G N. No.439

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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT, 2003

REGULATIONS

ARRANGEMENT OF REGULATIONS

SCHEDULE

FIRST SCHEDULE

CATEGORY "A"-Laboratory Services.

CATEGORY "B"-Other Services.

G N. No.439

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT, 2003

(No. 1 of 2003)

REGULATIONS

Made under section 122(1)(i)

THE FOOD, DRUGS AND COSMETICS (FEES AND CHARGES) REGULATIONS, 2005

Citation

1. These Regulations may be cited as the Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2005;

Application

2. These Regulations shall apply in all areas to which the Act applies and shall have effect on the date of publication in the *Gazette*;

Interpretation

3. In these Regulations unless the context otherwise requires-

"Act" means the Tanzania Food, Drugs and Cosmetics Act, 2003;

Act No. 1 of 2003

"alteration fee" means a fee paid by a registrant in relation to alteration to be made regarding product composition, formulation, packaging, labeling or any other changes relating to alteration made to a registered product;

"annual retention fee" means a fee paid by a registrant for the purpose of retaining a registered product in the register of the Authority;

"Authority" means Tanzania Food and Drugs Authority or its acronym "TFDA" established under section 4(1) of the Act;

"duplicate certificate" means a certificate issued to replace a certificate, permit or license, previously issued by the Authority;

"fees" includes any charge made or levied in connection with but not limited to services rendered by the Authority;

"FoB" means Free on Board value of regulated product(s) to be imported into Tanzania mainland;

"Good Manufacturing Practices (GMP)" means practices prescribed by the Authority for manufacture of products to ensure that such products are of good quality, safe and effective for the intended use;

"manufacturing" means all operations involved in the product preparation,processing,compounding,formulating,filling,refining,transformation,parcking and labeling of product regulated under the Act;

"manufacturer" means person or firm that is engaged in the manufacture of a product regulated under the Act;

"large scale enterprise" means an enterprise with capital investment exceeding eight hundred million shillings;

"Local Authority" means and includes City Council, Municipal Council, Town Council or District Council;

"medical representative" means a person representing a drug or medical devices manufacturer in Tanzania mainland for the purpose of marketing such company's product(s).

"medium scale enterprise" means an enterprise with capital investment of not less than two hundred million but not exceeding 800 million shillings;

"micro scale " means an enterprise with capital investment of not exceeding five million shillings;

"new medicine" means a medicine whose chemical moiety is new, or little documented or in a new formulation with a new route of administration or with a new indication;

"old medicine" means a medicine whose chemical moiety is subject to pharmacopoeia documentation and its pharmacological actions are known and well documented;

"pre-licensing or registration inspection" means inspection carried out on premises to verify compliance with set requirements prior to granting of a license or permit or registration certificate;

"product carrier" means any box, detachable compartment, tank or container, receptacle or any other arrangement in which a product may be carried in

"product dealer" means a product manufacturer, packer, importer, exporter, distributor, seller or any other dealer in any product business to which the Act applies;

"regulated products" means food, drugs, cosmetics, herbal drugs, medical devices or related products as prescribed in the Act;

"registrant" means any person who under his own name or under a trade, design or word mark, trade name or other name work or mark controlled by him intends *to sell or sells* food, drugs, cosmetics and medical devices and includes a firm, partnership or corporation;

"registration certificate" means a certificate issued by the Authority in respect of a registered product or premises;

"restoration fee" means fees paid for restoration of a license or permit or registration certificate suspended by the Authority; and

"small scale enterprises" means an enterprise with capital investment exceeding five million shillings but less than two hundred million shillings.

Restriction on conducting business without paying fees and dues

4. - (1) No person shall carry on any business related to products regulated under the Act unless he has paid the necessary fees prescribed under these Regulations.

(2) Any person found operating a business using an expired permit, certificate or license previously issued by the Authority thirty days after its expiry date, shall be required to pay in addition to the due fees or charges a penalty of 25%. Such

penalty also applies to delayed payment of any due fees or charges covered under these regulations. Such person shall be required to meet other requirements prescribed by the Authority for such a business.

