ITP506: Current Issues in Food Industry

WRAP UP
Bottom Line Issues: Food Safety

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TREN MANAJEMEN INDUSTRI

→ Pertama dan utama: Keamanan (food safety)
→ Evolusi konsep

- MAIN TRENDS
  - MAKE
  - SERVICE
  - CARE
  - SMART (personalized, prescribed)
FSMA
(http://www.fda.gov/food/foodsafety/fsma/default.htm)

→ Latar Belakang

• Penyakit bawaan pangan merupakan beban signifikan pada ekonomi USA
  • Sekitar 48 juta (1 diantara 6 orang US) sakit setiap tahunnya karena pangan
  • 128,000 harus dirawat di RS
  • 3,000 meninggal

• Pasokan pangan menjadi lebih “high-tech” & kompleks
  • 15 % pasokan pangan US dipenuhi dengan IMPOR
  • Lebih banyak jenis pangan di pasaran
  • Munculnya ancaman bahaya baru (emerging hazards)
"I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action."

Margaret A. Hamburg, M.D., Commissioner of Food and Drugs

January 4th, 2011
FSMA (http://www.fda.gov/food/foodsafety/fsma/default.htm)

• Prevention is the core principle of the FDA Food Safety Modernization Act that President Obama signed into law in 2011

• “Preventing problems before they cause harm is not only common sense, it is the key to food safety in the 21st century,”

• “We cannot afford to wait until people become ill to realize there is a problem.”

FDA Commissioner
Margaret A. Hamburg
FSMA (http://www.fda.gov/food/foodsafety/fsma/default.htm)

• Prevention is the core principle of the FDA Food Safety Modernization Act that President Obama signed into law in 2011

• The proposed rules will establish requirements for farmers, food companies and importers to prevent foodborne illness.

• Proposed rules build on existing voluntary industry guidelines for food safety, which many producers, growers and others currently follow.
FSMA (http://www.fda.gov/food/foodsafety/fsma/default.htm)

→ Pengaruhnya?

UNDERSTANDING THE US FOOD SAFETY MODERNIZATION ACT 2011
Its Implications and Impacts on Suppliers, Producers and Exporters in Europe

FSMA (http://www.fda.gov/food/foodsafety/fsma/default.htm)

→ Kerangka Baru Peraturan Pangan (Model FSMA)

Pencegahan
(Prevention)

Meningkatkan Kemitraan
(Enhanced Partnerships)

Pengawasan/Inspeksi
(Inspections, Compliance, and Response)

Keamanan Pangan Import
(Import Safety)
**FSMA** (http://www.fda.gov/food/foodsafety/fsma/default.htm)

→ *Kerangka Baru Peraturan Pangan (Model FSMA)*

**Pencegahan**
((Prevention))

**Pendekatan Umum:**

**Pengendalian untuk Pencegahan**
((Preventive Control))

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**FSMA** (http://www.fda.gov/food/foodsafety/fsma/default.htm)

→ Pengendalian untuk Pencegahan (Preventive Control)

1. **Identifikasi Bahaya**
2. **Identifikasi Penyebab**
3. **Implementasi Upaya Pencegahan**
4. **Monitor Effektivitasnya**
5. **Review & perbaikan**

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MPTP 2015/2017
FSMA

➔ Standar pencegahan ➔ Memandatkan (1)

- Sec. 103. Hazard analysis and risk-based preventive controls
  - Requires human and animal food facilities to:
    - Evaluate hazards that could affect food safety;
    - Identify and implement preventive controls to prevent hazards;
    - Monitor controls and maintain monitoring records; and
    - Conduct verification activities.

FSMA

➔ Standar pencegahan ➔ Memandatkan (2)

Perlunya menunjukkan program:

- Sanitasi
- Pelatihan thd pegawai dan supervisor
- Pengendalian dan monitoring lingkungan
- Pengendalian alergen pangan
- Rencana Recall dalam kondisi darurat (contingency plan)
- Good Manufacturing Practices (GMPs)
- Verifikasi pemasok (supplier verification program)
Section 103 – Preventive Controls Rules

1. Preventive Controls for Human Food
2. Preventive Controls for Animal Food
3. Mitigation Strategies to Protect Food from Intentional Adulteration

HARPC
→ Hazard analysis and risk-based preventive controls
HARPC

→ Hazard analysis and risk-based preventive controls

APA?
BAGAIMANA?
1. Analisis Bahaya (Hazards Analysis).
2. Pengendalian berbasis Risiko untuk Pencegahan (Risk-based Preventive Controls)
3. Pemantauan Keefektifan (Monitoring of Effectiveness)
4. Tindakan Koreksi (Corrective Actions)
5. Verifikasi (Verification)
6. Penyimpanan Arsip dan Dokumentasi (Record keeping and Documentation).
HARPC

→ Hazard analysis and risk-based preventive controls

FDA’s HARP C
Is Like HACCP
The agency’s newest FSMA ruling requires all food processors to create risk-based preventive control plans.

