the M.D who revealed that he was aware of the trending video on Naptrene. He informed the team that the association of drug sellers which he belongs to has informed all group members to stop the sale of the drug and those in possession of the drug should submit to the association. The team lead enlightened him on the importance of notifying the Agency on such matters. <b>24 packs of Naptrene x 10 sachets each (same date markings as stated above)</b> were found in the premise and retrieved from the store. Inventory of items form was issued to the shop attendant. Invoice of Purchase sighted by the team indicated that <b>Green Access Healthcare Pharmacy Ltd. Section F, Lugbe FHA, 07085584669, 081345700172</b> supplied the drug to the MD. (see attached)
8	Medicine Store, Moonlight Plaza, close to NNPC filling station Paseli- Kabusa village	21/09/22	M.D Nurse Perpetual Frank 08165039618, 08089216488. Attendant	Based on the information received from the external mystery shopper, NAFDAC team of Inspectors visited the medicine store which was observed to be a retail drug store, small in size and had few drugs and non -drug items on the shelf at the time of visit. The store attendant met informed the team that her M.D was not available. Invoice of purchase of the drug was not provided. A call was placed to the MD, she informed the team lead she was in school and couldn't have a lengthy conversation with us. She promised to call back and provide the information requested for.

#### Update on Naptrene Laboratory Analysis:

- A total of 300 capsules of Naptrene tetracycline 250mg purchased were sent to the Kaduna laboratory for analysis on the 22<sup>nd</sup> of September, 2022.

- The laboratory analysis received from the NAFDAC Kaduna Laboratory Services indicated that the sample NAPTRENE Tetracycline 250mg was unsatisfactory. According to the result, the sample physical appearance did not conform to the compendial requirement of the colour of tetracycline.

#### **7. Investigative Surveillance on Mop-Up of Imported Tomato Pastes in Retail Packs Carried Out In Supermarkets Within FCT- Abuja.**

Imported tomato paste and its derivatives was reported to have flooded Nigerian markets despite being banned following its inclusion in the revised Import Prohibition List in 2019. Recently in October 2022, the Agency was alleged to be complacent in preventing /controlling the sale and distribution of these imported tomato paste and other products in the market. Sequel to the allegation, the DG NAFDAC directed a nationwide mop-up of all unregistered imported tomato pastes and its derivatives in circulation. Due to insufficient regulatory officers in PMS Unit Abuja in comparison to the magnitude of the mop up activity in FCT, PV-PMS Abuja collaborated with NAFDAC-FCT office to conduct the mop-up activity in supermarkets within FCT. The collaboration yielded maximum positive impact. The mop up activity was conducted in 3 days (11<sup>th</sup>, 12<sup>th</sup>, and 17<sup>th</sup> October 2022).

Due to collaboration of PMS Unit Abuja and FCT FSAN Unit, eight (8) teams were constituted, and each visited minimum of 5 supermarkets. **A total of 62 supermarket stores were visited. Forty (40) supermarket stores** visited had the violating item(s) on display in their stores while the rest had none at the time of visit.

- The inventory of all imported tomato pastes and its derivatives found in the supermarkets visited were taken and placed on HOLD within the supermarkets. The unit is still awaiting directives on these products placed on hold.
- A letter of invitation was issued to all supermarket operators who had these products in stock and on their shelves.
- PMS division held a meeting with the supermarket operators invited on the 13<sup>th</sup> and 19<sup>th</sup> October 2022.

#### **Quality Management Internal Audit/ Self Assessment**

As part of the on-going implementation of Quality Management System according to the requirements of ISO 9001:2015, a self-assessment of Divisions of the PV/PMS Directorate was conducted on 8<sup>th</sup> and 9<sup>th</sup> March, 2022. The PMS Division was assessed on the 8<sup>th</sup> March,2022.

#### **Disposal of Mopped Up Counterfeit Drugs and Food Items**

All counterfeit, substandard and falsified drugs and food were disposed to Kyami for destruction on the 8<sup>th</sup> March, 2022. The destroyed products include drugs such as Anti- malarial, Herbal Remedies and Food products.

#### **Trainings/ Meetings/Other Activities:**

The Division held several meetings, and trainings within the period under review.

- Association of Food Beverage and Tobacco Employers -AFBTE on 14th february,2022
- Establishment of Pharmacovigilance and Post Marketing Surveillance Department by Marketing Authorization Holders (MAHS) and Manufacturers on 14th february,2022
- USP MedRS tool training at Goshen Guest House Hotel, Goshen, Nasarawa State 28 Feb 2022
- USP MedRS tool training 28 Feb 2022
- Traceability Technical working Group meeting 4<sup>th</sup> February 2022

- Review of NAFDAC/USP RBPMS protocol 20th March, 2022
- WHO Strategic Agenda for Filovirus Research and Monitoring (AFIRM) - Roadmap Meeting 30<sup>th</sup> March 2022
- Stakeholders engagement for hospital pharmacists, led by NPSCMP, FMOH in Lagos 28<sup>th</sup> March 2022
- Risk Managers quality training 23- 27th May 2022
- Truscan Chemometrics Training for method developers 6th May, 2022
- (5) days Inter Agency working/ fact finding visit to the UK on food Export control Processes held in the United Kingdom. 11<sup>th</sup>- 15<sup>th</sup> Sept, 2022
- Participated in a Pharmacovigilance training of state health workers (DSNOs, PV focal Person) on Med safety App at Ilorin. 26<sup>th</sup>Sept, 2022

