

ADDITIVES AND PROCESSING AIDS EVOLVING REQUIREMENTS FOR FOOD SAFETY

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Introduction:

Food and Consumer Safety have been in the forefront of the news with numerous problems documented both with intentional food contamination as well as unintentional handling problems across several Global and North American Food Processing facilities. The problems have resulted in illnesses and deaths to both pets and people.

How does this impact the Sugar Industry? Most sugar customers are associated with final consumable products in the beverage, bakery, prepared foods, desserts and other consumables. Because of the potential liabilities surrounding a recall or contaminated product, increased supplier audit requirements and third party audited certifications are becoming cornerstones of the customer's new internal Food Safety programs.

Discussion:

The United States has enacted new legislation - The Food Safety Modernization Act (FSMA - December 2010) - associated with the FDA structure and funding and Food Safety. This brings the United States more in line and up to the standards of many international countries who have already strengthened their food safety laws – EU, Canada, Japan, Australia and New Zealand with countries like China, Taiwan, Brazil and Korea all working towards new and tighter legislation. The act also puts more emphasis on processing aids used in the industry.

The Global Food Safety Initiative (GFSI) is becoming a standard that is driving many of the multi-national food companies in building their internal policies. Programs such as SQF (Safe Quality Foods) 2000 Level 2 or 3, Dutch HACCP (Hazardous Analysis of Critical Control Points) Option 3, AIBI (American Institute of Baking International) HACCP Gold, Synergy 22000, International Food Standard Version 5 and others are being used as the third party certifiers of these standards. The certification standards that these programs are based on are well documented GMP's (Good Manufacturing Practices) that include / require full management support of new internal control policies for cleanliness, manufacturing, handling and packaging, traceability / recall proficiency, employee knowledge of policies, lab and QC excellence as well as complete auditing of their supplier supply base! In essence, the new standards are forcing the Global Food Safety Initiative standards towards a "Farm to Fork" line of traceability and liability.

Several global incidents which acted as catalysts for the new legislation were brought to the forefront in 2007 were melamine contaminated pet food (pet & human health issue), baby formula with insufficient protein and nutritional content (infant

deaths), bacterial contamination of vegetable and meat products (human deaths and illnesses) and antifreeze tainted cough syrup in Panama (significant number of deaths).

Continuing into 2008 – 2009; 1,2 Dioxin detected in pork in Ireland, unintentional handling issues with Spinach and Hamburger Meat in the United States and Europe, Maple Leaf Foods Lysteria contaminated deli meats in Canada (21 Deaths / Court approves \$27 Million Settlement - May 2009), Salmonella tainted peanut butter (9 Deaths, 600 + reported illnesses, 1900 products pulled from market, company bankrupt).

The year 2010 produced further food contamination issues. Each of the issues brought significant and sensational media coverage on a global basis. Reactions globally were the same, the product or products associated with the contamination or adulteration were recalled, consumers refused to buy the products after the problems were supposedly corrected, the companies suffered huge losses or went out of business. Law suits proliferated and were settled as quickly as possible, legal actions were taken against those personally responsible; to the extent of execution (hangings, firing squads) and prison. Unfortunately, there was loss of both pet and human life; some times at a rate difficult to quantify due to poor record keeping.

The responses of global governments differed by method, but were all targeted to minimize their population's potential exposure to contaminated / adulterated products whether through purposeful or accidental means. Rules and regulations were examined; strengthened and more detailed enforcement was planned. Various countries reviewed "intended use", additives, process aids, ingredients & process compliance closely against more rigid standards. The importance of understanding where products associated with your application(s) are defined is essential.

What is "Food"? What items are often included under Food Regulations? The term "Food" as defined in FD&C (Food, Drug and Cosmetic) Act Section 201(f) encompasses a variety of substances beyond the common food user's experience. The statutory definition includes: (1) Articles used for food or drink for man or other animals; (2) chewing gum; (3) and articles used for components of any such article. "Articles used for components" includes food when combined and processed to become other food, but also food additives and/or other substances that could migrate into food. Food, Animal/Pet Food, Food additives, Food processing aids, Food-contact items such as food packaging inks, food packaging and containers for food additives/processing aids all fall under the new FSMA guidelines, but an important question is what category do items fall under?

