檔　　號：
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衛生福利部食品藥物管理署　函

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受文者：財團法人台灣優良農產品發展協會

發文日期：中華民國103年6月18日
發文字號：FDA食字第1039011935號
速別：最速件
密等及解密條件或保密期限：
附件：駐美國代表處經濟組103年6月4日經美字第10300007560號函影本乙份

主旨：函轉美國公布人類食品及動物飼料設施登記註冊之符合性政策指引供參，請轉知所屬會員如擬輸銷食品至美國者，應依據該國食品設施登記註冊(Food Facility Registration)相關規定辦理，請 查照。

說明：依據駐美國代表處經濟組103年6月4日經美字第10300007560號函（如附件）辦理。

正本：中華民國全國工業總會、中華民國全國商業總會、社團法人中華民國乳業協會、中華民國直銷協會、中華民國食油商業同業公會全國聯合會、中華民國家畜肉類商業同業公會全國聯合會、中華民國酵素食品發展協會、中華民國糕餅西點烘焙職業工會全國聯合會、中華有機與自然食品協會、台灣省冰果飲品商業同業公會、台灣省豆腐商業同業公會聯合會、台灣省食油商業同業公會聯合會、台灣區乳品工業同業公會、台灣省製麵商業同業公會聯合會、台灣區人造奶油工業同業公會、台灣省醬類[redacted]業同業公會聯合會、台灣省雜糧商業同業公會聯合會、台灣區冷凍水產工業同業公會、台灣食品發展協會、台灣區冷凍肉類工業同業公會、台灣區大麥製品工業同業公會、台灣區冷凍食品工業同業公會、台灣區植物油製煉工業同業公會.、台灣區玉米類製品工業同業公會.、台灣區紅糖工業同業公會、台灣區蜜餞工業同業公會、台灣區製冰冷凍冷藏工業同業公會、台灣區製茶工業同業公會、台灣區釀造食品工業同業公會、台灣區飲料工業同業公會、台灣省糕餅商業同業公會聯合會.、台灣罐頭食品工業同業公會、台灣食品科學技術學會、台灣食品良好作業規範發展協會、財團法人中央畜產會、財團法人中華穀類食品工業技術研究所、財團法人台灣優良農產品發展協會、財團法人食品工業發展研究所、台灣胺基酸工業同業公會、台灣省進出口商業同業公會聯合會、高雄市進出口商業同業公會、台中市進出口商業同業公會、台北市進出口商業同業公會、新北市進出口商業同業公會、台南市進出口商業同業公會、桃園縣進出口商業同業公會、宜蘭縣進出口商業同業公會、基隆市進出口商業同業公會、新竹市進出口商業同業公會、新竹縣進出口商業同業公會、苗栗縣進出口商業同業公會、台中縣進出口商業同業公會、南

投縣進出口商業同業公會、彰化縣進出口商業同業公會、雲林縣進出口商業同業公會、嘉義市進出口商業同業公會、嘉義縣進出口商業同業公會、高雄縣進出口商業同業公會、花蓮縣進出口商業同業公會、屏東縣進出口商業同業公會、台東縣進出口商業同業公會、中華民國開發性製藥研究協會、中華民國健康食品協會、中華民國營養食品協會、台灣保健食品學會、台灣食品產業發展協會、台灣區米穀工業同業公會、台灣區冷凍蔬果工業同業工會、台灣區麥粉工業同業公會、台灣製藥工業同業公會、台灣區蔬果加工工業同業公會、台灣區味精工業同業公會、台灣省商業會、中華民國製藥發展協會、台北市西藥代理商業同業公會、中華民國藥品行銷暨管理協會、中華民國西藥商業同業公會全國聯合會、中華香料協會、台灣國際生命科學會、新竹市米粉商業同業公會、台灣區麵粉工業同業公會、台灣省米穀商業同業公會聯合會、台灣糖菓餅乾麵食工業同業公會、台灣省魚類商業同業公會聯合會、台灣營養醫學推廣協會

衛生福利部食品藥物管理署校對之章

副本：

署長葉明功 出國

副署長 吳秀英 代行

本案依分層負責規定
授權組室主管決行

檔　號：
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電子公文

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受文者：衛生福利部食品藥物管理署

發文日期：中華民國103年6月4日
發文字號：經美字第10300007560號
速別：最速件
密等及解密條件或保密期限：
附件：如文(附件一 103-0756.pdf)

