



THE GLOBAL LANGUAGE
OF BUSINESS

Food Traceability: From Produce Fields to Consumers' Tables

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CURRENT STATE OF FOOD SAFETY AND TRACEABILITY REGULATORY STRUCTURE

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Home | About HHS |

HHS Home > ASL Home > Testimony > 2009 > 03

ASL Home
ASL Mission
ASL Leadership
Grants
Testimony
Legislative Offices within HHS
Related Links

Testimony

Statement by
Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services (HHS)

on
Traceability in the Food Supply

before
The House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug

Thursday March 26, 2009

Good morning, Madam Chairwoman and Members of the Subcommittee. I am Daniel Levinson, Inspector General for the U.S. Department of Health and Human Services.

Recent outbreaks of foodborne illness involving peanut butter, peppers, and spinach have raised serious questions about the Food and Drug Administration's (FDA) ability to protect the Nation's food supply. The Office of Inspector General (OIG) has identified FDA oversight of food, drugs, and medical devices as a top management challenge, and has conducted several reviews on FDA's oversight of food safety over the past decade. I recognize your leadership on this and other important issues related to FDA and appreciate the opportunity to appear before you today to discuss OIG's most recent work on the traceability of the food supply.

In short, our most recent work, being released today and now available on our Web site at <http://oig.hhs.gov>, found that only 5 of the 40 products we purchased could be traced through each stage of the food supply chain back to the farm or border. The ability to trace the remaining food products through each stage of the food supply chain was limited because: (1) food facilities often did not maintain lot-specific information, (2) some products were not labeled with lot-specific information, and (3) a number of food facilities mixed raw food products from a large number of farms. In addition, more than half of the facilities that handled these food products failed to meet FDA requirements to maintain records about their sources, recipients, and transporters of food. A quarter of food facilities reported that they were not even aware of these requirements. These factors affect FDA's ability to identify the source of a contamination and remove unsafe food products from the food supply chain.

ROLE AND RESPONSIBILITIES OF OIG

Our office was created in 1976 as the first statutory OIG in the Federal Government. Two years later, the Inspector General Act of 1978 established OIGs at other Cabinet-level departments of the Federal Government, as well as at some independent Government agencies. Congress created OIGs to be independent and objective units within Federal departments and agencies for the purposes of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing

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KEY REGULATIONS IN THE EU AND IN THE US

- EU Regulation for bovine animals and beef products (EC) No 1760/2000
- **EU Food Law (EC) 178/2002**
- EU Regulation for Food of Animal Origin (EC) 931/2011
- EU Fish Regulations (EC) 404/2011, 1224/2009
- EU Food Information Regulation (EC) 1169/2011

- US Bioterrorism Act
- **US FDA Food Safety Modernization Act (FSMA)**

EU FOOD LAW (EC) 178/2002

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in

- Traceability for all food feed products
- Each operator is responsible
- One step-up, one step-down principle

U.S. FDA FOOD SAFETY MODERNIZATION ACT (FSMA)

- A reform of the U.S. food safety laws (in more than 70 years)
- Signed into law by President Obama on 4 January 2011
- Focuses to ensure the U.S. food supply is safe by prevention



SEC. 204. <<NOTE: 21 USC 2223>> ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING.

(a) Pilot Projects.

(1) In general.--Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and mitigate a food consequences section 402 of section 403(w) (2) Content.-- coordination with processors. The Secretary food supply a significant out are selected in (A) develop a manner that is (B) develop a date of enactr (C) inform the (3) Report. << enactment of food. (b) Additional (1) In general (A) the costs a

[[Page 124 STAT. 3931]]

(A) evaluate domestic and international product tracing practices in commercial use; (B) consider international efforts, including an assessment of whether product tracing requirements developed under this section are compatible with global tracing systems, as appropriate; and (C) <<NOTE: Consultation.>> consult with a diverse and broad range of experts and stakeholders, including representatives of the food industry, agricultural producers, and nongovernmental organizations that represent the interests of consumers.

