

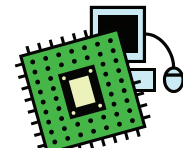
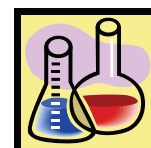
Explanatory material for Guidelines for the Management of Chemical Substances in Products (Ver. 2)

Joint Article Management Promotion-consortium (JAMP)



What is Chemical Substances in Products ?

- The substances which are contained or present in products:
 - the certain hazardous substances in electrical and electronic equipment (Directive 2002/95/EC)
 - substance is present in those article (Article 7.2 REACH)
 - substance in articles (Article 8.1 REACH)
- Chemical substances:
 - may give negative impacts on human health and ecosystems; and
 - should be clarified how much a product contains (concentration) and which part of the product contains such substances, in order to satisfy laws and regulations as well as voluntary actions.
 - (Every chemical substance has some hazardous nature.)
- Various reasons/processes that chemical substances are contained in a product.



What is management of chemical substances in products?

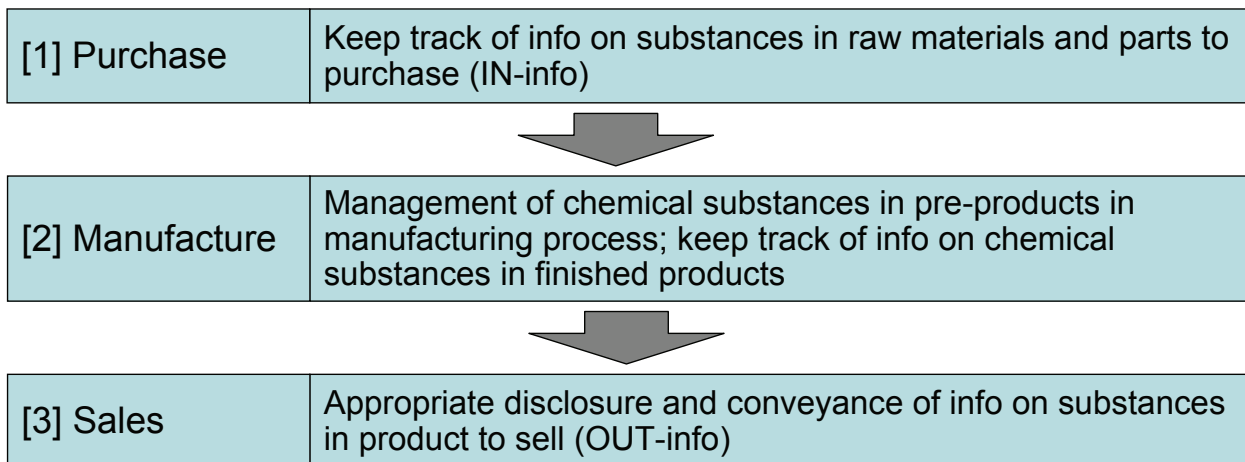
- Why is management system for chemical substances in products needed?
 - To respond to regulations (or de-facto banning of use), eg. RoHS Directive.
 - To respond to the REACH regulation.
 - To establish a basis of information conveyance in a supply chain to respond to such regulations.
 - To ensure that “by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health” (Strategic Approach to International Chemicals Management: SAICM)
- What should be done for management of chemical substances in products? For example:
 - Confirm type and volume (concentration) of subject chemical substances contained in raw materials to be purchased.
 - Prevent erratic use, mixture and contamination in manufacturing process within the company.
 - Understand and confirm changes in manufacturing conditions and facilities, including that in suppliers.
 - It is important to conduct necessary actions in a systematic way.
- Who does conduct the management?
 - Divisions relating to own products, such as design/development, manufacturing technology, purchase, manufacturing, quality management, environmental management, marketing.
 - Outsourcing manufacturers, suppliers



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Practice of management of chemical substances in products

- Management of chemical substances
 - Manufacturers should know and manage types, volume (concentration) of specific chemical substances in own products to manufacture (or to sell), as well as which part of the product contains such substances. Based on this management system, information on chemical substances in products should be conveyed in an appropriate manner.



This 3-step process is the basis for management of chemical substance in product!!

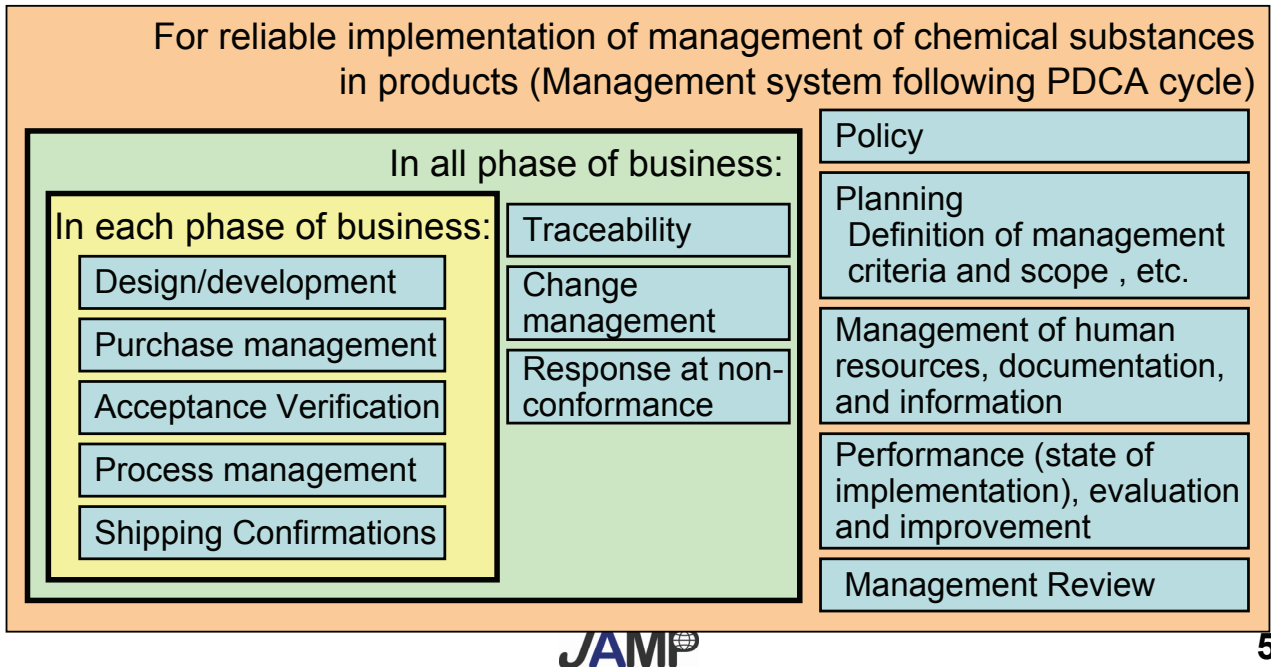


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Guidelines for the Management of Chemical Substances in Product

- Prepared for business operators that engage in manufacturing industry; compiling common requirements necessary to conduct management of chemical substances in products by themselves.
- Co-published by JAMP and JGPSSI in March 2008

JGPSSI: Japan Green Procurement Survey Standardization Initiative



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Issues in terms of sharing information on chemical substances in products within a supply chain

- Issues in conventional framework:
 - No system to convey information on chemical substances in articles
 - Companies conduct individual/item-by-item inspection: it generates huge financial burden which is an issue.
 - No consensus on management of chemical substances in articles
 - It decreases credibility of info based on research results; and it remains unclear who to take responsibility for management.
- Issues for a future framework:
 - “Inspection sheet for content of specific chemical substance,” provided by upstream companies, does not correspond to the REACH.
 - The sheet for specific inspection, currently used by downstream companies, does not correspond to the REACH.
 - In the current situation there is no system to convey necessary information on chemical substances and compounding to respond to the REACH.

