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 1986 (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.

A. General Provisions	B. Current GMPs	C. Hazard Analysis	D. Modified requirements	E. Withdrawal of an exemption	F. Records	Final Report

- 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.

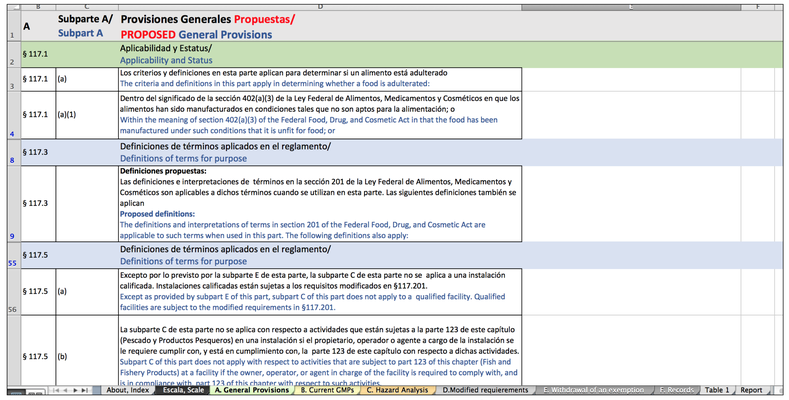
0	1	2	3	4	5

No Aplicable/ Not Applicable
No preparada/ Not preparedness
Preparación parcial/ Partial preparation
Preparada/ Preparedness
Substancialmente preparada/ Substantial Preparedness

- 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.

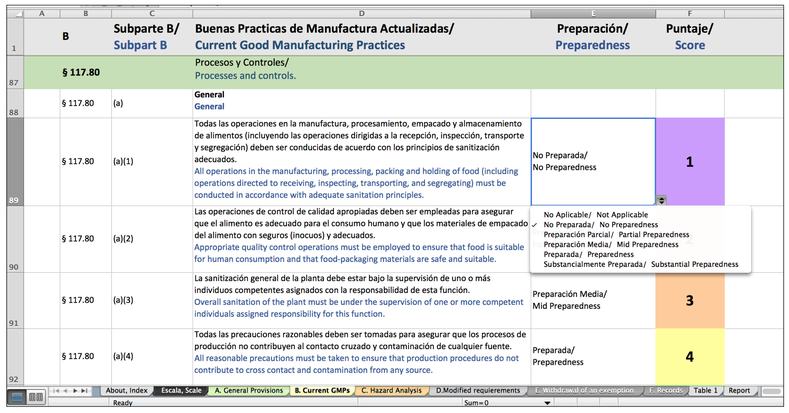
Results

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.



	A	Subparte A/ Subpart A	Provisiones Generales Propuestas/ PROPOSED General Provisions
2	§ 117.1		Aplicabilidad y Estatus/ Applicability and Status
3	§ 117.1	(a)	Los criterios y definiciones en esta parte aplican para determinar si un alimento está adulterado The criteria and definitions in this part apply in determining whether a food is adulterated:
4	§ 117.1	(a)(1)	Dentro del significado de la sección 402(a)(3) de la Ley Federal de Alimentos, Medicamentos y Cosméticos en que los alimentos han sido manufacturados en condiciones tales que no son aptos para la alimentación; o Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or
8	§ 117.3		Definiciones de términos aplicados en el reglamento/ Definitions of terms for purpose
9	§ 117.3		**Definiciones propuestas:** Las definiciones e interpretaciones de términos en la sección 201 de la Ley Federal de Alimentos, Medicamentos y Cosméticos son aplicables a dichos términos cuando se utilizan en esta parte. Las siguientes definiciones también se aplican **Proposed definitions:** The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:
55	§ 117.5		Definiciones de términos aplicados en el reglamento/ Definitions of terms for purpose
56	§ 117.5	(a)	Excepto por lo previsto por la subparte E de esta parte, la subparte C de esta parte no se aplica a una instalación calificada. Instalaciones calificadas están sujetas a los requisitos modificados en §117.201. Except as provided by subpart E of this part, subpart C of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in §117.201.
	§ 117.5	(b)	La subparte C de esta parte no se aplica con respecto a actividades que están sujetas a la parte 123 de este capítulo (Pescado y Productos Pesqueros) en una instalación si el propietario, operador o agente a cargo de la instalación se le requiere cumplir con, y está en cumplimiento con, la parte 123 de este capítulo con respecto a dichas actividades. Subpart C of this part does not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 of this chapter with respect to such activities.

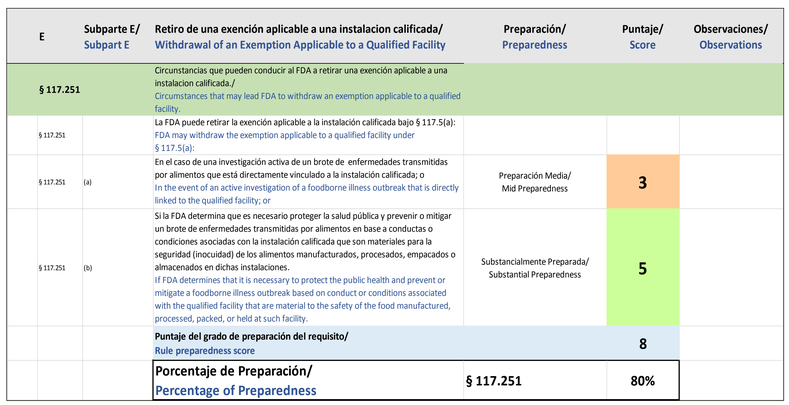
Figure 1. Subparts of the FSMA proposed rule according to the original CFR document.



