Content

Title：	Regulations Governing Undenatured Ethyl Alcohol Ch
Date：	2012.11.22
Legislative：	1. Full text of 16 articles enacted and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 0890351440 on December 30, 2000 2. Full text of 19 articles amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 09303509830 on June 29, 2004 3. The Standard Chart of Ethyl Alcohol Denaturant of Article 11 amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 09403510960 on June 27, 2005 4. Article 9 and 17 amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 09403525530 on December 1, 2005 5. Article 7 and 10 amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 09503515970 on November 8, 2006 6. Article 3 and 19 amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 09703507780 on May 16, 2008 7. Article 19 and Appendix of Article 11 of the Regulations amended by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 10103732710 on November 22, 2012, unless otherwise prescribed, shall be implemented six months after the promulgation of this Act.
Content：	Article 1 The Regulations are enacted pursuant to Article 4, Paragraph 4 of the Tobacco and Alcohol Administration Act (hereinafter referred to as the Act) Article 2 The manufacture, importation, and sale of undenatured ethyl alcohol and the addition of denaturant shall be governed by the Regulations. Other relevant Acts and regulations shall apply with regard to those not provided for herein. Article 3 Undenatured ethyl alcohol (hereinafter referred to as "ethyl alcohol") referred to in the preceding article shall mean ethyl alcohol having an alcohol content by volume of over ninety percent (90%) without denaturant. The alcohol content referred to in the preceding paragraph shall mean the volume percentage of ethyl at 20 degrees Celsius ( ). Article 4 Ethyl alcohol manufacturers shall be organized in the form of a company limited by shares. Prior to establishment of an ethyl alcohol manufacturer, an existing company shall submit the following documents to the central competent authority for approval. A company may only produce and operate its business with the permit license after the approval is granted, and shall additionally complete the company alteration registration after receiving said permit license: 1. Application form for the establishment of tobacco/alcohol manufacturing; 2. Evidencing documents of company registration; 3. Evidencing documents of factory registration; 4. Production and operation plans; 5. The satisfactory factory examination report issued by the competent authority of fire control where the factory is located; and 6. Other documents required by the central competent authority. Where a company during the process of establishment applies for the establishment of an ethyl alcohol manufacturer, it shall first submit the documents as prescribed under Subparagraphs 1, 4, and 6 of the preceding paragraph to the central competent authority for the establishment approval. After receiving the company registration and the factory registration, it shall file said documents along with the satisfactory factory examination report issued by the competent authority of fire control with the central competent authority to apply for the issuance of the ethyl alcohol manufacturing permit license.

Article 5 Where the industrial by-product of a company is ethyl alcohol, the company shall apply to the central competent authority for the ethyl alcohol manufacturing permit license in accordance with Article 10 of the Act and the preceding article herein. The company shall begin selling its by-product after receiving the permit license.

Article 6 Where an existing company, a partnership or sole proprietorship enterprise applies for the establishment of an ethyl alcohol importer, it shall submit the following documents to the central competent authority for approval. It may only operate with the permit license after the approval is granted, and shall complete the company or business alteration registration after receiving the permit license:

1. Application form for the establishment of tobacco/alcohol importation;
2. Evidencing documents of the company or business registration;
3. Plans regarding the importation of undenatured ethyl alcohol; and
4. Other documents required by the central competent authority.

The plans regarding the importation of undenatured ethyl alcohol as referred to in the Subparagraph 3 of the preceding paragraph shall clearly specify the storage location, transportation plans, route/traffic plans, the origin and purpose of ethyl alcohol, and the sales target.

Where a company, a partnership or sole proprietorship enterprise during the process of establishment applies for the establishment of an ethyl alcohol importer, it shall first submit the documents as prescribed under Subparagraphs 1, 3, and 4 of Paragraph 1 to the central competent authority for the establishment approval. After receiving the company or business registration, it shall file said documents with the central competent authority to apply for the issuance of the ethyl alcohol import permit license.

Article 7 An ethyl alcohol seller shall submit the evidencing documents of the company, business or other approved operations to the municipal government or county (city) government located in where the business place is for registration prior to the operation. However, ethyl alcohol manufacturers, importers, and those who sell ethyl alcohol in accordance with Article 15 with the pharmacy license or pharmaceutical business permit license are not subject to this article.

