Amendment of the Chemical Substance Control Law (CSCL)

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TODAY'S TOPICS

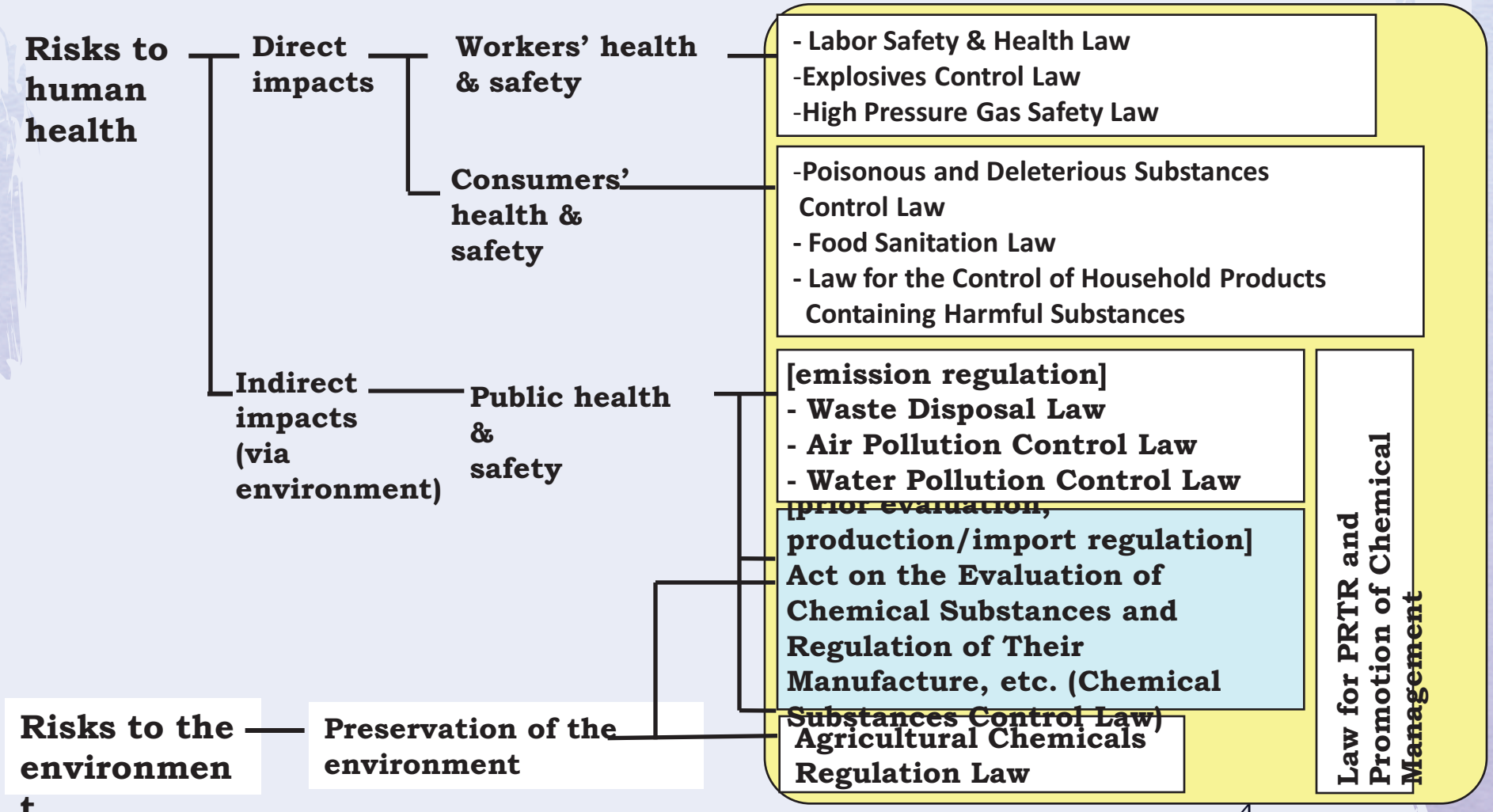
- Background and history of CSCL
- Regulation under current CSCL
  - Chemical types regulated
  - New chemicals / existing chemicals
- Background of the amendment
- New chemical management system
  - Risk assessment : tiered approach
  - Risk reduction : enhanced regulation on high risk chemicals
- Schedule

BACKGROUND OF CSCL

"Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.", abbreviated as "Chemical Substances Control Law" (CSCL), regulates industrial chemicals in Japan.

