Guidelines for the Management of Chemical Substances in Products

Ver. 2

March 2008

Joint Article Management Promotion-consortium (JAMP)

Introduction to These Guidelines

Authors and Publication of Guidelines

These Guidelines for the Management of Chemical Substances in Products have been prepared by the Joint Article Management Promotion-consortium（JAMP） and the Japan Green Procurement Survey Standardization Initiative (JGPSSI).

JGPSSI published Ver. 1 of the Guidelines for the Management of Chemical Substances in Products in September 2005, and JAMP subsequently published Ver. 1 of the Guidelines for the Management of Chemical Substances in Products for its members in July 2007 and proceeded with verification. However, since both guidelines have a common root, joint investigations were enthusiastically conducted by the two parties based on investigations by the JAMP Committee for Preparation and Proliferation of Management Guidelines and the JGPSSI CP Investigation Working Group, and discussions between JGPSSI and JAMP, to evolve the guidelines, and to proliferate the concept of management of chemical substances in products. The summary of this series of investigations was approved by both JGPSSI and JAMP, and each organization then published Guidelines for the Management of Chemical Substances in Products with the same content.

Requirements for Management of Chemical Substances in Products Shown in These Guidelines

These guidelines are intended to provide practical support for organizations engaged in management of chemical substances in products, forming a basis for provision of information on the products and contained chemical substances. Common requirements for management of chemical substances in products to be dealt with by organizations engaged in the manufacture or sale of products using chemical substances in the supply chain are therefore shown as Action Items (Chapter 5).

Within the context of strengthening and expansion of regulations for chemical substances in products, improvement in management of the entire supply chain to a target level is a matter of urgency. While management of chemical substances in products is a matter for individual organizations, these guidelines are a collection of the knowledge of a large number of companies and related organizations, and as such provide effective encouragement in this endeavor. When a structure and system for management of chemical substances in products has been established, a more efficient and reliable implementation of management can be expected through reference to the management requirements described in these guidelines.

The requirements for management of chemical substances in products described in these guidelines require modification and renewal in response to knowledge obtained through practical management of chemical substances in products, and through progress made with experience, and must be updated in response to related legal restrictions. Even though technically possible, it is not intended that the requirements for management of chemical substances in products of these guidelines be used as requirements for third party certification systems.

Self-declaration of Conformance Based on These Guidelines

Self-declaration of conformance under these guidelines implies an assertion and an undertaking by the responsible person in the organization to:

(1) Develop and put into practice a management structure in accordance with these guidelines, or

(2) Develop and put into practice a management structure in accordance with criteria and policies which are equal to or better than those existing, and which satisfy the management requirements described in these guidelines.

Practical criteria and methods for self-declaration of conformance are described in Chapter 6.

Earnest self-declaration of conformance by large numbers of enterprises, its acceptance by purchasers, and it being held in sufficient regard, are important to the effective operation of self-declaration of conformance and its healthy development.

Standards Referenced in These Guidelines

These guidelines reference ISO Guide 72:2001. Self-declaration of conformance under these guidelines references the Japanese JIS Q 17050-1:2005 and JIS Q 17050-2:2005 (international standards ISO/IEC 17050-1:2004 and ISO/IEC 17050-2:2004).

Contents

1. Background

[International Initiatives for Management of Chemical Substances]
'Agenda 21' adopted by UNCED (United Nations Conference on Environment and Development) in 1992 is a practical action plan for implementation of sustainable development for the 21st century. Agenda 21 requires 'provision of information related to toxicity and risk, and strengthening of efforts for the international management of chemical substances' as a basic direction and topic for management of chemical substances.

The international summit conference held ten years later in 2002 agreed 'to minimize the serious adverse effects on human health and the environment of the manufacture and use of chemical substances by 2020' within the context of providing an appropriate response to problems related to human health and the environment, and agreed to develop the Strategic Approach to International Chemicals Management (SAICM) as one measure. SAICM agreed upon in 2006 aims at the implementation of appropriate management of all chemical substances, including products incorporating chemical substances, and fabricated products, throughout the life cycle of all chemicals.

[Expansion of Regulations Related to Chemical Substances in Articles]
Evaluation and management of chemical substances currently in use is progressing in association with the international expansion in management of chemical substances. Obligations for prior assessment were imposed on companies only for new chemical substances due to the belief that 'long-term use of existing substances presents no problems' and 'natural substances are safe', together with the difficulties involved in investigating all existing substances. However, progress in the technology of analysis has shown that extremely small amounts of chemical substances which are bioaccumulative, and which are persistent, are present over a wide range within the environment. The scope of management of these substances, for example, the effect on the ecosystem, is expanding, and international organizations, national governments, and international chemical companies are cooperating in investigation of existing chemical substances.

Regulation of toxic substances (e.g. suspect substances) in articles (e.g. automobiles, electrical and electronic equipment and related parts and packaging materials, fabricated products), and demands for international provision of information on contained substances, is increasing. Since management of chemical substances has conventionally considered effects on human health, management of chemical substances in articles has been focused on regulation of leakage (elutes) and emissions. This is due to the fact that the chemical substances in the articles are enclosed within a solid matrix, moving only slowly to the surface and the exterior, and were consequently thought to have minimal effects on human health. On the other hand, the trend towards regulation of content, before considering the possibility of exposure, is increasing. The purpose of regulation of chemical substances in articles, and the demand for disclosure and transmission of information, is to increase the safety and efficiency of recycling, and to reduce the effects of products in use, and processing of used products, on human health and the ecosystem.

Regulations related to chemical substances in articles are expanding worldwide. This is an important problem for all manufacturing sectors, and an efficient response is necessary to succeed in the face of

strong competition.

[The Need for Cooperation Between Enterprises in the Supply chain]
Sale of products in overseas markets requires a response to the regulations of each country on chemical substances in articles, and cooperation among enterprises in the supply chain (manufacturers of chemical products, parts, and final assemblies) is important in management of the chemical substances in each product, and in transmitting this information.

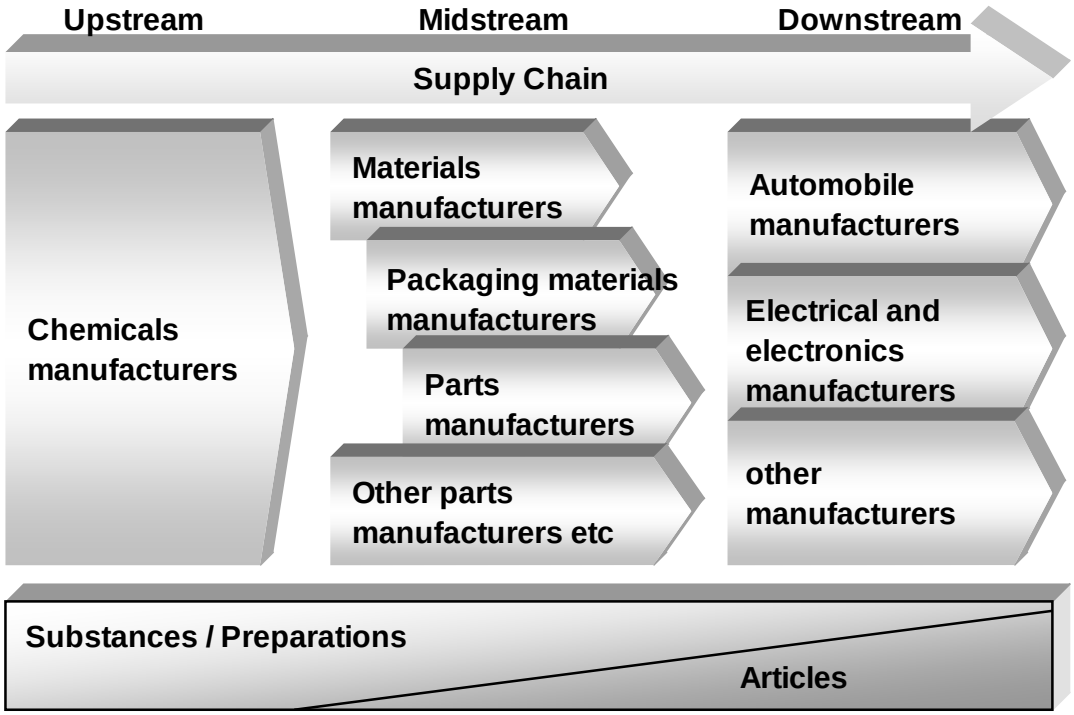

Figure 1-1 Manufacture of Articles Through the Supply Chain

Voluntary regulation and standardization has been implemented for some time in such areas as construction materials, food containers, and toys. Voluntary regulations for food containers in Japan is a good example.

In the area of automobiles, an international data collection system has been developed to collect information on materials and contained chemical substances, and is used by the primary automobiles manufacturers and their suppliers.

In the area of electrical and electronic products, substances to be investigated, and a common format for the investigation, have been considered in order to investigate efficiently the chemical substances contained within parts and raw materials. This format is currently being adopted worldwide.

Requirements for management of chemical substances in products have been developed to improve the reliability of information on contained chemical substances, and their use is currently increasing.

A structure for management of information on chemical substances contained in products supplied through the supply chain, and its disclosure and transmission in order to manage the use of substances/preparations in manufacture of articles, is considered across industrial sectors, and use is expanding.

