December 15, 2014

By Electronic Submission

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD  20852


Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to share its views on the Food and Drug Administration's (FDA) proposed requirements regarding economically motivated adulteration (EMA) as part of its proposed rules “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Humans,” “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” and “Foreign Supplier Verification Program for Importers of Food for Humans and Animals” under the FDA Food Safety Modernization Act (FSMA). GMA is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation's economy.
GMA supported the passage of FSMA and has adopted a comprehensive program to support its implementation. We look forward to continuing to work with the agency for successful implementation of this groundbreaking law.

GMA is filing separate comments to each respective docket addressing the agency’s supplemental proposed rules for preventive controls for human foods, preventive controls for animal food, and the Foreign Supplier Verification Program (FSVP). We are filing these comments to address one cross-cutting issue that affects each of the supplemental proposed rules: FDA’s proposed requirements for controlling occurrences of food safety related economically motivated adulteration (EMA).

Executive Summary

In each of the supplemental proposed rules mentioned above, FDA proposes to require facilities/importers to consider the potential for food safety hazards that may be intentionally introduced for economic gain as part of the entity’s hazard analysis. As discussed in more detail in the comments that follow, although EMA is an issue that needs to be addressed at some point, we recommend that it be deferred until after completion and implementation of FDA’s seven major FSMA rules.

EMA is not a good fit for the hazard analysis and preventive controls framework for addressing food safety hazards because EMA is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards. Moreover, whereas traditional food safety hazards are primarily both identified and addressed at the facility level, EMA is typically handled by the corporate parent company. This is where supply chain management programs are typically located and preventive controls to address EMA cannot be applied at the facility level. Further, because food safety-related EMA is extremely rare and because predicting EMA to prevent it is extremely difficult, there will be no measurable benefit to food safety by imposing requirements to consider EMA hazards as part of a food safety plan or foreign supplier verification program.

Addressing EMA requires a completely different paradigm than unintentional adulteration, and we urge that industry be allowed to focus on the significant task of implementing FSMA effectively. Therefore, FDA should not include requirements directed to EMA in the preventive controls rules or in the FSVP rule. We urge FDA to focus on the major components of FSMA and first complete the seven major rulemakings and their successful implementation before taking on EMA as an independent issue.

EMA is Not a Good Fit for the Hazard Analysis and Preventive Controls Framework

The hazard analysis and preventive controls framework is not the right fit for EMA because EMA is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards. Food safety training, experience, process controls, GMPs, and other systems used to address food safety hazards are largely ineffective in controlling or mitigating against the effects of EMA. Whereas as traditional food safety hazards are primarily both identified and addressed at the facility level,
EMA is typically handled by the corporate parent company. This is where supply chain management programs are typically located and preventive controls to address EMA cannot be applied at the facility level.

EMA perpetrators go through painstaking efforts to ensure that the nature of their misdeed is not discovered. Thus, GMA members have found that EMA requires an approach that encompasses the entire supply chain and relies significantly on supplier verification activities (which are not preventive controls). Some GMA members lean toward mitigation of supply chain risks at the ingredient safety stage, subsequent to establishing a customer-vendor relationship. Others include specifications, supplier controls, written agreements, and contracts as tools to ensure a proper understanding of requirements. Plant audits by company or third party personnel can be employed to ensure a firm fully understands their suppliers and co-packers. Some GMA members simply choose to work only with the most reputable suppliers and co-packers. For example, some infant formula manufacturers will only use US dairy protein in their product. In addition to audits, members also may attempt to have a periodic presence in the facilities for a range of activities, including R&D work, process monitoring and business meetings. In sum, based on our member's experience, GMA asserts that EMA can be effectively addressed through business-to-business relations, expectations, and contracts. It does not demand specific regulatory requirements.

EMA is typically an issue of food integrity and quality. Historically, food safety incidents resultant from EMA are unintentional occurrences with unintentional harm. Only in the rarest of circumstances is it an issue of food safety. In fact, the unfortunate use of melamine to misrepresent the quality of diluted milk by disguising the true protein content should be thought of as an exceptional adverse circumstance—an outlier. Close review of the sources FDA cites as references for EMA events shows that food safety related EMA events rarely occur. Specifically, in the article by Everstine et. al, of the 137 events catalogued, only 47 (34%) occurred in the US. Ninety-six percent (96%) of the 47 US events were either not food safety related EMA issues or are outside the scope of these FSMA rulemakings, leaving 4% of the 47 events, or approximately two incidents of US food safety related issues attributable to EMA. Both of these events were part of the overall melamine incident. Similarly, the 2014 report from the Congressional Research Service cites statistics from the National Center of Food Protection and Defense’s EMA database, which show that only 0.7% of all EMA events involve “Intentional distribution of potentially hazardous materials.” The other 99.3% of EMA events involve adulteration by substitution and dilution (65%) and other non-food safety EMA related events.

