

Department of State Health Services
Council Work Session Agenda Memo for State Health Services Council
May 18, 2016

Agenda Item Title: Repeal of rules and new rules concerning Current Good Manufacturing Practice and Good Warehousing Practice in Manufacturing, Packing, or Holding Human Food and new Sanitary Transportation of Human Foods.

Agenda Number: 1.b.

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Foods Group within the Regulatory Services Division, Environmental and Consumer Safety Section, inspects food manufacturers, food wholesalers, and salvage establishments statewide. The program includes licensing, inspections, complaint investigations, enforcement, technical guidance, and emergency response for manufactured, wholesaled, and salvaged foods.

Approximately 14,785 food manufacturers, 2700 food wholesalers, and 125 food salvagers are inspected using the Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food.

The Group is funded from dedicated fees charged for licenses issued to food manufacturers, food wholesalers, and salvage establishments.

Summary:

The purpose of the repeal and new rules is to incorporate changes to the federal rules regarding manufacturing, packing, or holding of human food and sanitary transportation of human foods adopted by the U.S. Food and Drug Administration in September 2015 and March 2016. The rule requirements phase in over three years.

Additionally, the proposed rule revision responds to the intent of Senate Bill 81, 82nd Legislature, Regular Session, 2011, requiring DSHS to provide more transparency on which specific federal rules, adopted as a state rule under Texas Health and Safety Code §431.241 and §431.244, apply to regulated industry and are enforced by DSHS.

The new manufacturing rules include requirements to train food safety staff, perform hazard analyses on products produced, adopt a food safety plan, and institute preventive controls to mitigate identified hazards. The rules include the requirements for risk-based environmental monitoring, product testing, and a supply chain program appropriate to the food. In addition, the rules contain specific requirements for companies manufacturing products under modified atmosphere packaging. The new sanitary transport rules include requirements for vehicles and transportation equipment, transportation operations, training, and recordkeeping.

Key Health Measures:

The proposed rules take a proactive approach to food safety with the outcome of safer food supply. The

rules focus on elements that have been shown on a national level to cause recalls and foodborne illness outbreaks. The effectiveness of the proposed rule revision will be indicated over time by a reduction of food recalls and foodborne illness outbreaks.

The program will collect and analyze data on violations issued related to food manufacturers, food wholesalers, salvage establishments, and transport vehicles from the various databases, as well as monitor recall and food-borne illness outbreaks.

The program will use the quality assurance and enforcement action process to confirm the satisfactory resolution of food manufacturers, food wholesalers, salvage establishments, and transport vehicles that have been found to be out of compliance. There may be a temporary increase in violations to the rules due to the transition from the current food rules.

The program will collect and analyze data on violations issued related to food manufacturers, food wholesalers, salvage establishments, and transport vehicles from the various databases, as well as monitor recalls and food-borne illness outbreaks.

Summary of Input from Stakeholder Groups:

There was extensive stakeholder input at the federal level. There was extensive stakeholder input at the federal level. The program sent a draft version of the manufacturing rules by email to stakeholders in February 2016. The program will send a draft version of the transportation rules by email in May 2016.

**Approved by Assistant
Commissioner/Director:**

Kathryn C. Perkins, R.N.,
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Date: 3/15/2016

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Approved by CPEA:

Carolyn Bivens

Date: 5/13/2016