McGUIREWOODS

Food and Beverage Industry Seminar

McGuireWoods London LLP

October 3, 2013

Agenda

- 2:00 – 2:05 p.m. Introduction and Welcome
- 2:05 – 2:40 p.m. A Comparison of Food Safety Regimes
- 2:40 – 2:45 p.m. Break
- 2:45 – 3:20 p.m. Import / Export Developments
- 3:20 – 3:25 p.m. Break
- 3:25 – 4:00 p.m. Labeling Claims
- 4:00 – 4:05 p.m. Break
- 4:05 – 4:45 p.m. Governmental and Third Party Inspections
- 4:45 – 4:50 p.m. Break
- 4:50 – 5:30 p.m. Recalls and Crisis Management
- 5:30 – 6:30 p.m. Drinks and Canapés

INTRODUCTION AND WELCOME

M. Melissa Glassman, Deputy Managing Partner, McGuireWoods LLP (London and Tysons Corner)

Melissa is the firm's deputy managing partner of business development. Prior to this role, she was a member of the firm's eight-person Executive Committee and chairman of McGuireWoods' complex commercial litigation department. She was the first woman to serve as an office managing partner and founded the McGuireWoods' Women's Business Development Committee, now known as McGuireWoods' Women Lawyers Network, and served as its first chair. She has served as chair of the Nominating Committee for McGuireWoods' Board of Partners and served on the firm's Associate Committee.

Melissa focuses her practice on litigating complex commercial cases including shareholder matters, lender/borrower relationships, energy, construction, commercial leasing, real estate, land use, zoning and all manner of business disputes. She has also litigated eminent domain cases in Virginia and Maryland on behalf of water, sewer, natural gas and electrical utility companies. Over the past 24 years, she has litigated in state and federal courts throughout the United States. She also has extensive experience in handling the arbitration of all types of commercial disputes. In addition to litigation, she drafts and negotiates contracts related to commercial development, design and construction, including architectural, project management and general contractor agreements.

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J. Kate Harris Hatcher, Partner, McGuireWoods LLP (Charlotte)

Kate is chair of the firm's food and beverage industry group. She regularly advises global beverage and food companies on a variety of transactional topics. In addition, she counsels many companies with their domestic and international procurement and supply chain needs by ensuring clients have strong contractual relationships and strategic partnering arrangements with their vendors and customers. Kate's five-years' in-house experience at an S&P 500 company gives her deep insight into her clients' needs, priorities and goals from both legal and business perspectives. She routinely structures and negotiates complex commercial transactions involving acquisition of raw materials, components, goods and services; supply and manufacturing; disposition of assets; intellectual property development and licensing; outsourcing of non-core business functions; logistics and warehousing; risk management; boilerplate form development, design and web-based implementation; sales, reseller and distribution agreements; marketing, advertising, sponsorship and promotion arrangements; telecommunications; wireless and dedicated access; and professional services. Because technology is a critical function of a business' supply chain, she regularly drafts and negotiates numerous types of technology agreements, from both the vendor and the licensee perspective, including those related to patent, source code and open source license agreements; collocation; hosting; escrow; maintenance and support; and virtualization.

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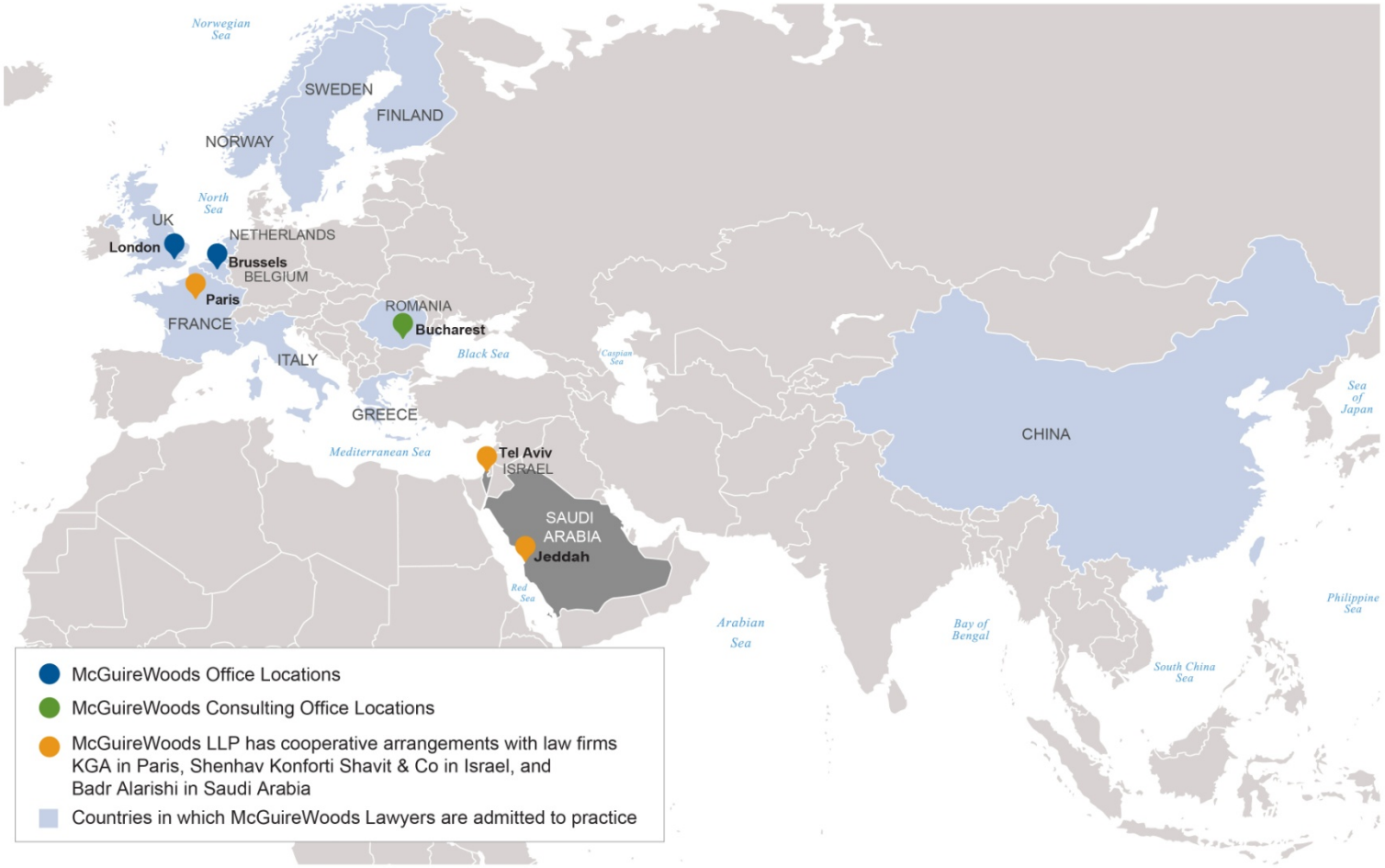
McGuireWoods

- **Global reach** — McGuireWoods has more than 900 lawyers in 19 offices, and our lawyers speak 35 languages.
- **Client service** — For more than a decade, the firm has been named to the BTI Consulting "Client-Service A-Team," a distinction maintained by few other U.S. firms.
- **Diversity and Inclusion** — We have been recognized for diversity and inclusion by many, including *Multicultural Law*, the Minority Corporate Counsel Association, Working Mother and Equality Illinois.
- **McGuireWoods Consulting LLC** — Our full-service public affairs subsidiary, McGuireWoods Consulting, complements our legal services with advice on federal, state and local government relations; strategic communications; grassroots advocacy; and infrastructure and economic development.
- **Value through alternative fee arrangement** — McGuireWoods was an early adapter and is a strong proponent of offering a wide range of value billing arrangements and fee structures. More than 25 percent of major firm clients are working with us using one or more alternative-fee and value-billing arrangements.

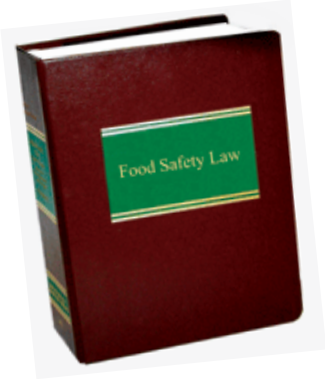
McGuireWoods EMEA Locations with Bar Admissions



McGuireWoods & McGuireWoods Consulting U.S. Office Locations with Bar Admissions

Food and Beverage Industry Team

- McGuireWoods' food and beverage industry team provides comprehensive services domestically and internationally.
- We have focused groups dedicated to representing the particular needs of companies in the following sectors:
  - Retail
  - Manufacturing
  - Wholesale/distribution
  - Alcoholic and Non-Alcoholic Beverage



- We "Wrote the Book" on Food Safety (Neale & Spivey, *Food Safety Law*, ALM (2011)).

Food and Beverage Industry Team Services

- Food Safety/Food Recall
- Regulatory Compliance Issues
- Food Safety Modernization Act Changes in Supply Chain
- Food Labelling Class Action Consumer Fraud Cases
- Criminal Defense of OCI and USDA Inspector General Investigations
- Private Label Goods
- Vendor Agreements
- Supply Chain
- Fleet Services
- Distribution and Logistics
- Fires/Explosions
- Immigration Compliance
- Anti-trust Training
- OSHA
- Environmental Compliance
- FDA Form 483 Responses
- Recall Plans and Drills
- Inspection Plans and Drills

A COMPARISON OF FOOD SAFETY REGIMES

James F. Neale, Partner, McGuireWoods LLP (Charlottesville)

Jim is a trial lawyer. His varied trial practice focuses on high exposure cases in courts across the country. He has substantial mass tort and class action litigation experience and currently serves as co-chair of the firm's food borne illness litigation practice group. His first chair trial experience includes personal injury, products liability, premises liability, transportation, insurance coverage, land valuation and ERISA cases. He has won jury verdicts in both state and federal court trials.

In addition to these focused areas, Jim has defended clients in a variety of other adversarial arenas, including high exposure cases before the Judicial Panel on Multidistrict Litigation and numerous arbitration panels. He has briefed and argued appeals to the Virginia Supreme Court, the U.S. Court of Appeals for the 4th Circuit and 11th Circuit, and the full Virginia Workers Compensation Commission.

From 1990 to 1995, Jim served as an Airborne Ranger and Light Infantry Platoon Leader in the U.S. Army and was awarded a Ranger Tab, Senior Parachutist's Badge, Air Assault Badge and Expert Infantryman's Badge.

Following law school, Jim served as a law clerk to the Honorable Richard L. Williams, Senior U.S. District Court Judge in the Eastern District of Virginia. While earning his law degree from the University of Virginia School of Law, he won the John Kingdon Award for Outstanding Oral and Written Advocacy and the Stephen P. Traynor Award for Outstanding Appellate Advocacy. He was also named the winner and outstanding oralist in the William M. Lile Moot Court Competition.

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Eric Smith, Head of Food Safety and Product Recall, red24 Assist (London)

Eric has vast experience in crisis management in the food industry. During the past 30 years, he has carried out numerous assignments across the world, linked to standards for the meat and food industry. A former senior lecturer at the University of Salford, Manchester, Eric taught in the areas of food safety, food auditing, food control, epidemiology, food law and development of quality systems for the food industry. He has experience auditing and instructing a number of industry-related government bodies.

A specialist in meat safety and product recall, Eric worked closely with international government officials during the BSE crisis in Europe in 1996; he also has extensive experience in China, the Americas, Africa and Scandinavia.

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Sunland, Inc.

- Organic, private label PB
- Salmonella (multiple strains) Outbreak
  - 42 confirmed illnesses, no reported deaths
  - Nov. 14, 2012 FDA Form 483 Issued
    - 18 Positives in Distributed Product
    - 9 Additional Product Positives Discovered by FDA
    - 28 Environmental Positives in Plant
- Company Voluntarily Recalls Product
- 9/26 FDA Revokes Registration
- 12/25 Limited Shelling Begins Again
- August 2013 Product Restocked
- September 2013, Insurer Files Dec Action

The Fragmented Food Regulatory System in the U.S.

