



***NEW FOOD SAFETY
LEGISLATION - WHERE ARE
WE GOING?***

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**3-A SANITARY STANDARDS
ANNUAL MEETING
MAY 2011**

WHERE HAVE WE BEEN?



THE PURE FOOD & DRUG ACT (1906)



FEDERAL FOOD, DRUG & COSMETIC (FDC) ACT (1938)

- **RESCINDED AND “MODERNIZED” PURE FOOD AND DRUG ACT**
- **GENERAL INTENT**
 - **PREVENTION OF ADULTERATION & MISBRANDING OF FOODS, DRUGS, COSMETICS AND MEDICAL DEVICES IN INTERSTATE COMMERCE**



FDA ENFORCEMENT OPTIONS UNDER FDC ACT

- **NON-JUDICIAL**
 - **RECALLS (VOLUNTARY)**
 - **WARNING LETTERS**
 - **PUBLICITY**
- **JUDICIAL**
 - **CIVIL ACTIONS**
 - **INJUNCTIONS**
 - **SEIZURES**
 - **CRIMINAL ACTIONS**



FOOD SAFETY LEGISLATIVE AND REGULATORY ACTIVITY IN THE NEW MILLENNIUM



WEBSITES OF POTENTIAL INTEREST

- WWW.THOMAS.GOV
- [HTTP://WWW.GOVTRACK.US](http://WWW.GOVTRACK.US)
- [HTTP://WWW.FDA.GOV](http://WWW.FDA.GOV)
- WWW.LEAVITTPARTNERSBLOG.COM



***PUBLIC HEALTH SECURITY AND
BIOTERRORISM PREPAREDNESS AND
RESPONSE ACT (2002)
[“BIOTERRORISM ACT”]***



IMPACT OF BIOTERRORISM LEGISLATION ON FDA FOOD REGULATORY PROGRAMS

- ***PROTECTION AGAINST ADULTERATION***
 - **INCREASED FDA BUDGET**

- **AMENDED FDC ACT AT SECT 304(H) & 801 (M)**
 - **ADMINISTRATIVE DETENTION AUTHORITY**
 - **PRIOR NOTICE OF IMPORTED FOODS**
 - **FACILITY REGISTRATION**
 - **MAINTENANCE AND INSPECTION OF RECORDS**



