THE EXECUTIVE AGENCIES (THE TANZANIA FOOD AND DRUGS AUTHORITY (ESTABLISHMENT) ORDER, 2004

AND

THE EXECUTIVE AGENCIES (THE TANZANIA FOOD AND DRUGS AUTHORITY (ESTABLISHMENT AMENDMENT) ORDER, 2008

Muhuri wa Halmashauri ya Wilaya ya Kibaha ulibandikwa kwenye Sheria Ndogo hizi kwa azimio la Mkutano wa Halmashauri uliofanyika tarehe 20/10/2003 na ulibandikwa mbele ya:-

L.S.

COL. D. H. MKWEJI,
Mwenyekiti wa Halamshauri
ya Wilaya ya Kibaha

MAIFRN M. N. SHIRIMA,
Mkurugenzi Mtendaji
Halmashauri ya Wilaya ya Kibaha

NAKUBALI

BRIG. JEN. (MSTAAFU) HASSAN NGWILIZI (MB.),
Waziri wa Nchi, Ofisi ya Rais
Tawala za Mikoa na Serikali za Mitaa

Dodoma,
2 Aprili, 2004

GOVERNMENT NOTICE No. 264 published on 23/7/2004

THE EXECUTIVE AGENCIES ACT, 1997

(No. 30 OF 1997)

ORDER

Made under section 3 (1)

THE EXECUTIVE AGENCIES (THE TANZANIA FOOD AND DRUGS AUTHORITY (ESTABLISHMENT) ORDER, 2004

Citation

1. This Order may be cited as the Executive Agencies (The Tanzania Food and Drugs Authority -(TFDA) (Establishment) Order, 2004 and shall be deemed to have come into operation on the 1st day of January, 2004.

Establishment of TFDA

2. There is hereby established an Executive Agency to be known as the Tanzania Food and Drugs Authority, in its acronym TFDA.

G.N No. 264 (contd.)

TFDA Frame Work Document

3. Governance, objectives, functions, responsibilities, authority, performance standards and all matters relating to the administration and management of TFDA shall be as specified in the framework document set out in the Schedule to this Order and other laws related to the establishment of the Authority.

SCHEDULE

(Under paragraph 3)

FRAME WORK DOCUMENT FOR THE TANZANIA FOOD AND DRUGS AUTHORITY

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7.0 PUBLIC ACCOUNTS COMMITTEE AND PUBLIC ENQUIRIES.

7.1 THE PUBLIC ACCOUNTS COMMITTEE.

7.2 PARLIAMENTARY AND OTHER INQUIRIES

THE TANZANIA FOOD AND DRUGS AUTHORITY FRAMEWORK DOCUMENT

FOREWORD

The Government of the United Republic of Tanzania has decided to establish the Tanzania Food and Drugs Authority (TFDA) as an Executive Agency under the Ministry of Health. TFDA assumes the roles and responsibilities of the then Pharmacy Board and the National Food Control Commission.

TFDA is a statutory body responsible for ensuring that foods, drugs, medical devices and cosmetics are of good quality, safe and effective. Its major activities include; regulating manufacturing, labeling, importation, distribution, storage and selling of food, drugs, cosmetics, medical devices and related products, prescribing standards of quality and carrying out or facilitating analysis to determine fitness for the intended use.

TFDA faces a challenge of providing adequate protection of consumers against hazards related to aforementioned products and constantly adjusting to technological, social-economic, policy and environmental changes.

In recognition of the sensitivity and magnitude of the roles and responsibilities facing TFDA, the Ministry of Health shall provide it with the necessary support to achieve its objectives.

Lastly, let me take this opportunity to congratulate the TFDA Implementation Team, the Secretariats of the National Food Control Commission and the Pharmacy Board and other stakeholders for their contribution towards the establishment of this Authority.

I am confident that the Director General of the Tanzania Food and Drugs Authority will meet the challenges that lie ahead and I wish her and the staff every success.

Dar es Salaam,
19 th January, 2004

ANNA MARGARETH ABDALLAH (MP),
Minister for Health

G.N. No. 264 (contd.)