- Enacted in 1973
- Originally aimed at preventing pollution of environment from PCBs and other hazardous chemicals
- Based on two pillars:
  - pre-marketing evaluation of new chemicals
  - regulation on manufacture/import and use

COVERAGE OF CSCL



HISTORY

- 1973 original law :
  - Banned the production, import and use of persistent, bioaccumulative and chronically toxic chemicals such as PCBs.
- 1986 amendment :
  - Regulated persistent and chronically toxic but non-bioaccumulating chemicals such as trichloroethylene, depending on the situation where they remain in the environment.
- 2003 amendment :
  - The law introduced the regulation on persistent and ecotoxic chemicals.
  - Chemicals with low possibility of exposure became exempt from notification or some of data requirement.

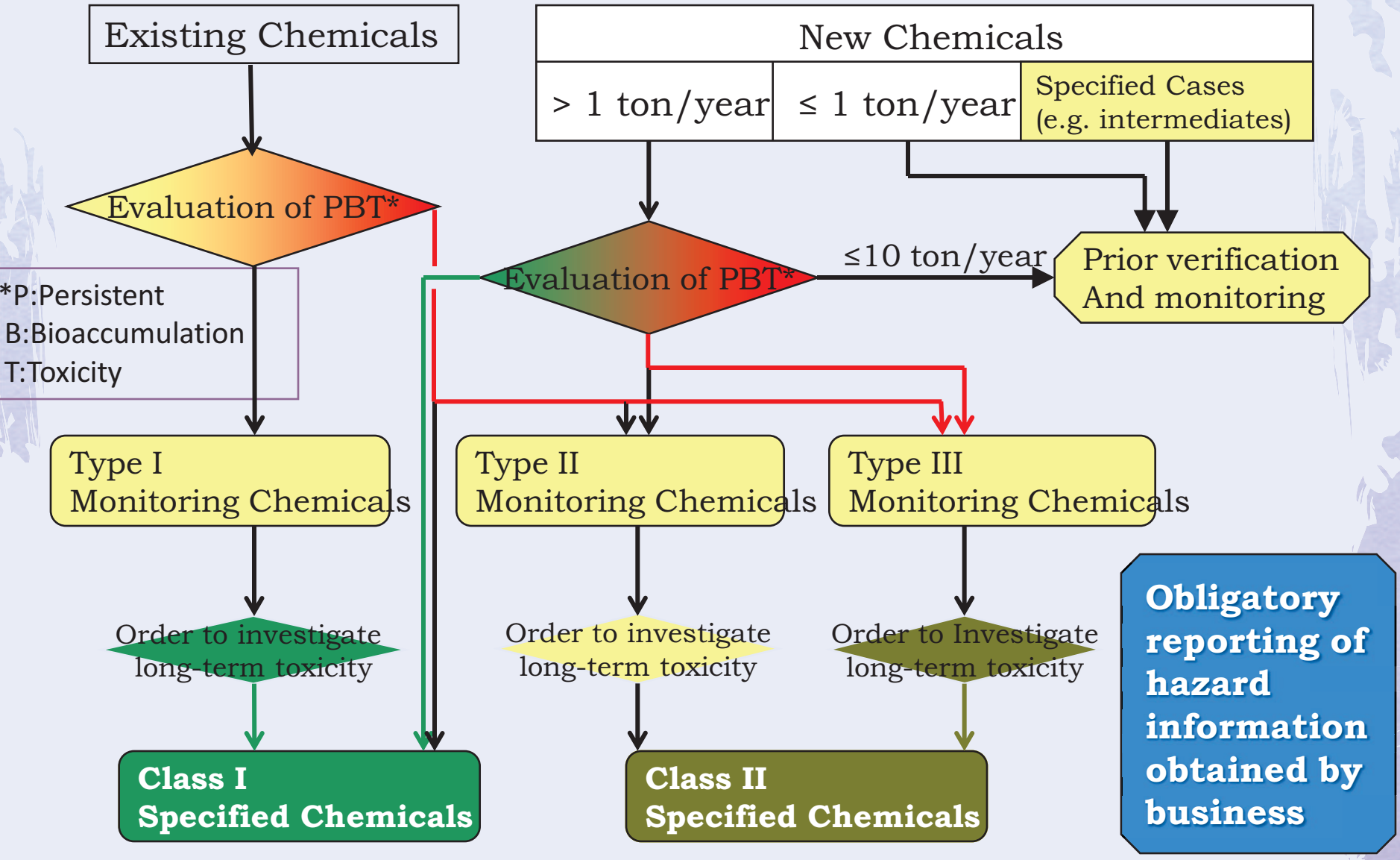
STRUCTURE OF CSCL

CSCL consists of two main features.

- Pre-marketing evaluation system for new chemicals
- Regulation of chemicals specified according to the potential for adverse effects

CSCL is enforced by three ministries.

- Ministry of Health, Labour and Welfare
- Ministry of Economy, Trade and Industry
- Ministry of the Environment


Existing Chemicals
New Chemicals
> 1 ton/year
≤ 1 ton/year
Specified Cases
(e.g. intermediates)
Evaluation of PBT*
Evaluation of PBT*
≤10 ton/year
Prior verification
And monitoring
*P:Persistent
B:Bioaccumulation
T:Toxicity
Type I
Monitoring Chemicals
Type II
Monitoring Chemicals
Type III
Monitoring Chemicals
Order to investigate
long-term toxicity
Order to investigate
long-term toxicity
Order to Investigate
long-term toxicity
Class I
Specified Chemicals
Class II
Specified Chemicals
Obligatory
reporting of
hazard
information
obtained by
business

CHEMICAL TYPES

*as of Feb 2009.

Name	Explanation	*No. of substances
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and hazardous (long-term human toxicity or ecotoxicity to higher predators.	16
Class-II Specified Chemical Substances	Persistent, hazardous (long-term human toxicity or ecotoxicity to living organisms), with concern for long-term existence in the environment.	23
