

Session Lecture 19

Emerging Global Food Quality and Human Health Protection Issues

**Positive List System for
Agricultural Chemical Residues in Foods**

Impact on Human Health Protection in Japan

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Outline

- **Background:** *Growing concerns on food quality and human health protection*
- **Process:** *Establishing provisional MRLs*
- **Impact:** *Introduction of Positive List System, May 2006*
- **Implementation/Validation:** *Role of risk assessment*
- **Challenge:** *Contribution to global food quality and human health protection*

Provide an overview on the positive list system in Japan and discuss challenges to improve food quality and human health protection



Background: *Growing Concerns*

■ 2001

- The first case of BSE detected in Japan

Report from the Committee to investigate the BSE issues in Japan (April, 2002) recommended:

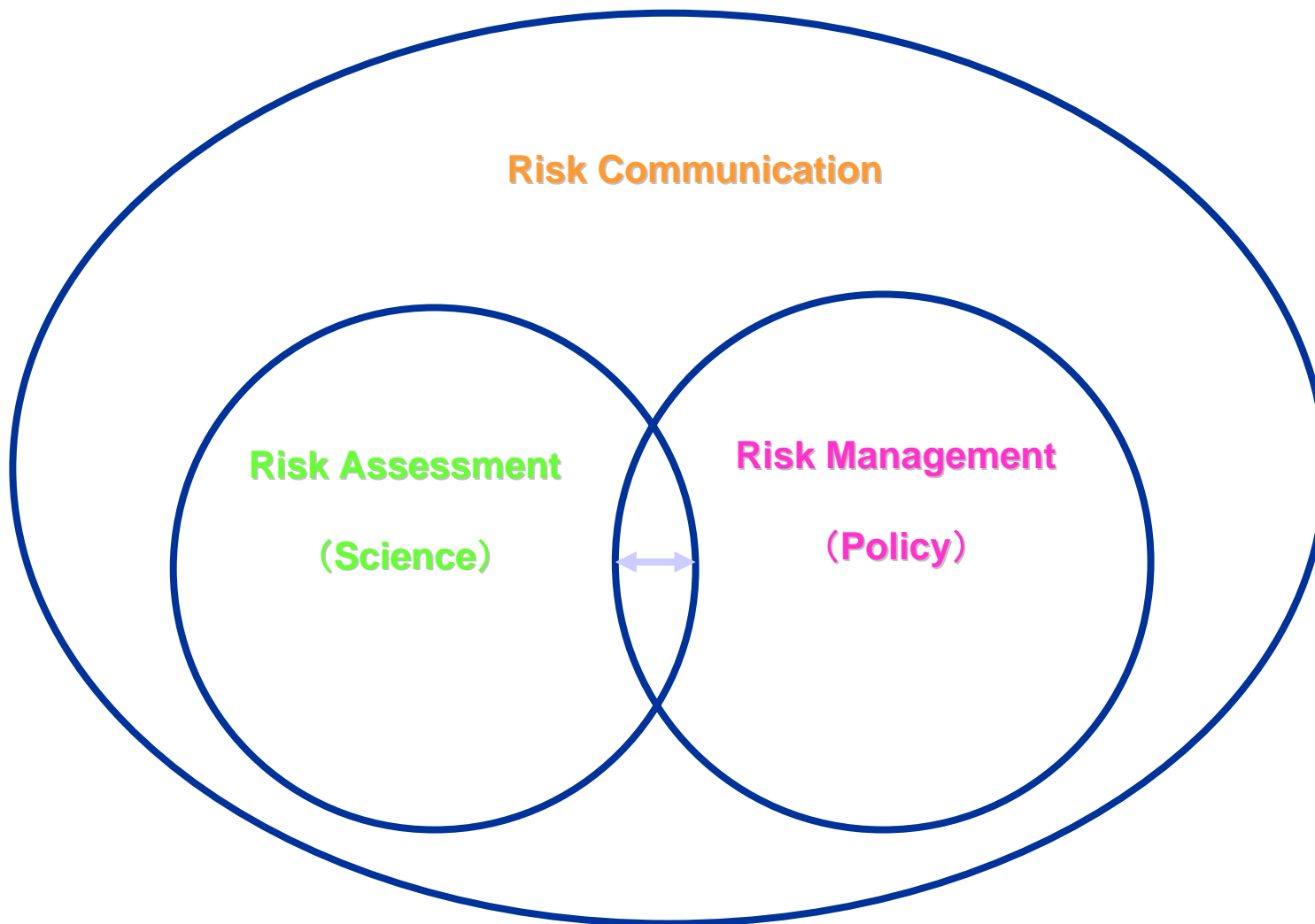
- To establish basic guidelines on risk analysis
- To establish organizations and mechanisms for implementation of risk analysis
- To introduce a new law as the legal basis of implementing risk analysis to ensure consumer protection

