Regulations Governing Undenatured Ethyl Alcohol

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.
8. Articles 11, 12, 17, 19 amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 10303667220 on May 16, 2014.
9. Full text of 15 articles amended and promulgated by the Ministry of Finance with Order Tsai-Ku-Tzu-No. 10303785130 on December 26, 2014, which shall be enforced from January 1, 2015.

Article 1 These Regulations are enacted pursuant to Article 4, Paragraph 6 of the Tobacco and Alcohol Administration Act (hereinafter referred to as the "Act").

Article 2 An applicant to operate undenatured ethyl alcohol (hereinafter referred to as "ethyl alcohol") production or import business shall apply to the central competent authority for an establishment permit pursuant to the Act and the Regulations Governing the Approval and Review of Establishment and Modification of Alcohol and Tobacco Importer and Producer Licenses, and may operate business only after obtaining an ethyl alcohol producer or ethyl alcohol importer permit license.

Article 3 Where the industrial by-product of any business is ethyl alcohol, the business shall apply to the central competent authority for an establishment permit in accordance with the Act and the Regulations Governing the Approval and Review of Establishment and Modification of Alcohol and Tobacco Importer and Producer Licenses, and may begin selling its by-product ethyl alcohol only after obtaining an ethyl alcohol producer permit license.

Article 4 An ethyl alcohol seller shall submit the evidencing documents of the company, business, or other approved operations to the municipal or county/ city competent authority in where the business place is located for registration prior to the operation. However, ethyl alcohol producers, importers, and those who sell ethyl alcohol in accordance with Article 11 with a pharmacy license or pharmaceutical business permit license are not subject to this article.

Article 5 Where an ethyl alcohol importer applies to import ethyl alcohol for purposes of processing or repackaging and sale in the manufacturing of alcohol, it shall complete an application form and submit it with the following documents to apply to the central competent authority for approval:

1. For the importer to process or repackage in the manufacturing of alcohol, the satisfactory factory examination report issued by the competent fire control authority where the factory is located shall be submitted.
2. For provision to other people to process or repackage in the manufacturing of alcohol, the import entrustment contract and the satisfactory factory examination report issued by the competent fire control authority where the factory is located shall be submitted.

Where imported alcohol is utilized as self-use raw materials for industrial, pharmaceutical, medical, military, testing, experimental research, energy purposes, or other uses which have been publicly announced by the central competent authority, the ethyl alcohol importer's permit license may be exempted; however, the following documents shall be submitted during customs clearance:

1. For industrial purposes excluding alcohol manufacturing and pharmaceutical manufacturing: it shall submit documents of approval or evidencing the purpose of purchase issued by the Industrial Development Bureau, Ministry of Economic Affairs.
2. For pharmaceutical manufacturing industry purposes: for pharmaceutical manufacturing industry purposes excluding medicated alcohol, it shall submit the pharmaceutical business permit license and the permit certificate of the pharmaceuticals to apply for the approval or document verifying its use to the Industrial Development Bureau, Ministry of Economic Affairs. For the purpose of developing new medication, however, it can use the research & development plan to replace the permit certificate of the pharmaceuticals; for medicated alcohol manufacturing industry purposes, submit the documents of approval or evidencing the purpose of purchase issued by the Ministry of

Health and Welfare.

3. For medical purposes: it shall submit the documents evidencing the commencement of business issued by the competent health authority.
4. For military agencies, military schools, and military hospitals: it shall submit documents of approval or evidencing the purpose of purchase issued by the Ministry of National Defense.
5. For testing purposes: it shall submit documents of approval or evidencing the purpose of purchase issued by the competent authorities for the testing products.
6. For experimental research purposes: it shall submit documents of approval or evidencing the purpose of purchase issued by the Ministry of Education or Academia Sinica.
7. For energy purposes: it shall submit documents of approval or evidencing the purpose of purchase issued by the Bureau of Energy, Ministry of Economic Affairs.
8. For use for purposes other than those set out in the preceding seven subparagraphs, as publicly announced by the central competent authority: it shall submit documents of approval or evidencing the purpose of purchase issued by the authority with responsibility for the purpose as publicly announced by the central competent authority.