**Statistical Summary of Activities from January-June, 2022**

<b>Zones/Offices</b>	<b>No of PMS Activities</b>	<b>No Of Investigations Carried Out</b>	<b>No Of Establishments Visited for Mop-Up</b>	<b>No of Products Mopped-Up</b>	<b>No of Consumer Complaints Received</b>	<b>No of Institutions Visited for PV Advocacy</b>	<b>No Of ADR Reports Received &amp; Sent to PV Center</b>	<b>No of Sanctions Issued</b>	<b>Revenue Generated (N)</b>
Lagos PV/PMS	97	19	48	2796	15	7	5	47	59,446,250.00
Northeast Zone	849	73	13	19	4	33	0	3	3,683,846.00
Northwest Zone	1208	562	489	1314	42	101	14	196	2,120,645.00
North Central	2040	12	113	395	20	3	0	359	5,026,852.00
Southeast Zone	201	0	69	339	1	130	0	18	4,087,963.00
Southwest Zone	239	23	17	3	4	1	0	5	1,037,500.00
Southsouth Zone	311	19	99	200	1	17	11	5	2,044,156.00
Abuja	120	13	36	0	21	10	5644	11	458,790.00
<b>Total</b>	<b>4381</b>	<b>637</b>	<b>806</b>	<b>4548</b>	<b>91</b>	<b>201</b>	<b>5674</b>	<b>515</b>	<b>73,973,581.00</b>

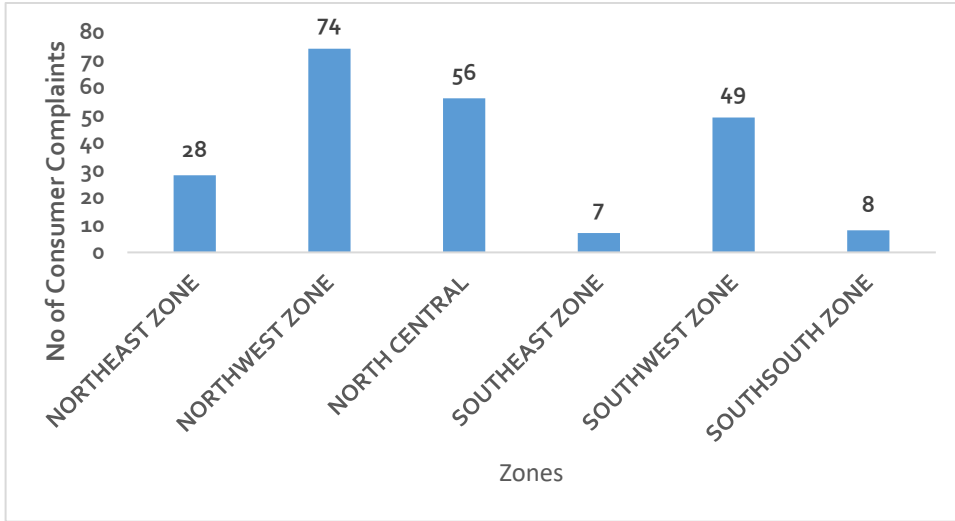
**Statistical Summary of Activities From July-December, 2022**

GPZ	STATE	No of PMS Activities	No of Investigations Carried out	No of Establishment Visited for Mop-up	No of Products Mopped-up	No of Consumer Complaints Received	No of Institutions Visited for PV Advocacy	No of Adverse Events Reports Received and Sent to PV	No of Sanctions Issued	Monthly Revenue Generated
North Central Zone	Plateau	379	2	96	319	1	3	12	11	780,000.00
	Benue	314	9	52	1	0	5	0	103	2,309,425.00
	Nasarawa	194	12	8	24,589	1	12	0	61	2,367,661.25
	Kogi	233	2	0	0	2	0	0	50	140,000.00
	Kwara	2820	56	23	38	1	0	6	28	304,500.00
	Niger	193	3	0	0	1	2	7	24	915,000.00
	FCT	184	16	122	41	10	7	7359	40	-
	<b>Sub-Total</b>	<b>4,317</b>	<b>99</b>	<b>300</b>	<b>24,988</b>	<b>15</b>	<b>22</b>	<b>7,372</b>	<b>317</b>	<b>6,816,586.00</b>
North West Zone	Jigawa	132	12	34	9	3	10	3	0	-
	Sokoto	255	135	133	236	7	7	0	37	735,000.00
	Katsina	56	0	68	1	0	0	0	4	140,000.00
	Kaduna	168	4	41	0	5	2	1	16	600,000.00
	Kebbi	425	115	125	8	5	11	3	2	467,500.00

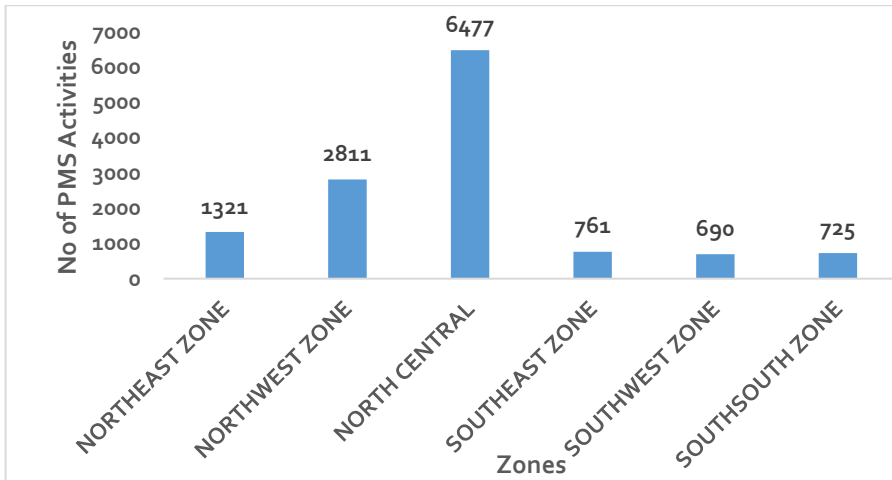
	Kano	267	19	27	4	12	1	5	20	4,546,250.00
	Zamfara	324	196	329	4	0	1	0	41	325,000.00
	<b>Sub-Total</b>	<b>1,603</b>	<b>481</b>	<b>743</b>	<b>262</b>	<b>32</b>	<b>28</b>	<b>12</b>	<b>120</b>	<b>6,813,750.00</b>
South West Zone	Osun	45	0	4	4	0	10	0	2	390,300.00
	Ondo	70	8	3	40	5	8	0	5	3,629,325.00
	Oyo	17	2	3	14	3	20	0	2	4,072,610.00
	Ogun	20	1	1	8100	1	0	0	0	-
	Ekiti	76	0	4	200	1	0	0	0	686,954.00
	Lagos	126	18	44	1839	20	19	9	61	10,850,000.00
	<b>Sub-Total</b>	<b>354</b>	<b>29</b>	<b>59</b>	<b>10,197</b>	<b>30</b>	<b>53</b>	<b>9</b>	<b>70</b>	<b>29,866,689.00</b>
North East Zone	Taraba	156	2	0	0	0	11	0	4	535,000.00
	Adamawa	106	0	0	0	0	105	1	5	848,750.00
	Bauchi	364	59	204	129	1	4	0	40	356,250.00
	Borno	132	16	24	3	3	2	0	11	-
	Gombe	220	43	26	860	20	24	46	15	600,000.00
	Yobe	270	270	0	0	0	4	0	0	-
	<b>Sub-Total</b>	<b>1,248</b>	<b>390</b>	<b>254</b>	<b>992</b>	<b>24</b>	<b>150</b>	<b>47</b>	<b>75</b>	<b>2,340,000.00</b>
	Abia	162	0	52	32	4	5	0	0	200,000.00

