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HARPC Exemption Decision Tree

Your HARPC and Supply-Chain Program Decisions

There are two significant provisions in the new Food Safety Modernization Act regulations that could seem challenging to implement:

- Hazard Analysis and Risk-Based Preventive Controls (HARPC) (21 CFR 117 Subpart C)
- Supply-Chain Program (21 CFR 117 Subpart G)

Fortunately, the new regulations contain some small-business exemptions and alternatives for these requirements. In summary, if you can be considered a “Qualified Facility” under the FDA rules, your HARPC and Supply-Chain Program compliance activities may be significantly reduced... and postponed.

HARPC and Supply Chain Program Questions

Is my business a “Qualified Facility” under the FDA’s definitions?

Answer these two questions to determine if your company is a Qualified Facility and exempt from a formal HARPC and Supply-Chain Program:

1. For the previous three years, did your company’s food sales average less than \$500,000 per year (adjusted for inflation)? Yes No
2. Was the majority of your food gas sales to a consumer, restaurant or retail food establishment within your state or within 275 miles of your plant? Yes No

If you answered “Yes” to both questions, you can claim FDA’s “qualified facility exemption”.

How does the qualified facility exemption affect me?

If you have a qualified facility, you can avoid conducting a formal HARPC and Supply-Chain Program. Instead, you need to send the FDA an “attestation” (by December 2018) that you:

- Have identified the potential hazards associated with the food gas being produced
- Are implementing preventive controls to address the hazards and are monitoring the performance of the preventive controls to ensure that such controls are effective
- Or are subject to food safety laws of other jurisdictions along with licenses, permits, inspections, etc.

The attestation would be resubmitted every two years (during reregistration) and anytime a change is needed.

HARPC and Supply-Chain Program Summary

If your firm qualifies for the exemption above, you have until 2018 to make your decision about whether you will do the formal HARPC or a less-formal attestation. If your firm does not qualify for the exemption above (e.g. your food gas sales are over \$500K), the soonest you will need to have the HARPC in place is 9/17/2016. Similarly, the Supply-Chain Program regulation subparts are not required for “qualified facilities.”

Even if you can qualify for the “qualified facility” exemption, you may decide to implement the HARPC anyway. We have pre-developed sample HARPC’s and written procedures for your consideration. These HARPC’s cover CO₂ cylinder filling, CO₂ mini-bulk, other high pressure gases and mixtures.

Please direct questions or requests for sample procedures/white papers to:
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