The Impact of FSMA on Manufacturers

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Fast Facts about Mondelez International

Created in October 2012 with spin-off of Kraft Foods Group

Net Revenues of $35 billion in 2012

Global snacks powerhouse

Products marketed in 165 countries

No. 1 in Biscuits, Chocolate, Candy and Powdered Beverages

No. 2 in Gum and Coffee

Approximately 110,000 employees

Donated more than one billion servings of food since 1997
We offer many of the world’s favorite brands
Our Categories & Power Brands

- **Biscuits**
  - ~65% of Biscuit Revenue
  - OREO, TUC, belVita, Chips Ahoy!, Barix, Newtons, Wheat Thins, Triscuit

- **Chocolate**
  - ~50% of Chocolate Revenue
  - Cadbury Dairy Milk, Milka, LACTA, Toblerone, Côte d’Or

- **Gum & Candy**
  - ~60% of Gum & Candy Revenue
  - Trident, Halls, Calippo, Stride, Chicle

- **Beverages, Cheese & Dairy**
  - ~50% of Beverages, Cheese & Dairy Revenue
  - Tang, Tassimo, Kenco, Jacobs, Carte Noire, Philadelphia
Food Safety Management at Mondelez International
Food safety management occurs at multiple levels

**Level**

- **MDLZ International Board of Directors**
  - Review food safety management

- **MDLZ Executive Team:**
  - Assess company risk profile and management programs

- **Food Safety & Quality Senior Management**
  - Establish food safety policy, control programs, and compliance mechanisms

- **BU’s/ Regions:**
  - Implementation of company food safety policy and programs, ensure regulatory compliance

- **Special Situations Management Team**
  - Assess and proactively manage issues, issues prevention, and communication of lessons learned
We have an Integrated Quality Chain Management Approach that focuses on Systems across Key Factors

**Risk Categories**
- Chemical
- Microbiology
- Physical

**Scope**
- Design
- Procure
- Convert*
- Distribute
- Trade
- Consumer

**Quality Risk Prevention Programs**
- Design Safety Analysis
- Specifications
- HACCP
- Allergen Mgmt
- Supplier QA
- Plant & Equipment Design/Capability
- Package Integrity
- Contracts
- Selection/Approval
- Material Monitoring
- Continuous Improvement
- Specifications
- HACCP
- Supplier QA
- Traceability
- Sanitation & Allergen Control
- Complaint Mgmt
- Process Capability/Lean Six Sigma
- Traceability
- Warehouse Controls
- Complaints
- Warehouse Control
- Specification
- Labeling
- Consumer Feedback
- Process Capabilities

*Applies to internal & external plants*
Quality / Food Safety Programs Assess, Manage, and Mitigate Risk

- **Risk Assessment**
  - **Supplier Approval & Management** – determines suppliers risk profile and ability to meet MDLZ standards before use and on an ongoing basis
  - **Design Safety Analysis (DSA)** – new/changed product concepts are evaluated to design out potential physical hazards
  - **Hazard Analysis & Critical Control Points (HACCP)** – focused on prevention, identifies conversion risks, controls, and monitoring compliance
  - **Third Party Validation** - validation of key systems; Design, HACCP, Micro, Allergen, Supplier, Auditing

- **Risk Management**
  - **Auditing** – risk based approach to assesses compliance to policy and execution of programs leading to corrective/ preventive actions
  - **Material Monitoring** – incoming material testing program to verify the effectiveness of preventative programs
  - **Training** – drives awareness of policies, programs, roles & responsibilities and enhances organizational competency
  - **Traceability** – programs to manage and trace materials thru finished goods
  - **Spec Management** – specification development and change management process for materials, processes, and finished goods
  - **Contingency Planning** for single/ sole source and regionally isolated ingredients

- **Risk Mitigation**
  - **Special Situations Management** – defined company wide process for proactive and effective management of issues minimizing potential impact to the business
Quality Management – QCMS

• Quality Policy
  – Policies set our worldwide standards for food safety and quality
  – Based on ISO standards, provides a foundation and common language to communicate design, product safety and quality requirements throughout the supply chain.

