



**REGULATIONS GOVERNING CONTROL OF ETHYL ALCOHOL FOR
INDUSTRIAL, MEDICAL, LABORATORY AND COSMETIC USE IN RWANDA**

(Rwanda FDA Law N° 003/2018 of 09/02/2018, Article 9)



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ADOPTION AND APPROVAL OF THE REGULATIONS

In exercise of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby adopts these regulations No.: [QMS No] Version_.....Governing Control of Ethyl Alcohol for Industrial, Medical, Laboratory and Cosmetic Use in Rwanda.

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Director General



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CHAPTER I GENERAL PROVISIONS

Article 1: PURPOSE OF THE REGULATIONS

These Regulations enforce the legal framework for the control of the manufacturing, importation, exportation, distribution, storage, denaturation, of Ethyl Alcohol for industrial, medical, laboratory, cosmetic use.

Article 2: SCOPE

These Regulations apply to all manufacturers, importers, exporters, distributors, retailers, wholesalers, and alcohol denaturation service providers of ethyl alcohol involved in industrial, medical, laboratory and cosmetic use within the territory of the Republic of Rwanda.

The provisions herein cover ethyl alcohol intended for industrial applications, including but not limited to the manufacture of alcoholic beverages, food ingredients, household and industrial chemical products, as well as ethyl alcohol used in cosmetic formulations, pharmaceutical preparations, medical and laboratory applications, and any other sector where ethyl alcohol is utilized as a raw material, processing aid, or finished product component.

Article 3: CITATION

These Regulations are cited as the “Regulations **XX/XXX/XXX/001 REV-0**, Governing Control of Ethyl Alcohol for Industrial, Medical, Laboratory and Cosmetic Use in Rwanda”.

Article 4: DEFINITIONS

“**Applicant**” means any person or legal entity established within Rwanda, seeking to obtain or having obtained the authorization to manufacture, store, distribute, wholesale, retail ethyl alcohol intended for industrial, medical, laboratory, cosmetic and pharmaceutical use.

“**Approval**” means official written consent by the Authority as an acceptance of a product, a practice, or a license of processed food and related products or practices related to that in the Rwandan market.

“**Authority**” means the Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established by Law N° 003/2018 of 09/02/2018.

“**Authorization**” means a legal document granted by Rwanda FDA to an applicant under the Law No 003/2018 of 09/02/2018, it includes licenses, permits, and certificates.

“**Authorized person**” is an individual recognized by the authority as having the necessary basic scientific and technical background and experience to conduct or oversee a certain task.

“**Batch** (or lot)” means a total quantity of goods produced at one time.



“**Batch number** or (**lot number**)” means a distinctive combination of numbers and/or letters which uniquely identifies a batch.

“**Consignment**” means a quantity of goods that are sent to a consignee or a place covered by a single transport documents on a single customs’ document.

“**Container**” means the material employed in the packaging of ethyl alcohol and other raw materials. Containers include primary, secondary and tertiary containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary packaging encloses the primary packaging and tertiary packaging material means an outer carton in which multiples of saleable units are packed. Secondary and tertiary containers are not intended to be in direct contact with the product.

“**Corrective and preventative actions or its acronym “CAPA”**” means a system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.

“**Falsified**” means an imitation of ethyl alcohol with an intention to deceive or to defraud. Counterfeit products may include products that is deliberately and fraudulently mislabelled, products with the wrong ingredients, with an incorrect quantity of ingredients or with misleading or fraudulent packaging.

“**Unapproved ethyl alcohol**” means ethyl alcohol that has not been duly authorized for use by Rwanda FDA in accordance with applicable laws and regulatory requirements, including ethyl alcohol that is manufactured, imported, stored, distributed, marketed, supplied, sold or otherwise handled without a valid and corresponding license issued by the Authority, produced or handled in closed, unlicensed or otherwise unauthorized facilities, subject to quarantine, seizure or not formally released by the Authority, operated under conditions that differ from those approved in the relevant license without prior notification to and approval by the Authority, imported without a valid import license or marketed or used after importation without proof of physical inspection by the Authority, transported without proper required documentation, diverted or used for purposes other than those expressly authorized.

“**Substandard ethyl alcohol**” means ethyl alcohol that do not comply with established provisions of ethyl alcohol legislation such as Laws, Regulations, Guidelines, Standards, Instructions. misrepresented through false, misleading or inaccurate labelling, certification or declarations, or failing to comply with applicable quality, safety or specification standards established by the Authority.

“**Denatured Ethyl alcohol**” Ethyl Alcohol to which denaturants have been added in order to render it unsuitable for human consumption.