Ministry of Agriculture, Forestry and Fisheries

http://www.maff.go.jp/soshiki/seisan/eisei/bse/bse_tyosaiinkai_yoyaku.pdf



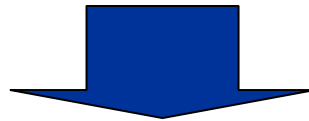
Framework of Risk Analysis



Background (Cont'd)

■ 2002

- Agricultural chemical residues exceeding MRLs detected in imported vegetables
- Deregistered agricultural chemicals illegally distributed and used for plant protection in Japan



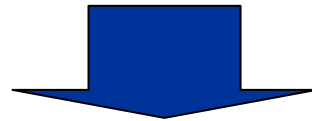
- **Agricultural Chemical Regulation Law** revised to strengthen prohibitions/penalty to farmers



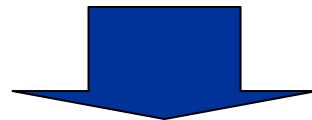
Background (Cont'd)

■ 2003

- **Food Safety Basic Law**, a new law enforced to ensure food safety and consumer protection



Concept and framework of risk analysis introduced into the food regulation in Japan



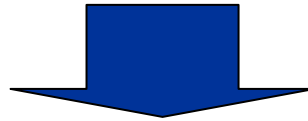
- **Food Safety Commission (FSC)**, a new independent regulatory body established to conduct science-based risk assessments of substances and issues related to food safety



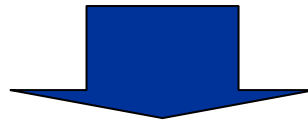
Background (Cont'd)

■ 2003

- **Food Sanitation Law** revised to strengthen regulation to ensure food safety



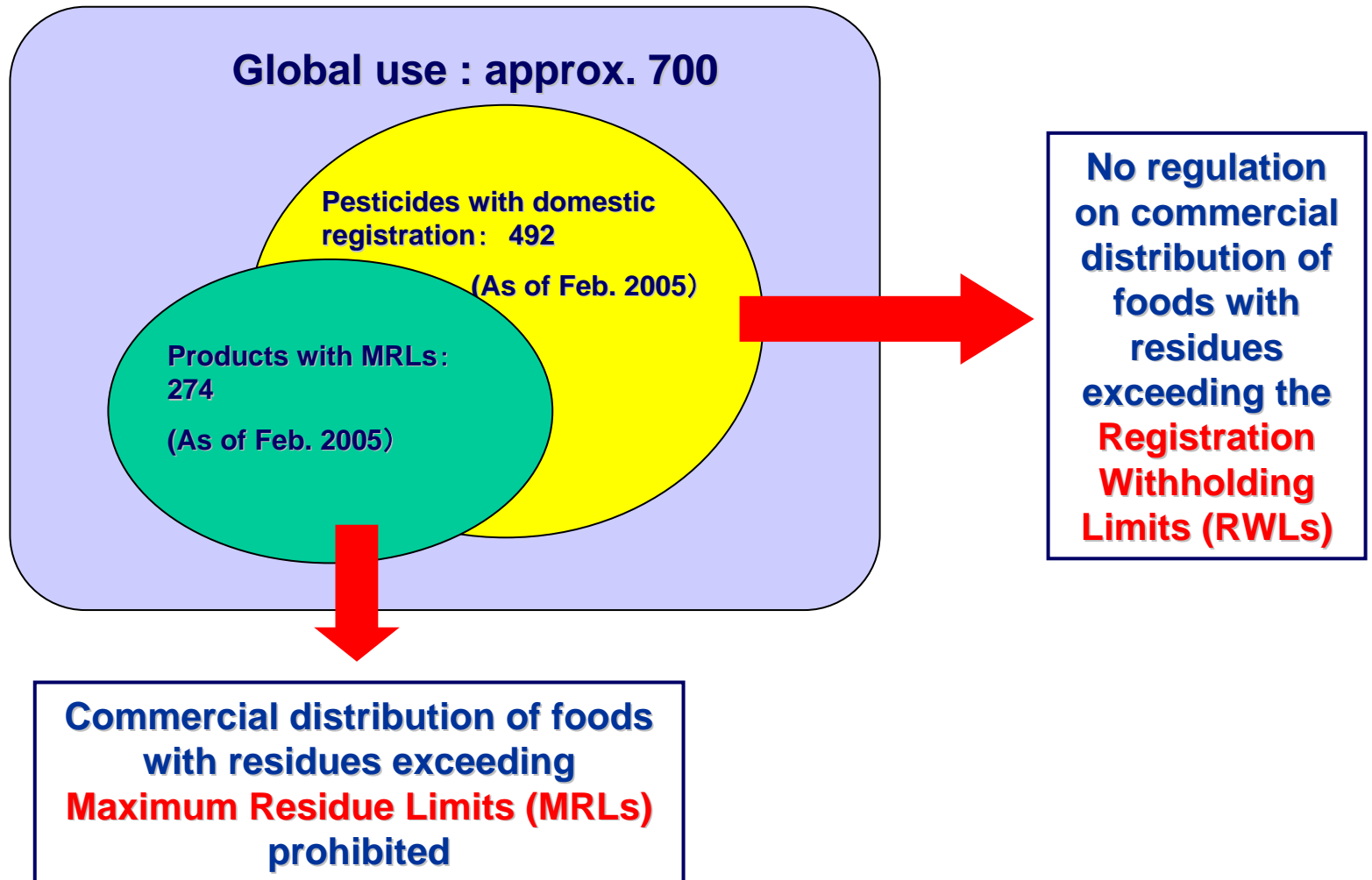
More stringent regulation of
agricultural chemical residues in foods