2 This is not surprising because perpetrators of EMA do not intentionally introduce hazards to food, as the intent of EMA is economic gain, not the introduction of a hazard.
3 Of these 47 events, 22 (47%) of them involved seafood and another eight (17%) involved meat, pork products, all of which are outside the scope of these FSMA related rulemakings. Eleven of the events (23%) involved non-food safety adulteration such as added water, beet sugar, organic label fraud, and counterfeit goods. Four (9%) events involved corn syrup in sweeteners, which is not a food safety issue, and chloramphenicol in honey, which is not an EMA issue. Chloramphenicol occurs in honey when beekeepers overly treat their hives with the antibiotic. It does not involve chloramphenicol being intentionally added to the honey for economic gain.
4 Food Fraud and “Economically Motivated Adulteration” of Food and Food Ingredients by Renée Johnson, January 2014. Figure 6. Leading EMA Incidents by Type of Adulteration (1980 to date), page 19.
In addition to being rare, EMA related to food safety is not reasonably foreseeable. We support FDA’s decision that it “would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their food products.” And although we appreciate FDA’s attempt to narrow the field of potential EMA scenarios to “circumstances where there has been a pattern of such adulteration in the past,” GMA does not agree this is the appropriate scope. It is both too broad and too narrow at the same time. It is too broad, because FDA expects facilities to consider patterns of adulteration from the past “even though the past occurrences may not be associated with the specific supplier or the specific food product.” A requirement to consider every potential product and potential supplier makes the task open ended. At the same time, a focus on patterns of adulteration in the past is unlikely to reveal potential future EMA events because those intending to defraud purchasers for economic gain are trying to avoid detection. Once a food safety related EMA event is uncovered, EMA perpetrators quickly move to carry out their fraudulent activities in a different way. Finally, in those few EMA instances where a hazard was introduced through EMA activity, the underlying intention was not to cause harm; it was to defraud. The food safety hazard was an unintended consequence. Thus, food safety related EMA events are extremely difficult to effectively predict.

Because food safety related EMA is both extremely rare and difficult to predict, GMA asserts that there will be no net food safety benefit derived from diverting precious agency and industry resources by requiring manufacturers and importers to consider EMA as part of a hazard analysis. Measuring any gain would be nearly impossible because as FDA states in the preliminary regulatory impact analysis, the agency does “not know how many illnesses and deaths are caused by EMA of food ingredients used in food manufacturing, so we are unable to quantify the benefits of this additional requirement.” Yet, requiring food facilities and importers to consider EMA as part of their hazard analysis, which as discussed below is not the right fit for EMA, will consume limited resources without a corresponding increase in consumer protection.

FDA Should Wait to Impose EMA Related Requirements

Accordingly, we recommend that FDA refrain from proposing regulations to address EMA at this time. Instead, FDA should allow the seven major FSMA rules to take effect. After these rules are in place, and compliance has been assessed, the agency can reconsider whether EMA needs to be addressed through regulatory requirements. We suspect that the aforementioned rulemakings and industry initiatives will significantly address EMA such that additional regulatory requirements are not necessary.

In the meantime, the agency has several tools available to address EMA when it occurs, such as through import alerts; administrative detention and seizure; and even new mandatory import certification. Other organizations are also developing means to address EMA. Less than one month ago, the U.S. Pharmacopeial Convention pre-released a guidance document that offers a framework to develop and implement preventive management systems to deal with EMA. GMA recently held a two day meeting to discuss proactive approaches to EMA with several stakeholders from academia, NGOs and industry.

---

7 PRIA at 30.
Should FDA choose to include EMA requirements in the final rules, GMA respectfully requests that the agency clearly explain the food safety focus of the requirements by stating the facility or importer must consider “food safety hazards that may be intentionally introduced for purposes of economic gain.”

* * * * *

We appreciate the opportunity to submit these comments and look forward to continuing to work with the agency to ensure FSMA implementation is a success. Please do not hesitate to contact us if you have any questions regarding these comments.

Sincerely,

Leon Bruner, DVM, Ph.D.
Executive Vice President for Scientific and Regulatory Affairs & Chief Science Officer