JAMA and JAPIA

Guidelines for the Management

of Chemicals in Products

Ver.1

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JAMA and JAPIA Guidelines for the Management of Chemicals in Products

Introduction

The JAMA and JAPIA Guidelines for the Management of Chemicals in Products summarize points to be noted on management in each company from upstream to downstream of the supply chain as well as communication between business partners with the aim of managing chemicals in products reliably and efficiently throughout the supply chain in the automotive industry.

The Guidelines were created in line with the requirements for managing chemicals in products in the automobile supply chain in conformity with 2017 Revised Edition of the Japanese Industrial Standard, *JIS Z 7201 Management of chemicals in products—Principles and guidelines* and referring to *the Guidelines for the Management of Chemicals in Products (Edition 4.0)* issued by the Joint Article Management Promotion-consortium (JAMP) (referred to as the JAMP Guidelines below). The Guidelines conform to the JAMP Guidelines and provide better convenience as a guidance document specially designed for the automotive industry.

For reference, the JAMP is an organization that promotes activities to properly manage information on chemicals and other substances in parts, articles, and other items and that creates and disseminates a specific system to disclose and communicate the information smoothly in the supply chain across industries.

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1. About the Guidelines for the Management of Chemicals in Products

1.1 Background and purpose

Automobiles are designed and manufactured using an enormous number of parts and materials that consist of a wide range of chemical substances. Completed automobiles provide fullness, convenience, comfort, and other values in social life to society and customers as a means of transportation.

However, automobiles could pose a danger to people and the environment due to the chemical substances used throughout the lifecycle from manufacture to disposal. To minimize the impact of automobiles on people and the environment and contribute to environmental protection, preservation, and enhancement, movements to require the identification and proper handling of chemicals in products as well as the disclosure and communication of information are globally spreading.

The supply chain in the automotive industry is long, complicated, and globally linked. In terms of legal compliance, the automobile supply chain is expected to conform to restrictions on chemical substances in each country and region.

Given trends for the global strengthening and expansion of restrictions on chemical substances and the characteristics of the automotive industry, we must build and implement a system and framework to enable the management of chemicals in products in each company and reliable exchange of information on chemicals in products between business partners. For this purpose, the automotive industry has faced an increasing need for guidelines that summarize important implementation items in addition to the conventional Japanese Industrial Standard, *JIS Z 7201 Management of chemicals in products—Principles and guidelines* and the provisions of each company. The Japan Automobile Manufacturers Association (JAMA) and the Japan Auto Parts Industry Association (JAPIA) consolidated past experiences and insights learned from them and created the JAMA and JAPIA Guidelines for the Management of Chemicals in Products (referred to as the Guidelines below) to provide practical support to people who actually manage chemicals in products and provide guidelines for management in each company to understand the need to manage chemicals in products.

If your company has already built a system to manage chemicals in products, you can improve the efficiency and reliability of management by referring to Chapter 4, “Basic Concept of Management of Chemicals in Products in the Automotive Industry” and Chapter 5 “Implementation Items for Proper Management of Chemicals in Products in the Automotive Industry” in the Guidelines.

Self-assessment sheet in Appendix A is intended to verify the situation of each company’s management system related to chemicals in products based on Chapter 5. The Guidelines and the self-assessment sheet can be used for self-assessment of management systems related to chemicals as well as assessment and verification with business partner.

However, note that the Guidelines are not intended to show the necessity of the following:

- Standardizing various efforts to manage chemicals in products
- Matching relevant documented information such as provisions for management of chemicals in products to the document structure of the Guidelines
- Using specific terms in the Guidelines in the organization
- Building a new or independent management framework to manage chemicals in products

1.2 Scope

The Guidelines show the concept of management of chemicals in products at each stage, that is, design, development, procurement, manufacturing, and delivery, as the management challenges of the organization that should be shared throughout the supply chain regardless of scale, type, or maturity so that all companies and organizations that work on the management of chemicals in products related to automobile manufacturing can manage them properly and efficiently.

In addition to upstream, midstream, and downstream companies in the supply chain including organizations involved in manufacturing, that is, organizations that manufacture chemical substances, mixtures, parts, and end products and trading companies that deal in these products, companies that directly manufacture automobiles and automobile parts, and even companies and organizations that do not have business with these companies can refer to the Guidelines.

Companies that have domestic and overseas subsidiaries, affiliated companies, and subcontractors can refer to the Guidelines for management of chemicals in products in these companies and governance over them.

Note that substances for information exchange are not defined in section 1.2, "Scope," in the JAMP Guidelines referred to when creating the Guidelines because the JAMP Guidelines are intended to be referred to in every industry sector. However, the Guidelines are specifically applied to the automobile manufacturing supply chain. Therefore, the GADSL (Global Automotive Declarable Substance List) is specified as the standard list in the automotive industry that shows the scope of the management of chemicals in articles as described later.

1.3 Anticipated audience

The anticipated audience is as defined below.

(1) All people in charge, managers, and supervisors who are engaged in building, verification and relevant operations of the management framework for chemicals in products

Respective organizations can refer to and utilize the Guidelines as described below when building a management framework for chemicals in products and performing relevant operations.

