正　本

檔　　號：
保存年限：

行政院農業委員會　函

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受文者：財團法人臺灣優良農產品發展協會

發文日期：中華民國104年12月02日
發文字號：農際字第1040063133號
速別：普通件
密等及解密條件或保密期限：
附件：如文

主旨：有關美國向WTO通知其食品安全現代化法之「外國供應商查核計畫」與「第三方驗證機構之認證規則」兩項執行法規最終規則事，請查照轉知。

說明：

一、依據中華民國常駐世界貿易組織代表團104年11月25日世貿字第10400012040號函（影本如附件）辦理。

二、旨揭兩項規則完整名稱為「人類與動物食品進口商之外國供應商查核計畫（Foreign Supplier Verification Programs for Importers of Food for Humans and Animals）」（案號：FDA-2011-N-0143）與「稽核與核發食品安全證明第三方驗證機構之認證規則（Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications）」（案號：FDA-2011-N-0146），相關實施摘要及豁免食品清單詳如附件說明，請轉知所轄會員廠商參考。

收文 104年 12月 4日 9:50
優農字第1040003325號

正本：中華民國農會、中華民國全國漁會、中華民國對外貿易發展協會、財團法人臺灣優良農產品發展協會、臺灣蔬果輸出業同業公會、臺灣區冷凍蔬果工業同業公會、臺灣區冷凍食品工業同業公會、臺灣糖果餅乾麵食工業同業公會、臺灣區米穀工業同業公會、臺灣罐頭食品工業同業公會、財團法人中央畜產會、臺灣區製茶工業同業公會、臺灣區茶輸出業同業公會、臺灣省茶商業同業聯合會、臺灣精緻農業外貿發展協會、財團法人台灣區花卉發展協會、臺灣區冷凍水產工業同業公會、中華民國水產種苗協會、台灣區鰻蝦輸出業同業公會、台灣區鰻魚發展基金會

副本：本會漁業署、本會畜牧處(均含附件)

主任委員 陳保基 公出

副主任委員 陳志清 代行

本案依照分層負責授權單位主管決行

檔　　號：
保存年限：

中華民國常駐世界貿易組織代表團　函

地址：Avenue de Tournay 7, 1292 Chambesy, Geneva, Switzerland
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受文者：行政院農業委員會

發文日期：中華民國104年11月25日
發文字號：世貿字第10400012040號
速別：普通件
密等及解密條件或保密期限：
附件：附件1.pdf、附件2.pdf

主旨：有關美國向WTO通知其食品安全現代化法之「外國供應商查核計畫」與「第三方驗證機構之認證規則」兩項執行法規最終規則事，詳如說明，請　查照。

說明：

一、依據WTO本（104）年11月16日G/SPS/N/USA/2569/Add.3（附件1）及G/SPS/N/USA/2570/Add.4（附件2）通知文件辦理。

二、旨揭兩項規則完整名稱為「人類與動物食品進口商之外國供應商查核計畫（Foreign Supplier Verification Programs for Importers of Food for Humans and Animals）」（案號：FDA-2011-N-0143）與「稽核與核發食品安全證明第三方驗證機構之認證規則（Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications）」（案號：FDA-2011-N-0146）。

三、「外國供應商查核計畫（FSVP）」重點摘要如下：

(一)進口商定義：美國境內進口食品之業者或承銷商，或外國業主在美國之代理商或代表人。

(二)進口商有責任查核外國供應商提供之食品，與美國國內生產食品達到相同公衛保護水準，並確認食品未經攙假或標示錯誤。

(三)進口商須擬與執行「外國供應商查核計畫」，計畫內容應包括危害分析、食品風險估算、供應商表現評量與查廠確認、矯正行動、至少每三年複評一次與紀錄保存等。

(四)豁免食品：符合危害分析與重要管制點（HACCP）規定工廠生產之果汁與水產品、供研究或評估用途食品、供個人使用食品、酒精飲料、進口後再加工出口食品、低酸性罐頭食品、由美國農業部管理之進口肉品、禽肉與蛋產品。

(五)企業協助：美國食品藥物管理局（FDA）將制定FSVP準則供進口商參考，及與教育訓練機構合作提供訓練與技術協助。

(六)進口商符合規則期程如下：

1、最終法規公布後18個月。

2、倘自須符合「食品預防控制規則」或「農產品生產安全規則」之供應商進口食品，進口商須於供應商應符合前述規則後6個月符合FSVP。

3、倘進口商亦屬「食品預防控制規則」供應鏈計畫條款規定之製造廠或加工廠，應自須符合該規定時符合FSVP。

四、「第三方驗證機構之認證規則」重點摘要如下：

(一)美國FDA將認可認證機構（accreditation bodies），由其認證第三方驗證機構（third-party certification bodies），執行外國食品廠之食品安全稽核並核發證明書，以符合美國食品安全現代化法。

