

# Chemical Control Legislation In Japan

Outline of the 2003 Partial Amendment to  
the Chemical Substances Control Law



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Chemical Management Policy Division  
Ministry of Economy, Trade and Industry



# Contents

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- ***Background to the amendment of the Chemical Substance Control Law***
- ***Major contents of the amendment***

Evaluation and regulation on adverse effects on living organisms in the environment

Measures for persistent and high bioaccumulative existing chemical substances

Reform of the evaluation system for new chemical substances

Introduction of obligation to report the hazard information voluntarily obtained by businesses

Other (announcement period of substance names, stronger penalties, etc.)



# About the Chemical Substances Control Law (CSCL)

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## **Established in 1973**

- Introduced hazard-based evaluation of new chemical substances
- Restricts manufacturing, import and use of PBT

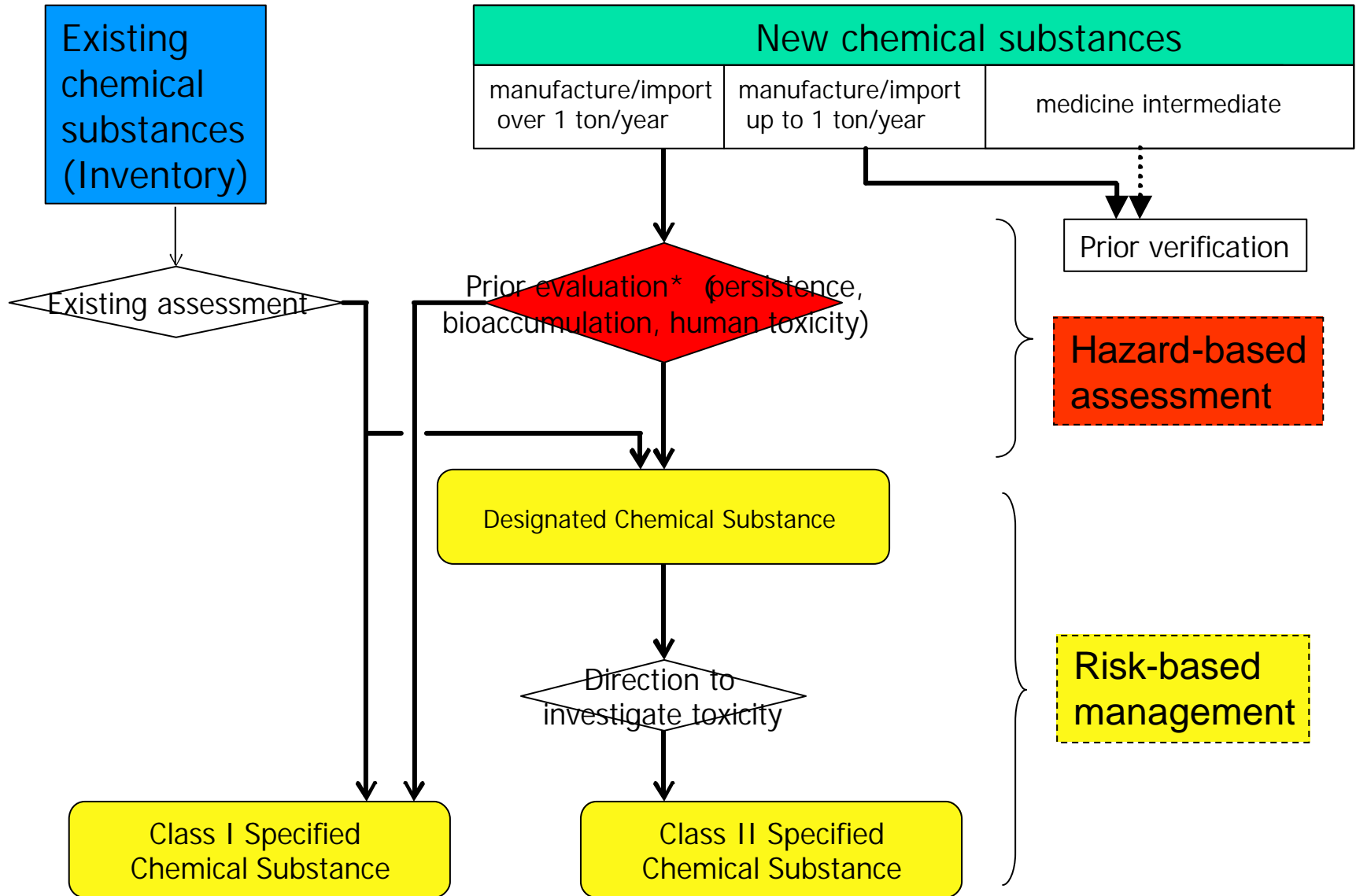
## **First Amendment in 1986**

- Introduced risk-based regulation for persistent chemical substances with long-term toxicity

