Status of Chemical Substance Management Policy in Japan

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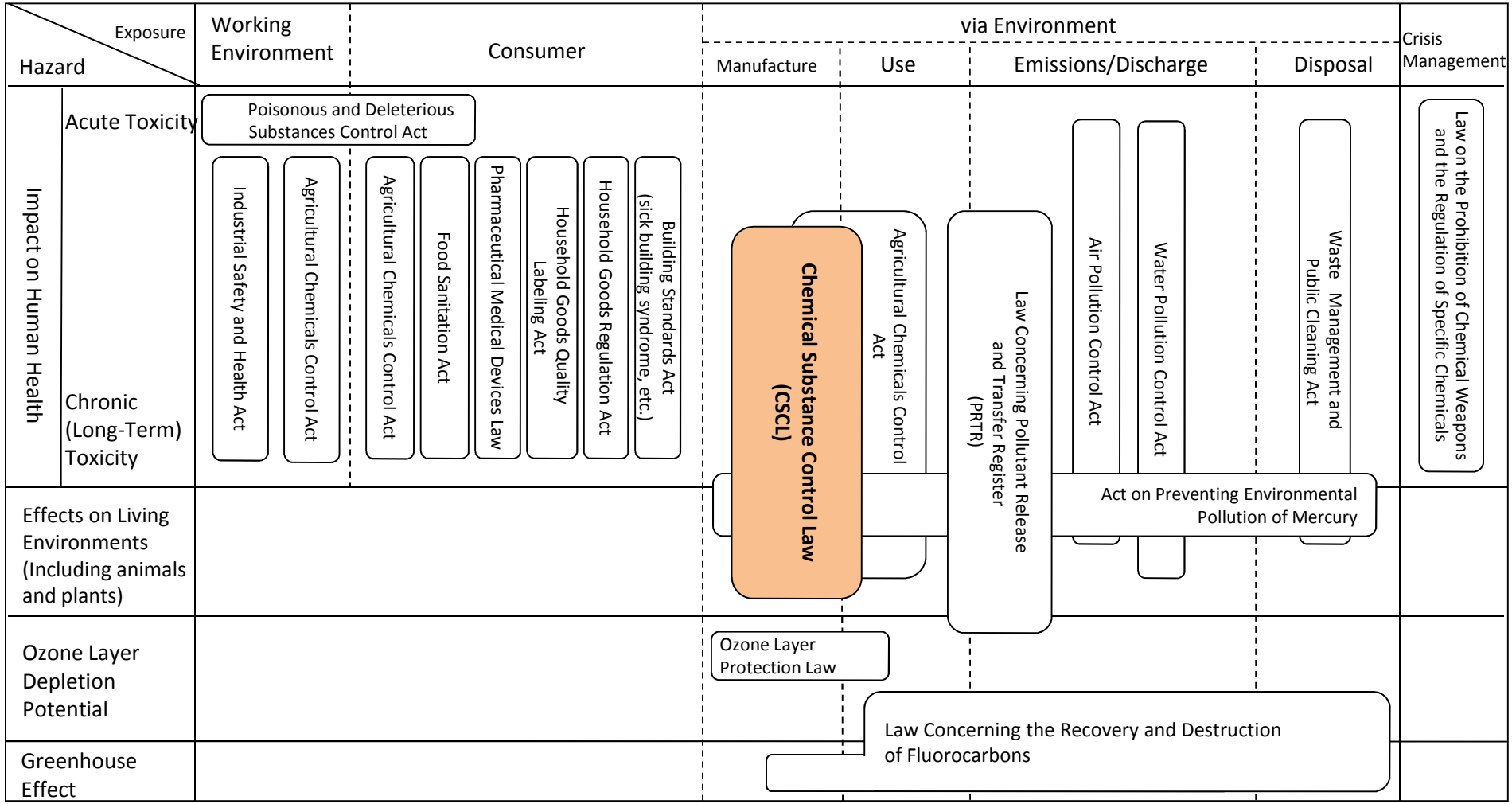
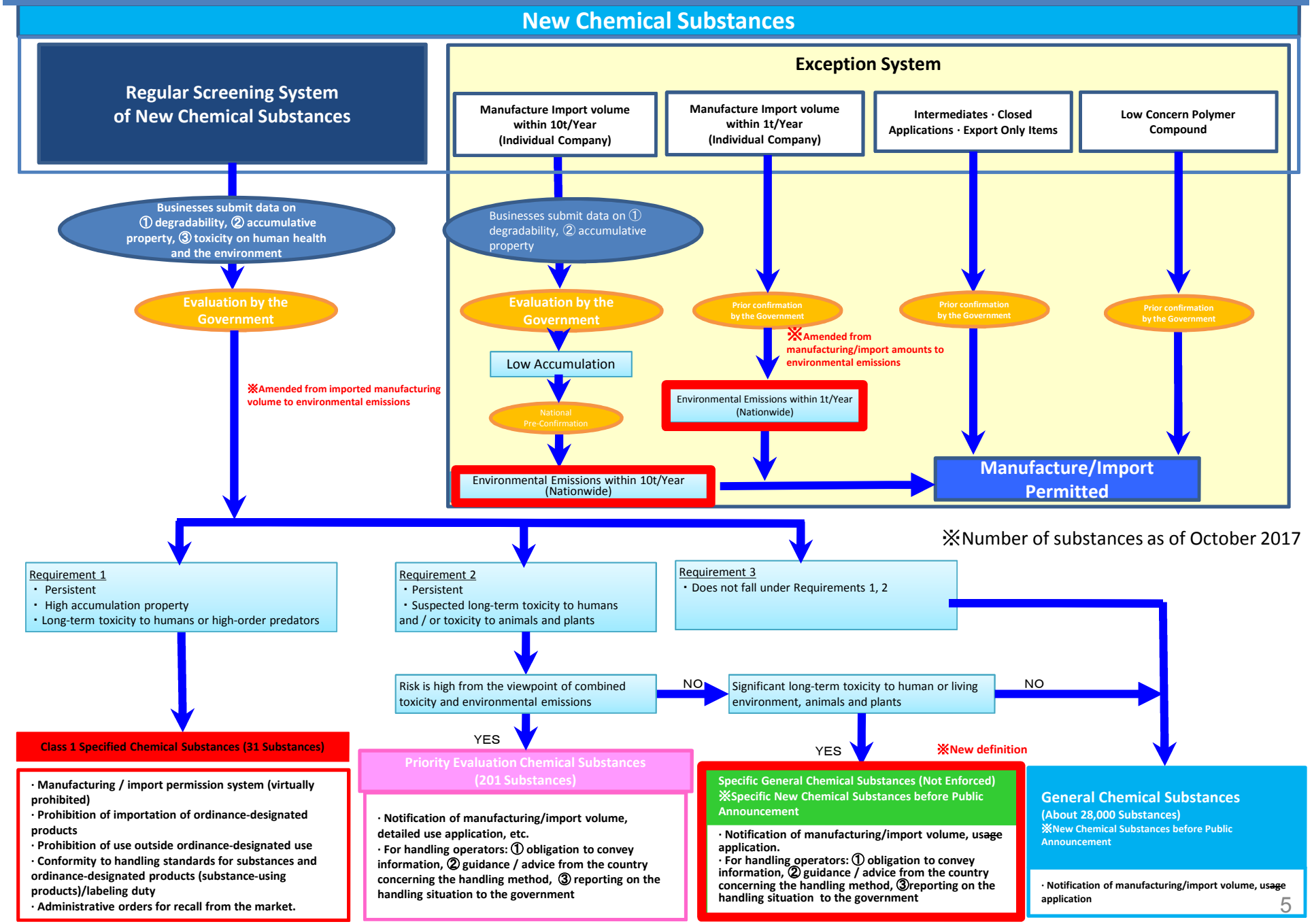
① Outline of the Chemical Substances Control Law (CSCL)