Article 8 The importation of ethyl alcohol shall be limited to the industrial, pharmaceutical, military, processing, or repackaging purposes and shall not be utilized for purposes inconsistent with declaration.

The storage location of imported ethyl alcohol shall be limited to the factory location stated in the tobacco/alcohol manufacturing permit license, pharmaceutical business permit license, or the factory registrations of other industries, or the storage location clearly specified in the plans regarding the importation of undenatured ethyl alcohol prescribed in Article 6, Paragraph 1, Subparagraph 3 hereof.

Article 9 Where an ethyl alcohol importer applies to import ethyl alcohol for processing or repackaging, it shall submit the following documents and applies to the central competent authority for approval:

1. For self-processing or repackaging alcohol, the photocopies of the alcohol manufacturing permit license and the satisfactory factory examination report issued by the competent authority of fire control where the factory is located shall be submitted;
2. For other people to process or repackage alcohol, the entrustment contract, the photocopy of the principal's alcohol manufacturing permit license, and the satisfactory factory examination report issued by the competent authority of fire control where the factory is located shall be submitted; or
3. The evidence of place of production issued by the government or chamber of commerce authorized by the government of the place (country) of production or the government or chamber of commerce authorized by the government of the place (country) of exportation;

Where imported alcohol are utilized as self-use raw materials for the industrial, pharmaceutical, and military purposes, the alcohol import permit license may be exempted, however, the following documents shall be submitted during the customs clearance:

1. For industrial purposes excluding alcohol manufacturing and pharmacy: documents of the approval or evidencing the purpose issued by the Industrial Development Bureau, Ministry of Economic Affairs;
2. For industrial purposes of pharmacy: for industrial purpose of pharmacy excluding medicinal liquor, it shall submit the pharmaceutical business permit license and the permit certificate of the pharmaceuticals for applying the approval or document of verifying its use to the Industrial Development Bureau Ministry of Economic Affair. For purpose of development new medication, however, it can use the Research & Development Plan to replace the permit certificate of the pharmaceuticals; for industrial purpose of medicinal liquor manufacturing, it can apply the approval documents of the central competent authority; or
3. For military agencies, military schools, and military hospitals: documents of the approval or evidencing the purpose issued by the Ministry of National Defense.

When an agency issue documents of approval or evidencing the purpose as referred to in Subparagraphs 1 to 3 of the preceding paragraph, said agency shall also notify the central competent authority and shall supervise or administer the utilization of imported ethyl alcohol.

Article 10 Ethyl alcohol manufacturers, importers, and sellers shall handle affairs concerning the factory establishment, storage equipment, transportation, and labor working environment in accordance with the relevant public safety Acts and regulations, such as the Fire Act, Labor Safety and Health Act, Labor Inspection Act, and Statute Governing Road Traffic, prior to the business operation.

Article 11 Where denaturant is added to denature ethyl alcohol, the denaturation method shall conform to the "Standard Chart of Ethyl Alcohol Denaturant" (Appendix). Ethyl alcohol denatured without conforming to the provision of the preceding paragraph shall be deemed as undenatured.

Article 12 Denatured ethyl alcohol, without reporting to the competent authority for approval, shall not be transformed back to the undenatured status.

Article 13 Ethyl alcohol manufacturers, importers, and a sellers without the pharmacy license or pharmaceutical business permit license shall fill out the "Monthly Report of the Production, Importation, and Sale of Undenatured Ethyl Alcohol" and the "Sale Detail Statement of Undenatured Ethyl Alcohol" of the previous month and file the same with the local competent authority prior to the tenth (10th) day of each month. The local competent authority shall transfer said documents to the central competent authority for review.

When selling more than five (5) liters of ethyl alcohol at a time, the seller shall ask for evidencing documents of purpose and ID from the purchaser for checkup prior to the sale and shall keep said documents for two (2) years for the competent authority to examine.