Type-I Monitoring Chemical Substances	Persistent and bioaccumulative, but hazardous properties unknown. *(Candidates for the Class-I Specified Chems.)*	36
Type-II Monitoring Chemical Substances	Persistent and suspected as hazardous to human health. *(Candidates for the Class-II Specified Chems.)*	921
Type-III Monitoring Chemical Substances	Persistent and hazardous to living organisms. *(Candidates for the Class-II Specified Chems.)*	124

CHEMICAL TYPES (contd)

Class I Specified Chemical Substances	-prior permission required for manufacture and/or import (Note: Permission is prohibited virtually.) - prohibition of use unless authorized in advance - prohibition of import of products containing them - recovery of the products
Class II Specified Chemical Substances	- mandatory reporting of planned manufactured and/or imported amounts - subject to governmental orders that require the change of planned amounts - labeling - compliance with technical guideline provided by GOJ and/or governmental recommendation on a legal basis - compliance with guidance provided by GOJ
Monitoring Chemical Substances (Type I, II and III)	- mandatory reporting of manufactured and/or imported amount annually (Note: These amounts are announced publicly.) -compliance with guidance provided by GOJ -The GOJ can instruct manufacturer/importer investigate their long-term toxicity

NEW CHEMICALS

Manufacturers and importers of new chemicals must notify the government before putting them into the market and submit data on their properties and toxicities.

The government evaluates the data and decides whether the chemicals fall within the types above-mentioned.

A new chemical is any chemical other than:

- Chemicals in the Inventory of Existing Chemical Substances
- Chemicals already designated as Specified or Monitoring Chemical Substances
- Chemicals already publicized as substances that do not need to be designated as Specified or Monitoring Chemical Substances.

