



Sweeping Overhaul of FDA Regulation of Food Industry Promises New Challenges

By Fern P. O'Brian and Eric Daniel of Thompson Hine LLP. Reprinted with permission.

The Thanksgiving feast may be over, but food is still on Congress' agenda. The United States Senate voted overwhelmingly in favor of the FDA Food and Safety Modernization Act ("FSMA" or "the Act") this week, and the House of Representatives is expected to follow suit - granting the Food and Drug Administration ("FDA") broad authority to monitor food production to prevent food-borne illnesses and to respond more effectively to any outbreaks that do occur.

The Act applies to producers and/or distributors of domestic and imported food products, but does not cover restaurants, which are regulated on a state or local basis, nor producers of meat and poultry, which are regulated by the USDA. Enacted in response to a string of outbreaks of food-borne illnesses involving eggs, lettuce, peanut butter, and spinach, the FMSA is designed to improve the FDA's ability to prevent, detect, and respond to food safety problems and to improve the safety of imported food. The Act empowers the FDA with increased oversight authority of facilities to prevent food contamination and the power to minimize the damage

when tainted food enters the stream of commerce.

Since these changes will be implemented pursuant to the Federal Food, Drug, and Cosmetic Act, violation of the proposed rules will carry the risk of civil penalties and imprisonment. Thus, the FDA not only will have the directive to make the food industry safer, they also will have the power to severely penalize those who violate the Act. Some of the key provisions in the Act are as follows:

- ◆ **Mandatory Recalls.** A substantial provision under the Act gives FDA power to initiate a mandatory recall if it determines that a food facility has sold tainted food products and the company fails voluntarily to recall the foods at the FDA's request. Thus, while FDA previously could only recommend that a company implement a voluntary recall, now it has the authority to ensure that the recall actually occurs.
- ◆ **Inspections.** The Act mandates an increase in the number of FDA inspections

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[www.http://www.hamilton-co.org/cinlawlib/](http://www.hamilton-co.org/cinlawlib/)

Tech Tip: Edit PDF documents now with a free PDF editor

By Julie Koehne, Systems Librarian

Download PDF-XChange 4 Lite!

Go to http://www.tracker-software.com/free_lite_home.html

The screenshot shows the Tracker Software Products website. At the top, there is a navigation bar with links for Home, Buy Now, Support, Developers, and Resellers. Below this is a search bar and a list of site sections including Home, Products, Downloads, Company, Knowledgebase, Tracker Clients, My Account, and Site Search. The main content area features a large blue starburst graphic that says "LIMITED TIME OFFER!". To the right of the starburst, text explains the offer: "If you are a Home or Academic user - for a limited time we are offering PDF-XChange Lite for FREE - no strings or catches, the only restriction being you must not use for business or commercial use in any way - so now all home users/students have access to a truly robust, 'industrial' strength PDF creation tool, for use with any Windows application - just open a document and 'Print' to PDF-XChange Lite to create your PDF documents!". Below this, it states "No other purchase necessary." and "You can download this directly by [clicking here](#) and unzip/install to your system!". Further down, there is a paragraph describing PDF-XChange 'Lite' as a simplified version of the Standard print driver. At the bottom left, there is a copyright notice: "© 1997 - 2010 Tracker Software Products".

Once you install the software the following icon will be available. Open the viewer first and then the PDF document and you can start editing.



The screenshot shows the PDF-XChange Viewer application window. The title bar reads "Motion for payment of Counsel fees* - PDF-XChange Viewer". The menu bar includes File, Edit, View, Document, Comments, Tools, Window, and Help. The toolbar contains various icons for file operations, navigation, and editing. A red arrow points from a text box to the "Typewriter" tool icon in the toolbar. The main document area displays a PDF form titled "MOTION, ENTRY, AND CERTIFICATION FOR APPOINTED COUNSEL FEES". The form includes fields for "In the", "Court of Hamilton County, Ohio", "Case No.", "Appellate Case No.", "Jim Shoe", "Party Represented", and "Judge:". Below the main form, there is another section titled "MOTION FOR APPROVAL OF PAYMENT OF APPOINTED COUNSEL FEES AND EXPENSES" with a paragraph of text.

By using the Typewriter feature you will now be able to fill in PDF's and save them with data for FREE!

