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A "Shift in Perspective": FDA Proposes Food Defense Rule to Protect against Terrorism; Burdens Food and Dietary Supplement Industries

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On December 24, 2013, the U.S. Food and Drug Administration (FDA) published in the ***Federal Register*** proposed new rules that are intended to protect the food supply from intentional "adulteration" (*i.e.*, contamination) intended to cause large-scale harm to public health. Although well intended, the rules would provide an uncertain level of protection from an admittedly very unlikely occurrence, at a significant cost to industry.

Importantly, the proposed rules would **not** exempt certain industry segments, such as dietary supplements, juice, and seafood, which are exempted from certain other provisions under the Food Safety Modernization Act (FSMA) as a result of their being covered under special good manufacturing practice (GMP) or Hazard Analysis and Critical Control Points (HACCP) regulations. The proposed rule is open for comment through March 31, 2014.

Subject to limited exemptions (including very small businesses, animal food manufacturers, certain alcoholic beverage manufacturers, and farms), the proposed rule would cover domestic and foreign food manufacturing facilities that are required to register with the FDA. Facilities that only hold food (other than in liquid storage tanks) or that pack or label food where the container that directly contacts food remains intact would be exempt.

The proposed rule takes a facility-specific approach, requiring that a written food defense plan be developed for, and accessible at, each covered facility. As FDA acknowledges, the proposed rule would require a "shift in perspective," as its requirements are unlike any regulations to which this industry has ever been accountable. Although not limited to preventing the actions of organized terrorists, the proposed rule is not intended to cover the acts of disgruntled employees, competitors, or consumers where the primary goal is not large-scale harm to public health. Moreover, as proposed, a food defense plan generally need not address acts that could occur after the food leaves the facility (with the possible exception of bulk liquid food shipments).

The FDA has identified the following "actionable process steps" for which the plan would be required to include "focused mitigation strategies" to reduce vulnerabilities:

- Bulk liquid receiving and loading (*e.g.*, receiving or shipping tanker truck or railcar loads of juice, milk, or liquid sugar);
- Liquid storage and handling (includes not only bulk storage tanks, but also smaller tanks or totes);
- Secondary ingredient handling (includes staging, measuring, weighing, pre-mixing, or other ingredient manipulation, or rework steps); and
- Mixing and similar activities.

As an alternative to accepting the above list of actionable process steps, a facility may choose to conduct its own vulnerability assessment. The FDA cautions, however, that the latter approach may require specialized subject matter expertise that many facilities may not have on staff. If no actionable process steps are identified, the facility is still required to keep a written analysis supporting that conclusion. As noted below, it would also be required to periodically reanalyze that conclusion.

Once the actionable process steps at a facility are identified and documented, the next step is to develop focused mitigation strategies to reduce the vulnerability at each such step. Examples suggested in the proposed rule illustrate the significant costs that could be incurred in doing so. For example, the FDA's suggestions (none of which are individually presented as hard requirements) include the following:

- Installation of closed-circuit TV systems or other monitoring devices;

- Restricting performance of certain operations to senior or "trusted" staff;
- Using a "buddy system," *i.e.*, having two personnel on a task that could be handled by one;
- Installing checkpoints for incoming tanker truck deliveries;
- Installing locks on tank hatches and cabinets holding certain equipment and controlling access to the keys;
- Color-coding personnel uniforms and limiting access to certain production areas by color code;
- Reducing staging time for ingredients; and
- Installing alarm systems to sound in the production control room when mixer lids are opened.

Additional requirements under the proposed rule would include: (1) development of a written monitoring plan to check that the focused mitigation strategies are being properly implemented; (2) development of a corrective action plan describing steps to be taken in case monitoring reveals that implementation has not been effective; (3) verification of corrective action, implementation, and effectiveness; and periodic reanalysis of the food defense plan; (4) employee training on food defense awareness and responsibilities; and (5) recordkeeping, retention, and disclosure to the FDA upon request.

Although one may submit comments on any aspect of the proposed rule, the FDA has specifically requested comments on the following points:

- The appropriateness of a HACCP-type system (as proposed) and whether there are other approaches that would be more suitable.
- From which entities would implementation of measures to protect against intentional adulteration derive the greatest benefit to public health protection? How could the proposed rule be modified to better target such entities?
- Would it be feasible to require measures to protect against intentional adulteration only in the event of a credible threat?

  If so, would such an approach be consistent with FSMA? How would such requirements be communicated to industry in a timely and actionable manner?
- What is an appropriate level of public health protection, considering the intentional adulteration provisions of FSMA?
- Are there other ways to further focus the scope of the rule?
- Whether transportation carriers should also be covered by the rule.
- Whether the scope of the exemptions is appropriate and whether additional exemptions should be provided.
- How the rule should be implemented with respect to the dairy industry in particular.

Given the significant burdens that would be imposed if the proposed rule is finalized in its current form, stakeholders would be well advised to take advantage of this opportunity to provide comments. Indeed, commenting on proposed rulemaking can have significant influence, as illustrated by a recent FDA **announcement** that it will be pulling back on certain aspects of other proposed FSMA rules that would otherwise have placed undue burdens on farmers.

Facilities would have one year to comply with the rule when finalized, except that small businesses (employing fewer than 500 persons) would have two years to comply. Very small businesses (less than $10,000,000 in annual food sales) would be exempt, except that they would be required to maintain documentation of their exemption.

For additional information on the proposed rule or assistance in preparation of comments, please contact **John G. Moore** at 202.344.4592 or ; or your usual contact on Venable's **Food and Drug** team.