

# Impacto y Retos de la nueva Ley FMSA para la industria alimentaria en América Latina

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TEXAS TECH UNIVERSITY



Public Law 111-353  
111th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

Jan. 4, 2011  
[H.R. 2751]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “FDA Food Safety Modernization Act”.

(b) **REFERENCES.**—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; references; table of contents.

**TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS**

- Sec. 101. Inspections of records.
- Sec. 102. Registration of food facilities.
- Sec. 103. Hazard analysis and risk-based preventive controls.
- Sec. 104. Performance standards.
- Sec. 105. Standards for produce safety.
- Sec. 106. Protection against intentional adulteration.
- Sec. 107. Authority to collect fees.
- Sec. 108. National agriculture and food defense strategy.
- Sec. 109. Food and Agriculture Coordinating Councils.
- Sec. 110. Building domestic capacity.
- Sec. 111. Sanitary transportation of food.
- Sec. 112. Food allergy and anaphylaxis management.
- Sec. 113. New dietary ingredients.
- Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters.
- Sec. 115. Port shopping.
- Sec. 116. Alcohol-related facilities.

**TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS**

- Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.
- Sec. 202. Laboratory accreditation for analyses of foods.
- Sec. 203. Integrated consortium of laboratory networks.
- Sec. 204. Enhancing tracking and tracing of food and recordkeeping.
- Sec. 205. Surveillance.
- Sec. 206. Mandatory recall authority.
- Sec. 207. Administrative detention of food.
- Sec. 208. Decontamination and disposal standards and plans.
- Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials.
- Sec. 210. Enhancing food safety.

FDA Food Safety  
Modernization  
Act.  
21 USC 2201  
note.

# FSMA Food Safety Modernization Act

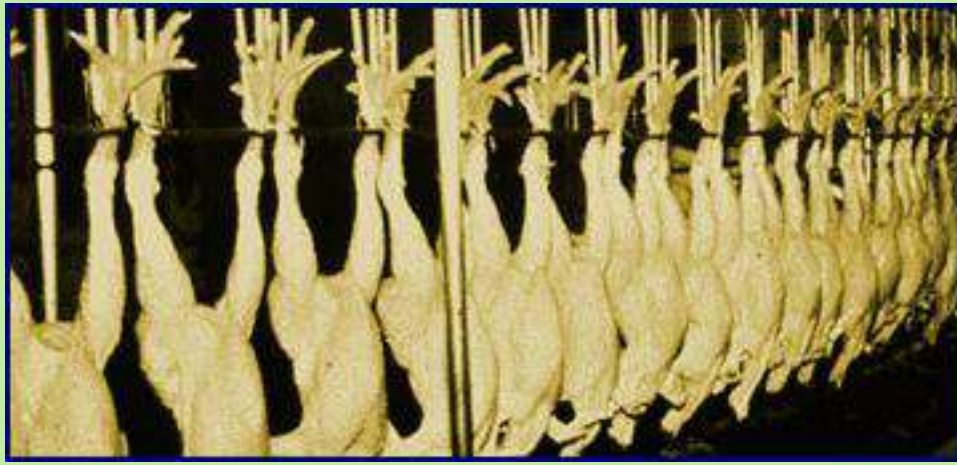
## Ley de modernización de inocuidad de los alimentos

- **FDA**
- La reforma en la regulación de alimentos mas importante de los últimos 70 años
- Firmada como ley por el Presidente Obama en 2011



Los reglamentos de inocuidad son realmente una  
**barrera comercial?**

# Cambios en producción de alimentos





# Cambios en producción de alimentos





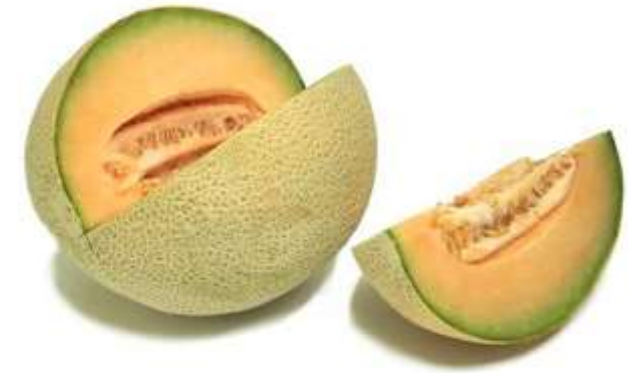


Cambios en  
la  
alimentacion



# RETIROS DEBIDO AL BROTE DE MELONES

- Investigaciones por parte de las autoridades locales, estatales y federales.
- Varios retiros del producto
  - Carol's Cuts LLC, a Kansas Procesador de alimentos.
    - La compañía retiró **594 libras de melón fresco cortado, 4,800 paquetes individuales**
  - Otras empresas tuvieron que retirar productos comprados a Jensen Farms
- **Treinta muertes (30)**
- **Un aborto**
- **Siete hospitalizados**
- **146 Infectados**



