檔　　號：
保存年限：

正本

衛生福利部食品藥物管理署　函

機關地址：11561 臺北市南港區昆陽街161-2號
傳　　真：02-26531062
聯絡人及電話：楊小姐　02-27877351
電子郵件信箱：yyc1205@fda.gov.tw

10452
台北市民權東路一段67號5樓

受文者：中華民國藥師公會全國聯合會

發文日期：中華民國105年9月20日
發文字號：FDA食字第1051303344號
速別：
密等及解密條件或保密期限：
附件：駐美國代表處經濟組105年8月26日經美字第10500008940號函影本1份

主旨：函轉我駐美國代表處經濟組提供有關美國食品藥物管理署要求食品廠商擬訂「食品安全計畫」事，請貴單位協助轉知所屬會員周知，請查照。

說明：依據駐美國代表處經濟組105年8月26日經美字第10500008940號函（影本如附件）辦理。

正本：中華民國藥師公會全國聯合會
副本：

署長 姜郁美

RECEIVED 2016/08/27 06:03

檔號	/	保存年限	
	/ /		

駐美國代表處經濟組 函

機關地址：4301 Connecticut Ave. NW #420 Washington DC 20008 USA
承 辦 人：徐秘書崇欽
聯絡電話：(202)6866400
電子郵件：tchsu@moea.gov.tw

受文者：

發文日期：中華民國 105 年 8 月 26 日
發文字號：經美字第 10500008940號
速別：最速件
密等及解密條件或保密期限：普通
附件：如文(894.pdf)

收 105.8.29 文

食品藥物管理署 1059905621

主旨：有關美國食品藥物管理署(U.S. Food and Drug Administration,簡稱 FDA)要求食品廠商擬訂「食品安全計畫」事，詳如說明，請查照參辦。

說明：

一、查本(105)年 8 月 19 日媒體報導「業者賣食品到美國，要先提食安計畫」(網址http://udn.com/news/story/7600/1905218)，文中提及曾任美國 FDA 副署長之 Mr. David Acheson 訪臺，表示美國食品安全現代化法(Food Safety Modernization Act, FSMA)將於下(9)月實施，其中「食品安全計畫」相關條文，要求絕大多數國內外食品廠商都須擬訂食安計畫，展現挖掘、控管及評估風險能力，並隨時修正錯誤，才能在美販售。

二、為進一步瞭解前述 FSMA 相關內容，本組於 8 月 18 日洽請 Akin Gump 法律事務所研析提供相關資訊，並頃於 8 月 25 日獲復如次：

RECEIVED 2016/08/27 06:03

(一)「食品安全計畫(Food Safety Plan)」是否為美方法案正式用語：FSMA 本身並未使用該語辭，該用詞出現於執行該法律之行政規則（共 262 頁，檔案較大，請洽本組承辦人另電郵提供），該行政規則要求涵括的食品廠商(covered facilities)建立並執行一食品安全系統，此系統包括對風險之分析(hazard anlalysis)及預防管控(risk-based preventive control)，此食品安全系統必須包括書面之「食品安全計畫」。

(二)廠商需具備「食品安全計畫」之實施期程：(1)對於每年食品營業額在 1 百萬美元以下之微型企業(Very Small Business)，應在前述行政規則於 2015 年 9 月 17 日公布後之 3 年內（即 2018 年 9 月 17 日之前）具備食安計畫；(2)對同時受到殺菌乳條例(Pasteurized Milk Ordinance)規範之廠商，亦為前述行政規則公布後 3 年；(3)雇用人數少於 500 名全職員工之小型企業(Small Business)，應在公布後之 2 年內（即 2017 年 9 月 18 日之前）具備食安計畫；(4)所有其他企業：應在公布後 1 年內，即本(2016)年 9 月 19 日前備齊。<u>但對於位處供應鏈下游之食品廠商，則另訂有實施期程</u>：(1)上游供應商不受人為預防管控(human preventive control)或農產品安全(produce safety)規範且下游廠商(Receiving Facility)屬小型企業時，該下游廠商應在公布後之 2 年內（即 2017 年 9 月 18 日之前）具備食安計畫；(2)上游供應商受人為預防控制或農產品安全規範且下