- Revised law required the introduction of positive list system **within three years** after the enforcement

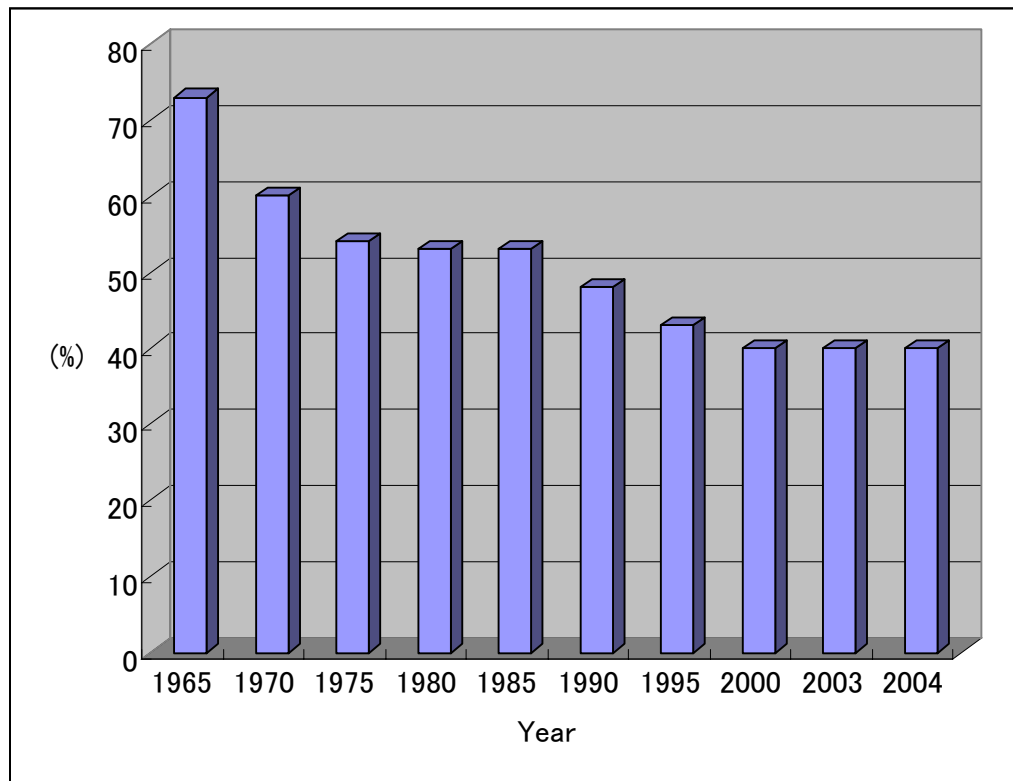


Negative List System



Process: Establishing MRLs

Food Self-Sufficiency Ratio in Japan (Caloric Base)



