

# **Regulatory Changes Affect Litigation Risks: What You Need To Know Now**

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# ***What Regulatory Changes Affect Litigation Risks?***



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# RFR: What Is Required Now

- “Reportable Food”
  - “Reasonable probability” of “serious adverse health consequences to humans or animals”
- “Responsible Party”
  - FDA-registered facility where product is “manufactured, processed, packed, or held”
- “Requirement”
  - Report to FDA portal within 24 hours



# Amendments to RFR (FSMA § 211)

- New “critical information” required
- Within 18 months, FDA will require “consumer-oriented information” including
  - Description
  - Product ID codes
  - Contact information
  - Anything else FDA deems necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food



# RFR: Increased Litigation Risks?

- Consequences of an RFR Report?
- What Happens If RFR Report Is Mistaken?
- What Happens if RFR Report Is Not Filed?
- Is FDA Following The Law When “Requesting” Reporting? If Not, Consequences?



# Stronger Records Access Authority (FSMA § 101)

- When “reasonable probability” of “serious adverse health consequences”
- Includes records of other food affected in similar manner – **NEW**
- Proper credentials and written notice



# Records Access: Increased Litigation Risks?

- Plaintiffs' Bar Has Greater Access To Records
  - More Claims?
  - Basis for Punitives?
- Trade Secrets More Likely To Be Disclosed
  - Supplier/Customer Liability?
  - Unfair Business Advantage?



# Mandatory Recall Authority (FSMA § 206)



- Recall ordered if “reasonable probability” (1) food is adulterated or misbranded and (2) serious adverse health consequences
- Opportunity for voluntary recall
- Hearing within two days of the order’s issuance

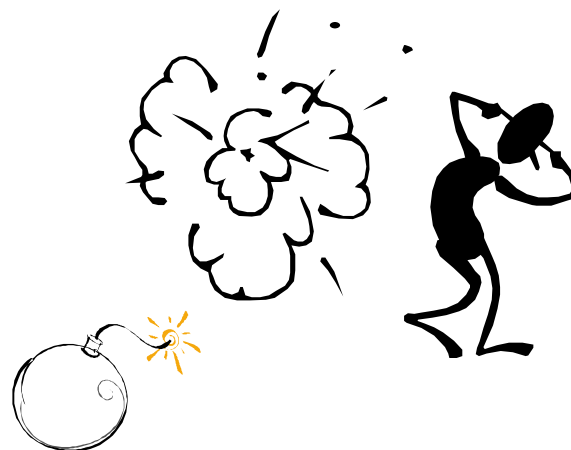
# Mandatory Recall: Increased Litigation Risks?

- Administrative Litigation (though limited due process)
- Bigger Issue: Changes in Politics of A Recall
  - Liability in Supply Chain for Recall That May Have Been “Unnecessary”
  - Liability to Consumers (Possibly Punitive) For No Recall



# Suspension of Registration

- If FDA determines “reasonable probability” of food causing “serious adverse health consequences,” MAY suspend registration
- Facilities that are “responsible” and those that knew or had reason to know in jeopardy
- Informal hearing within 2 days
- FDA to consider corrective plans within 14 days
- Effective in 18 months



# Preventative Controls (FSMA § 103)

- Hazard analysis and implement preventative controls re:
  - sanitation
  - training
  - environmental controls
  - allergen controls
  - a recall contingency plan
  - GMPs
  - supplier verification activities



# Preventative Controls: Increased Litigation Risks

- New Industry Standards?
- What Exactly Are The Standards?
- What If FDA Doesn't Complete Its Rule-Making within 18 Months?



# ***Management of Chemical Hazards***

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Sections 103 and 105 of the Act



## Section 103

- The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the [Chemical] hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards.



# What Does This Include?

- Not clear, but:
  - Language is broad enough to include all handling in the plant including intermediate and final packaging
  - Could include any potential exposure to chemicals during processing, or
  - Any exposure during storage or transport.



## Section 105

- STANDARDS FOR PRODUCE SAFETY.
  - Appears to allow the regulation of procedures that will prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards including....hazards that naturally occur and may be unintentionally introduced



## What Does This Include:

- This broad language could include a variety of materials that are naturally occurring such as lead or mercury, that have in the past been non-regulated because they were naturally occurring.
- Could be a way to regulate procedures or as actual levels allowed in certain food.
- Industry needs to be involved in the rule making to make sure that, to the extent possible, products are not improperly regulated.