Role of the Chemical Substances Control Law in Japans Chemical Substance Control

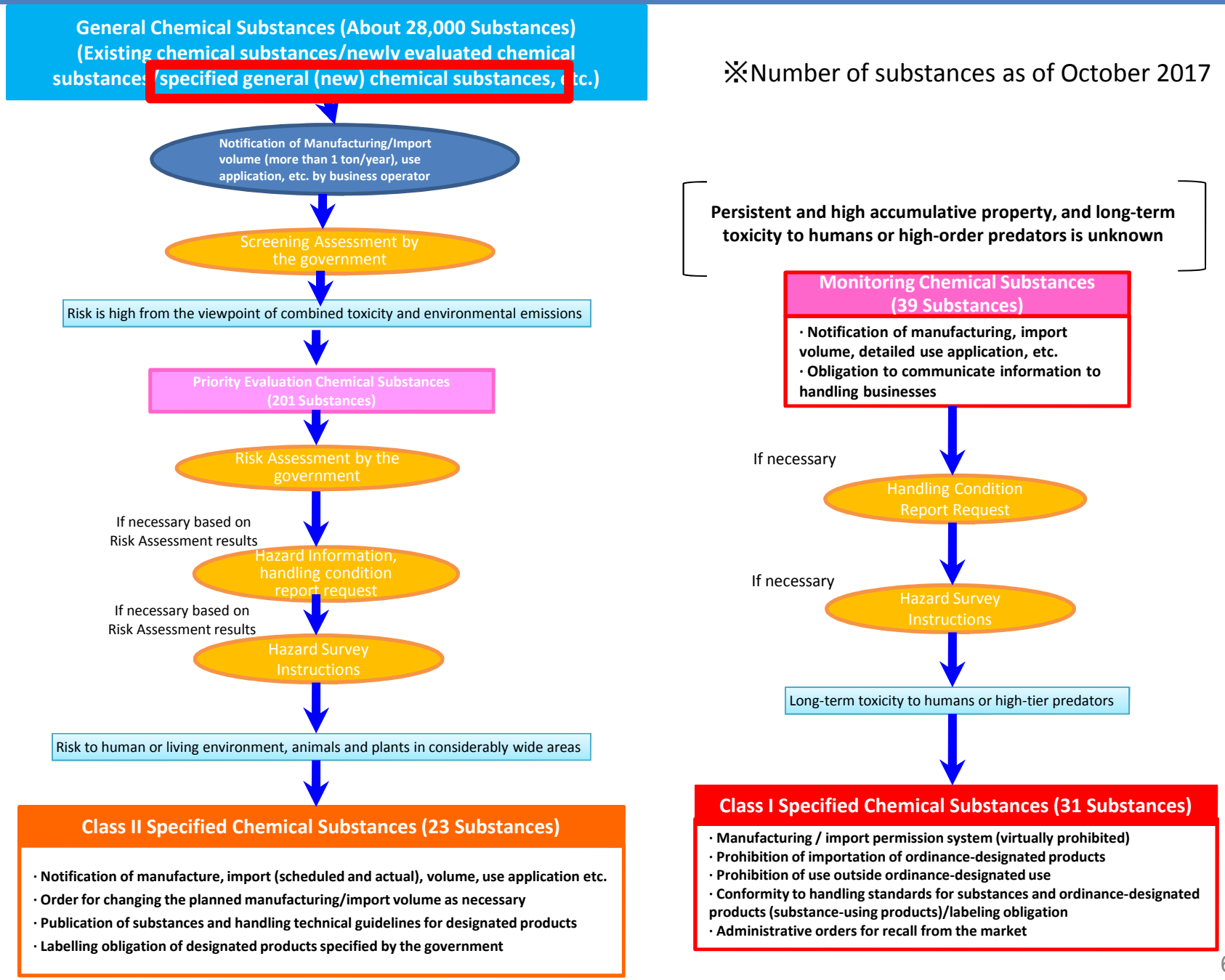
- In Japan, chemical substances are regulated by a variety of laws according to their exposure routes and the life cycle stages, etc.
- The objective of CSCL is to evaluate the long-term toxicity to human via the environment, and the effect on the living environment and ecosystem.