RECEIVED 2016/08/27 06:03

游廠商屬小型企業時，該下游廠商應在公布後之 2 年內（即 2017 年 9 月 18 日之前）或其上游廠商遵守本行政規則最終期限後 6 個月內，具備食安計畫；(3)上游供應商不受人為預防控制或農產品安全規範且下游廠商非屬微型或小型企業時，該下游廠商應在公布後之 18 個月內具備食安計畫；(4) 上游供應商受人為預防控制或農產品安全規範且下游廠商非屬微小或小型企業時，該下游廠商應在其上游廠商遵守本行政規則最終期限後 6 個月內，具備食安計畫。

(三)FDA 提供擬具「食品安全計畫」之指引：前述行政規則已包括 FDA 對於廠商擬具食安計畫時應備要點之看法。此外，FDA 在相關法規中亦提及書面計畫內容應包括：(1)風險分析(hazard analysis)；(2)預防管控(preventative controls)；(3)供應鏈計畫(supply-chain program)；(4)回收計畫(recall plan)；(5)監控執行預防管控措施之程序(procedures for monitoring the implementation of the preventative controls)；(6)矯正行動之程序(corrective action procedures)；及(7)驗證程序(verification procedures)。前述食安計畫之各項重點亦包括保存紀錄之義務(recordkeeping obligations)，這些紀錄必須以原始、真實或電子紀錄方式保存，必須包括在監督及驗證時實際觀察之數值及內容，必須正確、不可磨滅且清晰，必須在行動當時即紀錄，且必須詳細至足以提供已執行工作之歷程資料。此外，相關

RECEIVED 2016/08/27 06:03

紀錄必須包括足以指認工廠之資訊(例如名稱及地址)、相關行動執行之日期及時間、執行者之簽名及產品之身分資訊或批號。FDA 另設有關於 FSMA 法案之常見問答網頁供各界參考(網址為 http://www.fda.gov/food/GuidanceRegulation/FSMA/ucm247559.htm)。其中針對請 FDA 提供食安計畫範本(template)之要求，FDA 表示拒絕，認為廠商可就如何撰寫食安計畫保有彈性，只要該計畫具備行政規則中要求之所有資訊即可(a facility has flexibility to format its food safety plan in a way that works best for the facility, provided that the plan includes all required information)。

(四)向 FDA 提交食安計畫之步驟：根據 FDA 公布之行政規則，廠商必須準備並執行食品安全書面計畫，但並未被要求需向 FDA 提交該計畫。此外，所謂「書面(written)」計畫可以是紙本或電子文件，至於紀錄保存(recordkeepting)，倘現場可以經由電子方式取得(accessible from an onsite location)紀錄，視為已符合現場需保存紀錄之要求。

(五)FDA 如何檢查廠商是否執行食安計畫：如前所述，廠商無須向 FDA 提交食安計畫，但必須按照 FDA 要求保存書面食安計畫及相關執行紀錄，當 FDA 進行檢查(inspection)或潛在食品安全議題產生時，FDA 可要求查核前述計畫及執行紀錄。FSMA 賦予 FDA 更多檢查食品廠商之權力，當

FDA 合理相信食品摻假或有嚴重健康威脅，或有合理機率顯示使用或接觸某食品可能導致嚴重健康威脅時，FDA 可要求查看相關執行紀錄。

(六)廠商逾期未實施食安計畫之後果：由於食安計畫無須提交，FDA 不會立即得知廠商逾期未實施該計畫，惟廠商倘缺乏食安計畫，則 FDA 檢查時將發現並可能強化相關執法作為。故建議廠商：(1)牢記 FSMA 有關保存紀錄之要求並持續執行；(2)擬具書面食安計畫並切實執行；(3)指定專人或團隊進行內部檢查(inspection)，特別著眼於記錄之取得(access to records)。

三、檢附 Akin Gump 法律事務所提供之研析資訊如附件，併請卓參並惠轉相關食品公協會參考。

正本：衛生福利部食品藥物管理署、經濟部國際貿易局

副本：經濟部王次長室、經濟部國際貿易局局長室、經濟部國際貿易局徐副局長室（均含附件）

駐美國代表處經濟組

RE: (Ref No: 1050818A03): Inquiry about "food safety plan" in the FDA's Food Safety Modernization Act (FSMA)

Liu, Cynthia <liuc@akingump.com>

週四 2016/8/25 19:07

收件者:徐崇欽 <tchsu@moea.gov.tw>;

副本: Rado Wang <cywang1@moea.gov.tw>; 楊 組長 淑媚 <smyang1@moea.gov.tw>; smyang2816@gmail.com <smyang2816@gmail.com>; williamliu0427@gmail.com <williamliu0427@gmail.com>; Kho, Stephen <skho@akingump.com>;

1 個附件

FDA-2011-N-0920-1979.pdf;

Dear Ben,

We provide our responses to your questions regarding the Food Safety Modernization Act (FSMA) below. Please let us know if you have any further questions.