The appropriate information on chemical substances in products must be received via the supply chain in order to respond to regulation of chemical substances contained in articles. However, the structure for management of chemical substances in products throughout the entire supply chain (from upstream to downstream), at which forms the basis for the sending and receiving of information, cannot be said to be sufficiently established.

Cooperation between companies, from upstream to downstream, is essential in ensuring that responses to strengthening and expansion of regulations on chemical substances in articles for the purpose of life cycle management of chemical substances are free from confusion, efficient, and reliable. Companies in the supply chain associated with the manufacture of articles are required to (1) manage and prepare the necessary information on chemical substances in products for compliance with statutes of each country based on common rules, and (2) to provide downstream enterprises with the information. For this purpose, management throughout the supply chain together with information-provision chain is necessary. Accordingly, upstream, mid-stream and downstream enterprises are required to fulfill each role.

2. Definition of Terms

Terms	Definition and description
Substance (chemical substance)	A chemical element or compound that either exists in nature or is obtained via a manufacturing process. A substance includes impurities introduced in manufacturing processes, and additives required for maintenance of stability. Solvents that can be separated without affecting the stability of the single chemical substance or without changing its composition, are excluded from this definition. Examples: Lead oxide, nickel chloride, benzene Sorting by CAS number is effective when processing large amounts of data, however care is required since CAS numbers and substances do not always directly correspond, and in some cases the relationship may be one-to-many, many-to-one, or more rarely, many-to-many. 'Substances', in some cases, do not have a CAS number, and rules for CAS use are therefore necessary between users.
Preparation (mixture)	A mixture intentionally comprising two or more individual chemical substances. Examples: Paints, inks, solders prior to use, adhesives, alloys.
Article (product formed into a shape)	An item of specific shape, appearance, or design provided during manufacture which determines functions in final use at a level beyond that provided by its chemical composition. [Reference 1] TSCA Definition The United States' Toxic Substances Control Act (TSCA) refers to an 'article' as a 'product' or 'goods', and defines an 'article' as an item that: - Is formed into a specific shape or design during manufacture, - Has end use functions dependent in whole or in part upon its shape or design during end use, - Has either no change of chemical composition during its end use, or only those changes of composition which have no commercial purpose separate from that of the article, with the added provision in the United States Occupational Safety and Health Agency Hazard Communication Standard and the Code of Federal Regulations (CFR) Toxic Chemical Release Reporting (40 CFR Part 372) that the item 'does not release a toxic chemical under normal conditions of processing or use', where - Fluids or particles are not considered articles regardless of their shape or design. Examples: Molded objects such as personal computer keyboards and main units. The application of the terminology is broader than that of Original parts. [Reference 2] REACH Definition The European Union's REACH (Registration, Evaluation and Authorization of Chemicals) regulations provide the following definition: - An article is an object made from a chemical substance or mixture that is given a specific shape, appearance, or design in manufacturing that determines the ultimate function in use more than does the chemical composition thereof.

Terms	Definition and description
Raw material	Liquid chemical products such as paints, pellets and particles such as polymer pellets and master batches, materials such as solders used in a molten state, which are converted to other chemical products (substances/ preparations) and articles. Materials often referred to as subsidiary materials (e.g. greases and oils, paints for identification purposes) can be considered as raw materials when they remain in the product.
Original part	An article first made from substances/preparations through a process of forming, drying, heating, and application in which its chemical content is fixed. Examples: Plastic cases, a key on a personal computer keyboard, solder after use, a condenser
Part	An article manufactured by combining and/or processing original parts.
Product	A product refers to that which is shipped to the market by a company. This includes not just the final product, but also materials, parts, and semi-completed goods requiring further processing or conversion prior to being sent to the market.
Manufacturing process	Manufacturing is divided into four manufacturing process - manufacture of substances/preparations, manufacture of original parts, manufacture of parts, and manufacture of completed products. These four manufacturing processes are each comprised of purchasing, manufacture, and sales activity.
Unit process	Purchasing, manufacturing, and sales actions for each substance/preparation and articles respectively, resulting in a total of six actions (purchasing, manufacturing, and sales) as unit processes for management.
Management framework	A management framework for chemical substances in products comprised of the framework of the management items I-VI for each of the six unit processes, and the common management framework (VII) being common management items (e.g. policy and planning formulation).

Terms	Definition and description
Inclusion of substances to be managed, and impurities	'Inclusion of substances to be managed' refers to the detection of constituents and content of products as managed substances. Impurities have no role in specific functions of the product, however they are detectable, and have CAS numbers (or other identifying numbers) distinct from the CAS numbers of substances in the product (or other identifying numbers). Impurities remain following the general industrial refining stage. However these impurities and residues are considered not to be included (apart from the case in which they exceed thresholds and permissible values as specified by national and international regulations) if they cannot be predicted by technical methods, or are in trace amounts and therefore no substance information is available.
Substance to be managed	Substances determined by the company, on the basis of regulations and industry standards, to be subject to management.
Supply chain	The supply chain generally refers to the series of operations linking supplier to consumer, from development through procurement, manufacturing, distribution, and sale. In this document, this extends to manufacture of the final product, where the supply chain relates to materials manufacturers, original parts manufacturers, parts manufacturers, and set manufacturers etc.
Self-declaration of conformance	Self-declaration of conformance in this document is the assertion and an undertaking by the responsible person of development of a structure and system in accordance with these Guidelines for the Management of Chemical Substances in Products within the management system of the organization. Self-declaration of conformance in this context is in accordance with the Japanese JIS Q 17050-1:2005(International standards ISO/IEC 17050-1:2004).
MSDS	The abbreviation of Material Safety Data Sheet. Referred to as SDS (Safety Data Sheet) in the EU, and as the Safety Data Sheet for Chemical Products under ISO standards (ISO 11014-1). A document created and provided for companies who handle chemical substances, so that the environment and human health may be protected, work safety may be maintained, and necessary measures may be addressed. In Japan, submission of the MSDS is required by the Industrial Safety and Health Law, the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR Law), and the Poisonous and Deleterious Substances Control Law. The form is stipulated in ISO11014-1 (corresponding JIS: JIS Z 7250) and guidelines for the preparation of the MSDS are published by the Japan Chemical Industry Association.
JAMP MSDSplus	A data recording format for transmission of necessary substance information for preparation of AIS to augment MSDS in relation to substances/preparations. Abbreviated as MSDSplus under these guidelines.

Terms	Definition and description
JAMP AIS	A data recording format for disclosure and transmission of information on substances contained in articles. Referred to as AIS (Article Information Sheet) in these guidelines.
JIG	Guidelines regarding disclosure of information related to chemical substances in products, created jointly by the JGPSSI, EIA and EICTA and issued after approval of the JGPSSI and EIA. Referred to officially in English as the 'Joint Industry Guide (JIG) for Material Composition Declaration for Electronic Products' and issued by the EIA. The Japanese version of this guide is issued by the JGPSSI. The guide is abbreviated as the JIG.
JGP file	Refers to the JGP file format established by the JGPSSI, for electronic files used in standardized green procurement survey responses. JGP files establish the types of response data, the sequence of response data, and the data delimiters (tab characters). The 'Survey Response Tools' in Excel format is provided by the JGPSSI as a freeware template for creating JGP files. In association with introduction of the JIG, the JGPSSI will propose a JGPSSI-recommended format meeting JIG standards and release Survey Response Tools Ver. 3 (standard and detailed), an upgraded version of the existing Survey Response Tools Ver. 2.
JAMA/JAPIA integrated data sheet	As a result of progress towards standardization of surveys to determine environmental load of substances in the automobile sector (requiring integration of report requirements and coordination with IMDS (International Material Data System)), the Japanese Automobile Manufacturers Association (JAMA) and the Japanese Auto Parts Industries Association (JAPIA) agreed on a format for use in surveys of materials and compounds contained in products in response to environmental regulations. IMDS is a system for the collection of information on materials and substances in automobiles developed in 1998 by EU and US automobile manufacturers in response to the EU's ELV Directive on automobile disposal. IMDS is currently used worldwide by the major automobile manufacturers.
CAS Registry Number	A system of numbers applied to chemical substances by the Chemical Abstracts Service (CAS) of the American Chemical Society.

3. Role of These Guidelines

3.1 Purpose of These Guidelines

These guidelines focus primarily on the main point of management of contained chemical substances – the process of converting substances/preparations to articles, to ensure that the management of contained chemical substances is conducted efficiently and rationally throughout the entire supply chain. A further focus is placed on the processes before and after the core process, noting the requirements for standardized management of contained substances to ensure accurate and efficient management of contained chemical substances.

Use of these guidelines by the various companies connected to the supply chain, from upstream to downstream, is designed to assist in the integrated use of information related to contained substances.