# What Was Left Out: BPA

- **Bisphenol A**, commonly abbreviated as **BPA**, is an organic compound with two phenol functional groups. It is used to make polycarbonate plastics.
- It appears that this chemical, despite Feinstein's original insistence that it be included, was left out because of opposition to its inclusion by a number of industries.
- Other attempts to regulate BPA have also been stalled at least temporarily, including both under the Toxic Substances Control Act (TSCA) and California's Proposition 65.



## **BPA: The Toxic Substances Control Act/and Proposition 65**

- In December 2009 EPA announced that it will, for the first time, use its authority under the TSCA to list chemicals that may present an unreasonable risk of injury to health or the environment.



# BPA Action Plan

- On March 29, 2010 EPA released an action plan for BPA
  - Consider rulemaking to develop further data with respect to environmental effects to determine whether BPA presents an unreasonable risk of injury to the environment;
  - Consider rulemaking to identify BPA on the Concern List as a substance that may present an unreasonable risk of injury ;
  - Initiate collaborative alternatives assessment activities encourage reductions in BPA releases and exposures



# BPA Action Plan (Continued)

- In May of 2010 the EPA proposed the rule that was to list BPA and several other chemicals as Chemicals of Concern.
- This is the first time EPA has used the TSCA's authority to list chemicals that "may present an unreasonable risk of injury to health and the environment."
- Once a product is listed, chemical companies can provide information to EPA if they want to demonstrate that their chemical does not pose an unreasonable risk.
- The "chemical of concern" designation also triggers export and production notifications under the TSCA.



# Chemicals of Concern Regulation

Even though the process is supposed to take only 90 days and was submitted in May, the proposed rule was never released out of Office of Management and Budget.



# Proposition 65

- Although California has banned BPA in baby bottles it has not yet listed it on the Proposition 65 list.
- On July 15, 2009, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) received a petition from the Natural Resources Defense Council asking that OEHHA initiate the process for listing BPA as a reproductive toxicant under the Safe Drinking Water and Toxic Enforcement Act of 1986.



# Criteria for Listing

- A chemical must be listed under the Proposition 65 regulations when OEHHA determines one of two conditions are met:
  - The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g)).
  - An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)).
- However, the chemical is not listed if scientifically valid data that were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(h)).



# NTP Report

- OEHHA is relying on the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS) established the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR). Their conclusions were that BPA causes reproductive toxicity. The NTP-CERHR report concludes that there is clear evidence of adverse developmental effects in laboratory animals at “high” levels of exposure.



# DART Postpones a Decision

- However, the state's Developmental and Reproductive Toxicant Identification ("DART") Committee (one of the two divisions of the Prop 65 Scientific Advisory Committee) decided not to include BPA at its meeting on October 21, 2010
- The DART Committee voted to postpone a decision about whether to list BPA until its next meeting in **the spring of 2011**.
- The DART Committee declined to decide the issue because it wanted more information regarding the authoritative bodies' (NTP-CERHR) listing mechanism before the members cast their votes.



# Recommendations as to Chemical Hazards

- Need to review and comment on regulations and potential statutory changes.
- Need to watch the Food Safety Act as well as TSCA, Proposition 65 and the Green Chemistry Initiatives.



# ***What You Should Do Now To Reduce Risk***



# Record Keeping

- Know What Records You Will Have To Produce
- Strategize To Protect Trade Secrets
- Strategize To Protect Records Of Unaffected Products
- Use FOIA Where Possible To Protect Records



# Food Safety Plan

- May Not Want To Wait Until Regulations
- HACCP May Not Be Sufficient Though It's a Start
- Look Specifically At Environmental Risks Such As:
  - Allergens
  - Listeria
- Be As Specific As Possible With Suppliers
- Anticipate Living Without FDA Regulations



# Rehearse/Follow Recall Plan

- Steps To Assure Food Safety Plan Is Followed
- Rehearse Recall Plan
- Strategize About Recall Team
- Make Sure Everyone on Recall Team Understands His/Her Role
- RFR Training



# Written Policy for FDA Inspection/Investigation

- **Who Will Be Involved?**
- **Documents to Be Released and Signed:** If documents are going to be released, have a standard “FOIA Letter”
- **Test Results**
- **Photographs**
- **Interviews (who and review of legal counsel)**
- **What Else?**



# Manufacturing Practices

- How Can You Limit Recalls or Their Scope?
- Look at:
  - “Carry-Over” Practices
  - Cleaning SOPs
  - Testing SOPs



