

公告自本(103)年10月31日起CCC1501.10.00.00-0「第0209或1503節除外之熟豬油」等89項貨品增列輸入規定代號「255」、「827」、「828」、「829」、「830」、「831」、「832」。

作者：經濟部國際貿易局 公布日期：2014/10/24 最新檢視日期：2014/10/24

經濟部國際貿易局公告

發文日期：2014/10/24

發文字號：貿服字第1037028270號

附件說明：如文(1037028270-1.doc)

主旨：公告自本(103)年10月31日起CCC1501.10.00.00-0「第0209或1503節除外之熟豬油」等89項貨品增列輸入規定代號「255」、「827」、「828」、「829」、「830」、「831」、「832」。

依據：貨品輸入管理辦法第8條及衛生福利部食品藥物管理署本年10月22日FDA食字第1039023435號函、財政部關務署本年10月23日台關業字第1031023576號函辦理。

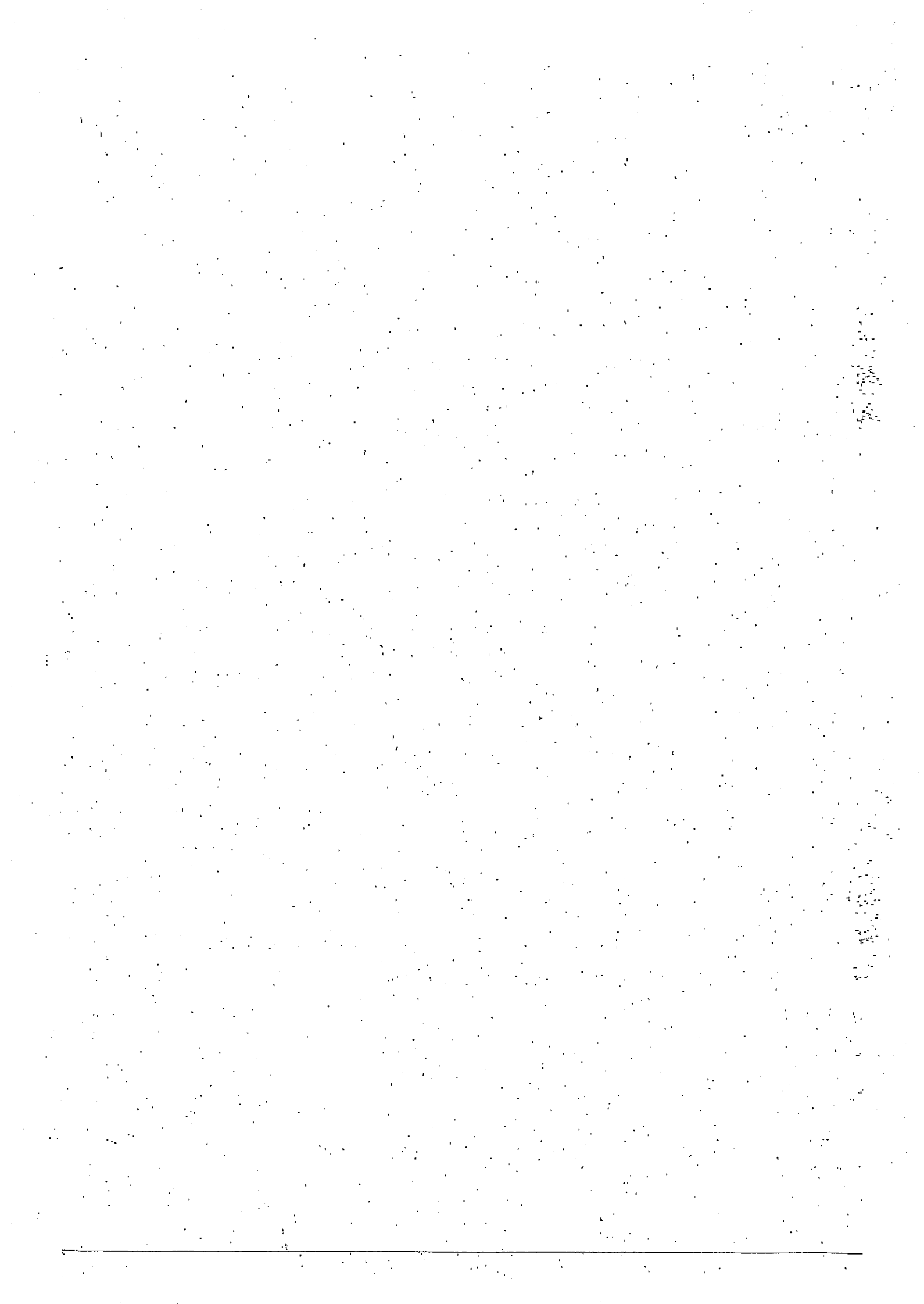
公告事項：

一、國內發生劣質豬油事件以來，政府為期能解決進口非食用油品違法流用問題，經跨部會開會研商決定未來進口油品將採分流管理，於相關油品項下增列複合輸入規定代號，由各權責主管機關辦理後續流向用途之追蹤控管，爰公告旨揭貨品輸入時應依其項下相關輸入規定代號內容辦理，並自本年10月31日起實施。

二、檢附貨品輸入規定變更明細表1份。

附件：1037028270-1.doc

附件



貨品輸入規定變更明細表

序號	貨品號列	貨品中英文名稱	原列 輸入規定	改列 輸入規定
1	1501.10.00.00-0	第 0209 或 1503 節除外之熟豬油 Pig lard, other than that of heading 02.09 or 15.03.	F02	827
2	1501.20.00.00-8	第 0209 或 1503 節除外之其他豬脂 Other pig fat, other than that of heading 02.09 or 15.03	F02	829
3	1501.90.00.00-3	第 0209 或 1503 節除外之禽脂 Poultry fat, other than that of heading 02.09 or 15.03	F02	827