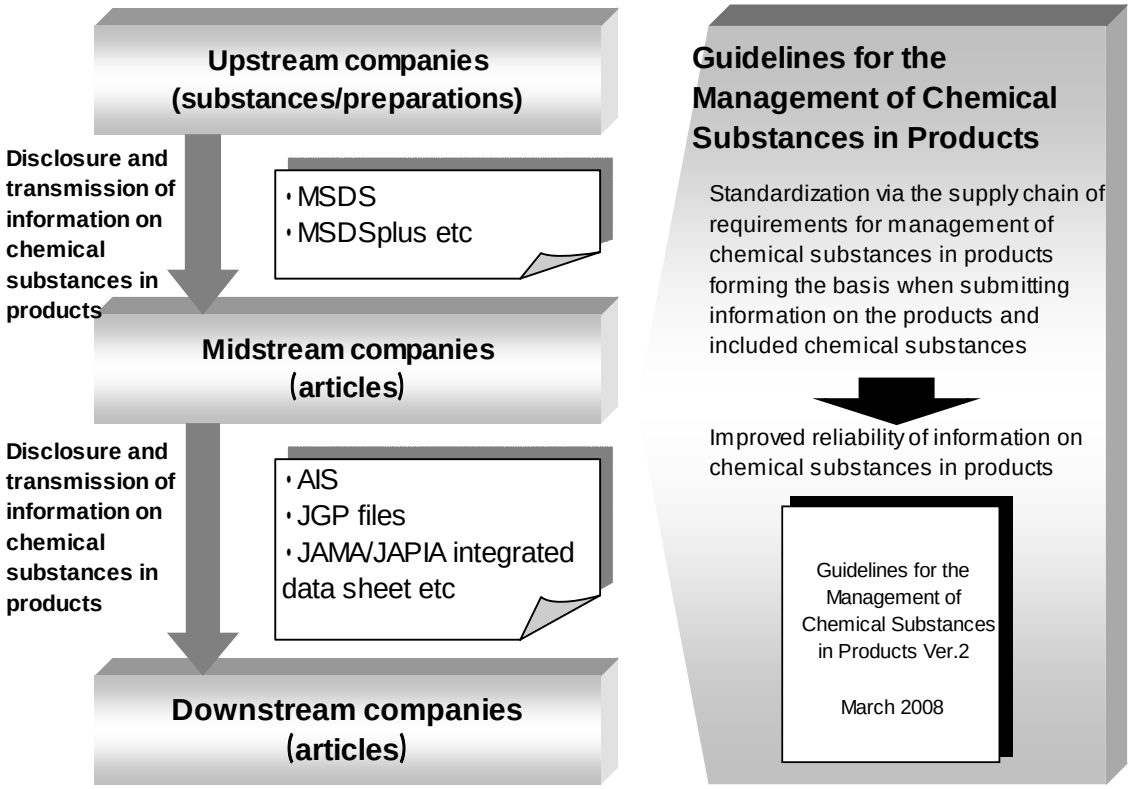

Figure 3-1 Management of Chemical Substances in Products, and Related Transmission of Information on Contained Chemical Substances

3.2 Applicable Industries

These guidelines apply to all industries in supply chains for manufacture of articles.

Manufacturers within the supply chain, including manufacturers of chemical products supplying substances/preparations, parts manufacturers manufacturing articles from purchased substances/preparations, manufacturers of products such as automobiles and electrical and electronic

equipment manufacturing new articles (e.g. assembled products) from articles such as parts. These guidelines are designed for reference by enterprises irrespective of position in the supply chain - for example, paint manufacturers, manufacturers of molded plastic products, manufacturers of coatings, plating firms, and firms involved in the assembly of parts.

3.3 Anticipated Users

Anticipated users of these guidelines are as follows:

(1) Parties Responsible For Developing and Verifying Systems for Management of Chemical Substances in the Products of Their Firms

These guidelines are considered as a reference when systems for managing chemical substances in products are developed in individual firms.

When the systems are developed within the company, the parties with primary responsibility for developing the systems engage in the work after referencing these guidelines. These guidelines can be used as training tools within the company after the systems have been developed, making it possible to insure a shared knowledge of the critical points of the system for managing chemical substances in products.

Moreover, in organizations which have already developed systems for management of chemical substances in products in accordance with equal or higher standards or directives, these guidelines may be used to verify that the implemented structure actually satisfies the management requirements, and as reference when making any necessary improvements.

Furthermore, these guidelines may also be used when the firm's compliance department performs an internal audit to determine whether or not the system for managing the chemical substances in products is functioning.

(2) Individuals Auditing the Systems for Managing Chemical Substances in Products on the Supplier Side

These guidelines are anticipated to be used as a reference by external organizations, including purchasers, in order to confirm whether a system for managing chemical substances has been developed by the supplier.

3.4 Units and Targets of Management

The units and targets for management in these guidelines are described below:

(1) Units for Management

In these guidelines, the unit for managing chemical substances in products is envisioned as the 'organization', rather than the 'product'. Here the term 'organization' indicates companies, corporations, business departments, and individual contractors, and part or complete combinations of the above.

Example: ○○ Inc. ○○ Factory, ΔΔ Inc. ΔΔ Division, xx Group xx Product Division

(2) Substances Subject to Management

Substances subject to management, and provision and receipt of information, are as determined by a consensus of related persons in consideration of all industries in the supply chain. Not specified in these guidelines. Industry standards are to be followed in addition to the relevant statutes.

3.5 Use of These Guidelines

These guidelines may be used by following the flow described below:

(1) Develop the Management System

The first task to be performed by each company in the supply chain is to develop and verify a system for managing the chemical substances contained in its products. Although the optimal form of the management system will vary depending on the type of industry, industry conditions, and details of the company's operations, these guidelines will serve as a reference during development of management systems.

(2) Declare Development of the Management System

These guidelines employ self-declaration of conformance as a method of indicating to external organizations (e.g. purchasers), that a management system satisfying requirements for management of chemical substances in products in these guidelines has been developed. Refer to Chapter 6. Using These Guidelines for evaluation of conformance of action items and criteria for self-declaration of conformance.

Note that these guidelines provide only information to serve as a reference in developing the system for managing chemical substances in products. The self-declaration of conformance for developing the system based on these guidelines does not form a guarantee for commercial transactions between the supplier and the purchaser.

3.6 Adoption of These Guidelines

These guidelines may be freely used by companies which do not belong to JAMP/JGPSSI. Companies improving management of chemical substances in products in-house, and companies requiring management in relation to suppliers, should understand fully the content of these guidelines and follow their intent.

3.7 Incorporation in Existing Systems (e.g. ISO 9001, ISO 14001)

Depending on the decision of the company undertaking the management, it is also possible to employ existing structures such as ISO 9001 (ISO/TS16949) and ISO 14001 in the structure for management of chemical substances in products. While it is possible to develop a new structure, the use of an existing structure is recommended if possible. It is, however, necessary to ensure that the action items in these guidelines are satisfied in practice.

The action items of these guidelines and ISO 9001 and ISO 14001 are compared in Reference 1.

4. The Basis of Management of Chemical Substances in Products

The basis of management of chemical substances in products is to pay attention to the form in which chemical substances exist (substance/ preparation, or article), and apply the appropriate management in each stage (purchasing, manufacture, and sales). Management of chemical substances in this context is not a matter of safety management and handling management, but of the requirements for smooth disclosure and transmission of information on chemical substances in products.

4.1 Principles

The management of chemical substances in products can be described as 1) acquisition of content information for purchased materials (IN information), 2) manufacture of products using those materials in a manufacturing process, and 3) provision of content information for the products sold (OUT information). These three processes must be managed throughout the entire supply chain.

1) Chemical Substances Information for Products Purchased (IN): Obtain content information (IN information) for each substance/ preparation and article, and confirm the reliability of the content information.
2) Manufacturing Process Information: Increase the reliability of daily management activities, such as preventing incorrect use, mixture, and contamination.
3) Chemical Substances Information for Products Sold (OUT): Increase the reliability of content information provided for each substance/preparation and article.

4.2 Processes of Converting Substances/Preparations to Articles

Looking at the supply chain through the example of a personal computer, upstream we have parts manufactured from substances/preparations such as polymer pellets (articles manufactured initially from substances/preparations) which are in turn assembled into parts and final products. Since the types and amounts of chemical substances in articles manufactured from substances/preparations are fixed, these articles are referred to as ‘original parts’.

It is important to accurately manage the ‘amount of chemical substances’ contained in the original parts in order to manage chemical substances in products. In practice, it is not only necessary to understand the amount of chemical substances contained in raw materials used in manufacture of original parts, but also to manage change in these amounts in the process of conversion to articles, changes in the chemical substances themselves, and contamination in the process of manufacture of original parts.