Intended Use: "Processing Aid" vs. "Food Additive". Some countries distinguish the regulatory requirements based upon these and other categories: Generally, the definitions have been -

■ **Processing Aid –**

- A material used to process the food, but has no intentional technical effect on the food itself.
- Potentially trace levels of such process aids may remain in the food after the manufacturing process.

■ **Food Additive –**

- A direct food ingredient, intentionally added to impart some effect on the food product itself.
- The level used corresponds to that required to obtain the desired technical effect.

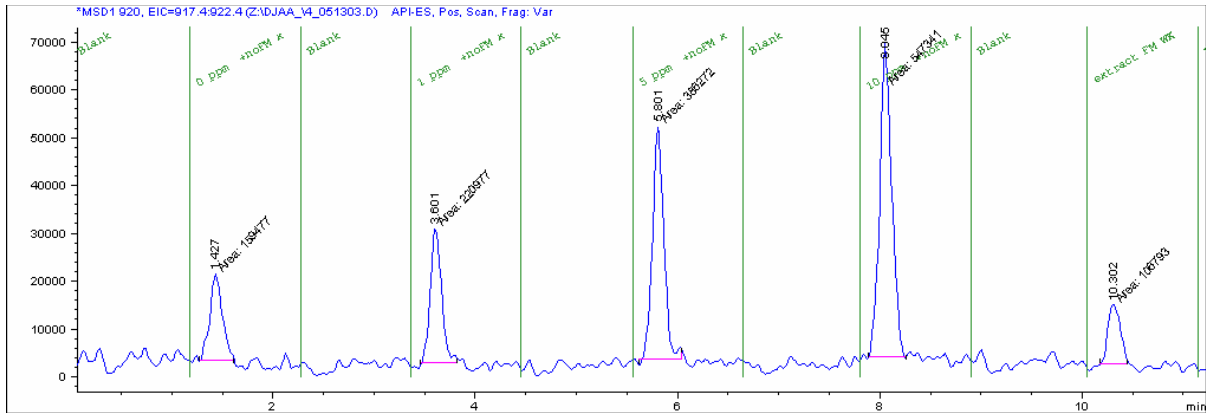
Some products can be classified as both a Processing Aid or a Food Additive only differentiated by the application point / purpose. For example, defoamers can be classified in either category. An example of a processing aid application is the use of defoamers in the sugar process or chip making process. The product is added to reduce foam generation in the process to allow the final product to be pumped, moved and produced in an efficient and repeatable manner. Residual defoamer may be present in the final product unintentionally, but it has no intentional effect on the performance, taste, texture, viscosity or other characteristics of the final product.

On the other hand, an example of a Food Additive defoamer application would be the packaging of a beverage product or molasses. The final product is being packaged on a high speed filler line into containers or into trucks, railcars or tanks and the foaming characteristic of the product minimizes the ability to transfer the product in an efficient manner. Application of a defoamer to the final product to minimize foaming characteristics actually modifies the final product via an intentional application with known residual – the defoamer would then be listed as a Food Additive if the final product becomes a direct consumable or part of a direct consumable (animal feed is included).

Not yet a requirement, but an important consideration and one that will eventually be asked or required, is what residual levels of processing aids in the final product exist. Although the processing aid residual is not there intentionally, the question remains if it is present at some level. As an added safeguard and proactive approach to minimizing liability, residual testing or quantification by your supplier of possible residual levels is an added safeguard for your Regulatory & Compliance file. Some of this type of testing has been conducted and more is being targeted, an example is outlined below:

■ **An experiment to validate/quantify “trace levels” in a potato processing aid application was performed by an independent laboratory. Protocol for the testing had to be developed as previous protocol for this type of testing is not available.**

- Electrospray ionization mass spectroscopy (ESI-MS) was used as the quantifying measurement.
- Calibration curves generated with known quantities of the processing aid added to blank potato extract were developed to determine detection levels of the processing aid.
- Acetone extracts of unprocessed raw potatoes vs. processed French Fries were measured to determine potential levels of the processing aid.
- Graphical outputs were developed to approximate residual levels, if any, of the processing aid.
- Complete technical report was generated around the testing for reference.