## **Second Amendment in 2003**

- Introduced evaluation and regulation on the adverse effect on living organisms
- Reform of the evaluation system for new chemical substances

# Evaluation and regulation systems under the Former CSCL



\*Prior evaluation: conducted prior to the manufacture or import

## Regulatory measures for control substances

Class I Specified Chemical Substance	<ul style="list-style-type: none"><li>• Permission is required for manufacture and/or import (actually prohibited)</li><li>• Any use other than that specified is prohibited</li><li>• Import of the products (articles) specified by Cabinet Order is prohibited</li><li>• Injunction to take measures such as recall (when the substance/product is designated, or when the law is violated)</li></ul>
Class II Specified Chemical Substance	<ul style="list-style-type: none"><li>• Mandatory reporting of planned and actual quantity manufactured/imported, use, etc.</li><li>• If deemed necessary in terms of risk, the government issues orders to change the planned quantity manufactured/imported, etc.</li><li>• Government provides technical guidelines and related recommendations</li><li>• Mandatory labeling and related recommendations from government</li><li>• Guidance and advice (where necessary to prevent environmental pollution)</li></ul>
Designated Chemical Substance	<ul style="list-style-type: none"><li>• Mandatory reporting of actual quantity manufactured/imported, use, etc.</li><li>• Publication of the name and reported quantity of the designated chemical substance (only when more than 100 tons/year)</li><li>• Guidance and advice (where necessary to prevent environmental pollution)</li><li>• Government directs manufacturers and importers to investigate hazardous properties when deemed necessary in terms of risk</li></ul>



# Background to the amendment

**Development of international and domestic efforts on chemical substance management since the last amendment of the law (1986)**

## **(1) International**

**OECD Environmental Performance Reviews: Japan (January, 2002)**

<Recommendations>

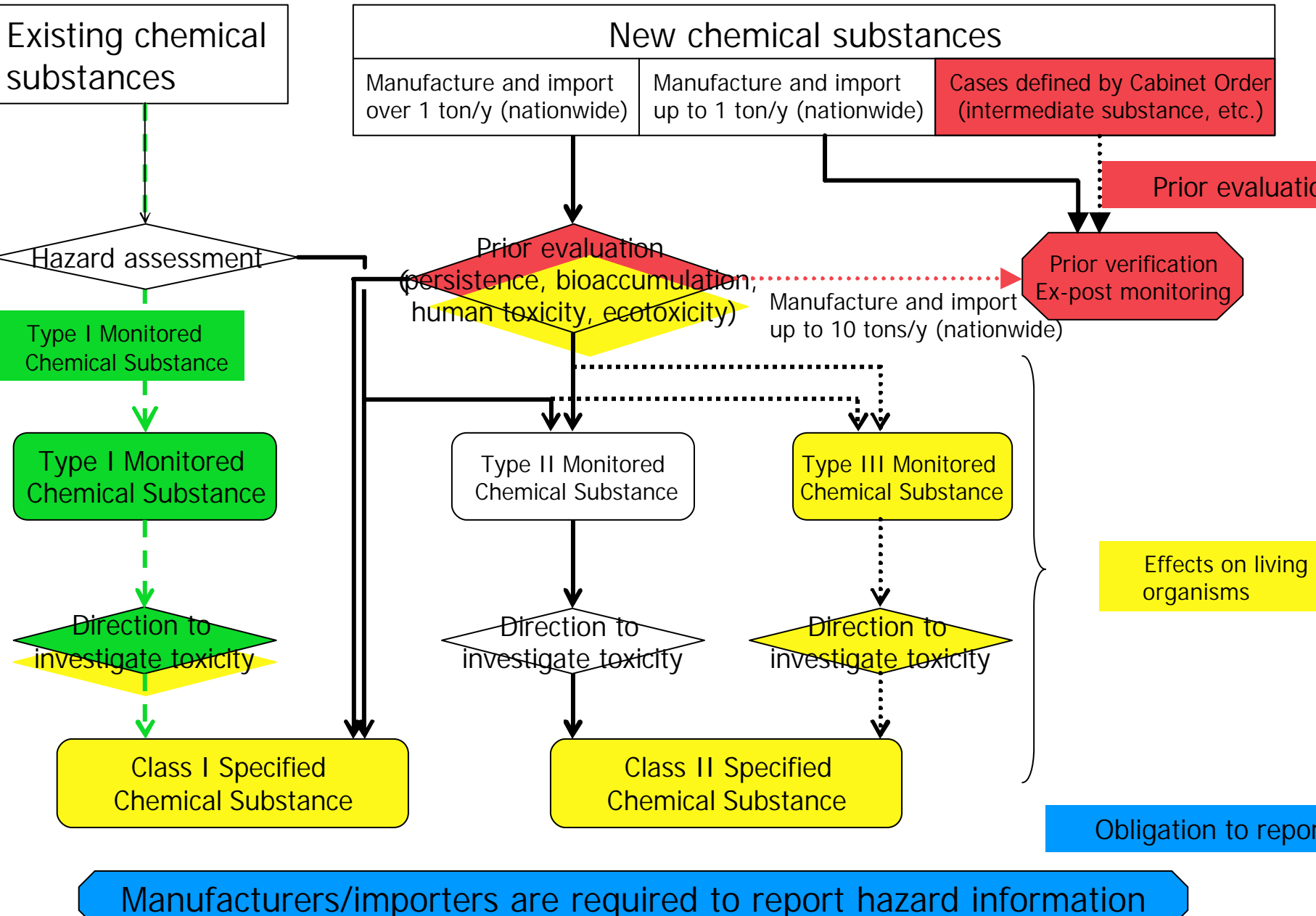
- Extension of the scope of regulation to protect ecosystem
- Further improvement of the effectiveness and efficiency of chemical management  
(Many industrialized countries have been carrying out risk-based evaluation and regulation to protect human health and environment.)