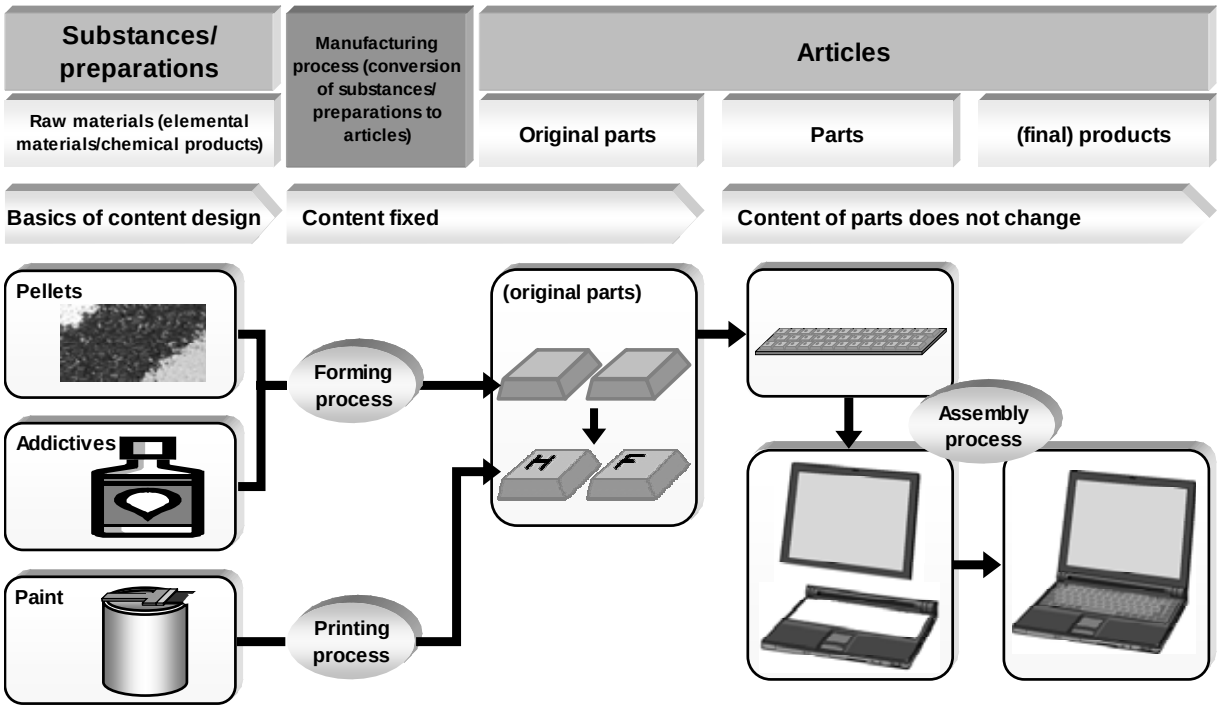

Figure 4-1 Process of Conversion from Substances/Preparations to Articles in the Supply Chain

In the case of 'painting', a representative example of conversion to an article, the 'paint' preparation is applied to the steel sheet parent material (i.e. the article), to produce a new article (painted steel sheet). The constituents of ordinary paint are a solvent (a substance), of which all or part is a volatile material (constituent subtraction), a solid component which remains on the parent material, forming a film on the parent material and having a fixed concentration of each substance. In the case of a 'UV paint' (paint based on photo-hardening resins), a mixture of a photo-initiator and a reactive monomer (preparations), and a polymer as an anti-shrinkage agent, is applied to the steel sheet parent material, part of which undergoes a polymerization reaction under the effects of light, and is converted to a different polymer. The constituents of the paint are thus fixed, forming a paint film on the surface of the parent material.

In the case of 'non-electrolytic plating', the metal part to be plated is immersed in a 'plating fluid' (a preparation) containing a reducing agent and a compound comprising a form of the metal to be applied as plating. The metal precipitates onto the surface of the metal, and a new article, the plated metal part is produced. The metal component to be applied to the part is chemically transformed from a metal compound to a metal element.

In the case of 'aluminum die-casting', aluminum ingots are placed in a crucible and melted, and the molten metal poured into a die, cooled, and removed to produce a new article (an aluminum die-cast product). The ingots placed in the crucible are single constituents, and if no other substances/preparations are introduced, no significant change occurs in the constituents.

Examples of conversion of substances/preparations to articles, including the examples above, are shown in Table 4-1.

Table 4-1 Examples of Conversion of Substances/Preparations to Articles

Process	Substance/ Preparation	Original article	New article	
Painting	Paint	Parent material	Painted steel sheet	Volatile: Some or all of the original substances in the preparation evaporate and are lost (subtraction).
Printing	Ink	Parent material	Ink printed product	
Printing and firing	Glass paste	Parent material	Glass sheet with formed pattern	
Plywood gluing	Adhesive	Parent material	Plywood	
UV printing	UV ink	Parent material	UV ink printed product	Hardening: Conversion to a substance differing from the original, and hardening (conversion rather than subtraction).
Epoxy sealing	Epoxy resin	Sealed chip	Sealed semiconductor chip	
Plating	Plating fluid	Parent material	Plated parent material	Precipitation: Multiple chemical constituents of the preparation are mutually changed, and part of the substance appears on the surface of the existing article as a solid (conversion rather than subtraction).
Plastic molding	ABS pellets	–	ABS plastic case	Fusion: The original solid preparation is heated in order to physically change it to a liquid state (the constituents of the preparation are not changed in many cases).
Soldering	Solder	Circuit board	Soldered circuit board	
Die casting	Alloy, ingots	–	Die-cast part	

4.3 Seven Management Frameworks for Chemical Substances in Products

A variety of companies are involved in the supply chain, each having its own diverse manufacturing processes. The manufacturing process in which the substances/preparations are converted to articles is important in the management of the chemical substances in the articles.

The various manufacturing processes of the manufacturing companies associated with the supply chain may be generally classified as ‘substance/preparation manufacturing processes’, ‘original part manufacturing processes’, ‘parts manufacturing processes’, or ‘finished goods manufacturing processes’. While it is important to determine management methods for each process, each process has its own unit processes, for example, purchase, manufacture, and sales, and management methods may therefore be determined based on unit processes.

Of greater importance is the state of the chemical substances handled in each unit process – whether it is a substance/preparation or article, and management accordingly. When an understanding of the state of the

chemical substances is combined with the unit processes of purchase, manufacturing, and sales, all processes may be classified into six unit processes of purchase, manufacture, and sales of substances/preparations, and purchase, manufacture, and sales of articles.

All methods of supply chain management are determined once the management method is determined based on these six unit processes. Organizations involved in management of chemical substances in products must employ the relevant of the management frameworks I-VI. Management framework VII provides common management, and covers all organizations involved in management of chemical substances in products.

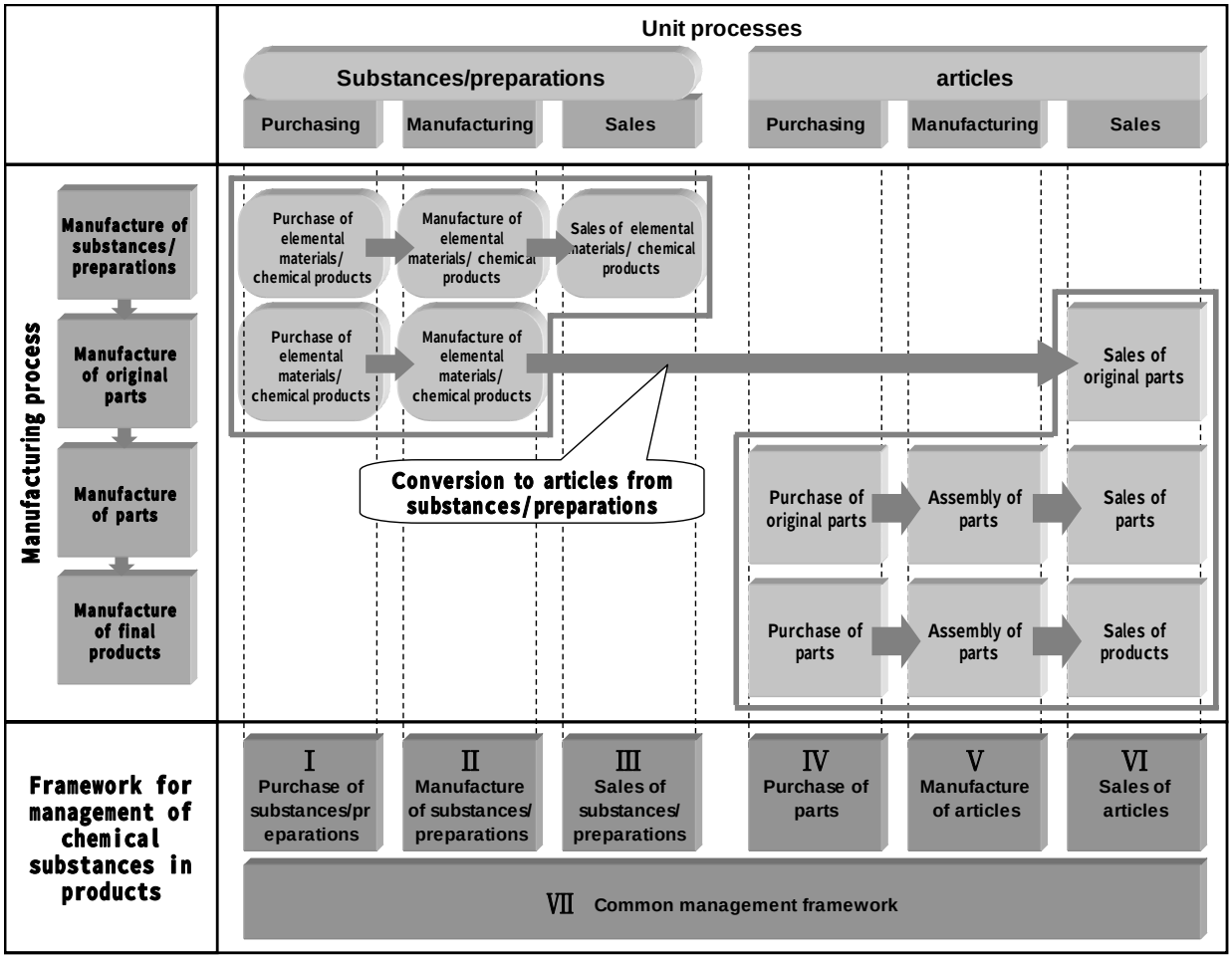

Figure 4-2 Seven Management Frameworks for Chemical Substances in Products

Apart from manufacturing industries, organizations such as sales companies, trading companies, and importers involved in sales of raw materials, original parts, parts, and final goods are also covered by these guidelines. Such organizations are involved in unit processes, and require internal management.