NEW CHEMICALS (contd)

Data to be submitted		Production volume	
		1-10t	10t <
Fate	Ready biodegradability	x	x
	Pow or bioconcentration in fish	x[1)]	x[1)]
Mammalian toxicity	Repeated dose 28-day oral toxicity in mammals		x[1)]
	Bacterial reverse mutation test		x[1)]
	Chromosome aberration in mammalian cell culture		x[1)]
	Mammalian chronic toxicity, toxicity to reproduction and offspring, teratogenicity, carcinogenicity, biotransformation and pharmacological effects		[2)]
Ecotoxicity	Algae growth inhibition		x[1)]
	Daphnia acute immobilisation		x[1)]
	Fish acute toxicity		x[1)]
	Avian reproduction toxicity, and mammalian toxicity to reproduction and offspring		[2)]

1) If a substance is found to be ready biodegradable, other tests are not required. However, tests for the degradation products are also required.
2) These tests are used to designate a chemical as a Class I Specified Chemical Substance. Therefore, these tests are not required first.

NEW CHEMICALS (contd)

Number of the notifications

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Japan CSCL	320	325	352	323	373	322	292	362	426	443
EU Directive	441	437	408	430	424	352	398	337	312	* 174
US TSCA	1472	998	1105	1418	1233	948	1083	869	959	844

* Tentative figure

EXISTING CHEMICALS

When the CSCL was passed in 1973, the Diet requested that the government should assess the safety of existing chemicals.

- Number of Existing Chemicals :about 20,000
- Number of substances evaluated (as of March 2008) :

Degradation & bioaccumulation	1543	by METI
Toxicity to human health	326	by MHLW
Ecotoxicity	509	by MOE

Meanwhile, worldwide approaches to existing chemicals were advanced in the 1990s. When the CSCL was amended in 2003, the Diet resolved that government and industry cooperate to investigate the safety of existing chemicals.

- Japan Challenge Program (JPC) , announced in 2005, is now under way => Next slide

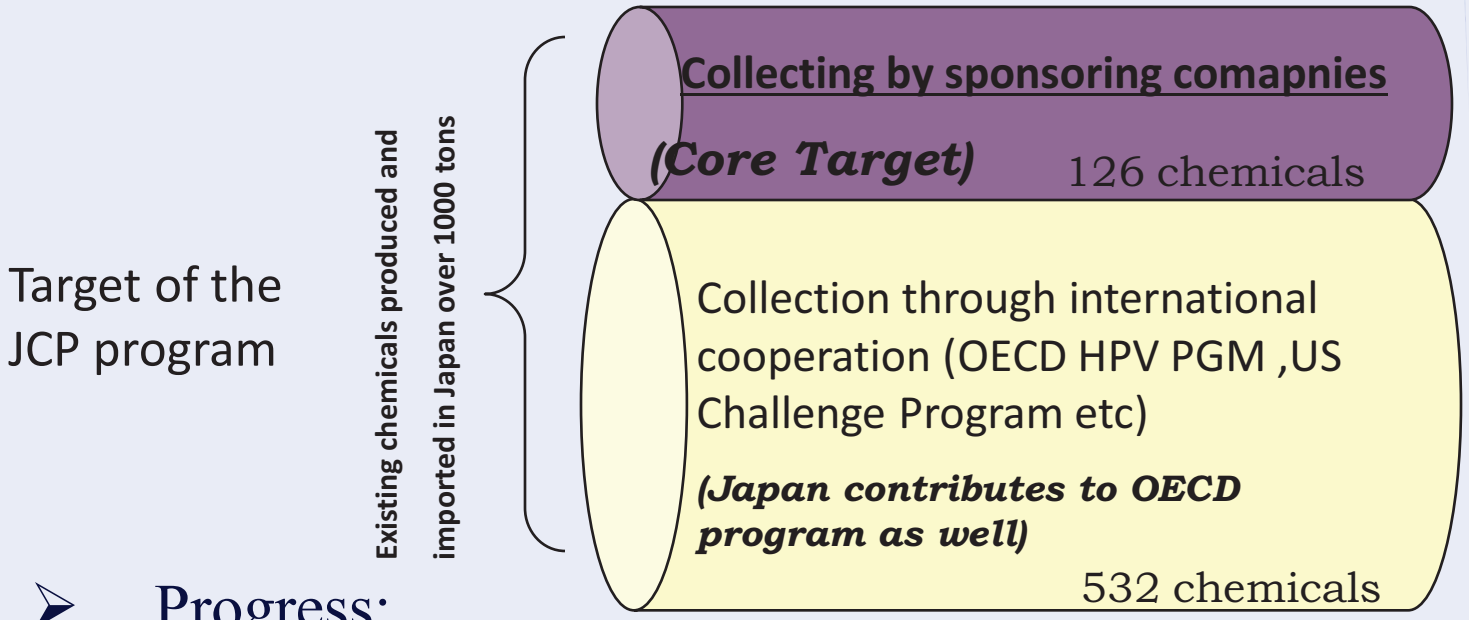
EXISTING CHEMICALS (contd)