4	1502.10.10.00-7	第 1503 節除外之牛、羊脂，已熬製，酸價不超過 1 Fats of bovine animals, sheep or goats, rendered, acid value not exceeding 1, other than those of heading 15.03	F02	827
5	1502.10.20.00-5	第 1503 節除外之牛、羊脂，已熬製，酸價超過 1 Fats of bovine animals, sheep or goats, rendered, acid value exceeding 1, other than those of heading 15.03	F02	827
6	1502.90.00.00-2	第 1503 節除外之牛、羊脂，未熬製 Fats of bovine animals, sheep or goats, unrender, other than those of heading 15.03	B01 F02	827 B01
7	1503.00.11.00-7	豬、牛、羊硬脂，酸價不超過 1 Lard stearin, oleostearin and tallow stearin, acid value not exceeding 1	F02	827
8	1503.00.12.00-6	豬、牛、羊硬脂，酸價超過 1 Lard stearin, oleostearin and tallow stearin, acid value exceeding 1	F02	827
9	1503.00.21.00-5	豬、牛、羊脂油，酸價不超過 1 Lard oil, oleo oil and tallow oil, acid value not exceeding 1	F02	827
10	1503.00.22.00-4	豬、牛、羊脂油，酸價超過 1 Lard oil, oleo oil and tallow oil, acid value exceeding 1	F02	827
✓ 11	1504.10.00.00-7	魚肝油及其餾分物 Fish-liver oils and their fractions	F02	827
12	1504.20.00.00-5	魚類油脂及其餾分物（魚肝油除外） Fats and oils and their fractions, of fish, other than liver oils	F02	827
13	1504.30.00.00-3	水產哺乳動物之油脂及其餾分物 Fats and oils and their fractions, of marine mammals	F02	827