The most urgent issue is to develop/disseminate a management system which can be used in response to international regulations of chemical substances in products:

- a system to convey information on chemical substances in articles
- a system to share such information across industry (via supply chains)

Ideal way of management of chemical substances in products

Passive management → Self-directed management & information provision

Regulations on chemical substance are expanding: suppliers' capacity to respond to it is limited.

Manufacturers have responsibility to manage and provide information on own products in an appropriate manner.

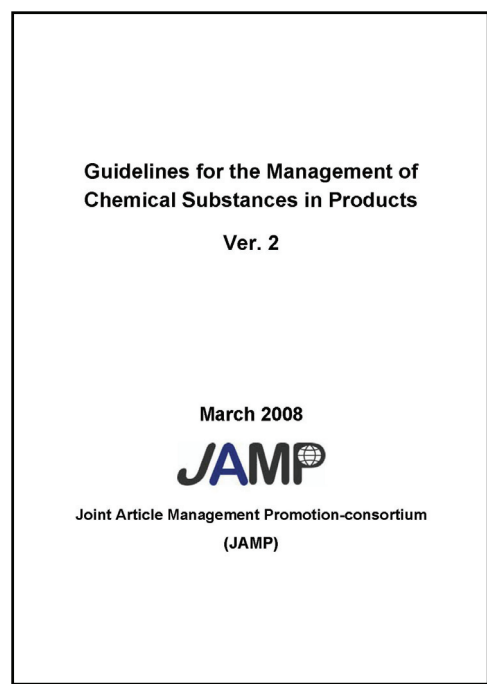
- Technically, manufacturer is responsible for chemical substances in its own products.
- Practically, chemical substances have been under user-oriented management: information was provided upon users' request.



Need a paradigm shift for appropriate management of chemical substances in product

- Manufacturers shall bear responsibilities for chemical substances in its own products.
- Under such self-directed management, manufacturers shall disclose and provide uses with necessary information to meet regulations, as its own role in a supply chain.

Guidelines for the Management of Chemical Substances in Products (Ver. 2)



Guidelines for the Management of Chemical Substances in Products (main text)

Actions with regard to the management guideline

Main text

Descriptions on concept and procedure for management of chemical substances in product, as well as information disclosure and provision

For the first two processes, it's been discussed to give fulfilling descriptions.

Guidance

Explanatory notes to give detailed and specific descriptions on procedures by important sector/industry.

Process to be covered:

- Resin molding (under discussion)
- Plating (under discussion)
- Painting (planned)
- Bonding (planned), etc.

Points to develop guideline for management of chemical substances in products (1)

■ Clarifying roles/responsibilities of companies in a supply chain

✚ What should be done by upstream/midstream/downstream companies, and for what are they responsible? The Guideline explains such aspects based on detailed description.

■ Focusing on conversion process: from substance/preparation to article

✚ The conversion process from chemical substances to an article by chemical reactions is the most difficult part in chemical substance management and the crucial point of management. In this Guideline, explanatory notes are prepared for the most important/representative processes by sector/industry for more specific explanations.

■ Changing from passive to self-directed management (self-declaration on conformance)

✚ Manufacturers should be responsible for chemical substances in own manufacturing products: under a self-directed management, manufacturers provide necessary information to meet regulations to uses.

■ Paying attention to consistency and continuity with existing management for chemical substances

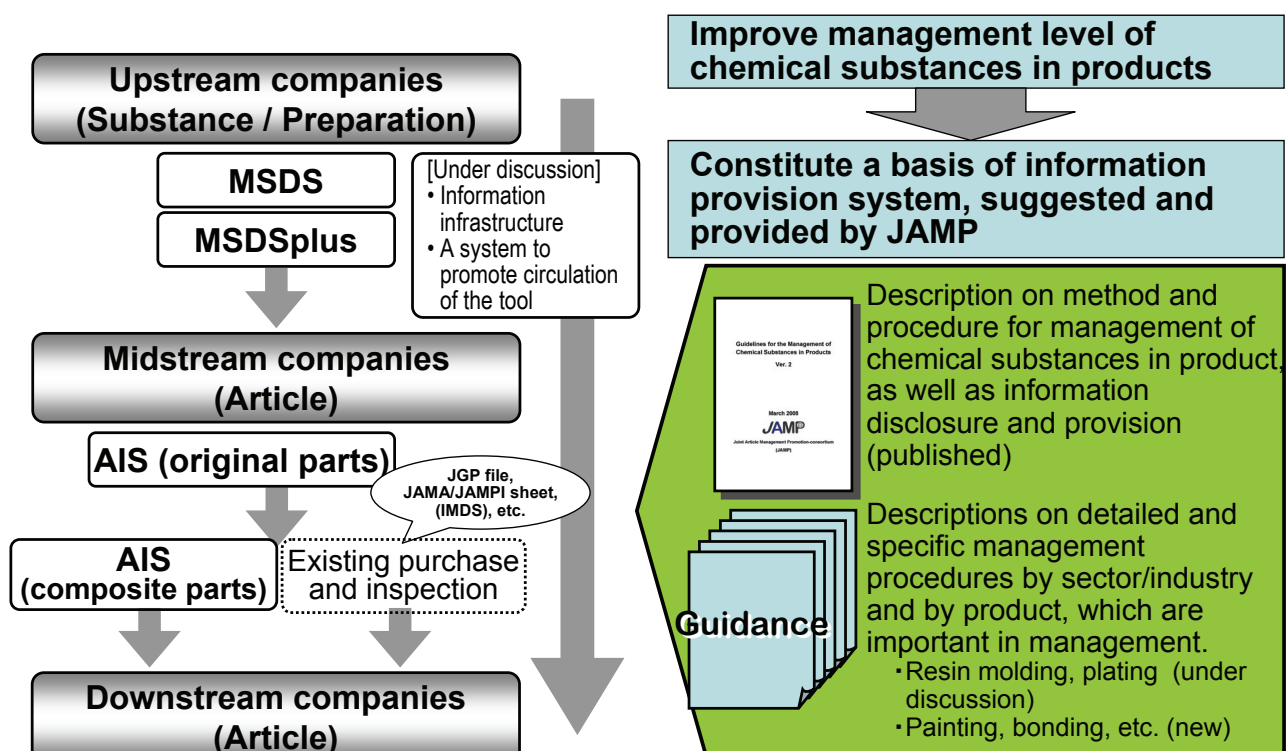
✚ It can avoid to waste time and energy by maintaining consistency and continuity with available system and notion in existing framework.

■ Paying attention to expression and structure in the Guideline to help everyone in a supply chain understand the management system

✚ Descriptions in the Guideline should be easy to understand so that all manufacturers including SMEs can implements the management.