“**Distribution**” means the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products regulated by the Authority.



“**Distributor**” means an organization or an entity, such as a wholesaler that distributes the ethyl alcohol to market. They serve as an intermediary in the manufacturer’s supply chain, promoting and selling the products to wholesalers or other entities, excluding the end consumer.

“**Business Operator**” means a person, or company who undertakes, whether for profit or not, any activities related to manufacturing, distribution, storing, exhibit, wholesale or retail activities of ethyl alcohol.

“**Labelling**” means the process of identifying a product including the following information, as appropriate: name of the product. active ingredient(s), type and amount. batch number. expiry date (when applicable). storage conditions or handling precautions. directions for use, warnings. names and addresses of the manufacturer.

“**Licensed person**” means a manufacturer, denaturer, distributor, retailer, wholesaler, importer or exporter of ethyl alcohol with a valid license issued by the Authority.

“**Manufacturer**” means a company that carries out at least one step of manufacturing process and any other step that would be determined by the Authority.

“**Medical product**” includes human and veterinary drug, human and animal vaccines and other biological products used in clinical as drug, herbal medicines and human and veterinary medical devices.

“**Owner of premises**” means a person authorized to deal in the business of storage, transport and distribution of ethyl alcohol.

“**Person**”: for the purposes of these regulations means an individual, a trust, estate, partnership, association, company, or corporation. the estate of a deceased individual, a government or a body that is a society, a union, a club, an association, a commission or another organization of any kind.

“**Premises**” means any plot of land, buildings or boats, aircraft, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed. intended for manufacturing, storing, exhibit, wholesale or retail activities of specific products.

“**Production**”, means all operations involved in the preparation of ethyl alcohol, from receipt of materials, through processing, packaging and repackaging, labelling and labelling, to completion of intended finished product.

“**Quarantine**” means the status of products isolated physically or by other effective means while a decision is waited on their release, rejection or reprocessing.

“**Raw material**” means any basic ingredients or substance which is intended for use in the production of processed food product.



Ethyl alcohol related products

“Substantial modification” means a change to the premises, equipment, personnel, procedures, and processes that is likely to have a significant impact and affect the quality, safety and the integrity of the products manufactured, stored, distributed, and used.

“Suspension of a license” means a temporary cessation of the license issued to the manufacturer, storage facility, distributor, wholesaler, or retailer of ethyl alcohol due to violation of conditions of issue.

“Evade” means the act of avoiding interaction with an inspector to prevent or delay an inspection to take place, including but not limited to providing repetitive excuses for why an inspection cannot take place at a particular time, closing the entire facility temporarily, not responding to calls or notifications, or misleading the inspector about the location of operations.

“Obstruction” means the deliberate act of hindering, interfering with, or preventing an ongoing inspection including but not limited to refusing access to certain sections of the premises, hiding evidence, or providing falsified record, threatening the inspector, or tampering with samples they require for analysis.

“Wholesaler” is an entity that is authorized to carry on the business of selling ethyl alcohol in large quantities to other authorized sellers with the exception of dispensing or providing ethyl alcohol directly to the consumer.

“Withdrawal of a license” means termination of a license issued to the manufacturer, storage facility, distributor, wholesaler, or retailer of ethyl alcohol due to violation of conditions of issue.

“Traceability” means the ability to follow the movement of a given product through specified stage(s) of production, processing and distribution.

“Transit” means the period during which products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

“Transporter” means a person who transports products from one point to another within the supply chain.

In these Regulations, the following verbal forms are used:

“Shall” indicates a requirement.

“Should” indicates a recommendation.

“May” indicates a permission. and

“Can” indicates a possibility or a capability

“Vehicle” means any transportation device, aircraft or other conveyance designed to be driven or drawn by any means including muscular power, and any part thereof, and includes any equipment necessary for the proper operation of the vehicle and any appurtenances of the vehicle.



CHAPTER II: LICENSING AND INSPECTION

Article 5: Obligations of a licensed person

1. No person shall import, export, manufacture by any means, sell, purchase, transport, distribute, store, purify, denature or repack ethyl alcohol without a corresponding valid license issued by the Rwanda FDA upon fulfilling all the requirements detailed in applicable guidelines.
2. A manufacturer, a distributor or an importer shall not sell ethyl alcohol to a person unless the buyer provides a valid license issued by a competent authority regulating the activity for which ethyl alcohol is being purchased.
3. Rwanda FDA may at any moment conduct announced or unannounced inspections at ethyl alcohol manufacturing plants, storage facilities, or distribution points.
4. The inspectee shall at all times grant unrestricted access to Rwanda FDA to all the parts of the inspected premises.