- FDA:
  - Regulates All Food Not Regulated by USDA (80% by $$)
  - FDA food-side Budget = 1/10 of USDA's food-side budget
  - Very Infrequent Inspections
  - Very Few Inspectors
  - No Label Pre-Approval Process

- USDA:

  - Regulates Meat, Egg Products, Poultry
  - Food-side Budget = 10x FDA's Food-side Budget
  - Inspectors Always On-site
  - Pre-Approve Labels:
    - 9 CFR 317 / 9 CFR 381.132

Our Fragmented Regulatory System cont'd

- FDA Statutes
  - Food Drug and Cosmetic Act, 21 U.S.C. 301
  - Fair Packaging and Labeling Act of 1966, 15 U.S.C. 1451
  - Nutritional Education and Labeling Act, 21 U.S.C 343

- USDA Statutes
  - Meat Inspection Act, 21 U.S.C. 601
  - Poultry Products Inspection Act, 21 U.S.C. 1451
  - Egg Products Inspection Act, 21 U.S.C. 1031

Who Else Regulates Food?

- TTB (BATF) – alcohol
- FTC – food and dietary supplement advertising
- EPA – pesticides in foods, water
- APHIS – Live Animals / Plants
- F&WS – Endangered Species
- CBP – imports
- CDC – epidemiology
- Local Governments
- State Governments

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ALL LIVE ANIMALS AND ANIMAL PRODUCTS
ALL PLANTS AND PLANT PRODUCTS

APHIS DETERMINES ENTERABILITY OF A COMMODITY BASED ON THE DISEASE AND PEST STATUS OF THE EXPORTING COUNTRY

FOOD SAFETY AND INSPECTION SERVICES

ALL MEAT AND POULTRY
PROCESSED PRODUCTS CONTAINING MORE THAN 3% RAW MEAT
PROCESSED PRODUCTS CONTAINING 2% OR MORE COOKED POULTRY OR MEAT
FSIS WORKS WITH NATIONAL AUTHORITIES TO APPROVE MEAT INSPECTION SYSTEM
APHIS GENERALLY DETER-MINES DISEASE FREEDOM BEFORE MEAT/POULTRY IMPORTS

FOOD AND DRUG ADMINISTRATION

JURISDICTION OVER IMPORTED FOODS, FISH, AND MEATS NOT COVERED BY FSIS. (SUCH AS GAME MEAT)
INSPECTION AT PORT OF ENTRY

ENVIRONMENTAL PROTECTION AGENCY

ESTABLISHES PESTICIDE RESIDUE LIMITS.

FISH AND WILDLIFE SERVICE

ALL ANIMALS, PLANTS AND THEIR PRODUCTS WHICH ARE CITES LISTED (ENDANGERED SPECIES)

All Regulators Increasing Focus on Food Safety

- FDA:
  - Food Safety Modernization Act (FSMA) (21 U.S.C. 2201)
  - Reportable Food Registry (21 U.S.C. 350f)
  - Office of Criminal Investigation
- USDA:
  - Expansion of pathogens considered adulterants
  - USDA Rule 34-12

Enforcement Mechanisms

- FDA
  - Court May Enjoin Refusal to Inspect 21 U.S.C. 332
  - Court May Enjoin Food Produced Under Insanitary Conditions. 21 U.S.C. 332 (a)
  - FDA May Revoke Facility Registration and Shut Down
  - FDA Now Has Mandatory Recall Authority. 21 U.S.C. 350(1)(d)
  - FDA May Administratively Detain Food for 20 Days if "Reason to Believe Adulterated or Misbranded". 21 U.S.C. 334 (h)(1)(A)
- USDA
  - May Refuse to Inspect (=Shutdown). 9 C.F.R. 500.7
  - May Receive Approval After Inspection. 9 C.F.R. 500.8
  - May Withdraw Grant of Inspection. 9 C.F.R. 500.6
  - May Sue to Enjoin Production/Detain Product. 9 C.F.R. 329.1 and 392.6

Recall Authority

- FDA Recall Authority.
  - Previously Voluntarily. 21 U.S.C. 350(a)(d).
  - FDA Could/Always “Request” a Recall. 21 C.F.R. 746(a).
  - FSMA Gives FDA Mandatory Recall Authority. 21 U.S.C. 350(1)(d).
- USDA Recall Authority.
  - Ability to Withdraw Roughly = Mandatory Recall Authority.

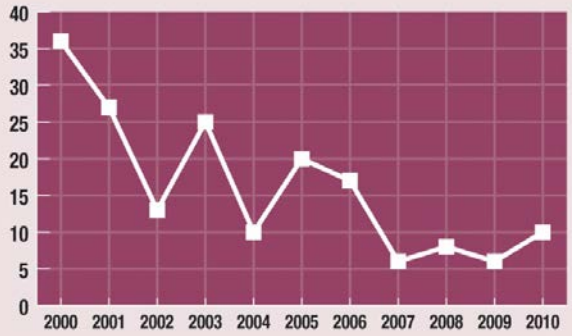
FDA Statistics

FDA Enforcement Statistics — Fiscal Year 2010

Seizures	10
Injunctions	17
Warning Letters	673
Recall Events	3,799

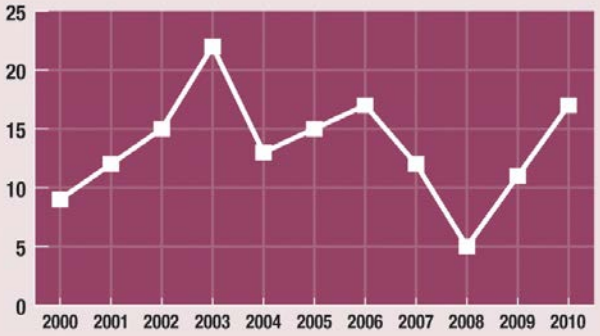
Source: U.S. Food and Drug Administration.

FDA Seizures — Fiscal Years 2000-2010



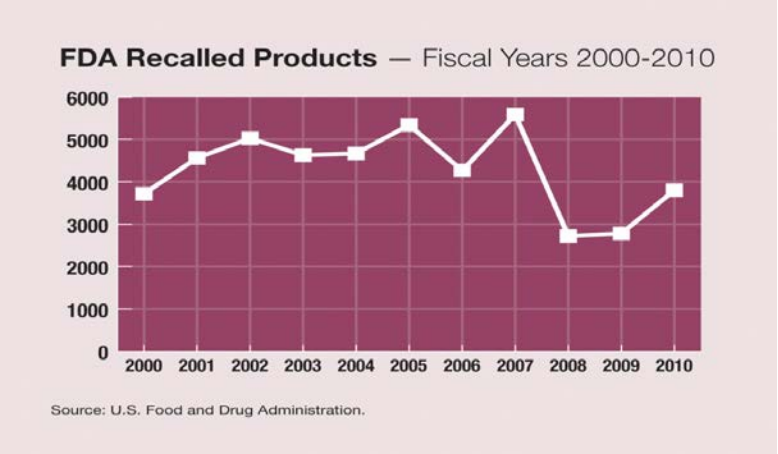
Source: U.S. Food and Drug Administration.

FDA Injunctions — Fiscal Years 2000-2010



Source: U.S. Food and Drug Administration.

FDA Statistics cont'd



FSMA, 21 U.S.C. 2201, *et seq*.

- Amends Food Drug & Cosmetic Act (21 U.S.C. 301)
- Intended to Strengthen FDA Regulations:
  - Increase Inspection Frequency
  - Require More Robust Countermeasures (Preventative Controls)
  - Equip FDA with Mandatory Recall Authority and Registration Susp.
  - Tighten Import Regulations
  - Regulate Labs and Auditors
  - Expanded Records Access and Ability to Detain Food

Major Components of FSMA

- Registration/Suspension of Registration (Section 102 or 21 U.S.C. 350d) required for those who "manufacture/process, pack, or hold food, as defined in 21 CFR 1.227, for consumption by humans or animals ."
  - Informs FDA of Existence of Facility
  - Must Renew Registration Every Two Years
  - Provides Funding Mechanism
  - Provides Leverage to Administratively Shut Down
- Mandatory Recall Authority (21 U.S.C. 350l)
  - Producers Retain Right to Voluntarily Recall
  - If Mandatory Recall, then Hearing within Two (2) Days

Other Major Components of FSMA cont'd

- Preventative Control Plans (Section 103 or 21 U.S.C. 350g)
- Specifies Frequency of Inspections (21 U.S.C. 350j)
- Establishes Accreditation Criteria for Labs (21 U.S.C. 350k)
- Establishes Accreditation Criteria for Auditors (21 U.S.C. 381)
- Foreign Supplier Verification Program (Section 301)

Reportable Food Registry, FDA Amendments Act of 2007, Section 417

- Applies to "Responsible Parties"
  - Registered under Bioterrorism Act
  - Registered under FSMA
- Must Affirmatively Report:
  - When there is "reasonable probability that use of/or exposure to an article of food will cause serious adverse health consequences to humans or animals."
    - Generally = Class I Recall Standard
  - Notify ASAP and NLT within 24 hours
    - Through Electronic Portal (http://www.safetyreportingpanel.hhs.gov/)
    - 866-300-4374 = 24 hour "hotline"

Reportable Food Registry (continued)

- Reports are Subject to FOIA
- Reports can Include Liability Disclaimer
- Need not report if:
  - Condition originated with your facility
  - Condition detected prior to transfer to any other person
    - Intra-Company shipment is not a “transfer”
  - Condition Corrected or all Effected Food Destroyed
- “Encouraged” to Report all Abnormal Tests, even Presumptive Tests

Criminal Liability under FD&CA

- Office of Criminal Investigation.
  - Criminal Actions under FDCA:
    - Introduction, Manufacturer Delivery of Adulterator or Misbranded Food. 21 U.S.C. 331(a)(c).
    - Refusal to Allow Inspection.
    - Violation of Guarantee.
    - No Scienter Requested. 21 U.S.C. 333(a)(1).
    - Felony = with Scienter or Repeat Violation. 21 U.S.C. 333(a)(2).
- Park Doctrine = Personal Criminal Prosecution of Responsible Parties.
    - Park v. U.S., 421 U.S. 658 (1975).
    - Individual can also be Debarred from Industry.

Criminal Liability cont'd

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF GEORGIA ALBANY DIVISION

UNITED STATES OF AMERICA	:	**CASE NO. 1:13-CR-12- WLS**
	:	
v.	:	**VIOLATIONS:**
	:	**21 U.S.C. §§ 331(a) & 333(a)(2)**
STEWART PARNELL,	:	**18 U.S.C. § 1505**
MICHAEL PARNELL,	:	**18 U.S.C. § 1349**
SAMUEL LIGHTSEY, and	:	**18 U.S.C. § 1343**
MARY WILKERSON,	:	**18 U.S.C. § 1341**
Defendants.	:	**18 U.S.C. § 371**
	:	**18 U.S.C. § 2**
	:	

INDICTMENT

THE GRAND JURY CHARGES:

Current Legislation

- The European Food Safety Authority [EFSA]
- EU Directives
- EU 852/2004 Hygiene of Foodstuffs
- EU 852/2004 laying down specific rules for food

Areas to Consider

- Background Information
- Breaches of Legislation
- Damage to **‘Brand’,** the **‘Market’** and **‘Reputation’**
- Withdrawal and Recall
- Client Protection
- Case Studies
- A Lasting legacy
- Conclusion

Background Information

GMA/A.T. KEARNEY STUDY

Food Fraud IN THE GLOBAL SUPPLY CHAIN

The best way to protect consumers—and your brand—is to apply a comprehensive set of deterrence strategies to prevent adulteration before product enters the supply chain.

By Jim Morehouse, Constanze Freienstein and Lola Cardoso

The Grocery Manufacturers Association (GMA) and its Science and Education Foundation (SEF) partnered with A.T. Kearney to execute a study on consumer product fraud in the food, beverage and consumer product industry.

This study was requested by the GMA following a series of incidents where substitute food ingredients in China and elsewhere were deliberately introduced into food products, the most famous being the melamine episode in 2007. Since food fraud can take place at any stage along the global value chain, this is an issue that is of particular importance to supply chain executives, distributors and retailers.

For the purposes of this discussion, food fraud is defined as the deliberate placement of food on the market, with the intention of deceiving the consumer for financial gain. The Food Standards Agency in the United Kingdom considers two main types: 1) the sale of food that is unfit and potentially harmful, such as recycling animal by-products back into the food chain, and 2) the deliberate misclassification of food. While not necessarily unsafe, the latter fraud deceives the consumer as to the nature of the product (wherein a cheaper alternative is substituted), for example, farmed salmon sold as wild salmon.

Melamine was perhaps the proverbial straw that broke the camel's back and acted as the trigger point for all industry stakeholders. From melamine, the industry recognized that one economic adulteration incident could have global market consequences, with broad and deep implications for company brands, industry performance, peoples' lives and countries' reputations. With a $40 billion price tag, 200,000 consumers affected around the world, more than 9,000 hospitalizations and six deaths in China, the melamine contamination created a new reality.