序號	貨品號列	貨品中英文名稱	原列 輸入規定	改列 輸入規定
14	1505.00.10.00-6	純淨羊毛脂 Lanolin		832
15	1505.00.90.00-9	其他羊毛脂及其衍生之脂肪質 Other wool grease and fatty substances derived therefrom		832
16	1506.00.10.00-5	蛋黃油 Oil, egg-yolk	F02	827
17	1506.00.20.00-3	骨髓油 Bone-marrow oil	F02	827
18	1506.00.90.10-6	鱉(甲魚)脂肪 Fat of soft-shell turtle (terrapin)	F02	827
19	1506.00.90.90-9	其他動物油及脂 Other animal oils and fats	B01 F02	827 B01
20	1507.10.00.00-4	粗製大豆(黃豆)油, 不論是否去膠質者 Crude soy-bean oil, whether or not degummed	F02 MW0	827 MW0
21	1507.90.00.00-7	精製大豆(黃豆)油及其餾分物 Refined soybean oil and its fractions	F02 MW0	827 MW0
22	1508.10.00.00-3	粗製花生油 Crude ground-nut (peanut) oil	F02 MW0	827 MW0
23	1508.90.00.00-6	精製花生油及其餾分物 Refined ground-nut (peanut) oil and its fractions	F02 MW0	827 MW0
24	1509.10.00.00-2	橄欖原油 Virgin olive oil	F02	827
25	1509.90.00.00-5	精製橄欖油及其餾分物 Refined olive oil and its fractions	F02	827
26	1510.00.00.00-1	其他油類及其餾分物, 僅由橄欖所提煉, 不論是否精煉但未經化學改質, 包括本節與第1509節之油類或其餾分物混合者 Other oils and their fractions, obtained solely from olives, whether or not refined, but not chemically modified, including blends of these oils or fractions with oils or fractions of heading 15.09	F02	827
27	1511.10.00.00-8	粗製棕櫚油 Crude palm oil	F02	827
28	1511.90.00.00-1	精製棕櫚油及其餾分物 Refined palm oil and its fractions	F02	827
29	1512.11.10.00-4	粗製葵花子油 Crude sunflower-seed oil	F02	827
30	1512.11.20.00-2	粗製紅花子油 Crude safflower oil	F02	827
31	1512.19.10.00-6	精製葵花子油及其餾分物 Refined sunflower-seed oil and its fractions	F02	827

序號	貨品號列	貨品中英文名稱	原列 輸入規定	改列 輸入規定
32	1512.19.20.00-4	精製紅花子油及其餾分物 Refined safflower oil and its fractions	F02	827
33	1512.21.00.00-4	粗製棉子油，不論是否去除棉子醇者 Crude cotton-seed oil, whether or not gossypol has been removed	F02	827
34	1512.29.00.00-6	精製棉子油及其餾分物 Refined cotton-seed oil and its fractions	F02	827
35	1513.11.00.00-5	粗製椰子（乾椰子肉）油 Crude coconut (copra) oil	F02	827
36	1513.19.00.00-7	精製椰子（乾椰子肉）油及其餾分物 Refined coconut (copra) oil and its fractions	F02	827
37	1513.21.10.00-1	粗製棕櫚仁油 Crude palm kernel oil	F02	827
38	1513.21.20.00-9	粗製巴巴樹油 Crude babassu oil	F02	827
39	1513.29.10.00-3	精製棕櫚仁油及其餾分物 Refined palm kernel oil and its fractions	F02	827
40	1513.29.20.00-1	精製巴巴樹油及其餾分物 Refined babassu oil and its fractions	F02	827
41	1514.11.00.10-2	低芥子酸之粗製油菜子油 Crude rape or colza oil of low erucic acid	F02	827
42	1514.19.00.00-6	低芥子酸之精製油菜子油及其餾分物 Refined rape or colza oil and its fractions of low erucic acid	F02	827
43	1514.91.10.00-5	其他粗製之油菜子油 Other crude rape or colza oil	F02	827
44	1514.91.20.00-3	粗製芥子油 Crude mustard oil	F02	827
45	1514.99.10.00-7	其他精製油菜子油及其餾分物 Other refined rape or colza oil and its fractions	F02	827
46	1514.99.20.00-5	精製芥子油及其餾分物 Refined mustard oil and fractions thereof	F02	827
47	1515.11.00.00-3	粗製亞麻仁油 Crude linseed oil	F02	827
48	1515.19.00.00-5	精製亞麻仁油及其餾分物 Refined linseed oil and its fractions	F02	827
49	1515.21.00.00-1	粗製玉米油 Crude maize (corn) oil	F02 MW0	827 MW0
50	1515.29.00.00-3	精製玉米油及其餾分物 Maize (corn) oil and its fractions	F02 MW0	827 MW0
✓ 51	1515.30.00.00-0	蓖麻油及其餾分物 Castor oil and its fractions	508	828