The evidencing documents of purpose referred to in the preceding paragraph shall mean the following documents:

1. For selling, the documents shall refer to the certificates of selling registered at the municipal government or county (city) government located in where the business place is.
2. For alcohol manufacturing, the documents shall refer to the permit license of alcohol manufacturing.
3. For pharmacy, the documents shall refer to the pharmaceuticals permit.
4. For industries other than alcohol manufacturing and pharmacy, the documents shall refer to the evidencing documents of purpose issued by the competent authorities of relevant businesses.
5. For medical treatment, the documents shall refer to the practice license of the medical institutions.
6. For sanitation and sterilization, the documents shall refer to the company or business registration documents or the documents issued by the agencies, schools, or hospitals.
7. For military, academic, and scientific research, the documents shall refer to those issued by each competent authority or the agency (organization) that utilized ethyl alcohol.

With regard to those that purchase for sanitation and sterilization, if the purchaser purchases over four hundred (400) liters of ethyl alcohol at one time or the same purchaser aggregately purchases over four hundred (400) liters of ethyl alcohol within the same month, in addition to submitting the evidencing documents of purpose prescribed in Subparagraph 6, the purchaser shall also provided the utilization plan. Ethyl alcohol may only be purchased after the competent authority grants its approval.

A purchaser shall use the purchased ethyl alcohol in accordance with the purpose.

Article 14 With those who have the pharmacy license or pharmaceutical business permit license, when purchasing more than five (5) liters of ethyl alcohol at one time, Paragraphs 2, 3, and 4 of the preceding article shall apply.

With those whose sales amount accumulates up to four hundred (400) liters, the relevant reports shall be filled and filed with the local competent authority and be transferred to the central competent authority for review prior to the tenth (10th) day of each month in accordance with Paragraph 1 of the preceding article.

Article 15 With regard to ethyl alcohol used for pharmacy or medical sanitation and sterilization, the inspection specifications shall conform to the standards stipulated in the Chinese Pharmacopoeia.

Sellers of ethyl alcohol referred to in the preceding paragraph shall be limited to those who possess the pharmacy license or pharmaceutical business permit license.

Article 16 Where ethyl alcohol manufactures, importers, and sellers dissolve or terminate their operations or where their permit licenses are revoked, the remaining ethyl alcohol stock, except for those that are approved to extend the handling period by the local competent authority, shall be appropriately handled within three (3) months after the fact occurs. With regard to those that fail to handle by the deadline, the local competent authority may directly dispose of the stock. The expenses occurred therefrom shall be borne by such business operators.

Where the central competent authority revokes or abolishes an ethyl alcohol manufacturer's permit or forbids or suspends the ethyl alcohol production during a certain period, the central competent authority shall notify the local municipal or county (city) government in conjunction with the competent tax collection agency to dispatch personnel to check the inventory and record the finished goods and half-finished goods of ethyl alcohol and take the goods under supervision.

After the central competent authority abolishes the permit or forbids or suspends the ethyl alcohol production during a certain period, the ethyl alcohol manufacturer may, with regard to those finished goods completed before the day when the permit is abolished or when the production is forbidden or suspended, pay the taxes and sell said goods. The production of the remaining half-finished goods of ethyl alcohol shall not be continued. Where an ethyl alcohol manufacturer's permit is revoked, in order to maintain public interest or avoid the beneficiaries' property loss, the provision hereof shall apply mutatis mutandis.

Article 17 Where ethyl alcohol manufacturer, importers, and sellers violate Articles 7, 8, 12, 13, or 14 hereof, the punishment pursuant Article 56 of the Act is as follows:

1. An ethyl alcohol seller that fails to register with the municipal or country (city) government located in where the business place is, in violation of Article 7 hereof, shall be punished by fines and may also be forbidden to sell;
2. An ethyl alcohol importer that uses ethyl alcohol imported for purposes inconsistent with declaration, in violation of Article 8 hereof, shall be punished by fines. Those that recommit the violation shall be punished by fines and may also be forbidden to import.
3. Those that transform ethyl alcohol back to the undenatured status after the ethyl alcohol was denatured without reporting to the competent authority for approval, in violation of Article 12 hereof, shall be punished by fines.
4. Those that fail to fill out and file the reports by the deadlines or evidencing documents of purpose and ID from the purchaser or evidencing documents of purpose issued by the competent authorities of relevant businesses and keep in 2 years, in violation of Article 13 or Article 14 hereof, shall be punished by fines. Those that make false statements in the reports for the first time shall be notified to take corrective measures within a specified time period by the competent authority. For the second violation, a fine shall be imposed. For the third violation, besides a cumulative fine, those business operators may also be forbidden to manufacture, import, and sell.