Article 6: General premises requirements

A licensed person shall at all times ensure premises are suitable for the business being conducted and adequate for preserving the quality and safety of the ethyl alcohol and ensure prevention of any consequences on the surrounding environment. The premises suitability requirements shall be detailed in applicable guidelines.

Article 7: Application for license to manufacture

1. Where a person makes application for license to manufacture ethyl alcohol, the application shall be in the approved form, accompanied by the documents that are required by Rwanda FDA in applicable guidelines .
2. For the purposes of these regulations, the manufacturing license fee for an ethyl alcohol manufacturer shall be prescribed by applicable regulations (tariffs and fees).

Article 8: Denaturing Ethyl alcohol

1. Ethyl alcohol not intended to be used in the food industry shall be denatured.
2. Any other use that requires a non-denatured ethyl alcohol shall be approved by Rwanda FDA.
3. Ethyl alcohol not intended to be used in the pharmaceutical and food industry shall be denatured in accordance with formulas prescribed in the applicable guidelines.
4. A person who intends to denature ethyl alcohol must first apply for the license to denature ethyl alcohol and obtain written authorization upon fulfilling all the requirements set forth in applicable guidelines.



5. No person shall use denatured ethyl alcohol in the manufacture of other products except when justified and approved by Rwanda FDA.

Article 9: Display of Licenses

A copy of the license issued under these regulations shall be kept available and displayed in a visible place for inspection purposes in the licensed premises.

Article 10: Changes affecting a license

When a licensed person wishes to implement a change relating to any of the information contained in the application for the license to import, export, manufacture by any means, sell, purchase, transport, distribute, store, purify, denature or repack ethyl alcohol, the licensed person shall, at least within 30 calendar days prior to implement the change, file a written notice of the change addressed to Rwanda FDA, explaining the nature of the change using the appropriate form annexed in the applicable guidelines and obtain a written authorization by Rwanda FDA.

Article 11: Safety monitoring

1. For the purposes of safety monitoring and market surveillance, Rwanda FDA may enter any premises where operations related to ethyl alcohol are carried out at any time and may examine materials, equipment, processes, records and facilities, and make any gauges and inventories.
2. The inspector may seize or quarantine ethyl alcohol and/or related products suspected of non-compliance, pending further investigation or laboratory test results.
3. The owner of the premises is required to provide to the mandated officials full and timely access to the inspected facilities in order to effectively conduct the inspection. In cases where Rwanda FDA utilizes control measures such as temporary closure, license suspension/revocation or any other means to effectively minimize the propagation of suspected substandard ethyl alcohol, the owner of the premises must obtain a written approval from Rwanda FDA prior to re-opening the premises and/or resuming the operations.

Article 12: Sampling for safety monitoring

An inspector is authorized to take samples of ethyl alcohol and related products, or other materials for analysis, testing, or to determine whether the product complies with law, regulations and standards.



Article 13: Obligation to provide a remote view of the premises

1. A licensed person shall install systems to enable a remote view of production processes in the licensed premises to facilitate remote control and monitoring.
2. Rwanda FDA shall prescribe, in applicable guidelines, the specifications of the systems required for remote viewing of the premises specified under these regulations.
3. For the purposes of these regulations, the licensed person shall grant Rwanda FDA unrestricted access to the remote viewing system by the Authority.

Article 14: Storage, transportation and delivery of ethyl alcohol

1. All ethyl alcohol shall, after the process of manufacture, denaturing or importation has been completed, be immediately stored in dedicated and restricted area. The suitable restriction methods shall be detailed in applicable guidelines.
2. The transported ethyl alcohol shall fulfill labelling requirements described in these regulations.
3. The transporter shall at all times have documents indicating the quantity, origin and destination of transported ethyl alcohol. The transportation supporting documentation shall be detailed in applicable guidelines.
4. The transporter shall be predisposed to grant unrestricted access to the transported consignment during a mobile inspection activity.

Article 15: Suspension/ Revocation and Termination of licenses

1. Upon Suspension or revocation of a license, the person with a suspended or revoked license shall immediately cease all activities related to the suspended/ revoked license.
2. Rwanda FDA may, for safety purposes, require the licensed manufacturer to remove the condemned ethyl alcohol from the premises to another place approved by the Authority.
3. Rwanda FDA shall, for safety purposes engage law enforcement agencies and/or security organs, local authorities to control the Storage, transportation and delivery of ethyl alcohol.
4. Licenses issued under these regulations shall not be transferable from a user to another or from one product to a different product.
5. In the event of business lease, sale, or other transfer of the licensed operations, the license shall, except officially notified in writing by Rwanda FDA, automatically be terminated.

