A PHASED APPROACH TO PROVIDE A COMPLETE AND COMPLIANT CHEMICAL HAZARD ANALYSIS OF YOUR INCOMING INGREDIENTS
Overview: Why the Need?

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. Simply stated, it enables the Food and Drug Administration (FDA) to better protect public health by focusing on preventing food safety problems rather than reacting to issues after they occur.

In January of 2013, FDA published the proposed rule on preventive controls for human food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. This rule requires food companies to develop a written food safety plan that includes a hazard analysis and risk-based preventive controls on known or reasonable foreseeable hazards that could affect food manufactured, processed, packed or held at a facility. This plan will be required to include several elements, most notably:

- Hazard analysis (including all potential biological, chemical, and physical risks that occur naturally, unintentionally, or which are intentionally introduced)
- Preventive controls
- Monitoring procedures
- Establishing corrective action procedures
- Validation and Verification of effectiveness of the entire food safety system, not just the critical limits (CLs) that support Critical Control Points (CCPs)
- Record keeping of the above activities

The proposed hazard analysis and risk-based preventive control requirements are similar to Hazard Analysis and Critical Control Points (HACCP) systems. As shown in Figure 1, there are six (6) basic principles.

**Figure 1: Hazard Analysis and Risk-Based Preventive Control Requirements**
While FDA’s proposed rules are based on HACCP, there are three major differences:

1. Preventive control may be required at points other than critical control points
2. Critical limits would not be required for all preventive controls
3. Radiological hazards must also be identified

When conducting a chemical hazard analysis of your ingredients, The National Food Lab uses a risk analysis based on Codex Alimentarius. The risk analysis follows a structured approach comprising the three distinct but closely linked components of risk analysis: risk assessment, risk management and risk communication, as shown in Figure 2.

**Figure 2: Elements of a Risk Analysis**

Risk Assessment

Risk Assessment relates to understanding and attempting to quantify how big the risk is, as well as the main factors that influence the risk. A comprehensive chemical risk assessment of ingredients includes evaluating many factors, i.e., inherent risk, incidence history, supplier history, source geography, target markets, percent of the ingredient in the final formulation, etc. The most thorough risk assessments include an in-depth on-site evaluation of selected processing facilities to assess further risks.

Risk Management

Once the risks are satisfactorily identified, risk management can then be employed. This element identifies and prioritizes the options or scenarios a company should consider to mitigate and manage the risks. Supplier contracts, certificates of analyses (COAs), analytical testing to verify COAs and supplier audits are key components to managing the chemical risk of incoming ingredients.
Risk Communication

Risk Communication is utilized throughout the risk analysis process to promote awareness and understanding of the specific issues under consideration during the analysis. While often taken for granted, this element is critical for consistency and transparency in formulating risk management options, recommendations and directions a company should speak about in regards to the risks and how those may be impacted by such risks. For example, communication between purchasing and the quality assurance teams is critical for a successful program. It can be very easy for these two teams to have conflicting goals.

A Phased Approach and Scope

Companies approach risk analysis initiatives in a number of ways. Based on our experience, we have identified best-in-class commonalities, elements and phases that should be considered in producing a chemical risk analysis that achieves compliance with FSMA and company-specific needs.

When tackling a complex project, a wise person once commented, “The only way to eat an elephant is one bite at a time!” Therefore, The NFL employs a phased approach to risk analysis. Using a phased approach offers a robust and flexible means of achieving objectives. As depicted below in Figure 3, we typically align two of the main key elements – Risk Assessment and Risk Management – across three phases, with the third element, Risk Communication, spanning the entire project.

Figure 3: Risk Analysis – A Multi-Phase Approach
Phase 1: Document Review

The document review must be comprehensive enough to be able to uncover all chemical hazards for the ingredient. At this point, we do not try to mitigate the hazards. The assessment should be made to just identify the hazard, determine the likelihood the hazard will occur, and the severity if it does.

In order to accomplish this daunting task, we partner with our clients’ Food Safety Team to conduct a deep dive assessment of numerous documents including:

- Ingredient Specifications
- Supplier Information
- Supplier Audits
- Formula Review
- Marketing information
- Agricultural Reviews
- Purchasing information

Phase 2: Risk Model Development

Information gleaned from the above assessment forms the starting point for data that eventually serves as input into The NFL’s Risk Assessment Model. A simple ranking system is used to build the model and eventually segment ingredients that are either more or less prone to potential risks, thus providing management with indications of where to focus actions or scrutiny. The overall ingredient determination and classification can involve multiple factors, as summarized below in Table 1.

Table 1: Factors for Ingredient Classification

<table>
<thead>
<tr>
<th>Factors for Risk Assessment Model</th>
<th>Specific Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inherent Risk Factors</td>
<td>Pertain to food safety hazards and the potential impact to finished product quality. Includes: incidence history; analytical data; evaluation of growing, harvesting, storage, processing and distribution practices; economic adulteration potential; other categories as required.</td>
</tr>
<tr>
<td>Supplier History</td>
<td>Risks based on past experience of the supplier with specific attention to incidence and frequency of rejections, food safety and quality advisories, and audit results.</td>
</tr>
<tr>
<td>Volume Driver</td>
<td>The greater the purchase volume the greater the risk.</td>
</tr>
<tr>
<td>Percent of Formula</td>
<td>As the percentage of the ingredient in the final product increases, so does the risk.</td>
</tr>
<tr>
<td>Targeted Market</td>
<td>Ingredients for products targeted to infant, children, or immunosuppressed populations carry a higher risk.</td>
</tr>
<tr>
<td>Source Geography</td>
<td>Risks due to manufacturing standards, national regulations and related quality systems.</td>
</tr>
</tbody>
</table>
Data and observations from the above can be synthesized and summarized a number of ways. The NFL's approach is to assign a numerical value to each factor with a definition assigned to each number. An overall risk classification value is calculated using the assessment and aggregation of results from each factor. Figure 4 illustrates the calculation.