*Listeria monocytogenes*  
Brote afectó 28 estados  
July-October 2011

**JENSEN FARMS**



# Brote de Mantequilla de Mani

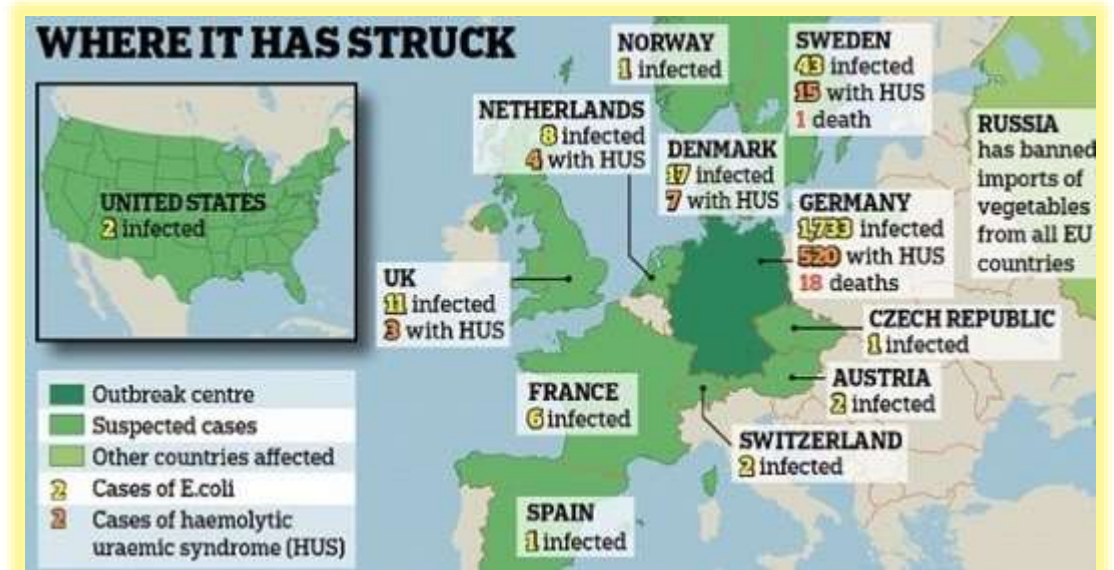
- Brote de *Salmonella* asociado a la planta de mani Stewart Parnell's ocurrió en 2009
- 714 enfermos
- 9 muertos
- Conllevó al retiro de alimentos mas grande en los Estados Unidos
- Dueno de la empresa (Presidente) fue sentenciado a 28 en la carcel
- Jefe de calidad sentenciada a 5 años en prision





# Alemania – *E. coli* O104:H4

- Brote con el mayor numero de muertes en la historia, por *E. coli*
- Inicio en Alemania y afecto otros paises
- Afecto tambien a los Estados Unidos
- Sprouts – brotes de Egipto
  - **50 muertes**
  - **4075 afectados en 16 paises**
  - **908 contrajeron el sindrome hemolitico uremico (HUS)**



## Listeria (Listeriosis)

### Listeria (Listeriosis)

Definition & Symptoms

Outbreaks -

Listeriosis Linked to Raw Milk +

[CDC](#) > [Listeria \(Listeriosis\)](#) > [Outbreaks](#)

## Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products (Final Update)



Posted June 10, 2015 10:30 AM ET



## Department of Justice investigating Blue Bell for listeria outbreak

POSTED 7:26 AM, JANUARY 2, 2016, BY [ASSOCIATED PRESS](#), UPDATED AT 11:11AM, JANUARY 2, 2016

# Por que se crea FSMA?

- Alrededor de **48 millones** de personas (1 en 6 Americanos) **se enferman**, **128,000 son hospitalizados** y **3,000 mueren** cada ano por enfermedades transmitidas por alimentos segun informes del CDC (Centers for Disease Control and Prevention).
- Esta es una carga muy alta para la salud publica y se puede prevenir
- **LA INOCUIDAD DEBE SER UNA PRIORIDAD!**



Quién regula FSMA?

# Regulación de alimentos en Estados Unidos

## The United States Department of Agriculture

Ministerio de Agricultura  
USDA

[www.usda.gov](http://www.usda.gov)



## The United States Department of Health and Human Services

- Ministerio de Salud y Servicios Humanos
- USHHS
- [www.hhs.gov](http://www.hhs.gov)



# FSIS



*Food Safety and Inspection Service*

**Servicio de Inspección e Inocuidad de Alimentos**

- Responsable de asegurar la integridad de los **productos cárnicos y avícolas y huevos procesados** en comercio internacional e interestatal
- FSIS es responsable de la evaluación y análisis de riesgos asociados con la producción de **productos alimenticios que contengan más de 2% de carne o pollo** entre sus componentes

Con mas de 2% de carne





**The United States**  
**Department of Health and Human Services**  
*Ministerio de Salud y Servicios Humanos*



- CDC** Center for Disease Control and Prevention
- FDA** Food and Drug Administration
- CFSAN** Center for Food Safety and Applied Nutrition
- CVM** Center for Veterinary Medicine

# Food and Drug Administration (FDA) Administración de Alimentos y Medicamentos



- Responsable de proteger a los consumidores contra alimentos impuros, inseguros o etiquetados fraudulentamente.
- FDA es responsable de la inocuidad de todos los alimentos, con la excepción de los productos que contengan más de 2% de componentes cárnicos o avícolas o alimentos que contengan huevos procesados (estos son jurisdicción del USDA-FSIS).
- Alimentos para animales