ADMINISTRATIVE DETENTION GIVES FDA AUTHORITY TO -

○ DETAIN SUSPECT FOOD

- IF *“CREDIBLE EVIDENCE”* THAT IT *“PRESENTS A THREAT OF SERIOUS ADVERSE HEALTH CONSEQUENCES OR DEATH ...”***

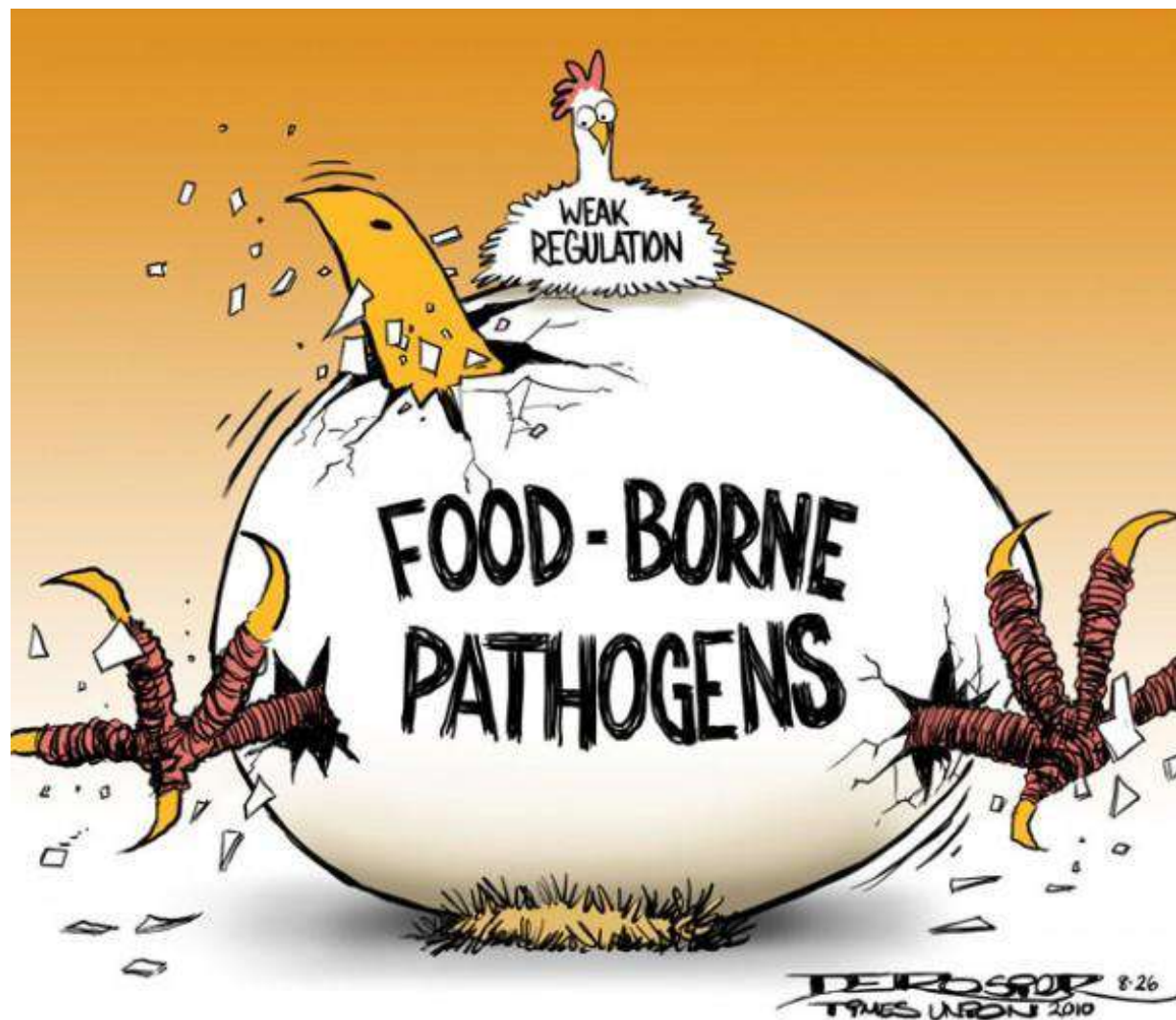


SANITARY FOOD TRANSPORTATION ACT

- **TRANSFERRED FROM DOT TO FDA ENFORCEMENT**
- ***ADVANCE NOTICE OF PROPOSED RULE (ANPR) – FDA (APRIL 2010)***
- **[HTTP://EDOCKET.ACCESS.GPO.GOV/2010/2010-10078.HTM](http://edocket.access.gpo.gov/2010/2010-10078.htm)**
 - **TO REQUEST DATA AND INFORMATION ON THE FOOD TRANSPORTATION INDUSTRY AND ITS PRACTICES.**
 - **TO REQUEST DATA AND INFORMATION ON THE CONTAMINATION OF TRANSPORTED FOODS AND ANY ASSOCIATED OUTBREAKS**



FOOD SAFETY MODERNIZATION (2009-2011) ???



US HOUSE OF REPRESENTATIVES

- **H. R. 759 - *FDA GLOBALIZATION ACT OF 2009* - DINGELL (MI)**
 - **1/28/2009**
- **H. R. 814 - *TRACING AND RECALLING AGRICULTURAL CONTAMINATION EVERYWHERE ACT (TRACE) OF 2009* - DEGETTE (CO)**
 - **2/3/2009**
- **H. R. 875 - *FOOD SAFETY MODERNIZATION ACT OF 2009* - DELAURO (CT)**
 - **2/4/2009**
- **H.R. 1332 - *SAFE FOOD ENFORCEMENT, ASSESSMENT, STANDARDS, AND TARGETING (FEAST) ACT OF 2009* – COSTA (CA)**
 - **3/5/2009**



***HR. 2749 - FOOD SAFETY ENHANCEMENT ACT
(2009)***



GENERAL ASPECTS OF HR. 2749

- **COMBINED OTHER BILLS**
 - **ESPECIALLY**
 - **H. R. 759 - *FDA GLOBALIZATION ACT* - DINGELL (MI)**
 - **H. R. 875 - *FOOD SAFETY MODERNIZATION ACT* - DELAURO (CT)**
- **INTRODUCED**
 - **6/8/2009**
- **PASSED HOUSE (AS AMENDED)**
 - **7/30/2009**
- **WRAPPED INTO *S 510 FDA FOOD SAFETY MODERNIZATION ACT***