• Compliance with regulations, code of conduct and industry standards

• Scope includes MDLZ Int. sites, external manufacturers, and suppliers
  – Training program builds understanding & competencies
  – Consistency across entire company
  – Audits verify adherence
How it fits together

Prerequisite Programs
Food Safety (HACCP)
Quality Systems
Cultural & Managerial Approaches

GMP/GHP
HACCP
QCMS/ISO
QM
What FSMA means to manufacturers
Feedback to FDA from GMA on proposed rules:
Foreign Supplier Verification

• GMA is very supportive of the statutory structure for supplier verification specified in FSMA. **Supplier verification** is an important function, as a number of visible product recalls have been linked to supplier issues.

• GMA believes that import safety and supplier verification should apply to oversight of both foreign and domestic suppliers.

However, some areas need further study and comment:

• The proposal is not necessarily reflective of leading industry practices. **Industry practices are flexible and risk-based,** therefore a prescriptive approach to supplier verification will likely hinder continuous improvement.

• GMA is very supportive of a **supplier-based verification** and not based solely on a hazard analysis. It should be based on an evaluation of the supplier’s entire food safety system.
Feedback to FDA from GMA on proposed rules: Foreign Supplier Verification

Areas needing further study and comment (cont):

• FDA does not need access to complete audit reports. These reports need to remain confidential and not subject to FDA inspection
  – Continuous improvement audits rely on a high level of confidentiality so suppliers will be completely open with manufacturers – importantly, such confidentiality will enhance food safety by providing manufacturers full and open access to supplier operations

• GMA supports the FDA in allowing the use of qualified third-party auditors to meet supplier verification responsibilities
  – Such a system needs to be outside of the formal third party accreditation process and reporting requirements

• FDA’s implementation of all rules will require extensive training to a new regulatory paradigm and a culture change within FDA
Feedback to FDA from GMA on proposed rules:
Third Party Auditing and Certification

• GMA is very supportive of the statutory structure for the accreditation of third parties for the two purposes specified in FSMA.
  – Mandatory Import Certification (MIC)
  – Voluntary Qualified Importer Program (VQIP)

• Believe that FDA is following the FSMA structure in that the agency will recognize accreditation bodies and those accreditation bodies will in turn accredit (oversee) the third party auditor/certification orgs

• This requires the 3rd party auditor to report to FDA of findings from the food facility being audited. This makes sense for:
  – MIC: Where the FDA has such a high concern about the food at issue that an extra set of independent eyes and ears are needed to assure the agency that it is safe
  – VQIP: Where the company is seeking a special benefit from the agency, in terms of expedited entry of its imported food
Feedback to FDA from GMA on proposed rules: Third Party Auditing and Certification

Areas needing further study and comment:

- FDA does not need to extend the program to cover the Foreign Supplier Verification Program (FSVP), as has been suggested
- FDA needs to ask whether such application – which FDA acknowledges is not referenced in FSMA – would advance or potentially detract from food safety
  - Ask FDA to keep an open mind as we do not want unintended consequences
  - Want to be sure that third party auditing is leveraged in appropriate ways as it is growing in size and capability
- GMA is equally concerned about how FDA proposes to treat “consultative audits” for FDA reporting purposes. These audits are conducted for internal company purposes and continuous improvement
- Need to examine the trigger to the immediate reporting provision, in terms of how that compares with existing reporting mechanisms under the reportable food registry
GFSI Board concerns on proposed rules: 3rd Party Auditing

• FDA’s self-appointment as an Accreditation Body (AB) sets itself apart and above other public- and private-sector ABs.

• FDA’s self-appointment as an AB may cause food safety authorities in other countries to do the same, creating duplicative and potentially conflicting third-party certification and auditing programs – an outcome GFSI was created to avoid.