Points to develop guideline for management of chemical substances in products (2)

● Clarifying of roles/responsibilities in a supply chain



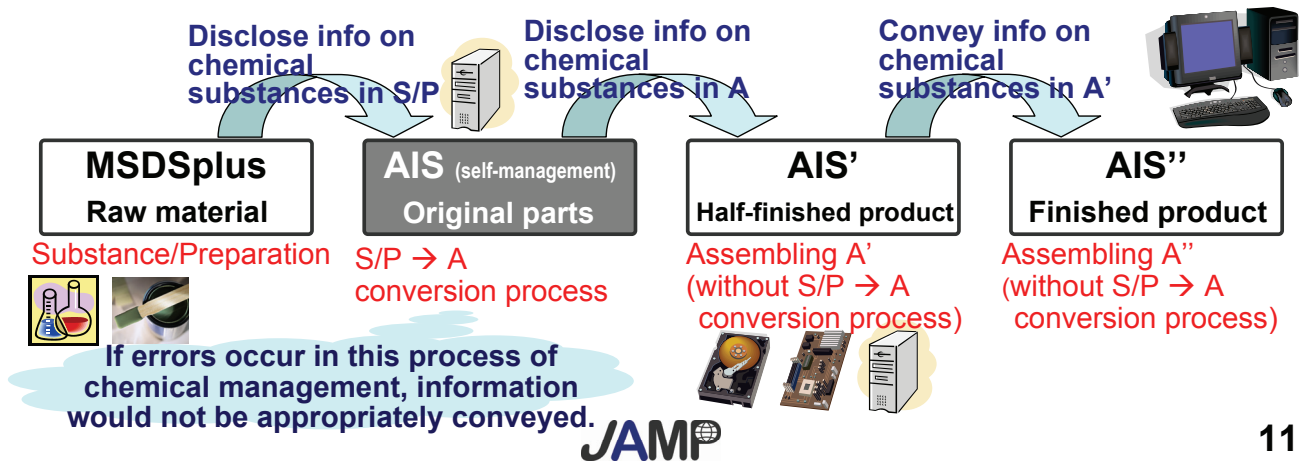
Points to develop guideline for management of chemical substances in products (3)

- Focusing on conversion process: substance/preparation → article

The process of conversion from chemical substances to an article by chemical reactions is the most difficult part of management of chemical substances in product, and the crucial point of management.

→ For important/representative processes, explanatory notes are prepared for more specific descriptions by sector/industry. (under discussion)

* If not for appropriate management in this process, information on AIS is not appropriately conveyed.

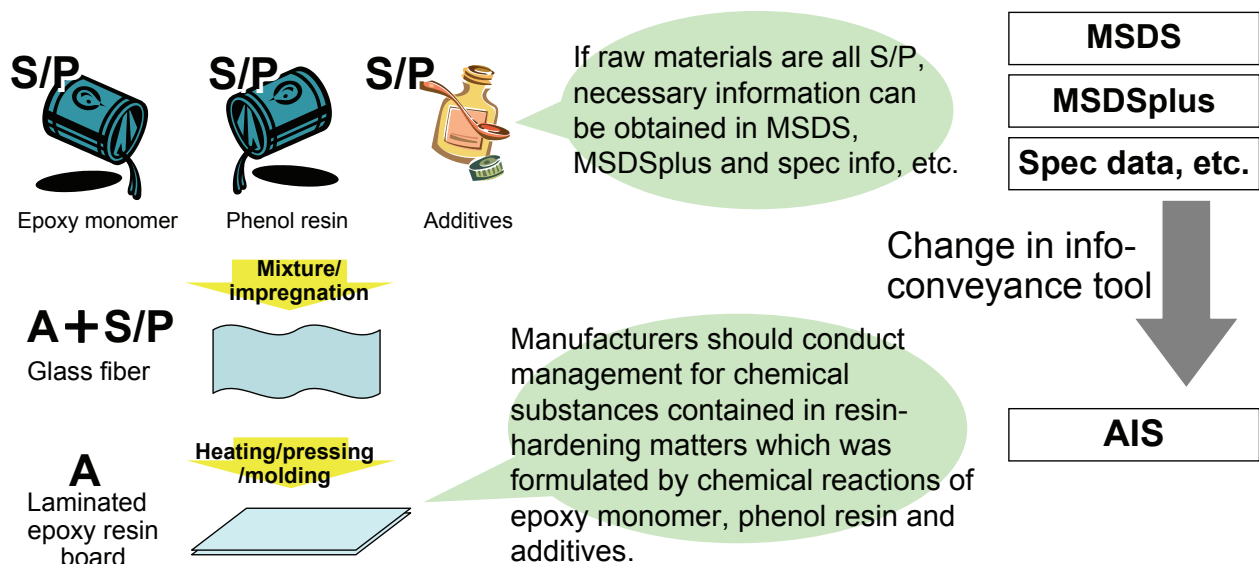


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<Reference> Article conversion process: Example 1

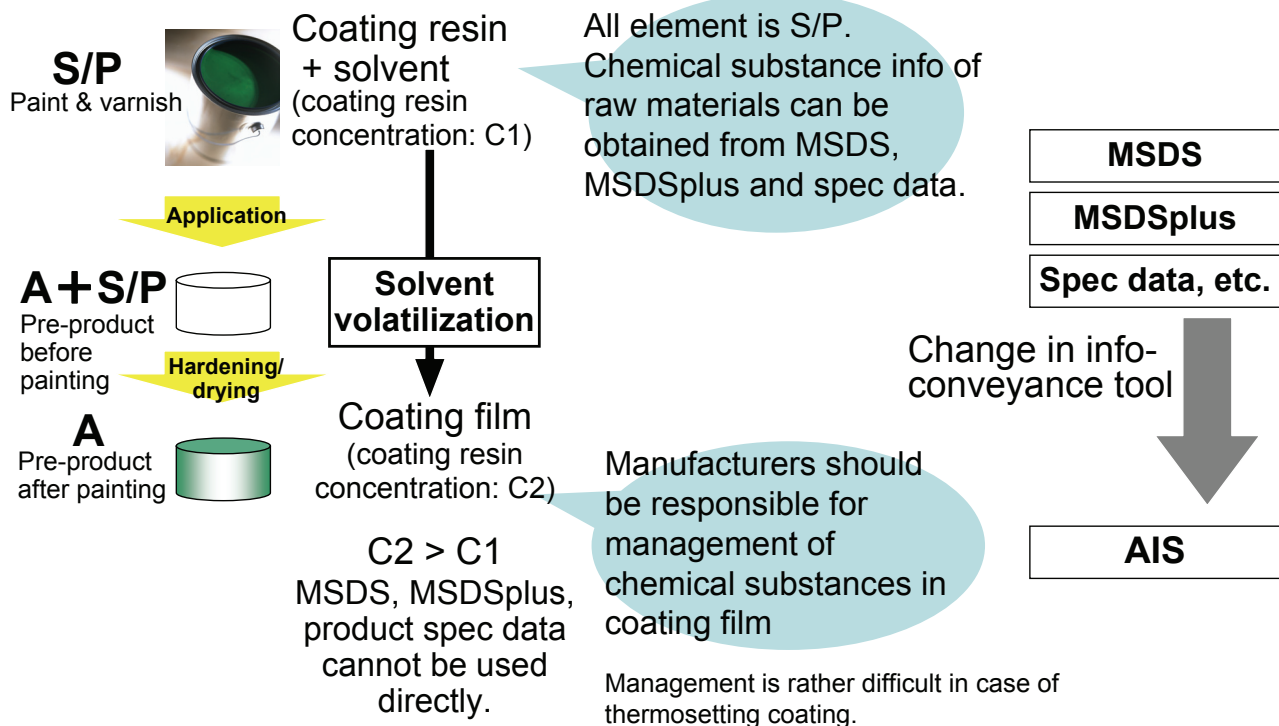
A new "matter" is manufactured by chemical reactions of substances and preparations (S/P) which are raw materials. When the "matter" is article, this process is the conversion process from S/P to article.