**International momentum to harmonize the evaluation systems of all countries**

## **(2) Domestic**

- Establishment of environmental standards in Japan for water quality to protect aquatic organisms (2003)
- Review of the standard of registration under the Pesticide Regulation Law from the viewpoint of the adverse effects on living organisms (2002)

# Framework for evaluation and regulation under the Amended CSCL



# 1. Introduction of an evaluation/regulation system focused on effects on living organisms

## (1) Pre-manufacturing/import evaluation on eco-toxicity

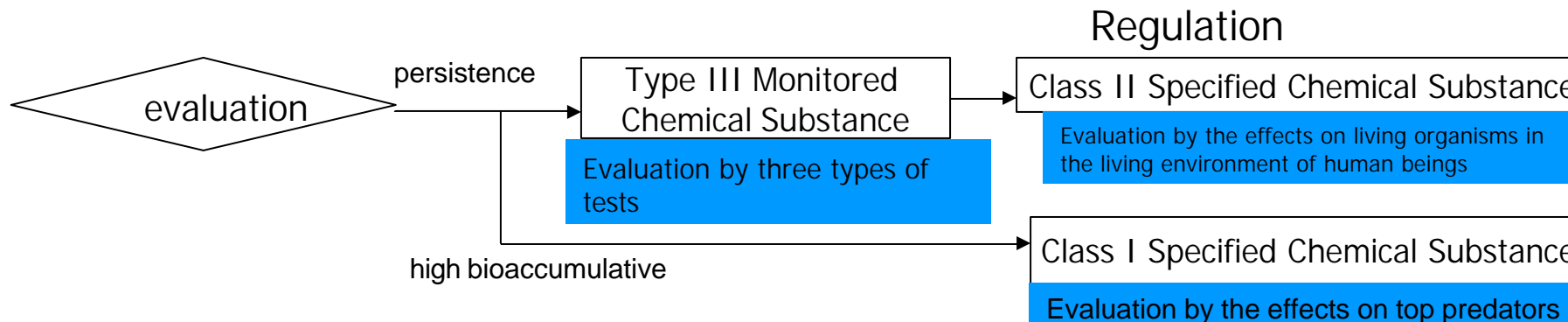
taking account of

the framework of the pre-manufacturing/import evaluation of the former CSCCL  
(e.g., relationship with the regulatory measures)  
eco-toxicity test items using worldwide (OECD-MPD)  
(e.g., acute toxicity tests on algae, daphnia and fish)