**Figure 4: Example Risk Classification Calculation**

The overall risk classification values can then be summarized into ‘High,’ ‘Medium’ and ‘Low’ classifications with definitions for each. (See Table 2 for example definitions). While based on fictional data, Figure 5 is an example of a risk assessment report format used to summarize the data.

**Table 2: Example Risk Classification Definitions**

<table>
<thead>
<tr>
<th>Risk Classification</th>
<th>Assumptions and Interpretation for Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>Risk of food safety and quality related issues are HIGH due to the risk factors and must be mitigated with an effective Quality Assurance (QA) program to manage food safety and regulatory risks. Any deviations may have a significant impact on product safety.</td>
</tr>
<tr>
<td>MEDIUM</td>
<td>Risk of food safety and quality related issues are MEDIUM due to the risk factors. An effective QA program will manage the food safety and regulatory risks. Any deviations may have an impact on product safety.</td>
</tr>
<tr>
<td>LOW</td>
<td>Risk of food safety related issues are LOW due to the risk factors. An effective QA program will manage food safety and regulatory risks to an acceptable level.</td>
</tr>
</tbody>
</table>
Figure 5: Example Chemical Risk Assessment Summary

<table>
<thead>
<tr>
<th>Ingredient Category</th>
<th>Ingredient Name</th>
<th>Country of Origin</th>
<th>Supplier Name</th>
<th>Actual Purchased (lbs)</th>
<th>Volume Driven</th>
<th>Supply to Factories</th>
<th>Source Geography</th>
<th>Chemical</th>
<th>Total Risk Factor Calculation</th>
<th>Total Risk Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit Juice Concentrates</td>
<td>Apple Juice Concentrates</td>
<td>China</td>
<td></td>
<td>1,000,000</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>225.0</td>
<td>High</td>
</tr>
<tr>
<td>Spice</td>
<td>White Pepper</td>
<td>Vietnam</td>
<td></td>
<td>5,000</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>12.0</td>
<td>Low</td>
</tr>
<tr>
<td>Flour</td>
<td>Wheat Flour</td>
<td>US</td>
<td></td>
<td>3,000,000</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>30.0</td>
<td>Med</td>
</tr>
</tbody>
</table>

Phase 3: Risk Management Follow Up Activities: Execution and Management of Strategy

Once the risk has been identified it must be mitigated. This can be accomplished by establishing preventive controls. Typical preventive controls that can be used to mitigate chemical risks in ingredients are:

- Supplier verification programs
- Supplier contracts
- COA Requirements
- Verification /Testing Programs
- Audits
- Ingredient Tool-Kit for product development

An example of output from phase 3 can be viewed in Figure 6.
Figure 6: Example Risk Management Report

<table>
<thead>
<tr>
<th>Ingredient Category</th>
<th>Ingredient Name</th>
<th>Country of Origin</th>
<th>TOTAL RISK</th>
<th>Supplier Verification Program</th>
<th>AUDIT COMPLIANCE - Food Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tests Required</td>
<td>Number of tests per year (budget dependent)</td>
<td>Audit Schedule</td>
</tr>
<tr>
<td>Fruit Juice Concentrates</td>
<td>Apple Juice Concentrates</td>
<td>China</td>
<td>High</td>
<td>Pesticide, Patulin, Heavy Metals, Adulteration</td>
<td>6 Lots</td>
</tr>
<tr>
<td>Spice</td>
<td>White Pepper, Irradiated</td>
<td>Vietnam</td>
<td>Low</td>
<td>Aflatoxin, Ochratoxin, Heavy Metals, Pesticides, Adulteration</td>
<td>3 Lots</td>
</tr>
<tr>
<td>Flour</td>
<td>Wheat Flour</td>
<td>US</td>
<td>Med</td>
<td>Deoxynivalenol, Zearalenone, T2 and HT2, Ergot Alkaloids, Pesticides</td>
<td>1 Lots</td>
</tr>
</tbody>
</table>

**Focused and Forward-Looking Prevention**

Relying on a phased approach that encompasses several factors maximizes the opportunities of identifying inherent risks associated with a corporation’s ingredient portfolio. Identifying, and then ranking, such risks is the first step in ultimately preventing food safety concerns. As FSMA requirements continue to evolve, corporations will need to consider or re-assess their approaches to risk assessments to ensure that complete and compliant systems exist for microbial, physical and chemical hazards. The approach described in this paper offers a systematic process for identifying and prioritizing the often neglected chemical hazards. The NFL’s risk analysis tool is rugged enough to uncover and rank your chemical hazard and flexible enough to easily add newly identified risk factors and threats.

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