Japan Ministry of Agriculture, Forestry and Fisheries

<http://www.maff.go.jp/jikyuuritsu/index.html>

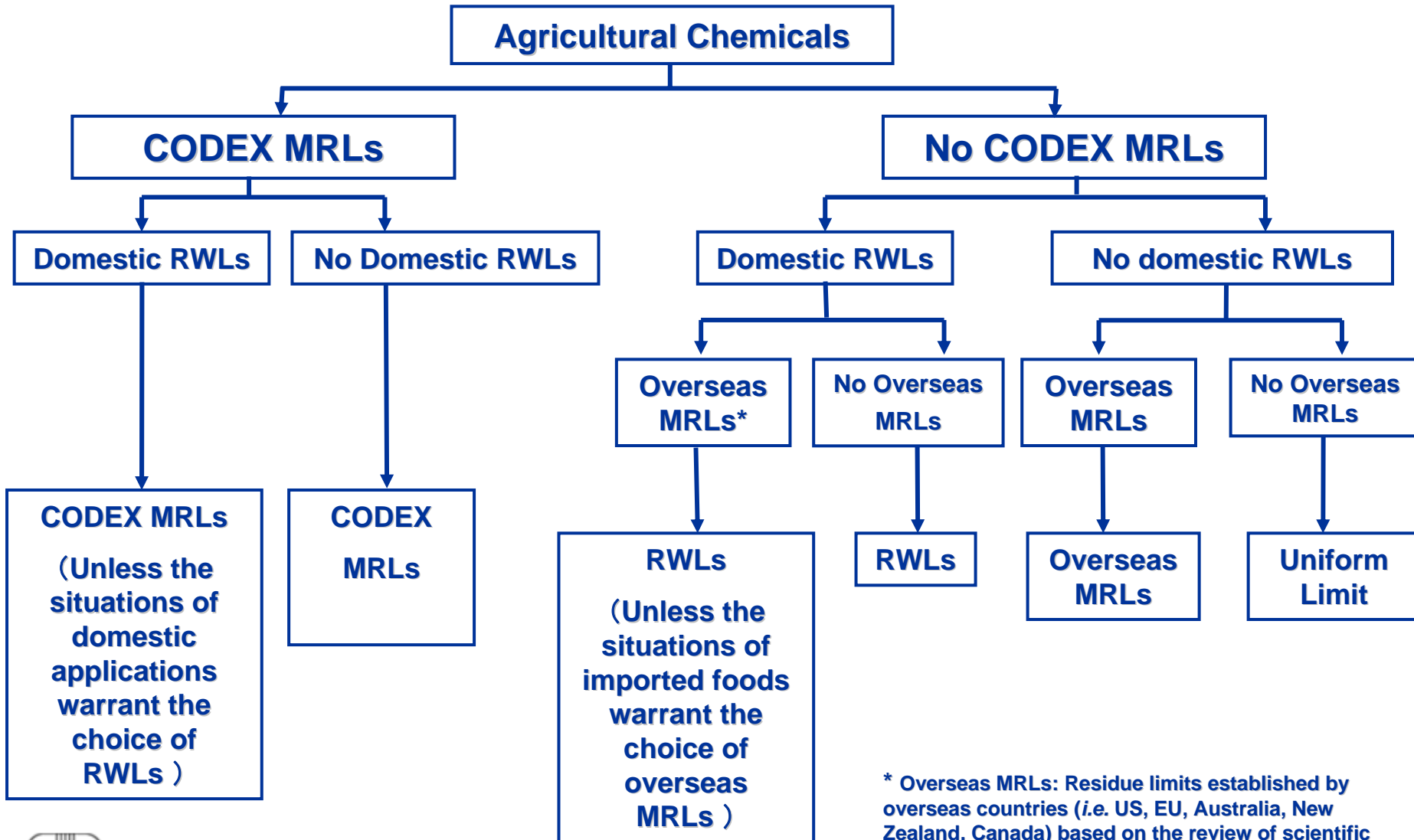


Process (Cont'd)

- June 2003:** Deliberations started at MHLW (Ministry of Health Labor and Welfare) on introduction of positive list system
- Oct. 2003:** Public comment started on the first draft list of provisional MRLs (three months)
- Aug. 2004:** Public comment started on the second draft list of provisional MRLs, the proposed uniform limit, and the draft list of products exempted from the system (three months)



Process (Cont'd)



* Overseas MRLs: Residue limits established by overseas countries (i.e. US, EU, Australia, New Zealand, Canada) based on the review of scientific data meeting the requirements of JMPR review, etc.



Process (Cont'd)

- Apr. 2005:** Review by Food Safety Commission (FSC) and the comments provided to MHLW
- May 2005:** Review within MHLW
Review by FSC
- June 2005:** Public comment and WTO notification of the final draft list of provisional MRLs, the uniform limit, and the list of products exempted from the system



Process (Cont'd)

Aug./Sep. 2005:

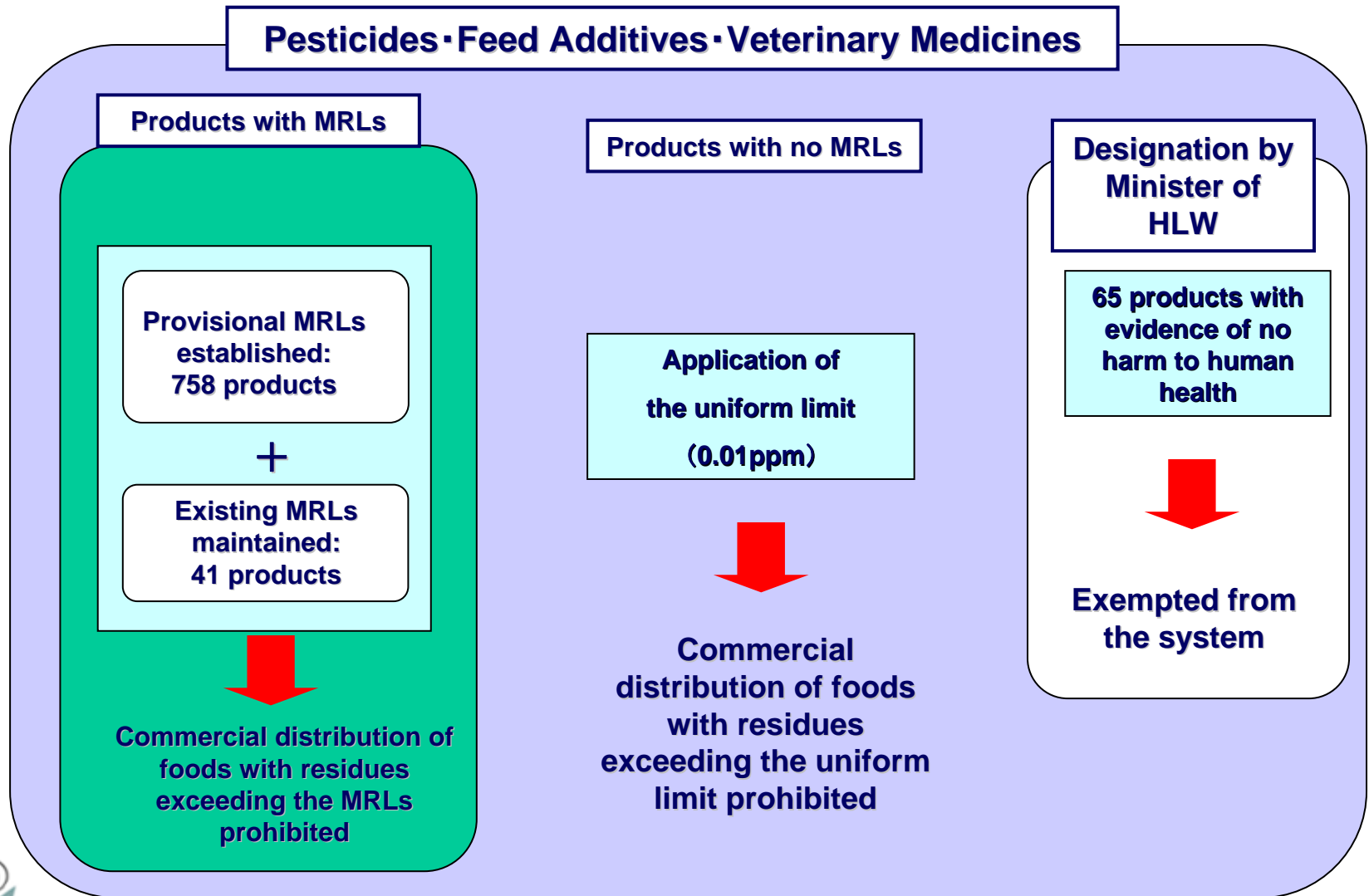
**Review by FSC on the final proposed system
Deliberation of the final proposed system
within MHLW**

**Nov. 2005: Response from FSC on the proposed system
Public announcement of the final list of
provisional MRLs, the uniform limit, and the
list of products exempted from the system
(six months before enforcement)**

May 29, 2006: Introduction of positive list system



Positive List System



Website

In English

<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p>

In Japanese

<http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/zanryu2/index.html>

<http://www.mhlw.go.jp/topics/yunyu/tp0130-1.html>

<http://www.fsc.go.jp/senmon/nouyaku/index.html>



Impact: *Introduction of Positive List System*

■ **Dramatic increase of products with MRLs:**

From 283 before May 29 to 799

Products with existing MRLs maintained: 41

Products with provisional MRLs: 743

Products of which ND is required: 15

1) genotoxic carcinogens

2) chemicals that have been determined by JMPR or JECFA as those for which no ADI can be established



Impact (Cont'd)

■ Issues:

- **Communication within Japan and globally of the new system, and provisional MRLs:**
 - ✓ **Excessive demands from domestic food distributors/retailers: certificate of analysis/proof of no residues exceeding MRLs**
 - ✓ **Confusions among food importers/manufacturers**
 - ✓ **Confusions among domestic farmers**
 - ✓ **Confusions outside of Japan**



Impact (Cont'd)

Media coverage before introduction:

日本経済新聞 (夕刊) 2006年(平成18年)4月5日(水曜日)

食材の調達 「安全」徹底

日本水産もシレハ、トリーなど大手食品メーカーは、食料の調達に「安全」を徹底している。特に水産物は、輸入品が増えている。日本水産は、中国産の魚介類を輸入している。トリーは、海外産の野菜を輸入している。大手食品メーカーは、食料の調達に「安全」を徹底している。特に水産物は、輸入品が増えている。日本水産は、中国産の魚介類を輸入している。トリーは、海外産の野菜を輸入している。