- Manufacturing process of epoxy resin board



<Reference> Article conversion process: Example 2

● Painting process

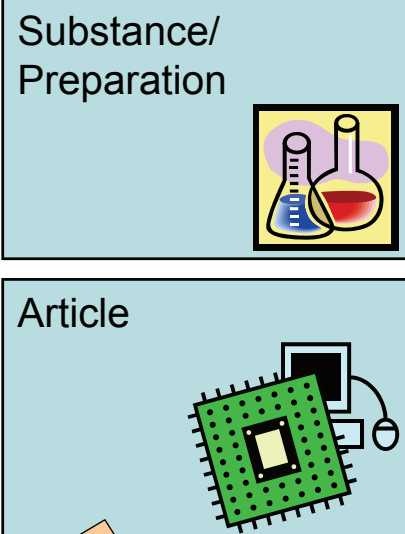


Basis of management: Principle

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- (1) Purchase:
Keep track of info on substances in raw materials and parts to purchase (IN-info)
- (2) Manufacture:
Management of chemical substances in semi-products in manufacturing process; keep track of info on chemical substances in finished products
- (3) Sales:
Appropriate disclosure and conveyance of info on substances in product to sell (OUT-info)

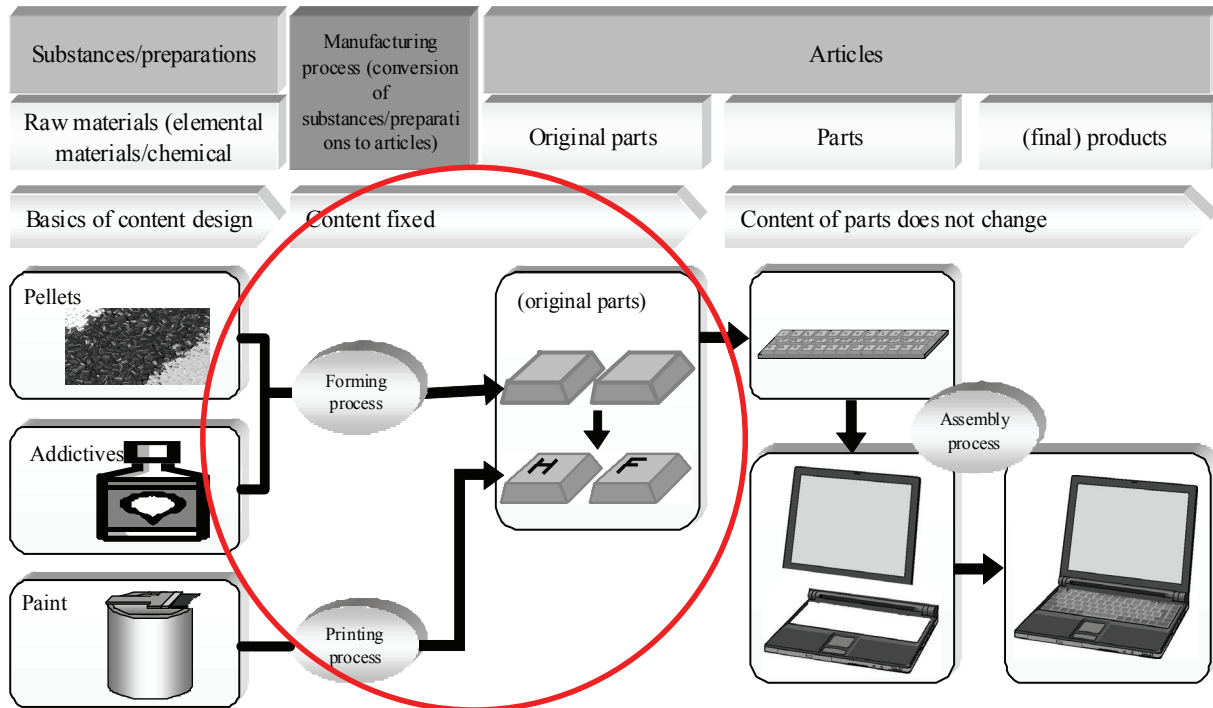
This 3-step process is the basis for management of chemical substance in product!!



Be aware which category you are going buy/produce/sell. Is it a substance/preparation, or an article?

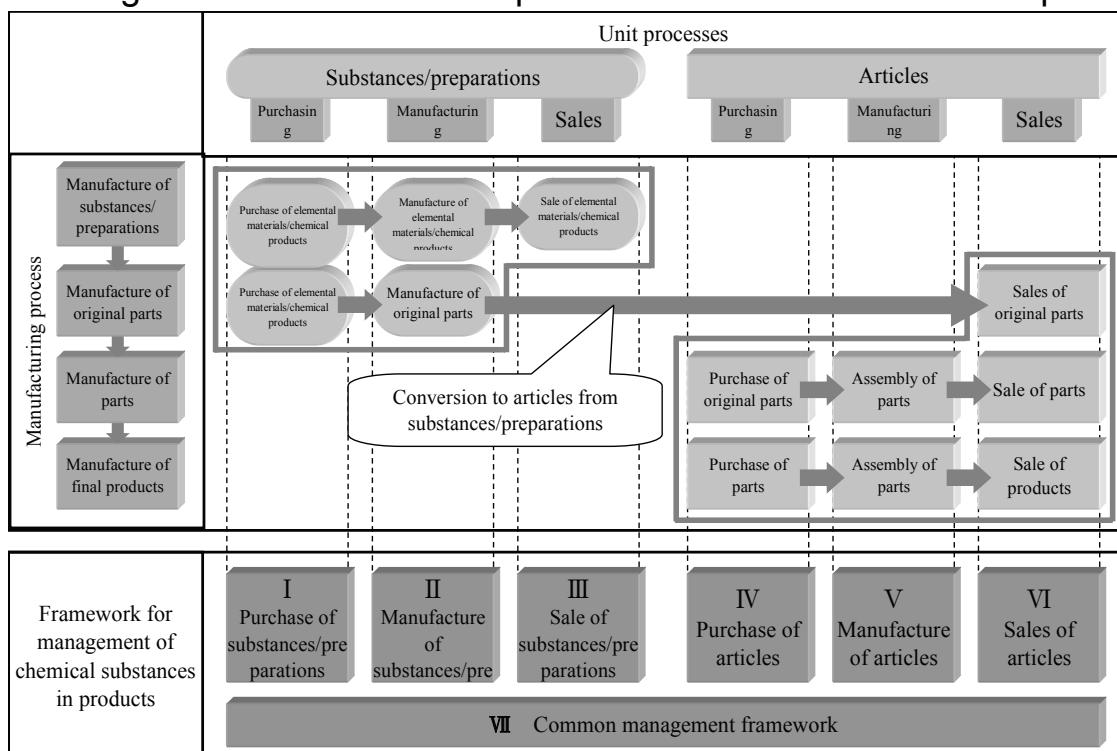
Basis for management: Process of conversion to articles

- Focusing on article conversion process, the crucial point of management of chemical substances in products



Basis of management: Management frameworks (I-IV)

- Paying attention to consistency/continuity with existing management systems
→ 7 management frameworks adopted for chemical substances in products



Basis of management: Prioritized Management Considering Management Risks

p.14

- Identification of Items for prioritized management
 - Identify items for prioritized management in consideration of risks in management of chemical substances in products
 - Determine the management level (actual response) for prioritized management and other general management

[Raw materials]

- ✚ Chemical substances which have been used previously, but are now restricted in use by new regulations. Chemical substances which are very possibly used in in-house processes, or very possibly included in purchased items, and which must therefore be reconsidered
- ✚ Raw materials including, or very possibly including, substances subject to management
- ✚ Recycled materials. In particular, open-recycled materials (materials from outside the process). Different method of management may be necessary for recycled materials
- ✚ Ores and natural materials
- ✚ When included chemical substances are unidentified.

