

FSMA

**FDA FOOD SAFETY
MODERNIZATION ACT
(FSMA)**

Update & Pengaruhnya untuk Indonesia

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 BPOM RI
Jakarta, 30 April 2014

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

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

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Food Safety

- Food Safety Modernization Act (FSMA)**
- About FSMA
- Full Text of the Law
- Implementation and Progress
- Dockets Open for Comment
- Meetings, Hearings, and Workshops
- Press Releases
- Speeches, Statements, and Articles
- Presentations and Print Material
- Videos, Webinars, and Interviews
- Frequently Asked Questions
- Translations of Key FSMA Resources

The New FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 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.

[Get FSMA Updates by E-mail](#)

The Food Safety Law and the Rulemaking Process: Putting FSMA to Work

FDA will be issuing a number of rules to implement FSMA. This new publication describes the rulemaking process and how you can participate. [More >](#)



TP-TERRORS... Emerging Chal... Food Safety Chal... 22 - US Food Saf... Computer Documents Computer Prita - Search Res... The New FT

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→ 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*)



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→ Pengaruhnya?

- Peraturan FSMA akan diberlakukan untuk 97,000 perusahaan di AS dan 109,000 perusahaan asing
- Fasilitas yang dipersyaratkan untuk mendaftar adalah (i) *manufacturers*, (ii) *processors*, (iii) *warehouses*, (iv) *storage tanks* dan (v) *grain elevators*.
- Perusahaan Indonesia yang mengekspor produknya ke AS harus mempersiapkan diri.



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- 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

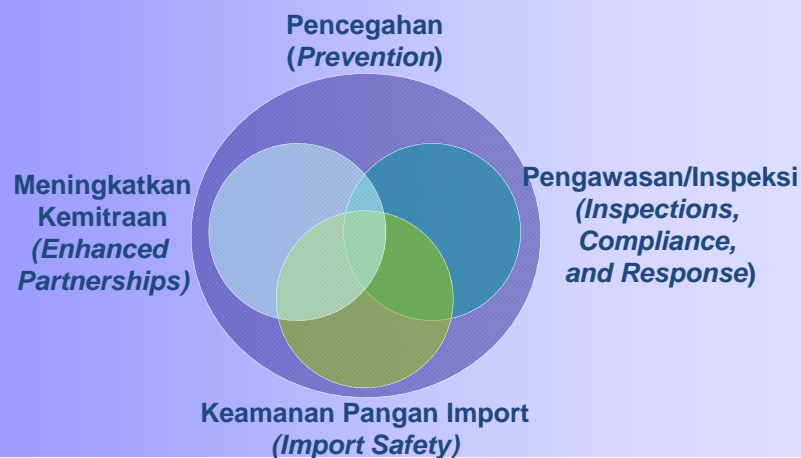


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FSMA (<http://www.fda.gov/food/foodsafety/fsma/default.htm>)

→ Kerangka Baru Peraturan Pangan (Model FSMA)



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→ *Kerangka Baru Peraturan Pangan (Model FSMA)*

Pencegahan
(*Prevention*)

Pendekatan
Umum:
Pengendalian
untuk
Pencegahan
(*Preventive Control*)


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FDA Commissioner
Margaret A. Hamburg, M.D :

- “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.”

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→ Pengendalian untuk Pencegahan (*Preventive Control*)

```
graph TD; 1((1)) --> 2((2)); 2 --> 3((3)); 3 --> 4((4)); 4 --> 5((5)); 5 --> 1
```

1 Identifikasi Bahaya

2 Identifikasi Penyebab

3 Implementasi Upaya Pencegahan

4 Monitor Efektivitasnya

5 Review & penyesuaian

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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.*

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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*)



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HARPC

→ Hazard analysis and risk-based preventive controls

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

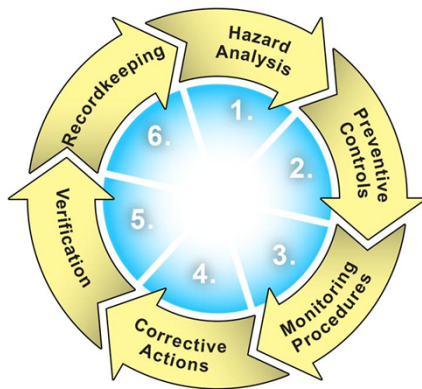


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HARPC

→ Hazard analysis and risk-based preventive controls



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

HARPC


- Konsep? Mirip dengan HACCP
- Tetapi; ada beberapa penekanan yang berbeda dengan HAACP

HARPC → vs HACCP

- US Standard
- Limited FDA products

→ Vs

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

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HARPC → vs HACCP

- No Preliminary Tasks

→ Vs

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

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HARPC → vs HACCP

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

→ Vs

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

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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

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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


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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"

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


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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


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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


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HARPC → vs HACCP


- FDA will evaluate the plans and continue to inspect facilities to make sure the plans are being implemented properly.

BUT:
Next Steps...


Do not make any changes to your haccp plan!

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HARPC → vs HACCP



The diagram illustrates the relationship between HACCP and HARPC. At the center is a red rounded rectangle with the text **HACCP**. Surrounding this central box are four orange rounded rectangles, each containing a component of HARPC: **Radiological Hazards and Controls** (top-left), **Hazard Research** (top-right), **Vulnerability Assessment** (bottom-left), and **Validation of Process Controls** (bottom-right).