Understand Product Portfolio Vulnerabilities

The first step to incorporating defensive measures relating to food fraud into an existing quality and safety program is to understand the vulnerabilities in the product portfolio. This requires creating a data repository to gather more and better information and intelligence and using

www.foodlogistics.com • Food Logistics MARCH 2010 31

- The issue at the moment is not one of contamination, but substitution and food fraud.
- This makes it an adulteration problem with the product not being **‘of the nature’** that the consumer expects.
- There is evidence to suggest contravention of a number of food related statutory requirements and criminal intent.
- To combat problems of this kind the industry has been forced to adopt new methods and systems.

Background Information cont'd

The recent Equine meat scandal has without doubt focussed the retail and manufacturing industry on the importance of adequate protection from such a widespread adulteration and criminal problem.

Breaches of Legislation

- Food Hygiene (England) Regulations 2006 and associated EU Directives 852/2004 and 853/2004
- Food Safety Act 1990 – section 14 and section 21 relate to the defence of **‘due diligence’**
- Can you prove beyond reasonable doubt that your business has ***‘taken all the necessary steps to satisfy the statutory and recommend precautions to produce food which is not only safe and is of the nature, substance and quality demand by the consumer’***

Damage to ‘Brand’, the ‘Market’ and ‘Reputation’

- This is terribly difficult to control and to be frank is simply a damage limitation exercise.
- With the advent of social media - bad news travels fast.
- The increasingly seamless spread of information through social networking platforms makes it easier for a potential problem to escalate out of control **(Viral)**
- It is now more difficult to contain a problem locally.

Client Protection

- Recently the food sector has been allocating less resources on crisis management, business continuity and recovery, and even less, if at all, on food product testing.
- People no longer have the time, the budget or the inclination to do things that are not directly impacting the bottom line.
- In this regard, organisations are starting to scrutinise and spend very carefully and prioritise as required, putting even further pressure on the individual links in the supply chain.

Client Protection cont'd

Dependency on suppliers is increasing as a greater emphasis is placed on **'ASSURITY'.**

Case Studies

- There has been extensive coverage of the current Equine incident both in the EU and USA through widespread **Food Standards Agency and other media coverage**.
- All parties of the food chain have been asked to account for their actions.
- Terms used such as **'Gross Contamination'** have been used to describe the current situation.
- In some ways the Equine scenario has overshadowed the implications of discovering small amounts of Porcine DNA in other foodstuffs for which there are Implications for religious groups.

Learning The Lessons from an Unavoidable Crisis

- Consider how GMO slipped quietly under the radar, yet it was and still is a major crisis, unlike horse-gate it has received subtle media coverage over a long period
- Horse-gate a major impact for many, fuelled by the media, politicians and lack of understanding and enforcement by the Food Standards Agency has, and will continue, to bring about major change and additional expenditure for the industry and the consumer.

Case Studies

Present/Emerging Food Issues:

- Consider Food Fraud and New Technologies, *i.e.* Nanotechnology
- In Food Defence we talk about Threats
- Threat Analysis Critical Control Point 'TACCP'
- To ensure a safe and robust supply chain consider:

Temptation Analysis Critical Control Point:

- Identify where in the value chain there is a temptation for fraudulent activity, where most value can be added, what the benefits are and the potential for detection.
- Consider **Economic** Temptation

A Point to Consider

Stop being a Food Technologist / Safety Specialist, Quality Manager or Supply Chain Specialist.

and;

Think like a Criminal !!!

- What do you buy a lot of and could be subject to **'bulking'** or **'diluting'** to a degree that will not impact on the safety, sensory qualities of the product, nor change it visually or physically, is expensive and remains untested

Supply Chain Management

- Trust
- Audits and Inspections
- Regulations, Contracts and Specifications
- De Globalisation of our Food System
- TACCP and Thinking like Criminals
- Testing and Surveillance
- Brand or Government Responsibility
- Price and the cost of Science and Expertise

Nanotechnology

Consider a particle that has the ability to:

- Cross the blood brain barrier
- Cross the maternal/foetal placenta
- Cross the respiratory blood barrier

- A particle that can so easily produce systemic disturbance and has very little history or recent research on the possible reaction to the human host

Nanotechnology cont'd

- The use of nanotechnology is now massive by 2015 it is expected that investment and returns on this technology will be in excess of 1 trillion £s

- Its use is quite widespread however we feel the consumer will see the real evidence in food packaging

A Lasting Legacy

- The current situation has rocked all aspects of society
- Consider the implications of a further Horse-gate aptly named ‘Nano-gate’ with the consumer more so the media
- Picking up on silver in food, and the blue man
- Primarily - there will be on going questions raised relating to current practice, procedure and accountability
- Secondly, there will be a legacy relating to future conduct, operation and standards.

Review of Risk Related Food Safety

Chartered Institute of Environmental Health

The Food Law Code of Practice Review

Response to the FSA consultation document

September 2013

Conclusion

- Considering some of the problems which we have encountered in the recent practical situation, Supplier chain management now requires a major overhaul as does risk assessment.

IMPORT/EXPORT DEVELOPMENTS

Angela M. Spivey, Partner, McGuireWoods LLP (Atlanta)

Angela defends and counsels food manufacturers, suppliers, distributors, and packaging entities on a host of issues, including implementation of recalls, defense of widespread international outbreaks and resulting civil litigation, defense of corporations and individuals in OCI criminal investigations, and regulatory oversight and compliance. Angela is a national speaker at various industry group conferences on a wide array of issues unique to the food industry. In addition to consulting with food-industry clients, Angela has first-chair trial experience before state and federal courts, matters ranging from product liability, personal injury, contract disputes, and business torts.

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Yves Melin, Partner, McGuireWoods (Brussels)

Yves concentrates in EU trade regulations, with an emphasis on trade remedies (anti-dumping measures, countervailing measures and safeguards), customs laws and procedures, export controls; and WTO dispute settlement.

He advises governments and corporations on specific issues relating to EU, Russian and WTO international trade laws and practices; and regularly speaks at seminars, conferences and training sessions organized on various international trade law and regulatory topics. Yves provides assistance to clients throughout trade remedies investigations, and represents clients before the General Court and the Court of Justice of the EU in disputes relating to international trade and customs laws.

Yves also handles files in a wide range of commercial and regulatory matters, and in particular competition, data protection, public procurement, contracts, distribution, trade practices and marketing, health & safety, environmental law and product liability.

Yves Melin has been recognized as a leading lawyer in the field of trade law by the *Legal 500 Europe* in 2013 and by *Chambers Europe* in 2011, 2012 and 2013.

Chambers Global 2013 says, “Yves Melin is commended for his skill and experience in the trade arena.” *Chambers Global* 2012 says, “Younger partner Yves Melin ‘is fantastic, and highlights the issues we are dealing with immediately.’”

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Matthew Hall, Partner, McGuireWoods (Brussels)

Matthew's practice includes all areas of EU and UK competition law. He has substantial experience with merger control (including worldwide multijurisdictional investigations), state aid, cartels, competition litigation, competition compliance/training, competition audits, market investigations and issues arising out of trading agreements and practices, such as abuse of dominance, distribution, agency and cooperation agreements between competitors. He advises main parties and third-party complainants and he has regular dealings with the European Commission, UK Competition Commission, UK Office of Fair Trading and other government bodies and regulators.

Matthew is vice chair of the American Bar Association, Section of Antitrust Law's International Committee and of the British Chamber of Commerce in Belgium, EU Committee's Competition and Trade Task Force.

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Matthew also advises in relation to EU internal market rules, including in particular free movement, market liberalization, and public procurement. He has experience in a range of other EU/UK regulatory topics, including anti-dumping, trade, sanctions, REACH and the specific regimes covering, amongst other sectors, pharmaceutical products, medical devices, veterinary products, chemicals, transport, food & beverage and energy. He is a past member of the Steering Group of the UK Procurement Lawyers' Association.

Nadia C. Crisan, Managing Director, Emerging European Markets McGuireWoods Consulting LLC (Bucharest)

Nadia Crisan is the managing director for McGuireWoods Consulting Romania. She joined the McGuireWoods team in February 2007 to help open the firm's office in Bucharest. Based on a combination of skills in diplomacy and international and media relations, Nadia focuses her practice primarily on business development, government relations and strategic communications.

Prior to joining the firm, Nadia served as first secretary at the Embassy of Romania in Washington. In that capacity, she was responsible for promoting Romania's policies and interests before the United States Senate; strengthening relations with American investors in Romania; and articulating the Romanian perspective on international security to various Washington think tanks. Before that role, she worked as a consultant for the International Olympic Truce Center of the Greek Ministry of Foreign Affairs and a program assistant for the International Center for Journalists. Nadia is also an accomplished journalist having worked for two newspapers and as a correspondent for Romanian National Television. She has written extensively on foreign policy related to the United States, Europe, the Middle East and Latin America.

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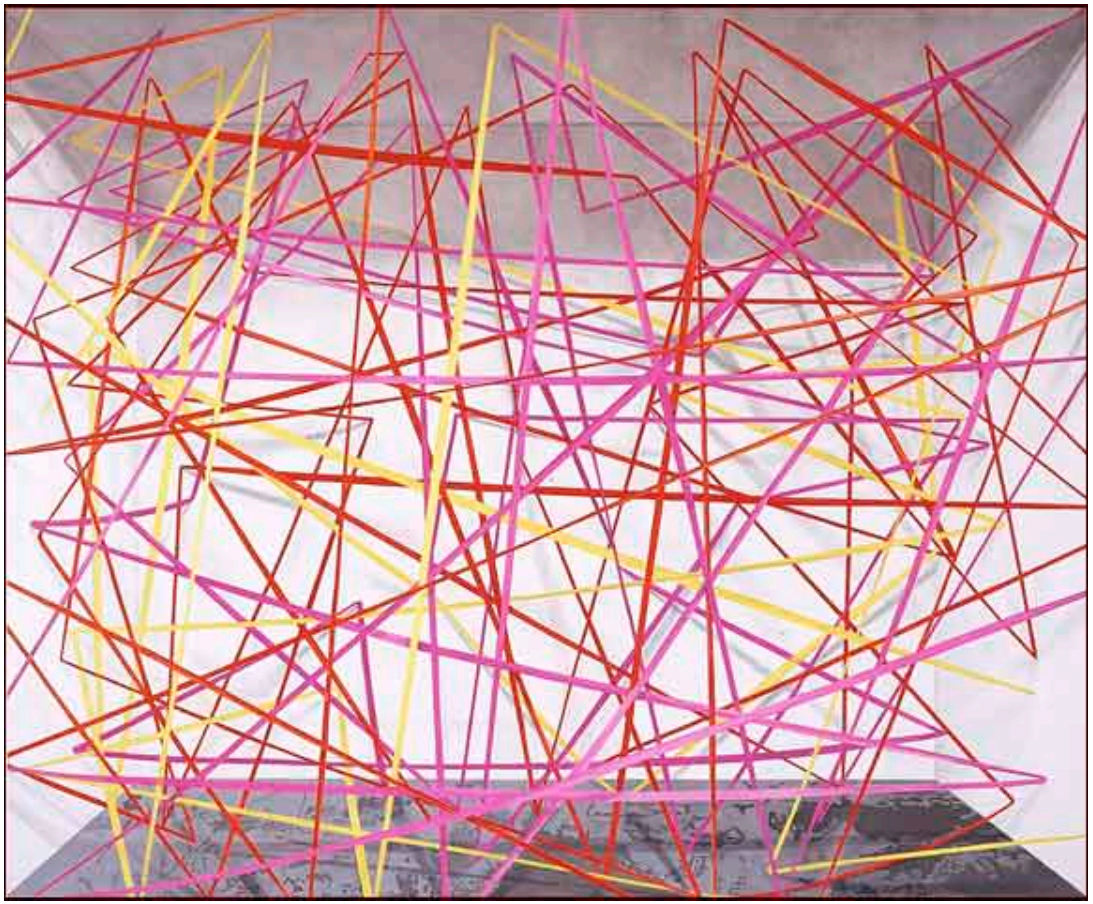
While earning her master's degree at Tufts University, Nadia served as editor-in-chief of the *Fletcher Ledger* and was honored as a recipient of the HB Earhart Fellowship. As an undergraduate, she studied at the Universidad Nacional Autonoma de Mexico in Taxco, Guerrero and Babes-Bolyai University in Cluj-Napoca, Romania.