Best,
Steve and Cynthia
++

(1) Is the "food safety plan" the official term used in the FSMA?

a. *"Food safety plan" is not referenced explicitly in the Food Safety Modernization Act (FSMA).* Instead, it is mandated by the FSMA Final Rule for Preventative Controls for Human Food (September 2015) – a rule promulgating regulations that implement the statute. The Final Rule is attached. As you know, the Final Rule requires that covered facilities establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. This food safety system must include a written food safety plan. The requirements for such plans are now finalized as regulations at 21 C.F.R. section 117.126 (Food safety plan).

(2) What is the implementation timeline for the "food safety plan"?

a. Compliance Dates
   i. Compliance dates for businesses are staggered over several years after publication of the Final Rule (published in 2015).
      1. Very small businesses (averaging less than $1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years,

except for records to support its status as a very small business (January 1, 2016).

2. Businesses subject to the Pasteurized Milk Ordinance (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years
3. Small businesses (a business with fewer than 500 full-time equivalent employees): Two years
4. All other businesses: One year

ii. Compliance dates after publication of the final rule for the requirements of the supply chain program (The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for human food rule or the produce safety rule.) --

1. Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule: Two years
2. Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule: Two years or six months after the supplier is required to comply with the applicable rule, whichever is later
3. Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule: 18 months
4. Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule: Six months after the supplier is required to comply with the applicable rule

(3) Is there a guideline or guidance provided by the FDA for food producers/facilities to create a plan?

a. The Final Rule, attached, provides context regarding FDA's thinking for facilities required to create a food safety plan.
b. Additionally, FDA regulations at 21 C.F.R. 117.126 require that the food safety plan contain the following elements, detailed further in specifically referenced regulations:
   i. The written hazard analysis, as required by 21 C.F.R. 117.130(a)(2);
   ii. The written preventative controls as required by 21 C.F.R. 117.135(b);
   iii. The written supply-chain program as required by 21 C.F.R. 507.105;
   iv. The written recall plan as required by 21 C.F.R. 117.139(a);
   v. The written procedures for monitoring the implementation of the preventative controls as required by 21 C.F.R. 117.145(a)(1);
   vi. The written corrective action procedures as required by 21 C.F.R. 117.150(a)(1); and
   vii. The written verification procedures as required by 21 C.F.R. 117.165(b).
c. Each element of the food safety plan has additional recordkeeping obligations, outlined below. Please refer to FDA regulations for detailed recordkeeping requirements.
   i. Implementation Records Required for Food Safety Plan:

1. Documentation of the basis for not establishing a preventive control (21 C.F.R. 117.136(a));
2. Records that document the monitoring of preventive controls;
3. Records that document corrective actions;
4. Records that document verification, including, as applicable:
    a. Validation;
    b. Verification of monitoring;
    c. Verification of corrective actions;
    d. Calibration of process monitoring and verification instruments;
    e. Product testing;
    f. Environmental monitoring;
    g. Records review; and
    h. Reanalysis;
5. Records that document the supply chain program; and
6. Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

ii. Requirements that Apply to Records (Subpart F, 21 C.F.R. 117.301-.335)

1. Records must:
    a. Be kept as original records, true copies or electronic records
    b. Contain the actual values and observations obtained during monitoring and, if appropriate, during verification activities
    c. Be accurate, indelible and legible
    d. Be created concurrently with performance of the activity documented
    e. Be as detailed as necessary to provide history of work performed
2. Records must include:
    a. Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);
    b. The date and, when appropriate, the time of the activity documented;
    c. The signature or initials of the person performing the activity; and
    d. Where appropriate, the identity of the product and the lot code, if any.

d. FDA's website has an FAQ page, "Frequently Asked Questions on FSMA," which addresses food safety plans (albeit briefly). Pursuant to that guidance, a facility must reanalyze the food safety plan as a whole at least once every three years. The facility must also review portions of the food safety plan under certain circumstances, such as when a preventive control is found to be ineffective.

e. Although some comments to the Final Rule asked FDA to provide templates that facilities can use as models to develop their food safety plans, FDA declined to do so. The Final Rule and FDA regulations do not specify the format of a food safety plan, and FDA in the Final Rule notes that "a facility has flexibility to format its food safety plan in a way that works best for the facility, provided that the plan includes all required information." 80 Fed. Reg. 56022.