# Labeling - ETIQUETADO

- 21 CFR 101
- <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf>

## 4. NAME OF FOOD

1. What is the name of the food statement called and where must it be placed?

**Answer:** The statement of identity is the name of the food. It must appear on the front label, or PDP as well as any alternate PDP. 21 CFR 101.3

2. Should the statement of identity stand out?

**Answer:** Use prominent print or type for the statement of identity. It shall be in bold type. The type size must be reasonably related to the most prominent printed matter on the front panel and should be one of the most important features on the PDP. Generally, this is considered to be at least 1/2 the size of the largest print on the label. 21 CFR 101.3(d)

3. What name should be used as the statement of identity?

**Answer:** The name established by law or regulation, or in the absence thereof, the common or usual name of the food, if the food has one, should be used as the statement of identity. If there is none, then an appropriate descriptive name, that is not misleading, should be used. Brand names are not considered to be statements of identity and should not be unduly prominent compared to the statement of identity. 21 CFR 101.3(b) & (d)

4. Where should the statement of identity be placed on the label?

**Answer:** Place the statement of identity on the PDP in lines generally parallel to the base of the package. 21 CFR 101.3(d)

5. When are fanciful names permitted as the statement of identity?

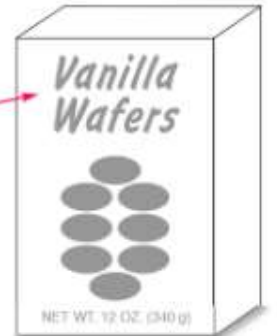
**Answer:** When the nature of the food is obvious, a fanciful name commonly used and understood by the public may be used. 21 CFR 101.3(b)(3)

6. Is it necessary to use the common or usual name instead of a new name?

**Answer:** The common or usual name must be used for a food if it has one. It would be considered misleading to label a food that has an established name with a new name. If the food is subject to a standard of identity it must bear the name specified in the standard. 21 CFR 101.3(b)(2)



STATEMENT OF IDENTITY



Example of Graphic Enhancements used by FDA

**Annotations:**

- Helvetica Regular 8 point with 1 point of leading
- Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point
- 3 point rule
- 7 point rule
- 1/4 point rule centered between nutrients (2 points leading above and 2 points below)
- 6 point Helvetica Black
- 8 point Helvetica Regular with 4 points of leading
- All labels enclosed by 1/2 point box rule within 3 points of text measure
- 1/4 point rule
- Type below vitamins and minerals (footnotes) is 4 point with 1 point of leading
- 8 point Helvetica Regular, 4 points of leading with 10 point bullets

## Nutrition Facts

**Ingredients:** Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono- and diglycerides.

Any Cookie Company  
College Park, MD 20740

## Nutrition Facts

Serving Size 1 cup (228g)  
Servings Per Container 2

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Amount Per Serving

<b>Calories 260</b>	<b>Calories from Fat 120</b>
% Daily Value*	
<b>Total Fat 13g</b>	
Saturated Fat 5g	
Trans Fat 2g	
<b>Cholesterol 30mg</b>	
<b>Sodium 660mg</b>	
<b>Total Carbohydrate 31mg</b>	
Dietary Fiber 0g	
Sugars 5g	
<b>Protein 5g</b>	
<b>Vitamin A 4%</b>	<b>Vitamin C 2%</b>
<b>Calcium 15%</b>	<b>Iron 4%</b>

\* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	60g	80g
Sat Fat	Less than	30g	35g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

1. Include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major food allergen does not appear elsewhere in the ingredient statement for another allergenic ingredient.