Outline of the Preliminary Evaluation System for New Chemical Substances Under the CSCL



Screening Assessment of General Chemical Substances etc. - Risk Assessment



② Evaluation & Confirmation of New Chemical Substances

Evaluation and Confirmation of New Chemical Substances

With regard to manufacturing or importing new chemical substances that have never been manufactured or imported in Japan, the chemical substance are evaluated and judged prior to the manufacture and import for the following properties, based on notification from the manufacturer/ importer.

① Whether it is difficult for chemical changes to occur under natural processes (degradability)

② Whether it is easily accumulated in living organisms (bioaccumulation) [here and above, Ministry of Economy, Trade and Industry]

③ In case of continuous ingestion, whether there is a risk of damage to human health (long-term toxicity to humans) [Ministry of Health, Labour and Welfare]

④ Whether there is a risk of interfering with habitats or the growth of animals and plants (eco-toxicity) [Ministry of the Environment]

Judgment of New Chemical Substances (Article 4)

Regular Review and Judgments on New Chemical Substances (FY2016 Results)

No. of Reviews	No. of Judgments					
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6
202	0	9	6	43	171	0

※Regular new substances based on polymer flow schemes, as well as those subjected only to the degradation test, are also included.

① Items falling under any of the items of Article 2, Paragraph 2 (Class I Specified Chemical Substances) ... **No. 1**

② When it is persistent in the degradation test, and it is judged that it is not highly accumulative by the accumulation test or the Pow measurement test ... **No. 2 - No. 5**

No. 2: Human health toxicity yes, eco-toxicity no

No. 3: Human health toxicity no, eco-toxicity yes

No. 4: Human health toxicity yes, eco-toxicity yes

No. 5: Human health toxicity no, eco-toxicity no

③ When judged to be of good degradability by the degradation test … **No. 5**

④ When it is unclear if it falls under No. 1 through No. 4 … **No. 6**

Review and Judgment on Low Production Volume New Chemical Substances (below 10 tons/year nationwide) (FY2016 results)

No. of Reviews	No. of Judgments
155	155

※Low production volumes for new chemical substances based on polymer flow schemes are also included.

Preliminary Review and Prior Confirmation of New Chemical Substances

- ○ Able to manufacture and import by notification of new chemical substances and undergoing the regular preliminary examination [Regular New]
- ○ Regardless of the regular notification, there are cases where substances can be manufactured/imported by prior notification/confirmation. (Special case system, notification exemption system). [New Low Production Volume, New Small Volume, Low Concern Polymer, Intermediate, etc.]
- ○ While the Japanese chemical industry shifts to small-quantity multi-varieties, on the premise of preventing environmental pollution from chemical substances, we are adopting a rational system design that takes into consideration small-volume and multi-product industries. Depending on each procedure, information such as on hazardous property to be submitted to the government is different.