Fees to be paid by product dealers

5. -(1) The fees shown in the *Schedule* to these Regulations shall be paid by a product dealer in connection with the following matters:-

(a) Laboratory sample analysis;
(b) Product evaluation and registration;
(c) Pre registration GMP inspection;
(d) Annual medical representative permits;
(e) Certification of export;
(f) Annual dealers license/permit;
(g) Approval of product advertisement;
(h) Annual retention for registered products;
(i) Product alteration;
(j) Duplicate certificate, permit or license;
(k) Restoration of licenses, certificates or permit;
(l) Trade fair permit; and
(m) Laboratory training fees.

(2) All laboratory tests shall not be charged any overhead expenses in addition to the cost of tests carried on.

Training and consultancy services

6(1) Consultancy and Expert Services offered by the Authority shall be charged US$ 250 per Man-day. Reimbursable expenses and traveling & accommodation expenses shall be charged as per the actual expenses incurred.

(2) Training of any person other than Tanzanian student at TFDA shall be charged a fee as provided under the schedule to these regulations.

Duty to collect fee

7.-(1) Fees paid under these Regulations shall be collected and appropriated by the Authority;

(2) Notwithstanding the provision of sub-regulation (1) of this regulation the Authority shall devise a safe and good method of fees collection and may delegate the duty of fees collection to any Local Authority or any agent in whose area the business in respect of which the fees is paid operates.

(3). Fees paid under these Regulations shall be paid in Tanzania shillings, U$ or its equivalence in convertible currency.

Fees and charges not refundable nor transferable

8. All fees payable under these regulations are neither refundable nor transferable.

Offence

9. Any person who contravenes or fails to comply with these regulations or directly or indirectly aid any other person to commit an offence under these regulations shall be guilty of an offence;

Penalty

10. Any person found guilty of an offence under these regulations shall be liable on conviction to the penalty prescribed by the Act;

Revocation of GN No 394 of 1984 and GN No 363 of 1990

11. The Food (Control of Quality) (Fees and Charges Regulations of 1984 and the Pharmaceuticals and Poisons Regulations of 1990 which relate to fees and charges are hereby revoked.

SCHEDULE

TFDA SERVICE CHARGES

CATEGORY A: LABORATORY SERVICES

S/n	Product Types	Parameters to be tested	Cost (US $)
1	**Drugs and cosmetics - all dosage forms**	All parameters	300
2	**Food products**		
2.1	**Cereal, cereal products, food and pulses**		
		Physical Test	
		Visual Appearance	2
		Insect damage	2
		Heat damaged grains	2
		Coloured grains	2
		Discoloured grains	2
		Immature or shriveled grains	2
		Foreign matter	2
		Chalky grain	2
		Paddy grain	2
		Other tests	
		Glutein	5
		Sieve test	5
		Moisture	10
		Ash	15
		Acidity	10
		Solubility	5
		Microbiology	50
		Protein	25
		Presence of sodium chloride	25
		Potassium Bromate	25

		Pesticide residues	45
		Total carbohydrates	10
		Acid insoluble ash	25
		Urease Activity	10
		Per Vitamins	25
		Starch content	10
		Microscopic	10
		Fibre	25
		Atropine level	20
		Aflatoxin	50
		Glycosidic Cyanide	20
		Talc	15
2.2	**Non-alcoholic beverages**		
		Physical	2
		Acidity	10
		Sugar	5
		Preservatives	20
		Sweeteners	20
		Microbiology	50
		Carbon dioxide	10
		Food colour	10
		pH	5
		Metals - each by AASS	20
		Alcohol	14
		Total Solids	7
2.3	**Fermented products**		
		Total Acidity	10
		pH	5
		Fixed Acidity	10
		Volatile Acidity	10
		Total Solids	7
		Reducing Sugar	10
		Tannin	10
		Free Sulphur	10
		Specific Gravity	7
		Metals-each by AAS	20
		Ash Content	10
		Carbon Dioxide	10