1. INTRODUCTION

Prior to 1978 drug and food control in Tanzania were administered by the Ministry of Health through Food and Drugs Ordinance (Cap. 93) of 1937, the Pharmacy and Poisons Ordinance (Cap. 94) of 1937 and the Dangerous Drugs Ordinance (Cap. 95) of 1937. In addition the Meat Hygiene Ordinance Cap.432 of 1961 provided for control of meat safety and hygiene under the Ministry of Agriculture. These legislation were found to be inadequate to cope with the rapid developments in food and pharmaceutical industries and consequently the Food (Control of Quality) Act, 1978 and Pharmaceuticals and Poisons Act, 1978 were enacted. As time went on, new thinking and philosophy emerged calling for improved controls of food and drug dealings, and hence establishment of Tanzania Food and Drugs Authority (TFDA).

2.0 STATUS AND GOVERNANCE

2.1 *Declaration of the Agency Status*

The Tanzania Food and Drugs Authority is an Executive Agency of the Ministry of Health established under section 3(1) of the Executive Agencies Act, 1997 and section 4(1) of the Tanzania, Food, Drugs and Cosmetics Act, 2003. It replaces the Pharmacy Board and National Food Control Commission.

TFDA shall come into operation on the day 1st of January, 2004 and shall operate in accordance with the provisions of the laws establishing the Authority.

2.2 *Governance*

The Director General, who will be the Chief Executive of the Authority, shall be appointed by the Minister for Health. The Director General and Directors shall form the TFDA Management Team. The Director General may co-opt any other staff to attend management meeting as need arises.

The Permanent Secretary, Ministry of Health is responsible for the strategic management of TFDA and for that purpose, may give directions to the Director General, but with due regard to the need to uphold the Authority's autonomy in the day-to-day management of its affairs. The Permanent Secretary shall oversee the interest of the Ministry and the Government in general.

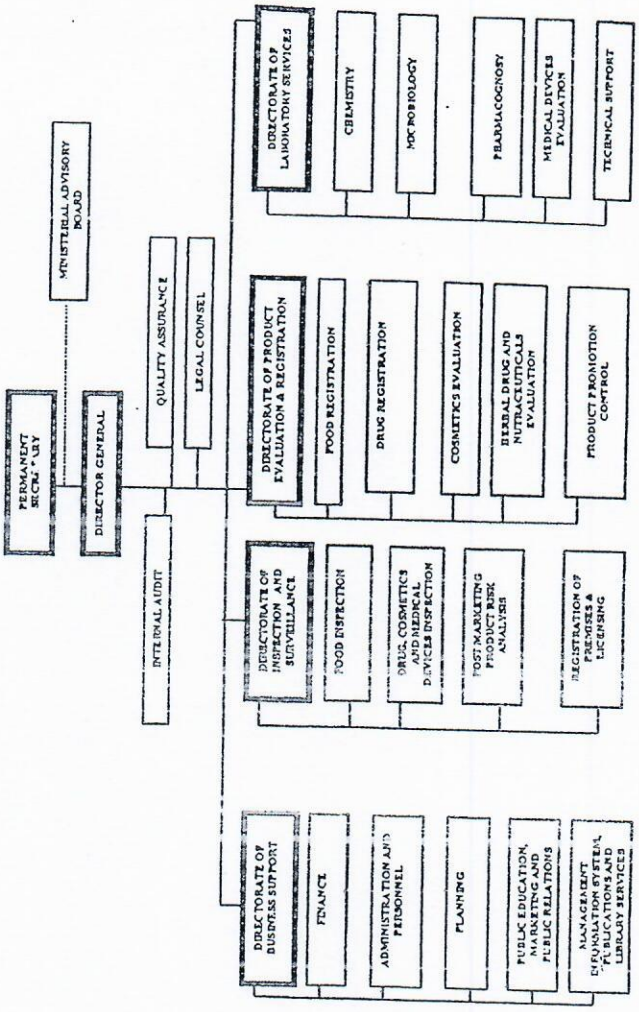
The Ministerial Advisory Board of the Tanzania Food and Drugs Authority, shall advice on the strategic objectives of the Authority, priorities and annual performance targets and the acceptability of the Director General's plans, associated budgets, annual reports and accounts which will form the basis for Performance Agreement between the Director General and the Permanent Secretary.

3.0 ORGANISATIONAL STRUCTURE

The Director General may make changes to the organizational structure of TFDA

ANNEX I

TFDA ORGANISATION STRUCTURE



G.N. No. 264 (contd.)

as may be considered necessary to maintain and improve the efficiency and overall performance of the Agency in consultation with the Permanent Secretary.