Complex Global Food Supply System & Tangled Web of Regulations – Roadblock to Trade?

- Fractured Food Safety System in U.S.:
  - USDA
  - FDA
  - TTB
- EC Regulations
- Host Nation Amenability?



FDA Attempts to Secure the Border – FSMA Impact on Imports to the U.S.

- FSMA, 21 U.S.C. 2201, *et seq*, amends Food Drug & Cosmetic Act (21 U.S.C. 301)
- Signed January 4, 2011
- Significantly Tightens Import Regulations:
  - Facility Registration, includes foreign facilities
  - Increase Inspection Frequency, domestically & abroad
  - FDA must inspect 9600 foreign facilities by 2016
  - All domestic regulations now applicable to imported food
  - Creates Foreign Supplier Verification Program
  - Creates Voluntary Qualified Importer Program (VQIP)

Foreign Supplier Verification Program (301), FSMA

- Effective Date, January 4, 2013
- Proposed Rule issued, August 2013
- Subject to 120-day public comment period
- Importer =
  - U.S. owner or consignee of food at time of entry
  - includes U.S. agent or representative of foreign owner
- Importers Must Audit Foreign Suppliers, including:
  - Compliance Status Review
  - Conduct & Document Risk-Based Analysis (HACCP)
  - Verification Procedures: Verify Food is Produced in Compliance with US Regulations (303)
  - Review & Correct
  - Reassess every 3 years
  - Recordkeeping

FSMA, The Enforcement Stick

- FDA will Refuse Admission of imported food, if
  - Food is from Unregistered Facility
  - Importer Verification is Lacking
  - Host Country Has Denied FDA Inspection Access

- FDA Must Be Notified if Food Denied Entry in Other Countries (304)

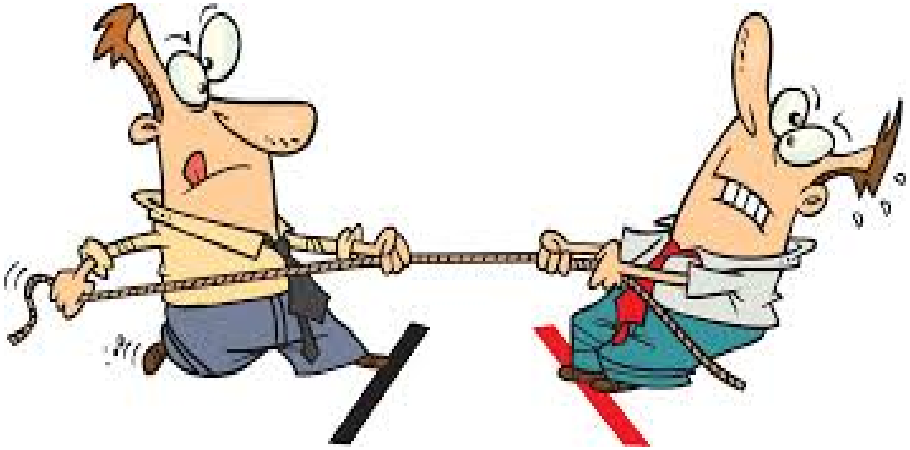
- Take Away – Any EU food companies importing to U.S. must incorporate U.S.-style compliance programs

Us Versus Them – Labelling of GMOs?

- **40 countries, including EU, mandate GMO labelling**

- **U.S. FDA**: GMOs not materially different, no specific labelling req'd

- **U.S. Consumers** disagree & continue "All natural" litigation



TTIP: A Free Trade Area between the EU and the U.S.

- **Objective:** facilitate trade between the EU and the US, by:
- **Lowering borders tariffs**. The easy part. On average 4% tariff. Some higher tariffs for agricultural products.
- **Harmonizing regulatory requirements in <u>all sectors</u>**
  - → **Mutual recognition** of those existing regulatory schemes that are equivalent
  - → **Gradual harmonization** of existing schemes that are currently not equivalent
  - → Future regulatory schemes to be **harmonized from the outset**
- **When:** Two years? Four? Ten?
- **Priority** given to sectors where there is an industry demand for harmonization in both the EU and the US

TTIP: A Free Trade Area between the EU and the U.S.

- Harmonization, but **no compromise on policy objectives**

  "*reduce unnecessary costs and administrative delays stemming from regulation, while achieving the levels of health, safety and environmental protection that each side deems appropriate*"
- However: harmonization can be **UP**, or **DOWN**
  - **Ex: GMOs**
- How: regulatory changes will be <u>negotiated and implemented by the regulators</u>
  - In the food sector: the FDA and the EFSA will have to talk
  - Keep the best regulatory practices
  - Based on science and international standards
- In the EU: Likely impact on the Commission's proposal for a modernized legal framework (Healthier Animals and Plants and a Safer Agri-Food Chain) of 6 May 2013

TTIP: Some Examples of Impact on the Food Sector

- Lowering of tariff on food and agricultural products. Easier access to the US market for EU meat (30% duty) drinks (22-23%), dairy products (up to 139%)
- Harmonization of technical and sanitary regulations, by removing "unnecessary" regulatory requirement: non-pasteurized blue cheese is good for you.
- Protection of EU geographical indications in the US: 'Château Springfield', I don't think so
- Plant health: access to US market for EU apples
- Harmonization of food labelling
- Mutual recognition of self-certification schemes (relevant to food safety liability)
- **Worth it?** In the food industry, regulatory costs are estimated to be USD 20 billion in the EU and US. Objective: a 25% reduction
- Tariff elimination: USD 1.4 billion each year

EC Green Paper on Unfair Trading Practices

An Unfair Trading Practice?

“Small firms condemn M&S for change to payment terms”

“Marks & Spencer came under fire from small business campaigners yesterday after it abruptly informed clothing suppliers that it would be delaying its payments to them to nearly 11 weeks after they deliver goods…”

“Chuka Umunna said . . . ‘Given the relative power larger companies have, this is simply unfair’…”

The Times, 7 September 2013

Key Dates

- November 2011: Principles of Good Practice (High Level Forum for a Better Functioning Food Supply Chain)
- January 2013: Enforcement Principles (High Level Forum)
- January 2013: ERAP, Green Paper and Impact Assessment; “common set of enforcement principles”?
- June 2013: UK Government response to Green Paper; “extremely sceptical” of legislation
- 16 September 2013: Supply Chain Initiative; active EC support
- September 2013: individual responses to the EC consultation and a summary
- By end 2013: proposed legislation to complement the SCI?

How the EC Sees It; Twin-Track Approach

Unfair practices (inefficiencies)
Diverse range of national measures

Supply Chain Initiative
(EU private sector)

- Launched 16 September 2013 in Brussels

> Problem: (good) enough signatories?
> Problem: parts only voluntary

Impact Assessment (EC)

- Green paper (31 January 2013)
- Public consultation (closed 30 April 2013)
- Studies

> Various options, including legislation

How the EC Sees It; Next Steps

- Another banking sector?
- Pressure for legislation
- Problems with legislative timetable (and EP not supportive)
- Result likely to be:
  - food only (not DIY etc.)
  - build on voluntary initiative
  - ensure enforcement

"The more successful the SCI is the less there will be a need for intervention"

Steps to Take

- Keep abreast of developments from the EC
- Review contracts for UTPs
- Review practices for UTPs
- Sign up to, use and implement the SCI including enforcement

Only demonstrable continuing and effective use of the SCI will keep EC legislation at bay…

Audit Diligence and Requirements – The Romanian Experience

- Romania: “Europe’s breadbasket”- presence of largest US and EU investors
- Romania follows the EU Member States Requirements and works closely with Health and Consumer Protection DG
- Requests for import/export come from companies and sometimes through commercial diplomacy, when strategic matters are lifted at the government level (i.e. US Food Safety and Inspection Service, Chinese AQSIQ)
- Romanian Sanitary Veterinary Authority and its counterparts work together on the required process and approvals
- Focus on EU Trade- frequent audits of the Food and Veterinary Office (i.e. Romania free to export pork compartments/national)
- Outside of the EU- assessment on a case by case basis and veterinary agreements are required

Romania – Import/Export Main Agri-food Products

- **Exports:** cereals, fresh meat, poultry meat, pork meat, beef meat, dairy, live animals (cattle, pork, sheep, swine and piglets), meat products, other products of animal origin, honey, etc.

- **Imports:** beef, poultry, pork, sheep and goat meat, milk and diary products, fish and seafood, other meat products, etc.

Romania Main Export/Import Markets

- **Export**
  - EU: Spain, Italy, etc. and the Balkans: Croatia, Serbia, Bosnia
  - Asia: China, Hong Kong, Vietnam
  - Russia, Ukraine and Republic of Moldova
  - Middle East: Jordan, Saudi Arabia, Lebanon, Syria, Iraq
  - Africa: Libya, South Africa, Nigeria, Angola, Tunisia, Namibia
- **Import**
  - EU: Germany, Italy, Austria, France, Netherlands, Denmark, Belgium, UK, etc.
  - Non EU: Brazil, Argentina, US, Thailand, etc.

Romania – The Way Forward

- Great interest to promote policies that stimulate growth of the Food/Beverage trade with focus on “bio” and “Made in Romania”
- Major efforts to keep all markets and open new ones
- Monitoring and Strong food safety efforts
- Larger presence of private sector field leaders
- EU pushed EU Financial Institutions (European Investment Bank and the European Bank for Reconstruction and Development) to have a minimum number of agri projects in the member states

LABELING CLAIMS

James F. Neale, Partner, McGuireWoods LLP (Charlottesville)

Jim is a trial lawyer. His varied trial practice focuses on high exposure cases in courts across the country. He has substantial mass tort and class action litigation experience and currently serves as co-chair of the firm's food borne illness litigation practice group. His first chair trial experience includes personal injury, products liability, premises liability, transportation, insurance coverage, land valuation and ERISA cases. He has won jury verdicts in both state and federal court trials.

In addition to these focused areas, Jim has defended clients in a variety of other adversarial arenas, including high exposure cases before the Judicial Panel on Multidistrict Litigation and numerous arbitration panels. He has briefed and argued appeals to the Virginia Supreme Court, the U.S. Court of Appeals for the 4th Circuit and 11th Circuit, and the full Virginia Workers Compensation Commission.

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From 1990 to 1995, Jim served as an Airborne Ranger and Light Infantry Platoon Leader in the U.S. Army and was awarded a Ranger Tab, Senior Parachutist's Badge, Air Assault Badge and Expert Infantryman's Badge.

Following law school, Jim served as a law clerk to the Honorable Richard L. Williams, Senior U.S. District Court Judge in the Eastern District of Virginia. While earning his law degree from the University of Virginia School of Law, he won the John Kingdon Award for Outstanding Oral and Written Advocacy and the Stephen P. Traynor Award for Outstanding Appellate Advocacy. He was also named the winner and outstanding oralist in the William M. Lile Moot Court Competition.

Paul Van den Bulck, Partner, McGuireWoods (Brussels)

Paul focuses on legal issues concerning technology law, data privacy and security, intellectual property, media and entertainment (including gaming and gambling), and fair trade practices. Paul also counsels clients on day to day IP and IT issues, provides strategic advice and manages IP and IT due diligence. He also manages large IP portfolios.

Paul advises clients on all aspects of international and domestic data privacy and security, such as compliance, data transfer, security and data breaches, data transfer for the needs of discovery procedures or whistleblowing schemes, processing of sensitive data, etc. He assists clients in their relationships with certain national data protection authorities.

Besides his activity as an attorney, Paul also acts regularly as a mediator and arbitrator in information technology and intellectual property disputes.

Paul is a member of the Brussels and Paris Bars. He represents clients across a broad range of industries.

Paul lectures at the Université de Strasbourg. Paul is also the recipient of a BAEF fellowship as a Hoover Foundation Brussels fellow (1992) and of the Wiener-Anspach fellowship for Cambridge University (1992).