[Original parts and parts]

- ✚ Original parts and parts manufactured from raw materials requiring prioritized management

[Processes]

- ✚ Process using raw materials requiring prioritized management
- ✚ Process using original parts and parts requiring prioritized management



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Basis of management: Other elements

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- Basis of management: Supports by upstream/downstream companies
 - ✚ It is important that all companies involved in the supply chain understand the requirements for management of chemical substances in products in these guidelines, and provide support to upstream and downstream companies to ensure that the appropriate management is implemented.
- Basis of management: Information on chemical substances in products
 - ✚ Information must be accompanied by scientific corroboration.
 - ✚ All information on chemical substances in products, which is required to be submitted to related persons for management of chemical substances in products, should be provided in principle.
 - ✚ When new information is obtained, and when information is changed due to updating of regulations etc, the revised information must be provided within the appropriate time limit.
- Basis of management: protection of company secrets
 - ✚ Information related to the composition of chemical substances may contain important corporate secrets, so that continued protection of these secrets is required. The same applies to provision of information on articles throughout the supply chain, and associated risk management is necessary.

List of Action Items

● 23 Action Items

1. Policy
2. Planning
 - 2.1 Definition of Management Criteria
 - 2.2 Definition of Scope of Management
 - 2.3 Establishment of Objectives & Planning for Implemented Processes
 - 2.4 Definition of Organizational System, Responsibility & Authority
3. Implementation & Management
 - 3.1 Design and Development
 - 3.1.1 Design for Manufacture of Substances/Preparations
 - 3.1.2 Design for Manufacture of Articles Using Substances/Preparations
 - 3.1.3 Design for Manufacture of Articles Using Articles
 - 3.2 Purchase Management
 - 3.2.1 Verification and Acquisition of Chemical Substances in Products Information
 - 3.2.2 Verification of Supplier Management Status
 - 3.3 Acceptance Verification
 - 3.4 Process Management
 - 3.4.1 Preventing Incorrect Use, Admixture, and Contamination
 - 3.4.2 Appropriate Management of Reaction Processes
 - 3.4.3 Management of Sub-contractors
 - 3.5 Shipping Verification
 - 3.7 Change Control
 - 3.8 Non-conformity Response
4. Management of Human Resources, Documentation, and Information
 - 4.1 Training
 - 4.2 Management of Documentation and Records
 - 4.3 Communication (Provision of Information)
5. Performance (State of Implementation) Evaluation and Improvement
6. Management Review (Correction by Management)

Action Items in the Guidelines for the Management of Chemical Substances in Products (1)

p.19

1. Policy

I	II	III	IV	V	VI	VII
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As for (5), see the description in Preface of the Guidelines for details

- Declare items to be dealt with in management of chemical substances in products.

[Additional Explanations]

- (1) Measures dealing with management of chemical substances in products shall include the following related legislation in accordance with these guidelines, and development of a system for management of chemical substances in products.
- (2) It is important that policies incorporating approval by managers shall be well-known and understood by related personnel.
- (3) It is important that policies are periodically reviewed and maintained.
- (4) Methods used for declaration of policy shall include explanations of policy to groups of related personnel, publication of policy on bulletin boards etc, and writing policy on cards for distribution
- (5) When developing structures for quality management and environmental management etc, existing structures may be employed to implement management to satisfy the action items shown in these guidelines.

Action Items in the Guidelines for the Management of Chemical Substances in Products (2)

p.19

2. Planning

2.1 Definition of Management Criteria

Manufacturers set management criteria in accordance with legal systems and industrial standards.

I | II | III | IV | V | VI | **VII**

● Management criteria to be followed shall be clarified based on legislation and industry criteria related to management of chemical substances in products, and conveyed to related corporate units.

[Additional Explanations]

- (1) Legislation includes legislation which must be followed by the customer.
- (2) Industry criteria are voluntary criteria determined by the industry.
- (3) Maintenance and management on information related to the most recent legislation and industry criteria is important.
- (4) It is important to verify that information transmitted to related corporate units is understood and is translated into the necessary action.
- (5) With sub-contracted manufacture as well, it is important to understand legislation to be followed, and to clarify company management criteria.



Action Items in the Guidelines for the Management of Chemical Substances in Products (3)

p.19

2. Planning

2.2 Definition of Scope of Management

Constituent materials: raw materials, parts, and subsidiary materials comprising the product

I | II | III | IV | V | VI | **VII**

● 'Organizations', 'business', 'chemical substances', 'constituent materials', 'processes', and 'products' etc shall be clarified as the scope of application of management criteria for chemical substances in products.

[Additional Explanations]

- (1) Constituent materials refer to raw materials, parts, and subsidiary materials comprising the product.
- (2) In some cases, management of information on chemical substances in products (OUT information) is concentrated upstream in the supply chain, and measures suited to the nature of the manufacturing process are necessary.
- (3) Processes also include sub-contractors and original equipment manufacturers.
- (4) The scope of application may differ with the legislation. For example, products may be exported, or they may be limited to the domestic market.

Action Items in the Guidelines for the Management of Chemical Substances in Products (4)

p.20

2. Planning

2.3 Establishment of Objectives & Planning for Implemented Processes

I | II | III | IV | V | VI | **VII**

● Objectives and plans for management of chemical substances in products shall be prepared. Objectives and plans shall be revised as necessary.

[Additional Explanations]

- (1) Clarification of the state of progress of objectives and plans. Objectives and plans require modification depending on their state of progress.
- (2) Even if objectives have been achieved (e.g. response to EU RoHS directives complete), response is still required for maintenance and management, and new legislation and industry criteria.

Action Items in the Guidelines for the Management of Chemical Substances in Products (5)

p.20

2. Planning

2.4 Definition of Organizational System, Responsibility & Authority

I | II | III | IV | V | VI | **VII**

● Rights and responsibilities for management of chemical substances in products shall be clarified.

[Additional Explanations]

- (1) A number of methods are available for clarification, for example, rules for chemical substances in products, and organization charts.
- (2) It is important to clarify the scope of rights and responsibilities for sub-contractors and original equipment manufacturers as well.
- (3) In organizations for which 'clarification of the scope of management' is required, it is important to identify the information necessary for management of chemical substances in products, and to convey and share that information.

Including communication
(information sharing)

Needs responses according
to management level of
outsourcing manufacturers.

Action Items in the Guidelines for the Management of Chemical Substances in Products (6)

p.20

3. Implementation & Management

3.1 Design and Development

3.1.1 Design for Manufacture of Substances/Preparations



I | II | III | IV | V | VI | VII

- When manufacturing substances/preparations, information on chemical substances in raw materials shall be verified, and products and manufacturing processes shall be designed to satisfy management criteria. Specify specifications of purchased products if necessary.