## (2) Regulation

Hazard-based evaluation → Monitoring measures

Risk-based evaluation → Quantitative management measures







# 1 . Introduction of an evaluation/regulation system focused on effects on living organisms

## Test items for determination of toxicity to living organisms

<b>(1) Type III Monitored Chemical Substance</b>	Algae growth inhibition test (OECD 201) Daphnia sp. acute immobilization test (OECD 202) Fish, acute toxicity test (OECD 203)
<b>(2) Class I Specified Chemical Substance</b>	Two-generation reproduction toxicity study (OECD 416) Avian reproduction test (OECD 206)
<b>(3) Class II Specified Chemical Substance</b>	Alga, growth inhibition test (OECD 201) Daphnia magna reproduction test (OECD 211) Fish, early-life stage toxicity test (OECD 210) Sediment-water chironomid toxicity test using spiked sediment (OECD 218) <limited to the case when two ministers judge it necessary, based on the status of residue in the environment>



# 1 . Introduction of an evaluation/regulation system focused on effects on living organisms

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## Test procedures

- The specific test procedures are provided by the Director-General notice (MHLW, METI, MOE )
- Test procedures are equivalent to the corresponding OECD test guidelines

## Good laboratory practice (GLP)

- Standards concerning test facility and operation of GLP are provided by the Director-General notice (MHLW, METI, MOE)
- Ministry of the Environment has been added as the GLP compliance monitoring authority for eco-toxicity tests

# 1 . Introduction of an evaluation/regulation system focused on effects on living organisms

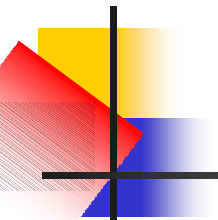
## Classification of the notice of judgment

former		after the amendment
•Class I specified C. S.	→	• Class I Specified Chemical Substance
•Designated C. S.	→	• Type II Monitored Chemical Substance (does not fall under Type III Monitored Chemical Substance ) • <b>Type III Monitored Chemical Substance</b> (does not fall under Type II Monitored Chemical Substance ) • <b>Type II and Type III Monitored Chemical Substance</b>
•Exempted from the regulation	→	•Substance exempted from the regulation
•Impossible to determine	→	• Impossible to determine

## Difference between Type II and Type III Monitored Chemical Substances

Type II Monitored Chemical Substance (human toxicity is suspected)	Type III Monitored Chemical Substance (ecotoxicity has been found)
When a toxicity study has proved that there is no long-term toxicity, the <u>designation as Type II Monitored Chemical Substance is cancelled.</u>	When a toxicity study has proved that there is no chronic toxicity to living organisms in the human living environment, <u>the name of the substance is announced (designation is not cancelled, but notification of the actual quantity manufactured and imported, etc. is not required).</u>

## 2 .Measures for persistent and high bioaccumulative existing chemical substances



### Background to the introduction

Existing chemical substances that are found to be persistent (P) and high bioaccumulative (B)

→ If they have long-term toxicity (T), they fall under Class I Specified Chemical Substances

However,

- assessment of long term toxicity requires a long period of time, and
- there was no legal measure to collect the actual exposure information, etc. before completion of the assessment.

Type I Monitored Chemical Substance is thus introduced to improve the management system.

Monitoring system similar to that of the former Designated Chemical Substances  
(i.e. reporting/publishing of actual quantity, guidance/advice for prevention of environmental pollution,  
direction to study hazardous properties)

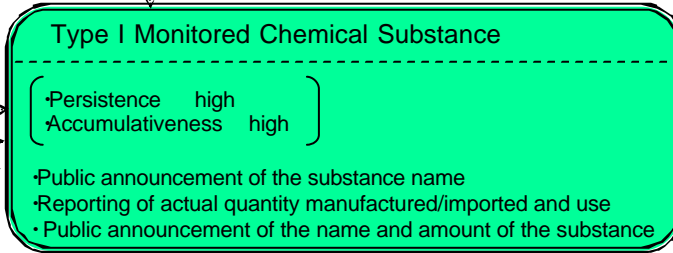
Risk-based management measures

Applicable only to existing chemical substances

# The new management measures relating to Type I Monitored Chemical Substance

Based on the assessment of existing chemical substances ]

·Persistence high  
·Accumulativeness high  
↓ designation



None or very little

Assessment of exposure

Concern

Quantity manufactured/imported or consumption for open systems exceeds certain amount.

Preliminary toxicity assessment (on human beings and top predators)

Reporting of hazard information (toxicity test data, etc) by businesses

Risk assessment based on the above data

Low concern

High concern

Guidance/advice to reduce release into the environment (risk reduction measures)

Assessment of effect of the risk reduction measures

Low concern

High concern

Government directs manufacturers and importers to study hazardous effects (reporting of long-term toxicity for humans/living organisms).