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Labeling Defined

- **Label:** display of written, printed, or graphic matter upon the immediate container of any article. 21 USC 321(k)

- **Labeling:** all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 USC 321(m)

- **"Misbranded":** Something is wrong with the labelling, e.g., False or misleading in any particular; Required label information not present or not provided in the manner required

Basic Label Requirements (Mandatory Content)

- Principal Display Panel "PDP" Must Contain:
  - Statement of Identity
  - Net Weight
  - Inspection Legend
  - Country of Origin (if imported)
  - Signature Line (Manufacturer, Packer or Distributor)

Basic Label Requirements Mandatory Content (cont'd)

- **Nutrition Fact Panel Must Contain:**
  - Ingredient List
  - Nutritional Content
- **Label Must Include:**
  - Handling Statement and Safe Handling Instructions

Nutrition Facts
Serving Size 3 Fried Slices (15g)
Servings Per Container About 7

Amount Per Serving	
Calories 60	Calories from Fat 45
	% Daily Value*
Total Fat 5g	**8%**
Saturated Fat 2g	**10%**
Trans Fat 0g	
Cholesterol 15mg	**5%**
Sodium 250mg	**10%**
Total Carbohydrate 0g	**0%**
Dietary Fiber 0g	**0%**
Sugars 0g	
Protein 4g	

Vitamin A 0% • Vitamin C 0%
Calcium 0% • Iron 2%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Safe Handling Instructions
THIS PRODUCT WAS PREPARED FROM INSPECTED AND PASSED MEAT AND/OR POULTRY. SOME FOOD PRODUCTS MAY CONTAIN BACTERIA THAT COULD CAUSE ILLNESS IF THE PRODUCT IS MISHANDLED OR COOKED IMPROPERLY. FOR YOUR PROTECTION, FOLLOW THESE SAFE HANDLING INSTRUCTIONS.

KEEP REFRIGERATED OR FROZEN. THAW IN REFRIGERATOR OR MICROWAVE.
KEEP RAW MEAT AND POULTRY SEPARATE FROM OTHER FOODS. WASH WORKING SURFACES (INCLUDING CUTTING BOARDS), UTENSILS, AND HANDS AFTER TOUCHING RAW MEAT OR POULTRY.
COOK THOROUGHLY.
KEEP HOT FOODS HOT. REFRIGERATE LEFTOVERS IMMEDIATELY OR DISCARD.

CURED WITH WATER, SALT, SODIUM PHOSPHATES, SODIUM ERYTHORBATE, SODIUM NITRITE.

Helvetica Regular 8 point with 1 point of leading

3 point rule

8 point Helvetica Black with 4 point of leading

1/4 point rule centered between nutrients (2 points leading above and 2 points below)

8 point Helvetica Regular with 4 points of leading

8 point Helvetica Regular, 4 points of leading with 10 point bullets

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point.

7 point rule

6 point Helvetica Black

All labels are enclosed by 1/2 point box rule within 3 points of text measure

1/4 point rule

Type below vitamins and minerals (footnotes) is 6 point with 1 point of leading

Nutritional Labelling on Alcoholic Beverages

- FFB Ruling 2004-1 (Apr. 7, 2004)
  - Allowed Use of “Lite” or “Light”
  - Prohibited Additional Nutritional Information

- TTB Ruling 2013-2 (May 28, 2013)
  - Now Allows voluntary nutritional labelling on beer, wine, liquor
  - Modifies TTB Ruling 2004-1
  - May specify calories, carbs, fat, protein per serving, and alcohol content by volume.

Malt Beverage (4 % ABV)

Serving Facts	
Serving Size 12 fl oz	
Servings Per Container 1	
Amount Per Serving	
Calories	90
Alcohol	0.5 fl oz
Fat	0g
Carbohydrates	2.2g
Protein	0.8g

Some Specific Nutrient Content Claims Are Regulated

- “Good source,” “high,” “more,” and “high potency.” 21 CFR 101.54
- “Light” or “lite.” 21 CFR 101.56
- Calorie content of foods. 21 CFR 101.60
- Sodium content of foods. 21 CFR 101.61
- Fat, fatty acid, and cholesterol content of foods. 21 CFR 101.62
- Implied nutrient content claims and related label statements. 21 CFR 101.65
- Use of nutrient content claims for butter. 21 CFR 101.67

Some Other Defined Terms Are Regulated

- Organic
- Healthy
- Fresh
- Whole Grain
- Gluten free

Different Label Approval Processes and Pre-Emption for FDA and USDA

- FDA
  - No Label Pre-Approval Process
- USDA (and TTB)
  - USDA Requires Label Pre-Approval (21 U.S.C. 607(d))
  - Requires Label Pre-Approval (21 U.S.C. 607(d))
    - Sketch
    - Temporary
    - Generic
  - Very Extensively Regulated (USDA Form 7234-1)
    - 9 CFR 317.2
    - 9 CFR 381.118

USDA Preemption

". . . Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter . . . "

21 U.S.C. 678 (Meat Inspection Act)

21 U.S.C. 458(b) (Poultry Products Inspection Act)

Federal Alcohol Administration Act (FAA Act)

- Preemption
  - FAA Contains Express Preemption Provision
    - 27 USC 213
    - Similar to Meat Insp. Act. (21 U.S.C. 678)
  - TTB Requires Labeling Pre-Approval
    - Similar to USDA
    - Usually guarantees Pre-emption

How Does USDA Define “Natural”?

- 2005 Labeling Policy Book allows use of “Natural” where
  - product does not contain any artificial flavor/color/chemical preservative per 21 CFR 101.22; and
  - product/ingredients are only minimally processed

- 2005 Policy modified to add exceptions for (1) ingredients in the National Organic Policy; and (2) corn-derived sodium lactate

How Does FDA Define "Natural"? cont'd

- 1993 Policy:

  "FDA has not established a formal definition for the term 'natural', however the agency has not objected to the use of the term on food labels provided it is used in a manner that is truthful and not misleading and the product does not contain added color, artificial flavors, or synthetic substances. Use of the term 'natural' is not permitted in the ingredient list, with the exception of the phrase 'natural flavorings.'"

- Does Define "Natural Flavors:"

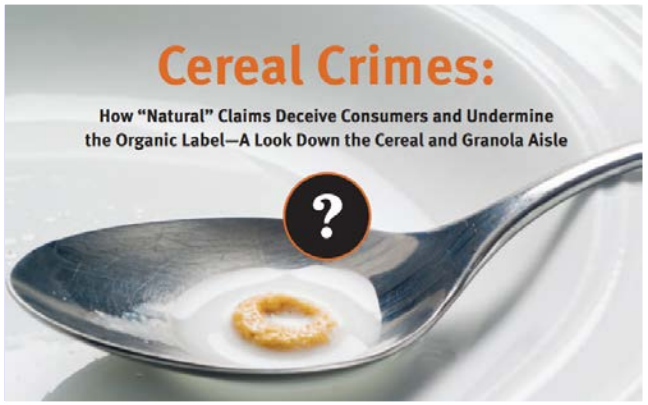
  The essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.

- Refusal to Regulate Otherwise (several petitions have been outstanding for years)

“Wannabe” Regulators: NGOs

- CSPI
  - “Warning” Letters
  - March 2010 “Food Labeling Chaos” Report
- Cornucopia Institute
  - Organic industry association
  - “Cereal Crimes” Report
- Consumer Union (CU)

CENTER FOR Science IN THE Public Interest



ConsumersUnion POLICY & ACTION FROM CONSUMER REPORTS

Not in My Food.org

Recent Article from *The New York Times*

"Lawyers From Suits Against Big Tobacco Target Food Makers"

- "*It's a crime — and that makes it a crime to sell it*," said Mr. Barrett, citing what he contends is the mislabeling of [certain] products. "*That means these products should be taken off the shelves*."
- "*Food companies will argue that these are harmless crimes — the tobacco companies said the same thing*," Mr. Barrett said.

Lawyers From Suits Against Big Tobacco Target Food Makers

Jim Wilson/The New York Times

Christine Sturges, a hairdresser from California, is one of the plaintiffs in a suit against ConAgra involving its Pam cooking spray.

Holk v. Snapple

- Third Circuit found no preemption (9th Cir. 2009)
  - No express preemption clause
  - No field preemption because NLEA states no preemption unless explicitly preempted under 21 U.S.C. 343-1, and Congress clearly stated its intent not to occupy field
  - No conflict preemption because FDA's policy statement on "natural" is not a formal definition entitled to preemptive effect
- Numerous courts have since cited and followed
- Primary Jurisdiction:
  - Court stayed case on primary jurisdictional grounds for 6 months
  - Along with two other Courts, sought FDA guidance on "natural"
  - FDA responded by letter indicating no action due to lack of agency resources

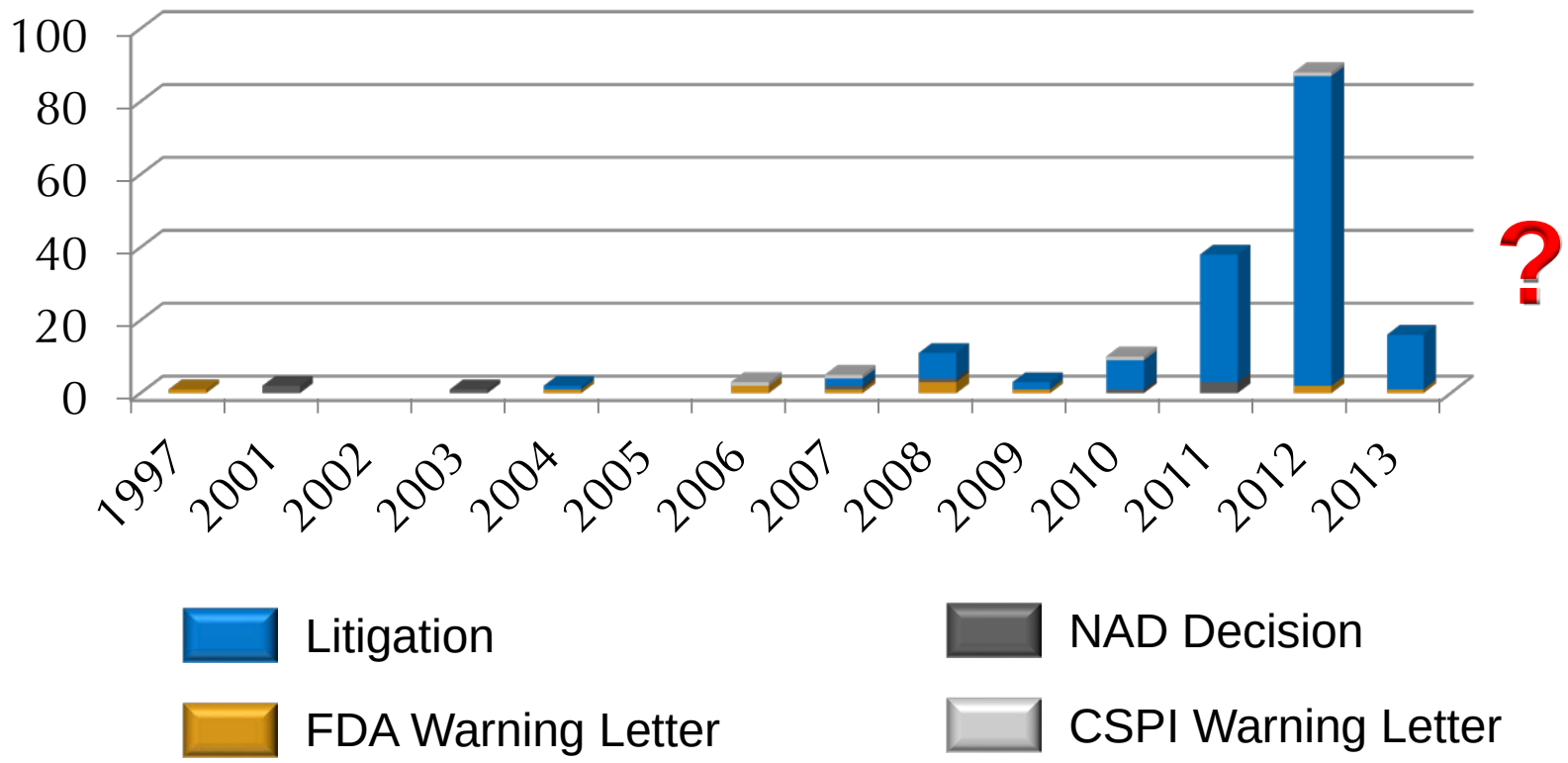
Non-Preempted (FDA) Claims

Werbel v. Pepsico, Inc., 2010 U.S. Dist. LEXIS 76289 (N.D. Cal. 2010)

- Court grants motion to dismiss holding that no reasonable consumer could be deceived as “[t]his Court is not aware of, nor has Plaintiff alleged the existence of, any actual fruit referred to as a "crunchberry."

- Thus, a reasonable consumer would not be deceived into believing that the Product in the instant case contained a fruit that does not exist. . . . So far as this Court has been made aware, there is no such fruit growing in the wild or occurring naturally in any part of the world.”