[Additional Explanations]

- (1) When constituent materials are selected not only by the design section, but also by the company, a 'design function' is implied, and this action item is 'Applicable'.
- (2) Included content (upper limit values) for managed chemical substances are determined from legislation and industry criteria related to products subject to management.

Management framework I & II

Action Items in the Guidelines for the Management of Chemical Substances in Products (6) -- continued (i)

p.20

3. Implementation & Management

3.1 Design and Development

3.1.1 Design for Manufacture of Substances/Preparations



[Additional Explanations]

- (3) Purchasing and procurement conditions, manufacturing processes, manufacturing conditions, inspection and shipping conditions etc are determined such as to satisfy management criteria for the product, and in consideration of chemical substances in raw materials and subsidiary materials, and chemical substances added, created, and removed in processes.
- (4) Manufacturing conditions include prevention of incorrect use, admixture, and contamination, and appropriate management of reaction processes.
- (5) It is important to verify at each stage (e.g. testing, prototype manufacture, mass production) in the design and development stage.

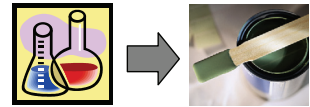
Action Items in the Guidelines for the Management of Chemical Substances in Products (6) -- continued (ii)

p.20

3. Implementation & Management

3.1 Design and Development

3.1.1 Design for Manufacture of Substances/Preparations



[Additional Explanations]

- (6) The results of design and development are shown in specifications, drawings, manufacturing specifications, work specifications, and manuals etc.
- (7) When constituent materials are separated by the customer, specifications and management criteria etc are determined in discussion with the customer.
- (8) Use of MSDS and MSDSplus etc is recommended for verification of information on chemical substances in substances/preparations.

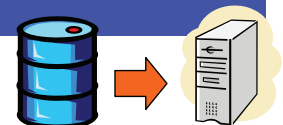
Action Items in the Guidelines for the Management of Chemical Substances in Products (7)

p.21

3. Implementation & Management

3.1 Design and Development

3.1.2 Design for Manufacture of Articles Using Substances/Preparations



I | II | III | IV | V | VI | VII

- When manufacturing articles from substances/preparations, information on chemical substances in raw materials shall be verified. Any possible changes in concentration and type of contained chemical substances in processes shall be understood. Furthermore, the product shall be verified as conforming to the management criteria.

Management framework I & II

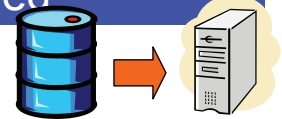
Action Items in the Guidelines for the Management of Chemical Substances in Products (7) -- continued

p.21

3. Implementation & Management

3.1 Design and Development

3.1.2 Design for Manufacture of Articles Using Substances/Preparations



[Additional Explanations]

- (1) Surface processes such as plastics molding, plating, painting, and printing, and fusion processes such as soldering and gluing, are examples of the manufacture of articles from substances/preparations. In the case of gluing, for example, there is a possibility that changes may occur in the concentration and type of contained chemical substances, and care is therefore required.
- (2) In many cases, a process is conducted simultaneously with the process of manufacture of a new article from an existing article, and care is required to ensure that action items (3.1.3) related to design and development are not missed.
- (3) When manufactured articles are supplementary to substances/preparations, it is important to verify information on chemical substances contained in those substances/preparations. For example, coolant, grease, lubricating oil, rust preventative oil.
- (4) Refer to 3.1.1 (1)-(8).

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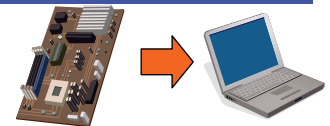
Action Items in the Guidelines for the Management of Chemical Substances in Products (8)

p.21

3. Implementation & Management

3.1 Design and Development

3.1.3 Design for Manufacture of Articles Using Articles



I	II	III	IV	V	VI	VII
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- When manufacturing new articles from existing articles, information on chemical substances in articles (e.g. parts), and conformance of the product to the management criteria, shall be verified.

Management framework IV & V

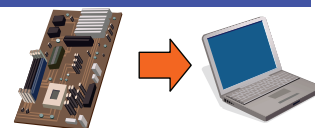
Action Items in the Guidelines for the Management of Chemical Substances in Products (8) -- continued

p.21

3. Implementation & Management

3.1 Design and Development

3.1.3 Design for Manufacture of Articles Using Articles



[Additional Explanations]

- (1) Processes such as assembly of parts, and machining of plastic and metal original components, are examples of the manufacture of new articles from existing articles.
- (2) When gluing and soldering etc, articles are manufactured simultaneously using substances/preparations, and care is required to ensure that action items (3.1.2) related to design and development for the same process are not missed.
- (3) The use of methods for transmission of information such as the AIS and JGP files, or the JAMA/JAPIA integrated data sheet, is recommended for verification of information on chemical substances in articles.
- (4) Refer to 3.1.1 (1)-(7). Not including responses related to chemical reactions.
- (5) Refer to 3.1.2 (3).

Management framework IV & V



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Action Items in the Guidelines for the Management of Chemical Substances in Products (9)

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3. Implementation & Management

3.2 Purchase Management

3.2.1 Verification and Acquisition of Chemical Substances in Products Information

I	II	III	IV	V	VI	VII
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- Information on the chemical substances in purchased products (IN information) shall be acquired, verified that it contains the necessary details, and that it is compatible with the management criteria. For new products and changed products, acquisition and verification of information on chemical substances in products in accordance with the management criteria shall be complete prior to commencing mass production.



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Action Items in the Guidelines for the Management of Chemical Substances in Products (9) -- continued

p.22

3. Implementation & Management

3.2 Purchase Management

3.2.1 Verification and Acquisition of Chemical Substances in Products Information

[Additional Explanations]

- (1) Information on chemical substances in products covers inclusion or not in substances subject to management, the contained amount and concentration, and use etc.
- (2) When the purchased product is a substance/preparation, MSDS and MSDSplus etc are available as means of obtaining information on the contained chemical substances.
- (3) When the purchased product is an article, AIS and JGP files, or the JAMA/JAPIA integrated data sheet, are available as means of obtaining information on the contained chemical substances.
- (4) Since substances subject to management may vary with use, it is desirable that the other party be informed of use when making inquiries.
- (5) The CAS number, or names, numbers, and symbols etc are used in identification of substances subject to management.

Action Items in the Guidelines for the Management of Chemical Substances in Products (10)

p.22

3. Implementation & Management

3.2 Purchase Management

3.2.2 Verification of Supplier Management Status

I	II	III	IV	V	VI	VII
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- When selecting a new supplier, the status of management of chemical substances in the supplier's products shall be verified. When continuing with an existing supplier, reconfirmation shall be conducted as necessary. Measures for verification results shall be fixed. Supplier items to be verified, criteria, frequency, and method etc may be set in relation to risk level.



Action Items in the Guidelines for the Management of Chemical Substances in Products (10) -- continued

p.22

3. Implementation & Management

3.2 Purchase Management

3.2.2 Verification of Supplier Management Status

[Additional Explanations]

- (1) Evaluation of the supplier risk level is based on acquired content information, the possibility of unintended inclusion (presence or absence of reaction processes, parallel production, constituent materials etc), the status of compatibility with these guidelines, the presence or absence of an environmental/quality management system, and past performance etc.
- (2) Verification of the status of management of chemical substances in products is based on documentation and visits etc.
- (3) Examples of measures to deal with results of verification are acceptance, continuing transactions, requests for improvement, guidance, discontinuing transactions.