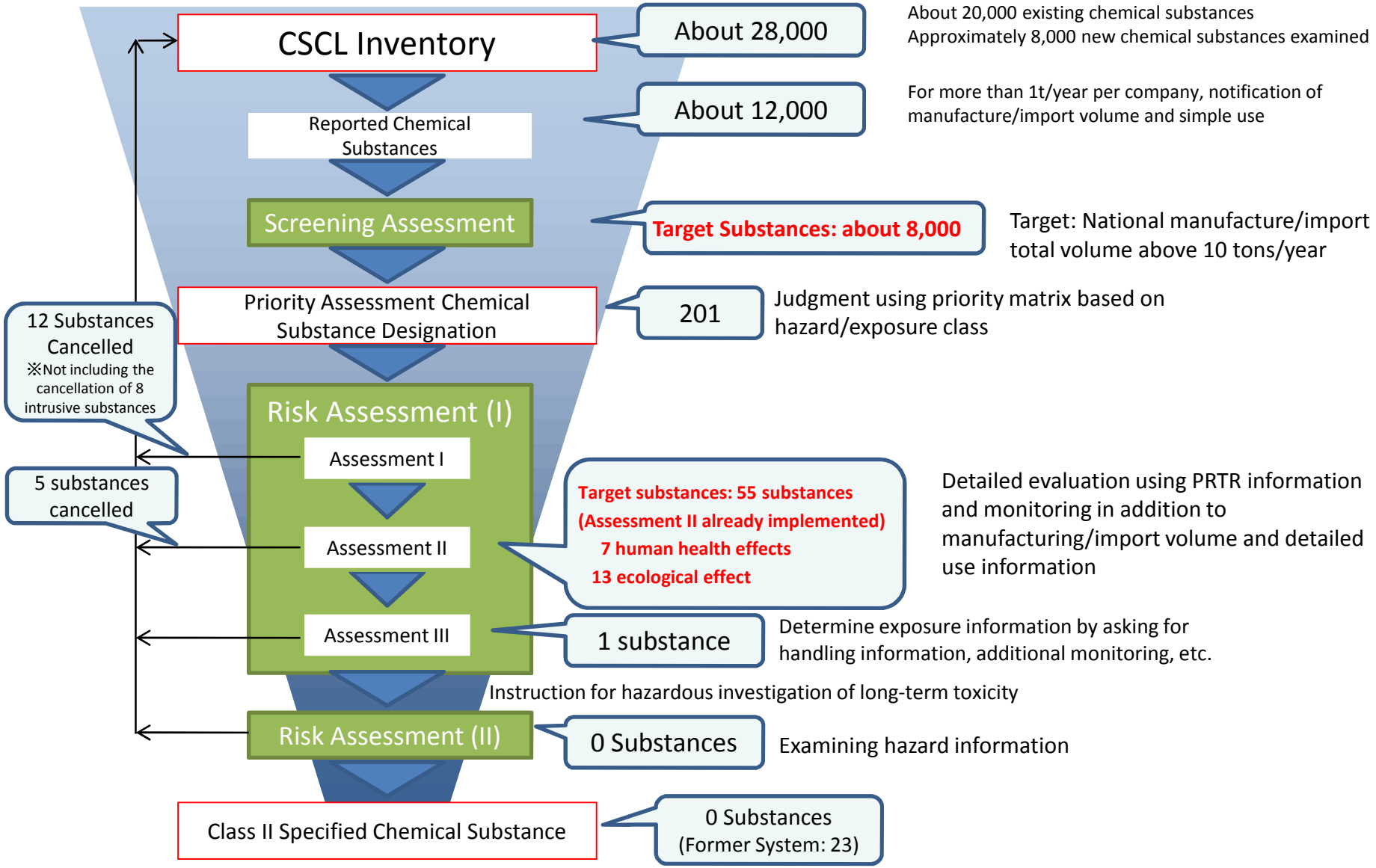
Procedure Type	Article	Procedure	Hazard Data Submitted at Notification	Other Submitted Materials	Volume Upper Limit	Volume Adjustment	Application Frequency	FY 2016 Results
Regular New	Article 3, paragraph 1	Notification →Judge	Degradability/accumulation/human health and ecological effects	Usage/planned volume, etc.	No	No	10 times/year	202
New Small Volume	Article 3, paragraph 1, No. 5	Application →Confirm	—	Usage/planned volume, etc.	Within 1t Nationwide	Yes	4 times/year	35,841
New Low Production Volume	Article 5, paragraph 1	Notification →Judge Application →Confirm	Degradability/accumulation (If there is data on human health /ecological effect, submit at time of report.)	Usage/planned volume, etc.	Within 10t nationwide	Yes	Notification: 10 times/year Application: Any time (Extension once /year)	1,678
Low Concern Polymer	Article 3, paragraph 1, No. 6	Application →Confirm	—	Molecular weight/physicochemical stability test data, etc.	No	No	Any time	28
Intermediate	Article 3, paragraph 1, No. 4	Application →Confirm	—	Handling method/drawing that show facility state, etc.	No	No	Any time	124
Small Volume Intermediate, etc.				(Simplification)	Within 1t per company	No	Any time	180

③ Risk Assessment of Existing Chemical Substances

Screening/Risk Assessment in CSCL

Risk Assessment by Phase

※As of October 2017



Screening Assessment

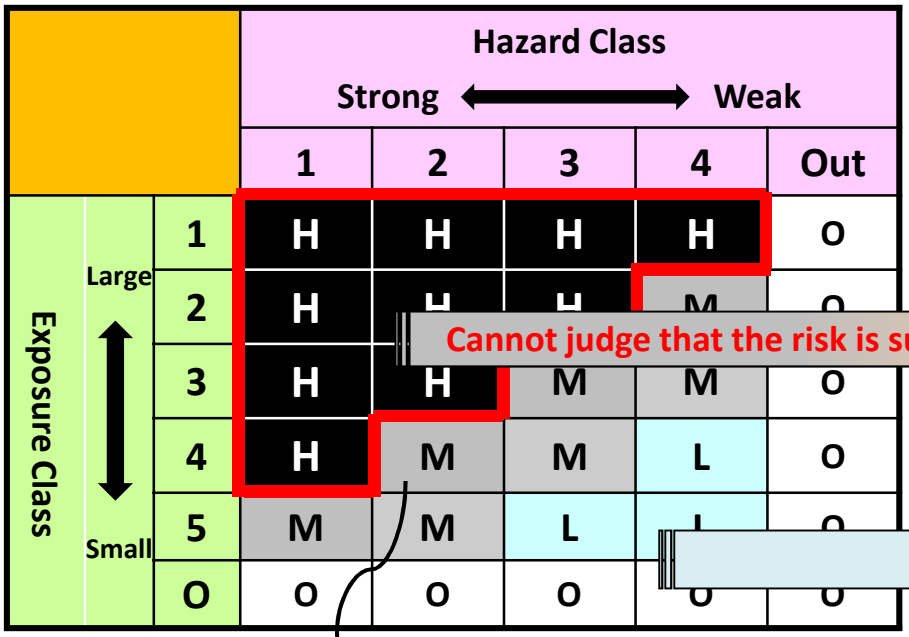
○Screening assessment (chemical substance selection where the risk can not be said to be sufficiently small) is conducted by assigning exposure classes (magnitude of estimated emissions) and hazard class (degree of harmfulness) for each general chemical substance using the following matrix.

