Application of the present Chemicals Risk management System to Nano-materials
(Extract)

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The present situation of each country's policy about Nano-materials safety

	Position in the Policy	Budget allocation to the Safety Research	Leadership and Adjustment of the Government action
USA	From the beginning of NNI(2000) , handled 「societal issues」 . Clearer position were revealed at revised plan (2004.12).	960 mil$ (2004FY), 10% of NNI budget Practical research and action for Health effect (under NTP etc.), environment implication assess, methodology, standardization, the guideline for workplace.	Government (President) initiative under OSTP Mechanism for intergovernmental cooperation and adjustment under SET (coordinating NNI, in NSF) .
EU	After several expert meeting ,European Strategy (2004.5) put emphasis on Health, Safety, Environment and Consumer Protection area。 Concrete measure are required to take.	Conducted 2 or 3 project for nano safety. But still limited preliminary approach. New project on Nano safety and environment are expected in 7th research FP (2007～) .	Double truck of EU and member country (esp. research, content is similar) . There is the clear trend to unify the regulative measure on safety or consumer protection to euro-standard of chemical management system (REACH, Cosmetic Directive).
JAPAN	Concentration on R&D. No policy back up for safety and environment so far.	Setting up the study group, collecting and assessing documents, information and getting ready for preliminary test.	

Raised issues & current Understanding

1) The comprehensive idea of nanotechnology isn't necessarily definite.

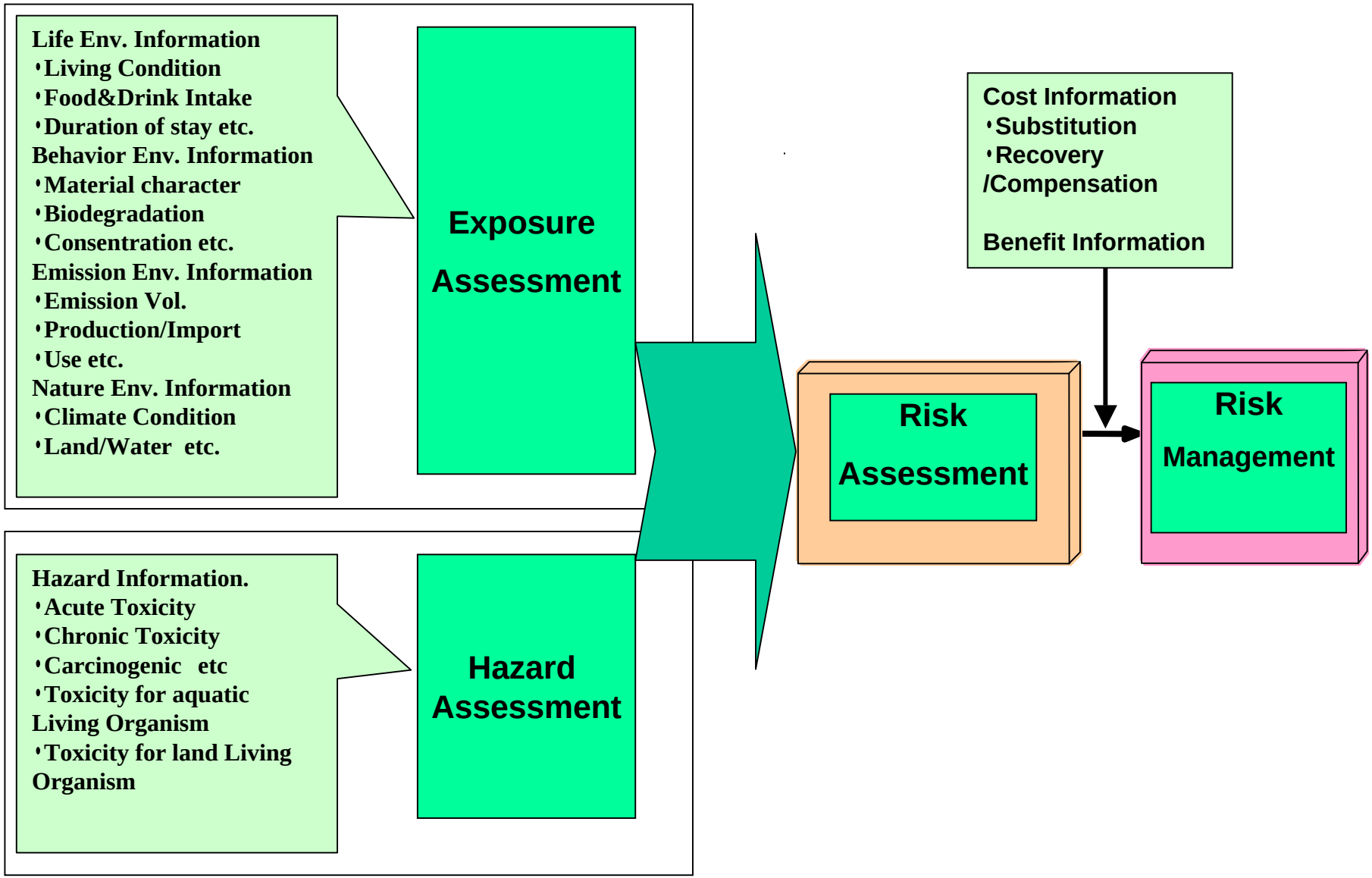
2) Many reports defined that nanotechnology is to produce or manipulate materials in the size from 1 nm to 100 nm.