Annual "Natural" Challenges by FDA, NAD, CSPI and Litigants



Susceptible Claims

- "All Natural"
- Health Claims
- Structure/Function Claims
- Product Characteristics:
  - "Grass Fed"
  - "Angus Beef"
  - "Cage-Free"
  - "Environmentally Friendly"
  - "Sustainable Packaging"

Recent “All Natural” Cases

- GMO’s
  - *Briseño v. ConAgra Foods, Inc.*, 2:11-cv-05379 (C.D. Ca. 2011) (Wesson oil with GM corn);
  - *Bevans v. General Mills, Inc.*, 2:12-cv-249 (D.N.J. 2012) (cereal);
  - *Zuro v. Frito-Lay North America*, 1:12-cv-00885 (E.D.N.Y. 2011) (tortilla chips with GMO corn);
  - *Shake v. Frito-Lay North America*, 1:12-cv-00408 (E.D.N.Y. 2011) (tortilla chips);

Recent "All Natural" Cases cont'd

High Fructose Corn Syrup (HFCS)

- *Holk v. Snapple*, 575 F.3d 329 (3d. Cir., 2009)
- *Lockwood v. ConAgra Foods, Inc.*, 597 F.Supp.2d 1028 (C.D. Cal. 2009) (HFCS in Healthy Choice® pasta sauce)
- *Wright v. General Mills, Inc.*, 2009 U.S. Dist. LEXIS 90576 (S.D. Cal. 2009)

Recent "All Natural" Cases cont'd

- "Synthetic" Additives
  - *Pappas v. Naked Juice Co.*, 2:11-cv-08276 (C.D. Cal.) (juice with ascorbic acid and lecithin)
  - *Astiana v. Ben & Jerry's Homemade, Inc.*, 2011 WL 2111796 (N.D. Cal. May 26, 2011) (ice cream with alkalized cocoa)
  - *Thurston v. Bear Naked, Inc.*, No 3:11-cv-02890 (S.D. Cal. 2011) (granola with potassium carbonate, glycerin and lecithin)
  - *Anderson v. Jamba Juice Co.*, No. 12-cv-01213 (N.D. Cal 2012)

Recent "All Natural" Cases cont'd

- Highly Processed Foods
  - *Brod v. Sioux Honey Ass'n*, No 1200291 (Cal. Super. Ct. 2012) (pollen removed from honey)
  - *Gallant v. General Mills, Inc.*, No. BC481325 (Cal. Super. Ct. 2012 (Greek Yogurt contains milk concentrate)

Structure/Function Claims

Tout food's effect on structure of body or function of body.

- *"Contains calcium, which builds strong bones."*
- *"Fiber maintains bowel regularity"*
- *"Antioxidants maintain cell integrity"*

Recent Labelling Challenges "Structure Function" Cases

- *Weinter v. Dannon Co.*, 255 F.R.D. 658 (C.D. Cal. 2012) (claimed digestive benefits for Activia yogurt)
- *Siddiqi v. Gerber Prods. Co.*, No. 12-cv-1188 (C.D. Cal. 2012) (probiotic toddler's milk claims brain and eye development)
- *Zeisel v. Diamond Foods, Inc.*, No. 3:10-cv-01192 (N.D. Cal. 2010)
- *Maxwell v. Unilever, Inc.*, No 5:12-cv-01736 (N.D. Cal. 2012) (antioxidants in tea)

Recommendations to Minimize Exposure

- Inform Marketers of Risks
- Obtain Pre-Approval Where Available
  - Build time into product launches (six weeks)
  - Don’t Rely on Generic Approval
  - USDA Pre-Approval = Near Immunity from Civil Claims
  - If Not Pre-Approved, Require Robust Pre-Market Review
- Focus on Higher Risk Products and Claims
  - Non-amenable products
  - Foods Marketed to Children

Recommendations to Minimize Exposure cont'd

- Audit Existing Labels at Retail Level for Compliance
  - Regular, Frequent
  - Third Party Review
  - Include Advertisements, End-Stack Displays, Websites, etc.
- Monitor FOIA Requests Re: Company
  - "Dear Manufacturer" Letters often Trigger Suits
  - FOIA requests = Trolling for Cases
- Monitor Website and Social Media Traffic:
  - Plaintiffs' Class Action Firms
  - Public Interest Groups

Resources

- FDA Food Labeling Guide
  - http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm
- FDA Labeling & Nutrition
  - http://www.fda.gov/food/labelingnutrition/default.htm
- USDA Basics of Labeling
  - http://www.fsis.usda.gov/regulations/Basics_of_Labeling/index.asp
- U.S. Food Labeling Guide, The Food Institute
  - http://www.foodinstitute.com/labeling.cfm

A. What is at stake?

- **Main European goals**
  - Protection of the consumer
  - Give enough information to the consumer
  - Ensure the good functioning of the market
  - Realization of public health *policies*
  - Enhance innovation

B. Applicable Law

B.1. Main European Directive/Regulation on foodstuffs labelling

- **Directive** 2000/13/EC relating to the **labelling, presentation and advertising** of foodstuffs (*still applicable until 13th December 2014*).

- **Regulation** n 1169/2011 on the **provision of food information** to consumers, (*will be applicable from 13th December 2014 onward*).

- Example of **specific regulation/Directives on foodstuff labelling**
  - Directive 90/1496/EEC of the Council of 24 September 1990 on nutrition labelling for foodstuffs.
  - Regulation (EC) n 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
  - Council Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption.
  - Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption.
  - Etc…

B. Applicable Law cont'd

B.2. Specific European Regulation on Nutrition and Health claims

Regulation n 1924/2006 on nutrition and health claims made on foods

(Completes Directive 2000/13/EC mentioned above)

- Scope of application : art. 1.2
  - Commercial communications intended to the final consumers;
  - Food intended to supply mass caterers.
- Restrictions : art. 1.2
  - non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread);
  - foodstuffs packed at the point of sale at the request of the purchaser; and
  - pre-packed foodstuffs with a view to immediate sale.

B. Applicable Law cont'd

Legislation Scheme

LABELING

- **Directive** 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs (*still applicable until 13th December 2014*).
- **Regulation** n 1169/2011 on the provision of food information to consumers, (*will be applicable from 13th December 2014 onward*).

NUTRITION & HEALTH CLAIMS

- **Regulation** n 1924/2006 on nutrition and health claims made on foods *(Completes Directive 2000/13/EC)*

C. Definitions in Regulation n 1924/2006

C.1. Nutrition claim

"Any claim which states, suggests or implies that a food has particular beneficial nutritional properties (…)" (art. 2.2.4).

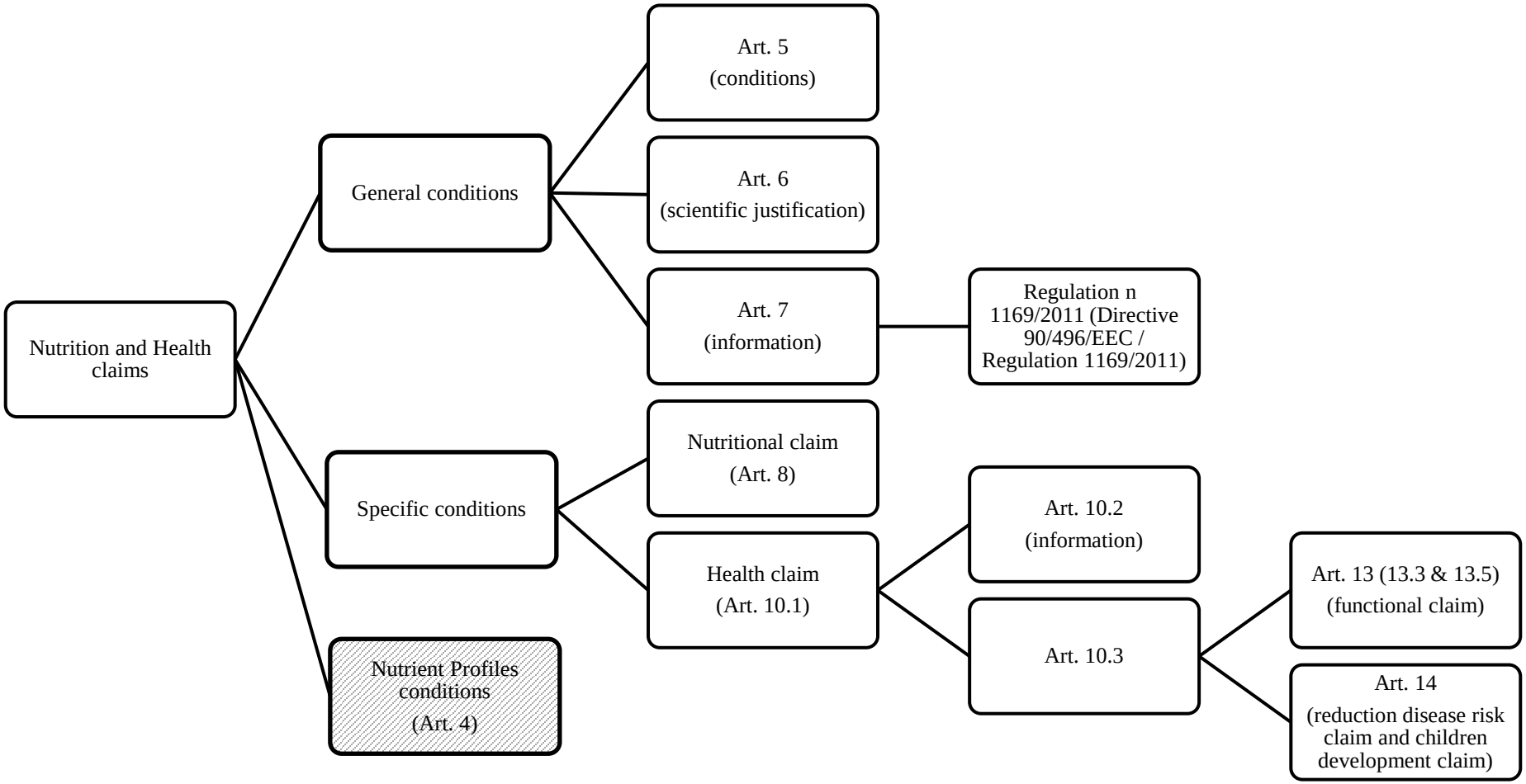
C.2. Health claim

"Any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" (art. 2.2.5).

C.3. Reduction of disease risk claim "*therapeutical claim*".

"Any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease" (art. 2.2.6).

D. Conditions for the Use of Nutrition and Health Claims



D. Conditions for the Use of Nutrition and Health Claims cont'd

D.1. Allowed use vs. prohibited use

See article 3 : comply with the provisions of the Regulation vs. false, ambiguous etc.

D.2. General conditions

- Principle (Art. 5): General conditions to be met.
- Scientific justification (Art. 6): Claims based on scientific evidence.
- Nutrition information (Art. 7)

  Where a nutritional claim appears (whether in labelling, in advertising or in presentation), nutrition labelling will be mandatory (art. 2 of the Directive 90/496/EC or 30 Regulation 1169/2011).

D. Conditions for the Use of Nutrition and Health Claims cont'd

D.3. Specific conditions

- Nutrition claims

  Only be permitted if they are :

  - listed in the Annex of the Regulation n 1924/2006;
  - are in conformity with the conditions set out in the Regulation (art. 8.1).

- Health claims

  - Article 10.2: specific information in labelling or presentation/ advertising
  - Article 10.3: quote of health claim (art 13 or 14)
  - Restrictions on the use of certain health claims

D. Conditions for the Use of Nutrition and Health Claims cont'd

D.4. Nutrient profiles

- Condition in order for foodstuff to have the authorization to use nutrition or health claim.

- Aim : to avoid that the consumer buys products with a *correct claim* but whose consumption will *harm his health*.

- But: No decision from the EU Commission.