By Eric Lindstrom, Keller and Heckman LLP

HARPC VS. HACCP

• Konsep? Mirip dengan HACCP
• Tetapi; ada beberapa penekanan yang berbeda dengan HACCP
HARPC

→ Vs HACCP

- US Standard
- Limited FDA products

→ Vs

- Global Standard (Codex Alimentarius)
- USDA: Meat and Poultry
- FDA: Seafood and Juice

HARPC

→ Vs HACCP

- No Preliminary Tasks

→ Vs

- Preliminary Tasks
  - Assemble a team
  - Describe product
  - Identify intended use
  - Construct flow diagram
  - Verify flow diagram
HARPC  vs HACCP

- Requires a **Qualified Individual**:
  - Prepare the Plan
  - Validate controls
  - Review records
  - Conduct re-analysis
  - Qualified by
  - Training
  - Experience

- **Vs**
  - Does not Require a Qualified Individual (Does require a team)

HARPC  vs HACCP

1. Bahaya biologi
2. Bahaya kimia
3. Bahaya fisika
4. Bahaya radiologi
5. Bahaya toksin alami
6. Bahaya pestisida
7. Bahaya residu obat
8. Bahaya hasil dekomposisi
9. Bahaya parasite
10. Bahaya alergen
11. Bahaya bahan tambahan yang tidak diijinkan
12. Bahaya lain yang mungkin masuk secara disengaja
   *(food defense related hazards).*

- **Vs**
  1. Bahaya biologi
  2. Bahaya kimia
  3. Bahaya fisika
HARPC

Vs HACCP

- Hazard research will need to be performed and documented by each facility

Vs

- Hazard Analysis is largely done for industry
  - Seafood Hazards and Controls Guide
  - Juice HACCP Hazards and Controls Guide

HARPC

Vs HACCP

- Identification of Preventive Controls
  - Does not distinguish CCP’s from other controls

Vs

- Identification of Critical Control Points
  - Does not recognize “Preventive Controls”
HARPC  vs  HACCP

- **Preventive Controls:**
  Reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe of food would employ to significantly minimize or prevent hazards

- **Critical Control Points:**
  A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

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HARPC  vs  HACCP

- **Monitoring:**
  Checking the Preventive Control to determine if it was effective Some controls have parameters and some don’t

- **Monitoring:**
  Checking the CCP to determine if Critical Limit has been met
HARPC

⇒ Vs HACCP

• Verification:
Those activities other than monitoring that establish the validity of the food safety plan and that the system is operating according to the Plan.

⇒ Vs

• Verification:
The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

HARPC

⇒ Vs HACCP

• Validation:
Element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan will effectively control the identified hazards.

⇒ Vs

• Validation:
Obtaining evidence that the elements of the HACCP Plan are effective.
How (i) to detect, (ii) to deter, and (iii) to prevent intentional contamination?

Unik

→ Termasuk Managing Intentional contamination/Adulteration

HARPC

→ Hazard analysis and risk-based preventive controls
Unik

→ Termasuk Managing Intentional contamination/Adulteration

→ Perlu ada paradigma baru: Pertahanan Pangan’’

**HARPC**

→ *Hazard analysis and risk-based preventive controls*

Program Keamanan Pangan

Program “pertahanan” Pangan

(Food Defense Program)

Unik

ASSURE: Pastikan semua bahan dan ingredien yang dipakai adalah “aman” dan dari sumber yang pasti

LOOK after: Pastikan semua bahan dan ingredien terawasi selama di pabrik

EMPLOYEES: Pastikan data semua karyawan; dan mobilitas selama dalam pabrik

REPORTS: Pastikan semua data mengenai keamanan produk Anda tercatat/tersimpan dgn baik, dan bisa dilaporkan dgn segera

THREAT: Pastikan Anda punya rencana tindakan –termasuk melapor kemana- jika ada ancaman; atau ada sesuatu yang mencurigakan
FSMA juga mempersyaratkan

- Pengembangan dan implementasi HARPC merupakan suatu siklus yang terus menerus perlu dilakukan.
- Industri perlu secara periodik mengevaluasi dan memperbarui system HARPC sehingga tetap relevan dengan kondisi dan tuntutan keamanan pangan:
  
  I. Ketika terjadi perubahan signifikan pada fasilitas yang diduga bisa meningkatkan risiko suatu bahaya; atau bahkan memungkinkan masuknya bahaya baru.
  
  II. Setiap adanya perubahan operasional di pabrik
  
  III. Setiap perubahan harus didokumentasikan secara tertulis pada arsip HARPC.

IV. Jika setelah re-analsisis, ternyata tidak perlu perubahan rencana HARPC, berikan alasan dan analisisnya, WHY?.

V. Jika ditengarai adanya ancaman bahaya baru, apakah itu bahaya biologi, kimia, radiologi, bahaya lain yang berkaitan dengan terrorism.

VI. Jika perubahan tidak perlu ditinjau dan dievaluasi setiap 3 tahun
The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. Below is a list of available fact sheets and information by topic.

**Final Rule Fact Sheets**
- Accredited Third-Party Certification Final Rule (PDF: 109KB)
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals Final Rule (PDF: 265KB)
- Mitigation Strategies to Protect Food Against Intentional Adulteration Final Rule (PDF: 252KB)
- Preventive Controls for Food for Animals Final Rule (PDF: 144KB)
- Preventive Controls for Human Food Final Rule (PDF: 156KB)
- Sanitary Transportation of Human and Animal Food Final Rule (PDF: 113KB)
- Standards for Produce Safety Final Rule (PDF: 405KB)

**Presentations**
- Proposed Rules to Help Ensure the Safety of Imported Food (PPT, 852KB)
- Food Safety Modernization Act: Overview (PPT, 2.0MB)
- Food Safety Modernization Act: Focus on Imports (PPT, 2.1MB)
- Food Safety Modernization Act: Focus on Prevention (PPT, 9.5MB)

**NOTE:** For presentations given at FSMA public meetings and webinars, please go to the main FSMA meeting page and select the desired meeting.

NEXT:

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm
PAS 96:2014
Guide to protecting and defending food and drink from deliberate attack

TERIMAKASIH