序號	貨品號列	貨品中英文名稱	原列 輸入規定	改列 輸入規定
52	1515.50.00.00-5	芝麻油及其餾分物 Sesame oil and its fractions	F02	827
53	1515.90.10.00-5	荷荷巴油及其餾分物 Jojoba oil and its fractions		829
54	1515.90.20.00-3	桐油及其餾分物 Tung oil and its fractions		829
55	1515.90.90.10-6	罌粟子油及其餾分物 Poppy-seed oil and their fractions	MW0	829 MW0
56	1515.90.90.90-9	其他固定性植物油脂及其餾分物 Other fixed vegetable fats and oils and their fractions	F02	827
57	1516.10.11.00-0	氫(硬)化動物油脂及其餾分物, 酸價不超過1 Hydrogenated (hardened) animal fats and oils and their fractions, acid value not exceeding 1	F02	827
58	1516.10.12.00-9	硬化魚油, 酸價不超過1 Hardened fish oil, acid value not exceeding 1	F02	827
59	1516.10.21.00-8	氫(硬)化動物油脂及其餾分物, 酸價超過1 Hydrogenated (hardened) animal fats and oils and their fractions, acid value exceeding 1	F02	827
60	1516.10.22.00-7	硬化魚油, 酸價超過1 Hardened fish oil acid value exceeding 1	F02	827
61	1516.20.11.00-8	氫(硬)化植物油脂及其餾分物, 酸價不超過0.6 Hydrogenated (hardened) vegetable fats and oils and their fractions, acid value not exceeding 0.6	F02	827
62	1516.20.12.00-7	氫化棕櫚油及氫化棕櫚核油, 酸價不超過0.6 Hydrogenated palm oil and hydrogenated palm kernel oil, acid value not exceeding 0.6	F02	827
63	1516.20.20.00-7	氫(硬)化植物油脂及其餾分物, 酸價超過0.6 Hydrogenated (hardened) vegetable fats and oils and their fractions, acid value exceeding 0.6	F02	827
64	1517.10.00.00-2	人造奶油, 液態人造奶油除外 Margarine, excluding liquid margarine	F02	830
65	1517.90.10.00-3	液態人造奶油 Liquid margarine	F02	830
66	1517.90.20.00-1	酥脆油 Shortening	F02	830

