The Food Compliance Cloud™

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Selerant Corporation
November 15, 2012

Innovation in Food Safety and Compliance
Company Background

- PLM-New Product Development software company founded in 1990
- Web-based Enterprise Software Product launched in 2003
- Global presence
  - Dual Headquarters in New York, NY and Milan, Italy
  - Offices in France, Spain, Switzerland, UK and Shanghai, China and India
- Specialized in the unique product lifecycle management needs of process industries
- Profitable, innovative and privately held software solution provider with continuous investment in R&D and Quality and 35% annual growth
- Over 200 global customers
- Over 250 employees
- Extensive in-house Implementation Services Organization
Industries served

Food & Beverage
Cosmetics & OTC goods
Chemicals, Paint, Ink & Coatings
Industry Challenges for Regulatory Compliance

- Unpredictable consumers
- Supply-chain accountability
- Investor pressures
- Global compliance
The Food Compliance Cloud Supports…

- Strengthens existing regulatory compliance programs.
- Serves as the foundation for developing new regulatory compliance programs.
An E. coli outbreak at Jack in the Box cost the company approximately $160 million in sales and 30 percent of its stock market value.

Menu Foods Pet Food: $42 million to pay for the recall, not including lost sales, plus $32 million in settlements.

For companies that have faced a recall in the past five years, 77% of respondents estimated the financial impact to be up to $30 million dollars; 23% reported even higher costs. *GMA, October 2011*
Make Regulatory Compliance a Competitive Advantage

Solutions
Selerant’s Food Compliance Cloud™

- Compliance by Design
  - Consistency of interpretation
  - Harmonisation of processes
  - Decrease time to market
Key Business Benefits of the Food Compliance Cloud™

Reduce Development Time

✓ Compliance checks that can be used throughout the product development cycle to identify and resolve compliance issues on a real-time basis.
Key Business Benefits of the Food Compliance Cloud™

Focus on strategic objectives

- Outsource tedious tasks (data collection, pre-validation, entry)
- On-demand access to regulatory data and legislation
- Dedicate more time to key regulatory issues
Key Business Benefits of the Food Compliance Cloud™

Control of regulatory data sets

- Accurate, validated and consistent interpretation of the regulations
- Supporting reports / regulation briefs sent on regular basis
Selerant’s Food Compliance Cloud™

- The new toolbox for Regulatory Compliance
  - Global Food Additives Database
  - Global Food Impurities Database
    - Nutritional labeling
    - Nutrient content claims (FDA, USDA, EU)
    - Microbiological criteria
    - Food contact materials
    - PARNUTS substance list
**Selerant’s Food Compliance Cloud™**

- Food Additive & Pesticide Data
  - US FDA & USDA
  - Canada
  - European Union
  - Codex
  - China
  - Taiwan
Regulatory Compliance without The Food Compliance Cloud™

Can I sell Lemon/Lime Beverage #2 in the U.S., China and the European Union?
Regulatory Compliance without The Food Compliance Cloud™

- Internal Data Review & Evaluation
- 3rd Party Data Search & Evaluation
- Country Regulation Review & Evaluation
- Meet with R&D to Review Issues and Discuss Alternatives
Regulatory Compliance with The Food Compliance Cloud™

INTERNAL DATA REVIEW & EVALUATION

3RD PARTY DATA SEARCH & EVALUATION

COUNTRY REGULATION REVIEW & EVALUATION

MEET WITH R&D TO REVIEW ISSUES AND DISCUSS ALTERNATIVES
Regulatory Compliance with The Food Compliance Cloud™

- Fully Integrated Knowledge Base
  - Search by material or country
<table>
<thead>
<tr>
<th>Code</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Guideline type for Codex Food Additives</td>
</tr>
<tr>
<td></td>
<td>Guideline type China Additives</td>
</tr>
<tr>
<td></td>
<td>Guideline type Taiwan Additives</td>
</tr>
<tr>
<td></td>
<td>Guideline type US Food Additives (FDA and USDA)</td>
</tr>
<tr>
<td></td>
<td>Guideline type for US Contaminants, pesticides, vet. drugs</td>
</tr>
</tbody>
</table>
Regulatory Compliance with The Food Compliance Cloud™