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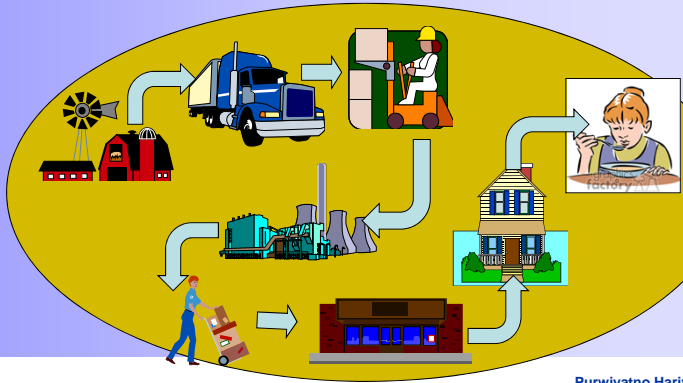
HARPC


→ Hazard analysis and risk-based preventive controls

Unik

→ Termasuk Managing Intentional contamination/Adulteration

How (i) to detect, (ii) to deter, and (iii) to prevent **intentional contamination**?



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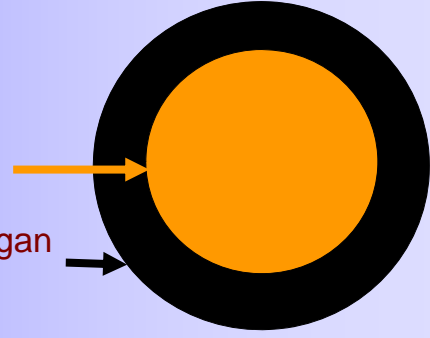
HARPC

→ Hazard analysis and risk-based preventive controls

Unik


→ Termasuk Managing Intentional contamination/Adulteration

→ Perlu ada paradigma baru : "Pertahanan Pangan"



Program Keamanan Pangan

Program "pertahanan" Pangan
(Food Defense Program)

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HARPC

→ Hazard analysis and risk-based preventive controls

Unik

- Termasuk Managing Intentional contamination/Adulteration
- Perlu ada paradigma baru : **Pertahanan Pangan**


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

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

E **EMPLOYEEES** : Pastikan data semua karyawan; dan mobilitas selama dalam pabrik

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

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

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HARPC

→ Hazard analysis and risk-based preventive controls

FSMA juga mempersyaratkan

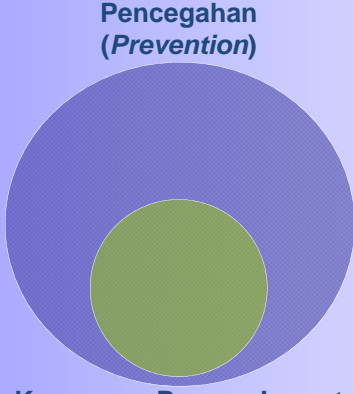
- Pengembangan dan implementasi HARPC merupakan suatu siklus yang terus menerus perlu dilakukan.
- Industri perlu secara periodik mengevaluasi dan memperbarui system HARPC sehingga tetap relevan dengan kondisi dan tuntutan keamanan pangan:
 - Ketika terjadi perubahan signifikan pada fasilitas yang diduga bisa meningkatkan risiko suatu bahaya; atau bahkan memungkinkan masuknya bahaya baru.
 - Setiap adanya perubahan operasional di pabrik
 - Setiap perubahan harus didokumentasikan secara tertulis pada arsip HARPC.
 - Jika setelah re-analisis, ternyata tidak ada perubahan yang diperlukan terhadap rencana HARPC, maka perlu pula diberikan alasan dan analisisnya mengenai hal itu.
 - Jika ditengarai adanya ancaman bahaya baru, apakah itu bahaya biologi, kimia, radiologi, bahaya lain yang berkaitan dengan terrorism.
 - Jika perubahan signifikan tidak terjadi → ditinjau dan dievaluasi setiap 3 tahun

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→ *Kerangka Baru Peraturan Pangan (Model FSMA)*



**Pencegahan
(Prevention)**

**Keamanan Pangan Import
(Import Safety)**

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

- New authorities, mandates work together to create integrated import safety system
 - Foreign supplier verification programs (sec. 301)
 - Voluntary qualified importer program (sec. 302)
 - Mandatory certification (sec. 303)
 - Enhancements to prior notice (sec. 304)
 - Building capacity of foreign governments (sec. 305)
 - Improved enforcement authorities (sec. 306)
 - Accreditation of third-party auditors (sec. 307)
 - Foreign offices (sec. 308)

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

- New authorities, mandates work together to create integrated import safety system



It is expected that food imported into the U.S. should meet the same level of public health protection as food produced domestically.

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

Proposed Rules Implement Preventive Framework

- Safety standards established by FDA
 - Standards for produce safety
 - Preventive controls for human food
- Industry must verify standards are met
 - Foreign supplier verification program
 - Accreditation of third-party auditors
- Additional rules and guidance coming

Proposed Regulations for Foreign Supplier Verification Programs (FSVPs):

- The FSVP regulations would implement section 301 of FSMA, which is codified in Section 805 of the Federal Food, Drug & Cosmetic Act.



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Proposed Rule Accreditation of Third-Party Auditors

- The FSVP regulations would implement section 301 of FSMA, which is codified in Section 805 of the Federal Food, Drug & Cosmetic Act.



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Saran:

- Ikuti perkembangannya di www.regulations.gov atau www.fda.gov/fsma
- Daftar (di www.fda.gov/fsma) untuk mendapatkan “FSMA updates” melalui email
- Berikan komentar dan pendapat

TERIMAKASIH