The Director General will be assisted by Directors as outlined in the TFDA organogram. The number and responsibilities of Directors may be reviewed periodically according to the business needs of the Agency. The Director General, Directors and coopted members who will be appointed by the Director General will constitute the Management Team of the Agency. An organization structure is attached as Annex I.

4.0 AIMS, ROLE, KEY RESULTS AREAS (KRA), STRATEGIC OBJECTIVES AND PERFORMANCE CRITERIA

4.1 *Aim*

The aim of TFDA is to protect consumers against health hazards associated with food, drugs, cosmetics, medical devices and practices related thereto.

4.2 *Tole*

The role of TFDA shall be:

(a) To strengthen food, drugs, cosmetics and medical devices and related products control services.

(b) To ensure that the products circulating in the market meet specified safety and quality standards.

4.3 *Key Results Areas*

TFDA shall address the following KRAs:

1. Quality and safety of food, drugs, cosmetics, medical devices and related products.

2. Timely information and education services on food, drugs, cosmetics, medical devices and related products to the relevant stakeholders.

3. Total quality management principles.

4.4 *Strategic objectives*

In order to attain the aims, TFDA is assigned to achieve the following strategic objectives:

(a) Develop and implement an efficient and effective food, drugs, cosmetics, medical devices and related products registration system within ten years.

(b) Review and improve the existing licensing system by 2006.

(c) Review and/or develop relevant food, drugs, cosmetics, medical devices and related products regulations by 2006.

(d) Develop and implement an efficient and effective inspection system by 2006.

(e) Develop and implement an efficient and effective education, information and communication system by 2006.

(f) To ensure that 80% of licensed food manufacturers, importers, exporters and distributors comply with good handling practices by 2006.

(g) Develop and implement Total Quality Management System by 2006.

4.5 *Performance criteria*

Performance indicators are general areas in which TFDA's performance will be measured. Specific performance targets will be set each year in each of the identified areas which shall be clearly stated in the Performance Agreements.

The Ministerial Advisory Board (MAB) shall regularly assess the performance of TFDA. Assessment will be on the basis of perfomance reports submitted by the Director General to the Permanent Secretary at least twice a year and in that regard, particular attention will be paid to the following areas:

4.5.1 *Quality services*

- Timely assessment of product quality, safety and effectiveness.
- Reduction of substandard and counterfeit food, drugs, cosmetics, medical devices and related products in the market.
- Promoting and ensuring that prescribed standards are maintained.
- Provision of analytical services for food, drugs, cosmetics, medical devices and related products in specified time.
- In-house quality audit system instituted, implemented and monitored regularly.
- Provision of timely, accurate and comprehensive information to the stakeholders.

264 (contd.)

4.5.2 *Operational efficiency*

- Use of the best internal procedures for issuance of licences, permits and certificates.
- Effective application of management information systems in all sectors of the Authority to raise productivity.
- Improvement in the ratio of the cost to revenue.
- Prompt response to complaints from the customers/stakeholders

4.5.3 *Financial performance*

- Prompt preparation of bills and collection of fees.
- Timely and accurate production of financial reports.
- Clean reports from the Controller and Auditor General.
- Effective and transparent procurement and stock control system.

5.0 ROLES, RESPONSIBILITIES AND ACCOUNTABILITY

5.1 *Responsibilities of Minister*

The Minister for Health is responsible for establishing TFDA and appointing the Director General of the Authority and members of the Board and for ensuring that the Government derives maximum benefit from the creation of the Authority.

The Minister for Health is ultimately responsible for determining the policy framework and the operational boundaries within the operations of Tanzania Food and Drug Authority (TFDA) as described in the Business Analysis Report (BAR). The Minister shall be responsible for the general direction and control of TFDA.

The Minister for Health shall not be involved in the day to day management of the Authority but shall be advised and informed by the Permanent Secretary on any operational matters and issues that may give rise to significant public or parliamentary concern.

5.2 *Responsibilities of Permanent Secretary*

The Permanent Secretary is the Accounting Officer of the Ministry and the principal policy adviser to the Minister on matters related to TFDA. In discharging his duty(s) he shall at all times uphold the

autonomy of the Authority in the day to day management of its affairs and also respect the delegation of powers in respect of financial accountability as delegated to the Director General.