South East Zone	Anambra	6	3	71	25	0	1	0	13	3,302,500.00
	Ebonyi	121	27	58	662	1	0	0	65	800,000.00
	Enugu	49	2	30	29	1	41	2	5	656,200.00
	Imo	87	0	0	0	0	54	0	0	-
	Sub-Total	425	32	211	748	6	101	2	83	4,958,700.00
South South Zone	C/River	45	36	40	325	4	0	0	6	700,000.00
	A/Ibom	69	1	27	59	1	18	3	4	70,000.00
	Bayelsa	91	0	36	140	0	6	0	0	-
	River	36	2	16	209	1	1	0	0	-
	Delta	75	1	22	207	0	11	0	7	2,400,000.00
	Edo	98	3	75	1	1	15	0	0	-
	Sub-Total	414	43	216	941	7	51	3	17	3,170,000.00
	<b>Grand Total</b>	<b>8,361</b>	<b>1074</b>	<b>1783</b>	<b>38128</b>	<b>114</b>	<b>405</b>	<b>7445</b>	<b>682</b>	<b>53,965,725.00</b>

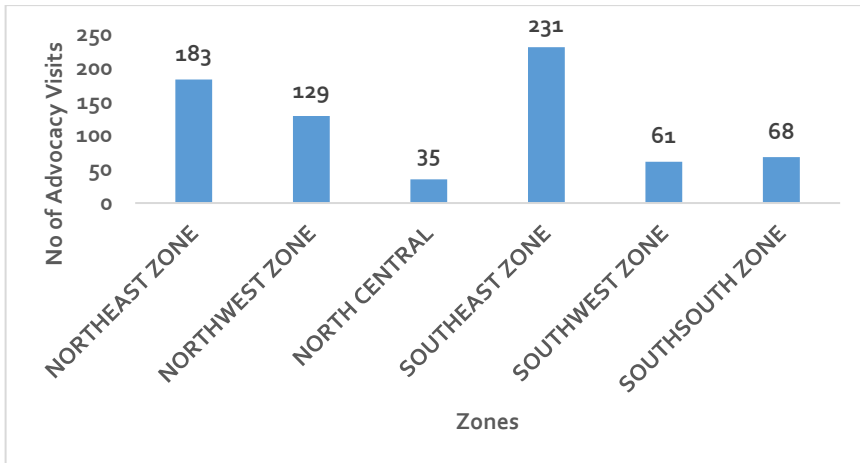
### No of Consumer Complaints



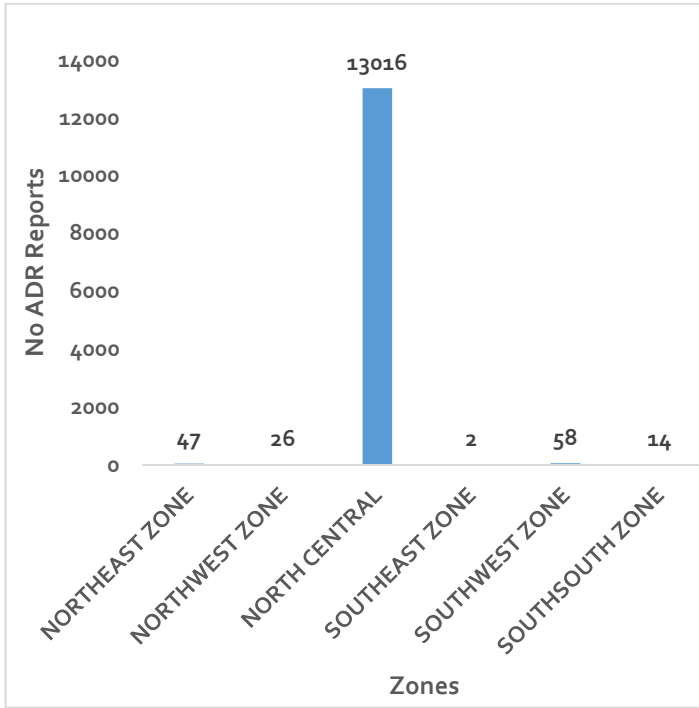
### No. of PMS Activities



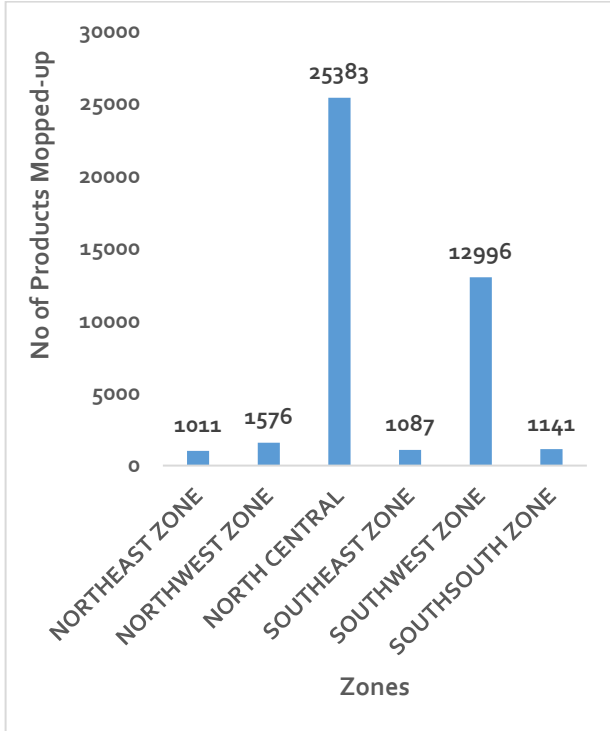
### No of Advocacy Visits



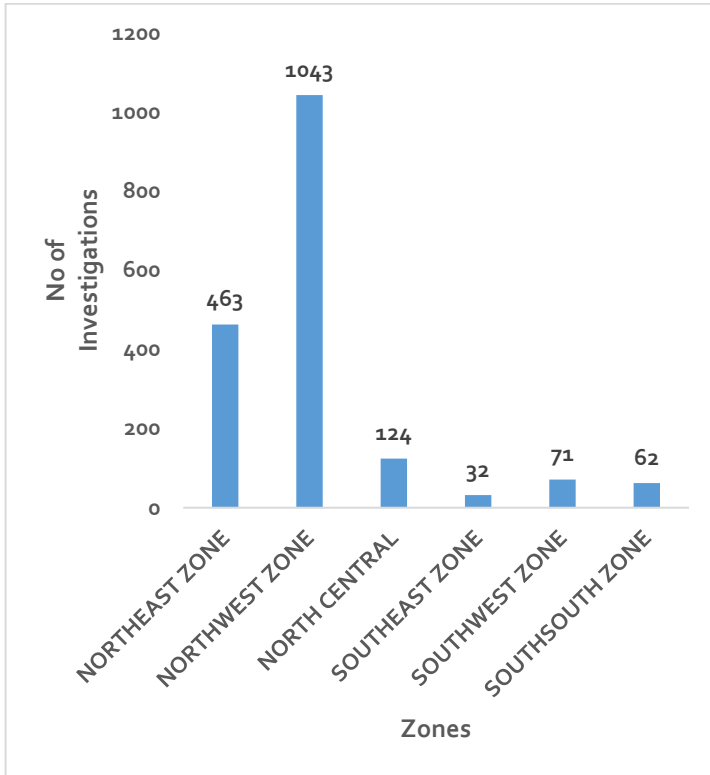
## No ADR Reports



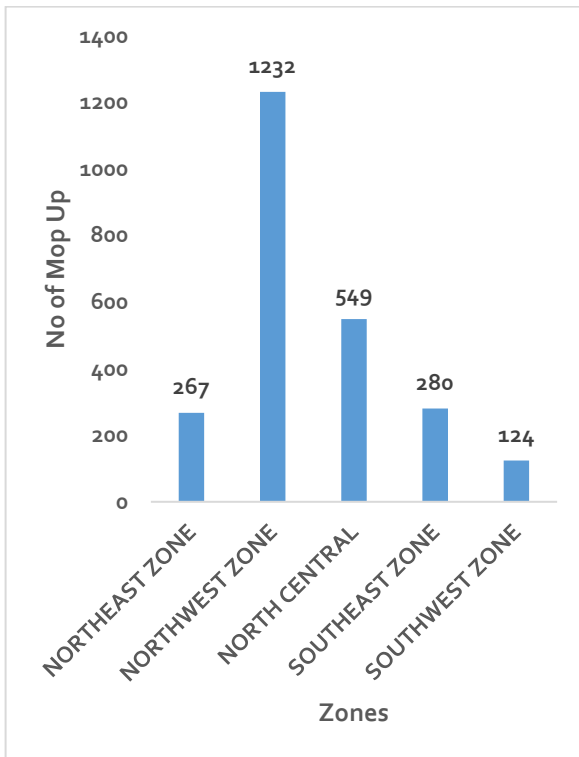
## No of Products Mopped-up



## No of Investigations



## No of Mop Up



## Chapter 18

### Legal Services Directorate

#### 1. Registration Documents

Below is a breakdown of registration documents treated by the directorate for the months under review.

Month	Drugs, Cosmetics & Medical Devices	Food	Total
January	84	18	102
February	86	20	106
March	96	39	135
April	55	25	80
May	60	24	84
June	-	29	29
July	-	-	-
August	82	58	133
September	34	84	118
October	30	50	80
November	42	72	114