ESI-MS Analysis of an extracted ion plot compares the area under the curve at a key frequency which corresponds to the processing aid component only to determine processing aid level.

Countries can regulate Processing Aids and Food Additives differently. It is important if you are exporting product (or your customer is exporting) to fully understand the destination country's rules associated with the category that your product is defined under – it could be different than the United States FDA definitions. Under the FMSA, the responsibility and liability associated with definitively determining if a product is correct, safe and not adulterated falls to the company purchasing and using the product. That is not to say that the company producing / manufacturing the raw material can not also be targeted for liability, but the first step for liability and prevention is the user. This is why it is important to know your supplier, trust your supplier and define how sustainable your supplier base is.

The FDA has been tightening their definitions and rules over the last 3 years leading to a complete overhaul of the programs under the FMSA. The guiding premise is the “Farm to Fork” approach to Food Safety which indicates “everything is linked from feed to animals to humans” and “guidelines impact everything that touches the food chain”. An FDA letter sent to food/feed manufacturers, May 16, 2007, highlighting food/feed manufacturer's legal responsibilities

- Every ingredient used is safe for its intended use.
- Must take their own measures to ensure the safety of their products.
- Must ensure only safe products are put on the market.

The Food Protection Plan – issued November 2007 – outlined steps associated with Prevention (increase Corporate Responsibility, ID vulnerabilities and risk and mitigation measures), Intervention (risk based sampling, inspection & surveillance) and Response (enhance reporting and recall procedure). There were also legislative proposals to enhance the powers of FDA which has taken the form of the FMSA.

Following is a breakdown of the FDA guidelines for defining Processing Aids vs. Food Additives compared to several other countries that are large trade partners with the United States:

FDA / United States Guidelines:

	Processing Aid	Food Additive
Criteria	<u>No</u> Technical Effect on Final Food Product	Technical Effect on Final Food product
Ingredients	No pre-approval process by FDA “Food Quality” under 21CFR Independent Evaluations + GRAS, EAFUS, FCC	<u>Requires</u> Pre-approval Process GRAS EAFUS Database - Everything Added to Food in the US FCC - Food Chemicals Codex & Codex Alimentarius
Level	Used at level to obtain needed effect. Some chemicals may have specified max allowable levels. Trace levels may be present in final food.	Used at the minimum level needed to achieve the technical effect
Process Compliance	GMP	GMP
What’s New?	Additional responsibilities for food safety placed on food manufacturers by FDA, including legislative efforts associated with Food Protection Plan.	

Health Canada Guidelines:

	Processing Aid	Food Additive
Criteria	<u>No</u> Technical Effect on Final Food Product	Technical Effect on Final Food product
Ingredients	Pre-approval under CFIA - Canadian Food Inspection Agency, or FCC Some ingredients required to appear on label	
Level	Typically Same as US FDA	
Process Compliance	GMP	
What’s New?	Potable Water Rinse Required to remove trace process aids	-

The European Union Guidelines (still requires full harmonization):

	Processing Aid	Food Additive
Criteria	Process aids and other food contact materials excluded from definition of “additive”.	Intentionally added to food stuffs to perform certain needed technological functions, i.e. color, sweeten, preserve etc.

Ingredients	Toxicological information of substances and levels must be met.	EFSA (European Food Safety Authority) is an independent, scientific point of reference for risk analysis of food & feed materials. Approved Ingredients Covered by Directive 89/107/EEC . Annex 1 covers 24 categories of additives, which includes anti-foaming agents. Certain items such as enzymes have applications that are AND are not considered additives.
Level	Must meet overall migration limit (OML) and specific migration limit (SML) for certain substances based on toxicological information.	Level, purity, conditions and restrictions covered by directive.
Process Compliance	GMP Required	
What's New?		2008-9 FIAP (Food Improvement Agents Package) – harmonize requirements for additives, flavorings and enzymes.