主旨：美國公布食品工廠及飼料工廠登記之符合性政策指引事，詳如說明，請 查照。

說明：

一、美國衛生部食品藥物管理局（FDA）於本（103）年6月3日公布「符合性政策指引」（Compliance Policy Guide）100.250節「食品設施登記-人類食品及動物飼料」，取代原「2002年公共衛生安全及生物恐怖主義防備及反應法案」110.300節之規定。

二、本次公布之「符合性政策指引」，除提供該局同仁工作指導外，並落實聯邦食品藥物及化妝品法（the FD&C Act, 21 USC 350d）第415條有關食品設施註冊規定，包括食品工廠及飼料工廠須向該局登記，已登記設施須每兩年更新登記。

三、檢附旨案有關之「符合性政策指引」100.250節資料9頁如附件，或可於https://federalregister.gov/a/2014-12786下載。各界如對本案有任何意見可向該局反應，或至http://www.regulations.gov網址提出書面評論意見。

正本：衛生福利部食品藥物管理署、行政院農業委員會畜牧處

副本：經濟部國際貿易局、行政院農業委員會國際處、行政院農業委員會動植物防疫檢疫局 [illegible]

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Contains Nonbinding Recommendations

Guidance for FDA Staff

Compliance Policy Guide
Sec. 100.250 Food Facility Registration – Human and Animal Food

Additional copies are available from:
Office of Policy and Risk Management
Office of Regulatory Affairs
Office of Global Regulatory Operations and Policy
Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857
(Tel) 240-632-6860
http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

June 2014

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction:

*The purpose of this document is to provide guidance for FDA staff on food facility registration under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d), including the requirement that certain human and animal food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The term food, when used in this document, has the meaning specified in 21 CFR 1.227(b)(4) and refers to both food for humans and food for animals.

II. Background:

Food Facility Registration

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188) amended the FD&C Act by adding section 415, which established requirements for food facilities to register with FDA. Under section 415 of the FD&C Act (21 U.S.C. 350d), the owner, operator, or agent in charge of a domestic or foreign facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States is required to register the facility with FDA, unless an exception applies (see 21

CFR 1.226 and 1.227). The term "facility" is described in section 415(c)(1) of the FD&C Act and defined by regulation in 21 CFR 1.227(b)(2). Facilities that do not have to register are listed in 21 CFR 1.226. Certain other establishments are not required to register because they do not manufacture, process, pack, or hold "food," as defined in 21 CFR 1.227(b)(4). This definition for "food" excludes food contact substances (including packaging materials), as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), and pesticides as defined in 7 U.S.C. 136(u). Thus, facilities that manufacture, process, pack, or hold only food contact substances or only pesticides are not required to register with FDA under section 415 of the FD&C Act.

A domestic facility means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures, processes, packs, or holds food for consumption in the United States (21 CFR 1.227(b)(2)(i)). A domestic food facility that is required to register must register whether or not food from that facility enters interstate commerce (21 CFR 1.225(b)). A foreign facility means a facility other than a domestic facility that manufactures, processes, packs, or holds food for consumption in the United States (21 CFR 1.227(b)(2)(ii)). Only facilities - domestic and foreign - that manufacture, process, pack or hold food for consumption in the United States are required to register with FDA under section 415 of the FD&C Act.

Under section 415(a)(2) of the FD&C Act, the registrant for a facility must notify FDA in a timely manner of changes to the facility's registration information. The failure to register a food facility in accordance with section 415 is a prohibited act under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)).

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, including the email address of the contact person for a domestic facility, the email address of the U.S. agent for a foreign facility, and an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. FSMA also amended section 415 of the FD&C Act to require food facilities to renew registrations with FDA biennially, and to provide FDA with the authority to suspend the registration of a food facility in certain circumstances, as discussed further below. Further, FSMA amended section 801(l)(1) of the FD&C Act (21 U.S.C. 381(l)) to provide that if an article of food being imported or offered for import into the United States is from a foreign facility for which a registration has not been submitted to FDA, as required by section 415 of the FD&C Act, or is from a foreign facility for which a registration has been suspended under section 415, the article must be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is registered. Unlike the requirements related to a drug or device establishment, which provide that the failure of such an establishment to register with FDA, as required under section 510 of the FD&C Act (21 U.S.C. 360), causes the drugs or devices manufactured, prepared, propagated, compounded, or processed in such an establishment to be misbranded under section 502(o) of the FD&C Act (21 U.S.C. 352(o)), and therefore subject such misbranded drugs and devices to refusal of admission under section 801(a) of the FD&C Act, the failure of a food facility to register with FDA, or the suspension of a food facility's registration, alone does not cause food manufactured, processed, packed, or held in such facility to be misbranded under the FD&C Act.