Announcement: Special Meeting of the Membership, Cincinnati Law Library Association

Cathy R. Cook, President of the Cincinnati Law Library Association, announces that the Association will hold a special meeting of its membership for the purpose of considering modifications to its Amended Articles of Incorporation and its Regulations. The meeting will take place Thursday, January 6, 2011 at 12:00 noon in the Hon. Robert S. Kraft Board Room of the Law Library.

The proposed changes to the Articles and Regulations may be viewed [at http://www.hamilton-co.org/cinlawlib/images/CLLA_Articles_proposed_changes.pdf](http://www.hamilton-co.org/cinlawlib/images/CLLA_Articles_proposed_changes.pdf) and http://www.hamilton-co.org/cinlawlib/images/regulations_proposed_changes.pdf or upon request of the Law Librarian.

The proposed changes were reviewed and approved by the Board of Trustees of the Cincinnati Law Library Association at its December 2, 2010 meeting for presentation to the membership.

The Board of Trustees' chief interest in proposing these modifications is to update the documents to reflect the statutory change in library governance that took effect January 1, 2010. Most fundamentally, the new law shifted law library governance from the Association to the County Law Library Resources Board. Therefore, wording about the Association's role in governing the library is no longer relevant. Further, since membership no longer provides the benefit of law library privileges (a benefit now associated with annual subscriber fees paid to the law library directly), changes regarding membership and use were also needed. While the Association will retain its nonprofit status should these modifications be approved, it would be considered a private foundation rather than a public charity going forward.

The Association's regulations identify members as those people who have paid dues as set by the Trustees. For the purposes of notification and voting at the January 2011 special meeting, the membership consists of those people who were members as of December 31, 2009. If you were a law library member in 2009, you are a voting member for purposes of this meeting.

If you have questions about the proposed changes, please contact an officer of the Board of Trustees: Cathy R. Cook, Stephen L. Black, or Mary Ann Jacobs, for more information. The Law Librarian, [Mary Jenkins](mailto:MJenkins@cms.hamilton-co.org), also has copies of the current and proposed changes.

If you plan to attend, please notify the Law Library in advance at 513.946.5300 or masweeney@cms.hamilton-co.org so that we may plan accordingly for seats and lunch.

Subscriber Renewals

All current subscribers should have received an invoice in December for 2011 subscriber fees. If you haven't seen yours or cannot find it, please contact Mary Ann Sweeney, library assistant, at 513.946.5300 or masweeney@cms.hamilton-co.org for another copy. Your timely payment will ensure your continued access to legal information resources and services including newsletters and news updates, borrowing privileges, CLE attendance, document delivery, and more. We'll send out second notices in late January. Privileges are revoked if payment is not received by late February.

at United States food facilities, and more frequent inspections at facilities with known safety risks. For high-risk facilities (which will be identified based on several factors, including the known safety risks of the facility's food, the facility's compliance history with regard to past food safety violations, and the rigor and effectiveness of the facility's efforts to prevent food-borne illness), FDA will conduct an inspection within five years of the Act's enactment and at least one inspection every three years thereafter. For facilities that are not determined to be high-risk, FDA will conduct one inspection within the first seven years after the Act's enactment and at least one inspection every five years thereafter. In addition, the Act mandates an increase in the number of inspections at foreign food facilities. Specifically, it accounts for a ramp-up of foreign facility inspections from 600 total inspections in the first year following the Act's enactment to nearly 20,000 such inspections by the end the sixth year following the Act's enactment. The FDA's inspection authority under the Act, both foreign and domestic, represents a dramatic increase from the FDA's current authority.

- ◆ Hazard Analysis. Facilities will be required to identify and cure reasonably foreseeable food safety hazards by creating and executing food safety plans aimed at preventing food safety hazards. FDA will have access to such plans and could require facilities to revise the plans if determined to be ineffective at eliminating food safety hazards.
- ◆ Imported Food. In an effort to hold foreign suppliers accountable under the same standards applicable to United States facilities, food importers will be required to verify the safety of foreign suppliers and imported food. Moreover, FDA may require certification before food produced by high-risk facilities can enter the country and also may bar entry of food that originated from a foreign facility that refused United States inspectors.