3) Possible influence of the physical character which becomes remarkable in nano scale or the added function by physical-chemical treatment of the surface .

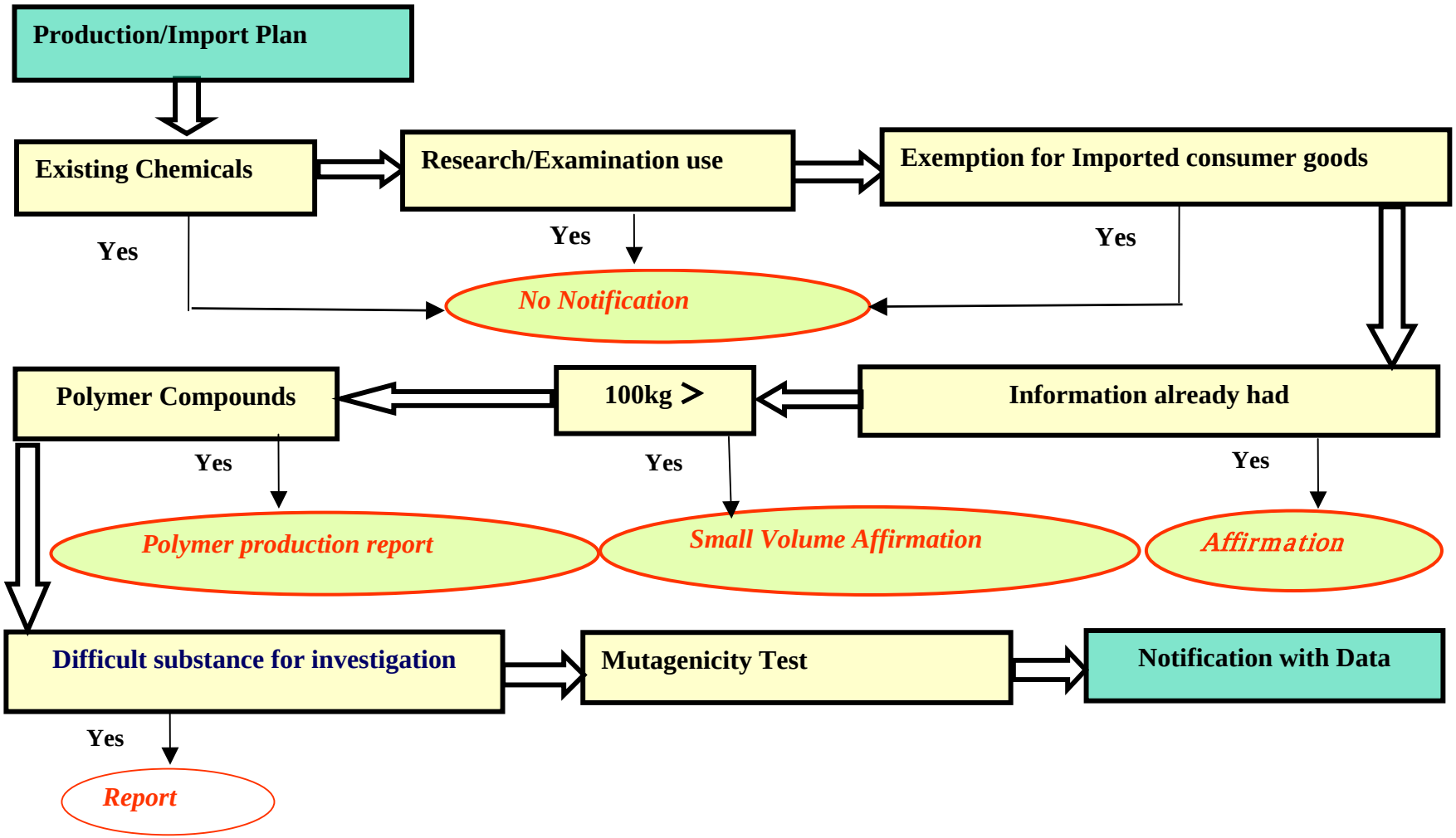
4) The samples used for the examination so far are not clear whether in the nano scale, in the condition of the mixture of the wide range of size, or some other forms.
Reported Information on the risk of each material is fragmentary.