Article 16: Discontinuation of a license

1. When a person permanently discontinues business, the person shall notify Rwanda FDA within 30 calendar days, and a written notice shall be given to the applicant within 30 calendar days to cover the discontinuation.



2. The discontinuation notice shall define applicable measures to ensure that the closed business does not harm public health.

Article 17: Disposal of non-complying products

1. Rwanda FDA may dispose of any ethyl alcohol or related products that is found to be not complying with quality and safety parameters described in relevant laws, regulations and standards.
2. A person intending to dispose of non-complying ethyl alcohol and related products shall apply for a written authorization from Rwanda FDA and the disposal shall be carried out under supervision of an official mandated by the Authority.

Article 18: Labelling requirements

1. Except otherwise provided, the immediate container of ethyl alcohol or related products shall be labelled in accordance with applicable guidelines.
2. The label of ethyl alcohol and related products shall be in one of the official languages used in Rwanda.

CHAPTER III: IMPORTS AND EXPORTS OF ETHYL ALCOHOL

Article 19: General requirements for importation of ethyl alcohol

1. All importers or exporters of ethyl alcohol whether denatured or undenatured must comply with eligibility requirements detailed in applicable guidelines.
2. Ethyl alcohol whether denatured or undenatured to be imported in Rwanda for industrial purposes either in food, medical and pharmaceutical, cosmetic or as a laboratory chemical or for any other purpose shall be authorized/ approved by the Authority.

Article 20: Importation of Ethyl alcohol

All persons who intend to import ethyl alcohol must comply with the following:

1. Every ethyl alcohol importer is required to apply for import license from Rwanda FDA for each consignment to be imported.
2. Importers/ exporters shall notify Rwanda FDA upon arrival of imported/ exported ethyl alcohol at point of entry/ exit for physical inspection.



3. Importers shall submit a distribution/ usage report of previously imported ethyl alcohol before applying for the next importation. The content and format of the report is specified in applicable guidelines.
4. Ethyl alcohol to be used as raw material shall be registered prior importation.

Article 21: Special importation circumstances

Under special circumstances, including but not limited to ethyl alcohol for use in public health emergencies, Rwanda FDA shall determine the alternative modalities for importation.

Article 22: Approved points of entry/ exit

Ethyl alcohol shall be imported or exported only through officially approved or gazetted points of entry/ exit.

Article 23: Physical Inspection, Sampling and Laboratory Testing

1. Ethyl alcohol consignments shall be subject to physical inspection by Rwanda FDA upon arrival at the officially approved or gazetted points of entry/ exit or any other licensed premises.
2. Rwanda FDA may take a sample of any imported ethyl alcohol during inspection and conduct laboratory testing to assess compliance with applicable regulatory requirements.
3. Rwanda FDA may apply a risk-based inspection model, where the frequency and intensity of inspection are determined based on the modalities described in the applicable guidelines

Article 24: Handling of inspected Ethyl alcohol

- 1) Rwanda FDA shall release the ethyl alcohol consignment upon complying with the applicable regulatory requirements specified in applicable guidelines.
- 2) Rwanda FDA may seize or quarantine any consignment of ethyl alcohol suspected of non-compliance, pending further investigation.
- 3) Ethyl alcohol found to be non-compliant with regulatory requirements shall be rejected and disposed of or returned to the country of origin within a period of 45 calendar days from the date of rejection. The cost related to this exercise shall be paid by the importer.
- 4) When suspected poor quality, Rwanda FDA shall seize or quarantine ethyl alcohol or close premises or any other item in relation with the suspected substandard ethyl alcohol.



CHAPTER IV: FINAL PROVISIONS

Article 25: Records keeping

1. Any person who manufactures, receives, distributes, packages, stores, disposes of, denatures or uses ethyl alcohol, shall keep relevant records which will enable inspectors to verify and trace the origin of and/or track the distribution channels of the ethyl alcohol.
2. Each retailer, distributor, wholesaler, manufacturer shall meticulously maintain separate records of ethyl alcohol and all the other products, whether received, packaged, destroyed, lost, transferred to another licensed user or any other relevant record for a timeline specified in applicable guidelines.
3. Separate records shall be maintained for denatured ethyl alcohol if the premises are licensed to handle both denatured and undenatured ethyl alcohol.
4. When requested by the Authority, the business operator shall submit the required records mentioned in clause (2 of this article) and failure to do so will be interpreted as a form of evading inspection and may result in suspension or revocation of a license in addition to other applicable sanctions.