序號	貨品號列	貨品中英文名稱	原列 輸入規定	改列 輸入規定
67	1517.90.90.00-6	其他可食用動植物油脂混合物或調製品，第1516節食用油脂或其餾分物除外 Other edible mixtures or preparations of animal or vegetable fats or oils, other than edible fats or oils or their fractions of heading 15.16	F02	830
68	1518.00.10.00-1	沸製亞麻仁油 Boiled linseed oil		830
69	1518.00.20.00-9	脫水蓖麻油 Dehydrated castor oil		831
70	1518.00.30.00-7	氧化亞麻仁油 Linoxyn		830
71	1518.00.40.00-5	環氧大豆(黃豆)油 Epoxy soy-bean oil		830
72	1518.00.90.00-4	其他沸製、氧化、脫水、硫化、吹製，在真空中或惰性氣體中行聚合化或經其他化學方法改質之動、植物油脂及其餾分物，但不包括第1516節所列產品 Other animal or vegetable fats and oils and their fractions, boiled, oxidised, dehydrated, sulphurised, blown, polymerised by heat in vacuum or in inert gas or otherwise chemically modified, excluding those of heading No.15.16		830
73	1520.00.00.00-9	粗製甘油；甘油水溶液及甘油鹼液 Glycerol, crude; glycerol waters and glycerol lyes		831
74	1521.10.00.00-6	植物蠟，不論已否精製或著色 Vegetable waxes, whether or not refined or coloured	508	831
75	1521.90.10.00-7	蜂蠟(黃蠟)，無論已否精製或著色 Bees wax (yellow wax), whether or not refined or coloured	MW0	830 MW0
76	1521.90.20.00-5	鯨蠟，不論已否精製或著色 Spermaceti, whether or not refined or coloured		832
77	1521.90.90.00-0	其他蟲蠟，無論已否精製或著色 Other insect waxes, whether or not refined or coloured		832
78	1522.00.10.00-5	鞣革餘油 Degras		832
79	1522.00.20.00-3	其他油脂及動植物蠟經加工處理後所餘之殘渣 Other residues resulting from the treatment of fatty substances or animal or vegetable waxes		832
80	3823.11.00.00-6	硬脂酸 Stearic acid		832
81	3823.12.00.00-5	油酸 Oleic acid		832

序號	貨品號列	貨品中英文名稱	原列 輸入規定	改列 輸入規定
82	3823.13.00.00-4	松脂油脂肪酸 Tall oil fatty acids		832
83	3823.19.10.00-6	粗製動植物性軟脂酸 Crude animal or vegetable palmitic acids		832
84	3823.19.20.00-4	動物性油脂精製所得之酸性油 Acid oils from refining, animal		832
85	3823.19.30.00-2	植物性油脂精製所得之酸性油 Acid oils from refining, vegetable		832
86	3823.19.90.00-9	其他工業用一元脂肪酸 Other industrial monocarboxylic fatty acids		832
87	3823.70.00.00-4	工業用脂肪醇 Industrial fatty alcohols		832
88	3824.90.99.90-2	其他第3824節所屬之貨品 Other articles of heading No. 38.24	C02	255 C02
89	3826.00.00.00-6	生質柴油及其混合物，不含或含石油或提自瀝青礦物之油類，以重量計低於70%者 Biodiesel and mixtures thereof, not containing or containing less than 70% by weight of petroleum oils or oils obtained from bituminous minerals		255