- Fully Integrated Knowledge Base
  - Evaluate product and market restrictions
    - Identify alternate ingredients
<table>
<thead>
<tr>
<th>Application 1</th>
<th>Application 2</th>
<th>Application 3</th>
<th>Application 4</th>
<th>Restriction Type</th>
<th>Upper UM</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Food Categories</td>
<td>Bakery wares</td>
<td>Bread and ordinary bakery wares</td>
<td>Breads and rolls</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Bakery wares</td>
<td>Bread and ordinary bakery wares</td>
<td>Bread-type products, including bro...</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Bakery wares</td>
<td>Bread and ordinary bakery wares</td>
<td>Other ordinary bakery products (e....</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Bakery wares</td>
<td>Bread and ordinary bakery wares</td>
<td>Crackers, excluding sweet crackers</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Cereals and cereal product...</td>
<td>Pastes and noodles and like product...</td>
<td>Pre-cooked pastes and noodles an...</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Confectionery</td>
<td>Confectionery including hard and so...</td>
<td></td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Confectionery</td>
<td>Cocoa products and chocolate prod...</td>
<td>Cocoa and chocolate products</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Confectionery</td>
<td>Chewing gum</td>
<td></td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Confectionery</td>
<td>Decorations (e.g., for fine bakery w...</td>
<td></td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Dairy products and analogue...</td>
<td>Condensed milk and analogues (pl...</td>
<td>Beverage whiteners</td>
<td>Limited in Form...</td>
<td>100 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Edible ices, including sherb...</td>
<td></td>
<td></td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Fats and oils, and fat emulsi...</td>
<td>Fats and oils essentially free from w...</td>
<td>Vegetable oils and fats</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Fats and oils, and fat emulsi...</td>
<td>Fat-based desserts excluding dairy-...</td>
<td></td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Fats and oils, and fat emulsi...</td>
<td>Fat emulsions mainly of type oil-in-...</td>
<td></td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
<tr>
<td>All Food Categories</td>
<td>Fats and oils, and fat emulsi...</td>
<td>Fat emulsions mainly of type water-...</td>
<td>Fat spreads. dairy fat spreads and ...</td>
<td>Limited in Form...</td>
<td>200 ppm</td>
<td>Antioxidant</td>
</tr>
</tbody>
</table>
Regulatory Compliance with The Food Compliance Cloud™

Determine formulation compliance in seconds:
**Global Food Additives**

1234Test  
Lemon Cola

<table>
<thead>
<tr>
<th>Overall Result</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison Result</td>
<td>Same as previous calc</td>
</tr>
<tr>
<td>Execution Mode</td>
<td>Standard</td>
</tr>
<tr>
<td>Execution On</td>
<td>9/14/2012, 9:51:50 AM</td>
</tr>
<tr>
<td>Execution By</td>
<td>DevEX Administrator</td>
</tr>
</tbody>
</table>

**Input Parameters:**
- **Food additives RSA guideline:** USFOODADD1_CH_ADD 0
- **Country description:** USA
- **Guideline type:** GTYPE_US_ADDITIVES
- **Multicountry option:** No

**Summary Result:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Additives Restrictions: (List of Additives Components and their Restrictions.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNITED STATES</td>
<td>All Food Categories</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>All Food Categories; Beverages and beverage bases, Nonalcoholic; Beverages, cola-type</td>
</tr>
</tbody>
</table>