December	20	85	105
		<b>TOTAL</b>	<b>1590</b>

#### 2. Agreements

- A total of Twenty (26) contract agreements were prepared for the months under review.

#### 3. Meetings

- Procurement Planning Committee meeting held on the 10<sup>th</sup> February, 2022
- 5<sup>th</sup>& 6<sup>th</sup> April 2022 Meeting at the Federal Ministry for Trade and Investment of selected stakeholders to develop Nigeria's Free Trade Agreement (FTA) Template.
- Tenders meeting held on the 16<sup>th</sup> May 2022.
- Meeting held between NAFDAC AND NYSC for the signing and implementation of the MOU between both bodies held on the 13<sup>th</sup> of May 2022.
- Meeting with respect to the Proposed Construction of NAFDAC Office at Edo State and Kano State, held on the, 27<sup>th</sup> May, 2022.

- A post review meeting was held on the 31<sup>st</sup> May, 2022 with respect to the proposed construction of NAFDAC office at Edo and Kano States.
- Meeting between NAFDAC and Indonesia representatives on the 3<sup>rd</sup> of August, 2022.
- Tenders Board meeting held on the 8<sup>th</sup> August 2022.
- Public Institution freedom of Information Desk Officers Interactive Engagement on proactive disclosure obligations held at the Federal Ministry of Justice on the 16<sup>th</sup> August 2022.
- FCT 18<sup>th</sup> zonal approval meeting was held on the 25<sup>th</sup> August, 2022 for registration of NAFDA regulated products.