日本水産▶枝豆 生産者を限定

日本水産は、中国産の枝豆を生産者に限定している。これは、品質管理を強化するためである。中国産の枝豆は、品質が安定している。日本水産は、中国産の枝豆を生産者に限定している。これは、品質管理を強化するためである。中国産の枝豆は、品質が安定している。

サントリー▶果物 検査体制拡充

サントリーは、果物の検査体制を拡充している。これは、消費者の安全を守るためである。サントリーは、果物の検査体制を拡充している。これは、消費者の安全を守るためである。サントリーは、果物の検査体制を拡充している。これは、消費者の安全を守るためである。

食品会社	主な対応
日本水産	中国・台湾産枝豆を契約農家から100%調達。品質管理体制を強化
ニチレイ	中国産の農場に日本から農業コンサルタントを派遣
サントリー	果物の残留農薬検査の委託先を4社に拡大
東洋水産	自社で農薬などの分析機器を整備
伊藤園	契約農家への指導を徹底
カゴメ	品質保証室に野菜の産地情報を収集する担当者を設置

Domestic farmers overly concerned with possible pesticide drifts to non-registered crops and detection

Major food manufacturers trying to secure "safer" foods by selecting procurement sources or enhancing capacity of inspection/analysis

日本経済新聞 (夕刊) 2006年(平成18年)5月2日

隣家の農薬付着しても規制 農家飛散にピリピリ

二十九日から導入される農薬物の規制は、農家の不安を煽っている。各地の農家は、農薬の飛散による被害を心配している。農家は、農薬の飛散による被害を心配している。農家は、農薬の飛散による被害を心配している。

月末から新制度

農薬物の規制は、月末から導入される。これは、農家の不安を煽っている。農家は、農薬の飛散による被害を心配している。農家は、農薬の飛散による被害を心配している。

出荷停止の恐れ

農家は、農薬の飛散による被害を心配している。農家は、農薬の飛散による被害を心配している。農家は、農薬の飛散による被害を心配している。



Impact (Cont'd)

■ Issues (cont'd):

● Analytical methods:

- ✓ Validation official methods/multiple analyses
- ✓ Availability of analytical standards
- ✓ Reliability of analyses

● Quarantine/analysis capacity

● Management of cases with detected residues exceeding MRLs

● Costs associated with regulatory compliance



Impact (Cont'd)

■ Situations after May 29:

- Cases increased of residues exceeding MRLs detected in imported foods:

	May	June
Total	89	122
Ag. Chemicals	7	13

Ministry of Health, Labor and Welfare

<http://www.mhlw.go.jp/topics/yunyu/1-4/0604.html>

- Food imports from certain countries slowing down for fears of possible detection of residues exceeding MRLs
- No excessive media coverage nor signs of increasing public concerns so far