Action Items in the Guidelines for the Management of Chemical Substances in Products (11)

p.23

3. Implementation & Management

3.3 Acceptance Verification

I | II | III | **IV** | V | VI | VII

- When accepting purchased products, such products shall be verified as compatible with company management criteria. Items to be verified, criteria, method, and frequency etc may be selected in relation to the risk level of the purchased products.



Action Items in the Guidelines for the Management of Chemical Substances in Products (11) -- continued

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3. Implementation & Management

3.3 Acceptance Verification

[Additional Explanations]

- (1) It is important that company acceptance procedures are clarified in response to risk in management of chemical substances in products.
- (2) Risk level for purchased products must be evaluated in terms of such factors as the degree of possibility of inclusion in chemical substances subject to management, supplier management level, past performance, and whether or not the purchased product is recycled materials.
- (3) Examples of items able to be clarified with acceptance procedures.
 - a) Method of evaluation (comparison of actual items and information, measurement by company as necessary etc)
 - b) Method of recording evaluation results
 - c) Method of managing identification
- (4) With purchasing by multiple companies (multi-sourcing), it is necessary to implement methods of verification appropriate to each supplier.

Action Items in the Guidelines for the Management of Chemical Substances in Products (12)

p.23

3. Implementation & Management

3.4 Process Management

3.4.1 Preventing Incorrect Use, Admixture, and Contamination

I | II | III | IV | V | VI | VII

- Implementation of measures to prevent incorrect use, admixture and contamination of chemical substances shall be subject to management.

[Additional Explanations]

- (1) In practice, it is possible to separate processes, and equipment and jigs etc, into those requiring priority management, and others. Processes requiring priority management are those in which chemical substances having management criteria are used, and it is important to manage these separately from other general processes. If processes requiring priority management are not separated, thorough identification, and appropriate procedures for changeover, are required.

Action Items in the Guidelines for the Management of Chemical Substances in Products (12) -- continued

p.23

3. Implementation & Management

3.4 Process Management

3.4.1 Preventing Incorrect Use, Admixture, and Contamination

[Additional Explanations]

- (2) In processes requiring priority management, it is important that this be extended to storage of materials, semi-finished products, and finished products, and to warehouses.
- (3) A minimal response may be sufficient when processes requiring priority management are not within the scope of management, however verification is necessary.
- (4) When using recycled materials, it is important to understand the degree of risk, determine the management method, and proceed on this basis.

Need to pay attention until finished products are stored

Action Items in the Guidelines for the Management of Chemical Substances in Products (13)

p.24

3. Implementation & Management

3.4 Process Management

3.4.2 Appropriate Management of Reaction Processes

I II III IV V VI VII

- Management shall ensure that residues do not remain, or are not created, when management criteria for chemical substances subject to management are exceeded, due to changes in constituents and concentrations.



Action Items in the Guidelines for the Management of Chemical Substances in Products (13) -- continued

p.24

3. Implementation & Management

3.4 Process Management

3.4.2 Appropriate Management of Reaction Processes

[Additional Explanations]

- (1) Identify processes for possible changes in the constituents of chemical substances such as oxidation, reduction, and reaction, and changes in concentration of chemical substances due to evaporation and vaporization, and implement the appropriate management.
- (2) The process of changing from a substance/preparation to an article may not be associated with any changes in chemical composition, and care is therefore required. For example, in the process of firing paint, the low molecular weight component of the paint film vaporizes, and in the process of the resin hardening, a monomer, hardener, and hardening initiator contribute to the hardening reaction, bonding with, and being incorporated in, the hardened resin, and forming a high-polymer compound with associated changes in chemical composition.
- (3) If an organization manufacturing articles from substances/preparations is unable to understand the change in chemical composition, it will be necessary to ask the raw materials supplier.



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Action Items in the Guidelines for the Management of Chemical Substances in Products (14)

p.24

3. Implementation & Management

3.4 Process Management

3.4.3 Management of Sub-contractors



I | II | III | IV | **V** | VI | VII

- Management of manufacturing sub-contractors shall be appropriate.

[Additional Explanations]

- (1) Sub-contracted manufacture should be managed through the structure for management of chemical substances in products within the sub-contractor's organization. The sub-contractor must be informed of the necessary details of process management, and the management system periodically verified.
- (2) When the sub-contractor is supplied with the necessary raw materials for manufacture, or when the sub-contractor procures the materials, management is required which is appropriate to the format of sub-contracted manufacture, and the risk.



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3. Implementation & Management 3.5 Shipping Confirmations

I II III IV V VI VII

- Products shall be shipped after verification that all specified items have been checked, including cases of implementation during acceptance, or during a process.



3. Implementation & Management 3.5 Shipping Confirmations

[Additional Explanations]

- (1) Examples of verifiable items.
 - a) Accepted raw materials and parts used in manufacture.
 - b) Manufacture with set manufacturing conditions, equipment, and work methods.
 - c) Appropriate measures implemented when non-conformance occurs.
 - d) Storage of history when changes occur.
 - e) Verification by sampling as necessary.
- (2) Examples of means of verification.
 - a) Identification tags to provide an understanding of the status of management within processes.
 - b) A production management system to provide an understanding of management data within processes.
- (3) Management is necessary for product warehouses and external distribution warehouses to prevent incorrect shipment and contamination.

Action Items in the Guidelines for the Management of Chemical Substances in Products (16)

p.25

3. Implementation & Management 3.6 Traceability

It partly depends on how far management level is improved in entire supply chain. It should be recognized as a future issue on chemical substances management.

I II III IV V VI **VII**

- Product traceability shall be reliable.

[Additional Explanations]

- (1) Traceability (history management) provides an understanding of constituent materials, timing and location of manufacture, chemical substances contained in constituent materials, and information on chemical substances contained in manufactured products, in terms of risk to permit identification of the scope of any non-conformance occurring, and provision of information when a change occurs, and provides a structure for the rapid and smooth use, disclosure, and transmission of that information.
- (2) In processes, it is important to control management information, information on abnormalities, and information on changes in causal factors etc.
- (3) It is important to implement identification and isolation in response to risk.

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Action Items in the Guidelines for the Management of Chemical Substances in Products (17)

p.25

3. Implementation & Management 3.7 Change Control

I II III IV V VI **VII**

- Rules for control of changes in management of chemical substances in products shall be determined, and the following details clarified.
- (1) Elemental changes having possible effects on chemical substances in products.
 - Changes and additions in suppliers, changes in purchased items, and changes in processes etc (including changes not only in the company such as manufacturing conditions, molds, and jigs, but changes in sub-contractors etc).
 - (2) Company internal and external procedures.
Details to be verified, means of verification, approval processes etc.
 - (3) Methods of transmitting information inside and outside the company.
Recording changes, notification, identification information etc.



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3. Implementation & Management
3.7 Change Control

[Additional Explanations]

- (1) Examples of details to be verified are changes in chemical substances in products, and compatibility with criteria.
- (2) It is necessary to ensure that information on changes in suppliers is reliably obtained.
- (3) Verify compatibility with criteria before making changes.
- (4) Provide updated information on chemical substances in products as soon as possible following any changes. Provide the customer with product lot information and identification information as necessary.
- (5) It is difficult to provide prior notification when changes occur in chemical substances in products (products sold via catalog, general market) delivered to the general public, and it is important to identify products by methods such as handling as separate products.