#### 4. Committees

The Directorate has had full representation on the following committees:

- a) Food and Drugs Registration Committee (Final and Sub)
- b) GBT Team
- c) NAFDAC Traceability Office

#### 5. Public Hearings at the National Assembly

- Invitation to a meeting with the Technical Committee on Bills and Motions referred to the House Committee on Agric. Production and Services held on the 16<sup>th</sup> February 2022.
- Invitation for an interactive session by the Committee on FOI (Reforms of Government Institution) held on the 8<sup>th</sup> March, 2022.
- Public hearing held on the 9<sup>th</sup> -10<sup>th</sup> March, 2022 at the national assembly organized by the House of Representatives Committee on Health Institutions.
- Public hearing on a Bill for an Act to establish Microbiology Council of Nigeria held on the 17<sup>th</sup> March 2022 by the Senate Committee on Establishment and Public Service.
- A 2 day Public hearing held on the 23<sup>rd</sup> March, 2022 by the House Committee on Healthcare Services.
- Public Hearing on a Bill for an Act to prohibit chemical and Biological weapons and establish the National Authority for the effective implementation of the chemical and Biological weapons conventions in Nigeria and for related matters held on the 5<sup>th</sup> April 2022 by the House Committee on Treaties and Protocols and Agreements.
- Request for Nominal Roll/ invitation for meeting by the House Committee on Federal Character held on the 6<sup>th</sup> April 2022
- Public Hearing held on the 12<sup>th</sup> -13<sup>th</sup> April 2022, by the senate Committee on Health.
- Request for detailed information on efforts to stabilize the prices of commodities, Goods and Services across the Nation, since 2015- date submitted on 14<sup>th</sup> April 2022.
- Public hearing at the National Assembly for A Bill to 25/07/2022 on a bill food safety.
- **Public Hearing By The House Committee On Healthcare Services On The Repeal And Enactment Of Counterfeit And Fake Drugs And Unwholesome Processed Food (Miscellaneous Provisions)** :After the approval of the council, the draft Bill was submitted to the National Assembly. The Bill passed the 1<sup>st</sup> and 2<sup>nd</sup> Reading at the House of Representatives and the Public hearing was held on 29<sup>th</sup> September, 2022. The response at the haering was positive.The Bill has been adjourned for 3<sup>rd</sup> reading before being sent to the senate for concurrence.

## 6. Cases

### a. Judgement:

#### **Charles Nwachukwu v. NAFDAC & 6 Ors FHC/ASB/CS/111/2021**

The Applicant filed a Suit at the Federal High Court, Asaba against the Agency, 2 Agency staff, a Police Officer attached to the I&E/FTF, Asaba, IGP, Police Service Commission & Commissioner of Police, Delta State. The claimant alleged breach of his Fundamental Rights and claimed over **One Hundred Million Naira in damages**. He challenged the enforcement activities of the I&E Asaba (particularly, the seizure of his products, sealing of his premises and his detention). In the course of the hearing, he filed form 48 & 49 for contempt against the Agency and reopened his sealed shop. The Agency approached and prayed the court to grant it permission and protection of court and security personnel to re-seal the premises. The court granted the prayer. The claimant also challenged the contempt proceedings and it was averted.

The Court delivered judgment in favour of the Agency on 20/7/2022.

b. LESD has filed and will be filing the defence of the Agency in the following cases:

- a) **LELASSCORN Vs NAFDAC (Suit No: FHC/KN/CS/202/22)** - The Incorporated Trustees of League of Lawyers for the Support and sensitization of Consumers Rights in Nigeria (LELASSCORN) sued the Agency and asked the Court to Order the Agency to give it access to information and record on the Agency's investigation on sale, distribution and consumption of fake and adulterated flavoured drink in Kano. State.
- b) **ARICONTINENTAL LTD Vs NAFDAC & 3Ors (Suit No: ID/1428MSAR/2022)** - The plaintiff suing the Agency for breach of his fundamental human rights and is seeking the Court amongst other declaration to Order the Agency to pay him the sum of N240,000.00 for cost of demurrage, N200,000.00 for rent of makeshift shop and N10,000,000.00 as general damages.
- c) **BASIL NWANKWO Vs NAFDAC STATE COORDINATOR & ANOR (Suit No; FHC/ASB/CS/208/2022)** - The plaintiff is suing the Agency for breach of his fundamental human rights and is seeking the Court amongst other declarations to declare that the seizing of his goods (regulated products) during NAFDAC operation is a violation of his fundamental right, to direct the Agency to release his goods or to pay the value of the goods at N11, 000,000.00 and for the Court to grant him N20,000,000.00 as damages.
- d) **VALENTINE CHINWEIKE GERALD DURU Vs CHAIRMAN NAFDAC & 2Ors (Suit No: FHC/L/CS/2295/2022)** - The plaintiff is suing the Agency for breach of his Fundamental human rights and seeking the Court amongst other declarations to declare that his arrest and detention is illegal and a breach of his rights and to grant him N500,000,000.00 as damages

**All other cases are still ongoing at the various Courts.**

**Note :Reports of court proceedings cannot be presented monthly as it is dependant on the Courts.**

**Details of concluded cases will be submitted as at when due**

## 7. Training/Workshop/Conference

- **Legal English: Legal Writing and Drafting, Contracts and Negotiation Skills Course** held on the 20<sup>th</sup> June-1<sup>st</sup> July, 2022 at Mombasa Kenya. Two (2) legal Officers were in attendance. Step down training on the above has already commenced.
- **NBA Conference 2022:**  
Four (4) Legal Officers were in attendance at the conference which held at Eko Hotel and Suites from the 21<sup>st</sup> to 26<sup>th</sup> of August, 2022.

## **8. Laws**

- a) **AMENDMENT OF NAFDAC ACT, CAP N1 LFN 2004** - Amendment of certain sections of the Act to enhance the activities of the Agency is pending at the Senate for Concurrence.
- b) **BILL FOR THE REPEAL AND RE-ENACTMENT OF THE COUNTERFEIT ACT, CAP C34 LFN 2004** - Work is ongoing at the Secretariat of the House committee of Healthcare in preparation for Third Reading at Plenary of the entire House.