The Permanent Secretary shall advise the Minister on policy issues related to food, drugs, cosmetics and medical devises control and shall be responsible for the strategic management of TFDA. For this purpose the Permanent Secretary may give directions to the Director General but with due regard to the need to uphold the TFDA's autonomy in the day - to-day management of its affairs.

The MAB shall assist the Permanent Secretary with the view of TFDA's Strategic Plan and Business Plan and performance reports and in setting objectives and key for targets.

The Permanent Secretary shall be responsible for the discipline and control of the Director General.

The Permanent Secretary as the Principal Accounting Officer of the Ministry of Health may be required to appear before the Parliamentary Accounting Committee in response to TFDA's audit report.

5.3 *Responsibilities of Ministerial Advisory Board*

The Board shall give advise to the Permanent Secretary and Minister on the following:

(a) The development and maintenance of a strategic framework;

(b) The objectives of the Authority;

(c) The acceptability of the Authority's plans and associated budgets;

(d) The setting of priorities and annual performance targets for the Authority;

(e) The Authority's annual reports and accounts;

(f) The evaluation of the Authority's performance; and

(g) Any other matter provided for in the Executive Agencies Act of 1997 and the Tanzania Food, Drugs and Cosmetics Act, 2003.

5.4 *Responsibilities of Director General*

The Director General is accountable to the Permanent Secretary. He is responsible for managing the Authority within terms of this Framework Document and

the performance agreements with the Permanent Secretary. He is the Authority's Accounting Officer responsible for the day-to-day operations of the Authority, the proper management of its funds, property, business and personnel, according to approved rules and regulations.

The Director General is specifically responsible for:

(a) Preparation and submission of strategic plans, business plans and associated budget to the Permanent Secretary Ministry of Health;

(b) The implementation of approved strategies and business plans including achievement of performance targets;

(c) Ensuring that the relevant legislation on food, drugs cosmetics, medical devices and related products are well enforced.

(d) Ensuring that the requirements of the government's Executive Agency Regulations, other Government financial regulations and the Public Accounts Committee (PAC) recommendations are met.

(e) Organisation and management of the assets and resources allocated to him in an efficient and cost effective manner;

(f) Management, organization, control and discipline of the Authority's employees;

(g) Managing the procurement and control of supplies for the Authority;

(h) Ensuring that all aspects of the management and organization are kept under review and that they enable best possible performance of the Authority;

(i) Providing the Board and Permanent Secretary with information to enable best possible performance of the Authority.

(j) Coordination and collaboration with other institutions regarding the enforcement of relevant legislation

(k) Preparation of annual reports and audited financial statement for the submission to the parliament through the Permanent Secretary.

(l) Contributing to the development and formulation of policy and strategic plans for the health sector and ensuring that TFDA is in a position to implement changes expeditiously and efficiently;

(m) Promoting public confidence on the safety and quality of regulated products.

6.0 POWERS OF THE DIRECTOR GENERAL

6.1 *Personnel Management*

The powers of the Director General in relation to personnel management are prescribed in the Executive Agencies (Personnel Management) Regulations, 1999 and related amendments.

6.2 *Financial and Related Matters*

The powers of the Director General in relation to financial and related matters are prescribed in the Executive Agencies (Finance, Procurement and Stores) Regulation, 1999.

7.0 PUBLIC ACCOUNTS COMMITTEE AND PUBLIC ENQUIRIES

7.1 *The Public Accounts Committee*

The Director General may be required to appear before the Public Accounts Committee to represent at the hearing related to the Authority.

7.2 *Parliamentary and Other Inquiries*

The Director General shall be required to prepare responses to parliamentary questions and inquiries for the Permanent Secretary and the Minister.

8.0 FINANCE, PLANNING AND STRATEGIC CONTROL

8.1 *Funding, Expenditures and Accounting*

The Authority's resources requirement will be met from the revenue accrued from Government subventions as shown to be necessary in the Authority's Business Plan, loans, grants, sale of goods and services, fees, commissions, royalties and interest from deposit.

8.2 *Strategic and Business Plans*

TFDA's Director General shall prepare for approval by the Permanent Secretary, a Strategic Plan covering a period of three to five years and a Business Plan covering one year which gives details of operations.