Investigation and reporting

Judgment on hazardous properties

Long-term toxicity is found

No long-term toxicity

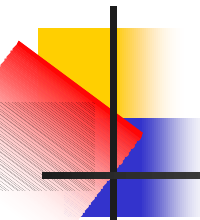
Not designated as Class I

Designated as Class I

(After direction to study

Recommendation to limit manufacture, import and use

( based on article 29 of the Law )



# 3 .Reform of the evaluation system for new chemical substances

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## Introduction of exemption of evaluation

Manufacture/import is permitted after obtaining prior verification from three Ministers that the new chemical substance has a low possibility of causing environmental pollution due to the planned handling measures.

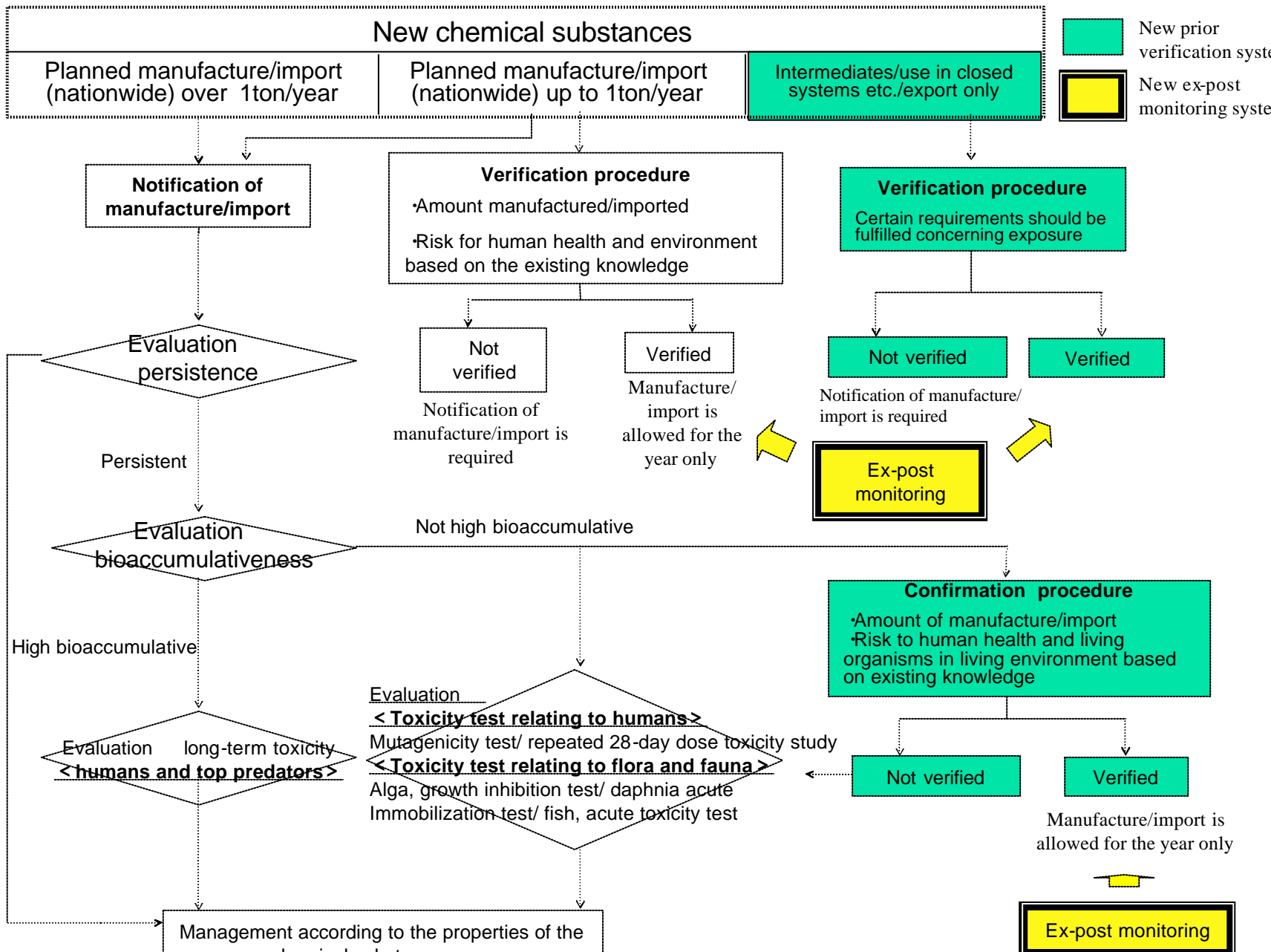
(i.e., intermediates/ substances used in closed-system/ substances export only)

## Introduction of stepwise evaluation of chemical substances manufactured or imported in low quantities

As for substances that are evaluated to be persistent but not high bioaccumulative in the process of evaluation, manufacture/import is permitted after obtaining prior verification from three Ministers that the manufacture/import amount per year (nationwide) of the substance shall be 10 tons or less. (i.e., no obligation to submit toxicity data or eco-toxicity data)

Note : Three Ministers may order the notifiers who have received a verification to submit reports related to their business operations or to have on-site inspections by ministry personnel, if deemed necessary.