## SIETE REGLAMENTOS FSMA

# FSMA

1.  
Inocuidad  
Frutas y  
Vegetales

3. Controles  
Preventivos  
Alimentos  
para  
Animales

2. Controles  
Preventivos  
Alimentos  
para  
Humanos

5. Transporte  
sanitario de  
alimentos

4.  
Prevención  
de la  
adulteración  
intencional

6.  
Verificación  
de  
proveedores  
extranjeros

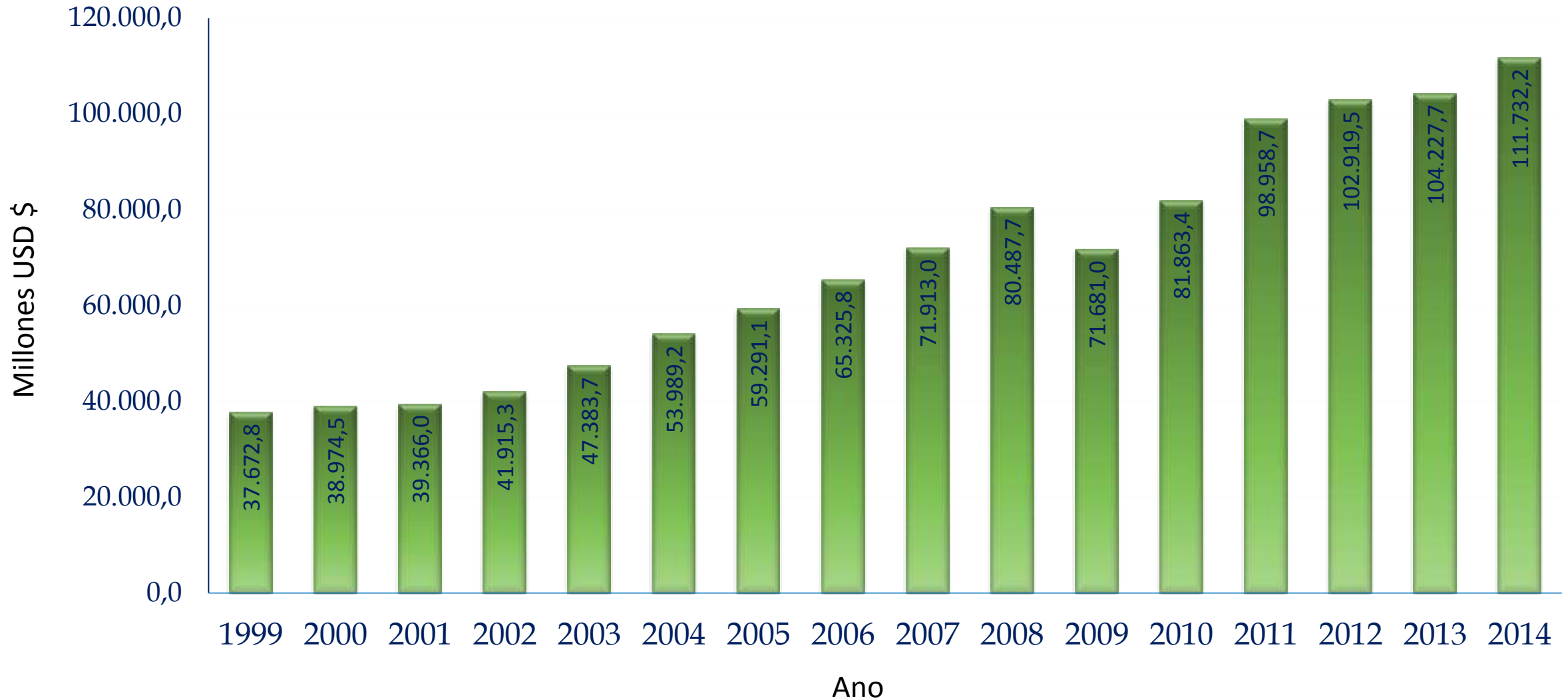
7.  
Acreditación  
de auditores  
de tercera  
parte



La reforma y mejora mas importante de  
FSMA  
*Alimentos Importados*

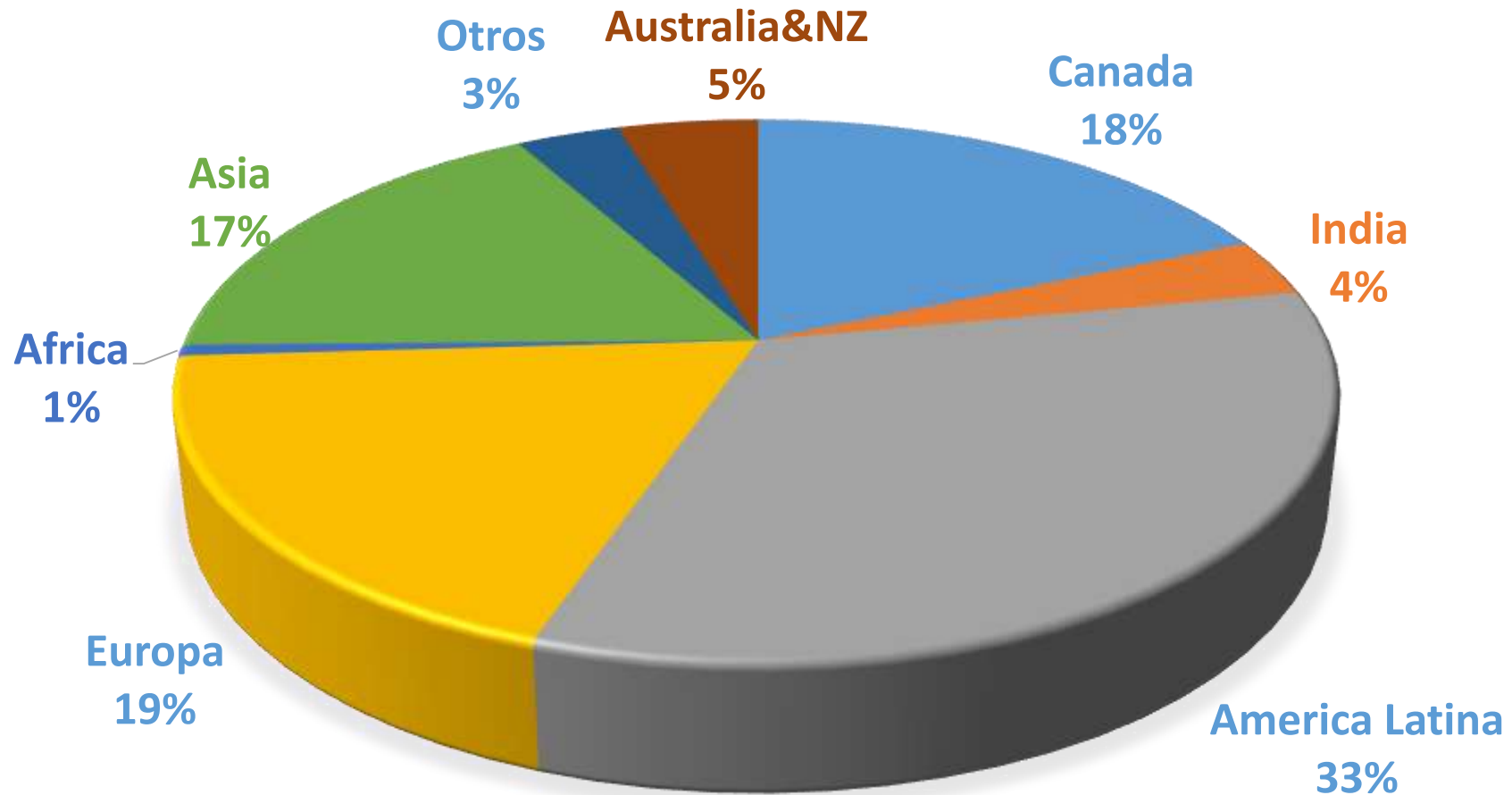
**Inspecciones en el puerto de entrada no son  
suficientes para asegurar la inocuidad de los  
alimentos importados**