Human Health
Set the toxicity class from hazard information※ on general toxicity, reproductive developmental toxicity, mutagenicity, carcinogenicity
Ecosystem
Set the harmfulness class from the hazard information※ related to eco-toxicity test data (algae, crustaceans, fish) of aquatic organisms

※Information reported or submitted by the CSCL, existing inspection information carried out by the government, document information collected by the government, arbitrary report information from the business operator, etc.

Total Estimated Environmental Emissions
・Report information on manufacturing/import volume, etc.
・Estimate environmental emissions from decomposition judgment results, set exposure class (update yearly)

Exposure Class	Environmental Emissions Total Estimate
Class 1	above 10,000
Class 2	1,000 – 10,000 tons
Class 3	100 – 1000 tons
Class 4	10 – 100 tons
Class 5	1-10 tons
Outside Class	Less than 1 ton



For the priorities "Medium" and "Low", they will be designated as a Priority Assessment Chemical Substance as necessary by expert judgment.

Risk Assessment (1st)

The Risk Assessment (1st) is composed of 3 stages – Assessment I, II, III

Assessment I

Hazard assessment is performed using the same information※ as at screening assessment, and exposure assessment is conducted using only notification information such as manufacture/import volume. Through this, priorities for implementing Assessment II are determined.

※Information reported or submitted by the CSCL, existing inspection information carried out by the government, document information collected by the government, arbitrary report information from the business operator, etc.

Assessment II

For hazard assessment, hazard information is additionally collected, and exposure assessment is subject to risk assessment by increasing the scope of application. We also make use of existing PRTR data and monitoring data. Through these measures, risk assessment is carried out, and designation of Class II Specified Chemical Substances, or the determination of a hazard assessment is immediately made. If there is no optimal decision, Assessment III is applied.