- The person in charge builds a management framework, referring to the Guidelines.
- Once the management framework is built, the Guidelines can be utilized as an educational tool in the company to keep internal related parties informed about the essential points of management of chemicals in products.
- Companies that have already built a management framework for chemicals in products according to other equivalent or more stringent criteria, guidelines, etc. can refer to the Guidelines for other reasons, such as to verify that current management practices effectively satisfy the management requirements in the Guidelines or make improvements when needed.
- The organization can also utilize the Guidelines to conduct self-assessment such as internal audit to verify that the management framework for chemicals in products is functioning.

(2) People in charge who verify suppliers' management framework for chemicals in products and their managers and supervisors

External organizations in the company (such as procurement) can also refer to and utilize the Guidelines to verify that suppliers have built their management framework for chemicals in products.

1.4 Unit of management of chemicals in products

The Guidelines were written with organizations in mind as the unit of management of chemicals in products rather than products. Organization as used here refers to a company, a corporation, a department in an office, a private business, or any subset or combination of them.

Examples: XX Plant in XX Company, YY Division in YY Company, ZZ Manufacturing Department in ZZ Group

1.5 Procedure for following the guidelines

The steps for following the Guidelines are outlined below.

(1) Building a management framework for chemicals in products

Each organization in the supply chain shall build their management framework for chemicals in products. Each organization can refer to the Guidelines both when utilizing their existing management framework and when building a new management framework although the best form varies depending on the industry sector, business category, and nature of business.

(2) Evaluating the management framework for chemicals in products

Each organization shall evaluate whether the management framework for chemicals in products that the organization has built satisfies the management requirements shown in the Guidelines.

You can evaluate the framework efficiently and objectively by using the *Self-assessment sheet in Appendix A.* It is important to improve and maintain the management framework as needed.

1.6 Applying the guidelines to the existing management system

When management frameworks for quality management, environment management, or other purposes are already built, the organization can utilize them to manage chemicals in products at its own discretion.

If you have existing management frameworks, it is advisable to utilize them to work on management efficiently, although you can build a new management framework. However, when using existing management frameworks, you must verify that the implementation items shown in the Guidelines are effectively satisfied.

1.7 Revising the Guidelines for the Management of Chemicals in Products

The following document management applies to the Guidelines to cover the latest requirements for managing chemicals in products.

As described above, the Guidelines were created, satisfying the requirements for managing chemicals in products in the automobile supply chain in conformity with *JIS Z 7201 Management of chemicals in products—Principles and guidelines* and referring to the JAMP Guidelines. Therefore, the Guidelines shall remain consistent with these documents.

(1) Document management framework

A review committee shall be established under the JAMA Product Chemicals Management Subcommittee for document management such as verification and consideration of whether the Guidelines must be revised or abolished. The review committee consists of the members of the JAMA Product Chemicals Management Subcommittee and the members of the JAPIA Product Environment Subcommittee.

(2) Revision and abolition of the Guidelines

Whether the Guidelines must be revised or abolished shall be verified every April.
Revision and abolition shall be considered if the following conditions are met.

- JIS Z 7201 is revised or abolished
- The Guidelines shall be abolished if the necessity of revision or abolition is not examined for one year after the JIS Z 7201 is revised or abolished.
- The Guidelines for chemicals in products issued by the JAMP are revised or abolished.

- Laws or regulations related to chemicals in products in the automotive industry are changed or abolished, the specifications of the IMDS or JAPIA sheets, which are tools for management of chemicals in products, are changed, or these sheets are abolished or otherwise modified.
- Other related information is changed

2. Reference Standards of the Guidelines for the Management of Chemicals in Products

As described above, the Guidelines are in conformity with *JIS Z 7201:2017 Management of chemicals in products—Principles and guidelines*. The Guidelines also refer to other standards in Table 2.1.

Table 2.1 Governing and Reference Standards of the Guidelines for the Management of Chemicals in Products

Management of chemicals in products	- *JIS Z 7201:2017 Management of chemicals in products—Principles and guidelines*
Related to the management system	- *JIS Q 9000:2015 Quality management systems—Fundamentals and vocabulary (ISO 9000:2015 Quality management systems—Fundamentals and vocabulary*) - *JIS Q 9001:2015 Quality management systems—Requirements (ISO9001:2015 Quality management systems—Requirements)* - *JIS Q 14001:2015 Environment management systems—Requirements with guidance for use (ISO 14001:2015 Environmental Management System - Requirements with guidance for use)* - *ISO/IEC Directives, Part 1, Consolidated ISO Supplement Procedures specific to ISO Annex SL*

Some of the efforts shown as implementation items in the Guidelines have much in common with processes in the quality management system or environment management system operated by the organization. For compatibility with the structure of other management system standards, the Guidelines refer to the upper-level structure of the management system in the ISO/IEC Directives, Part 1, *Consolidated ISO Supplement—Procedures specific to ISO Annex SL* (referred to as the Annex SL below), which is adopted in ISO 9001:2015 (JIS Q 9001:2015) and ISO14001:2015 (JIS Q 14001:2015), for implementation items. The Guidelines also refer to section 8, “Operation,” in the ISO 9001:2015 (JIS Q9001:2015) quality management system for the processes in chapter 5, “Implementation Items for Proper Management of Chemicals in Products in the Automotive Industry.”