Article 26: Prohibitions

1. For the purposes of public health protection, ethyl alcohol that does not meet regulatory requirements, is prohibited from being manufactured, exhibited and/or promoted, imported, sold, distributed, donated, used as raw material.
2. Undiluted ethyl alcohol or ethyl alcohol diluted to the levels exceeding 45% of alcohol by volume shall be considered not suitable for direct human consumption, in accordance with the “*Law N°03/2012 of 15/02/2012 Governing Narcotic Drugs, Psychotropic Substances and Precursors in Rwanda*”.

Article 27: Withdrawal or suspension of licenses

Rwanda FDA shall suspend or withdraw an operational license, an import/ export license or any other issued authorization if the licensed business operator violates the conditions under which the license was granted or has ceased to be fit to carry out the business. The conditions under which the license may be suspended or withdrawn are detailed in Annex A of these regulations.

Article 28: Reinstatement

A premises whose license is withdrawn may be reinstated after three (3) years from the day the withdrawal was issued. The conditions of reinstatement shall be detailed in the applicable guidelines.

Article 29: Appeals and Review

- 1) An authorization holder or applicant may within fifteen (15) days after receiving the regulatory decision, notify Rwanda FDA of his/ her grounds when he/ she objects regulatory decision in writing.



- 2) Rwanda FDA shall, within thirty (30) working days from the date of receiving the written appeal review it and inform the final regulatory decision.
- 3) If a person is dissatisfied with a decision after review, he/ she may appeal to the supervising Authority of Rwanda FDA whose decision shall be final.

Article 30: Power to issue guidelines

Rwanda FDA shall issue guidelines, and forms necessary for the implementation of these regulations.

Article 31: Penal Offences

Should the offences of these regulations result in death, temporary or permanent disability, serious injury, foodborne disease outbreak or otherwise deemed criminal, penal proceedings shall override administrative sanctions as per the Law N°059/2023 of 04/12/2023 amending Law N° 68/2018 of 30/08/2018 determining offences and penalties in general.

Article 32: Repealing

All prior provisions on ethyl alcohol contrary to these Regulations are hereby repealed.

Article 33: Commencement

These regulations shall come into force on the date of publication.

Article 34: Transitional provisions

Any person who was licensed prior to the coming into effect of these Regulations shall comply with any additional requirements under these Regulations within a period of one year from the date of commencement of these regulations.



ANNEX A: FAULTS AND ADMINISTRATIVE SANCTIONS

S/N	FAULT/ OFFENCE	ADMINISTRATIVE SANCTION
1.	Unapproved manufacturing, denaturing, importation/exportation, sale, storage and distribution of ethyl alcohol.	First-time violation, - Warning letter to the Business Operator, and - Administrative Fines: Triple the value of the condemned products plus charges for disposal (when disposal is compulsory) For subsequent violations, - Revocation of all Rwanda FDA authorizations, and - Administrative Fines: Five times the value of the condemned products plus charges for disposal (when disposal is compulsory)
2.	Manufacturing, denaturing, importation/exportation, sale, storage or distribution of substandard, unsafe, falsified of ethyl alcohol.	- Withdrawal of all Rwanda FDA authorizations related to the business of ethyl alcohol, and - Administrative Fines: Seven times the value of the condemned products plus charges for disposal (when disposal is compulsory).
3.	Violation of closure/ quarantine: Unauthorized opening of premises closed by the Authority, and / or unauthorized resuming of any activity previously suspended by the authority.	Administrative fines on condemned products : Ten times the value of the quarantined products plus Administrative Fines for violation of closure: 50,000,000 FRW.
4.	Operating in the absence of qualified personnel/ responsible technical person in an authorized facility dealing with ethyl alcohol.	- Administrative Fines: 1,000,000 FRW. For subsequent violations, - Administrative Fines: 5,000,000 FRW plus 6 months suspension of the premise license
5.	Operating with an expired Ethyl alcohol Operational License.	- Administrative Fine: 10,000,000 FRW
6.	Distribution and Transport of ethyl alcohol without proper documentation as specified within these regulations.	- Seizure of transported ethyl alcohol until proper documentation is availed.
7.	Obstruction to an inspection.	- Administrative fines: 35,000,000 FRW
11.	Evading an inspection.	- Closure of the facility, and - Administrative fines: 50,000,000 FRW
16.	Operating with pending administrative fines beyond payment period.	- Suspension of Operational License if the Fines are not paid within 30 days after signature of the warning letter.
24.	Violation of the provisions on promotion and advertisement for ethyl alcohol	- Revocation of the premises license



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