## **9. FOI Committee**

The formal inauguration of the FOI Committee is still pending. The inauguration will also include a one day training to be facilitated by Resource persons from the office of the Honorable Attorney General of the Federation (Head of FOI Unit), Federal Ministry of Justice.

## Chapter 19

### Human Resource Management Directorate

#### 19.0 Introduction:

The Directorate is one of the three Service Directorates and is involved in the day-to-day administrative matters as well as all issues affecting the workforce of the Agency to ensure efficient and effective use of Human and material resources for optimal productivity.

The Directorate has three (3) Divisions namely:

1. Appointment, Promotion, Discipline & Establishment
2. Staff Welfare and Training
3. General Services

The day-to-day functions of the Directorate are:

- Staff recruitment/appointment, staff, promotion, transfer and posting in the Agency.
- Dealing with complaints of staff misdemeanors/misconduct and recommends proper disciplinary actions to be taken by the Agency against erring staff.
- Documentation of new staff, prepares staff nominal roll and issues of identify cards.
- Custody of records of all the Agency's rented and owned properties.
- Handling of insurance matters as they relate to staff and NAFDAC assets.
- In charge of security services, environmental matters and other corporate issues.
- Coordination of matters relating to NAFDAC Council.
- Liaising with ministries, Government Departments and other Agencies (MDAs) in sourcing for and collecting all establishment circulars and relevant rules and regulations guiding the conduct of Government business.

#### 1. Appointment, Promotion, Discipline & Establishment

The Division handles all matters relating to Recruitment, promotion of staff and discipline of erring staff.

The 2021 Directorship promotion Interview was conducted in August 2021. A Total of 43 qualified staff members were invited, only 41 qualified staff members participated in the exercise. 4 most staff members were promoted to the ranks of Director,

##### a. Discipline

During the year under review, Disciplinary committee meetings were held and different types of disciplinary measures were meted out to erring staff. These include query and warning of officers who were found culpable of various offenses, as detailed below:

- Issued query - 8
- Staff issued warning - 3

**b. Records & Registry**

The Division keeps and updates records of all staff of the Agency.

Staff Position

- Staff strength -2 ,112
- Females - 909
- Males - 1, 203
- Senior Staff - 1, 858
- Junior Staff - 254
- Scientific Staff- 1348
- Support Staff- 764

Activities of the Directorate during the year under review are as follows:

**c. Leave Matters**

During the period, all staff of the Agency enjoyed various types of leave, such as the normal Annual leave, sick leave or casual leave.

Exited staff grew up to 41 in the period under review as shown in the breakdown below:

- No of resignation - 11
- Staff on transfer of service - 1
- Staff on secondment - 2
- No of retirement - 17
- Staff death toll - 10

**2. Staff Welfare and Training**

The Division is responsible for staff training and general staff welfare

**a. Welfare**

- During the period under review, a total of 89 staff members benefitted from the staff welfare package of N50, 000 each, for wedding ceremonies or loss of close family members.

**b. Training**

Functions of the Training Unit of the Division include:

- Identifying staff training needs of the various Directorates;
- Preparing annual training schedules for consideration;
- Processing and obtaining approvals for training.

There were various Local trainings coordinated by HRM Directorate in which 210 staff were trained, in order to enhance their productivity on the job after the training.

**3. General Services.**

This Division carries out the following activities:

- Handles insurance matters as they relate to staff and NAFDAC assets.
- Coordinated matters relating to NAFDAC Governing Council.
- Liaise with Ministries, Government Departments and other Agencies (MDAs) in sourcing for and collecting all establishment circulars and relevant rules and regulations guiding the conduct of Government business. Such Government organizations include Federal Ministry of Health, Federal character commission, PENCOM, National University Commission, National Health Insurance Scheme, Federal Ministry of Finance among others.
- Handles Cleaning and Sanitation issues.
- Handles security of Offices in NAFDAC formations.

**a. Maintenance & Engineering Unit-Office Accommodation/Development Projects**

Development of office accommodation, Labs and mini labs for some selected states.

The following States/Zonal office construction/projects are ongoing in the following States:

- I. Sokoto
- II. Yobe
- III. Kebbi
- IV. Kwara
- V. Osun

VI. Ogun

VII. Ebonyi

Besides these, the expansion of Drug Lab Yaba and the construction of a new Vaccine Lab as well as at a PID office, NAHCO are nearing completion.

The Calabar Laboratory is undergoing renovation.

- Purchase of furniture for some state offices.
- Renovation of some state offices.

**b. Insurance Matters**

- Group life Assurance in place for all staff of the Agency.
- NAFDAC Properties and Vehicle are duly covered.

**c. Council Matters**

The NAFDAC Governing Council meetings held intermittently during the year under review.

**d. Transport & Maintenance**

Activities of the Division are:

- The Agency currently has 225 functional vehicles and 34 non-functional vehicles.
- Additional 36 new vehicles were purchased.

## Chapter 20

### Planning Research and Statistics (PR&S) Directorate

The PR&S Directorate is a service Directorate that is charged with the responsibility of planning, researching, collecting, collating, storing and retrieving of data as well as coordinating the activities and achievements of other Directorates of the Agency. It functions as enumerated in enabling Act.

The Directorate is comprised of three Divisions;

- i. Planning, Training and Support services
- ii. Monitoring and Evaluation (M&E)
- iii. Research and Statistics (R&S)

#### 1. Planning, Training and Support Services (PT&SS)

##### a. Training

PR&S Directorate collated staff training needs and successfully coordinated the participation of staff in various trainings/staff development programmes. A total of **63 programmes** including 7 In-house were attended by **2,549 staff** of the Agency in 2022. That is **37 local** programmes were attended by **2,486 staff** while **63 staff** attended **26** various international programmes.