# Careful Review of Supplier/Vendor Agreement

## HOLD HARMLESS AGREEMENT AND GUARANTY/WARRANTY OF PRODUCT

Gentlemen:

The undersigned person or entity ("Seller"), for value received, hereby represents and agrees as follows:

1 The articles contained in any shipment or delivery made by Seller, its subsidiaries or divisions ("Product") made to or on the order of [REDACTED] its subsidiaries, affiliates or divisions (collectively referred to as "Buyer") is hereby guaranteed, as of the date of such shipment or delivery, to not be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act ("Act"), (b) to not be an article which cannot be introduced into interstate commerce under the provisions of Sections 404 and 505 of the Act, and (c) to be in compliance with all applicable federal, state and local laws.

2 Seller agrees to defend, indemnify and hold harmless Buyer and its employees, agents, representatives, directors and customers (individually, an "Indemnitee") from all actions, suits, claims, demands and proceedings ("Claims"), and any judgments, damages, losses, debts, liabilities, penalties, fines, costs and expenses (including reasonable attorneys' fees) resulting therefrom whether arising out of contract, tort, strict liability, misrepresentation, violation of applicable law and/or any cause whatsoever:

(i) brought or commenced by federal, state or local governmental authorities against any Indemnitee alleging that any Product shipped or delivered by Seller to or on the order of Buyer did not, as of the date of delivery, meet the guaranty set forth in Paragraph 1; or

(ii) brought or commenced by any employee (statutory or other), agent, representative, officer and director of Seller or its contractors and subcontractors for personal injury, death or loss or damage of property arising out of or alleged to have arisen out of any occurrence or alleged occurrence on owned, leased, permanent, or temporary property or premises of Buyer, whether or not such Claims are caused or alleged to be caused by the joint and/or concurrent negligence of Buyer; provided, however, that Seller's indemnification obligation shall not apply to the extent that Claims are caused by the sole negligence of Buyer; or,

(iii) brought or commenced by any person or entity against any Indemnitee for the recovery of damages for the injury, illness and/or death of any person, or loss or damage of property arising out of or alleged to have arisen out of (a) the delivery, sale, resale, labeling, use or consumption of any Product, or (b) the negligent acts or omissions of Seller; provided, however, that Seller's indemnification obligations hereunder shall not apply to the extent that Claims are caused by the negligence of Buyer.

Seller agrees to defend, indemnify and hold harmless Buyer

[... for the recovery of damages... arising out of or alleged to have arisen out of (a) the delivery, sale, resale, labeling, use or consumption of any Product...]



# Careful Review of Supplier/Vendor Agreement

Seller's agreement to maintain and provide insurance on behalf of Buyer under Paragraph 3 is a result of the requirement for indemnity and defense outlined in this paragraph. Indemnitees shall notify Seller promptly of the service of process or the receipt of actual notice of any claim.

3. Seller agrees to maintain in effect insurance coverage with reputable insurance companies covering workers' compensation and employers' liability, automobile liability, commercial general liability, including product liability and excess liability, all with such limits as are sufficient in Buyer's reasonable judgment, to protect Seller and Buyer from the liabilities insured against by such coverages. **Seller's insurance described herein shall be primary and not contributory with Buyer's insurance.** Seller shall furnish a certificate evidencing the obligation of its insurance carriers not to cancel or materially amend such policies without thirty (30) days prior written notice to Buyer. In addition, **Buyer shall be named as an additional insured** using form CG 20 15 Broad Form Vendor's Endorsement or its equivalent with respect to the commercial general liability policy including products liability. Automobile liability and excess/umbrella liability coverages will also name Buyer as an additional insured. All policies shall provide **waivers of subrogation** in favor of Buyer. The obligation to provide insurance set forth in this paragraph is separate and independent of all other obligations contained in this guaranty and agreement.

4. If any portion of this guaranty and agreement is ruled invalid for any reason, such ruling shall not affect the other portions of this guaranty and agreement, and all remaining covenants, terms and conditions of this guaranty and agreement shall remain in full force and effect.

5. This guaranty and agreement shall be in full force and effect and shall be binding upon Seller with respect to each and every Product shipped or delivered to buyer by the Seller before the receipt of the Buyer of written notice of rescission thereof.