DO	
Comply with **general conditions** set by: • Article 5: conditions to be met by the foodstuff • Article 6: scientific justification • Article 7: give nutrition information (Directive 90/496/EEC)	
Display nutrient profiles (if necessary) (article 4)	
Nutrition Claim	**Health Claim**
Use only **listed** nutritional claims (see Annex Regulation n 1924/2006)	Use only **listed** health claims (article 13: see Regulation n 432/2012, Regulation n 536/2013 and Regulation n 851/2013) > If not listed, ask authorization
For **beverages** containing more than 1,2 % by volume of alcohol, only nutrition claims referring to **low alcohol** levels, or the reduction of the alcohol content, or the reduction of the **energy** content, will be permitted	Use only **authorized** reduction of disease risk claims and claims referring to children's development and health > Specific procedure for authorization
	Include information in the labelling (or presentation or ads) mentioned in article 10.2

DON'T	
Use **false, ambiguous** or **misleading** claims	
Give rise to **doubt** about the safety and/or the nutritional adequacy of other foods	
Encourage or condone **excess consumption** of a food	
State, suggest or imply that a **balanced and varied diet cannot** provide **appropriate** quantities of **nutrients** in general	
Refer to changes in bodily functions which could give rise to or exploit **fear** in the consumer (either textually or through pictorial, graphic or symbolic representations)	
Nutrition Claims	**Health Claims**
	Use only **listed** health claims (article 13: see Regulation n 432/2012, Regulation n 536/2013 and Regulation n 851/2013) > If not listed, ask authorization
	Use only **authorized** reduction of disease risk claims and claims referring to children's development and health (article 14) > Specific procedure for authorization
	Include information in the labeling (or presentation or ads) mentioned in article 10.2

Illustrations of Nutrition and Health claims

Nutrition claim:
"naturally rich
in Magnesium "

Nutrition claim:
"Discover Actimel Vitamin C,
with acerola's natural vitamin C "

Illustrations of Nutrition and Health claims

Nutrition claim:
“Extra Light”

Nutrition claim:
“Surgarfree Gum”

Nutrition claim:
“Light”

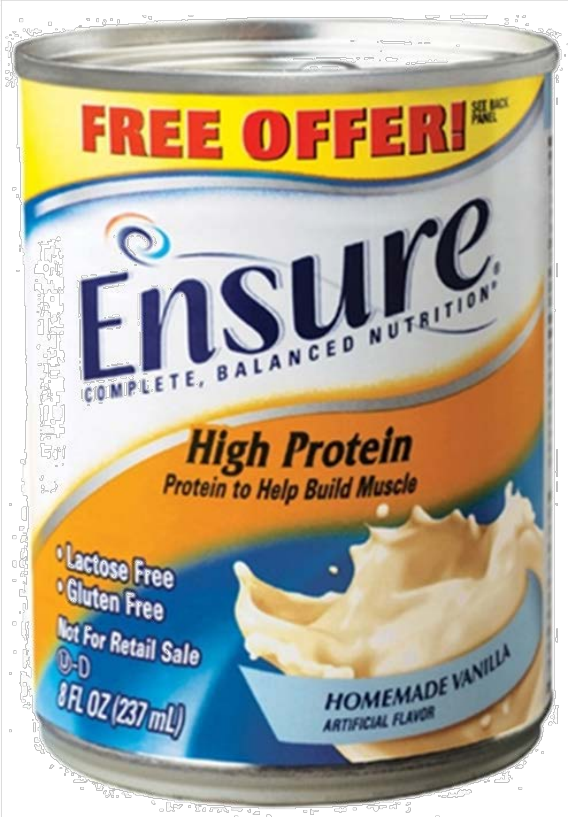
Illustrations of Nutrition and Health claims

Health claim:
"Proven to reduce cholesterol "

Health claim:
"Cocoa flavanols contribute to normal blood circulation in human body by helping to maintain elasticity of blood vessels "

Health claim:
“Now helps support your child’s immunity”, “25 % daily value of antioxidants and nutrients – vitamins A, B, C & E”

Illustrations of Nutrition and Health claims



Nutrition claims:
"High Protein", "Lactose Free", "Gluten Free"

Illustrations of Nutrition and Health claims

Health claim: "YESTIMUN® – SCIENTIFICALLY PROVEN TO MAINTAIN THE DEFENCE AGAINST PATHOGENS"

GOVERNMENTAL AND THIRD PARTY INSPECTIONS

Angela M. Spivey, Partner, McGuireWoods LLP (Atlanta)

Angela defends and counsels food manufacturers, suppliers, distributors, and packaging entities on a host of issues, including implementation of recalls, defense of widespread international outbreaks and resulting civil litigation, defense of corporations and individuals in OCI criminal investigations, and regulatory oversight and compliance. Angela is a national speaker at various industry group conferences on a wide array of issues unique to the food industry. In addition to consulting with food-industry clients, Angela has first-chair trial experience before state and federal courts, matters ranging from product liability, personal injury, contract disputes, and business torts.

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Eric Smith, Head of Food Safety and Product Recall, red24 Assist (London)

Eric has vast experience in crisis management in the food industry. During the past 30 years, he has carried out numerous assignments across the world, linked to standards for the meat and food industry. A former senior lecturer at the University of Salford, Manchester, Eric taught in the areas of food safety, food auditing, food control, epidemiology, food law and development of quality systems for the food industry. He has experience auditing and instructing a number of industry-related government bodies.

A specialist in meat safety and product recall, Eric worked closely with international government officials during the BSE crisis in Europe in 1996; he also has extensive experience in China, the Americas, Africa and Scandinavia.

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Governmental Inspections in U.S. & Abroad

- USDA, constant

- FDA Inspections (21 U.S.C. 350j)
  - Historically, infrequent
  - Domestically, Dependent Upon Perceived Risk
  - High-Risk Facilities:
    - Inspected Once in First Five (5) Years; and
    - At Least Once Every Three (3) Years Thereafter.
  - Other Facilities
    - Inspected Once in First Seven (7) Years; and
    - At Least Once Every Five (5) Years Thereafter

Governmental Inspections Abroad

- Facilities Outside U.S., FSMA Requires:
  - At least 600 in 2011
  - At least 1200 for each of the following 5 years

- 2 Problems:
  - Inadequate FDA manpower
  - no authority abroad to do so

- Solutions:
  - FSMA 306 , U.S. may enter agreements with foreign countries for independent inspections
  - Third Party Auditor Program

FSMA & Inspection of Facilities Outside U.S.

FDA Third Party Audit & Certification Program, FSMA

- 307, creates "third party auditors," defined as:
  - Foreign governments
  - Agents of foreign governments
  - Approved/accredited third parties
- FDA imposes strict rules for third party audits
  - Inspection must be unannounced
  - Include records review
  - On-site assessment
  - Environmental and/or product sampling, where appropriate
  - Auditor must notify FDA of any condition posing serious risk to public health
  - If deemed in compliance, auditor electronically submits certification, valid 12 months

Why Would Facility Outside U.S. Submit to Third Party Audit or Certification Program?

Two Benefits to Voluntary Audits

- FDA's Voluntary Qualified Importer Program (VQIP); food companies outside U.S., certified by accredited auditor, receive expedited review & entry of product
- Satisfy mandatory certification of certain foods that FDA determine pose a food safety risk due to location of origin (e.g., many regions within China) or nature of product

Refusal of Inspection

- If U.S. facility, criminal Offense Under Food Drug and Cosmetic Act
- Likely to Lead to Injunction or Warrant or Both
- If foreign facility or country refuses, ban on any imports to U.S.

FDA Inspections – Right of Access

- The FDA is at the door requesting access to inspect. What do you do?

- Generally
  - No-Notice and No Warrant Required (form 482)
  - Inspector Need Not Share Reason for/Target of Inspection
  - During Any Reasonable Time/Place/Manner
  - Can Enter Facility or Vehicle

FDA Inspections – Right of Access

- The Inspectors are asking for company documents. Should I give them up?

- Inspection of Documents
  - May Take Operational Documents
  - May Not Take Recipe/Customer Lists/Trade Secrets/Financial Documents
  - But Inspectors May and Do Ask for Such Documents
  - Code Documents as Green/Yellow/Red
  - Segregate Documents from Each Other
  - Duplicate Documents as They Are Provided Inspectors

FDA Inspections – Right of Access

- FDA Inspector has a camera and is taking pictures – must I allow it?

- In short, it depends.

- Photography/Videography
  - No explicit Authority Exists.
  - FDA will Claim Authority under:
    - *Dow Chem. Co. v. U.S.*, 476 U.S. 227 (1986)
    - *U.S. v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976)
  - Inspectors May Even Bring Media Inside (with Mgmt. Consent)

FDA Inspections – Right of Access

- The Inspector Breaks Down a Pallett and Takes Product Samples. Is that Okay? What Should I do?

- Inspector May take Samples
  - May Take Product and/or Environmental Samples
  - May Sample Ingredients
  - Will Issue Receipts (Form 484)
  - Company Should
    - Take Mirror Samples
    - Document FDA Methodology in Sampling

FDA Inspections – Right of Access

- The Inspector is not Wearing Gloves or Booties. He Stepped on the Drain of the Cooler before Swabbing it. What Should I do?

FDA Inspections – Right of Access

- While walking around the facility, the Inspector stops a member of the sanitation crew to ask specific questions regarding cleaning supplies and procedures. Can he do that?

Inspection Best Practices – Do's and Don'ts

- Develop a Facility-Specific Plan
  - Have an Inspection Team
  - Have an Inspection Protocol You're Willing to Make Public
  - Drill the Team and Test the Plan (Consider Including Counsel)
- Recommended Team:
  - Inspection Coordinator
  - Facility Manager
  - Production Liaison
  - Quality Assurance Liaison
  - Maintenance/Engineer Liaison
  - Vendor/Ingredient Supply Liaison
  - Counsel
- Designate and Train Back-ups

Inspection Best Practices cont'd

- Closing Documents
  - Establishment Inspection Report
  - Form 483 (Notice of Inspection Observations)
  - Generally Subject to FOIA

- Company Should Issue a Closing Document
  - Offer to Follow Up on Open Issues
  - Document Access to Facility/Documents
  - Document Corrective Actions

EU /UK Government Enforcement and Third Party Inspections - similarities/subtle differences

Auditors:

- USA auditors have no legal status in the EU/ UK equally EU/UK auditors have no legal status in the USA.
- Reliance on the third party audits, the company's internal audits, letters of guarantee and sampling protocols.
- Cannot demand records, embargo products or demand sampling and testing results from the supplier, they only have a commercial pressure.

EU /UK Government Enforcement and Third Party Inspections - Similarities and Subtle Differences

Enforcement Agencies:

- The Food Standards Agency which incorporates the Meat Hygiene Service providing constant inspections on site in the provision of meat and poultry abattoirs and cutting plants
- Environmental Health Departments [local government] providing planned/programmed system of inspections, high risk facilities every 6 months
- Inspections based totally on risk assessment backed up by quality management
- Environmental Health Practitioners [EHP] have the opportunity to amend the inspection protocol based on the quality of the food safety management system

EU /UK Government Enforcement and Third Party Inspections - Similarities and Subtle Differences

- EHPs in the EU and the UK have very similar enforcement powers to our colleagues in the USA

- By the use of improvement notices, prohibition notices formal caution and if necessary prosecution

Third Party Audit Provision

Provided by competent professionals, vetted to meet very demanding requirements

The most recent BRC standard version 6 July 2012 is divided into 7 chapters:

- Senior Management Commitment and Continual Improvement:
- The Food Safety Plan (HACCP) or the product safety system if non-food
- Food Safety and or Product Quality Management Systems
- Site Standards
- Product Control
- Process Control
- Personnel Control
- Expanded sections on foreign body control, hygiene and housekeeping, allergens and supplier approval.
- Introduction of a new voluntary 2 stage unannounced audit scheme.

Benefits

- Audits all sections of the business
- Provides evidence of a robust food safety system
- Provides a **‘Crutch’** for companies to lean on
- Aids in the defence of due diligence
- Meets the requirements to trade with large multiples

Areas for Concern

- This is not a legal document it will support crisis only
- Interpretation of specific sections do present a major problem, such a product recall documentation and product specifications
- Audits are only annually

Industry Response

- Triple AAA audits
- Removal of intermediate supply companies such as agents and importers
- Increased sampling plans to meet proposed new legislation expected in mid 2014
- Changes in labelling and product descriptions

Future Consideration

Statistics to Consider:

- **85%** of food recalls are linked to errors in the supply chain
- **50%** of food consumed in the UK comes from countries outside the UK
- **67%** of product recalls on consumer goods emanate from manufacturing sources outside the EU, USA, Canada and Australia.

Emerging Points of Interest:

- Nanotechnology
- Re-evaluation of Risk based approach to Food Safety

RECALLS AND CRISIS MANAGEMENT

Steven Thompson, red24Assist (London)

Steven has over 20 years of experience in the military and 13 years of experience in the commercial sector. Since 2000 he has worked both as a crisis consultant and as a security manager, operating at a strategic level for international corporations and organisations. Prior to joining red24, Steven worked in a global telecommunications company, where he used his knowledge and expertise to facilitate the implementation of corporate security policies and procedures. While operating at this level Steven developed an in-depth understanding and appreciation of the complex regulatory environment in which corporate entities operate.