The authorities with responsibility for the purposes set out in the subparagraphs of the preceding paragraph shall supervise or administer the utilization of ethyl alcohol after its import.

When an ethyl alcohol importer imports dehydrated alcohol for medical, testing, or experimental research purposes or other purposes as publicly announced by the central competent authority, and the alcohol content is 99.5 percent or greater, and the unit package volume is no more than five liters, the documents of approval or evidencing the purpose under Paragraph 2 need not be submitted during customs clearance.

Article 6 After ethyl alcohol is imported, it shall be used for the purposes declared and may not be provided for any purpose inconsistent with the declared purpose. However, if there is an intention to a purpose with just cause, the responsible persons of the users before and after the change of purpose shall jointly sign an application, accompanied by the relevant documents, and submit it to the authority responsible for the post-change purpose as set out in the preceding article, and may use it for that purpose only after that authority, in consultation with the

authority for the original purpose, has granted approval.

After ethyl alcohol is imported under the preceding paragraph, unless approval is obtained from the authority with responsibility for the given purpose as set out in Paragraph 2 of the preceding article, it shall be stored at the location set out below for the purpose for which it was declared:

1. For the manufacturing of alcohol: the location of the factory specified on the alcohol or tobacco producer permit license.
2. For the pharmaceutical manufacturing industry: the location of the factory specified on the pharmaceutical firm’s permit license.
3. For industrial purposes excluding alcohol manufacturing and pharmaceutical manufacturing: the location of the factory specified on the factory registration of the given industrial enterprise.
4. For purposes other than those in the preceding three subparagraphs: the location specified on the document of approval or evidencing the purpose of purchase as specified in Paragraph 2 of the preceding article.

Article 7 Where denaturant is added to denature ethyl alcohol, the kinds of added denaturing agent and volume shall conform to the "Standard Chart of Ethyl Alcohol Denaturant" (Appendix), and shall not be used in alcohol manufacturing.

Ethyl alcohol denatured without conforming to the provision of the preceding paragraph shall neither be used in alcohol manufacturing nor be imported unless it obtains the approval or evidencing documents as provided in Paragraph 2, Article 5.

Appendix：Standard Chart of Ethyl Alcohol Denaturant.doc

Article 8 Denatured ethyl alcohol shall not be converted back to the undenatured status.

Article 9 Ethyl alcohol producers, importers, and sellers without a pharmacy license or pharmaceutical business permit license shall fill out the Sources of Alcohol Purchased, Monthly Report of the Inventories of Ethyl Alcohol Purchased and Sold, and the Itemized Statement of Sales of Ethyl Alcohol of the previous month and file the same with the municipal or county/ city competent authority prior to the tenth day of each month for auditing.

When selling five liters of ethyl alcohol or greater at a time, the seller shall obtain the documents evidencing the purpose of purchase from the purchaser and check the purchaser's ID prior to the sale and shall keep the documents evidencing the purpose of purchase for two years for auditing.

The documents evidencing the purpose of purchase as 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 or county/ city competent authority of the location of the business place.
2. For alcohol manufacturing, the documents shall refer to the permit license of alcohol manufacturing.
3. For pharmaceutical manufacturing, the documents shall refer to the pharmaceuticals permit.
4. For industries other than alcohol manufacturing and pharmaceutical manufacturing, the documents shall refer to the documents evidencing factory registration or documents evidencing the purpose of purchase issued by the competent authorities of relevant businesses.
5. For medical treatment, the documents shall refer to the practicing 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 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 who purchase for sanitation and sterilization, if the purchaser purchases four hundred liters of ethyl alcohol or greater at one time or the same purchaser aggregately purchases four hundred liters of ethyl alcohol or greater within the same month, in addition to submitting the evidencing documents of purpose prescribed in Subparagraph 6, the purchaser shall also provided a utilization plan. Ethyl alcohol may only be purchased after the municipal or county/ city competent authority grants its approval.

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

Article 10 With those who have a pharmacy license or pharmaceutical business permit license, when purchasing five liters of ethyl alcohol or greater at one time, Paragraphs 2 to 4 of the preceding article shall apply.

With those whose sales amount accumulates up to four hundred liters, the relevant reports shall be completed and filed with the municipal or county/ city competent authority for auditing prior to the tenth day of each month in accordance with Paragraph 1 of the preceding article.