# Outline of reform of the evaluation system for new chemical substances in the CSCL



# 3 .Reform of the evaluation system for new chemical substances

< Exemption of evaluation: intermediates, etc. >

## Exemption Categories (defined by Cabinet Order)

### **Intermediates** 【Clause 1 of Paragraph 1 of Article 2】

Where the new chemical substance is manufactured or imported as an intermediate for another chemical substance and where measures are taken to prevent environmental pollution during the process when the said intermediate is being transformed into another substance.

### **Use in closed system** 【Clause 2 of Paragraph 1 of Article 2】

Where the new chemical substance that is manufactured or imported for use employs a method that has little or no possibility of release outside the facility or the equipment and measures are taken to prevent environmental pollution throughout the process until the time of its disposal.

### **Substance for export only** 【Clause 3 of Paragraph 1 of Article 2】

Where the new chemical substance is manufactured or imported for export, the destination of the export falls under the regions specified by the ministerial ordinance (i.e. that have already established the pre-import evaluation system of new chemical substances) and measures are taken to prevent environmental pollution until its export.



# 3 .Reform of the evaluation system for new chemical substances

< Exemption of evaluation: intermediates, etc. >

## Information to be submitted for prior verification request

< Example: intermediates >

(1) Entry items in a request form 【Ministerial Ordinance Form 2】

Name and structural or rational formula of the new chemical substance

Physicochemical properties and component composition

Planned annual amount of manufacture (import)

Name and location of the manufacturing site (for manufacturing)

Manufacturing country or region (for import)

Name and address of the user of the new chemical substance

Name and location of the use site

Name of the chemical substance manufactured by the user

References

# 3 .Reform of the evaluation system for new chemical substances

< Exemption of evaluation: intermediates, etc. >

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## (2) Documents to be attached to the request

Drawing that illustrates the production equipment and facility

Document that describes the handling measure for manufacturing

Document that describes the measures taken for the prevention of environmental pollution related to the production of the new chemical substance

Document that describes the management system of the manufacturer (importer) that intends to manufacture (import) the substance

Document that describes the shipment form and the measures taken to prevent the environmental pollution that can be caused by the new chemical substance during shipment

# 3 .Reform of the evaluation system for new chemical substances

< Exemption of evaluation: intermediates, etc. >

## (3) Confirmation form 【Ministerial Ordinance Form 3】

In the following exhibits, it is confirmed that the new chemical substance shall be used as an intermediate and that measures will be taken to prevent environmental pollution.

Name, address, etc. of the user

Location of facility where the substance will be used and stored

Drawing that illustrates the equipment and facility for use

Flow through which the new chemical substance is transformed into another chemical substance at the use site and the predicted amount of the new chemical substance to be released into the environment

Measures taken to prevent environmental pollution in the course of handling the new chemical substance

Management system of the user

Planned annual amount of use

Document that describes the measures taken by the manufacturer (importer) to confirm that the user is using the substance in accordance with the verification by three Ministers

# 3 .Reform of the evaluation system for new chemical substances

<Exemption of evaluation: intermediates, etc.>

Obligation to report items relating to the verified new chemical substance after it is manufactured or imported

The manufacturer (importer) who has obtained verification for the exemptions specified in the Cabinet Order, shall report to three ministers, by the June 30 every year.

Their report will include the following items for the previous year for each new chemical substance verified except when there was no manufacture/import in the previous year.

Name of the new chemical substance

Date of the verification

Actual amount manufactured (imported)

Actual amount of use by the user (actual amount exported by each export destination in the case of export only)

If the new chemical substance was released or transferred to the outside of the facility during the process of handling, describe the overall condition.

If there was a slight change in the verified content, describe the changes.