The features of Japan Challenge Program (JPC) include;

- Aim : accelerating collection of safety information for HPV chemicals
- Voluntary Program
  - Based on corporation between government and industry
- Information to be collected: OECD Screening Information Data Set (SIDS)
- Collected information will be made public
  - "Japan Chemicals Collaborative Knowledge Database (J-Check) http://www.safe.nite.go.jp/jcheck/

EXISTING CHEMICALS (contd)

- Target:



- Progress:
  - June 2008: registered sponsors for 89 chemicals, with 105 companies and 3 associations (including 27 consortia) participating
  - FY 2011: safety information on all chemicals will be public

BACKGROUND OF CSCL AMENDMENT

Schedule of legislative review

- PRTR Law: To be reviewed 7 years after the entry into force (in 2007)
- CSCL: To be reviewed 5 years after the entry into force of the 2003 Amendment of CSCL

Nov. 2006: Consulted the Central Environment Council on the future policy for the environmental chemicals management

Aug. 2007: Interim report on the review of PRTR Law (Joint report with the Industrial Structure Council)

Dec. 2008: Report on the review of CSCL (Joint report with the Health Science Council and Industrial Structure Council

24 Feb 2009: Bill submitted to the Diet

Summary of the bill to amend the Chemical Substances Control Law

To comprehensively control chemical substances, the government reviews the measures for risk assessment of chemical substances and the scope of the regulated chemical substances, while taking measures to rationalize regulations in view of international trends.

Background and necessity of the amendment

1. Increasing public interest in chemical substances (public safety and security)

2. Need to achieve international goals on chemicals management
   - There is a need to minimize adverse effects of all chemicals on human health and the environment by 2020 (agreement in the World Summit on Sustainable Development, 2002).
     - In Europe, a new regulation (REACH) entered into force in 2007.
   - Since the enactment of the Chemical Substances Control Law (in 1973), every new chemical substance has been subject to pre-marketing evaluation.
   - On the other hand, the government has been conducting safety assessment of part of the existing chemical substances (chemicals in the market before the legislation) and not all of them have been assessed yet.

3. Inconsistency with the international treaty
   - Under the international treaty (Stockholm Convention), an agreement is expected to be reached this spring to accept certain exceptional uses of the newly prohibited chemicals.
   - The existing law, which is more restrictive on exceptional uses, may fail to ensure the uses essential to Japan.

Summary of the Amendment

(1) Measures for existing chemical substances

- Companies that have manufactured or imported any chemical substance, including existing one, in excess of the specified amounts are newly obliged to notify applications containing quantity and other information to the government.
- Upon receipt of those applications, the government screens and prioritizes substances subject to detailed risk assessment. For these substances, the manufacturers/importers may be required to submit information on hazardous properties for government evaluation.
- Based on the evaluation, the government decides whether to regulate the manufacture/use of the substance and its product, etc.