However, the failure of a food facility to register with FDA is a prohibited act under section 301(dd) of the FD&C Act (21 USC 331(dd)). In addition, as discussed elsewhere in this CPG, under section 415(b)(4) of the FD&C Act, if the registration of a food facility is suspended, no person can import or export, offer to import or export, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States. The introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act under section 301(d) of the FD&C Act. In general, the commission of a prohibited act subjects persons to enforcement actions, which may include injunction or prosecution.

FDA's guidance "What You Need to Know About Registration of Food Facilities" provides information on how to submit registration for a food facility through FDA's electronic portal at www.access.fda.gov. It also provides information on how to submit paper registration.

Biennial Registration Renewal

Section 415(a)(3) of the FD&C Act, as amended by FSMA, requires food facilities required to register with FDA to renew such registrations biennially. Specifically, section 415(a)(3) requires that, during the period beginning on October 1 and ending on December 31 of each even-numbered year, a food facility that has submitted a registration to FDA must submit to FDA a renewal registration that contains the required information specified in section 415(a)(2). A registrant that has not had any changes to the previously submitted registration information may use an abbreviated registration renewal process provided by FDA. A food facility that fails to renew its registration with FDA, as required by section 415(a)(3), has failed to register in accordance with section 415 and thereby has committed a prohibited act under section 301(dd) of the FD&C Act.

Suspension of Registration

Section 415(b) of the FD&C Act, as amended by FSMA, provides that FDA may suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Under section 415(b)(4) of the FD&C Act, as amended by FSMA, if the registration of a human or animal food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States while the suspension order for the facility is in effect. Under section 301(d) of the FD&C Act (21 U.S.C. 331(d)), the introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act. Section 801(l) of the FD&C Act, as amended by FSMA, provides, in relevant part, that an article of food being imported or offered for import into the United States that is

from a foreign facility for which a registration has been suspended under section 415 must be held at the port of entry for the article of food, and may not be delivered to the importer, owner, or consignee of the article.

III. Policy:

Food Facility Registration

FDA will enforce the registration requirements of section 415 of the FD&C Act and implementing regulations in 21 CFR part 1, subpart H as appropriate in each situation. The failure to register a food facility in accordance with section 415 is a prohibited act under section 301(dd) of the FD&C Act. FDA may consider a facility to not be registered in accordance with section 415 if:

1. The facility has not submitted a registration to FDA;
2. The facility's registration is incomplete; or
3. The facility's registration has expired because the facility failed to renew its registration.

FDA's prior notice for imported foods system is the agency's primary tool for ensuring that foreign facilities that offer food for import into the United States are registered under section 415 of the FD&C Act. (See 21 CFR 1.285 and CPG Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Response Act of 2002). If FDA determines that a foreign food facility is not registered in accordance with section 415 and 21 CFR part 1, subpart H, the food being imported or offered for import into the United States from the foreign facility is subject to being held at the port of entry (as defined in 19 CFR 101.1), in accordance with section 801(l) of the FD&C Act, unless U.S. Customs Border Protection (CBP) concurrence is obtained for the export of the food and the food is immediately exported from the port of arrival (as defined in 21 CFR 1.276(b)(11) (see 21 CFR 1.285(b)). Food held in this circumstance shall not be entered and shall not be delivered to the importer, owner, or ultimate consignee until the foreign facility is registered in accordance with section 415 and 21 CFR part 1, subpart H, and the appropriate registration number is provided in prior notice as specified in 21 CFR 1.285(i). FDA may allow the food held at the port of entry to be moved to a secure facility, as appropriate (21 CFR 1.285(c)(2)). However, FDA ordinarily will not allow the food to be transferred by any person from the port of entry into the U.S. or from the secure facility.

Biennial Registration Renewal

FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by section 415(a)(3) of the FD&C Act. Thus, if a food facility that previously submitted a registration to FDA does not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired, and will notify the registrant for the facility that the facility's registration has expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415. As previously stated in this document, the failure of a food facility to renew its registration with FDA, as required by section 415(a)(3), means that the facility has failed to register in accordance with

section 415 of the FD&C Act. Accordingly, the failure to register a food facility in accordance with section 415 is a prohibited act under section 301(dd) of the FD&C Act.

Suspension of Registration

Under section 415(b)(4) of the FD&C Act, if the registration of a food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States while the suspension order for the facility is in effect. The introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act under section 301(d) of the FD&C Act.

If a domestic facility that is subject to a registration suspension order introduces food from such facility into intrastate or interstate commerce, FDA may pursue enforcement action, such as administrative detention, seizure, injunction, mandatory recall, prosecution, or a combination of such actions, as appropriate, provided that the applicable legal requirements are satisfied.