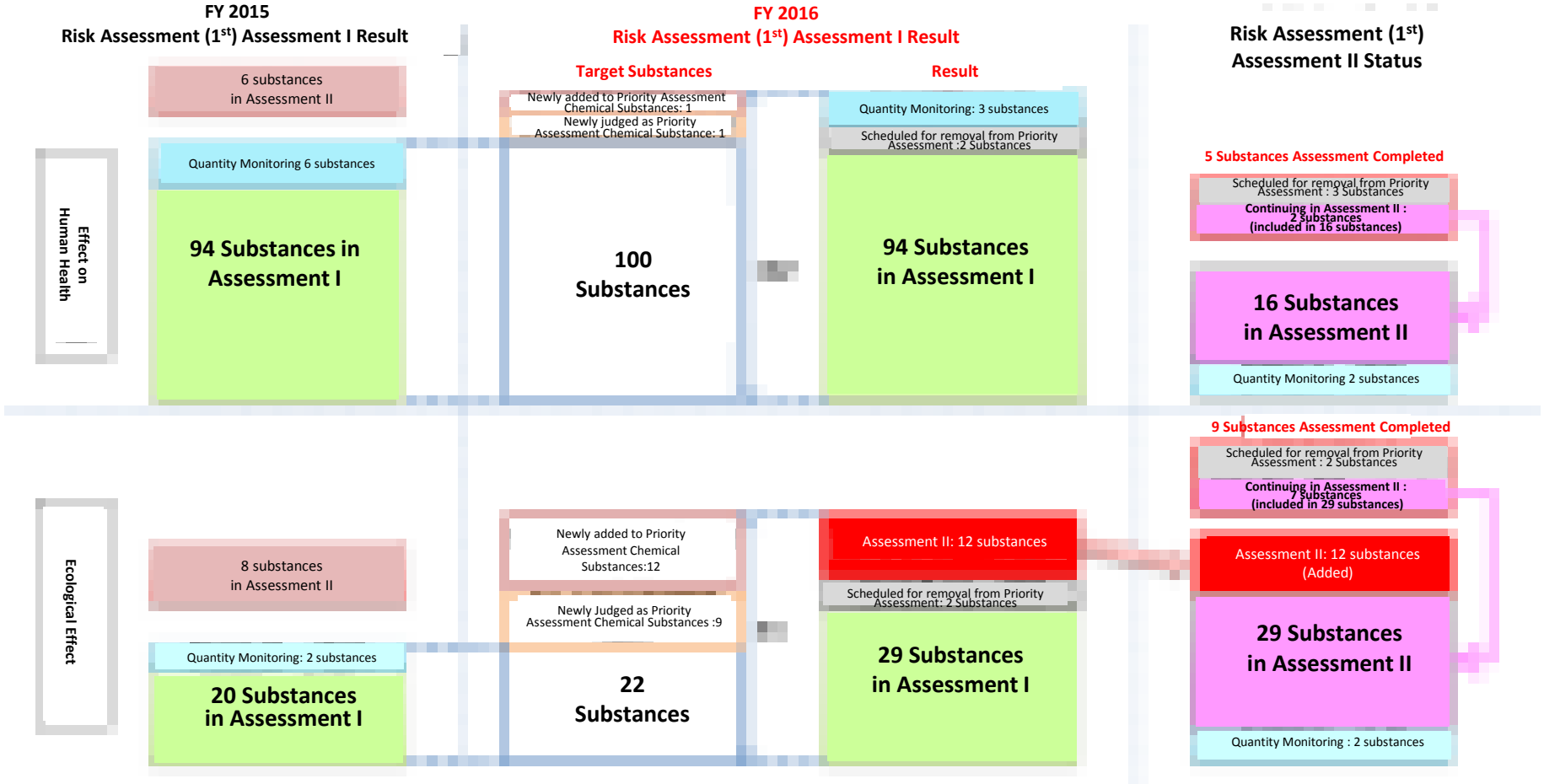
Assessment III

We will also refine risk assessment using handling information and additional monitoring data. The necessity of direction of hazard investigation is determined.

Risk Assessment (1st) Assessment I
Result of Priority Assessment Chemical Substances

As a result of Risk Assessment (1st) Assessment I in FY 2016, **there are 13 substances※ (ecological effect) that were initiated for the Risk Assessment (1st) Assessment II in FY 2016**.

※Of those, 2 substances have already been included in Assessment II, and 11 substances have been newly added to Assessment II.



※As of October 2017

Status of Risk Assessment II (1st) for Priority Assessment Chemical Substances

○Risk Assessment II (1st) for Priority Assessment Chemical Substances in FY 2016 was implemented for 8 substances by March 2017, and 1 substance by June, for a total of 19 substances so far (7 human health effect, and 13 for ecological effect※1).

○Based on the evaluation so far, the status of 6 substances※2 as Priority Assessment Chemical Substances have been cancelled.※2

○In the future, Risk Assessment II will be implemented on 8 substances in FY 2017 and 10 in FY 2018.

※1: Excludes hydrogen peroxide (6.17.2016) which reported the progress status of risk assessment from the viewpoint of ecological impact ※2: Includes cancelled substances from the end of FY 2016

Assessment Judgment Date	Substance Name	Evaluation	Evaluation Result and Future Measures (Outline)
6.17.2016	1,2-dichloropropane	Human Health	· Not applicable as a Class II Specified Chemical Substance in the current handling. · Designation of Priority Assessment Chemical Substances has been cancelled.
	Naphthalene	Ecology	· Not applicable as a Class II Specified Chemical Substance in the current handling. ・Collect hazard info on human health effects in the future.
	Bromomethane (aka methyl bromide)	Ecology	Same as above
1.31.2017	Dichloromethane	Human Health	· Not applicable as a Class II Specified Chemical Substance in the current handling. · Designation of Priority Assessment Chemical Substances has been cancelled.
	Benzyl benzoate	Ecology	· No sufficient information to judge the suitability of Class II Specified Chemical Substances. · Monitoring is enforced.
	Hydrazine	Human/Ecology	· As there are several uncertain aspects in regards to exposure assessment, proceed to Assessment III and conduct investigation.
3.24.2017	Xylene	Ecology	· Could not obtain exposure assessment results sufficient for the basis of judgment for Assessment II. · Perform monitoring after lowering the detection lower limit value.
	Zinc pyrithione	Ecology	・Could not obtain exposure assessment results sufficient for the basis of judgment for Assessment II. ・In the future, examine the method of risk assessment and monitoring after reviewing the relationship with copper pyrithione.
6.25.2017	1,3,5-trichloro-1,3,5-triazinane-2,4,6-trione	Ecology	・Could not obtain exposure assessment results sufficient for the basis of judgment for Assessment II. ・In the future, collect actual measured data from environmental monitoring of isocyanuric acid.

④ Amendment of CSCL

Evaluation System for New Chemical Substances (Current System)

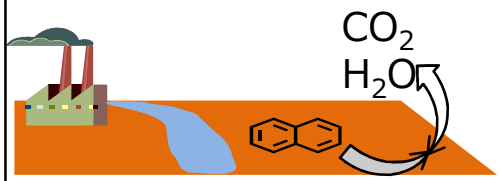
1: Regular New Evaluation System

- Those who intend to manufacture or import new chemical substances shall notify the government in advance.
- The government evaluates the properties of the newly notified chemical substance (degradability, accumulation, whether it has toxicity to human health/ecology) and regulates according to the result.

Test Items for the CSCL Regular New Evaluation System

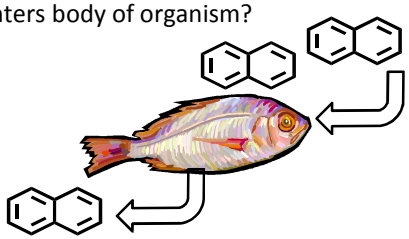
①Info related to degradability

Does substance degrade in natural environment?



②Info related to accumulativeness

Does substance accumulate easily if it enters body of organism?



③Effect on Human Health

Is substance toxic to humans?

④Ecological Effect

Is substance toxic to living organisms?