For the reference standards, see the text of the standards.

3. Terms and Definitions

The terms and definitions mainly used in the Guidelines are based on ISO 9000:2015 (JIS Q 9000:2015) and Table 3.1 below.

Table 3.1.1 Definitions of terms

Term	Definition
Chemical substance	Elements and their compounds that exist in nature or are obtained through some manufacturing process.
Mixture	Blend of two or more chemical substances. Note: Examples of mixtures contained in automobile products include paints, inks, adhesives, plating solutions, rubber materials, alloy ingots, solder, and plastic pellets that contain adhesive or pigment.
Chemical	Chemical substances or mixtures.
Article	Object whose end use functionality is determined more by the specific shape, appearance, or design given during manufacturing than by the functionality of its chemical composition. For reference, REACH-AIG version 4.0 defines whether article refers to a complex object made of two or more components or respective components only in relation to the obligations of article 7 (Report) and article 33 (Communication of Information) of the European REACH Regulations as follows. 1. An article is a separable single body. 2. A complex object is a combination of two or more articles. Note: Examples of articles and complex objects according to these definitions are as shown below. 1. Examples of articles: Plastic injection molded parts, pressed sheet steel parts, and gears 2. Examples of complex objects: Vehicle, seats, windshield wiper assemblies, headlamps, resistors, printed circuit board assemblies (PCBA), tires, airbag modules, and batteries
Part	Articles in processes up to end products. Note: Examples of parts are shown below. a) Examples of parts made by converting chemicals to an article for the first time Brake pad, urethane foam for seats, and headlamp covers b) Examples of parts manufactured by combining parts Brakes, seats, and headlamps
End product	Finished article manufactured by combining or processing chemicals and parts. The end product in the Guidelines is an automobile.

Product	Chemical, part, or end product that an organization delivers to customers as a result of their activities. Note: Packaging materials and protective materials used to package products may also be considered products.
Conversion process	Process for converting chemical substances or mixtures into an article. (See 4.5.)
Organization	Group that has its own functions associated with responsibilities, authorities, and interrelationships.
Supplier	Organization that delivers products downstream.
Customer	Organization that receives products from upstream. Note: In the Guidelines, customers do not include consumers.
Delivery	Act of dispatching products to customers. Note: Although a synonym, transfer, is used in JIS Z 7201:2017, delivery, which is generally used in the automotive industry, is used in the Guidelines.
Procurement	Act of purchasing necessary raw materials or parts from a supplier. Note: Although a synonym, purchasing, is used in JIS Z 7201:2017, procurement, which is generally used in the automotive industry, is used in the Guidelines.
Chemicals in products (product chemicals)	Chemical substances known to be contained in products.
Industry standard	Criteria related to the management of chemicals in products created and publicly announced by each industry organization. The industry standard for the automotive industry is the GADSL, the list of restricted chemical substances throughout the automotive industry defined by automobile, automobile part, and chemical manufacturers in Japan, the U.S., and Europe. https://www.gadsl.org/
Management criteria for chemicals in products (product chemicals)	Criteria that each organization defines according to laws and regulations related to chemicals in products, GADSL, and standards required by each customer. The criteria include a list of restricted chemical substances, management levels (such as prohibition of use or notification of inclusion), and scope.

Information on chemicals in products (product chemicals)	Information related to chemical substances in the scope of the management criteria for chemicals in products.
Traceability	Ability to track the records of procurement, manufacturing, and delivery of products.
Interested party	Individual or organization that can impact or be impacted by a decision or activity, or that recognizes the impact of the decision or activity on itself. Note 1: Examples of interested parties related to the management of chemicals in products include customers, suppliers, subcontractors, the government, and people in the organization. Note 2: A synonym is stakeholder.
Risk	Impact of uncertainty on goals. Note 1: An impact is a divergence from expectations in a desired or undesired direction. Note 2: Uncertainty is the state where information, understanding, or knowledge related to an event, its result, or likelihood are even partially deficient. Note 3: Risk is used for something that has not yet occurred but may occur in the future. Risk here does not refer to technical, statistical, or scientific risks. Note 4: This term is widely used in general but has different meanings in each field. In the Guidelines, risks are differentiated from risks due to chemical substances and refer to the impact of uncertainty on management of chemicals in products.
Opportunity	Convenient time for efforts to achieve the goals of the organization that may have a positive impact on it. Note: The target of opportunity is a situation or circumstances advantageous in achieving an already clarified event. Opportunity is not the opposite concept of risk.
Conformity	Satisfaction of the management criteria for chemicals in products. Conformity in terms of the evaluation of the management framework for chemicals in products according to the Guidelines means conformity to implementation items.