If significant changes in the matters such as the contents of measures to prevent environmental pollution occur, the manufacturer (importer) shall be required to obtain a new

# 3. Reform of the evaluation system for new chemical substances

<A special case for low quantities of new chemical>

Procedure of request for a special case of evaluation of low quantities of new chemical substance 【Paragraphs 1 through 5 of Article 4-2 of the Law】

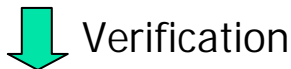
Request for a special case of evaluation



Notice of judgment



Request for amount verification



Notice of verification



Manufacture/import is allowed

A request for a special case of evaluation (Ministerial Ordinance Form 10) shall be submitted to three ministers when submitting notification of the manufacture/import of a new chemical substance according to Article 3 of the Law.

Judgment that the substance is persistent, not high bioaccumulative, and toxicity unclear

After receiving the judgment notice, a request (Ministerial Ordinance Form 11) is submitted to three Ministers.

Verification that the planned amount of manufacture/import for the year of the request does not exceed 10 tons in total

From the next year onwards, a request for amount verification shall be submitted every year during March 1-10.

# 3 .Reform of the evaluation system for new chemical substances

<A special case for low quantities of new chemical>

## **Resumption of evaluation after manufactured/imported**

**【Paragraph 7 of Article 4-2 of the Law 】**

Where a person who has received a judgment notice wants to resume the evaluation relating to the toxicity of the verified low quantities of new chemical substance, he or she may submit to three Ministers a request (Ministerial Ordinance Form 12) with the results of the toxicity test attached.

(for example, in the case where the planned amount manufactured/imported exceeds 10 tons/year)

## **Continued evaluation when verification is not made**

**【Paragraph 8 of Article 4-2 of the Law 】**

Where the ministers provided notice that the new chemical substance is not applicable due to its properties after evaluation

Where they have not verified after checking the quantity

Where they have cancelled the verification

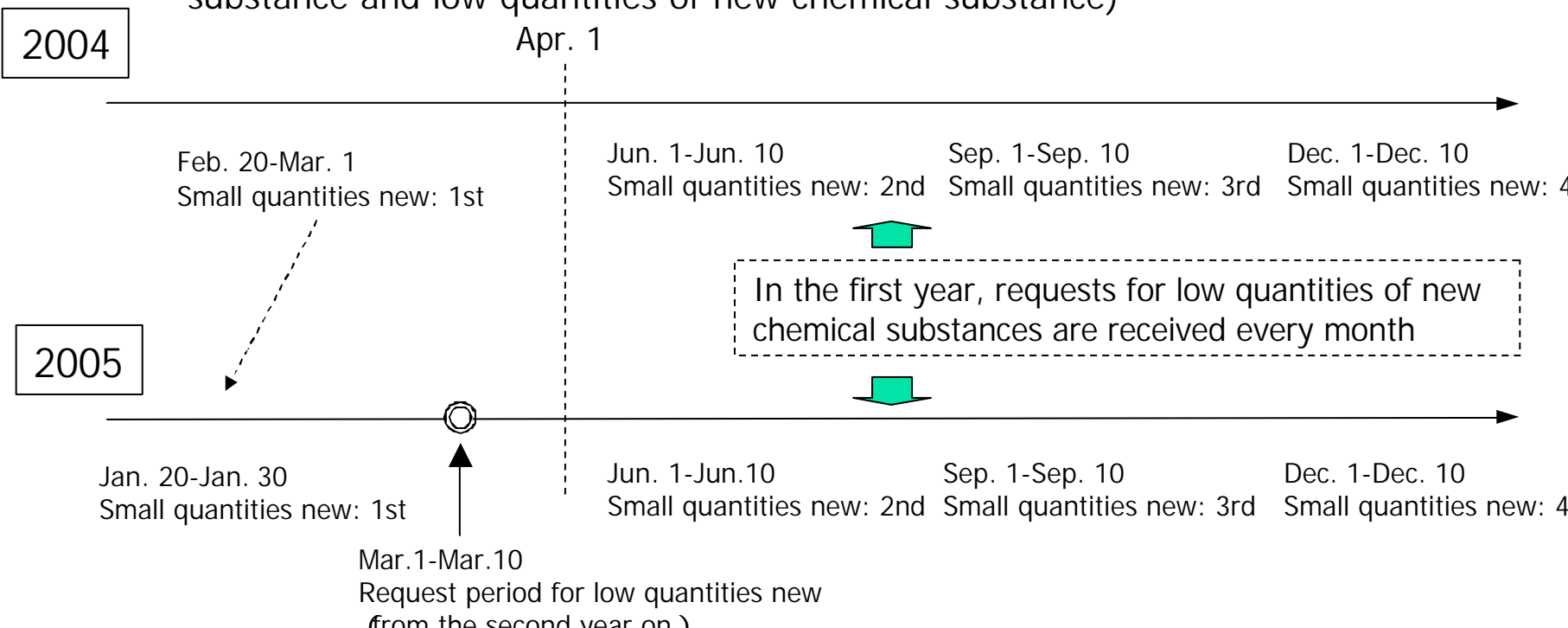
# 3. Reform of the evaluation system for new chemical substances