8.3 *Strategic Plan*

The Director General shall prepare a strategic plan covering a period of not more than five years, which shall be updated every year.

G.N. No. 264 (contd.)

The strategic plan shall reflect the outcome of the review of performance and expenditure, and shall clearly set out:

- The Director General's strategies for achieving TFDA's aim and objectives;
- Strategic performance targets;
- An assessment of the internal and external factors which influence TFDA' s activities including key planning assumptions about the service to be provided and resources;
- A capital expenditure programme;
- Efficiency, objectives and business plans in terms of institutional capacity building and development of human resources.

8.4 *Business Plan*

The Director General, with the Management Team shall prepare, and submit to the Permanent Secretary for approval a Business Plan that includes the estimates of income and expenditure for the next ensuing year not later than four months before the next financial year.

The Business Plan will set out in more details, TFDA's activities for the year under review on the Strategic Plan period, and will include:

- Key performance targets set by the Permanent Secretary;
- Priorities and other performance targets;
- Budgets, including estimated profiles of revenue and expenditure;
- The work programmes;
- The key assumption, which include resources, which are likely to underpin performance targets; and
- Plans to improve performance with respect to value for money and quality of service to be delivered.

The Director General may at any time before the end of a financial year, prepare, and submit before the Board any supplementary to estimates of a current year.

8.5 *Approval*

The Director General shall submit the Strategic and Business Plans to the Permanent Secretary for approval each year. The Permanent Secretary or the Director General may seek to review the Business Plan in the course of the year to reflect changes in policies, resources or priorities.

8.6 *Annual Report and Accounts*

The Director General shall submit an Annual Report and Statement of Financial Accounts to the Board and upon approval and the Permanent Secretary after the end of each financial year. The reports shall contain:

- A copy of the audited accounts of TFDA, together with the Auditor's report on those accounts;
- A report on performance against key targets;
- A report on the operations of TFDA during that financial year; and
- Any other information as may be required by the Permanent Secretary.

The Annual Report will also contain the annual performance agreement between the Permanent Secretary and the Director General.

8.7 *Financial Regulations*

The Director General has the authority to approve all expenditure which is consistent with the approved Strategic and Business Plans and which is in accordance with the financial regulations of the Executive Agencies, Act, 1997.

The Director General shall ensure that appropriate investment appraisal of all capital expenditure projects is carried out, taking into account of such guidance as the Ministry of Finance or Civil Service Department may issue from time to time. Major capital expenditure divisions will be considered in the context of the approved Strategic and Business Plans.

TFDA will undertake post implementation reviews to determine whether projects have achieved objectives set up.

8.8 *Value for Money*

The Director General is responsible for obtaining value for money in the procurement of goods and delivery of services. Accordingly, the Director General will implement a range of efficiency measures in accordance with the agreed programme and timetable set out in the Strategic and Business Plans. The Director General is responsible for maintenance of standards and value for money of any work contracted out and ensuring that the security and confidentiality safeguards are maintained.

G.N. No. 264 (contd.)

8.9 *Internal Audit*

The Director General is responsible for ensuring that adequate arrangements exist for the provision of an internal audit service. The internal auditing shall be done in accordance with the standards set by the Ministry of Finance and TFDA's Accounting Manual.

8.10 *External Audit*

TFDA shall be subject to external audit by the Controller and Auditor General of the United Republic of Tanzania who has the right to conduct interim audits, special audits and value for money studies relating to TFDA activities.

8.11 *Budgetary Flexibilities*

The Director General shall have powers which shall be exercised in accordance with existing laws, regulations and guidelines pertaining to finance and procurement.

8.12 *Capital Expenditure*

The Director General shall have powers in relation with the capital expenditure to:

- Authorise capital expenditure on individual capital projects;
- Transfer of resources allocated to one item in the budget to another;
- Carry over in full to the next financial year any underspent on capital provision from the previous financial year.

8.13 *Running Costs*

The Director General shall:

- Manage all running costs allocations as a single budget;
- Transfer resources allocated to one item in the budget to another;
- Carry over in full to the next financial year any unspent money from the previous financial year.

8.14 *Assets and Liabilities*

The Director General may:

- In accordance with the existing laws, regulations and guidelines authorise all write - offs or special payments;

- Authorise the disposal of assets in accordance with standing financial regulations;
- Authorise expenditure on consultancy services;
- Authorise expenditure on any relevant approved projects;
- Authorise single source negotiated tender for procurements.