(二)認證機構得為外國政府機關或私營企業，負責評量第三方驗證機構表現，並對FDA提交通知與報告。

(三)第三方驗證機構得為外國政府機關、私營企業或個人，負責稽核外國食品廠生產安全食品（包括動物食品）、核發證明書、評估與矯正問題、保存紀錄供FDA查詢。

(四)外國食品廠獲得證明書後，可交由進口商參加「自願性合格進口商計畫（Voluntary Qualified Importer Program）」，獲得進口食品快速通關審查優惠。

(五)為避免進口食品可能危害消費者健康，FDA得在特殊情形下要求進口食品應檢附第三方驗證機構核發之證明。

(六)豁免食品：酒精飲料及美國農業部管理之進口肉品、禽肉與蛋產品。

(七)執行期程：FDA將於「認證標準範本準則（Model Accreditation Standards Guidance）」與費用規則定案後儘速執行，第三方驗證機構得於FDA開始認可認證機構後申請認證作業。

正本：行政院農業委員會動植物防疫檢疫局
副本：外交部、行政院農業委員會、行政院農業委員會農糧署、衛生福利部、衛生福利部食品藥物管理署、經濟部標準檢驗局、經濟部國際貿易局、經濟部經貿談判代表辦公室、駐美國代表處經濟組 電子公文交換章 2015-11-26 08:59:29

裝 訂 線

WORLD TRADE ORGANIZATION

G/SPS/N/USA/2569/Add.3

16 November 2015

(15-6047)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 16 November 2015, is being circulated at the request of the Delegation of the United States of America.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Final Rule

The Food and Drug Administration (FDA) is adopting a regulation on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. The regulation requires importers to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. FDA is issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA). The regulation will help ensure the safety of imported food.

The text of the final rule can be found on the US Federal Register website at: https://federalregister.gov/a/2015-28158.

http://members.wto.org/crnattachments/2015/SPS/USA/15_4583_00_e.pdf

This addendum concerns a:

[ ] Modification of final date for comments
[**X**] Notification of adoption, publication or entry into force of regulation
[ ] Modification of content and/or scope of previously notified draft regulation
[ ] Withdrawal of proposed regulation
[ ] Change in proposed date of adoption, publication or date of entry into force
[ ] Other:

Comment period: ***(If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)***

[ ] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: Not applicable. This is a final rule.

Agency or authority designated to handle comments: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

For further information contact: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301 796 4614; or Domenic Veneziano, Office of Enforcement and Import Operations (ELEM-3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 301 796 6673

Text(s) available from: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: us.spsenquirypoint@fas.usda.gov

Text can also be found on the US Federal Register website at: https://federalregister.gov/a/2015-28158.

WORLD TRADE ORGANIZATION

G/SPS/N/USA/2570/Add.4

16 November 2015

(15-6049)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 16 November 2015, is being circulated at the request of the Delegation of the United States of America.

Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications; Final Rule

The Food and Drug Administration (FDA) is adopting regulations to provide for accreditation of third-party certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications, under the FDA Food Safety Modernization Act (FSMA). These certifications will be required for participation in the voluntary qualified importer program (VQIP) established under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, when FDA has determined that an imported food is subject to certification under FSMA, FDA may require a certification under this rule as a condition for admitting the food into the United States. FDA also expects that these regulations will increase efficiency by reducing the number of redundant food safety audits.

The text of the final rule can be found on the US Federal Register website at: https://federalregister.gov/a/2015-28160.

http://members.wto.org/crnattachments/2015/SPS/USA/15_4584_00_e.pdf

This addendum concerns a:

[ ] Modification of final date for comments
[**X**] Notification of adoption, publication or entry into force of regulation
[ ] Modification of content and/or scope of previously notified draft regulation
[ ] Withdrawal of proposed regulation
[ ] Change in proposed date of adoption, publication or date of entry into force
[ ] Other:

Comment period: ***(If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)***

[ ] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: Not applicable. This is a final rule.

Agency or authority designated to handle comments: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

For further information contact: Charlotte A. Christin, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301 796 7526

Text(s) available from: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: us.spsenquirypoint@fas.usda.gov

Text can also be found on the US Federal Register website at: https://federalregister.gov/a/2015-28160.