The Ethyl alcohol manufacturers, importers, and sellers that violate Article 10 shall be handled in accordance with the relevant Acts and regulations, such as the Fire Act, Labor Safety And Health Act, Labor Inspection Act, and Statue Governing Road Traffic.

Article 18 The forms required in the Regulations shall be additionally prescribed by the central competent authority.

Article 19 The Regulations shall be enforced as of the day of promulgation.

Article 3, Paragraph 1 of the Regulations amended and promulgated on May 16, 2008 shall be enforced from May 16, 2008.

The Appendix of Article 11 of the Regulations amended on November 22, 2012, unless otherwise prescribed, shall be implemented six months after the promulgation of this Act.

【In case of any discrepancy between this English version and the Chinese text of this Standards, the Chinese text shall govern.】

Appendix: Standard Chart of Ethyl Alcohol Denaturant

Item	The quantity of denaturant added into the alcohol per kiloliter (The standard of alcohol content is 95% by volume)	
1	Pine tar Ch.P or USP	↘10 kiloliter

2	Toluol CNS	↘50 kiloliter
3	Ethyl ether CNS or Ch.P	↘100 kiloliter
4	Lavender oil CNS or Ch.P	↘10 kiloliter
	Medicinal soft soap or Ch.P	↘100 kilogram
5	Strong ammonia water CNS or Ch.P	↘30 kiloliter
6	5% of water solution of zinc chloride	↘50 kiloliter
	Any kind of the following items, either one or more:	↘10 kiloliter
	Ⅰ1Ｋ Cinnamon oil; Cassia oil CNS or Ch.P Ⅰ2Ｋ Clove oil CNS or Ch.P Ⅰ3Ｋ Peppermint oil CNS or Ch.P	
	Note: The oil listed above must be dissolved into alcohol before added into zinc chloride.	
7	Any kind of the following items, either one or more:	↘10 kilogram
	Ⅰ1Ｋ Anethole Ch.P	
	Ⅰ2Ｋ Anise oil CNS or Ch.P	
	Ⅰ3Ｋ Bay oil CNS	
	Ⅰ4Ｋ Bergamot oil CNS or N.F	
	Ⅰ5Ｋ Bitter almond oil Ch.P	
	Ⅰ6Ｋ Cedar leaf oil USP	
	Ⅰ7Ｋ Chlorothymol N.F	
	Ⅰ8Ｋ Cinnamon oil;Cassia oil CNS or Ch.P	
	Ⅰ9Ｋ Citronella oil,natural CNS	
	Ⅰ10Ｋ Eucalyptus oil CNS or Ch.P	
	Ⅰ11Ｋ Guaiacol Ch.P	
	Ⅰ12Ｋ Lavender oil CNS or Ch.P	
	Ⅰ13Ｋ Peppermint oil CNS or Ch.P	
	Ⅰ14Ｋ Phenyl salicylate;Salol N.F	
	Ⅰ15Ｋ Rosemary oil CNS	
	Ⅰ16Ｋ Spearmint oil CNS	
	Ⅰ17Ｋ Spike lavender oil,natural CNS	
	Ⅰ18Ｋ Storax Ch.P	
	Ⅰ19Ｋ Thyme oil Ch.P	
	Ⅰ20Ｋ Thymol CNS or Ch.P	
	Ⅰ21Ｋ Tolu balsam USP	
	Ⅰ22Ｋ Turpentine oil Ch.P	
8	Sodium salicylate or Salicylic acid CNS or Ch.P	↘9 kilogram
	Fluid extract of quassia N.F	↘12.5 kiloliter
	Tert-Butyl alcohol	↘1.5 kiloliter
9	Sucrose octaacetate	↘1 kilogram
	Tert-Butyl alcohol	↘1.5 kiloliter
10	Other denaturants approved by the central competent authorities	

Footnote 1:

CNSù Chinese National Standards

Ch.Pù Chinese Pharmacopoeia

USPù Pharmacopoeia

N.Fù The National Formulary

Footnote 2:

Item ten shall be implemented after the promulgation of this regulation.