<A special cases for low quantities of new chemical>

## Request period (in relation to small quantities of new chemical substance )

In accordance with the following schedule, the planned amount of the year for which the request is made is verified in the order of request date.

(adjustment of the amount is done by the total of small quantities of new chemical substance and low quantities of new chemical substance)






## 4 .Obligation to report the hazard information voluntarily obtained by businesses


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### Background

- Implementation of similar systems in Western countries (safety net of the evaluation system)
- Progress of the voluntary action to collect hazard information by businesses (e.g., HPV, etc.)



Hazardous information obtained by businesses should be utilized for operation of the CSCL. (Example: evaluation of a new chemical substance, assessment of existing chemical substance, etc.)

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- Introducing obligation to report certain hazard information relating to the substances that have been manufactured or imported by the businesses (Fine of up to 200,000 yen for businesses that failed to submit a report or submitted a false report.)

- Upon receiving the report, the government is obligated to take the necessary measures (e.g., designating some Monitored Chemical Substances) based on the report and other knowledge. 【Article 31-2 of the Law】





# 4 . Obligation to report the hazard information voluntarily obtained by businesses

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## 1. Persons/substance subject to reporting

manufacturer/importer of the following chemical substances

Type I, II, and III Monitored Chemical Substance

Class II Specified Chemical Substance

Substances that have been announced to be exempt from the regulation

Small quantities (up to 1 ton/year) of new chemical substance

Low quantities (up to 10 tons/year) of new chemical substance

Existing chemical substances

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## 2. Hazard Information subject to reporting

the following properties that are related to test items of evaluation and hazard study of the CSCS (where tests have been conducted or equivalent knowledge has been obtained)

Persistence

High bioaccumulativenness

Human toxicity

Eco-toxicity

} Concrete standards of hazardous properties are specified in joint Ministerial Ordinance and related notice

However, exempted is any information that is in the public domain such as that included in major scientific journals and test data published by the government.

## 5 .Other

### (1) Amendment of the public announcement period after evaluation is completed

Provisions on the public announcement period of the name of the new chemical substance are partially amended to avoid significant competitive disadvantage to the first notifier (i.e., the notifier who bore the test expense). 【Paragraph 4 of Article 4 of CSCL】

Former system	Substance exempt from regulation	Designated chemical substance
	Publicly announced “without delay” after the notice of the judgment	Publicly announced “without delay” after the notice of the judgment
After the amendment	Substance exempt from regulation	Type II and Type III Monitored Chemical Substances
	Publicly not announced for 5 years after the notice of the judgment	Publicly announced “without delay” after the notice of the judgment



## 5 .Other

### (2) Strengthening of penalties

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#### Introduction of heavy penalties for corporations

Considering similar laws, heavy penalties are applied to especially serious breaches of duty from the viewpoint of the prevention of environmental pollution.

#### < Examples >

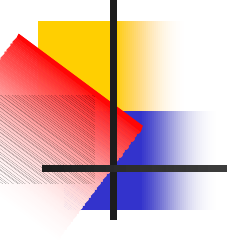
Violation in the manufacture/import/use of Class I Specified Chemical Substance	Maximum of 100 million yen
Violation of the restriction of the manufacture/import of new chemical substance	Maximum of 50 million yen

## 5 .Other

### (3) Strengthening of orders for measures regarding Class I Specified Chemical Substance

- Where any chemical substance has been designated as a Class I Specified Chemical Substance and the three Ministers deem that measures are particularly necessary in order to prevent the spread of environmental pollution by Class I Specified Chemical Substances, they can order measures such as recall of the chemical substance or products (articles) in which the chemical substance is used. 【Article 22 of the CSCL】
- The amendment allows such implementation in the following cases:

- (1) New product (article) which uses the substance that has already been designated as a Class I Specified Chemical Substance is added to the list of import prohibition
- (2) There is a violation of the regulations for Class I Specified Chemical Substance  
(regulation of manufacture/import, import regulation of products in which the substance is used, regulation of use)



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- END -

*Thank you*