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Key Considerations for the Successful Implementation of the FDA Food Safety Modernization Act

1. **FLEXIBILITY OPTIMIZES FOOD SAFETY OUTCOMES**. Outcome-based regulations provide flexibility in achieving public health objectives. Regulatory flexibility and transparency enable innovation and continuous improvement across the supply chain. Where appropriate, sector-specific guidance documents created by the FDA in partnership with stakeholders can provide further direction.

2. **HARMONIZATION WITH GLOBAL STANDARDS AND PRINCIPLES**. Regulations should be harmonized with recognized, global standards and principles for food safety, animal health, and plant protection systems established by the Codex Alimentarius Commission, the World Organization for Animal Health (OIE) and the International Plant Protection Commission (IPPC). International alignment raises global food safety standards and compliance, which minimizes food safety risks globally.

3. **UTILIZE A HOLISTIC FOOD SAFETY SYSTEMS APPROACH**. FDA should develop regulations and guidance that are science-based, risk-driven, harmonized with international recognized standards that strengthen and augment existing food safety systems. These systems must be based on prevention, intervention, and response approaches that improve public health.

4. **GLOBAL TRADE FACILITATES FOOD SAFETY**. Regulations and guidance developed by the FDA should not create barriers to the import and export of goods and services. FDA must develop food safety standards that are consistent with WTO SPS and TBT Agreements. FDA should seek multilateral, plurilateral, regional and bilateral agreements with US trading partners that include mutual recognition of inspection reports and acceptance of analytical laboratory methods and results, and commit to build technical, scientific, and regulatory capacity, especially in emerging markets.

5. **ROLE OF THIRD PARTY CERTIFICATION**. International accreditation programs for auditing must be established so all stakeholders have confidence in globally-harmonized food safety and regulatory systems. Accredited third-party audits can play an important international and domestic role in augmenting FDA inspections and focusing resources on areas of highest risk.

6. **FOOD SAFETY APPLIES TO ALL FOODS**. All registered facilities should be required to have pre-requisite programs and HACCP plans in place to manage food safety risks. All companies along the food chain, regardless of size or product type, should be accountable to implement the same food safety systems approach for protecting public health. FDA should develop regulations that are consistently applied across the food chain and that are outcome-based. The term food should be defined broadly to include feed, grain and direct and indirect food/feed ingredients and additives

7. **TESTING SHOULD BE USED AS A TOOL TO VERIFY THAT FOOD SAFETY SYSTEMS ARE PREVENTING HAZARDS**. Analytical testing of food samples is incapable of ensuring the safety of food due to inherent

statistical limitations. Testing can and should play an important role in verifying that food safety systems are preventing hazards as expected.