Nonconformity	Failure to satisfy the management criteria for chemicals in products. Products that do not satisfy the criteria are nonconforming products. Nonconformity in terms of the evaluation of the management framework for chemicals in products according to the Guidelines means nonconformity with implementation items.
Subcontractor	External organization to which the operations and functions of organization are partially or wholly outsourced.

The terms associated with the system, tools, and criteria related to the management of chemicals in products in the automotive industry are shown below.

Table 3.1.2 Definitions of terms related to the management of chemicals in products in the automotive industry

Term	Overview
IMDS	International Material Data System Materials data collection system for global automotive industry standards built to transmit information on product materials and substances in the supply chain. https://www.mdsystem.com/
JAPIA sheet	JAPIA Standard Material Datasheet Excel sheet created by the JAPIA to communicate information on product materials and substances. https://www.japia.or.jp/work/kankyou/datasheet/
SDS	Safety Data Sheet Document that contains information on chemicals in products, their hazards, and other matters issued when delivering and providing chemical substances and mixtures to customers.
GADSL	Global Automotive Declarable Substance List List of restricted chemical substances across the automotive industry defined by automobile, automobile part, and chemical manufacturers in Japan, the U.S., and Europe. https://www.gadsl.org/
SCIP	Substances of Concern In articles as such or in complex objects (Products) Obligation to register article or product substances (with a concentration of over 0.1 wt%) included in the list of candidate substances to be approved in the REACH Regulations (Candidate List) in line with the revision of the Waste Framework Directive (WFD) in Europe in 2018 (obligation to submit information to the European Chemicals Agency (ECHA)).

Conventions related to operations management and documents in the Guidelines and *self-assessment sheet in Appendix A* are as defined in the table below.

Table 3.1.3 Definitions of operations management and documents

Term	Definition
Criteria	Document that contains laws and regulations to be observed, restricted substances, and management methods
Provisions	Document that contains roles, criteria, workflows, frameworks, and other items agreed on by the company (organization) Criteria may be equivalent to provisions in some companies (organizations). In that case, this document shall be agreed on by the company

Rules	Conventions of roles, criteria, and workflows Rules may not be agreed on by the company. Rules agreed on by the company are included in provisions.
System	Conventions of roles, criteria, and workflows Systems may not be agreed on by the company. Systems agreed on by the company are included in provisions.
Manual	Document that contains procedures for applying rules Manuals may not be agreed on by the company. Manuals agreed on by the company are included in provisions.
Evidence	Evidentiary materials that can be provided when requested

4. Basic Concept of Management of Chemicals in Products in the Automotive Industry

It is important for the organizations involved in the management of chemicals in products to understand the basic concept of management of chemicals in products and build, implement, maintain, and evaluate a management framework.

4.1 Necessity of management of chemicals in products in the automotive industry

4.1.1 Risks due to chemical substances and management of chemicals in products

Products that use or apply the nature of chemical substances bring about the advancement of civilization to society. However, these products could also pose a danger to people and the environment. In other words, they have risks due to chemical substances.

Laws and regulations related to chemicals in products in processes up to the manufacturing of end products and chemicals in end products have been established in countries and regions around the world to address the harms of chemical substances and risks due to chemical substances throughout their lifecycle. In line with this trend, movements to require the management of chemicals in products as well as disclosure and communication of information on the management are spreading globally.

If chemical substances are not properly managed, companies may face direct risks. For example, companies that manufacture, sell, export, or import products may be ordered to stop selling or recall products that contain the chemical substances in question, be closed down, or pay a fine.

On the other hand, parties other than the manufacturers of the parts of the product or the materials of the parts cannot easily identify chemicals in products in many cases. Therefore, it is an important issue for companies that do not manufacture, sell, export, or import products to communicate and identify information on chemicals in products across all organizations and companies in the supply chain to properly manage chemical substances throughout the supply chain.

4.1.2 Laws, regulations, and social trends related to chemical substances that impact the automotive industry

In spite of the fact that automobiles provide society and customers with convenience as a means of transport and the comfort of personal mobility in the midst of various environmental changes, automobiles, automobile components, and their related products are manufactured using the characteristics of many chemical substances and they pose risks to people and the environment in the manufacturing process, use phase, and disposal due to the chemical substances used in them.

The history of restrictions on chemical substances is as follows: Before the 1980's, the mainstream of chemical substance management was hazard management to prohibit the use of harmful and hazardous substances such as substances that cause acute poisoning or cancer.

In the 1990's, risk management based on the degree of hazards as well as the amount of chemical substances people were exposed to (amount of exposure) were required.

Important movements in the trend of restrictions on chemical substances up to today include the UNEP Governing Council adopting the Strategic Approach to International Chemicals Management (SAICM) in 2002 meaning that each company is now expected to work on minimizing risks from chemical substances by 2020 based on the agreement to create an action plan at the Johannesburg summit in 2002.

Various restrictions have been established based on the concept of risk management described above. The POPs Convention (the Stockholm Convention, effective as of May 17, 2004) is a global treaty to prescribe activities such as discontinuation and restriction of manufacture and use of persistent organic pollutants (POPs) that have high levels of persistency, bioaccumulation, and harmful effects to people and living organisms in the environment and that are suspected to have long-range transport potential, reduction in their emissions, proper handling of waste that contains these substances, and so on. Once restricted substances are discussed at the POPs Review Committee (POPRC) and the decision is made to add them at the Conference of the Parties (COP), the ratifiers include them in their restrictions.