Implementation/Validation: Role of Risk Assessment

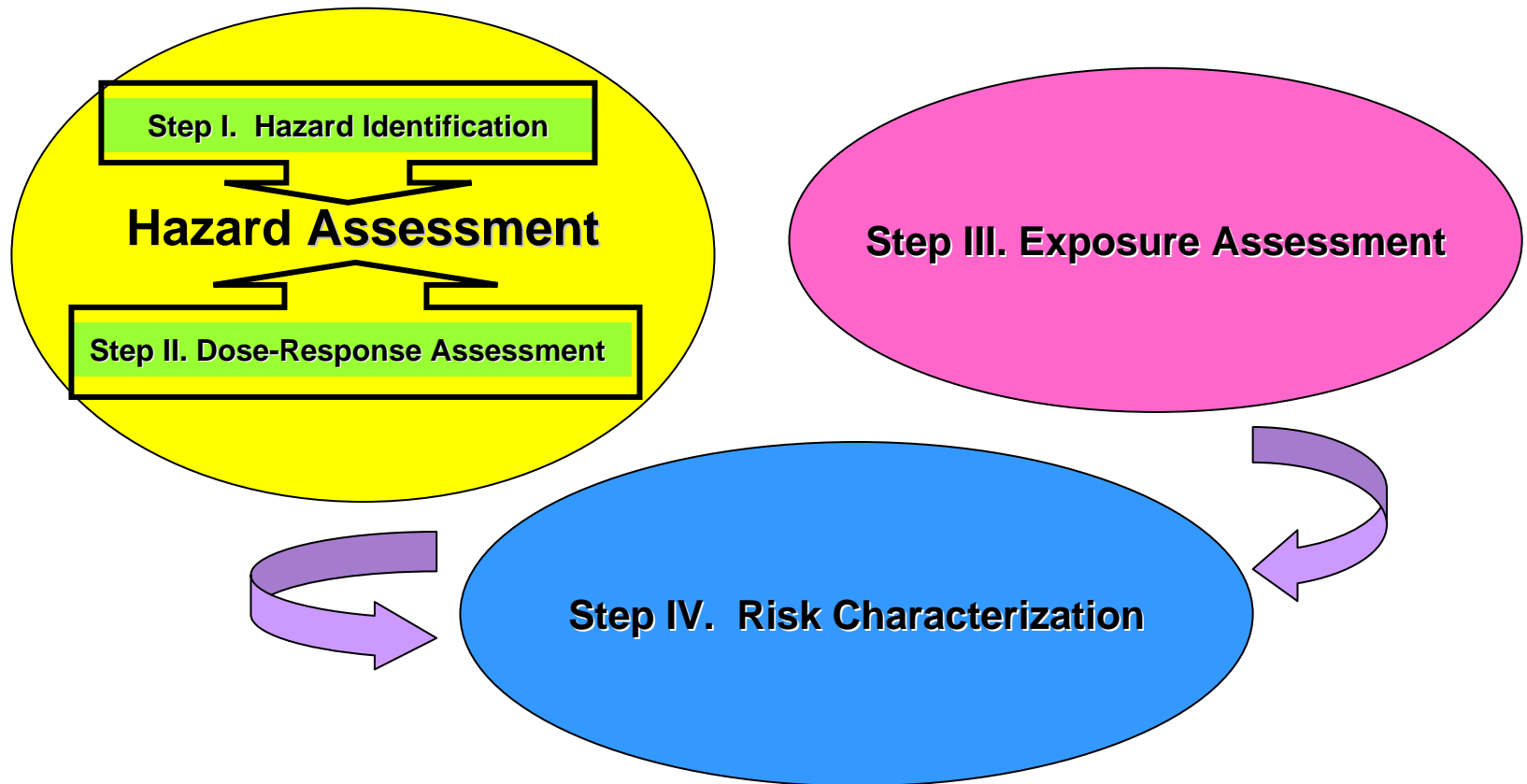
- **Positive list system: risk management introduced without a comprehensive risk assessment of each substance and its MRLs**



Need to confirm validity and effectiveness of the positive list system as a regulatory measure to ensure food safety and human health protection



Framework of Risk Assessment



Implementation/Validation (Cont'd)

■ Validation of the positive list system

- **FSC** is charged to conduct hazard evaluation of individual substances with provisional MRLs: **758** substances to review in about **5 years**:

Pesticide	516
Veterinary Drug	192
Feed Additive	3
Pesticide/Veterinary Drug	31
Veterinary Drug/Feed Additive	15
Pesticide/Feed Additive	1

- **MHLW** needs to improve and refine consumer exposure estimation
 - ✓ Residue database
 - ✓ Food intake database
 - ✓ Application of mathematical models (?)



Implementation/Validation (Cont'd)

- **Science-based risk assessment is a key:**
 - To confirm validity of the provisional MRLs and the uniform limit
 - To realize proper implementation of the positive list system to ensure health protection of the consumers as well as to prevent foods unnecessarily being discarded due to detection of residues exceeding MRLs

- **Assessment of socio-economic impact**

- **Considerations on possible risk trade-off:**
 - e.g. balance between quantity and quality