9.0 PERSONNEL

9.1 *Status and Conditions of Service*

TFDA staff are public servants, as such their terms and conditions of service will be governed by the Executive Agencies (Personnel Management) Regulations, 1999, as amended from time to time by the Ministry responsible for Civil Service and in accordance with the Executive Agencies Act, 1997.

9.2 *Personnel Management*

The Director General is responsible for the management of the personnel as set out in this Framework Document, the Executive Agencies Personnel Regulations, 1999, labour laws of Tanzania and may consult Trade Unions in that matter. He is responsible for ensuring that an equal opportunity policy is formulated and implemented. Within these parameters he may introduce such changes as are necessary to maximise the TFDA efficiency and effectiveness.

9.3 *Staff Complement*

The Director General shall be responsible to manage the affairs of the Authority efficiently and effectively. The end in that regard is to establish and keep up to date the TFDA's staff complement.

9.4 *Staff Relations*

The Director General is responsible for staff relations within the Authority. He is required to foster good relations as an important aid to the achievement of the Authority's objectives, and to ensure effective communications and consultation between the staff and with their recognised Trade Union representatives.

Permanent staff retain the right of appeal to the Permanent Secretary on personnel matters in the event of being dissatisfied by any decision made by the Director General.

G.N. No. 264 (contd.)

9.5 Health and Safety

The Director General is responsible for the health and safety of TFDA staff at their work place by complying with all relevant legislation and regulations. In this regard he shall consult the Trade Union representatives for negotiated agreement.

9.6 Freedoms and flexibilities

Delegation of authority and responsibility to a greater extent is the concept behind the formation of Executive Agencies. Most of the freedoms and flexibilities which TFDA requires are already provided under the Executive Agencies Act of 1997 and regulations made under the policy framework document, 1997.

10.0 AMENDMENTS, REVIEW AND PUBLICATION

10.1 *Proposed Amendments*

The Minister, Permanent Secretary, Board or the Director General may at any time propose amendments to this Framework Document in light of the Authority's operation experience or any change of circumstances. Any amendment shall be subject to consultations between the Ministry, the Board and the Director General and such changes of the Framework Document must be approved by the Chief Secretary before being effected by the Minister.

Any change affecting personnel shall be subject to consultation with staff and their recognised Trade Union Representatives. The incorporation of changes may require the approval of the Minister for Health, Ministry for Finance, the Minister responsible for the Civil Service as well as the approval of the Chief Secretary.

10.2 *Review of the Framework Document*

From time to time, but at intervals not exceeding five years review of the Framework Document shall be undertaken.

10.3 *Publications*

The Framework Document and any future amendments are public documents and shall be laid before the Parliament in accordance with the existing practice. Such approved documents shall also be made available to the public.

Copies of the Frame Work Document and further information about TFDA can be obtained from:

G.N. No. 264 (contd.)

The Director General,
Tanzania Food and Drugs Authority,
P. O. Box 77150,
DAR ES SALAAM.
Street Address: Adjacent to RTD -Mabibo or MSD office at Mabibo
Tel: 022 2450512
022 2450751
Fax: 022 2450793
Email: tfda@simbanet.net

Dar es Salaam
19th January, 2004

ANNA M. ABDALLAH,
Minister for Health

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THE EXECUTIVE AGENCIES ACT, 1997
(CAP. 245)

ORDER

Made under section 3 (1)

THE EXECUTIVE AGENCIES (THE TANZANIA FOOD AND DRUGS AUTHORITY (ESTABLISHEMENT AMENDMENT) ORDER, 2008;