**Detailed Results:**

<table>
<thead>
<tr>
<th>Result</th>
<th>Substance name</th>
<th>Applications</th>
<th>Substance legislative Limit</th>
<th>Quantity in Formula</th>
<th>Substance Source</th>
<th>Legislation Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
<td>GLYCERIN</td>
<td>All Food Categories</td>
<td>100% (Multi-Purpose)</td>
<td>25%</td>
<td>Glycerin</td>
<td></td>
</tr>
<tr>
<td>☢️</td>
<td>CAFFEINE</td>
<td>All Food Categories; Beverages and beverage bases, nonalcoholic; Beverages, cola-type</td>
<td>0.02% (Multi-Purpose)</td>
<td>5%</td>
<td>Caffeine</td>
<td></td>
</tr>
<tr>
<td>✔️</td>
<td>LEMON EO</td>
<td>All Food Categories</td>
<td>100% (Flavoring Agent)</td>
<td>3.25%</td>
<td>Lemon Essential Oil</td>
<td></td>
</tr>
<tr>
<td>☢️</td>
<td>TBHQ</td>
<td>All Food Categories</td>
<td>100% (Antioxidant)</td>
<td>3.25%</td>
<td>TBHQ</td>
<td>Alone or in combination with BHA and/or BHT. The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.</td>
</tr>
</tbody>
</table>
• Regulatory Compliance without the Food Compliance Cloud™

Manual  Disparate

Errors  Extended Timeline

• Regulatory Compliance with the Food Compliance Cloud™

Automated  Integrated

Accuracy  Expedited
PLM Product Solution
PLM Solution Maturity

- Custom Implementations (1985): Focus: Data & Technology
- Toolkit and Generic Applications (1990): Focus: Functions
- Business Solutions (2005): Focus: The Bottom Line
- Innovation (2012): Focus: The Bottom Line

Increasing Business Value:

- Cost
- Quality
- Time-to-Market
- Innovation
INGREDIENT SUPPLIER COLLABORATION

PRODUCT TESTING
FORMULA PROTOTYPES
PRODUCT SPECS

PROCUREMENT
FINANCE

FOOD SAFETY
REGULATORY

R&D

FINISHED BOM

PROJECT

PACKAGING PROTOTYPES

PACKAGE TESTING

Packaging Supplier Collaboration

Project / Concept → Development → Scale Up → Launch
## DevEX PLM Architecture

<table>
<thead>
<tr>
<th>Ideas / Customer Requests</th>
<th>Strategic Alignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage-Gate Process</td>
<td>Sustainability</td>
</tr>
<tr>
<td></td>
<td>Requirements</td>
</tr>
<tr>
<td></td>
<td>Project Management</td>
</tr>
<tr>
<td></td>
<td>Product Portfolio</td>
</tr>
</tbody>
</table>

### Data Alignment

<table>
<thead>
<tr>
<th>Formula &amp; Recipe Development</th>
<th>Eco-Design</th>
<th>Packaging</th>
<th>Optimization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Compliance &amp; Labeling</td>
<td>Specifications</td>
<td>Bills of Material</td>
<td></td>
</tr>
<tr>
<td>Supplier Data exchange</td>
<td>Supply Chain Integration</td>
<td>Manufacturing Scale-up</td>
<td></td>
</tr>
</tbody>
</table>

### Core Framework

<table>
<thead>
<tr>
<th>Material Management</th>
<th>Change Management</th>
<th>Document Management</th>
</tr>
</thead>
</table>

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DevEX Modular Platform

DevEX groups functionalities in 4 main areas


- *Product Data Management*: master data control via a state-of-the-art Specifications management system.

- *Regulatory Compliance*: enabling global compliance tools for material restrictions, product claims and labeling.

*Nutrition Facts*
Serving Size 1 Tsp (4.5g) Servings Per Container
IPM – Innovation Process Management

- Stage-Gate Process modeling
- Project Management and collaboration
- Product Requirements
- Project Analytics and reporting features
- Emails and notifications
- Project documentation repository
PD – Product Development

- Formula Design and simulations
- Optimization
- Online restrictions checks
- Ingredient introduction / Supplier Collaboration and testing
- Formula validation and approval
REG – Regulatory Compliance

- Country guidelines, rules & restrictions
- Multi language labeling capabilities
- Assisted Ingredient list generation
- Product Labeling
- Customer/brands restrictions
PDM – Product Data Management

• Full product Hierarchy (substance to pallet)
• Approval workflows
• Versioning
• Product Images and attachments
• Portfolio management and reporting
Selerant
Regulatory research and Scientific Affairs (RSA) Department

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