The REACH Regulations in Europe (effective as of 2007) are other restrictions on chemical substances based on this concept of management of risks due to chemical substances. The Amended Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (effective as of 2009) in Japan has also adopted this concept of management of risks due to chemical substances.

In the context of automobiles, the outflow of four types of heavy metals (lead, mercury, cadmium, and hexavalent chrome) from automobile waste and their impact on the natural environment, ecosystem, and human health gathered attention as risks due to chemical substances before the above mentioned the REACH Regulations in Europe. In 2000, the European Parliament and the European Council of Ministers issued Directive 2000/53/EC on end-of life vehicles (ELV Directive), which includes the restriction of use of these four heavy metals in disposed automobiles. As conforming to this restriction is an important requirement for vehicle model approval, the conformity of a wide range of applicable parts has been managed.

Most recently, it became obligatory for article suppliers to disclose and register information in the WFD SCIP Database as described below. In June 2018, the European Waste Framework Directive (WFD) was amended to show that whether products and materials contain substances of very high concern (SVHC) must be communicated throughout the lifecycle to realize a circular economy. To ensure communication, the following obligation is placed on article suppliers and ECHA.

- Article suppliers shall submit information on SVHC in articles defined in article 33 of the REACH Regulations to the ECHA after January 5, 2021.

Table 4.1 lists laws and regulations on chemical substances related to the manufacture and sale of automobiles as of October 2022. Nonconformity to these laws and regulations should be recognized as a business risk throughout the automobile supply chain.

Table 4.1 Main laws and regulations on chemical substances related to automobiles

Law or regulation	Restricted countries	Restricted chemicals	Other requirements
Stockholm Convention (POPs Convention)	Global	Persistent organic pollutants such as chlorinated or brominated pesticides and flame retardants and fluorochemical surfactants	
Montreal Protocol	Global	Gradual reduction in the ozone depleting substance, HFC	
Vehicle Recycling Laws (ELV Directive)	Europe, China, Korea, etc.	Four heavy metals (lead, cadmium, hexavalent chrome, and mercury)	Material information to calculate the recyclable rate
RoHS Directive	Europe	Lead, cadmium, hexavalent chrome, mercury, etc. and brominated flame retardants and phthalate compounds	Conformity evaluation, conformity declaration, CE mark
REACH Regulations	Europe, Korea	Carcinogenic, reprotoxic, mutagenic, persistent, bioaccumulative, and other kinds of substances	Registration of substances, report of use amount, information disclosure, information provision
Biocidal Products Regulation (BPR)	Europe, Korea	Unauthorized active substances in the product category	Labeling
Amended Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.	Japan	Japanese act on the substances restricted in the POPs Convention	

Furthermore, each country will establish laws and regulations related to chemical substance management and make new rules, considering the European Green Deal Policy, Chemical Strategy for Sustainability, etc. as well as the SAICM, Post SAICM (SAICM beyond 2020), SDGs, and recycling society (circular economy) in the future. Therefore, you must keep up with the latest trends.

Figure 4.1 UN 2030 Agenda

These movements are also considered in “Target 12.4: By 2020, achieve the environmentally sound management of chemicals and all waste throughout products’ life cycles, in accordance with agreed international frameworks, and significantly reduce the release of chemicals to air, water and soil in order to minimize their adverse impacts on human health and the environment.” under Goal 12, RESPONSIBLE CONSUMPTION AND PRODUCTION of the SDGs (sustainable development goals) in Figure 4.1, which were adopted at the UN Summit in 2015.

In every kind of manufacturing and industry, it is important to accurately identify and communicate information on chemicals in products along with the flow of products through the supply chain to properly conform to laws and regulations. In particular, an automobile contains about 30,000 parts. Therefore, to properly identify the types and amounts of materials and chemical substances restricted as a result of future expansion of laws and regulations, it is critical to properly identify and communicate the types and amounts of materials and chemical substances contained in automobiles throughout the complicated supply chain in which many parts and materials manufacturers are involved.

4.2 Basics of management of chemicals in products in the automotive industry

For the basic management of chemicals in products in the automotive industry, each organization involved in the design, development, procurement, manufacture, or delivery of automobile materials and parts shall clarify the management criteria for chemicals in products at each stage (laws and regulations on chemical substances in each country, GADSL, nonuse of chemical substances prohibited according to customers' standards and requirements, and understanding of how restricted chemical substances are used) and verify proper management according to the criteria. It is important that this management is properly implemented in each company that makes up the supply chain and throughout the supply chain and that information on chemicals in products is reliably communicated from upstream companies to downstream companies.

Regarding the above mentioned management operations, Figure 4.2 shows a full picture of the management of chemicals in products around a company and Figure 4.3 shows the flow of products and information on chemicals in the supply chain.