When reusing and recycling resources, management in accordance with these guidelines is necessary for sale and purchase of reused and recycled products.

4.4 Prioritized Management Considering Management Risks

The nature of the business, and the products, of companies involved in the supply chain are diverse, and it is desirable that each company employ its own sector knowledge, cooperate with other companies as necessary, and implement management of chemical substances in products in its processes. It is necessary that risks associated with management of chemical substances in products be predicted, evaluated, and the appropriate measures taken during such operations.

When companies are involved in management of chemical substances in products, it is important to focus on processes requiring management in the supply chain, and to prioritize management of processes (including purchase, manufacture, and sale) in which incorrect use or admixture of, or contamination with, managed substances is possible. Reference procedures for use in identifying items to be given priority in management are given below. Items to be given priority in management are included under action items, and may in some cases also be related to multiple action items.

(1) Verification of the Management Framework

- Verify the relevant management framework (I-VI) either in-house, or with subcontractors as necessary. Management framework VII is a common management framework, and as such requires a response by all organizations.
- Verify raw material, parts, and subsidiary materials.
- Verify equipment and jigs used in manufacture.

(2) 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.

It is important that companies having specialized and detailed knowledge of the raw materials used, and of the manufacturing processes, undertake to determine the items for prioritized management, and the response to those items, at their own responsibility. Furthermore, it is also necessary to illustrate the basis for this selection to upstream and downstream companies, and to request cooperation in management. The following provides examples of items considered to require prioritized 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 contained 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). A

different method of management may be necessary for recycled materials.
- Ores and natural materials.
- When contained chemical substances are unidentified.

[Original parts and parts]
- Original parts and parts manufactured from raw materials requiring prioritized management.

[Processes]
- Processes using raw materials requiring prioritized management.
- Processes using original parts and parts requiring prioritized management.

4.5 Upstream and Downstream Support for Companies for Which Autonomous Management is Difficult

In order to follow regulations for chemical substances in a single product manufactured via the supply chain, it is important to ensure that the management of chemical substances in products is appropriate in all companies involved in the chain.

In practice, however, many companies find autonomous management of chemical substances in products (e.g. data management, chemical reactions) difficult, notably mid-stream companies for which transmission of information on chemical substances in products is required.

It is therefore very 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.

4.6 Information on Chemical Substances in Products

When information provided on chemical substances in products is analytical data, it must be accompanied by scientific corroboration. Futhermore, it should be noted that the analytical data only represents data measured at a particular time and in a particular region chosen for analysis. Other information on chemical substances shall be furnished based on the corroborating and reasonable information, taking into consideration product design information and well-managed processes.
All companies involved in the supply chain must generally provide all of the information on chemical substances in products required to be submitted to related persons for management of chemical substances in products. Furthermore, 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.

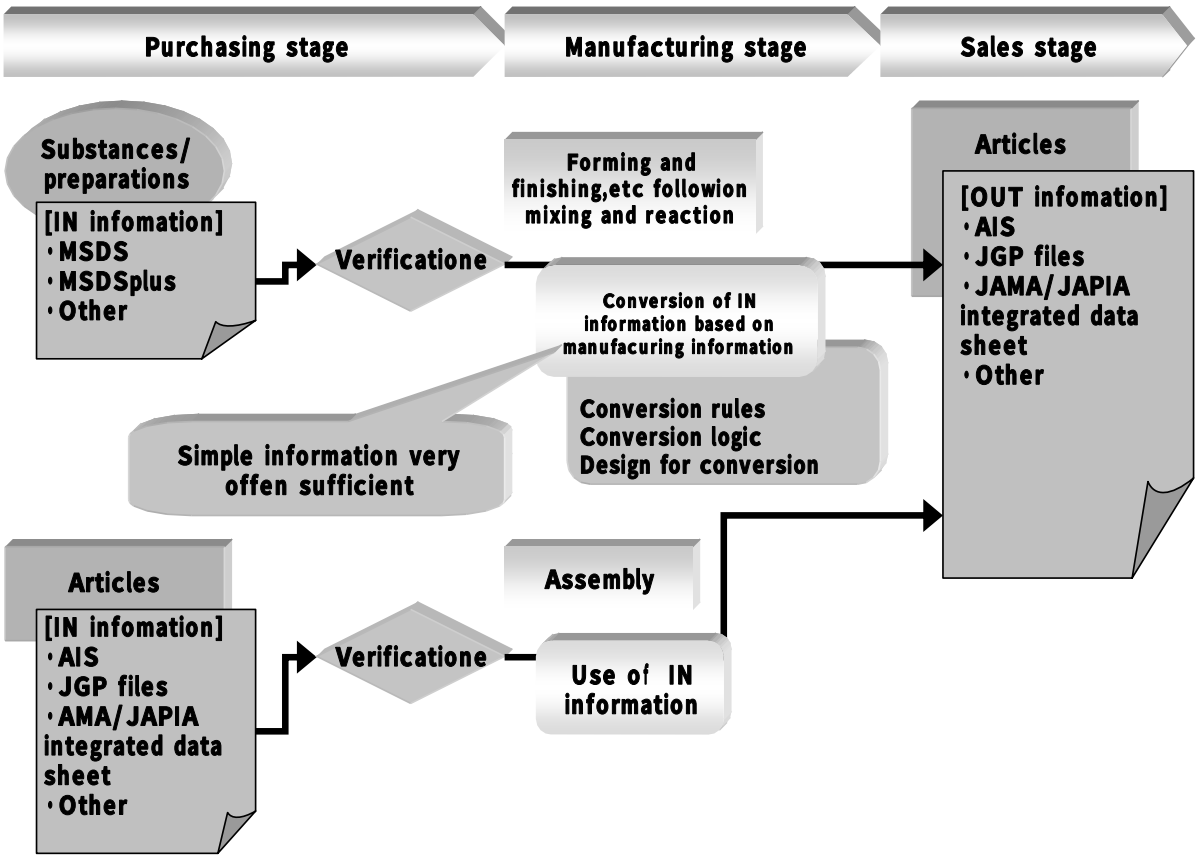

Figure 4-3 Flow of Information on Chemical Substances in Products

4.7 Protection of Company Secrets

Sufficient care must be taken of corporate secrecy protection when sending and receiving information. It is important to maintain corporate secrecy to ensure a healthy competition between companies. In particular, disclosure of the constituents of preparations and fabricated products may represent the manufacturer with serious problems. On the other hand, the information necessary under both domestic and overseas legislation must be provided, and corporate secrecy may be maintained by means of a secrecy agreement if necessary.

When purchasing, using, and disposing of products containing chemical substances which present risk factors, the names and composition of the chemical substances, and information on their effects on human health and the environment, are required throughout the supply chain, and implementation of appropriate risk management is required internationally. Submission of information related to chemical substances in products using MSDS etc is therefore regulated internationally for substances/preparations.

As described above, 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.

5. Action Items

Action items summarizing the actual points to be implemented in management of chemical substances in products in the seven management frameworks (I-VII) are shown on the following pages. The ‘Action Item List & Check Sheet’ (Annex 1) is used to evaluate whether the systems for managing chemical substances in products are properly developed and operated within companies implementing these guidelines.

In the Action Item List, the action items taken from among the frameworks I-VII have been organized and described using the PDCA format to ensure that items are easily understood. Note that PDCA refers to the act of ongoing improvement through performing a cycle of planning (P: establishing policies and plans), doing (D: implementing the plans and performing the operations), checking (C: evaluating and improving performance) and taking action (A: Performing a management review).

‘Systems (rules)’ must be created and ‘implemented (operated)’ to satisfy the requirements for action details in the Action Item List.

Action Items: These list the items required for managing chemical substances in products and comprise the major items from ‘Establishing Policies for the Management of Chemical Substances in Products’ to ‘Management Review’.

Action Details: Describe, in practical detail, what each action item is to accomplish.
Although it is important to have shared terminology throughout the entire supply chain, there may be cases where terms used are not understood in a specific industry. In such cases, ‘action details’ should be implemented according to the line of business of the relevant company based on an understanding and careful reading of the intent of the required management level and the ‘Additional Explanations and Cautions’. Since companies covering a diverse range of industries are involved in the supply chain, it is desirable that detailed explanatory material be prepared for each sector. Note that requirements for ‘action items’ not applicable to the company need not be satisfied.