(c) Product Tracing System.--The Secretary, in consultation with the Secretary of Agriculture, shall, as appropriate, establish within the Food and Drug Administration a product tracing to receive information that improves the capacity of the Secretary to effectively and rapid and trace food that is in the United States or offered for import into the United States. Prior establishment of such product tracing system, the Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of such system are adequately supported by the results of such pilot projects.

(d) Additional Recordkeeping Requirements for High Risk Foods.-- (1) In general. <<NOTE: Deadline, Publication, Notice.>>--In order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, the Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations), for facilities that manufacture, process, or hold food that the Secretary determines under paragraph (2) are high risk foods. The

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EU FISH REGULATION 1224/2009

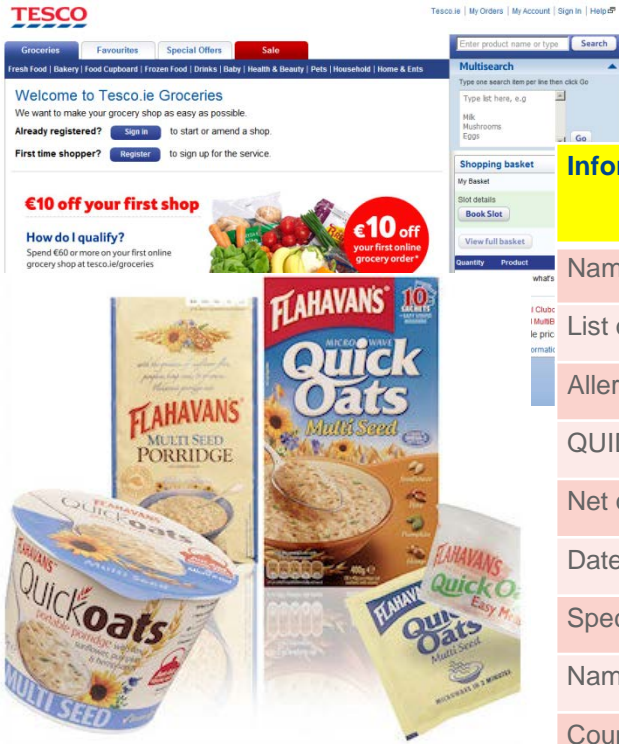
❑ Article 58.5 – Minimum Labelling Requirements

- ❑ The identification number of each lot;
- ❑ The external identification number and name of the fishing vessel or the name of the aquaculture production unit;
- ❑ The FAO alpha-3 code of each species;
- ❑ The date of
- ❑ The quantity and net weight of individuals;
- ❑ The name and
- ❑ The information Regulation (designation, area and the
- ❑ Whether the frozen or no

❑ Article 67.8

- ❑ Member States shall cooperate with each other to ensure that the information affixed to the lot and/or accompanying physically the lot can be accessed by the competent authorities of another Member State than the one where the fisheries or aquaculture products have been put into the lot, in particular when the information is affixed to the lot by way of an identification tool such as a code, barcode, an electronic chip or a similar device.
- ❑ Operators using such tools shall ensure that they are developed on the basis of internationally recognised standards and specifications.

FOOD INFORMATION REGULATION (FIR): EU 1169/2011



Information	New Regulations	Old regulations
Name of the food	✓	✓
List of ingredients	✓	✓
Allergens/intolerances	✓	✓
QUID	✓	✓
Net quantity	✓	✓
Date of minimum durability	✓	✓
Special storage conditions	✓	✓
Name of business	✓	✓
Country of origin labels	✓	✗ (only if omission misled or if beef)
Instructions for use	✓	✓
Alcoholic strength	✓	✓
Nutrition declaration	✓	✗ (only voluntary)

FIR APPLIES TO « DISTANCE SELLING »

Article 14

Distance selling

1. Without prejudice to the information requirements laid down in Article 9, in the case of prepacked foods offered for sale by means of distance communication:

(a) mandatory food information, except the particulars provided in point (f) of Article 9(1), shall be available before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. When other appropriate means are used, the mandatory food information shall be provided without the food business operator charging consumers supplementary costs;

(b) all mandatory particulars shall be available at the moment of delivery.