	B	Subparte B/ Subpart B	Buenas Practicas de Manufactura Actualizadas/ Current Good Manufacturing Practices	Preparación/ Preparedness	Puntaje/ Score
87	§ 117.80		Procesos y Controles/ Processes and controls.		
88	§ 117.80	(a)	General General		
89	§ 117.80	(a)(1)	Todas las operaciones en la manufactura, procesamiento, empacado y almacenamiento de alimentos (incluyendo las operaciones dirigidas a la recepción, inspección, transporte y segregación) deben ser conducidas de acuerdo con los principios de sanitización adecuados. All operations in the manufacturing, processing, packing and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.	No Preparada/ No Preparedness	1
90	§ 117.80	(a)(2)	Las operaciones de control de calidad apropiadas deben ser empleadas para asegurar que el alimento es adecuado para el consumo humano y que los materiales de empacado del alimento con seguros (inocuos) y adecuados. Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.		
91	§ 117.80	(a)(3)	La sanitización general de la planta debe estar bajo la supervisión de uno o más individuos competentes asignados con la responsabilidad de esta función. Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.	Preparación Media/ Mid Preparedness	3
92	§ 117.80	(a)(4)	Todas las precauciones razonables deben ser tomadas para asegurar que los procesos de producción no contribuyen al contacto cruzado y contaminación de cualquier fuente. All reasonable precautions must be taken to ensure that production procedures do not contribute to cross contact and contamination from any source.	Preparada/ Preparedness	4

No Aplicable/ Not Applicable
No Preparada/ No Preparedness
Preparación Parcial/ Partial Preparedness
Preparación Media/ Mid Preparedness
Preparada/ Preparedness
Substancialmente Preparada/ Substantial Preparedness

Figure 2. Drop down menu for scoring and color-coded score for each rule component.



	E	Subparte E/ Subpart E	Retiro de una exención aplicable a una instalacion calificada/ Withdrawal of an Exemption Applicable to a Qualified Facility	Preparación/ Preparedness	Puntaje/ Score	Observaciones/ Observations
	§ 117.251		Circunstancias que pueden conducir al FDA a retirar una exención aplicable a una instalacion calificada./ Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.			
	§ 117.251		La FDA puede retirar la exención aplicable a la instalación calificada bajo § 117.5(a): FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):			
	§ 117.251	(a)	En el caso de una investigación activa de un brote de enfermedades transmitidas por alimentos que está directamente vinculado a la instalación calificada; o In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or	Preparación Media/ Mid Preparedness	3	
	§ 117.251	(b)	Si la FDA determina que es necesario proteger la salud pública y prevenir o mitigar un brote de enfermedades transmitidas por alimentos en base a conductas o condiciones asociadas con la instalación calificada que son materiales para la seguridad (inocuidad) de los alimentos manufacturados, procesados, empacados o almacenados en dichas instalaciones. If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.	Substancialmente Preparada/ Substantial Preparedness	5	
			Puntaje del grado de preparación del requisito/ Rule preparedness score		8	
			Porcentaje de Preparación/ Percentage of Preparedness	§ 117.251	80%	

Figure 3. Percentage of preparedness for each individual section.

Herramienta Grado de Preparación Estándares Propuestos de Buenas Prácticas de Manufactura del FDA

FDA Proposed Current Good Manufacturing Practices Standards Preparedness Tool

Operación/ Operation: Farmer Joe Smith **Fecha/ Date:**

v 1.2

Puntaje Final/ Final Score		Color/Color (%)	Barra/Bar	Ícono/Icon
Subparte B/ Subpart B	Buenas Practicas de Manufactura Actualizadas/ Current Good Manufacturing Practices	Preparación/ Preparedness		
Personal/ Personnel	§ 117.10	71%		
Instalaciones y Alrededores/ Plant and Grounds	§ 117.20	34%		
Subparte C/ Subpart C	Análisis de riesgos y peligros basado en controles preventivos/ Hazard Analysis and Risk- Based Preventive Controls.	Preparación/ Preparedness		
Requisitos para un plan de seguridad alimentaria./ Requirement for a food safety plan.	§ 117.126	68%		
Análisis de peligros./ Hazard analysis.	§ 117.130	96%		
Subparte D/ Subpart D	Requisitos Modificados/ Modified Requirements	Preparación/ Preparedness		
Requisitos modificados que aplican a instituciones calificadas./ Modified requirements that apply to a qualified facility.	§ 117.201	36%		
Subparte E/ Subpart E	Retiro de una exención aplicable a una instalacion calificada/ Withdrawal of an Exemption Applicable to a Qualified Facility	Preparación/ Preparedness		
Emisión de una orden para retirar una exención aplicable a una instalacion calificada./ Issuance of an order to withdraw an exemption applicable to a qualified facility.	§ 117.254	80%		
Subparte F/ Subpart F	Requisitos aplicables a los registros que deben establecerse y mantenerse/ Requirements applying to records that must be established and maintained	Preparación/ Preparedness		
Divulgación pública./ Public disclosure.	§ 117.301	33%		
Requisitos generales aplicables a los registros./ General requirements applying to records.	§ 117.305	48%		
cGMP Standards	**Puntaje Final/ Final Score**	50%		

Figure 4. Final report with section scores, overall score, and color-coded, bar-graph and icon grading.

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

- Scallan, E., Robert. M. Hoekstra, Federick J. Angulo V., Robert V. Tauxe., Marc-Alain Widdowson., Sharon L. Roy., Jeffery L. Jones. And Patricia M. Griffin. 2011. Foodborne Illness Acquired in the United States-Major pathogens. *Emerg. Infect. Dis*. 17: 7 -15.
- U.S Food and Drug Administration (FDA). 2013. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food. Washington, D.C.: U.S FDA. Available from: http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0001 Accessed: Mar 8, 2015.

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