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
1. Policy								VII
	●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.							
2. Planning								
2.1 Definition of Management Criteria								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	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
2.2 Definition of Scope of Management	● ‘ 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.							VII
2.3 Establishment of Objectives & Planning for Implemented Processes	●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.							VII
2.4 Definition of Organizational System, Responsibility & Authority	●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.							VII

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
3. Implementation & Management								
3.1 Design and Development								
3.1.1 Design for Manufacture of Substances/Preparations	●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. (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. (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.	I	II					

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
3.1.2 Design for Manufacture of Articles Using Substances/Preparations	●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. [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).	I	II					
3.1.3 Design for Manufacture of Articles Using Articles	●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. [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).				IV	V		

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
3.2 Purchase Management								
3.2.1 Verification and Acquisition of Chemical Substances in Products Information	●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. 【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.	I			IV			
3.2.2 Verification of Supplier Management Status	●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. 【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.	I			IV			

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
3.3 Acceptance Verification		I			IV			
	●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. [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.							
3.4 Process Management								
3.4.1 Preventing Incorrect Use, Admixture, and Contamination			II			V		
	●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. (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.							

Action Items		Action Details	Management Framework						
			I	II	III	IV	V	VI	VII
	3.4.2 Appropriate Management of Reaction Processes	●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. 【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.		II					
	3.4.3 Management of Sub-contractors	●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.		II			V		

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
3.5 Shipping Verification				III			VI	
	●Products shall be shipped after verification that all specified items have been checked, including cases of implementation during acceptance, or during a process. 【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.							
3.6 Traceability								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.							

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
3.7 Change Control	●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. 【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.							VII
3.8 Non-conformity Response	●Rules for measures to deal with non-conforming products (emergency measures, determination of causes, preventing reoccurrence, horizontal deployment etc) shall be determined. 【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.							VII

Action Items	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
4. Management of Human Resources, Documentation, and Information								
4.1 Training								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.							
4.2 Management of Documentation and Records								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. 【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.							
4.3 Communication (Provision of Information)								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	Action Details	Management Framework						
		I	II	III	IV	V	VI	VII
5. Performance (State of Implementation) Evaluation and Improvement								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)								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.							

6. Using These Guidelines

6.1 Criteria for Conformance Evaluation

(1) Verification of Management Frameworks for Company Processes

For each action item, select the relevant management framework (I-VII) for the unit process of the company developing the management system. If none of the management frameworks are relevant, note the reason clearly.

(2) Conformance Evaluation for Each Action Item

Evaluation of whether the system for management of chemical substances in products has been developed and is in operation is conducted for each action item in the following four criteria. When other management structures for management of chemical substances in products have been developed and implemented in accordance with criteria and policies equal to or better than those of these guidelines, the judgment is made in substance for each action item.

Table 6-1 Criteria for Conformance Evaluation for Each Action Item

Evaluation	Criteria	Evaluation criteria	
		Rules	Operation
Conformance	Evaluated as 'Conformance' when the appropriate rule (structure) and operation (action) based on the rule to satisfy the action item are implemented. Results of the rule and operation documented are recorded for objective verification.	○	○
Partial conformance	Evaluated as 'Partial conformance' when the appropriate rule (structure) to satisfy the action item is implemented, however only part of the operation (action) is implemented and results are insufficient, or the operation to satisfy the action item is implemented, however only part of the rule is implemented and results are insufficient. In either case, it is important that actual operation is sufficient and the level of 'Partial conformance' is reached. Results of the rule and operation documented are recorded for objective verification.	○	Δ
		Δ	○
Non-conformance	Evaluated as 'Non-conformance' when any of the following are satisfied. (1) When a rule (structure) to satisfy the action item is implemented (including the case of 'Partial	○	×
		×	○
		Δ	Δ
		Δ	×
		×	Δ
		×	×

	conformance'), however operation (action) based on the rule has not been implemented. (2) Operation for the action details has been implemented (including the case of 'Partial conformance'), however there is no rule. (3) A rule exists, however it is lacking in some areas. Operation is implemented, however it is lacking in some areas.	
Not applicable	Evaluated as 'Not applicable' when the action item is not subject to management by the company.	–

○: Required level item is satisfied
Δ: Some actions are performed but partially insufficient
×: Required Level is not satisfied

(3) Total Evaluation

Deemed as 'passed' when the following criteria are satisfied for each action item.

Table 6-2 Total Evaluation Criteria

Total evaluation criteria	- When all relevant items for the action item are evaluated as 'Conformance', or - When there is no 'Non-conformance' and ¼ or less of relevant action items are evaluated as 'Partial conformance', and a corrective action plan is in place for such items.

(4) Scoring of Conformance of Action Items

As reference information, 3 points are assigned for 'Conformance', 2 points for 'Partial conformance', and 0 points for 'Non-conformance'. The maximum score is converted to 100 points. Since the maximum score changes when there are 'Not Applicable' items, these items are excluded and the maximum score converted to 100 points.

Table 6-3 Scoring of Action Items

Total score/(number of relevant action items x 3) x 100 = Score converted into maximum score of 100 points (evaluation points)

Evaluation points are not evaluation criteria. This scoring is employed by the company or supplier in verifying progress of development of the system for management of chemical substances in products.

6.2 Self-Declaration of Conformance

Self-Declaration of Conformance is a declaration that the company's system for managing chemical substances in products has been developed and implemented in conformance with these guidelines.

(1) Purpose of Self-Declaration of Conformance

To evaluate the system for management of chemical substances in products within the company, understand weaknesses, make improvements, and provide highly reliable data to the supply chain. Furthermore, to engender confidence by publicly disclosing actions taken by the company in management of chemical substances in products.

(2) Responsibilities Associated with Self-Declaration of Conformance

Rules 1) - 6) below should be followed when making the Self-Declaration of Conformance.

1) A company must assume its own responsibility for the contents of the Self-Declaration of Conformance.
2) Records for conformance validation must be stored. The period of storage may be decided at the discretion of the company.
3) Details of self-declaration must be included in the Self-Declaration of Conformance. Refer to the example of a Self-Declaration of Conformance in Annex 2.
4) The Self-Declaration of Conformance must be presented when there is a request from either inside or outside the company.
5) Details in the Self-Declaration of Conformance must reflect ongoing operations, and conformance to these guidelines must be validated periodically.
6) Results scored in the Check Sheet must be noted in the Self-Declaration of Conformance.

6.3 Disclosure of Validated Records

Self-declaration of conformance is conducted at the company's responsibility, and purchasers may request suppliers for disclosure of records for compliance validation related to the self-declaration. In such cases, it is desirable that validation records be disclosed after mutual consultation.

Attachment 1: Comparisons Between Action Item List and Existing Systems

The table below shows a technical comparison between the action items for these guidelines for management of chemical substances in products, and the quality and environmental management systems. The purpose of the comparison is to provide information for reference when companies already using one or both standards develop a new management system for chemical substances in products, and verify the efficacy of that system.

Correspondence between items is apparent when there is a certain degree of matching between action details for the various items, however it is necessary to be aware that in other cases there is a comparatively weak relationship between items.

Guidelines for management of chemical substances in products	ISO 9001:2000	ISO 14001:2004
	4. Quality Management System	4. Environmental Management System Requirements
1. Policy	5.1 Management Commitment 5.3 Quality Policy 8.5.1 Continual Improvement	4.2 Environmental Policy
2. Planning		
2. Planning 2.1 Definition of Management Criteria 2.2 Definition of Scope of Management	5.2 Customer Focus 7.2.1 Determination of Requirements Related to the Product 7.2.2 Review of Requirements Related to the Product	4.3.1 Environmental Aspects 4.3.2 Legal and Other Requirements
2.3 Establishment of Objectives & Planning for Implemented Processes	5.4.1 Quality Objectives 5.4.2 Quality Management System Planning 8.5.1 Continual Improvement	4.3.3 Objectives, Targets and Programmes
2.4 Definition of Organizational System, Responsibility & Authority	5.1 Management Commitment 5.5.1 Responsibility and Authority 5.5.2 Management Representative 5.5.3 Internal Communication 6.1 Provision of Resources 6.3 Infrastructure	4.4.1 (Planning) Resources, Roles, Responsibility and Authority
3. Implementation & Management		

Guidelines for management of chemical substances in products	ISO 9001:2000	ISO 14001:2004
3.1 Design and Development	7.1 Planning of Product Realization 7.2.1 Determination of Requirements Related to the Product 7.2.2 Review of Requirements Related to the Product 7.2.3 Customer Communication 7.3.1 Design and Development Planning 7.3.2 Design and Development Inputs 7.3.3 Design and Development Outputs 7.3.4 Design and Development Review 7.3.5 Design and Development Verification 7.3.6 Design and Development Validation	4.4.6 Operational Control
3.2 Purchase Management	7.4.1 Purchasing Process 7.4.2 Purchasing Information 7.4.3 Verification of Purchased Products	
3.3 Acceptance Verification	7.4.3 Verification of Purchased Products	
3.4 Process Management	7.5.1 Control of Production and Service Provision 7.5.2 Validation of Processes for Production and Service Provision 7.5.5 Preservation of Product	4.4.6 Operational Control
3.5 Shipping Verifications	7.6 Control of Monitoring and Measuring Devices 8.1 (Measurement, Analysis and Improvement) General 8.2.3 Monitoring and Measurement of Processes 8.2.4 Monitoring and Measurement of Product 8.4 Analysis of Data	4.5.1 Monitoring and Measurement 4.5.2 Evaluation of Compliance
3.6 Traceability	7.5.3 Identification & Traceability	4.4.6 Operational Control
3.7 Change Control	7.3.7 Control of Design and Development Changes	4.4.6 Operational Control