By Dec 2014



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Strawberry Jelly

Nutrition Facts

Amount Per Serving	% Daily Value
Calories 50	
Total Fat 0g	0%
Sodium 0g	0%
Total Carbohydrates 13g	4%
Sugars 12g	
Protein 0g	

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

Ingredients

STRAWBERRY JUICE, HIGH FRUCTOSE CORN SYRUP, CORN SYRUP, FRUIT PECTIN, CITRIC ACID.

Kosher Information

U Pareve

PUBLIC... AND PRIVATE REQUIREMENTS FOR TRACEABILITY



And others

THE PRODUCE TRACEABILITY INITIATIVE

“Trust but verify is the old saying as we are trying to incorporate private certification programs in the public approach. It needs to be transparent”.

Sharon Lindan Mayl, JD, Senior Advisor for Policy Office of Foods and Veterinary Medicine, U.S. Food and Drug Administration, USA
At the Global Food Safety Conference, Anaheim, February 2014

HACCP	BRC	IFS	SQF
<p>7.9 The Organisation shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.</p> <p>The traceability system shall be able to identify incoming material from suppliers, loaders and the initial distribution route of the end product.</p> <p>Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and may, for example, be based on the end product lot identification.</p>	<p>2.13 The company shall have a system which has the ability to trace and follow all raw materials (including primary packaging materials) from source through all stages of processing and distribution of the finished products to the customer.</p> <p>2.13.1. The system shall be regularly tested to ensure traceability can be determined from raw material to finished product and vice versa</p> <p>2.13.2. Where there is a requirement to provide identity preservation within the supply chain, e.g. to use a logo or mark, claim to a product characteristic or attribute, appropriate control and testing procedures shall be in place</p> <p>2.13.3. Where rework or any reworking operation is performed, traceability shall be maintained.</p>	<p>4.16.1. A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with food, packaging intended or expected to be in direct contact with food. The traceability system shall incorporate all relevant processing and distribution records.</p> <p>4.16.2. The traceability system shall be tested, documented and, where appropriate, audited at defined intervals to verify traceability in both directions of flow (from delivered products to raw material, and vice versa), including quantity checking.</p> <p>4.16.3. The traceability system shall be ensured at all stages, including work in progress, post treatment and rework.</p> <p>4.16.4. The lot labelling of semi-finished products or finished products, to ensure clear traceability of goods, shall be made at the time when the goods are directly packed. Where goods are labelled at a later time, the temporarily stored goods shall have been provided with a specific lot labelling. The shelf life (e.g. best before date) of the labelled goods shall be calculated from the original production date.</p>	<p>4.6.1. Finished product shall be clearly identified to the customer specification and/or regulatory requirements. The product identification system shall be traceable to the customer.</p> <p>4.6.2. Finished product shall be traceable to the customer. The product trace procedure shall be documented with responsibilities defined. It shall provide for the identification of raw materials and other inputs that may have an impact on finished product quality and safety. Raw materials and other inputs shall be traceable through the process to the finished product. Records of product dispatch and destination shall be maintained.</p>

THE FOOD INDUSTRY IS CHANGING THE WAY IT DOES BUSINESS

- The advancement and adoption of information technology
- Increasing the complexity of the global food supply
- The significant impact on the safety, quality and traceability of the foods consumers eat today.

WHAT IS ON THE HORIZON

- Industry progress is demonstrated by
 - Participation in the FDA food pilots that the IFT lead in 2012
 - Reviewing and updated traceability plans
 - Focusing on interoperability of information exchange
 - Industry knowledge sharing for potential improvements

CONTACT INFORMATION

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