3. Implementation & Management
3.8 Non-conformity Response

I | II | III | IV | V | VI | VII

- Rules for measures to deal with non-conforming products (emergency measures, determination of causes, preventing reoccurrence, horizontal deployment etc) shall be determined.

Action Items in the Guidelines for the Management of Chemical Substances in Products (18) -- continued

p.25

3. Implementation & Management 3.8 Non-conformity Response

[Additional Explanations]

- (1) Examples of emergency measures are identification of the scope of influence (identification of the affected lot, equipment involved etc), containment (halting shipping, halting production), communication within the company, communication to customers, communication to persons responsible for management of chemical substances in products, and managers, as necessary (escalation).
- (2) Following emergency measures, it is necessary to identify the cause, and determine and implement the appropriate measures to prevent reoccurrence.
- (3) Horizontal deployment is the deployment not only within one's own section, but also to related sections (within the group, related companies) as necessary.
- (4) It is desirable that preventative measures be developed to prevent problems before they occur. For example, periodic measurement of the concentration of the lead in solder tanks as part of process management.

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Action Items in the Guidelines for the Management of Chemical Substances in Products (19)

p.26

4. Management of Human Resources, Documentation, and Information 4.1 Education & Training

I | II | III | IV | V | VI | **VII**

- Details of training required for management of chemical substances in products, and related persons shall be identified and implemented.

[Additional Explanations]

- (1) Examples of details of training are details of business covered, concepts of management of chemical substances in products, related legislation, industry standards, management of chemical substance risk, efforts by industry organizations, cases of use and contamination of managed substances, and methods of analysis.
- (2) It is important to verify that none of the necessary items have been missed.



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Action Items in the Guidelines for the Management of Chemical Substances in Products (20)

p.26

4. Management of Human Resources, Documentation, and Information 4.2 Management of Documentation and Records

I II III IV V VI VII

- Rules related to management of chemical substances in products shall be documented, maintained, and managed. Records of results of operation shall be prepared and stored appropriately.

Action Items in the Guidelines for the Management of Chemical Substances in Products (20) -- continued

p.26

4. Management of Human Resources, Documentation, and Information 4.2 Management of Documentation and Records

[Additional Explanations]

- (1) It is important for the company to prepare a system for management of chemical substances in products, and a system of related documentation (document structure diagram).
- (2) It is important that documentation content is reviewed as required, and that the most recent version is available for viewing as necessary.
- (3) Examples of documents are policy documentation, manuals for management of chemical substances in products, related procedure documentation for management of chemical substances in products, rules, standards, criteria, norms, procedure documentation, document structure diagrams.
- (4) Examples of records are information on contained chemical substances, acceptance verification data, shipping verification data, internal audit results, survey data, and analysis data.



Action Items in the Guidelines for the Management of Chemical Substances in Products (21)

p.26

4. Management of Human Resources, Documentation, and Information 4.3 Communication (Provision of Information)

I | II | III | IV | V | VI | **VII**

● Information on chemical substances in products (OUT information) shall be provided appropriately to suppliers. Appropriate response shall be provided to enquiries on the management system for chemical substances in products.

[Additional Explanations]

- (1) Use of MSDS and MSDSplus is recommended when substances/preparations are supplied, and AIS, JGP files, and the JAMA/JAPIA integrated data sheet, when articles are supplied.
- (2) Clarify contracts with customers and purchasing manufacturers for handling of confidential information.



Action Items in the Guidelines for the Management of Chemical Substances in Products (22)

p.27

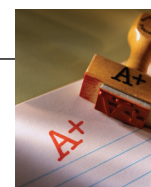
5. Performance (State of Implementation) Evaluation and Improvement

I | II | III | IV | V | VI | **VII**

● Status of management of chemical substances in products shall be verified periodically through an internal audit, and items requiring improvement shall be improved. Results of verification shall be reported to managers etc.

[Additional Explanations]

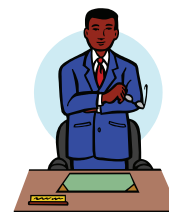
- (1) It is necessary to determine implementation procedures and implement an internal audit etc.
- (2) It is important that the person in charge of the internal audit implements the necessary training for management of chemical substances in products.
- (3) It is important that evaluation of, and improvements in, the status of implementation employ methods appropriate to the scale of the implementing organization.



6. Management Review (Correction by Management)

I | II | III | IV | V | VI | **VII**

● When the manager determines, from the results of an internal audit, that there are problems with non-conformance, improvements shall be implemented and reflected in the next objective.



- Self-declaration of conformance under the Guideline is the declaration and commitment made by person responsible in an organization, with regard to:

[1] the fact that the company has developed and implemented a management system in accordance with the Guidelines;
or

[2] the fact that a management system, which was established and implemented in accordance with other criteria or guidance equivalent to or better than this Guidelines, satisfies in practice the requirements in this Guidelines.

- Specific criteria and detailed method for self-declaration of conformance is as shown in Chapter 6.

- Declare to the society that it establishes and implements management system of chemical substances in products, by way of “self-declaration of conformance”.
- Total evaluation criteria for “self-declaration of conformance”:
 - ✚ When all relevant items for the action item are evaluated as ‘Conformance’, or
 - ✚ When there is no ‘Non-conformance’ and 1/4 or less of relevant action items are evaluated as ‘Partial conformance’, and a corrective action plan is in place for such items.

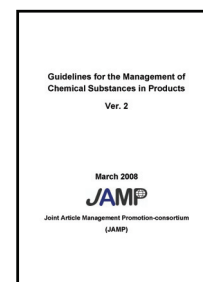
Self-Declaration of Conformance Regarding Systems for Managing Chemical Substances in Products

This document declares that our company has systems in place for managing chemical substances in its products and that such systems are functioning effectively.

1. Number:
2. Subject of declaration:
3. Issuing authority:
Company name :
Address :
4. The subject of the declaration above complies with requirements specified in the documentation below:
Document name: Guidelines for the Management of Chemical Substances in Products
Version no. : 2
Date of issue : March 2008
Issuing authority:
5. Additional information:
Score:
Other:
6. Place and date of issue:
Place :
Date of issue : XX (day), XX (month), XX (year)
Date of renewal: XX (day), XX (month), XX (year)
7. Representative, department:
Company name :
Person's name : Signature
Department :

If you have any queries regarding this declaration, please contact the person listed below:
Company name :
Person's name :
Department :
Telephone :
E-mail :

- Files provided
 - Guidelines for the Management of Chemical Substances in Products (Ver. 2)
 - provided in PDF format.
 - Action Item List/Check Sheet for Guidelines for the Management of Chemical Substances in Products
 - provided in MS-Excel format
 - Standard form for self-declaration of conformance
 - provided in MS-Excel format



These files are also available on the JAMP website for free download.

For implementing management of chemical substances in products in entire supply chain

- The goal is to expand the management system to an entire supply chain, with visible effects of manufacturers' actions in accordance with the Guidelines for Management of Chemical Substances in Products.
- To achieve this goal, it is important that more and more companies are implementing self-declaration of conformance seriously and such efforts are consequently accepted and appreciated by buyers and consumers.