It is important for each company's management to correctly understand the internal framework of each company and relationships with upstream companies (suppliers) and downstream companies (customers) in the full picture in Figure 4.2 and products that they handle and their flow in the product flow in Figure 4.3.

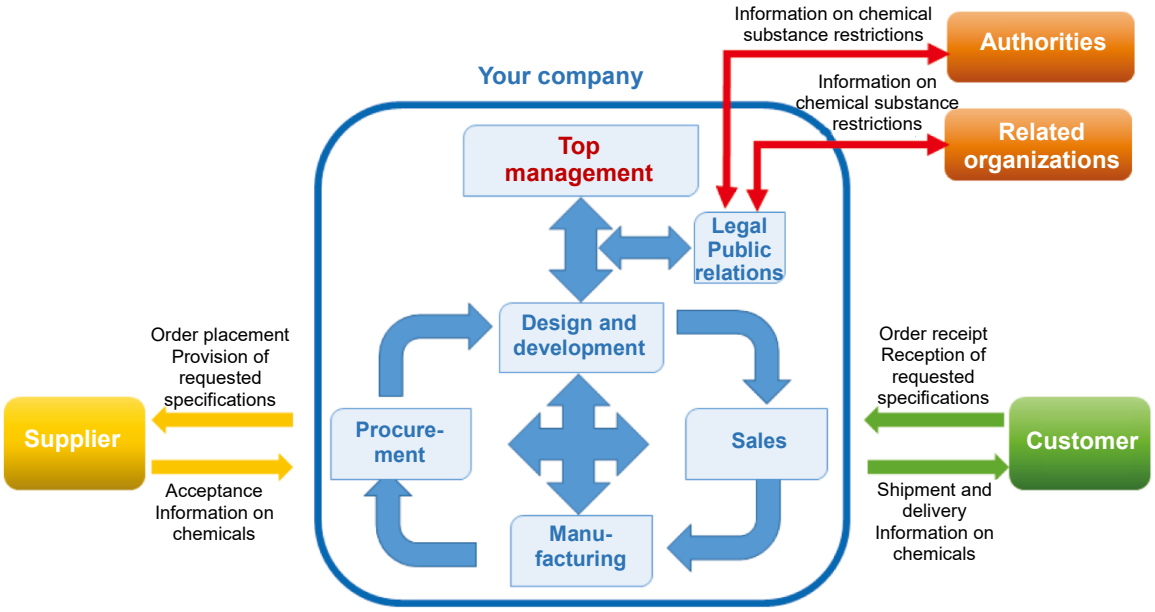

Figure 4.2 Full picture of management of chemicals in products around a company

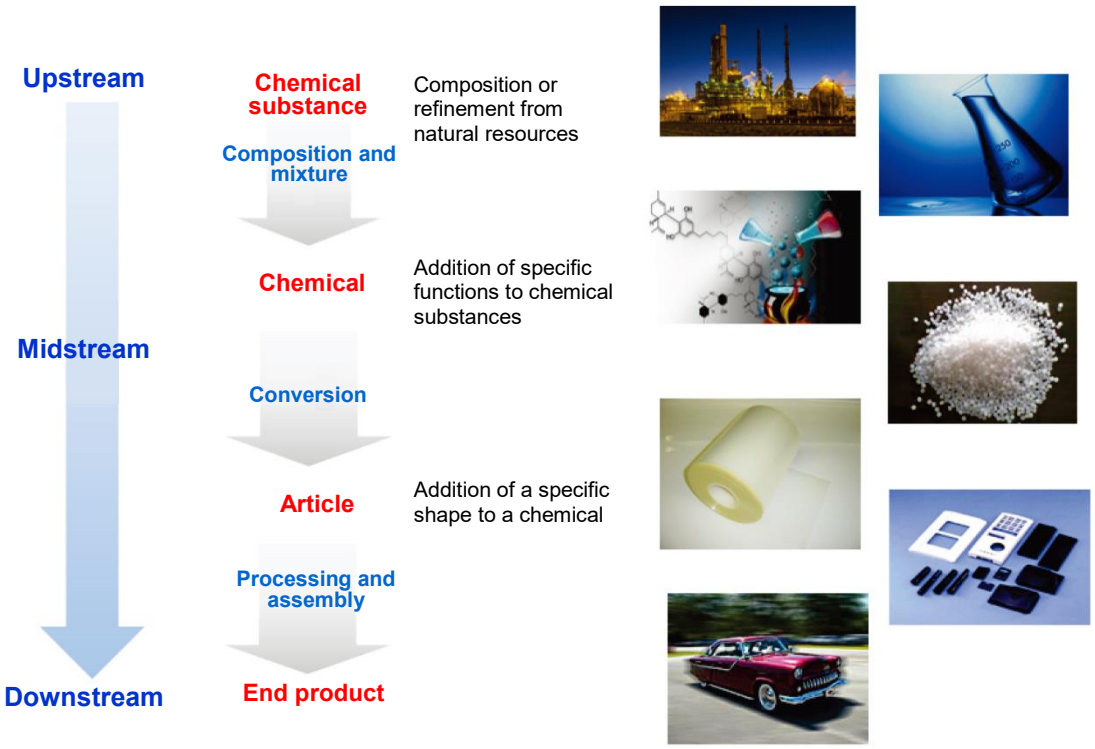

Figure 4.3 Product flow in the supply chain

It is important to manage chemicals in products scientifically and rationally. For example, phenomena including volatilization, hardening, precipitation, and melting generate a new article in the conversion process from chemicals to an article. You must scientifically understand the states of chemicals in products in this process based on factors such as the chemicals input to the manufacturing process as materials, the manufacturing process, and conditions for manufacturing management, employ a feasible rational management method, and identify and consolidate information on chemicals in products according to them.