Dated this 23rd day of September, 2013

**Seller's insurance described herein shall be primary and not contributory with Buyer's insurance**

**Buyer shall be named as an additional insured**

**waivers of subrogation**



# Example of What to Look Out for in Insurance Coverage

## ORGANIC PATHOGENS EXCLUSION

THE FOLLOWING IS ADDED TO SECTION IV-EXCLUSIONS-

ANY AND ALL LIABILITY FOR "LOSS" OF ANY NATURE, INCLUDING TO SETTLEMENTS, JUDGMENTS, COSTS, CHARGES, EXPENSES, COSTS OR THE FEES OF ATTORNEYS, EXPERTS, CONSULTANTS OR MEDICAL PERSONNEL, INCURRED BY, CONTRIBUTED TO, AGGRAVATED BY, OR RELATED OUT OF, CAUSED BY, RESULTING FROM, CONTRIBUTED TO, AGGRAVATED BY, OR RELATED IN ANY WAY, EITHER DIRECTLY OR INDIRECTLY, AND EITHER IN WHOLE OR IN PART, TO:

## ORGANIC PATHOGENS EXCLUSION

1. ANY ACTUAL, ALLEGED OR THREATENED EXPOSURE TO, EXISTENCE OF, PRESENCE OF, INGESTION OF, INHALATION OF OR CONTACT WITH ANY "BIOLOGICAL AGENTS" WHETHER OR NOT OCCURRING ALONE, IN COMBINATION WITH, BEFORE, AFTER OR CONCURRENTLY WITH ANY OTHER CAUSE, CONTRIBUTING CONDITION OR CIRCUMSTANCE, OR AGGRAVATING FACTOR, WHETHER MANMADE, NATURAL, OR ANY COMBINATION OF MANMADE OR NATURAL.
2. ANY REQUEST, DEMAND, ORDER, REGULATORY OR STATUTORY REQUIREMENT, THAT ANY INSURED OR OTHERS TEST FOR, MONITOR, CLEAN UP, REMOVE, CONTAIN, MAKE REPAIRS, TREAT, DECONTAMINATE, DETOXIFY, NEUTRALIZE, ABANDON, OR IN ANY WAY RESPOND TO OR ASSESS ANY EFFECTS OF ANY "BIOLOGICAL AGENTS." THIS INCLUDES, BUT IS NOT LIMITED TO, ANY DEMAND, DIRECTIVE, SUIT, ORDER OR REQUEST BY ANY GOVERNMENTAL OR NONGOVERNMENTAL ENTITY OR BY ANY ORGANIZATION, PERSON OR GROUP OF PERSONS.
3. ANY CLAIM, PROCEEDING, STEPS TAKEN OR AMOUNTS INCURRED BY ANY GOVERNMENTAL OR NON-GOVERNMENTAL ENTITY OR BY ANY ORGANIZATION, PERSON OR GROUP OF PERSONS TO TEST FOR, MONITOR, CLEAN UP, REMOVE, CONTAIN, REPAIR, TREAT, DECONTAMINATE, DETOXIFY, NEUTRALIZE, ABANDON, OR IN ANY WAY RESPOND TO OR ASSESS ANY EFFECTS OF ANY "BIOLOGICAL AGENTS."

1. Any actual, alleged or threatened exposure to, existence of, presence of, ingestion of, inhalation of or contact with any "biological agents" whether or not occurring alone.

THIS EXCLUSION APPLIES REGARDLESS OF WHETHER OR NOT THE "BIOLOGICAL AGENTS" OR ANY OF THEIR EFFECTS, WERE SUDDEN, ACCIDENTAL, GRADUAL, INTENDED, EXPECTED, UNEXPECTED, PREVENTABLE, NOT PREVENTABLE, MANMADE, NATURALLY OCCURRING, OR ANY COMBINATION OF THE FOREGOING.

AS USED IN THIS EXCLUSION, "BIOLOGICAL AGENTS" MEANS ANY:

1. BACTERIA, MILDEW, MOLD OR OTHER FUNGI, OTHER MICROORGANISMS, MYCOTOXINS, SPORES OR OTHER BY-PRODUCTS OF ANY OF THE FOREGOING;
2. VIRUSES OR OTHER PATHOGENS (WHETHER OR NOT A MICROORGANISM); OR
3. COLONY OR GROUP OF ANY OF THE FOREGOING.

THIS ENDORSEMENT DOES NOT CHANGE ANY OTHER PROVISION OF THE POLICY.



## Questions?

[www.foodliabilitylaw.com](http://www.foodliabilitylaw.com)

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