US SENATE

- **S.425 - *FOOD SAFETY AND TRACKING IMPROVEMENT ACT OF 2009***- BROWN (OH)
 - 2/12/2009
- **S.510 *FDA FOOD SAFETY MODERNIZATION ACT OF 2009***
(DURBIN IL; GREGG, NH)
 - 3/3/2009
- **S.1269 - *FOOD SAFETY RAPID RESPONSE ACT OF 2009*** -
KLOBUCHAR (MN)
 - 6/16/2009
- **S1477 – *BILL TO ESTABLISH A USER FEE.....*** - FEINGOLD
(WI)
 - 7/21/2009
- **S. 2819 - *PROCESSED FOOD SAFETY ACT OF 2009***
(FEINSTEIN, CA)
 - 11/30/2009



***S.510 FDA FOOD SAFETY
MODERNIZATION ACT***



GENERAL ASPECTS OF S.510

- **INTRODUCED**
 - 3/3/2009
- **PASSED UNANIMOUSLY BY THE HEALTH, EDUCATION, LABOR AND PENSIONS (HELP) COMMITTEE**
 - 11/2009
- **STRONG SUPPORT FROM CONSUMER AS WELL AS FOOD INDUSTRY TRADE ASSOCIATIONS**
- **AMENDED VERSION ENACTED INTO LAW**
 - 01/04/2011



TITLE I: IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

- **INSPECTION OF RECORDS**
- **REGISTRATION**
- **HAZARD ANALYSIS AND RISK BASED PREVENTATIVE CONTROLS**
- **PERFORMANCE STANDARDS**
- **STANDARDS FOR PRODUCE SAFETY**
- **PROTECTION AGAINST INTENTIONAL ADULTERATION**
- **AUTHORITY TO COLLECT FEES**
- **NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY**
- **FOOD & AGRICULTURAL COORDINATING COUNCILS**
- **BUILDING DOMESTIC CAPACITY**
- **SANITARY FOOD TRANSPORTATION**
- **FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT**
- **NEW DIETARY GUIDELINES**
- **GUIDANCE RELATING TO POST HARVEST PROCESSING OF RAW OYSTERS**
- **PORT SHOPPING**
- **ALCOHOL-RELATED FACILITIES**



INSPECTION OF RECORDS ~

- **ALLOWS RECORDS ACCESS AND INSPECTION**
IF REASONABLE PROBABILITY THAT THE USE
OF OR EXPOSURE OF FOOD WILL CAUSE
SERIOUS ADVERSE HEALTH CONSEQUENCES
OR DEATH
 - **EXCLUDES FARMS AND RESTAURANTS**



REGISTRATION

- **EXPANDED FOOD FACILITY REGISTRATION REQUIREMENTS**
- **ALL FOOD FACILITIES WILL NEED TO REGISTER, AND RENEW BIENNIALY.**
- **REGISTRATION MAY BE SUSPENDED IF THERE IS A REASONABLE PROBABILITY THAT FOOD WILL CAUSE SERIOUS ADVERSE HEALTH CONSEQUENCES.**



HAZARD ANALYSIS AND RISK BASED PREVENTATIVE CONTROLS - REQUIREMENTS

- **EVALUATE THE HAZARDS THAT COULD AFFECT FOOD (UNINTENTIONAL AND INTENTIONAL)**
- **IDENTIFY AND IMPLEMENT PREVENTIVE CONTROLS**
- **MONITOR THE EFFECTIVENESS OF THOSE CONTROLS**
- **ESTABLISH AND IMPLEMENT CORRECTIVE ACTION PROCEDURES**
- **VERIFICATION,**
- **RECORDKEEPING**
- **WRITTEN PLAN AND DOCUMENTATION**
- **RE-ANALYSIS REQUIREMENTS**



ALMOST HACCP! (AHACCP??)