Compliance related to chemicals in products is an important issue not only to avoid the impact on people and the environment caused by chemicals in products but also to maintain business continuity. Nonconformity with the management criteria for chemicals in products not only directly impacts business, but if restricted substances are shipped as part of end products, impacts such as discontinuation of sales and recall from the market can occur. You must correctly understand the details of laws, regulations, etc. on which the management criteria for chemicals in products are based, recognize compliance as an important issue of the organization, and work on activities for management of chemicals in products.

Trading companies that neither manufacture products in the organization nor directly handle products shall properly identify chemicals in products and communicate them in the supply chain as their basic management of chemicals in products. Efforts suitable for the business such as acquisition of information on chemicals in products, information provision, handling in the organization, and delivery management are required.

4.3 Efforts to address risks and opportunities in management of chemicals in products in the automotive industry

As defined in Chapter 3, “Terms and definitions,” a risk is the impact of uncertainty on goals and uncertainty is the state where information, understanding, or knowledge related to an event, its result, or likelihood are even partially deficient. An impact is a divergence from expectations in a desired or undesired direction and shows the concept that impacts the effectiveness of the management of chemicals in products. An opportunity

is a convenient time for efforts to achieve the goals of the organization. This may have positive impact on the organization and is not the opposite concept of risk.

As an example of risks in the management of chemicals in products in the automotive industry, if products that contain chemical substances prohibited according to laws and regulations are delivered to customers, damage to the health of people who touch them, like the past occurrence of dioxin as a result of incineration of disused automobiles, direct or indirect impact on people, animals, and plants due to soil and underwater contamination after landfill, and irreparable health damage due to accumulation in human bodies could occur. Impacts on business such as product recalls, damage compensation, or suspension of transactions may occur depending on the situation.

In addition, automobile parts and materials are often shared across multiple vehicle types or multiple automobile manufacturers rather than being used exclusively for a specific vehicle type. Therefore, if automobiles that contain chemical substances prohibited according to laws and regulations, etc., are shipped, business management may be largely impacted by recalls, fines, discontinuation of sales, or other forms of disposition associated with violation of laws or regulations. You must fully recognize that a nonconformity that occurs in some part of the supply chain can impact the supply chain across the automotive industry.

Examples of opportunities in the management of chemicals in products in the automotive industry include research and development of new products, new construction and update of facilities such as production equipment and information system, adoption of new parts, and actions to address changes in laws and regulations related to chemicals in products. By leveraging these opportunities to manage chemicals in products, you may achieve a desired situation. For example, you may be able to improve customers' evaluation of the organization and continue to develop and efficiently produce products that meet product chemical restrictions. Working on opportunities can include consideration of relevant risks.

You must also understand that these efforts make it possible for the company to enhance the brand value of their products, serve as an evaluation index for the recent company value, and lead to enhancement of the value of the company itself as an ESG (environment, social, governance) effort, which are currently being considered in many companies, and are increasingly becoming important in terms of corporate management.

In addition, opportunities are believed to contribute to the following 5 goals of the 17 SDGs mentioned in section 4.1:

3 Ensure healthy lives and promote well-being for all at all ages
6 Ensure availability and sustainable management of water and sanitation for all
9 Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation
12 Ensure sustainable consumption and production patterns
14 Conserve and sustainably use the oceans, seas and marine resources for sustainable development

4.4 Risk-based management of chemicals in products in the automotive industry

The products and businesses of the organizations that make up the supply chain in the automotive industry are diverse and extend globally. As a result, many different factors can cause risks related to the management of chemicals in products. The section that supervises the management of chemicals in products in each company identifies, analyzes, and evaluates risks related to the management of chemicals in products to clarify issues by leveraging the expertise of each section (such as design & development, procurement, manufacturing, or logistics) in the company, takes appropriate measures to prevent or reduce the risks, and manages chemicals in their products. Some organizations may have to manage chemicals in products not only in their company but also in their domestic and overseas subsidiaries, affiliated companies, and supply chain as a whole.

Factors that cause risks related to the management of chemicals in products include changes in laws and regulations related to chemicals and customers' management criteria for chemicals in products. Examples in Japan's automotive industry include amendments to the Act on Recycling of End-of-Life Automobiles (such as expiration of the exemption period for four restricted heavy metals) and revisions of the GADSL and each customer's criteria related to chemicals in products. Other risk factors include products from external suppliers and the improper handling of chemicals in products in the manufacturing, shipment or other processes in the organization, including changes to, misuse of, or contamination of such chemicals.