5) We already know the existence of the molecule at nano size.
Is it meaningful definition limited to certain range of nano length ?

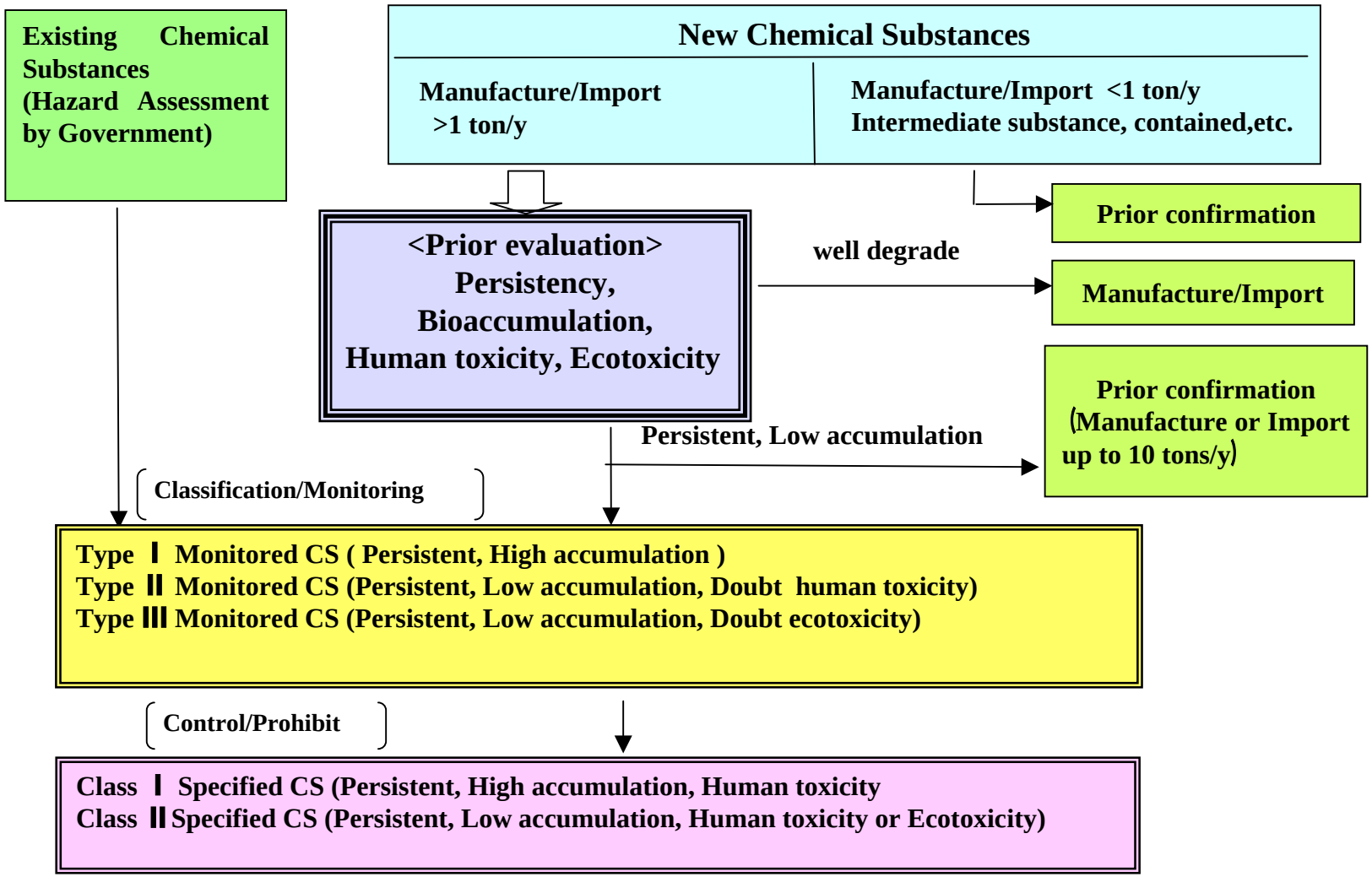
The basic system of the present chemicals management



The notification procedure of new chemical substance under Industrial Occupational Safety and Health Law (IOSHL)



Classification and Control System of Chemicals Substances Control Law (CSCL)