**HACCP WITHOUT SAYING HACCP
(HACCP- WSHACCP)**



EXEMPTIONS

- **SEAFOOD, JUICE, LOW ACID CANNED FOODS SUBJECT TO HACCP**
- **QUALIFIED FACILITIES**
 - **VERY SMALL BUSINESS**
 - **LIMITED ANNUAL MONETARY VALUE OF SALES**



PERFORMANCE STANDARDS – FDA TO-

- **REVIEW AND EVALUATE RELEVANT HEALTH DATA AND OTHER INFORMATION TO**
 - **DETERMINE THE MOST SIGNIFICANT FOOD-BORNE CONTAMINANTS**
- **ISSUE CONTAMINANT-SPECIFIC AND SCIENCE-BASED**
 - **GUIDANCE DOCUMENTS,**
 - **ACTION LEVELS, OR**
 - **REGULATIONS.**



PROTECTION AGAINST INTENTIONAL ADULTERATION

○ FDA SHALL

- CONDUCT VULNERABILITY ASSESSMENT OF FOOD SYSTEMS**
- CONSIDER THE BEST AVAILABLE RISK ASSESSMENT**
- DETERMINE SCIENCE-BASE MITIGATION STRATEGIES**



FEES – FDA CAN ASSESS FEES FOR

○ DOMESTIC FACILITIES

- **RE-INSPECTION**
- **FOOD RECALLS**

○ IMPORTS

- **IMPORTER RE-INSPECTION**
- **THE VOLUNTARY QUALIFIED IMPORTER PROGRAM**

○ EXPORTS

- **EXPORT CERTIFICATION**



ESTIMATED FY 2012 REVENUE FROM FEES

- **REINSPECTIONS**

- \$14,700,000

- **RECALLS**

- \$12,364,000

- **QUALIFIED IMPORTER PROGRAM**

- \$71,066,000

- **EXPORT CERTIFICATION**

- \$1,267,000

- **TOTAL**

- \$99,397,000



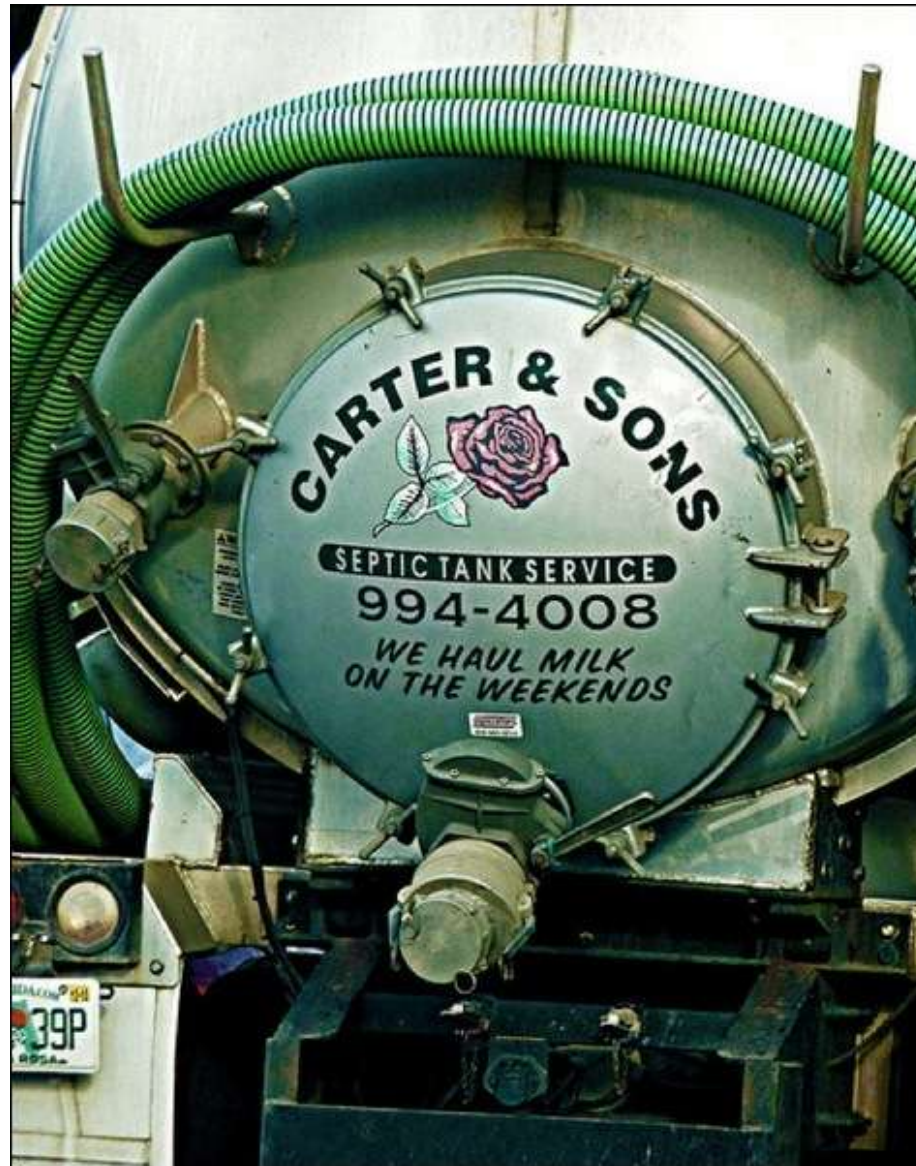
BUILDING DOMESTIC CAPACITY

– FDA TO SUBMIT TO CONGRESS

- **COMPREHENSIVE REPORT**
 - **ON PROGRAMS AND PRACTICES THAT PROMOTE SAFETY AND SECURITY OF FOOD**
- **BIENNIAL REPORTS ON PROGRAMS AND PRACTICES**
- **BIENNIAL FOOD SAFETY RESEARCH PLAN**



FOOD TRANSPORTATION



FLORIDA
PLATE



SANITARY FOOD TRANSPORTATION

- **TO SET REGULATIONS ON SANITARY TRANSPORTATION PRACTICES FOR THE TRANSPORTATION OF FOOD.**
 - **WITHIN 18 MONTHS**



TITLE II: IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

- **TARGETING OF INSPECTION RESOURCES**
- **LABORATORY ACCREDITATION FOR ANALYSES OF FOODS**
