Development of a bi-lingual semi-quantitative tool to assess the readiness level of a food processing establishment with the proposed rules of the Food Safety Modernization Act (FSMA) cGMP, Hazard Analysis and Preventive Controls for Human Food.

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Introduction

According to the US Centers for Disease Control and Prevention (CDC), each year approximately 9.4 millions foodborne illnesses, 55,961 hospitalizations, and 1,351 deaths are caused by foodborne pathogens (Scallan et al., 2011). Many of these illnesses are the result of improper food handling practices during harvesting and manufacturing. Based on these facts the Food Drug Administration (FDA) proposed the modernization of the actual food safety legislation that was last updated in 1996 (FDA, 2013). The set of regulations are known as FSMA and include several rules, among others, the “Current Good Manufacturing Practices (cGMP) and Hazard Analysis and Risk-Based Preventive Controls for Human Food.” FSMA was signed into law by President Obama in 2011, and enables FDA to focus on preventing food safety problems rather than relying primarily on a reactive approach (FDA, 2013). While FSMA regulations are implemented, it is important that food companies identify their level of readiness in order to comply with the requirements specified in the proposed cGMP rule.

Objective

To design a semi-quantitative assessment tool that allows companies to evaluate their readiness level with respect to the current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food proposed by FSMA.

Methods

- Requirements of the proposed rule were divided into sections.

- Evaluation sheets were created for each section and the specific requirements from the proposed rule were included.

- A color-coded scale from 0 (white/Not applicable) to 5 (green/Substantial preparedness) was designed.

- Using Microsoft Excel®, a series of formula and hyperlinks were created.

- The instrument automatically computes the percentage of preparedness when the user assigns a pre-determined subjective score.

- The scores of each section are displayed as graphs.

- A final score reveals how prepared the company is regarding the proposed cGMP rules and what areas should set priorities to implement changes.

- The tool was created in English and Spanish.

Results

Using the proposed current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulations, and Microsoft Excel® the tool was generated.

Significance

This bi-lingual tool will provide valuable information to food processing establishments to monitor and facilitate the implementation of food safety plans in their operations and assist them in complying with the new standard. Food companies need to assess their level of preparedness to potentially comply with the rule once implemented, so that their market access is not compromised.

References