2: Special Evaluation Scheme

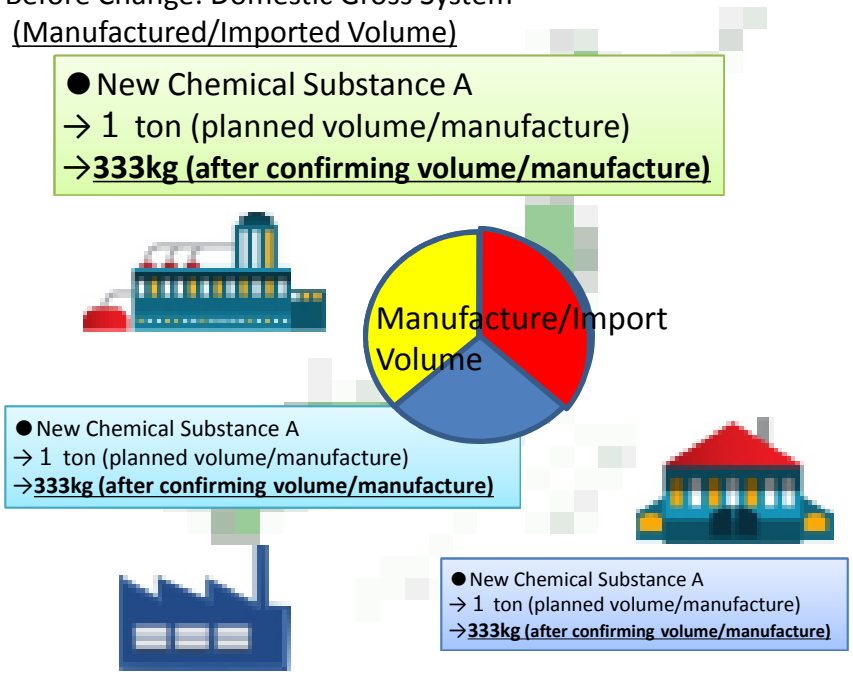
- In regards to new chemical substances whose manufacturing/import volume is below a certain amount, as a special measure, some or all of the above-mentioned evaluations will be exempted, and manufacturing and importing can be carried out after the volume is confirmed.
- A similar special evaluation exception scheme exists in Europe and the United States, but due to the existence of original domestic gross amount regulation in Japan, adjustment of the confirmation volume by the government may occur occasionally.

	Hazardous Items Requiring Evaluation	Individual Company's Maximum Volume	Nationwide Maximum Volume
New Scheme for Small Volume	None	1 ton (Manufacture/Import Amount)	1 ton (Manufacture/Import Amount)
New Scheme for Low Production Volume	Degradability/Accumulativeness (No Toxicity Required)	10 tons (Manufacture/Import Amount)	10 tons (Manufacture/Import Amount)

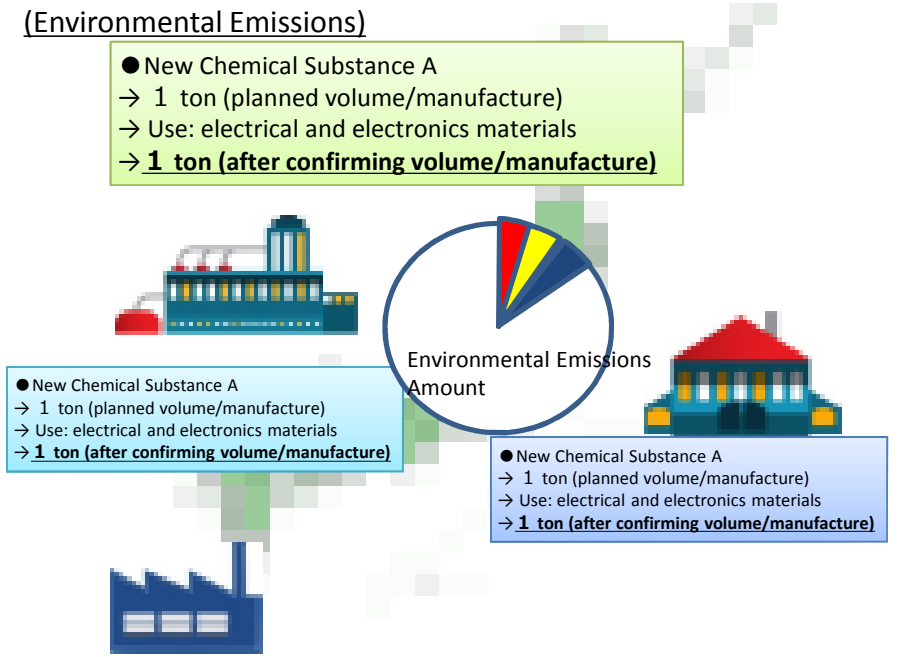
Proposed Review of the Special Evaluation Scheme

- Utilize the "emission factor" for each use, and review it as a more rational regulatory system on the premise of ensuring safety.
- Specifically, the domestic gross amount regulation of the special evaluation exemption scheme from the manufacture/import volume to the environmental emissions (manufacture/import volume multiplied by the emission factor for each use).

Before Change: Domestic Gross System
(Manufactured/Imported Volume)



After Change: Domestic Gross System
(Environmental Emissions)



・With an emission coefficient of 0.0012 for electric and electronic materials, the volume of production is 1 ton, the environmental discharge amounts to 1.2 kg, and the total discharge of the three companies is 3.6 kg, so there is no need to adjust the quantity.