• Submission of both regulatory and consultative audit reports goes well beyond FDA’s regulatory mandate. No company is going to hire an FDA accredited auditor if that auditor is required to report the findings from its audits and its facility test to FDA.

• Assessment reports are not like regulatory inspections. They contain highly proprietary information related to business systems and measures, with customer, equipment, operational and competitive information. They are confidential business information, not intended to be shared with outside interests

• Requiring CB/auditors to notify FDA of “serious risk” defined as a potential Class I or Class II recall discourages companies from undertaking voluntary internal audits to root out and prevent food safety incidents from happening.
Mondelēz International perspective and concerns on proposed rules: FSVP & 3rd Party Auditing

- MDLZ prefers option 2 under the proposed FSVP rules as it provides more flexibility and is more closely aligned with our approach today.

- How and when will FDA determine what other countries (other than NZ) receive the comparable country designation for food safety?

- 3rd party certification could be construed as a “surrogate” FDA inspection program.

- There is no system in place to manage audit and lab information with industry and government.

- Concerned about the inability to handle the volume of information of direct reporting to FDA with the low criteria of Class II type recalls for auditors to report.

- The reduced incentive for consultative audits has the potential to undermine the improvement of food safety systems that the industry has been driving (such as through GFSI).
Appendix:

GFSI at Mondelez International
MDLZ has made a strong commitment to the Global Food Safety Initiative. Steps that we have taken include:

- Sending a communication to all MDLZ raw material suppliers globally (~3000) with the expectation that they receive certification from one of the GFSI accredited standards by the end of 2014.
- Ensuring that all of our internal manufacturing facilities have a GFSI certification. (We have chosen FSSC 22000) by the end of 2014.
- Promoting GFSI to our external partners including Joint Ventures and External Manufacturers.
- Continued support to GFSI through our board membership and participation in Regional Focus Days and the Annual Conference.
Receiving certification by a GFSI recognized standard through an accredited third party provides numerous benefits:

- Improved consumer confidence in safer food
- Certified companies are more disciplined, more efficient and more profitable
- Cost efficiency in the supply chain – MDLZ has been able to supplement internal resources through our GFSI approach with third party certification bodies
- The GFSI recognized standards are accessible and are shared by many – Once you are certified, you can provide raw materials to any company who accepts GFSI certification in lieu of their own audit
- Certified companies show equivalence of process across countries and continents – MDLZ’s suppliers are now able to demonstrate that all of their facilities follow the same type of Quality Management System
Why have your plants certified by one of the GFSI schemes?

- Multiple stakeholder driven (Mondelēz International Food Safety expectation)
- Tool for continuous improvement in site performance on food safety
- Annual audit or surveillance/ a process check that compliments MDLZ expectations
- Accredited, independent verification of plant Food Safety Management Systems
- Customers want/demand it (i.e. Wal-Mart, Safeway, Ahold, etc.)
- Clear management system and performance (requirements) approach
- Reduction/elimination in number of customer 3rd party audits

Mondelēz International
Food Safety through the Quality Chain

How GFSI fits into the Mondelez framework

Non-Sensitive ingredient suppliers
- Identification of Suppliers
- Mdlz SQE Requirements
- GAP Assessment & Closure
- Mdlz SQE Audits or GFSI Recognised Certification Approval

Sensitive ingredient suppliers
- Identification of Suppliers
- GFSI & Mdlz SQE Requirements
- GAP Assessment & Closure
- Initial Mdlz SQE Audit & 3rd Party GFSI Certification Approval + Annual Technical visit

Internal Manufacturing
- Training on QCMS
- HACCP Implementation
- GAP Assessment & Closure
- Mdlz Global Audits & 3rd Party Certification

External Manufacturing
- Training on QCMS
- GAP Assessment
- Commercial Alignment
- Scheduled Mdlz Global Audits & 3rd Party Certification

Consumer Safety & Satisfaction