輸入規定代號	規定代號內容
(空白)	准許(免除簽發許可證) Import permitted (free from licensing)
251	應檢附經濟部工業局同意文件。 Approval from the Industrial Development Bureau, Ministry of Economic Affairs is required.
255	應檢附經濟部能源局同意文件。 Approval from the Bureau of Energy, Ministry of Economic Affairs is required.
404	<p>(一)進口飼料，應檢附行政院農業委員會核發之飼料輸入登記證影本或農委會、台北市、高雄市政府核發之飼料製造登記證影本(持飼料製造登記證申請進口者，僅限飼料工廠進口自用飼料原料)。(二)進口飼料添加物，應檢附行政院農業委員會核發之飼料添加物輸入登記證影本(以上飼料或飼料添加物品目以行政院農業委員會公告者為準)。(三)非飼料或飼料添加物登記證持有者，應加附持有者之授權文件，或於登記證影本上加蓋授權使用之章戳。(四)如屬樣品、贈品，應檢附行政院農委會或台北市、高雄市政府核發之進口同意文件。</p> <p>(1) For importation of feedstuff, a photocopy of registration certificate for importation of feedstuff issued by the Council of Agriculture, Executive Yuan or a photocopy of registration certificate for manufacturing of feedstuff issued by the Council of agriculture, Executive Yuan, Taipei or Kaohsiung City Government is required. (The importer who may use the registration certificate for manufacturing of feedstuff in applying for importation of feedstuff is limited to the manufacturer of feedstuff, who will use the feedstuff as materials by himself). (2) For importation of feedstuff additives, a photocopy of registration certificate for importation of feedstuff additives issued by the Council of Agriculture, Executive Yuan is required. (The above mentioned feedstuff and feedstuff additives should be limited to those duly announced by the Council of Agriculture, Executive Yuan). (3) For non-certificate holders, they shall submit an application for importation together with an authorization documentation issued by the owner of such a certificate or a stamp on the photocopy of the said certificate indicating that authorization to use the relevant certificate has been granted. (4) If the imported goods are samples or gifts, an approval from the Council of agriculture, Executive Yuan, Taipei or Kaohsiung City Government is required.</p>
503	<p>進口人用藥品(包括製劑、原料藥、助診藥類及人用生物製劑)：應檢附(一)藥商許可執照影本及衛生福利部核發之(輸入)藥品許可證影本，或(二)衛生福利部核發之同意文件。</p> <p>Importation of drugs (including pharmaceutical products, active pharmaceutical ingredients, diagnostics and biological products) for human use requires either of the following: (1) a photocopy of the drug (import) license issued by the Ministry of Health and Welfare together with a photocopy of the license of the pharmaceutical firm; or (2) an approval issued by the Ministry of Health and Welfare.</p>
508	<p>一、進口食品添加物應依下列規定辦理：(一)輸入衛生福利部發布「食品添加物使用範圍及限量暨規格標準」收載之單方食品添加物(香料除外)，應檢附衛生福利部核發之食品添加物許可證影本，並依F O I規定辦理。(二)如屬香料或複方食品添加物，應依F O I規定辦理。二、進口非食品添加物之食品原料，應依F O I規定辦理。三、如屬食品添加物之樣品、贈品，應檢附衛生福利部核</p>

輸入規定代號	規定代號內容
	<p>發之「貨品進口同意書申請書(食品、添加物樣品)」。四、進口非供食品或食品添加物用途者，於進口報單填列專用代碼DH999999999508，免依上述規定辦理。</p> <p>1. For importation of food additives must be handled according to the following regulations: (1) If the petitioned food additive (excluding flavorings) is a single chemical enlist in the current "Standards for Specification, Scope, Application and Limitation of Food Additives", a photocopy of the food additives license issued by the Ministry of Health and Welfare is required, and shall be governed by the regulation of "F01". (2) For importation of flavorings or food additive mixtures, shall be governed by the regulation of "F01". 2. For importation of foods but not food additives, shall be governed by the regulation of "F01". 3. If the imported food additives and it is samples or gifts, a "application import certificate" issued by the Ministry of Health and Welfare is required, 4. Importation of commodity not to be used as foods or food additives, should list the special code DH999999999508 on the import application and is exempted from the above regulations.</p>
827 ✓	<p>(一) 進口食品及相關產品，應依F01辦理。(二) 進口人用藥品，應依503規定辦理。(三) 進口一般工業用油脂，應依251規定辦理。(四) 進口生質柴油用油脂，應依255規定辦理。(五) 進口飼料或飼料添加物，應依404規定辦理。(六) 進口本項貨品未取得上開主管機關輸入許可文件者，不准進口。</p> <p>(1) Importation of foods and food-relevant products is governed by the regulation of "F01". (2) Importation of medicines for human use is governed by the regulation of "503". (3) Importing industrial oils and fats not for food, fodder and waste use is governed by the regulation of "251". (4) Importing oil for bio-diesel use is governed by the regulation of "255". (5) Importation of feedstuff or feedstuff additives is governed by the regulation of "404". (6) For importing good under this item without import approval document from the competent authority, is not allowed to be imported.</p>
828 ✓	<p>(一) 進口食品添加物或非食品添加物之食品原料，應依508規定辦理。(二) 進口人用藥品，應依503規定辦理。(三) 進口一般工業用油脂，應依251規定辦理。(四) 進口生質柴油用油脂，應依255規定辦理。(五) 進口飼料或飼料添加物，應依404規定辦理。(六) 進口本項貨品未取得上開主管機關輸入許可文件者，不准進口。</p> <p>(1) For importation of food additives or foods but not food additives, shall be governed by the regulation of "508". (2) Importation of medicines for human use is governed by the regulation of "503". (3) Importing industrial oils and fats not for food, fodder and waste use is governed by the regulation of "251". (4) Importing oil for bio-diesel use is governed by the regulation of "255". (5) Importation of feedstuff or feedstuff additives is governed by the regulation of "404". (6) For importing good under this item without import approval document from the competent authority, is not allowed to be imported.</p>
829	<p>(一) 進口一般工業用油脂，應依251規定辦理。(二) 進口生質柴油用油脂，應依255規定辦理。(三) 進口飼料或飼料添加物，應依404規定辦理。(四) 進口本項貨品未取得上開主管機關輸入許可文件者，不准進口。</p> <p>(1) Importing industrial oils and fats not for food, fodder and waste use is governed by</p>