- ◆ Traceability. The Act will increase efforts to track and trace high-risk foods (a list of "high-risk" foods will be created within one year of the Act's enactment, and will be based on several factors, including known safety risks of a particular food, likelihood of contamination, likelihood that consumption of a contaminated food will result in a food-borne illness, and likely severity of a food-borne illness attributed to that food). To establish tracking and tracing guidelines, the Act mandates the creation of a pilot project in coordination with the food industry to explore methods to rapidly and effectively identify recipients and producers of contaminated foods. These provisions are designed to streamline the recall process by eliminating unnecessary products and companies from recalls.
- ◆ Suspension of Registration. If FDA determines that a facility harbors food that is reasonably likely to cause serious adverse health consequences or death, the FDA may suspend the facility's registration. As a result, the facility would be forbidden from distributing the food in the United States.
- ◆ Whistleblower Protection. A facility may not discharge or otherwise discriminate against an employee based on that employee's reporting of a violation under the Act. If a facility does so, the Act provides legal protection and enables the employee to seek civil relief. Ultimately, if the employee proves that he was terminated due to his involvement in reporting a violation under the Act, he will be entitled to reinstatement, back pay with interest, and compensation for special damages. If reinstatement is unavailable or impractical, the discharged employee may be entitled to front pay.

The new regulations that will implement the Act are widely anticipated to affect most aspects of food production. Food producers would be well advised to monitor the regula-

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tory process and address the impact on their businesses, which could result in a substantial financial burden. In anticipation of increased oversight from the FDA, food producers should look at their food production processes to determine whether their food is likely to be viewed as "high-risk" and whether any additional steps should be taken to ensure that the food they produce is safe. This introspective approach particularly is important for food producers that are part of one of the industries that has experienced recalled food in the last few years. Finally, food producers should consider the steps that they should take to ease the transition to what promises to be a more inspection-oriented industry.

For More Information:

Please contact Elizabeth B. Wright, Fern P. O'Brian, or Kip T. Bollin or any member of Thompson Hine's Product Liability Litigation practice group for more information.

New Acquisitions

In addition to many new titles in BNA's Tax Management Portfolio series, we've added these items (and more) to the collection recently. We'll be glad to hold a book for you to pick up.

To view all new acquisitions in the Law Library's catalog (<http://www.hamilton-co.org/cinlawlib/catalog/>), click on Lists and then New Titles at the top of the screen.

Advanced workers' compensation [in Ohio]
 BOOT CAMP : foreclosure and loan workout procedures [in Ohio]
 Collier bankruptcy manual
 Corporate legal compliance handbook
 Courting your clients : the essential guide to legal marketing
 Criminal practice and procedure [Kentucky]
 Dirty litigation tactics : how to deal with the "Rambo" litigator [in Ohio]

Discovery strategy : finding the smoking gun [in Ohio]
 Electronic discovery and records management guide : rules, checklists, and forms.
 Employee benefits and executive compensation in corporate bankruptcy : a Collier monograph
 Employer's guide to health care reform
 Employment discrimination law
 The Fair Labor Standards Act
 The five types of legal argument
 Giannelli evidence [Ohio]
 Government contract guidebook
 HDR handbook of housing and development law.
 Health law practice guide
 Indiana model civil jury instructions.
 Indiana trial evidence manual
 Introduction to the United States District Court : Northern District of Ohio
 Kentucky business organizations laws & rules, annotated.
 Kentucky workers' compensation
 The law of condominium operations
 The legal guide for association board members
 Litigating the nursing home case
 Long-term care : how to plan and pay for it
 The new Wigmore : a treatise on evidence : expert evidence
 Next generation democracy : what the open-source revolution means for power, politics, and change /
 Ohio elder law Ohio summary judgment and related termination motions.
 Special needs trusts handbook Substantive criminal law [Kentucky]

Fastcase Webinar: Case Law Nuts and Bolts

Thursday, January 20

12:00-1:00

Join us for a live Fastcase webinar.

In this webinar you will learn the basics of researching case law using Fastcase. Fastcase's libraries include primary law from all 50 states, as well as deep federal coverage going back to 1 U.S. 1, 1 F.2d 1, 1 F.Supp. 1, and 1 B.R. 1. The Fastcase collection includes cases, statutes, regulations, court rules, and constitutions.

To register, call 513.946.5300.

Photocopying in the Library

Take full advantage of your subscriber benefits. Current subscribers as well as county and court employees can get a copy card from library staff and load value on the card at the photocopiers anytime. The benefit? You'll pay 8 cents per copy rather than the cash rate of 15 cents per copy.