Further breakdown is as shown in the tables below:

**Table 20.1:** Breakdown of Programmes in 2022.

Programme	Foreign	Local	Total
Conferences	1	2	3
Trainings/Workshops	25	28	53
In House	-	7	7
<b>Total</b>	<b>26</b>	<b>37</b>	<b>63</b>

**Table 20.2:** Breakdown of staff participation at Local & Foreign Trainings/workshops

Programme	Foreign	Local	Total
Conferences	2	8	10
Trainings/Workshops	61	956	1017
In House	-	1,522	1,522
<b>Total</b>	<b>63</b>	<b>2,486</b>	<b>2,549</b>

**Notes:** Three (3) Top Management Committee (TMC) Meetings were held in 2022.

##### b. Industrial Attachment

The students Industrial Work Experience Scheme (SIWES) was instituted by the National University Commission to ensure that what is taught theoretically to students in school is followed up with practical experience. The Agency has been engaging the services of students on Industrial attachment, with courses relevant to the operation of NAFDAC to our various laboratories in Lagos, Port-Harcourt, Agula, Maiduguri

and Kaduna. The successful IT students are exposed to the use of state-of-the-Art Laboratory equipment to enhance the practical experience.

During the year under review, a total of One Thousand Two hundred and fifty four (1,254) application letters were received out of which Five Hundred and Forty one (541) applications were processed, Three Hundred and nine (309) Assumption letters were received from the various laboratory and Three Hundred and Seventy Five (375) certificates were issued at the end of 2022.

**c. Report of Excursion from January - December, 2022**

- Application letters received from schools 23
- Excursion Implemented 3

**2. Monitoring and Evaluation (M&E) Division Activities 2022**

The Monitoring and Evaluation Division of PR&S is charged with the responsibility of;

- i.* Developing M&E systems that will aid in the implementation of the agency's Annual work plan;
- ii.* Collection, validation, storing and analyzing of monthly, quarterly, bi-annual and annual reports of all Directorates in the Agency;
- iii.* Collaborating with the Research and Statistics (R&S) Division in the development of an Annual report for the Agency;
- iv.* Providing supportive supervision by carrying out quarterly Field Visits of all Directorates to monitor and ensure that programmatic activities are being carried out as planned;
- v.* Coordinating the Internship programme in the Agency;
- vi.* Providing technical guidance to Directorates of the Agency by incorporating appropriate M&E systems into their programmes;

**a. Monthly Reports**

- The Division reviewed the 2022 Monthly reports received from all the Directorates of the Agency. These reports were validated for detailed statistical analysis and finalization of the Quarterly, Bi-Annual and Directorate Performance Evaluation Report which was presented in the Top Management Committee (TMC) by DD (M&E).
- The M&E Division also collated a total of One hundred and ninety-seven (197) monthly reports from the various directorates, out of which Twenty (24) were within specified timeline of 15<sup>th</sup> of preceding month, One hundred and Seventy three (173) were after specified timeline, which was validated and analyzed.

**b. Annual Report**

- The Division reviewed the 2021 Monthly reports received from all the Eighteen (18) Directorates of the Agency. These reports were validated and forwarded to the R&S Division of PR&S for detailed statistical analysis and finalization of NAFDAC 2021 Annual report.

**c. M&E Visit**

- The Division developed M&E tools for all the Directorates in the Agency for periodic monitoring and evaluation of the Agency's KPIs for the implementation of the agency's Strategic Plan (2018-2023). The physical visit was conducted in Two (2) Directorates within the Corporate Headquarter that is, PVPMS and Finance and Account.
- KPI Templates were also sent to all the Directorates for January to June 2022. However, four (4) Directorates; PID, I&E, F&A and HRM are yet to submit their completed templates.

#### **d. Internship**

- In accordance with the Pharmacists Council of Nigeria (PCN) Decree 91 of 1992, Pharmacy graduates are statutorily required to undergo a compulsory one-year continuous internship training programme in a registered Pharmacist Council approved internship centre. NAFDAC is one of the approved centres for training of Intern Pharmacists. The M&E Division in line with the Agency Internship policy coordinated the placement of Intern pharmacists in the agency. In the year under review, total of Three Hundred and Ninety-Four (394) Internship Application was processed,
  - Thirty-two Interns were engaged (32),
  - Sixty-five (65) were Discharged,
  - Fifty-six (56) were given Internship certificate of completion,
  - Thirty-two (32) are currently in the system.

#### **e. Others**

- The division developed M&E tools that were forwarded to Drug related Directorates for their response, the tools were completed and forwarded to the division. The tools were then evaluated and submitted to the GBT team.

### **3. Research and Statistics (R&S) Division Annual Report.**

The Research and Statistics Division is charged with the responsibility of conducting scientific research on NAFDAC regulated products as well as other subjects of interest to the Agency and making recommendations based on the findings to management for evidence based regulatory decision making.

The Division also provides Library Services to the staff of the Agency.

During the year under review, the Division among others did the followings:-

#### **a. Surveys and Statistical Analysis.**

- Participated in Large Scale Food Fortification (LSFF) survey in conjunction with Food Safety and Applied Nutrition Directorate.
- Received and Filed GMP reports.
- Collated Monthly/Quarterly Zonal performance reports.
- Monthly Analyzed of Presidential Enabling Business Environment Council (PEBEC) reports for the Office of Trade and International Relation (OTIR/OSIC).
- Developed Work plan and research protocol on Total Diet Study (TDS) for the Office of Research (OOR).

- Developed survey protocols for Large Scale Food Fortification survey for FSAN, 2021 MCH protocol for PV/PMS,) Honey and Milk AMR for D (Lab-Food), developed proposal for groundnuts contamination awareness sensitization in Kano, Work plan and research protocol on Total Diet Study (TDS) for the Office of Research (OOR), Bouillon Cubes Metal Assay Study in Nigeria.
- Analysis on monthly complaints received and Customer feedback system for Reforms Unit.
- Rendered Statistical support to other Directorates.

**b. Groundnuts Contamination Awareness Sensitisation Campaigns in Kano**

Following recent study conducted by NAFDAC, it was observed that **aflatoxin B1** concentration in Groundnut oil sample from Kano is beyond safe limit. Considering the high level of consumption of Groundnut oil in Kano and other parts of country, it became necessary to conduct awareness campaign.