Article 11 With regard to ethyl alcohol used for pharmacy or medical sanitation and sterilization, the inspection specifications shall conform to those standards stipulated in the Chinese Pharmacopoeia.

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

Article 12 If ethyl alcohol producers, importers, or sellers terminate their operations or where their permit licenses or registrations are canceled by the competent authority, the remaining ethyl alcohol stock, except for that which is approved for extension of the handling period by the municipal or county/ city competent authority, shall be appropriately handled within three months after the fact occurs. With regard to that stock which fails to be handled by the deadline, the municipal or county/ city competent authority may directly dispose of the stock. The expenses occurred therefrom shall be borne by such business operators.

When the central competent authority voids or revokes an ethyl alcohol producer's establishment permit, 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 semi-finished goods of ethyl alcohol and take the goods under supervision.

If the central competent authority revokes the establishment permit, the ethyl alcohol producer may, with regard to those finished goods completed before the permit is revoked, pay the taxes and sell said goods. The production of the remaining semi-finished goods of ethyl alcohol shall not be continued. If an ethyl alcohol producer's establishment permit is voided, in order to maintain public interest or avoid the beneficiaries' property loss, the provisions hereof shall apply mutatis mutandis.

Article 13 A violator of these Regulations shall be subject to penalties pursuant to Article 53 of the Act as follows:

1. Those who fail to register with the municipal government or county/ city competent authority of the location of the business place, in violation of Article 4 hereof, shall be punished by administrative fines.
2. Those who, after importing ethyl alcohol, provide it for purposes inconsistent with the declaration or to a storage site inconsistent with regulations, in violation of Article 6 hereof, shall be punished by administrative fines; if the violator is an ethyl alcohol producer or importer, if the violation is of a material nature or the offender fails to make improvements within a specified

period of time following notification to do so, the establishment permit of the offender may be revoked.

3. Those that convert ethyl alcohol back to the undenatured status after the ethyl alcohol was denatured in violation of Article 8 hereof, shall be punished by administrative fines.
4. Those that fail to fill out and file the reports by the deadlines, or file a report containing any false information, or fail to obtain from the purchaser documents evidencing purpose of purchase or documents issued by the competent municipal or county/ city authorities approving the purchase, or fail to keep such documents for two years, in violation of Article 9 or Article 10 hereof, shall be punished by administrative fines. Those that submit a report containing any false information shall, in the first instance, be notified to take corrective measures within a specified time period by the competent authority. For the second violation, an administrative fine shall be imposed. Beginning from the third violation, cumulative administrative fines shall be imposed.

Article 14 The forms required under Article 4, Article 5, Paragraph 1, and Article 9 hereof shall be additionally prescribed by the central competent authority.

Article 15 These Regulations shall be enforced from January 1, 2015.

Note

In case of any discrepancy between the English version and the Chinese text of this statute, 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
	（1）Cinnamon oil; Cassia oil CNS or Ch.P （2）Clove oil CNS or Ch.P （3）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
	（1）Anethole Ch.P	
	（2）Anise oil CNS or Ch.P	
	（3）Bay oil CNS	
	（4）Bergamot oil CNS or N.F	
	（5）Bitter almond oil Ch.P	
	（6）Cedar leaf oil USP	
	（7）Chlorothymol N.F	
	（8）Cinnamon oil;Cassia oil CNS or Ch.P	
	（9）Citronella oil,natural CNS	
	（10）Eucalyptus oil CNS or Ch.P	
	（11）Guaiacol Ch.P	
	（12）Lavender oil CNS or Ch.P	
	（13）Peppermint oil CNS or Ch.P	
	（14）Phenyl salicylate;Salol N.F	
	（15）Rosemary oil CNS	
	（16）Spearmint oil CNS	
	（17）Spike lavender oil,natural CNS	
	（18）Storax Ch.P	
	（19）Thyme oil Ch.P	
	（20）Thymol CNS or Ch.P	

	（21）Tolu balsam USP	
	（22）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:
CNS：Chinese National Standards
Ch.P：Chinese Pharmacopoeia
USP：United States Pharmacopoeia
N.F：The National Formulary

Footnote 2:
Item ten shall be implemented after the promulgation of this regulation.