Guidelines for management of chemical substances in products	ISO 9001:2000	ISO 14001:2004
3.8 Non-conformity Response	8.3 Control of Nonconforming Products 8.4 Analysis of Data 8.5.2 Corrective Action 8.5.3 Preventive Action	4.5.3 Nonconformity, Corrective Action and Preventive Action 4.4.7 Emergency Preparedness and Response
4. Management of Human Resources, Documentation, and Information		
4.1 Training	6.2.1 (Human Resources) General 6.2.2 Competence, Awareness, and Training	4.4.2 Competence, Training, and Awareness
4.2 Management of Documentation and Records	4.2.1 (Documentation Requirements) General 4.2.3 Control of Documents 4.2.4 Control of Records	4.4.4 Documentation 4.4.5 Control of Documents 4.5.4 Control of Records
4.3 Communication (Provision of Information)	7.2.3 Customer Communication	4.4.3 Communication
5. Performance (State of Implementation) Evaluation and Improvement	8.2.2 Internal Audit	4.5.5 Internal Audit
6. Management Review (Correction by Management)	5.1 Management Commitment 5.6.1 (Management Review) General 5.6.2 Review Input Review Output 5.6.3 Continual Improvement 8.5.1	4.6 4.6 Management Review

Attachment 2: Action Items Relevant to the Seven Management Frameworks for Chemical Substances in Products

The table below shows action items for the seven management frameworks for chemical substances in products. The action items in these guidelines are in PDCA format, and are provided as reference when verifying requirements for management of chemical substances in products necessary for the management frameworks.

Management frameworks		Relevant action items	
I	Substance/Preparation Purchasing	3.1.1	Design for Manufacture of Substances/Preparations
		3.1.2	Design for Manufacture of Articles Using Substances/Preparations
		3.2.1	Verification and Acquisition of Chemical Substances in Products Information
		3.2.2	Verification of Supplier Management Status
		3.3	Acceptance Verification
		3.7	Change Control
		3.8	Non-conformity Response
II	Substance/Preparation Manufacturing	3.1.1	Design for Manufacture of Substances/Preparations
		3.1.2	Design for Manufacture of Articles Using Substances/Preparations
		3.4.1	Preventing Incorrect Use, Admixture, and Contamination
		3.4.2	Appropriate Management of Reaction Processes
		3.4.3	Management of Sub-contractors
		3.7	Change Control
		3.8	Non-conformity Response
III	Substance/Preparation Sales	3.5	Shipping Verifications
IV	Article Purchasing	3.1.3	Design for Manufacture of Articles Using Articles
		3.2.1	Verification and Acquisition of Chemical Substances in Products Information
		3.2.2	Verification of Supplier Management Status
		3.3	Acceptance Verification
		3.7	Change Control
		3.8	Non-conformity Response
V	Article Manufacturing	3.1.3	Design for Manufacture of Articles Using Articles
		3.4.1	Preventing Incorrect Use, Admixture, and Contamination
		3.4.3	Management of Sub-contractors
		3.7	Change Control
		3.8	Non-conformity Response
VI	Article Sales	3.5	Shipping Verifications

Management frameworks		Relevant action items	
VII	Common Management Framework	1.	Policy
		2.	Planning
		3.6	Traceability
		3.7	Change Control
		3.8	Non-conformity Response
		4.	Management of Human Resources, Documentation, and Information
		5.	Performance (State of Implementation) Evaluation and Improvement
		6.	Management Review (Correction by Management)

Annex 1: Action Item List & Check Sheet

The Action Item List & Check Sheet is shown on the following pages. Also available in Excel format.

Guidelines for the Management of Chemical Substances in Products (Ver. 2) Action Item List & Check Sheet

Date prepared:	
Company name:	
Managed company:	
Person entering data section:	
Position:	
Name:	
Telephone:	
E-mail:	
Remarks:	

[Description of terms]

Action item:	A summary of requirements for management of chemical substances in products, classified into six broad categories of '1. Policy'-'6. Management Review', and further into 23 minor items.
Action details:	Action items describe the content to be put into practice. A common language throughout the entire supply chain is important in this section, however the appropriate expressions may be lacking in some industries. In this case, the concept for management of chemical substances in products and the intent of 'Additional Explanations' should be properly understood and 'Action Details' appropriate to the industry of the company implemented. If the noted action details are not applicable to the company, they need not be satisfied. For example, if the company has no design function, the action details in 3.1 Design Development may be considered as not applicable.
Additional Explanations:	Supplementing 'Action Items' and 'Action Details', and practical examples and reasons for implementation etc.
Management framework:	Items to be actioned for management of unit processes for substances/preparations and articles (4.3 in these guidelines). The position of each action item within the management framework is shown in this field. Used for entry in the 'Management Framework' field during compatibility checks.

[Entry requirements]

Step (1):	Clarify the framework required in the company's management scope, and place a check in the 'Management Framework' field (Ⅰ-Ⅶ) below.
Step (2):	Items to be included are those of the management framework fields for the Action Item List & Check Sheet for which● has been entered for the number of the management framework checked in Procedure (1).
Step (3):	Evaluation based on the criteria of Table 6-1 of these guidelines for each applicable action detail, and results entered with○ in the applicable position in the 'Evaluation' field (select from pull-down menu with Excel input). Enter 'Not applicable' if not applicable.
Step (4):	Enter facts as objective evidence of the evaluation in the 'Evidence' field separately for 'rules' and 'operation'. Enter the name of the document, and the details used in practical detail. If not applicable, enter reason(s) as comprehensively as possible. ※ Copies of documents may be attached as objective facts.

(The following procedures are calculated automatically with Excel input and are therefore not covered.)

Step (5):	Enter scores in accordance with the scoring method (* Note) described below for each action item evaluation result in Procedure (2). Leave the 'Score' field blank if 'Not applicable'. * Note: Action items are evaluated as 'Conforming' (3 points), 'Partial conformance' (2 points), 'Non-conforming' (0 points), or 'Not applicable' (leave blank).
Step (6):	Enter the total of all scores in the 'Total' field. The maximum score when all items are applicable (i.e. are all evaluated) is 69. This total is divided by 'three times the number of items scored', multiplied by 100, and rounded to an integer, to obtain the percentage score. The percentage score is obtained as follows. 〈Total score / (number of relevant action items x 3) x 100 = Score converted into maximum score of 100 points (evaluation points)〉
Step (7):	Perform an overall evaluation based on the criteria in Table 6-2 of these guidelines, and enter○ in the applicable field of 'Total Evaluation'.

[Management Framework]

From 'Management Frameworks (I - VII)', check all frameworks evaluated as necessary in the management scope of the company (VII is a common management framework for all organizations).

☐I ☐II ☐III ☐IV ☐V ☐VI ■VII

(Annex 1) Action Item List & Check Sheet Ver.2.1 (April 25, 2008)

(enter ○ in evaluation applicable result when hand-writing) (refer to Entry Methods)

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
1. Policy	● Declare items to be dealt with in management of chemical substances in products.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
2. Planning												
2.1 Definition of Management Criteria	● 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.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
2.2 Definition of Scope of Management	● '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.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
2.3 Establishment of Objectives & Planning for Implemented Processes	● Objectives and plans for management of chemical substances in products shall be prepared. Objectives and plans shall be revised as necessary.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
2.4 Definition of Organizational System, Responsibility & Authority	● Rights and responsibilities for management of chemical substances in products shall be clarified.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
3. Implementation & Management												
3.1 Design and Development												
3.1.1 Design for Manufacture of Substances/Preparations	●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.	(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. (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. (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 subs in substances/preparations.	•	•						*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.1.2 Design for Manufacture of Articles Using Substances/Preparations	● 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.	(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).	•	•						*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.1.3 Design for Manufacture of Articles Using Articles	● When manufacturing new articles from existing articles, information on chemical substances in articles (eg parts), and conformance of the product to the management criteria, shall be verified.	(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).				•	•			*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
3.2 Purchase Management												
3.2.1 Verification and Acquisition of Chemical Substances in Products Information	● 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.	(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.	•			•				*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.2.2 Verification of Supplier Management Status	● 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.	(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.	•			•				*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.3 Acceptance Verification	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.	(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.	•			•				*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.4 Process Management												
3.4.1 Preventing Incorrect Use, Admixture, and Contamination	● Implementation of measures to prevent incorrect use, admixture and contamination of chemical substances shall be subject to management.	(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. (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.		•			•			*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
3.4.2 Appropriate Management of Reaction Processes	● 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.	(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.		•						*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.4.3 Management of Sub-contractors	● Management of manufacturing sub-contractors shall be appropriate.	(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.		•			•			*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.5 Shipping Verification	● Products shall be shipped after verification that all specified items have been checked, including cases of implementation during acceptance, or during a process.	(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.			•			•		*Conforming *Partial conformance *Non-conforming *Not applicable	**Rules:** **Operation:**	
3.6 Traceability	● Product traceability shall be reliable.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
3.7 Change Control	● 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.	(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.						•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
3.8 Non-conformity Response	● Rules for measures to deal with non-conforming products (emergency measures, determination of causes, preventing reoccurrence, horizontal deployment etc) shall be determined.	(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.						•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
4. Management of Human Resources, Documentation, and Information												
4.1 Training	● Details of training required for management of chemical substances in products, and related persons shall be identified and implemented.	(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.						•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
4.2 Management of Documentation and Records	● 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.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
4.3 Communication (Provision of Information)	● 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.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	

Action Items	Action Details	Additional Explanations	Management Framework I	II	III	IV	V	VI	VII	Evaluation	Evidence (facts, document names etc) (Enter action details and areas of insufficiency)	Score
5. Performance (State of Implementation) Evaluation and Improvement	● 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.	(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.							•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	
6. Management Review (Correction by Management)	● 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.								•	*Conforming *Partial conformance *Non-conforming	**Rules:** **Operation:**	

Total Evaluation	**Passed**	**Conformance of all applicable items**		**Comments**	**Score converted into maximum score of 100 points**
	Passed	**No non-conformance, and ¼ or less of applicable action items evaluated as 'Partial conformance'.**			
	Failed	**Non-conforming action items present**			

(enter ○ in the applicable total evaluation result)

(reference) Total	
Number of applicable action items	0
Conforming	0
Partial conformance	0
Non-conforming	0

Annex 2: Self-Declaration of Conformance (Example), Data Entry Example, and Explanation

Self-Declaration of Conformance (Example)

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 :

Self-Declaration of Conformance Data Entry Example and Explanation

■ Entry obligatory

□ Entry optional

1. Number: PEMS-2008-01

■ Note 1 The party making the conformance declaration should allocate an identification number for reference when there are queries from within or outside the company. Identification numbers may include letters in addition to numerical figures.