Challenge: *Global Contribution*

■ Global communication of the hazard evaluation of 758 substances

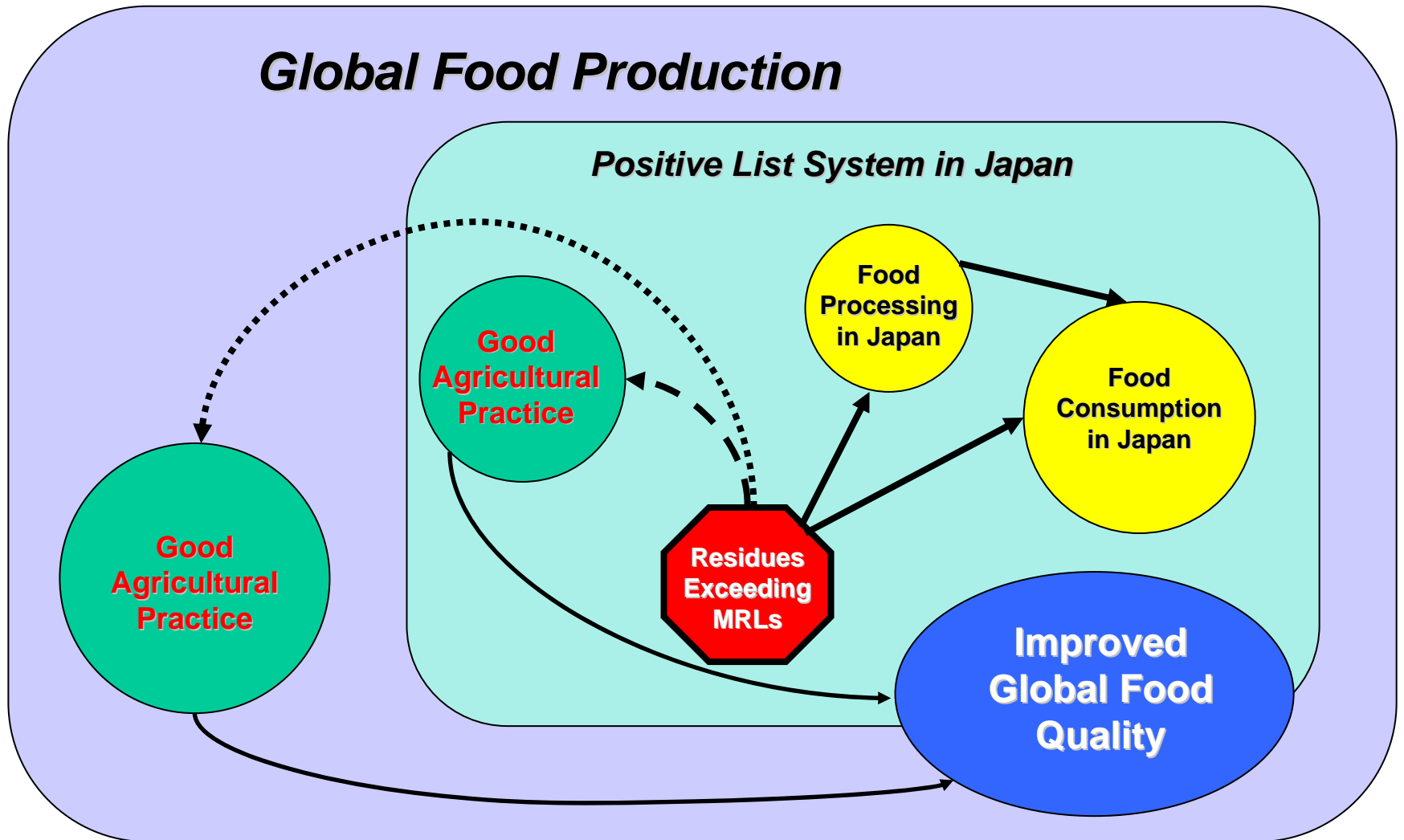
- To accelerate re-evaluation of existing agricultural chemicals globally
- To contribute to the global harmonization of the guidelines/methods/criteria for evaluation of agricultural chemicals

■ Global communication of the residue analyses of foods imported to Japan

- To ensure **Good Agricultural Practice (GAP)** and improve food quality globally
- To provide information/alerts on possible sources of residues other than agricultural chemicals used for plant protection, e.g. use during storage/transport, environmental contaminants, etc.



Challenge (Cont'd)



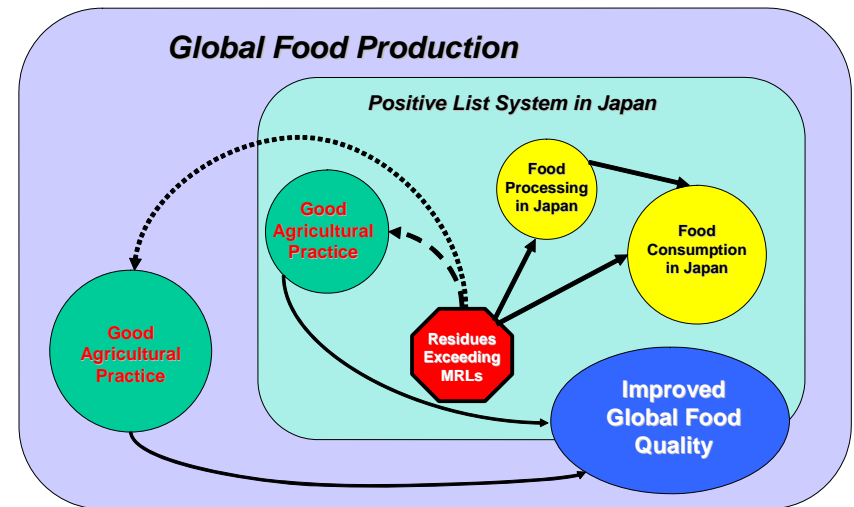
Challenge (Cont'd)

Success through:

Science-based risk assessment

Effective risk management

Global information sharing and risk communication



To improve food quality
and protect human health globally



Acknowledgement

Special thanks to:

Agricultural Chemical Subcommittee, Research Committee on Integrated Risk Management of Food Health Risks, ChemoBio Integrated Management Society, Japan, for their contributions to my presentation; and

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Thank you very much for your attention