		Alcohol	14
		Higher Alcohols	20
		Preservative quantification	20
		Non Sugar Solids	5
		Methanol (presence of)	20
		Microbiological	50
		Sugar Content	10
		Starch content	10
2.4	**Diary and Diary products**		
		Physical	2
		Moisture	7
		Milk fat	15
		Curd	15
		pH	5
		Specific Gravity	7
		Acidity	10
		Solubility	5
		Titrable Acidity	5
		Milk Solids	7
		Ash	10
		Lactose	10
		Microbiology	50
		Butter Salt	15
		Titrable acidity	10
		Metals-each by AAS	20
		Protein	25
		Casein in milk	15
		Antibiotic in milk	45
		Pesticide Residues	45
		Total Solids	5
		Solids and non fats	10
		Aflatoxin	30
		Albumin in milk	20
		Phosphate tests	15
		Colour additives	25
		Freezing point	5
		Sugar in milk	30
		Refractive index	7

		Fatty Acid Profile	45
2.5	**Sugar and Honey**		
		Physical	2
		Moisture	7
		Moisture under vacuum	10
		pH	5
		Polarization	10
		Reducing sugar	15
		Sulphur dioxide	15
		Colour in icumssa	15
		Total Ash	10
		Conductivity Ash	10
		Metals (each)	20
		HMF	25
		Diastase activity	20
		Water insoluble matter	10
		Total nitrogen	25
		Proline	20
		Free acidity	10
		Sucrose	15
		Lactose	15
		Antibiotic Residues	45
		Pesticide Residues	45
		Dextrose	15
2.6	**Edible Common Salts**		
		Physical	2
		Moisture	7
		pH	5
		Water Insoluble Matter	10
		Matter Insoluble in Acid	10
		Chlorides	10
		Metals-each by AAS or FP	20
		Sulphates	10
		Alkalinity	10
		Fluorides	15
		Iodine	15
2.7	**Fats and Oils**		
		Matter (volatile at 105C)	7

		Insoluble impurities	10
		Soap	5
		Metals (each) by AAS or FP	20
		Refractive index	7
		Relative density	7
		Saponification value	10
		Iodine value	15
		Free fatty acid	7
		Unsaponifiable matters	20
		Arachidic acid	10
		Melting point	5
		Clarity	3
		Halphen	5
		Hex bromide	5
		Poly bromide	5
		salt (as NaCL)	20
		Peroxide	7
		Colour by Tintometer	5
		Oil identification by GC	40
		Bandoin	5
		Bromine	5
		Chlorides	10
		Gossypol in	15
		Fatty Acid Profile by GC	45
		Starch	10
2.8	**Tea, Coffee, Cocoa**		
		Physical	2
		pH	5
		Alkalinity of insoluble matter	20
		Microscopic	5
		Starch	10
		Sugars	10
		Fats	15
		Water soluble Ash	20
		Moisture	10
		Volatile oils	10
		Non volatile oils	10

		Acid insoluble Ash	20
		Calcium	20
		Extraneous matter	2
		Total Ash	10
		Crude Fibre	15
		Metals (each)	20
		Melting point of fats	5
		Microbiology	50
		Alcohol extract	15
		Water extract	10
		Salt (NaCl)	20
		Caffeine	20
		Aflatoxin	30
2.9	**Fish and Fish Products**		
		Physical	2
		Total volatile bases	20
		Trim ethylamine	20
		Indole	20
		Histamine	20
		Preservatives	15
		Pesticides residues	45
		Microbiology	50
		Metals (each)	20
		Protein	25
		Ash	10
		Volatile fatty acid	25
		Fat content	15
		Salts	20
		Hypoxanthine	20
		Boric Acid	20
		Ammonia in Crabs	25
	Pesticide Residues	(i) Lassaigne	20
		(ii) FTIR/IR	25
2.10	**Meat and Meat Products**		
		Physical	2
		Protein	25
		Moisture content	7
		Total Volatile bases	20