If FDA determines that a food offered for entry into the United States is from a foreign food facility with a suspended registration, such article shall be held at the port of entry according to section 801(l) of the FD&C Act.

IV. Regulatory Action Guidance:

Food Facility Registration

The owner, operator, or agent in charge of a domestic facility, as defined in 21 CFR 1.227(b)(2)(i), must register the facility with FDA, unless exempted, as provided in 21 CFR 1.226, whether or not food from the facility enters interstate commerce. FDA anticipates that it, or a State agency acting on behalf of FDA, may discover a domestic facility's failure to be registered during a routine inspection of the facility. During an inspection, the investigator should determine whether a facility is registered and whether information in the registration is accurate and current. If the investigator identifies a registration violation, the investigator should advise the facility's management of the requirement to register or the requirement to update mandatory elements of the registration. The investigator should also provide the management with FDA's guidance, "What You Need to Know About Registration of Food Facilities." The investigator should document in the establishment inspection report the information obtained regarding the facility's registration. The investigator also should document information provided to the management of the unregistered facility regarding the registration requirements of section 415 of the FD&C Act.

The Districts have direct reference authority to issue an Untitled Letter to a domestic food facility and the Centers (CFSAN or CVM, as appropriate) may issue an Untitled Letter to a foreign or domestic food facility when the facility is required to register under section 415 of the FD&C Act, the facility has not registered, and the following conditions apply:

- The facility manufactures, processes, packs, or holds food for human or animal consumption in the U.S. and the facility is not exempt from the registration requirement;

- The establishment file documents that facility management has been advised orally or in writing that the owner, operator, or agent in charge must register the facility with FDA; and
- The office issuing the Untitled Letter has verified that the facility is not registered.

CFSAN or CVM, as appropriate, should advise the Division of Food Defense Targeting (DFDT), formerly known as the Prior Notice Center, when a foreign facility has not registered with FDA in accordance with section 415 for future shipment targeting. Articles of food from the foreign facility for which a registration has not been submitted to FDA in accordance with section 415 are subject to being held at the port of entry pursuant to section 801(l) of the FD&C Act.

Biennial Registration Renewal

CFSAN, Office of Compliance, or CVM, Office Of Surveillance and Compliance, or a District Office, as appropriate, may notify a facility that has not submitted a registration renewal to FDA, as required by section 415(a)(3) of the FD&C Act, of the requirement for biennial registration renewal. The process for notifying a food facility that has not submitted a registration renewal to FDA of the renewal requirement should be coordinated by the appropriate District Office and Center.

Suspension of Registration

The District or appropriate Center may recommend suspension of registration for a human or animal food facility based on evidence that food manufactured, processed, packed, received, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals and the facility:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability, and packed, received, or held such food. (See section 415(b) of the FD&C Act).

Suspension of a food facility's registration may be considered whenever the criteria for suspension in section 415(b) of the FD&C Act are met. Examples of circumstances in which the District or Center should give priority consideration to recommending suspension of a food facility's registration include, but are not limited to, the following:

1. Inspectional or other evidence (e.g., evidence of Class 1 recall situation or evidence of food associated with foodborne illnesses) indicates that the firm has significant violations of the FD&C Act and has not permanently corrected the source of the problem.
2. The firm is subject to a prehearing order to cease distribution and give notice under FDA's mandatory recall authority, section 423(b) of the FD&C Act (21 U.S.C. 350l(b)).
3. The firm is subject to an emergency permit order under 21 CFR part 108 or the District or Center is considering a recommendation to issue an emergency permit order to the firm.
4. The firm is a foreign facility and food from the firm is subject to an Import Alert that provides for detention without physical examination because the food may cause serious adverse health consequences or death to humans or animals.

Contains Nonbinding Recommendations

Under section 415(b)(4) of the FD&C Act, if the registration of a food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States while the suspension order for the facility is in effect. The introduction or delivery for introduction into interstate commerce of any article of food in violation of section 415 is a prohibited act under section 301(d) of the FD&C Act. While a registration suspension order is in effect for a domestic facility, the District in which the facility is located should take appropriate actions to ensure that food from the facility is not introduced into interstate or intrastate commerce in the United States.

CFSAN or CVM, as appropriate, should advise the DFDT when a registration suspension order is issued to a foreign facility for future shipment targeting. While the registration suspension order is in effect, articles of food from the foreign facility are subject to being held at the port of entry pursuant to section 801(l) of the FD&C Act.*

*Material between asterisks is new or revised."

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Revised: 11/2004, 8/2006, 6/2014