(4) What are the steps to submit the plan to the FDA?

a. Covered facilities must "prepare, or have prepared, and implement a written food safety plan." 21 C.F.R. 117.126. Notably, the regulations do not require that the plan be submitted to FDA.

b. Although FDA contemplated requiring facilities to submit a "facility profile" to FDA, which would cover a subset of the information in a food safety plan, the agency ultimately declined to require this submission for a number of reasons. *See* 80 Fed. Reg. 56025.
c. According to the Final Rule, a "written" food safety plan can be either a paper document or an electronic document, as provided by 21 C.F.R. 117.305(a). As provided in the recordkeeping provisions of applicable FDA regulations, electronic records are considered to be onsite if they are accessible from an onsite location.

(5) Will there be check-ups on food producers/facilities after the submission of their plan?

a. As noted above, plans do not need to be formally submitted to FDA. That said, food safety plans are considered "records" that are subject to FSMA recordkeeping requirements, and would be reviewed by FDA during an inspection or when a potential food safety issue arises.
b. FSMA mandates increased inspections of food facilities, and FDA will have increased access to records during routine inspections.
    i. FDA can now access records in 2 ways:
        1. If FDA reasonably believes the food is adulterated and presents a serious adverse health consequence or death, or
        2. If there is a reasonable probability that use of, or exposure to, food would cause a serious adverse health consequence or death.

(6) What consequences, if any, are there if producers/facilities miss the deadline?

a. Because the food safety plan is not required to be submitted to FDA, the agency would not be aware of failure to comply immediately. That said, FDA would become aware upon inspection of the facility, and the potential enforcement actions against the facility would be much greater if the facility lacked a comprehensive plan.
b. The best practices for a food safety system, in short, follow:
    i. Keep in mind FSMA's recordkeeping requirements, and manage them continuously.
    ii. Have a written food safety policy, and follow it.
    iii. Designate a response person or team for inspections, with an eye toward access to records.

From: 徐崇欽 [mailto:tchsu@moea.gov.tw]
Sent: Thursday, August 18, 2016 14:36
To: Liu, Cynthia
Cc: Rado Wang; 楊 組長 淑媚; smyang2816@gmail.com; williamliu0427@gmail.com
Subject: (Ref No: 1050818A03): Inquiry about "food safety plan" in the FDA's Food Safety Modernization Act (FSMA)

Ref Number of this case: 1050818A03

寄件者: 徐崇欽
寄件日期: 2016年8月18日 14:33
收件者: liuc@akingump.com

副本: Rado Wang; 楊 組長 淑媚; smyang2816@gmail.com; williamliu0427@gmail.com
主旨: Inquiry about "food safety plan" in the FDA's Food Safety Modernization Act (FSMA)

Dear Cynthia,

Recently a former FDA official Mr. David Acheson visited Taiwan. There, he mentioned that the FDA has plans to implement the Food Safety Modernization Act (FSMA) in September 2016. Among the new regulations in FSMA, one important new element is the requirement of the "food safety plan" for all incumbent and foreign food producers who sell food in the U.S. market.

From the FDA website, we have found the following information:

(1) http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

> "Key Requirements
>
> 1. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:..."

(2) http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm256826.htm

> "For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across all food supplies. This mandate includes:
> • Mandatory preventive controls for food facilities: Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise. (Final rule due 18 months following enactment)"

We would like to seek your help with the following inquiries:

(1) Is the "food safety plan" the official term used in the FSMA?
(2) What is the implementation timeline for the "food safety plan"?
(3) Is there a guideline or guidance provided by the FDA for food producers/facilities to create a plan?
(4) What are the steps to submit the plan to the FDA?
(5) Will there be check-ups on food producers/facilities after the submission of their plan?
(6) What consequences, if any, are there if producers/facilities miss the deadline?

We look forward to your reply by Aug 25. If there is any difficulty, please let us know.

Best regards,
Ben

Benjamin T.C. Hsu
Senior Executive Officer
Economic Division, Taipei Economic and Cultural Representative Office in the United States (TECRO)
4301 Connecticut Ave, NW, Suite 420
Washington, DC 20008
Office tel: (202)686-6400 ext. 106
Fax: (202)363-6294