		Thiobarbituric acid	20
		Free fatty acid	15
		Peroxide value	15
		Benzoic acid	10
		Colour additives	20
		Metals (each) by AAS or FP	20
		Ash	10
		Phosphorus in meat	20
		Hydroxyproline	15
		Nitrates and nitrites	15
		Microbiology	50
		Carbohydrates	25
		Starch	15
		Fats	15
		Pesticide Residues	45
		Antibiotic Residues	45
		Precipitin	30
		Lean Meat	30

CATEGORY B: OTHER SERVICES

1. Medicines

a. Evaluation of medicines

i. Evaluation of old medicine from local manufacturing company U$ 350
ii. Evaluation of new medicine from local manufacturing company U$ 530
iii. Evaluation of old medicine from foreign manufacturing company US$ 750
iv. Evaluation of new medicine from foreign manufacturing company US$ 1000

b. Retention fees for registered pharmaceutical products per annum

i. Local products U$ 45
ii. Imported products US$100

c. Inspection, surveillance and administrative costs for imported pharmaceutical products **2% FoB** value for each consignment as per Import Declaration Form (IDF)

2. Food

a. Imported pre-packaged food

i. Evaluation and registration fees per product for three years US$ 50
ii. Laboratory fee as per parameters specified in the food standard for that product
iii. Cost for inspection, surveillance and administrative costs 0.50% FOB value for each imported consignment

b. Locally manufactured products

i. Evaluation and registration fees per product for three years U$ 30
ii. Laboratory fee as per parameters specified in the food standard for that product

3. Cosmetics

a. Imported Cosmetics

i. Evaluation and registration per product for three years US$ 75
ii. Cost for surveillance and administrative 1% FOB value for each imported consignment as per Import Declaration Form (IDF)

b. Locally manufactured cosmetics

i. Evaluation and registration fees per product for three years U$ 45
ii. Laboratory fee as per parameters specified in the standard for that cosmetic

4. Medical devices

a. Imported

i. Evaluation and registration per product for 5 years US$ 500
ii. Inspection, surveillance and administrative costs 1% FoB value per imported consignment as per import declaration form (IDF)

b. Locally manufactured

i. Evaluation and registration per product for 5 years U$ 90

5. Pre registration GMP inspection fees for each manufacturing site

a. African countries: US $ 3,000
b. Abroad:

i. Far East US $ 3,500
ii. Asia/India US $ 3,500
iii. Europe US $ 4,000
iv. USA US $ 4,500

6. Annual dealers license/permit

a. Distributors (Tanzania shillings)

Firm category	**Capital Investment**	**Pharmaceutical**	**Food**	**Cosmetics**
Micro	Up to 5 mil	20,000	10,000	20,000
Small	Above 5 mill-200mill	30,000	20,000	30,000
Medium	Above 200 mill-800mill	50,000	40,000	50,000
Large	Above 800mill	100,000	75,000	100,000

b. Manufacturers (Tanzania shillings)

Firm category	**Capital Investment**	Pharmaceutical	**Food**	**Cosmetics**
Small	Above 5 mill-200mill	60,000	30,000	60,000
Medium	Above 200 mill-800mill	175,000	125,000	175,000
Large	Above 800mill	250,000	250,000	250,000

7. Annual medical representative

a. Foreign medical representative US $ 100
b. Local medical representative Tanzania Shillings, 50,000/-

8. Evaluation of product promotional material per advert Tanzania shillings, 30,000/-

9. Evaluation of registered product alteration information

a. Local product Tanzania shillings 10,000/-
b. Foreign product US$ 30

10. Export certificate Tanzania shillings 10,000/- for each certificate

Evaluation and registration of medicines and medical devices for clinical trials 50% of the product evaluation fee

11. Duplicate certificate US$ 10

12. License/permit restoration fee: 25% of the respective License or permit fee

13. Training in the TFDA laboratory is charged at Tanzania shillings 40,000/- per day for residents and US$ 50 per day for non-residents and free for Tanzanian students

14. Trade fair permit US $ 20

Dar es Salaam
October 2005

Anna M. Abdallah (MP)
Minister for Health