The photocopiers also act as scanners. Just choose Email instead of Copy. You will be prompted for the recipient's email address. The copier will scan your document, whether it's one page or twenty, and email it as an attachment to your recipient. If you would like a quick lesson in this function, ask a library staff member to demonstrate.

You and the Legal System: Bankruptcy

Speaker:

Thomas J. Geygan, Sr., Attorney at Law

Friday, January 21, 2011 at 12:00 noon

Hamilton County Law Library

Free to the public.

To register, call 513.946.5300.

Mr. Geygan will discuss:

- ◆ How to Decide If You Need Bankruptcy
- ◆ How to Find an Attorney to Assist You
- ◆ Different Types of Bankruptcy and How to Choose
- ◆ Timeline on a Bankruptcy

Please note that this is not a CLE event; it is intended for the general public. However, attorneys are welcome to attend and may also want to pass along the program announcement to clients, staff, and community organizations. For more information, please call 513.946.5300.

This program is brought to you as a public service by the Hamilton County Law Library, in conjunction with the Cincinnati Bar Association's Lawyer Referral Service.

Public Announcement

The Hamilton County Law Library Resources Board announces its 2011 meeting schedule. All meetings will be held at 1:00 p.m. in the Law Library's Board Room. Members of the public are welcome to attend. Minutes are posted on the web at <http://www.hamilton-co.org/cinlawlib/about/trustees.html>.

January 6, 2011

April 7, 2011

July 7, 2011

October 6, 2011

Bankruptcy Resources

We suggest the following print and online resources for your bankruptcy research. Ask a librarian for additional guidance.

Print Resources

Understanding Bankruptcy / Jeffery Thomas Ferriell

Bankruptcy Basics: a step-by-step guide for pro bono attorneys, general practitioners, and legal service offices / John Rao

Bankruptcy / Joe Lee

Bankruptcy Courts and Procedures / Pamella Everett Nolkamper

Bankruptcy Law and Litigation / Daniel A. DeMarco

Chapter 7 Commercial Bankruptcy Strategies
Leading Lawyers on Counseling Clients

Chapter 11: Reorganizing American
businesses: essentials / Elizabeth Warren

Chapter 13 Bankruptcy: keep your property
& repay debts over time / Stephen Elias

Consumer Bankruptcy Law and Practice /
Henry J. Sommer

The Foreclosure Survival Guide: keep your
house and walk away with money in your
pocket / Stephen Elias

Mastering bankruptcy / George W. Kuney

Fundamentals of Bankruptcy Law and
Procedure in Ohio / John A. Hollister

Foreclosure and Repossession in Ohio /
Glenn E. Algie

Foreclosures: defenses, workouts, and
mortgage servicing / John Rao, et al.

Electronic Resources

Aspen/CCH Bankruptcy Library

BNA's Bankruptcy Law Reporter
(In library only)

Tax Management: Discharge of indebted-
ness, bankruptcy, and insolvency
(In library only)

National Consumer Law Center's Bank-
ruptcy Law and Practice

United States Bankruptcy Court
[http://www.uscourts.gov/
bankruptcycourts.html](http://www.uscourts.gov/bankruptcycourts.html)

Bankruptcy Forms Manual
[http://www.uscourts.gov/bkforms/
bankruptcy_forms.html](http://www.uscourts.gov/bkforms/bankruptcy_forms.html)

Cornell University Law School/ Bankruptcy
Code
[http://www4.law.cornell.edu/uscode/html/
uscode11](http://www4.law.cornell.edu/uscode/html/uscode11)

CLE

We have tentative plans to offer a number of CLEs throughout 2011. We'll announce the schedule and details once approvals are received. If you have an interest in a particular topic, whether as a prospective attendee or speaker, please contact reference librarian [Laura Dixon-Caldwell](#) at 513.946.5300. We're grateful for your suggestions.

Upcoming Events

January 6: Special Membership Meeting, Cincinnati Law Library Association

January 20: Fastcase Webinar: Case Law Nuts & Bolts

January 21: You and the Legal System: Bankruptcy

January Holidays

The Law Library will be closed:

Monday January 17 in observance of Martin Luther King Jr. Day.

January 2011 Law Library Newsletter

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- Tech Tip: Editing PDF Documents with free PDF editor
- Bankruptcy Resources

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