- **INTEGRATED CONSORTIUM OF LABORATORY NETWORKS.**
- **ENHANCING TRACE-BACK AND RECORDKEEPING.**
- **SURVEILLANCE**
- **MANDATORY RECALL AUTHORITY**
- **ADMINISTRATIVE DETENTION OF FOOD.**
- **DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS.**
- **IMPROVING THE TRAINING OF STATE, LOCAL, TERRITORIAL, AND TRIBAL FOOD SAFETY OFFICIALS.**
- **GRANTS TO ENHANCE FOOD SAFETY.**
- **IMPROVING THE REPORTABLE FOOD REGISTRY**



TARGETING OF INSPECTION RESOURCES - FDA TO

- **ALLOCATE RESOURCES TO INSPECT FACILITIES AND ARTICLES OF FOOD IMPORTED INTO THE UNITED STATES BASED ON THEIR RISK PROFILES;**
- **INCREASE THE FREQUENCY OF INSPECTION OF ALL FACILITIES; AND**
- **REPORT TO THE APPROPRIATE CONGRESSIONAL COMMITTEES ANNUALLY ON FOOD FACILITY AND FOOD IMPORT INSPECTIONS.**



ENHANCING TRACE-BACK AND RECORDKEEPING

- **TO EXPLORE, EVALUATE AND IMPROVE METHODS FOR RAPIDLY AND EFFECTIVELY TRACKING AND TRACING PROCESSED FOOD**
- **TO ESTABLISH PILOT PROJECTS (2011)**
- **TO ENHANCE FOOD- BORNE ILLNESS SURVEILLANCE SYSTEMS TO IMPROVE**
 - **DATA COLLECTION**
 - **DATA ANALYSIS**
 - **REPORTING**
 - **USEFULNESS**
- **TO ISSUE PROPOSED RULE REQUIRING THE MAINTENANCE OF RECORDS BY FACILITIES THAT WILL ALLOW THE FDA TO TRACE HIGH RISK FOOD DURING AN OUTBREAK (BY 2013)**



MANDATORY RECALL AUTHORITY

– FDA AUTHORIZED TO

- PROVIDE A RESPONSIBLE PARTY WITH AN **OPPORTUNITY** TO CEASE DISTRIBUTION AND RECALL AN ADULTERATED OR MISBRANDED ARTICLE OF HIGH RISK FOOD;
- **ORDER** A RESPONSIBLE PARTY TO **IMMEDIATELY CEASE DISTRIBUTION** AND PROVIDE NOTICE TO RELEVANT PERSONS **IF** THE RESPONSIBLE PARTY **DOES NOT VOLUNTARILY CEASE DISTRIBUTION OF OR RECALL** SUCH ARTICLE OF FOOD; AND
- **ORDER A RECALL** IF THE SECRETARY DETERMINES THAT REMOVAL OF THE ARTICLE FROM COMMERCE IS NECESSARY, BUT ONLY AFTER PROVIDING AN OPPORTUNITY FOR A HEARING.