2. Subject of declaration: The management system for XXXX product used for the purpose of XXXX. The management system for XXXX product used for the purpose of XXXX.

■ Note 2 Enter the details of the management system covered by the declaration of conformance. If the amount of text is too great, the information may be entered on an attached document.

(Example 2-1) The management system for chemical substances in products for all companies.

(Example 2-2) The management system for chemical substances in XXXX product used for the purpose of XXXX.

(Example 2-3) The management system for development, manufacture and sale of XXXX product for the purpose of XXXX.

(Example 2-4) The management system for development, manufacture and sale of electronic components.

3. Issuing authority: Company name: The Corporate Headquarters of XXXX Co., Ltd. Address : 1-2-3, XXXX Ward, Tokyo Company name: The XXXX Factory of XXXX Co., Ltd. Address : 12-3, XXXX Machi, XXXX Gun, Ibaraki Prefecture

■ Note 3 Enter the organization making the declaration of conformance. For example, this information might be similar to the following examples. If the amount of text is too great, the information may be entered on an attached document.

A. If a specific organization within the company is making a declaration of conformance:

(Example 3-1) The XXXX Factory of XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Ibaraki Prefecture

(Example 3-2) The XXXX Business Division of XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Ibaraki Prefecture

(Example 3-3) The XXXX Business Division of XXXX Factory of XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Ibaraki Prefecture

B. If the declaration of conformance involves a number of organizations within a company, group companies or outsourcing entities working on the company's behalf etc, it is also possible to include outsourcing entities working on the company's behalf and have no capital relationship with the company.

(Example 3-4) The XXXX Factory of XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Ibaraki Prefecture
The XXXX Factory of XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Shizuoka Prefecture
The XXXX Factory of Tohoku XXXX Co., Ltd.
12-3, XXXX, XXXX City, Aomori Prefecture
The XXXX Factory of Shonai XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Yamagata Prefecture
XXXX Co., Ltd.
1234-56 XXXX, Dalian City, Liaoning Province, China

C. When a specific organization within a company is making a declaration of conformance:

(Example 3-1) The XXXX Factory of XXXX Co., Ltd.
12-3, XXXX Machi, XXXX Gun, Ibaraki Prefecture

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 : XX (month), 2008
Issuing authority: XXXX

■ Note 4 Enter the document name, the version number, the date of issue, and the issuing authority as indicated in the example.

5. Additional information:
Score: 94 points (Maximum score: 100 points)
Other: Based on the results of an internal audit (conducted on XX month, XXXX year), compliance was confirmed.

■ Note 5 (1) Enter after converting the score confirmed with the Action Item List & Check Sheet (Annex1) to a base of 100 points as the maximum possible score.

□ Note 5 (2) Enter the company's evaluation method used as the basis for the declaration of conformance.

6. Place and date of issue:
Place : 12-34-56 XXXX, XXXX City, Chiba Prefecture
Date of issue : XX (day), XX (month), 2008 (year)
Date of renewal: XX (day), XX (month), 2008

■ Note 6 For place of issue, enter the address given in '7. Representative, department'. Entry is required again even if it is same as in '3. Issuing authority' above.
The date of issue represents the date on which the Self-Declaration of Conformance was first made.
Renewal dates may also be listed if it is necessary to show that conformance is ongoing based on the results of a periodic internal audit.

7. Representative, department

Enter signature here

Company name: XXXX Co., Ltd.
Person's name : XXXX
Department : XXXX Management Department, Corporate Headquarters

If you have any queries regarding this declaration, please contact the person listed below:
Company name: XXXX Co., Ltd.
Person's name : XXXX
Department : XXXX Promotion Office, XXXX Management Department, Corporate Headquarters
Telephone : 03-XXXX-XXXX
E-mail : abcde-fghijklm@xyzxyz.co.jp

■ Note 7 List the name of the representative, and his/her department, position, and signature.
Depending of the size of the company and its management structure, it is possible to select from the president, director-in-charge, officer-in-charge, or person-in-charge of the department.
Both the company representative and the person actually responsible (the point of contact for queries) may be listed.
Point-of-contact telephone and E-mail address information may also be listed.

□ Note 9 The document attached to the Self-Declaration of Conformance may also contain a detailed explanation of the details of the Self-Declaration of Conformance.
If conformance to other requirements in addition to conformance with these guidelines is declared, include this information in the attached document.
Note that it is not necessary to disclose the attached document with the Self-Declaration of Conformance.

■ JAMP: Joint Article Management Promotion-consortium

The Joint Article Management Promotion-consortium (JAMP) is aware of its essential role in improving Japanese industrial competitiveness through appropriate management of information on chemical substances in articles (fabricated products), and development and proliferation of practical structures for the smooth disclosure and transmission of that information within supply chains. Seventeen companies covering the range of Japanese industry endorsed this ideal in September 2006 with their formation of the consortium. As of February 2008, the consortium includes 211 upstream, mid-stream, and downstream companies, and 10 associations of 221 members.

If structures for the disclosure and transmission of information on chemical substances in articles manufactured using chemical substances/preparations exist, they are employed in existing procurement and surveys, and may be helpful in reducing the load, and any confusion, associated with response to future legislation. The legislation currently of the greatest concern is the REACH regulations. In response to this legislation, the sharing of information between upstream and downstream companies in the supply chain is absolutely essential, and exceeds the ability of the industry and individual companies to respond with currently structures. The response to REACH, an essential requirement for expansion of the structure for promotion of activities, strongly affects the immediate for a new structure with consensus of the entire industrial sector. A dedicated committee has been established by JAMP with a specific mission to resolve this problem, and activities are currently underway to achieve this goal.

Visit the JAMP website (http://www.jamp-info.com/) for further details.

■ JGPSSI : Japan Green Procurement Survey Standardization Initiative

The Japan Green Procurement Survey Standardization Initiative (JGPSSI) is a self-regulating body established voluntarily in January 2001 by set manufacturers to standardize substances subject to survey, and survey formats, in order to efficiently survey chemical substances in products and materials used in electrical and electronic equipment. JGPSSI commenced operations with eight companies, and as of February 2008, comprises 77 companies in the materials, parts manufacture, and set manufacturing sectors, and two associations.

The JGPSSI secretariat has been operated and managed under the Japan Electronics and Information Technology Industries Association (JEITA) since April 2002. Within the context of globalization of supply chains, JGPSSI discussed standardization of surveys with the Electronics Industry Alliance (EIA) of the US, the European Information, Communications and Consumer Electronics Technology Industry Associations (EICTA). Research on usable common guidelines as a global standard was subsequently conducted, and in May 2005, the JIG (Joint Industry Guide) was published with the approval of the EIA and JGPSSI.

Material including the Ver. 3 Survey Response Tool and related manuals for standardized surveys are available at the website to encourage use. JIG was subsequently modified by inclusion of the latest information on legislation, and further edited, and published as JIG-101A. Furthermore, JGPSSI has improved reliability of information related to chemical substances as obtained through surveys, continuing its activities with new themes. In consequence, it published the Guidelines for the Management of Chemical Substances in Products in September 2005 as part of efforts to expand its activities.

Visit the JGPSSI website (http://www.jgpssi.jp) for further details.

Revision History	
09/27/2005	JGPSSI Ver. 1 (New publication)
11/07/2006	JGPSSI Ver. 1.1 (Revised content: correction of errors in text, addition of sectional explanations etc)
07/02/2007	JAMP Ver. 1 (publication for members)
03/31/2008	JGPSSI and JAMP Ver. 2 (Results of joint investigations by JGPSSI and JAMP published by each organization in Ver. 2)

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

March 31st 2008

Published by:

Joint Article Management Promotion-consortium (JAMP)
http://www.jamp-info.com/

&

Japan Green Procurement Survey Standardization Initiative (JGPSSI)
http://www.jgpssi.jp

These guidelines are translated from the original Japanese.
In the case of any variance between Japanese and English text, the Japanese shall prevail.

Joint Article Management Promotion-consortium