(2) Ensuring international consistency

- The government ensure that substances newly listed under the international treaty can be used under strict control.
  - Uses for semiconductors, fire fighting foam, etc.

(For reference) Related moves

1973 Enactment of the Chemical Substances Control Law
2002 World Summit on Sustainable Development → 2020 Completion of safety confirmation by respective countries
2004 Entry into force of the Stockholm Convention
2007 Entry into force of REACH (Europe) → 2018 REACH registration deadline

WSSD GOAL – BASIS FOR NEW CSCL

World Summit on Sustainable Development (2002) agreed:

- to achieve, by 2020,
- that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment,
- using transparent science-based risk assessment procedures and science-based risk management procedures,
- taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development

REACH Preambles mention WSSD 2020 goal and SAICM, and aims to finish the registration of all chemicals by 2018.

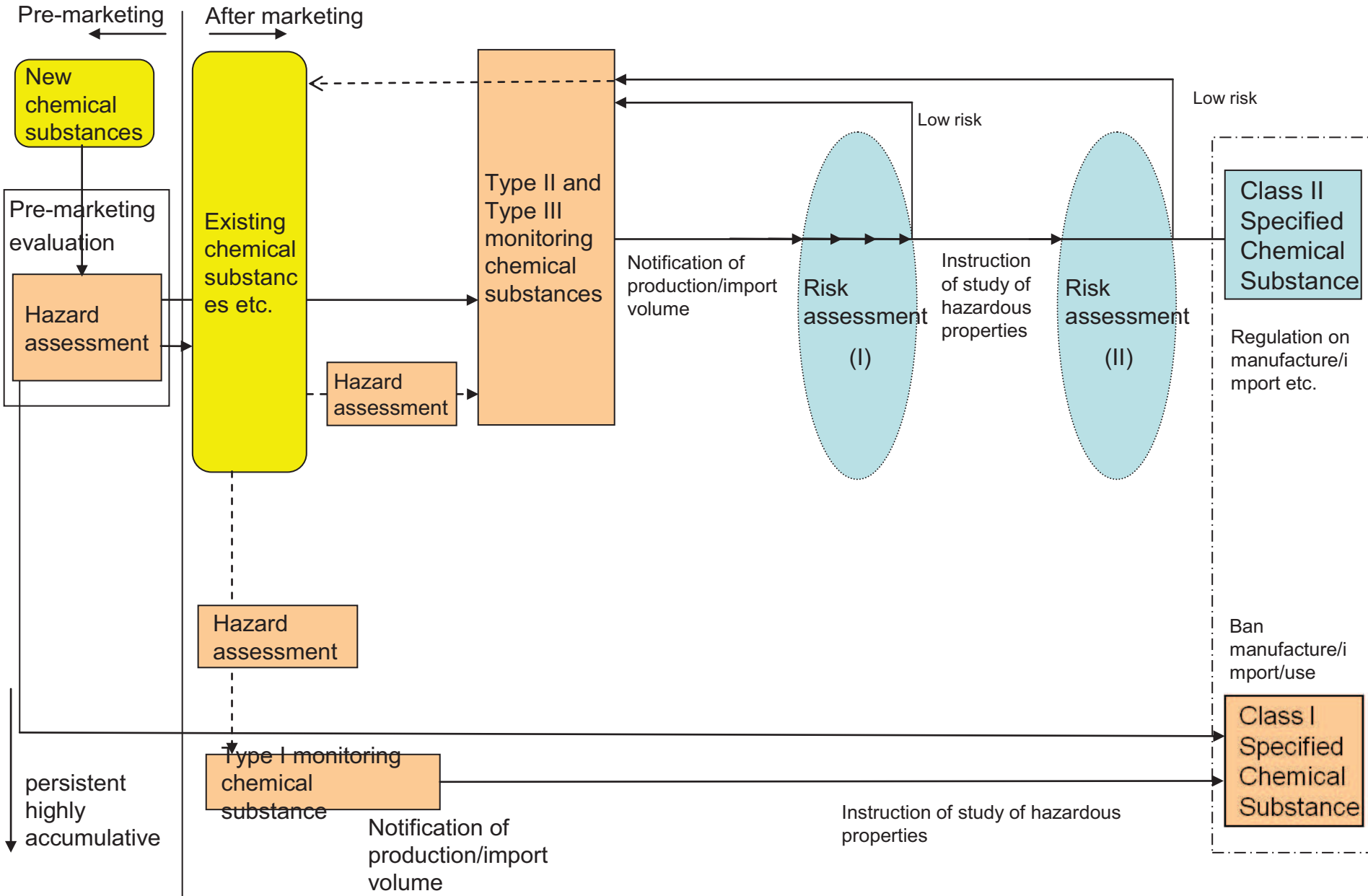
US EPA announced the Chemical Assessment and Management Program (ChAMP)