ADMINISTRATIVE DETENTION

- **REVISES AND EXPANDS THE STANDARD FOR THE ADMINISTRATIVE DETENTION**
 - **EXPANDS AUTHORITY TO ALL ADULTERATION AND MISBRANDING**
- **REVISIONS IN *FDC Act***
 - ***STRIKING “CREDIBLE EVIDENCE OR INFORMATION INDICATING” AND INSERTING “REASON TO BELIEVE”; AND***
 - ***STRIKING “PRESENTS A THREAT OF SERIOUS ADVERSE HEALTH CONSEQUENCES OR DEATH TO HUMANS OR ANIMALS” AND INSERTING “IS ADULTERATED OR MISBRANDED”***

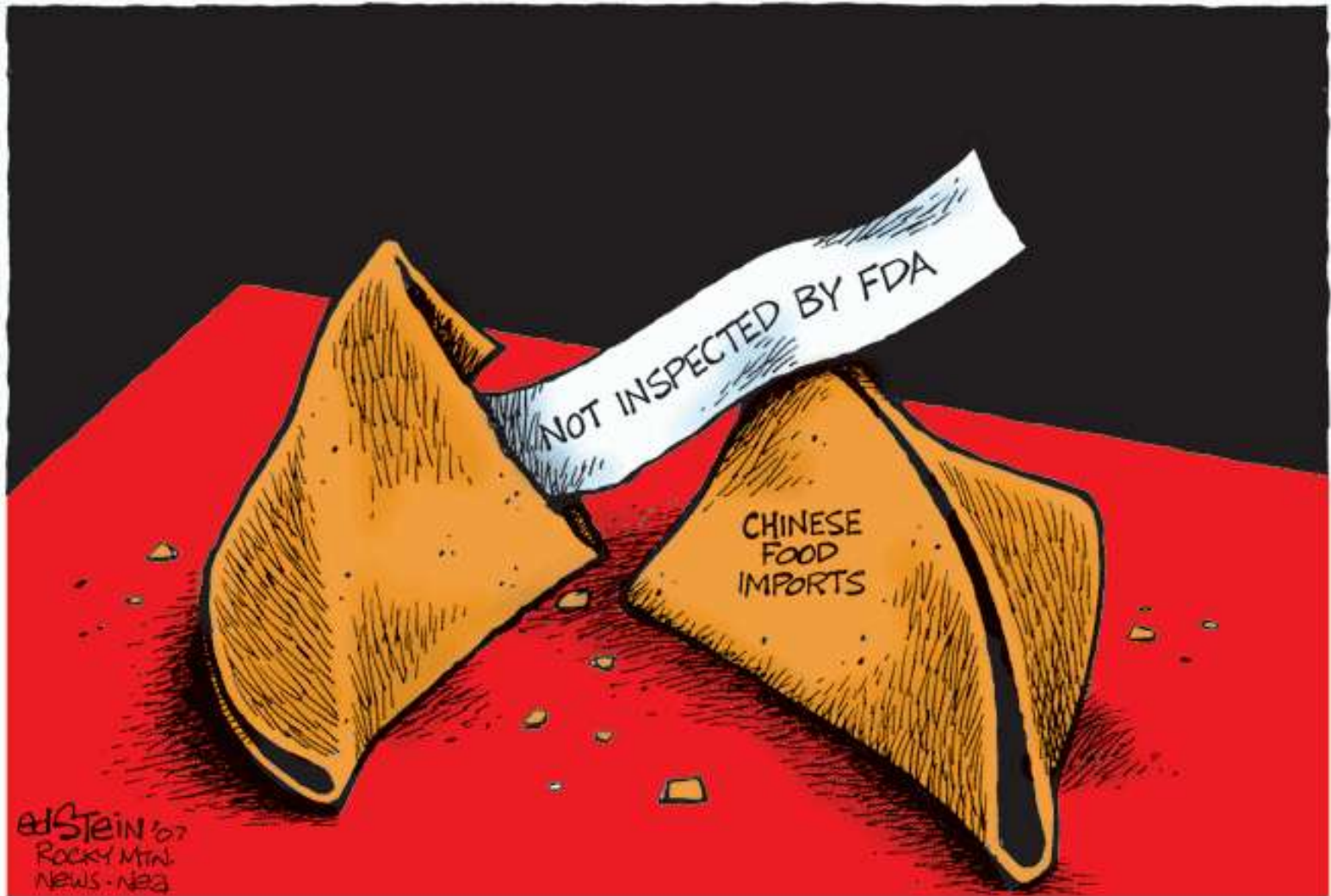


DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS

- **TO DEVELOP COLLABORATIVE PLAN BETWEEN
HHS AGENCIES AND EPA FOR DISPOSAL OF
CONTAMINATED FOOD**
 - **PLUS STATE – LOCAL INVOLVEMENT**