<Expected Result>

- ✓ Utilizing emission factors that take into account its use, volume adjustment will decrease, and production and import volume will increase.
- ✓ The uncertainty due to volume adjustment is eliminated, and business predictability will improve.

Necessity to review Chemical Substance Management with strong toxicity

○In recent years, in regards to the new chemical substances review, occasionally, there are chemical substances that pose a serious risk when released into the environment due to strong toxicity to human health and the habitat of animals and plants, while the emission is extremely small.

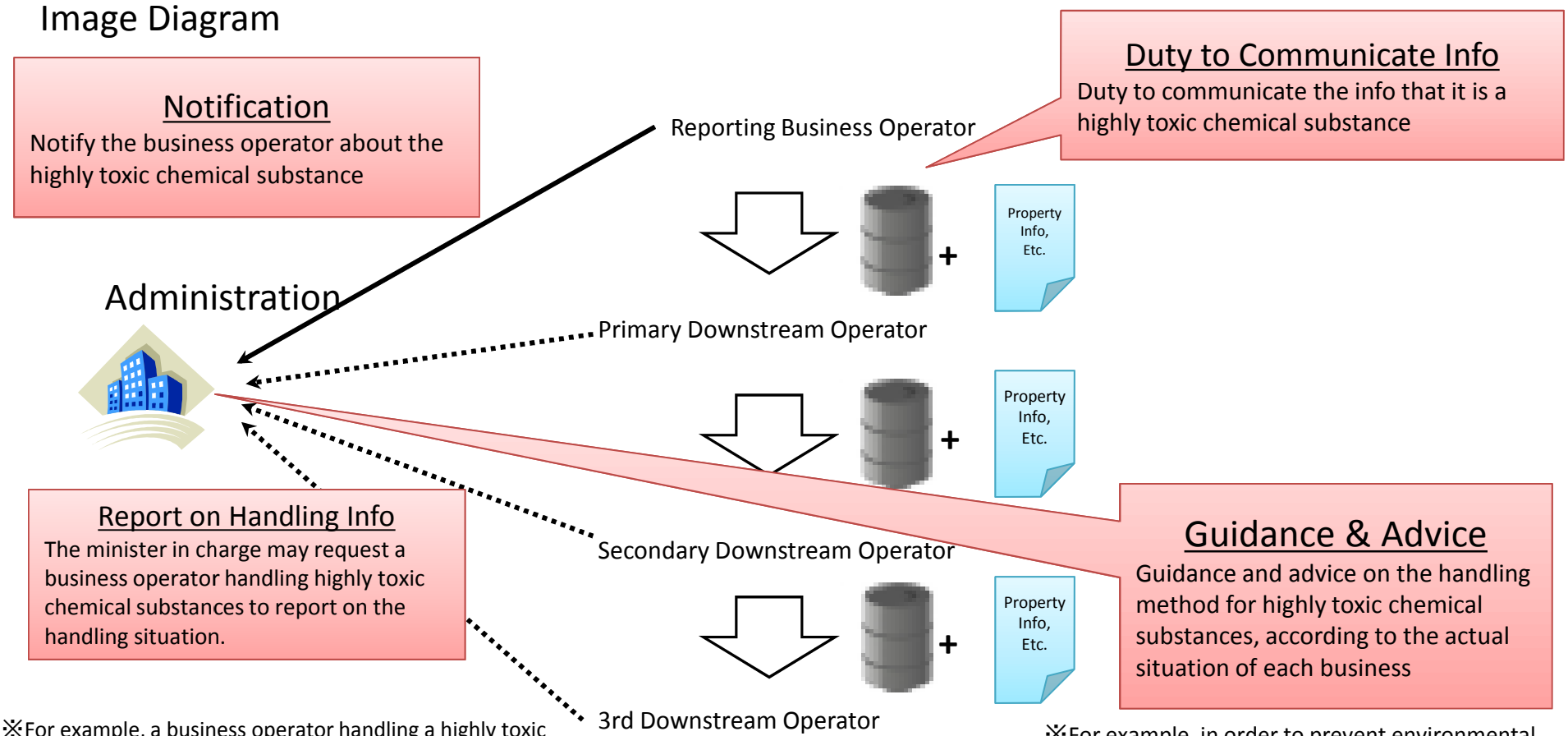
○However, even with such chemical substances, if emission to the environment is small, it does not correspond to the Priority Assessment Chemical Substances to which certain regulatory measures are imposed, and as a general chemical substance, there is only a notification obligation for the manufacture/import volume, making it impossible to take sufficient measures under the current CSCL.

○Therefore, it is necessary to take measures to encourage businesses to handle appropriate chemical substances that are highly toxic so that they are not accidentally discharged.

Proposed Review of Chemical Substances with Strong Toxicity

In order to call attention to businesses that deal with highly toxic chemical substances, we will establish jurisdiction, such as the obligation of business operators to communicate information, and national guidance and advice to business operators.

Image Diagram



※For example, a business operator handling a highly toxic chemical substance should keep records of the state of delivery and stock status of the chemical substance in advance, in the form of a document, for a certain period of time, so that it can respond when asked for reports.

※For example, in order to prevent environmental pollution, instruct and advise to provide information such as improvement measures for the management method along the supply chain.

Thank you for your attention!