輸入規定代號	規定代號內容
	the regulation of "251". (2) Importing oil for bio-diesel use is governed by the regulation of "255". (3) Importation of feedstuff or feedstuff additives is governed by the regulation of "404". (4) For importing good under this item without import approval document from the competent authority, is not allowed to be imported.
830 ✓	(一) 進口食品及相關產品，應依F 0 1辦理。(二) 進口人用藥品，應依5 0 3規定辦理。(三) 進口一般工業用油脂，應依2 5 1規定辦理。(四) 進口生質柴油用油脂，應依2 5 5規定辦理。(五) 進口本項貨品未取得上開主管機關輸入許可文件者，不准進口。 (1) Importation of foods and food-relevant products is governed by the regulation of "F01". (2) Importation of medicines for human use is governed by the regulation of "503". (3) Importing industrial oils and fats not for food, fodder and waste use is governed by the regulation of "251". (4) Importing oil for bio-diesel use is governed by the regulation of "255". (5) For importing good under this item without import approval document from the competent authority, is not allowed to be imported.
831 ✓	(一) 進口食品添加物或非食品添加物之食品原料，應依5 0 8規定辦理。(二) 進口人用藥品，應依5 0 3規定辦理。(三) 進口一般工業用油脂，應依2 5 1規定辦理。(四) 進口生質柴油用油脂，應依2 5 5規定辦理。(五) 進口本項貨品未取得上開主管機關輸入許可文件者，不准進口。 (1) For importation of food additives or foods but not food additives, shall be governed by the regulation of "508". (2) Importation of medicines for human use is governed by the regulation of "503". (3) Importing industrial oils and fats not for food, fodder and waste use is governed by the regulation of "251". (4) Importing oil for bio-diesel use is governed by the regulation of "255". (5) For importing good under this item without import approval document from the competent authority, is not allowed to be imported.
832	(一) 進口一般工業用油脂，應依2 5 1規定辦理。(二) 進口生質柴油用油脂，應依2 5 5規定辦理。(三) 進口本項貨品未取得上開主管機關輸入許可文件者，不准進口。 (1) Importing industrial oils and fats not for food, fodder and waste use is governed by the regulation of "251". (2) Importing oil for bio-diesel use is governed by the regulation of "255". (3) For importing good under this item without import approval document from the competent authority, is not allowed to be imported.
B01	進口時，應依行政院農業委員會動植物防疫檢疫局編訂之「應施檢疫動植物品目表」及有關檢疫規定辦理。 Importation shall be subject to the prescription set forth in the Table of Commodities Subject to Legal Animal & Plant Quarantine compiled by the Bureau of Animal and Plant Health Inspection and Quarantine Council of Agriculture, Executive Yuan.
C02	本項下部分商品屬於經濟部標準檢驗局公告應施進口檢驗商品。 Some of the commodities under this item subject to legal import inspection announced by the Bureau of Standards, Metrology and Inspection, ministry of economic affairs.
F01	輸入商品應依照「食品及相關產品輸入查驗辦法」規定，向衛生福利部食品藥物管理署申請辦理輸入查驗。【註：相關規定應洽衛生福利部食品藥物管理署】。 Importation of foods shall follow the "Regulations for Inspection of Imported Foods and Related Products". The importer shall apply for inspection to the Food and Drug Administration, Ministry of Health and Welfare(FDA). (Note: Please contact FDA for