FOOD IMPORT PROVISIONS



TITLE III: IMPROVING THE SAFETY OF IMPORTED FOOD -

- **FOREIGN SUPPLIER VERIFICATION PROGRAM.**
- **VOLUNTARY QUALIFIED IMPORTER PROGRAM.**
- **AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS FOR FOOD**
- **PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS**
- **REVIEW OF A REGULATORY AUTHORITY OF A FOREIGN COUNTRY.**
- **BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD.**
- **INSPECTION OF FOREIGN FOOD FACILITIES.**
- **ACCREDITATION OF THIRD-PARTY AUDITORS AND AUDIT AGENTS.**
- **FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION.**
- **SMUGGLED FOOD.**



TITLE IV: MISCELLANEOUS PROVISIONS -

- **FUNDING FOR FOOD SAFETY.**
- **EMPLOYEE PROTECTION (WHISTLE BLOWER PROTECTION)**
- **JURISDICTION; AUTHORITIES.**
- **COMPLIANCE WITH INTERNATIONAL AGREEMENTS**
- **DETERMINATION OF BUDGETARY EFFECTS.**



PROVISIONS OF FSMA WHICH IMPACT FOOD EQUIPMENT STANDARDS

o 3-A SANITARY STANDARDS

- SHALL BE DEVELOPED FOR ALL FOOD PROCESSING AND HANDLING EQUIPMENT**
- SHALL BE REQUIRED FOR ALL FOOD PROCESSING AND HANDLING EQUIPMENT**



IMPACT ON DAIRY INDUSTRY?

- **UNIQUE FEDERAL-STATE PARTNERSHIP UNDER NCIMS**
- **PASTEURIZED MILK ORDINANCE (PMO)**
- **LABORATORY PROGRAM**
- **FARM TO THE CUSTOMER**





**FDA REPORT
NATIONAL CONFERENCE ON
INTERSTATE MILK
SHIPMENTS
MAY 1, 2011**

**NEGA BERU, PH. D.
DIRECTOR, OFFICE OF FOOD SAFETY
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
FOOD AND DRUG ADMINISTRATION**

PMO/NCIMS ASPECTS

- **THE PMO**

- **MENTIONED IN FSMA SEC. 103**

- **LABORATORY ACCREDITATION**

- **WILL GRADE A LAB PROGRAM NEED TO BE ACCREDITED UNDER FSMA???**

- **TO SOON TO TELL.**



FSMA SECT.103 HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

- **THE SECRETARY SHALL REVIEW REGULATORY HAZARD ANALYSIS AND PREVENTIVE CONTROL PROGRAMS IN EXISTENCE ON THE DATE OF ENACTMENT OF THE FDA FOOD SAFETY MODERNIZATION ACT, INCLUDING THE GRADE 'A' PASTEURIZED MILK ORDINANCE TO ENSURE THAT SUCH REGULATIONS ARE CONSISTENT, TO THE EXTENT PRACTICABLE, WITH APPLICABLE DOMESTIC AND INTERNATIONALLY-RECOGNIZED STANDARDS IN EXISTENCE ON SUCH DATE.**



FSMA AND THE PMO

- **THE REQUIRED REVIEW HAS BEEN DONE AND IS BEING WRITTEN**
- **IT WILL BE A REFERENCE TO THE PREAMBLE FOR THE NEW PREVENTIVE CONTROLS REGULATION**
- **EARLY INDICATIONS ARE THAT NO SIGNIFICANT ISSUES ARISE BETWEEN PMO AND DRAFT TEXT UNDER DEVELOPMENT**



OTHER DAIRY ISSUE?

- **FOOD DEFENSE PLAN REQUIREMENTS UNDER FSMA**
 - **WILL IT IMPACT DAIRY FARMS UNDER NCIMS**
 - **YOUR GUESS IS AS GOOD AS MINE.**



THE END