Application to the nano materials 1

In case of IOSHL, CSCL in Japan

Existent Chemicals : Metal or Metal oxide particle (No evaluation for size-dependent risk)

New chemicals : Fullerene derivatives (IOSHL & CSCL)
(Fullerene and carbon nano tube not covered by CSCL, not clear to be covered by IOSHL)
(Carbon is regulated as dust under IOSHL)

At present, many nano materials are in the condition of small quantity exception（100 KG/Y（IOSHL)、1ton／Y（CSCL)）

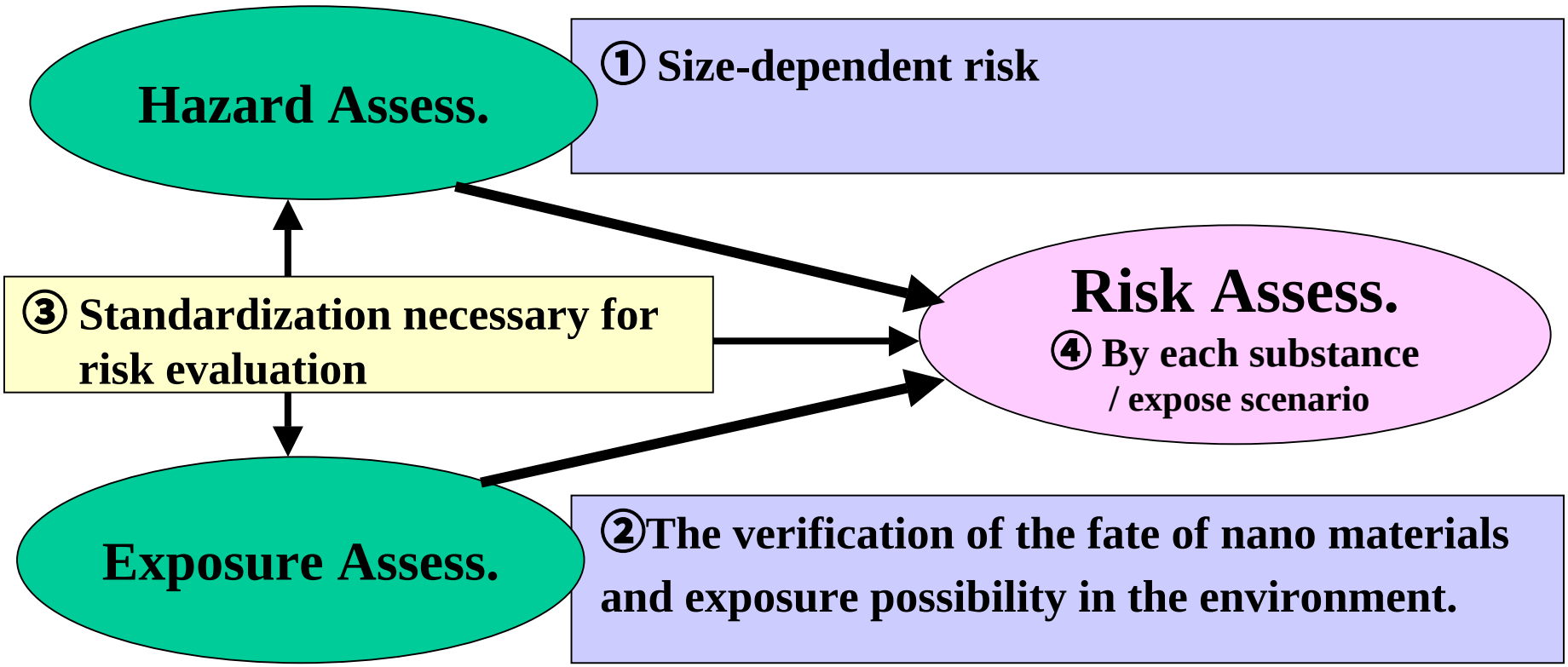
Testing Methods are insufficient ; difficulty of dissolvent in the solvent, dispersion of aggregates of smaller primary substance uniformly and measurement of nano scale.
Size-dependent risk is out of consideration

Application to the nano materials 2

Risk Evaluation of Chemical Substance in Nano Scale

A. The systematic and comprehensive approach for hazard evaluation, environmental fate, exposure and risk evaluation of nano materials.

B. Prioritize the investigation and research based on the possibilities of exposure.



Verification

of the influence of the particle size difference and the physical or chemical surface treatment

Improvement

of the existent hazard testing method

Measurement

the concentration and the character of nano materials in the body or solvent

Proposal

of the new testing method like in vitro method and the alternative experiment animal

Development

the exposure technology such as suspended particle generating device

Scientific evaluation of the papers

which pointed out or suggested some sorts of hazard of nano materials