RISK ASSESSMENT :TIERED APPROACH

- Companies that have manufactured or imported any chemical substance in excess of the specified amounts are newly **obliged to notify quantity and other information for every fiscal year**.
- Chemical substances which the government identifies , from the content of their notifications and available knowledge of their hazardous properties, as having higher priority in risk assessment shall be designated as "**Priority Assessment Chemical Substances**."
- Manufacturers and importers of those Priority Assessment Chemical Substances may be required to submit information on hazardous properties and companies handling them may be required to report their uses.
- Among the Priority Assessment Chemical Substances, substances which raise concerns about adverse effects on humans or the environment through the information gathering and the risk assessment shall be subject to regulations on manufacture and use as "Specified Chemical Substances," as in the existing Law.
- The amended law will cover non-persistent chemical substances, which were not covered by the current law.

RISK ASSESSMENT (contd)

<Current CSCL>



RISK ASSESSMENT (contd)

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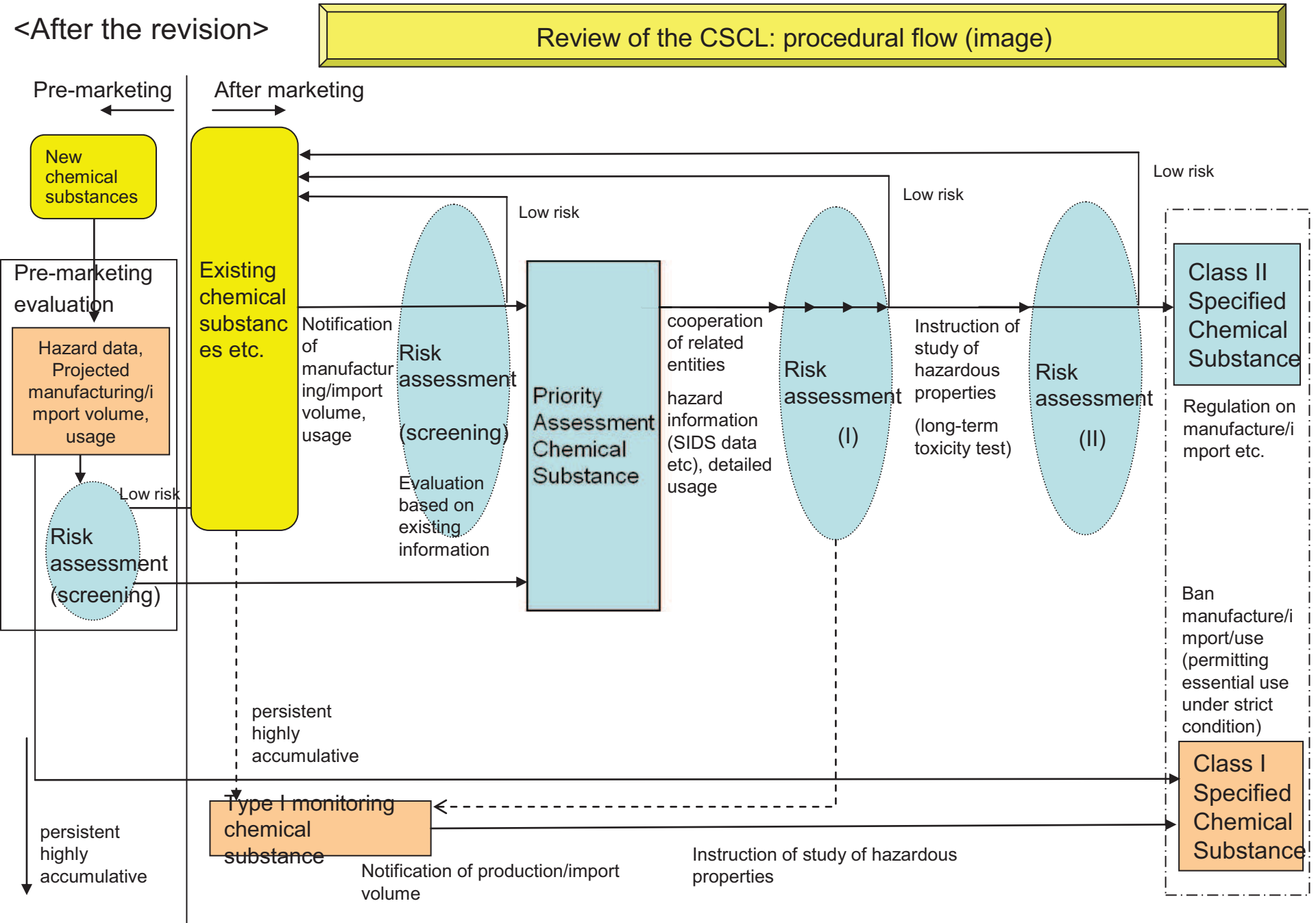