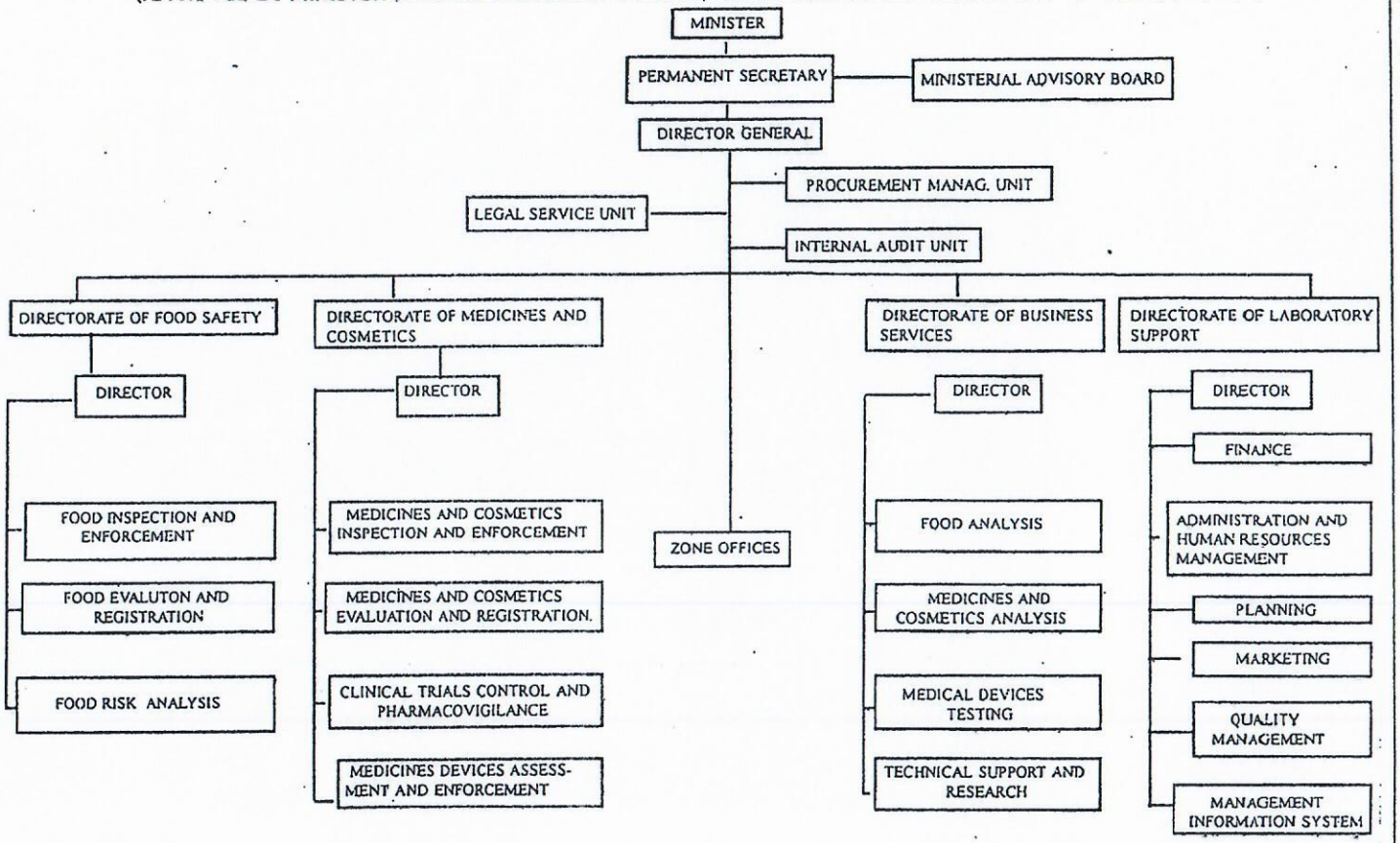
Citation and commencement. G.N. No. 264 of 2004

1. This Order may be cited as Excutive Agencies (The Tanzania Food And Drugs Authority (Establishment) Amendment Order, 2008. Shall be read together with the Executive Agencies (The Tanzania Food and Drugs Authority (Establishment) Order, 2004 hereinafter referred to as the "Principal Order" and shall be deemed to have come into operation on the 1st day of March, 2008.

Amendment of the schedule to the Principal Order.

2. This Principal Order is amended in paragraph 3.0 of the schedule by deleting the whole of ANNEX 1 relating to the organizational structure and substituting for it the following new organization structure attached to this Order as ANNEX 1.

ANNEX THE APPROVED FUNCTIONS AND ORGANISATION STRUCTURE OF TFDA
(APPROVED BY MINISTER OF STATE - PRESIDENT'S OFFICE, PUBLIC SERVICE MANAGEMENT ON 29TH JANUARY, 2008)



Dar es Salaam,
25th May, 2008.

DAVID H. MWAKYUSA,
Minister for Health and Social Welfare