Chinese Guidelines – (Requirements for additives and processing aids are the same. There are new Rules and lists just published)

	Processing Aid & Food Additive
Criteria	Any synthetic compound or natural substance put into food to improve its quality, color, fragrance or taste, or for the sake of preservation or <u>processing</u> .
Ingredients & levels	> 1,500 permitted food additives in 22 categories. Allowable uses and maximum levels are listed in the China Hygienic Standards for Uses of Food Additives, Updated 2007.

Process Compliance	Food Hygiene Law implemented in 1995 by People's Congress covering hygiene standards. (>500 standards). Global Trade is also a key factor. China hosted Codex Alimentarius in 2008. For example, the US-FDA audits/inspects producers who export.
What's New?	Challenge to address inspection, surveillance, traceability among a very large number, fragmented farm and food processing manufacturers. (78% food processors < 10 employees; most farms < 2 acres). <u>New Food Safety Law</u> effective June 1 calls for a nationwide mechanism to assess food safety risks of a biological, chemical and physical nature. Scientific methods and other relevant information will be used.

Japanese Guidelines - (Requirements for additives and processing aids are the same)

	Processing Aid	Food Additive
Criteria	The term "additive" refers to substances used in or on food, in the process of manufacturing of food or for the purpose of the <u>processing</u> or preserving of food, by adding, mixing, infiltrating, or other means. Japan External Trade Organization (JETRO) website: http://www.jetro.go.jp/en/market/regulations/pdf/food-e.pdf	
Ingredients & levels	Approved ingredients in Japan may be more stringent than Codex Alimentarius. Consult regulations/JETRO site for specifics. Onus on importers to prove the safety of their product before import is allowed into Japan. Extensive labeling & documentation requirements. Long list of substances that importers must test. High level of laboratory testing (>10%) of imported material.	
Process Compliance	Japanese Ministry of Health & Welfare Food Sanitation Laws enacted in 1947, revised several times. Comprehensive Law comprises 36 Articles.	
What's New?	Recent legislation in Japan has matched, or even surpassed, that of the EU.	

Beyond Product specifications, there are also Process Compliance measures that are being enacted and are part of the new guidelines and requirements. Most countries utilize US FDA GMP standards for their GMP compliance; however some have their own versions. The United States FDA established guidelines are under FDA 21 CFR Part 110. They establish Current Good Manufacturing Practice (cGMP) in Food manufacturing and packaging for Human Food. Standards are now established regarding food adulteration and defining conditions fit/unfit for food use as well as standards established for preparation, packing, or storage conditions to avoid conditions that are unsanitary, contaminated with filth, or whereby it may be injurious to health.

The HACCP (Hazard Analysis of Critical Control Point) /GMP Certifications create structured procedures which are difficult to shortcut. The Certification guidelines target analyzing, controlling, monitoring, correcting and documenting the processes to avoid contamination. Multiple contamination types must be addressed such as Biological (such as a microbe), Chemical (such as a toxin or allergen) or Physical (such as ground glass or metal fragments). In order to comply with these standards, suppliers / manufacturers must set housekeeping standards at high levels, review and design handling & packaging to avoid all sources of contamination as well as have control points to remove accidental contamination and employ 3rd Party Auditors to enhance / justify Certifications.

Conclusion:

Based on the new government legislations, enhanced media coverage and sensationalism, increased company and personal responsibility and heightened consumer vigilance and demands, the growing global Food Industry is undergoing a new level of increased controls through new certifications and standards. The standards are moving towards global harmonization:

- **“Farm to Fork” policy is driving certification standards.**
- **Each level will react to their customers “above” and their suppliers “below”.**
- **It will take time, but standardization of Food Laws will take place.**
- **LIABILITY will be transferable, shared and easily determined.....**

Because, the **BOTTOM LINE** is spelled out by a response from one of the foremost authorities on the new FSMA when asked “what if a company does not want to implement FSMA or take the guidelines seriously or do not press suppliers to follow the same?”.....

“Explain to him or her that times have changed. The new FSMA allows for things like pulling a plant’s registration, essentially shutting them down. A re-inspection will result in charges to the plant that could be extremely expensive. Some of the laws and criteria allow for criminal penalties. I suggest that if a company wants to stay in business, compliance will not be an option.”

.....at days end, we all have choices!

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