Consequently, NAFDAC organized awareness sensitisation campaign on the prevention and reduction of aflatoxins in groundnut and groundnut oil which are stable food among the population.

The awareness campaign took place on 22<sup>nd</sup> December, 2022 at Amani event center, No. 3 Tamandu Road, Nasarawa GRA, Kano State.

**c. Library Services.**

NAFDAC Library is charged with the responsibility of providing and accurate information resources that would help staff in (Lagos, Abuja, and Kaduna) achieving the Agency's mandate. The library has been providing quality library services to staff of the Agency and researchers within the year 2022. The library carried out the following activities: -

- Rendered reference service to library users.
- Carried out user education.
- Provide current awareness service by constantly informing users of new information resources available in the library.
- Carried out Selective Dissemination of Information (SDI) so as to encourage the use of library resources.
- Collected, organized, and preserved newspapers and other periodicals of interest to the users.
- In Lagos, Abuja, and Kaduna, a total of 754 users visited the library in the year under review.

## Chapter 21

### Finance and Accounts Directorate

#### 1. Introduction:

The Directorate is a service Directorate which is responsible for the management of financial resources of the Agency. The activities of Finance and Accounts Directorate are guided by Finance Act, Financial Regulations, Fiscal Responsibility Commission Act and series of Financial Circulars from Office of the Accountant General of the Federation, Budget Office of the Federation etc.

#### 2. Structure of the Directorate:

The Directorate is headed by a Director. It has three functional Divisions namely:

1. Accounts.
2. Finance.
3. Budget and Import.

These divisions are further segmented into Units as follows.

1. Accounts Division: Revenue Unit, Advances and Budget Allocation Unit, Plant, Property and Equipment Unit, Stores Unit, Final Accounts Unit and Aid and Grants Unit.
2. Finance Division: Expenditure unit, Treasury unit, Salary & Wages Unit.
3. Budget and Import Division: Vote Book Unit, Budget and Import Unit.

#### 3. Operational Activities:

- Payment of claims for both Staff and contractors
- Supervision of 2022 assets disposal exercise.
- Contributed to improvement in revenue generation capacity through constant monitoring on PIDCARMS and NAPAMS platforms
- Training of staff on topical issues on Financial Management and Reporting; IPSAS and FIRS.
- Successfully prepared 2023 Budget and defended the budget at both Committees of National Assembly and the Budget Office of the Federation
- Coordinating implementation of 2020 and the payment of 2022 staff promotion arrears
- Attended to visiting Auditors and successfully answered all financial enquiries from the Public Account Committee, Office of the Accountant General of the Federation and Office of the Auditor General for the Federation.

#### 4. Level of Implementation of 2022 Budget:

The level of Budget 2022 Implementation is summarized as follows:

**Table 21.1: Revenue Generation for 2022:**

Sources:		Budgeted (₦)	Actual (₦)	% Performance
1.	Internally Generated	3,638,093,669.70	3,031,013,872.98	83.31
2.	Revenue User Fees	14,310,400,508.25	12,933,212,594.84	90.37
	<b>Total</b>	<b>17,948,494,177.95</b>	<b>15,964,226,467.82</b>	<b>88.94</b>

**Table 21.2: Expenditures 2022:****Heads:**

1.	Capital	14,429,637,238.00	12,512,981,041.88	86.72
2.	Overhead	10,882,120,590.96	9,172,962,440.75	84.29
	<b>Total</b>	<b>25,311,757,828.96</b>	<b>21,685,943,482.63</b>	<b>85.68</b>

**Table 21.3: FGN Allocation 2022:**

	Appropriation	Actual Releases (₦)	Expenditure (₦)	% Performance
1.	Capital	525,906,668.00	517,752,417.48	89.78
2.	Personnel	6,784,953,593.00	6,377,526,813.72	99.97

**Note: No Overhead Allocation was given to NAFDAC in 2022.**

The 2022 operating surplus of 25% of IGR amounting to ₦2,571,083,806.43 was deducted at source from the Agency's revenue by Federal Government.

**5. Fixed Assets Verification:**

Fixed assets verification was successfully carried out in 2022 and the Fixed Assets Register was updated. The net book value of assets as at 2022 shall be available at the completion of Audited account. However, the net book value as at 2021 audited account is ₦11,337,337,000.00

**6. Finalization of Audit for 2021:**

The Directorate successfully completed 2021 Audited Accounts. Copies of the Accounts and the accompanying Management Letters were submitted to regulatory bodies such as Office of the Auditor General for the Federation, Office of the Accountant General of the Federation, Fiscal Responsibility Commission etc.

**7. Management Account for 2022:**

The preparation of 2022 Management Account is in progress and will soon be finalized for audit purposes.

## **8. New Accounting Software:**

In the year 2022 SAP Business By-Design Accounting Package was successfully installed and put to use and it is being deployed in phases to the various divisions and units of the Directorate. When it is completely configured it will replace the Sage X3 that has been in use since.

## **9. Outstanding Operating Surplus with Fiscal Responsibility Commission (FRC) in the Sum of ₦10,957,379,168.00:**

The Directorate successfully reconciled the outstanding accumulated operating surplus from 2007 - 2020 with the Fiscal Responsibility Commission. The initial amount of ₦10,957,379,168.00 declared by Fiscal Responsibility Commission as indebtedness of NAFDAC to Federal Government was reduced to ₦4,902,870,166.00 after the reconciliation between the Agency and Fiscal Responsibility Commission.

## **10. Assets Disposal 2022:**

Unserviceable assets with the net book value amounting to ₦756,430.00 were disposed off in the year. The sum of ₦37,995,600.00 was collected as proceeds from the disposals. Expenses of ₦1,899,780 representing 5% of the proceeds from the sales was paid to the Auctioneer, transportation expenses of ₦1,499,000.00 was incurred. The balance of ₦34,596,820.00 was remitted to the Consolidated Revenue Fund (CRF) as statutorily required.