# Importaciones de Alimentos en USA

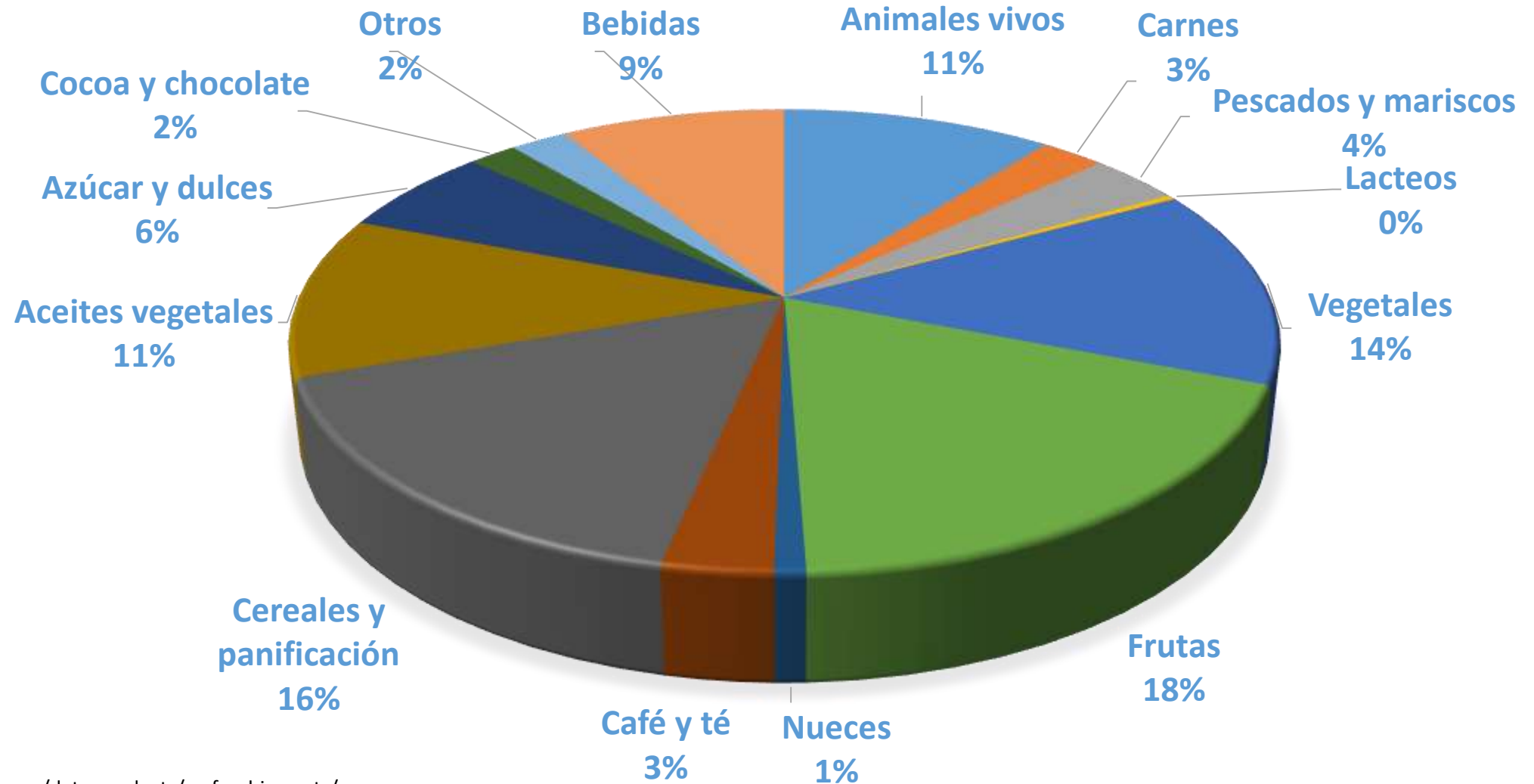




# Origen de las importaciones de alimentos a USA 2014



# Importaciones de alimentos a USA -por tipo de producto- 2014



ARTICLE

## Fresh Produce Remains Leading Cause of Outbreaks

Still, Americans Should Eat More, Not Less, Fruits and Vegetables

December 3, 2015

### OUTBREAK ALERT! 2015

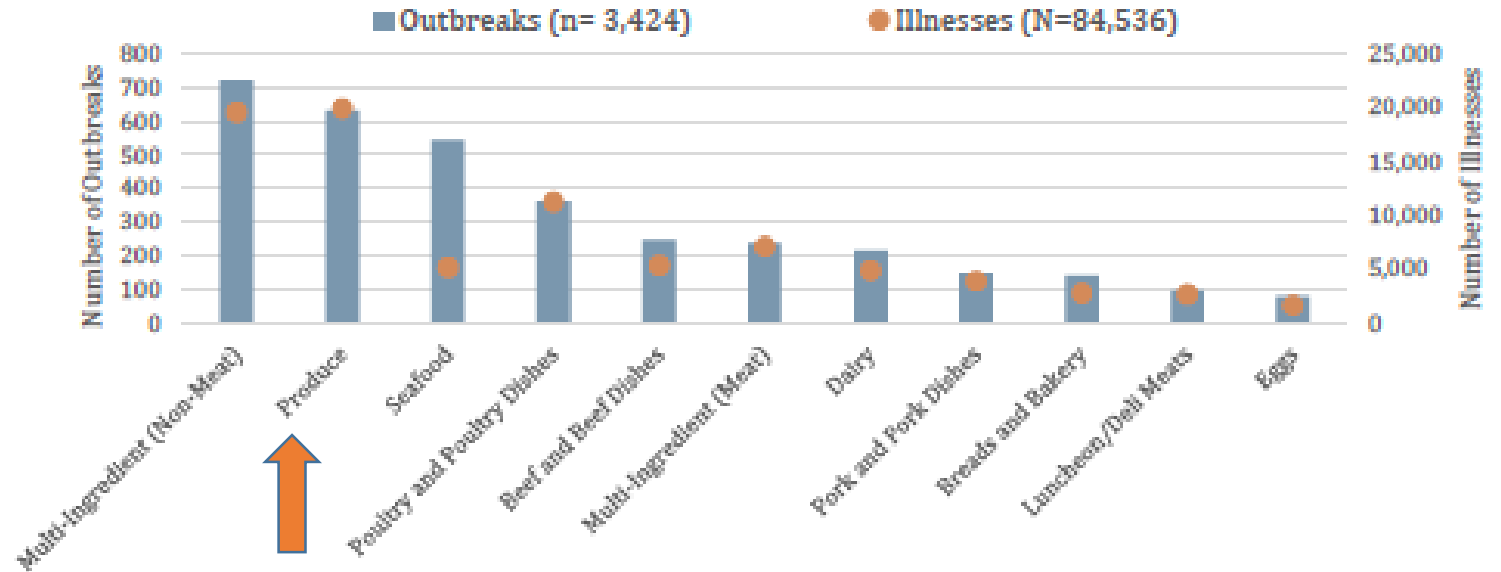


A REVIEW OF FOODBORNE ILLNESS IN THE U.S. FROM 2004 - 2013

AMERICAN SOCIETY FOR PUBLIC HEALTH  
NOVEMBER 2015

# FRUTAS Y VEGETALES ENFERMAN MAS PERSONAS COMPARADOS CON OTROS PRODUCTOS

Figure 5a. Solved Outbreaks and Illnesses Due to Food, 2004-2013



Datos de brotes de la FDA entre 1996-2014 relacionados con frutas y vegetales:

**173 brotes - 17,226 enfermedades - 68 muertes**



# MEJORAMIENTO DE CAPACIDADES ENTRENAMIENTO EN FSMA Y EVALUACION DEL NIVEL DE PREPARACIÓN RESPECTO A LA NORMA PROPUESTA FSMA AMERICA LATINA Y EL CARIBE

FAST: Food Safety and Agricultural Sustainability Training in Latin America and the Caribbean

*Un esfuerzo de diferentes instituciones:*





# Resumen de actividades desarrolladas



Países	Participantes	Genero		Tipo de participante				Empresas evaluadas	
		M	F	Civil Society	Producers	Public Sector	Private Sector	Frutas y vegetales	Alimentos procesados
<b>12</b>	<b>1458</b>	578	671	30	120	459	539	<b>34</b>	<b>8</b>