輸入規定代號	規定代號內容
	relevant inspection requirements of food imports.)
F02	<p>本項下商品如屬食品或含有食品，應依照「食品及相關產品輸入查驗辦法」規定，向衛生福利部食品藥物管理署申請辦理輸入查驗。【註：相關規定應洽衛生福利部食品藥物管理署】。</p> <p>Importation of foods or the products containing foods under this item shall follow the "Regulations for Inspection of Imported Foods and Related Products " promulgated by Ministry of Health and Welfare. The importer shall apply for inspection to the Food and Drug Administration, Ministry of Health and Welfare (FDA). (Note: Please contact FDA for relevant inspection requirements of food imports.)</p>
MW0	<p>大陸物品不准輸入。</p> <p>Importation of Mainland China products is prohibited.</p>

副本

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保存年限：

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受文者：本署藥物食品檢驗局

發文日期：中華民國98年7月30日

發文字號：署授食字第0981401222號

速別：

密等及解密條件或保密期限：

附件：

主旨：有關本署96年12月19日署授食字第0961401849號公告「西藥製劑製造工廠實施國際GMP標準（PIC/S GMP）之時程」之執行配套措施，修訂如說明段，請轉知所屬會員知照。

說明：國產藥品西藥製劑製造工廠實施國際GMP標準（PIC/S GMP）之執行配套措施說明如下：

- 一、新設廠、遷移、擴建、復業、新增劑型及新增加工項目之GMP評鑑申請案，自公告日（96年12月19日）起實施。
- 二、舊有西藥製劑GMP藥廠給予緩衝期至98年12月31日止，惟：

（一）緩衝期間（96年12月19日~98年12月31日）後續查核時，因採用PIC/S GMP標準造成之差異，查廠報告中暫不列為查核缺失，而列為建議事項。

（二）緩衝期後（99年1月1日~103年12月31日），以PIC/S GMP標準進行後續GMP查核：

- 1、不符合PIC/S GMP標準部分，於查廠報告中列為查核缺失，廠商需提出改善報告，經本局審查後通過查核。

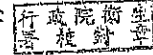
2、惟，其中若有涉及廠房、設施、設備等硬體改善之查核缺失，均暫不列為嚴重缺失，廠商並應於查廠改善報告中提出具體可行之改善計畫與時程，經藥檢局認可後，最遲須於103年12月31日前完成改善。

(三)104年1月1日起，所有西藥製劑製造工廠全面完成實施國際GMP標準（PIC/S GMP）。

三、藥品許可證之申請與展延於103年12月31日前不受影響，惟104年1月1日起產品之製造工廠未符合國際GMP標準（PIC/S GMP）者，或未檢附委託製造證明文件，或未切結不生產，則廢止該產品許可證。

正本：台灣區製藥工業同業公會、中華民國製藥發展協會、中華民國學名藥協會、社團法人中華無菌製劑協會、社團法人台灣藥物品質協會、財團法人醫藥工業技術發展中心

副本：經濟部工業局、本署藥政處、中央健康保險局、本署中醫藥委員會、本署管制藥品管理局、本署藥物食品檢驗局、財團法人醫藥品查驗中心



署長 葉金川