ASSESSMENT OF NEW CHEMICALS

Current pre-marketing evaluation for new chemical substances will be kept in place.

Exposure consideration will be introduced in addition to hazard consideration under the current CSCL. Using the submitted hazard information, the planned production volume and use category, the government will judge whether the new chemicals should be nominated as Priority Assessment Chemical Substances or not.

Some improvements will also be introduced for the effective and efficient evaluation of new chemicals, such as

- Enhanced use of QSAR (quantitative structure-activity relationships) and chemical category approach
- Reduced requirements for Polymers of Low Concern (PLCs)

REGULATION OF PRODUCTION etc

Chemicals identified through the phased risk assessment process will be regulated as Class II Specified Chemicals.

The strict regulation of persistent, bio-accumulative and toxic substances (Class I Specified Chemicals) will kept in place, with some modifications :

- The essential use of POPs permitted under the Stockholm Convention will also permitted under the new CSCL.
- Secondly, the report proposes to strengthen the flow of information on the safety of chemicals contained in products.
- Thirdly, the report proposes to introduce an obligation for information sharing for Type I Monitoring Chemicals (persistent and bio-accumulating substances with insufficient knowledge on toxicity)".

INFORMATION SHARING

In order to make safety (hazard) information of chemical substances public, the government will improve the existing databases such as J-CHECK, as well as enhancing interconnection with international databases.

The new CSCL will stipulate that the information collected under CSCL should be used for chemical management under different laws.

SOME OTHER TOPICS

East Asian Tripartite Cooperation - China, Japan and Korea

December 2006: At the 8th Tripartite Environmental Ministers Meeting, held in Beijing, three ministers agreed to proceed with information exchange regarding policies and regulations on chemicals management

March 2007: Working-level Meeting (Hayama, Japan)

November 2007: 1st Tripartite Policy Dialogue (Tokyo)

September 2008: 2nd Tripartite Policy Dialogue (Seoul)

SOME OTHER TOPICS

Japan Network for Strategic Response to International Chemicals Management

- Established in July 2007
- Information exchange network to co-operatively respond to international trend in chemicals regulation such as REACH
- Operates an informative website, mail magazines, electronic bulletin board, seminars
- 11 organizations form the management board
- http://www.chemical-net.info/eng

INFORMATION SOURCES

Ministry of the Environment :

http://www.env.go.jp/en/laws/chemi/cscl/index.html

NITE: http://www.safe.nite.go.jp/english/index.html