# Fase 1. Países CAFTA-DR

- 7 talleres
- 657 participantes
- 17 empresas evaluadas



No.	País	Ciudad	Fechas	No. Participantes	Genero		Tipo de participante				Evaluaciones	
					M	F	Civil Society	Producers	Public Sector	Private Sector	Produce	Processed Food
1	Panama	Panama	Sept 16-17, 2014	65	38	27	5	0	47	13	5	0
2	Guatemala	Guatemala City	September 29-October 4, 2014	129	76	53	7	29	23	70	2	0
3	Honduras	Tegucigalpa	October 13-18, 2014	135	92	43	0	8	35	92	1	0
4	El Salvador	San Salvador	October 19-22, 2014	148	61	87	4	0	25	119	4	0
5	Costa Rica	San José	October 23-24, 2014	104	37	55	2	5	39	46	5	0
6	Dominican Republic	Santiago	Feb 2-11	79	56	23	4	5	34	34	5	0
		Santo Domingo		62	29	33	2	1	43	15	0	0
				<b>657</b>	<b>351</b>	<b>294</b>	<b>19</b>	<b>48</b>	<b>199</b>	<b>376</b>	<b>17</b>	<b>0</b>
				Total	Males	Females	Civil Society	Producers	Public Sector	Private Sector	Produce	PC



# Fase 2.1 Sur América



- 3 talleres: Peru, Paraguay and Colombia
- 549 participantes
- 14 empresas evaluadas

No.	País	Ciudad	Fechas	No. Participantes	Genero		Tipo de participante				Evaluaciones	
					M	F	Civil Society	Producers	Public Sector	Private Sector	Produce	Processed Food
1	Peru	Lima	April 14-17, 2015	111	46	65	3	15	43	50	7	0
2	Paraguay	Asuncion	April 21-24, 2015	168	50	118	4	9	91	58	0	4
3	Colombia	Bogota and Armenia, Barranquilla, Cali, Ibague, Manizales, Medellin, Pereira, Procolombia Washington DC, Asocolhierbas (by Webex)	May 26-29	270*	87	107	1	7	13	36	3	0
*Virtual participants not fully tracked				<b>549</b>	130	230	8	31	147	144	<b>10</b>	<b>4</b>
				Total	Males	Females	Civil Society	Producers	Public Sector	Private Sector	Produce	PC

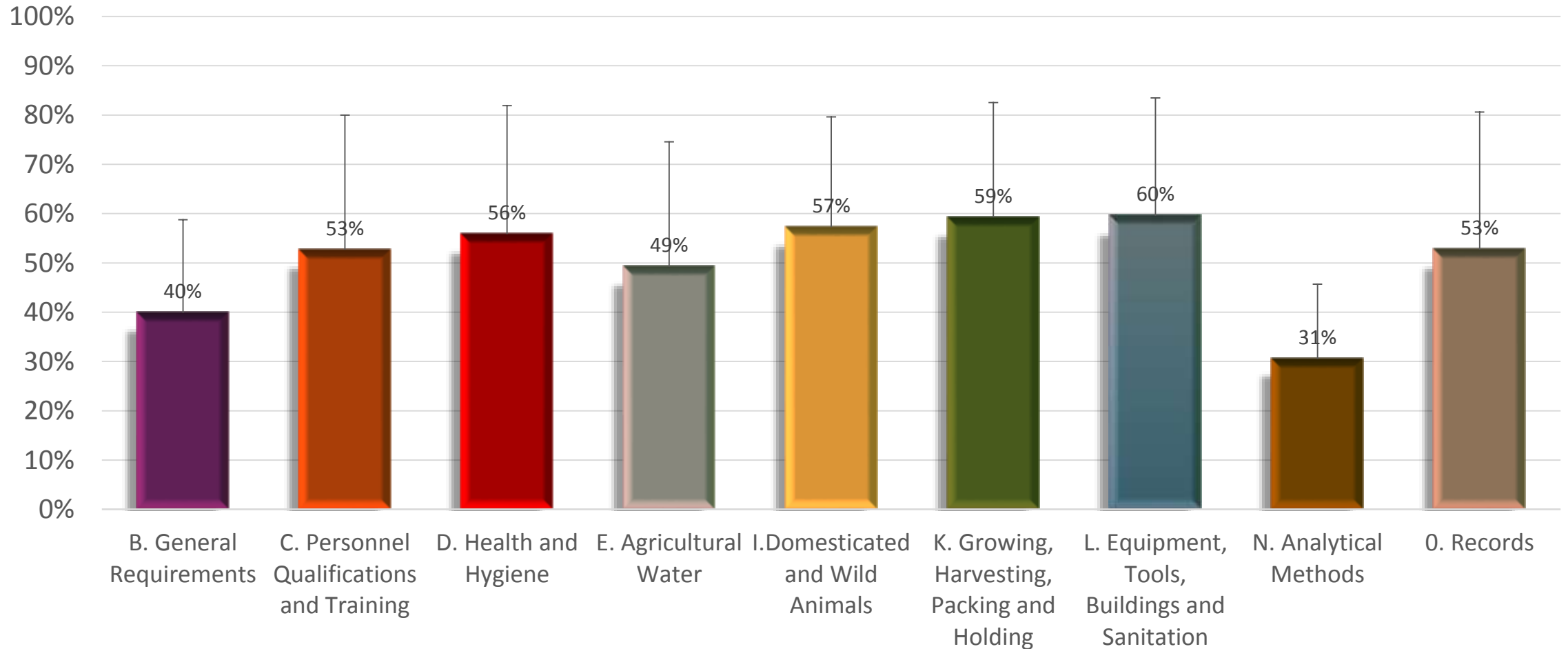
# Fase 2.2 Caribe

- 3 talleres: Jamaica, Trinidad and Tobago, Barbados
- 252 participantes
- 10 empresas evaluadas