Steven has produced and delivered several bespoke training sessions for corporate entities and NGOs, covering general crisis management and product recall scenarios. He has also reviewed security policies, product recall policies and travel procedures for numerous companies, as well as assisting our food safety experts on site visits.

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James F. Neale, Partner, McGuireWoods LLP (Charlottesville)

Jim is a trial lawyer. His varied trial practice focuses on high exposure cases in courts across the country. He has substantial mass tort and class action litigation experience and currently serves as co-chair of the firm's food borne illness litigation practice group. His first chair trial experience includes personal injury, products liability, premises liability, transportation, insurance coverage, land valuation and ERISA cases. He has won jury verdicts in both state and federal court trials.

In addition to these focused areas, Jim has defended clients in a variety of other adversarial arenas, including high exposure cases before the Judicial Panel on Multidistrict Litigation and numerous arbitration panels. He has briefed and argued appeals to the Virginia Supreme Court, the U.S. Court of Appeals for the 4th Circuit and 11th Circuit, and the full Virginia Workers Compensation Commission.

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From 1990 to 1995, Jim served as an Airborne Ranger and Light Infantry Platoon Leader in the U.S. Army and was awarded a Ranger Tab, Senior Parachutist's Badge, Air Assault

Badge and Expert Infantryman's Badge.

Following law school, Jim served as a law clerk to the Honorable Richard L. Williams, Senior U.S. District Court Judge in the Eastern District of Virginia. While earning his law degree from the University of Virginia School of Law, he won the John Kingdon Award for Outstanding Oral and Written Advocacy and the Stephen P. Traynor Award for Outstanding Appellate Advocacy. He was also named the winner and outstanding oralist in the William M. Lile Moot Court Competition.

Recalls/Market Withdrawals/Product Retrievals

- Recall = “Appropriate alternative to administrative seizure.”
  - Administrative Detention (21 U.S.C. 334(h))
    - Pre-FSMA: “Credible evidence or information indicating threat of serious adverse health consequences or death”
    - Post FSMA: “Reason to believe” food is adulterated or misbranded
  - Also appropriate if “exposure to” food is reasonably likely to cause injury (bottling hazard).
- Three Categories:
  - Voluntary
  - Requested (21 C.F.R. 7.40)
  - Mandatory (21 U.S.C. 350l)
    - New with FSMA
    - FDA has yet to exercise this authority

Lesser Options: Recall v. Withdrawal v. Recovery

- Market Withdrawal
  - Product already distributed but does not violate law, or
  - Clearly one against which FDA would not initiate action
  - i.e. Product fails internal quality standards, but is not adulterated
- Stock Recovery
  - Same, as a Market Withdrawal, but
  - Product not yet distributed.
- Do Not Confuse a Market Withdrawal with a Recall!

Differences Between Recalls and Market Withdrawals

- Recalls require:
  - Affirmative Disclosure to USDA/FDA/TTB
  - Approved Recall Strategy and Plan (21 CFR 7.3)
  - Approved Notices to Public (21 CFR 7.42)
  - Effectiveness Checks at Retail/Wholesale Level
  - Approved Destruction Plan of Product
  - Root Cause Determinations
  - Corrective Actions
  - Status Reports
  - Regulatory Termination
- Market Withdrawals Require None of These

Recall Classifications

- Class I: Exposure “will cause serious adverse health consequences or death.” (i.e. pathogenic adulterant)

- Class II: Exposure “may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is slight.” (i.e. very minor allergen)

- Class III: Exposure “is not likely to cause adverse health consequences” in humans. (i.e. mad cow)

Recall Plans

- It must be sanctioned and authorized by the CEO (and dated)
- It is vital that it is a working document and is tested regularly
  - It identifies those individual who will participate directly
  - Defined Roles & Responsibilities
  - Ability to make decisions
  - Access to internal and external resources
  - Individuals should carry easy to use check lists
  - The annexes should contain material in relation to
    - Notification – Holding Statements – Client Lists – Contact Lists
- It includes an instruction to evaluate its effectiveness after use

The Recall Team

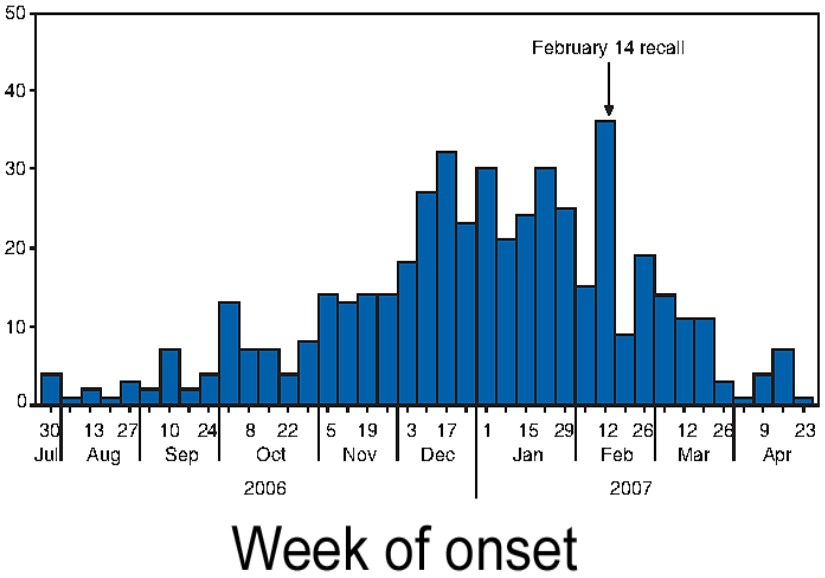
- Have a Recall Team (with redundancy):
  - Recall Coordinator preferably not the CEO
  - Quality Assurance Representative
  - Supply Chain Liaison
  - Distribution/Sales Liaison
  - Production/Operations Liaison
  - Communications Director with Social Media Coordinator
  - Regulatory Affairs Liaison
  - **Counsel**

Recall Procedure

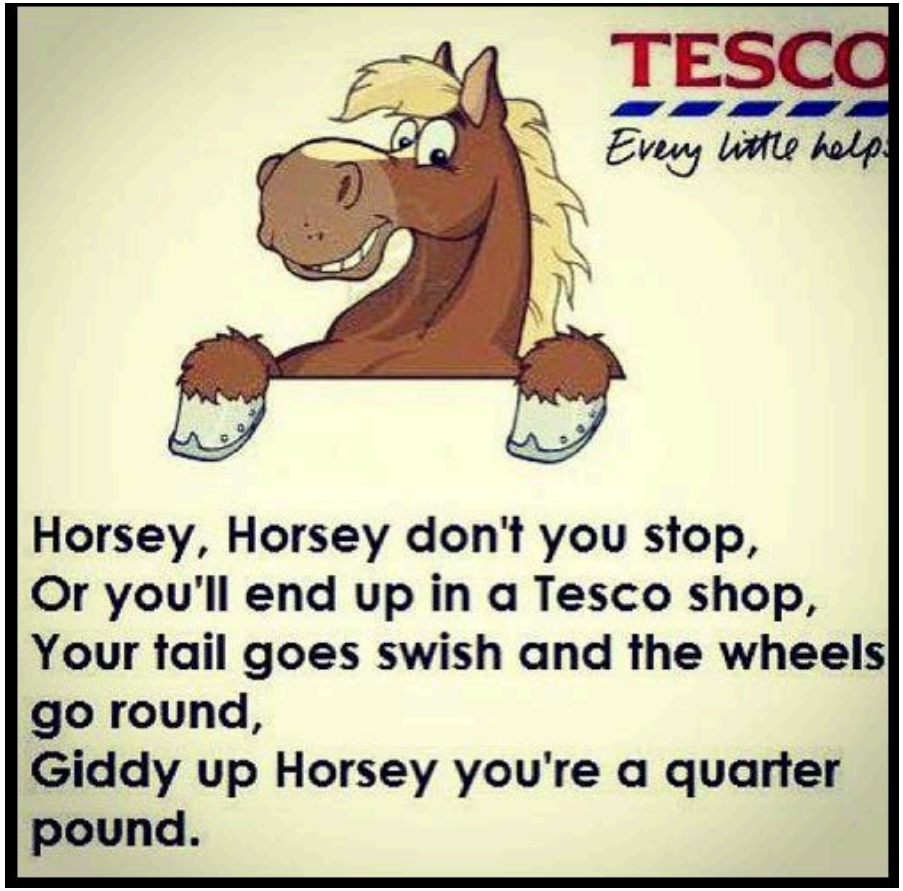
- Define/Isolate the Problem – **Priority 1**
  - Trace Ingredients/Packaging Components
  - Assess the impact – class 1 class 2 or class 3
  - Identify Product Flow
  - Identify Potentially Effected Lots
  - Segregate/Retain Potentially Effected Lots
  - Remember to Factor in Re-Worked Product
- The Team should know how to access Real-time Data:
  - Interpretation of QA/Testing Results
  - Customer Complaint Data
  - Laboratory Analysis – consider the use of accredited 3rd parties
  - Distribution/Sales Information

Recall Plans/Best Practices

- Recall Notices
  - Draft Form Recall Letters in Advance
  - Draft Call Center Scripts
  - Draft Press Releases in Advance
  - Set up Dummy Web Pages in Advance
  - Use Social Media Offensively
  - Monitor Social Media Defensively
- "Push the Red Button"
  - Have Software Lockouts in Distribution/Retail Chain
  - Ensure that All Marketing Media is Interconnected (apps/social media/website offers)
  - Validate No Sale Orders at Retail Level



Recall and Social Media



Getting the Message Right

Tesco rapped over misleading horsemeat ad: Supermarket accused of trying to fool customers by spreading blame for scandal

- Tesco said horsemeat scandal was problem for 'whole food industry'
- Advertising Standards Authority said ad breached industry codes and should not be repeated
- Claim outraged butchers who say they know where their meat comes from

By SEAN POULTER, CONSUMER AFFAIRS EDITOR

PUBLISHED: 00:41, 4 September 2013 | **UPDATED:** 00:45, 4 September 2013

Tesco hires farmers' voice to restore trust lost in horsemeat scandal

Senior executive at National Farmers' Union joins retailer as survey shows Britons are still sceptical about food safety

Rebecca Smithers
The Guardian, Wednesday 3 July 2013

Getting the Message Right

NEWS IN BRIEF

Britvic results hit by £17M Fruit Shoot recall

By Mike Stones, 28-Nov-2012

Soft drinks firm Britvic has reported a near 20% fall in profits, after an Essex boy choked on a newly designed lid of a Fruit Shoot bottle, forcing a £17M product recall.

The firm reported profits of £84.4M for the year to September 30 – a fall of 19% compared with the £105.1M posted in the previous year.

Total revenues fell by 0.8% to £1.26bn.

Britvic said Fruit Shoot production will be back to normal by January. But the recall could cost a further £8M in the next financial year.

Britvic says the health of its Fruit Shoot brand is back up towards the levels before its product recall in July, which was estimated to cost the company up to £25m.

Fruit Shoot marketing activity announcing the brand's return following the July product recall.

Recall Procedures

- Destruction Plans
  - Agency & Stakeholder Buy-In Before Prod. Destruction
  - Consider Testing/Retention of Returned Product
- Refund Plans
  - Publicize Refund Plan Broadly
  - Consider a Generous Refund Policy
    - No Questions Asked
    - No Documentary Requirements
    - No Quantity Limits
  - Avoids Exposure to Refund Class Actions
    - “Superior” under Rule 23(b) to Class Action

Recall Procedures

- **Financial Control**
  - Record all costs from the outset
  - Create an account for the incident
  - Make use of your nominated insurance responders
  - Do not over estimate the amount of your anticipated settlement from an underwriter
  - Use historic financial data to support your claim for compensation
  - Consider salvage value – a Loss Adjuster will

Recall Plans/Best Practices

- Outsource Specialized Functions
  - Call Center Staffing
  - Retail and Wholesale Product Reclamation
  - Media Monitoring
  - Laboratory testing
  - Claims/Refunds

Recall Simulation Best Practices

- Have a Recall Plan and Do Regular Recall Drills
- Plant and Trace Bad Inputs in the Drills
  - Reworked Product Compromises Traceability
  - Track Perception Time of Significant Customer Complaint
  - Test Media Inquiries of Low Level Employee
  - Simulate a Non-Compliant Distributor
  - Inject Outside Stakeholders
    - Regulators
    - Plaintiffs' Counsel
    - Media
    - Competitors
    - Insurers

Questions or Comments?

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