No.	País	Ciudad	Fechas	No. Participantes	Genero		Tipo de participante				Evaluaciones	
					M	F	Civil Society	Producers	Public Sector	Private Sector	Produce	Processed Food
1	Jamaica	Kingston	June 16-19	82	28	54	0	13	25	3	2	0
2	Trinidad & Tobago	Port of Spain	June 22-25	78	26	52	3	15	45	7	3	1
3	Barbados	Bridgetown (2 participants from Saint Lucia, Saint Vincent and the Grenadines, Antigua & Barbuda, St Kits and Nieves, Grenada)	July 20-24	92	43	41	0	13	43	9	2	3
				<b>252</b>	<b>97</b>	<b>147</b>	<b>3</b>	<b>41</b>	<b>113</b>	<b>19</b>	<b>7</b>	<b>4</b>
				Total	Males	Females	SC	PR	PG	PE	Produce	Processed Food

# Resultados generales

Produce Safety Standard Assessment Tool  
(n=34)





# Salud e Higiene





# Agua agrícola



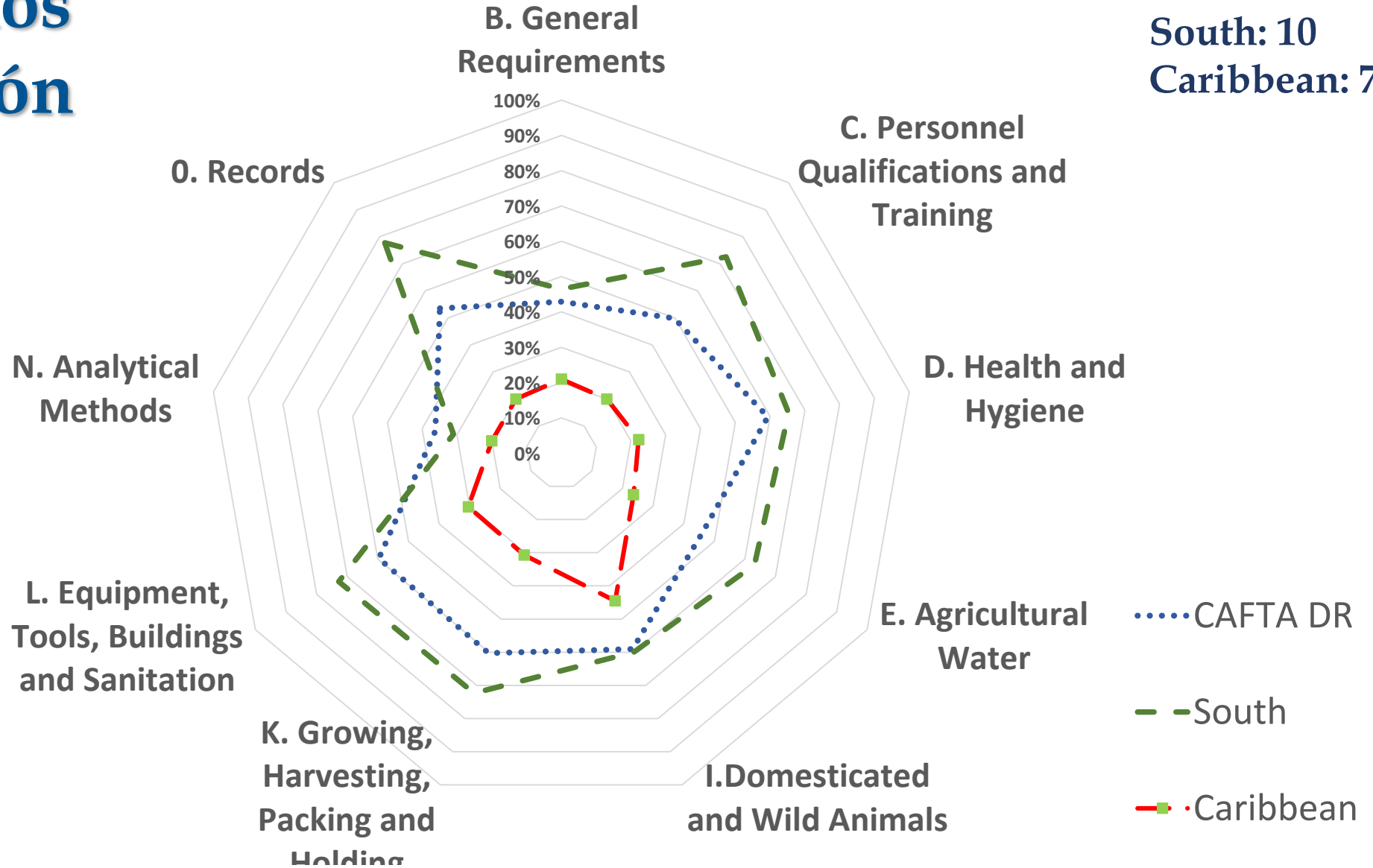


# Enmiendas biológicas de suelos



# Resultados por Región

CAFTA DR: 17  
 South: 10  
 Caribbean: 7





GRACIAS

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