It is important to consider the scale and rate of occurrence of a problem if a problem occurs, identify priority matters that you should focus on managing from among your processes based on your business category, and implement proper and efficient management. A reference procedure for identifying matters that you should focus on managing is as follows:

(1) Verifying how chemical substances are used and risks in terms of the management of chemicals in products
  – Verify chemicals, parts, secondary materials, etc. to be used.
  – Verify equipment, jigs, tools, etc. used for manufacturing.

(2) Identifying matters that you should focus on managing
  – Identify matters that you should focus on managing, considering risks in terms of the management of chemicals in products.
  – Define the management level (specific actions) for priority management and other general management.

4.5 Specific actions and points to be noted on management of chemicals in products in the automotive industry

To manage chemicals in products in the automotive industry, you must correctly understand your company's position in the automobile manufacturing supply chain, build a system to manage information on chemicals in products in each of the design, development, purchase, acceptance, manufacturing, and shipment processes given the management of chemicals in automobiles as end products, and properly manage and communicate information on chemicals in their own products (Figure 4.4).

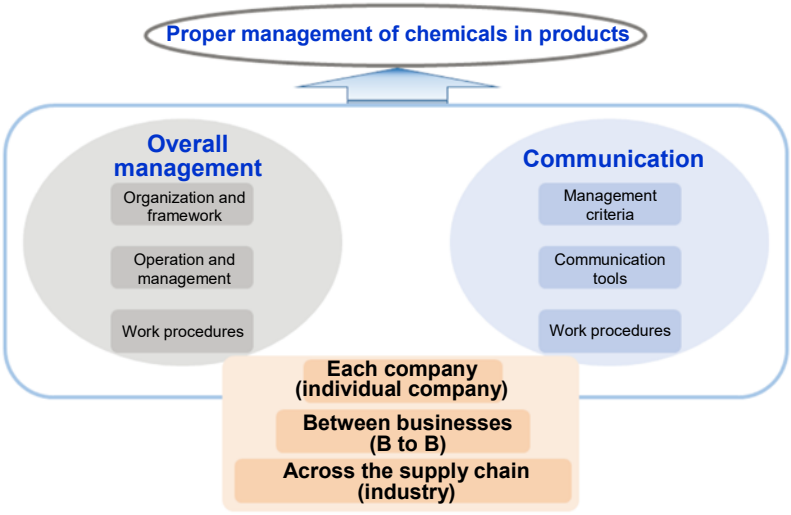

Figure 4.4 Proper chemical substance management

Specific priority implementation items that you should manage in each process are covered in Chapter 5, "Implementation Items for Proper Management of Chemicals in Products in the Automotive Industry." This chapter shows an overall flow of management operations and main implementation items.

Each company and organization shall position themselves in the full picture of the management of chemicals in products around a company in Figure 4.2 and the manufacturing processes across the automobile supply

chain in Figure 4.5, correctly understand their responsibilities in that context, and build an organization and system to fulfill the associated responsibilities.

In addition, to properly manage chemicals in products throughout the automobile supply chain, you must understand the extremely complicated flow of manufacturing chemicals, materials, and articles in Figure 4.6 and properly communicate information on chemicals in products between each process. This is an important point in managing chemicals in products.

One method of chemical communication is safety data sheets (SDSs). Chemical users can adequately use and manage chemical and other substances and recognize their hazards to the human body and the environment to handle them properly and safely based on information on hazards of chemical substances on an SDS. However, the SDS in Japan is intended for communication based on the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (also known as the Law concerning Pollutant Release and Transfer Register or PRTR Law), which covers all the poisonous and deleterious substances specified in the Poisonous and Deleterious Substances Control Act and enforcement ordinances in Japan and the chemical and other substances whose names have been announced as specified in the Industrial Safety and Health Act, etc. In other words, Japan's SDS does not cover some information in the scope of the management of chemicals in products defined in the Guidelines. Please note that this SDS may not be able to communicate information on chemicals in products when used alone.

Communication of information on chemical substances and materials from upstream companies to midstream companies is critical in the chemical substance information communication flow in the supply chain shown in Figure 4.5 and Figure 4.6. These companies deal in products that are manufactured and sold for purposes other than automobiles as well. In these cases, the companies may not recognize the necessity of communication tools exclusively used in the automotive industry such as the IMDS and JAPIA sheets. Actions for respective transactions are required.

Table 4.2 shows examples of articles the composition of which changes in the conversion process from chemicals to articles. It is important for companies that manufacture such articles to identify and communicate information on chemicals in articles.

To manage chemicals in products in manufacturing automobiles, it is important to accurately identify your company's position in the automobile manufacturing supply chain and the manufacturing processes of production items, correctly understand chemical and physical changes in the conversion process based on data and scientific information, and create IMDS and JAPIA sheets, which are tools to communicate article information.

How the conversion process should be understood and considered is detailed in the *Guidance on Management of Chemicals in Products, and Information Communication and Disclosure / Conversion Process [Common to the process for converting mixtures (preparations) into articles]* issued by the JAMP. Refer to it as needed.

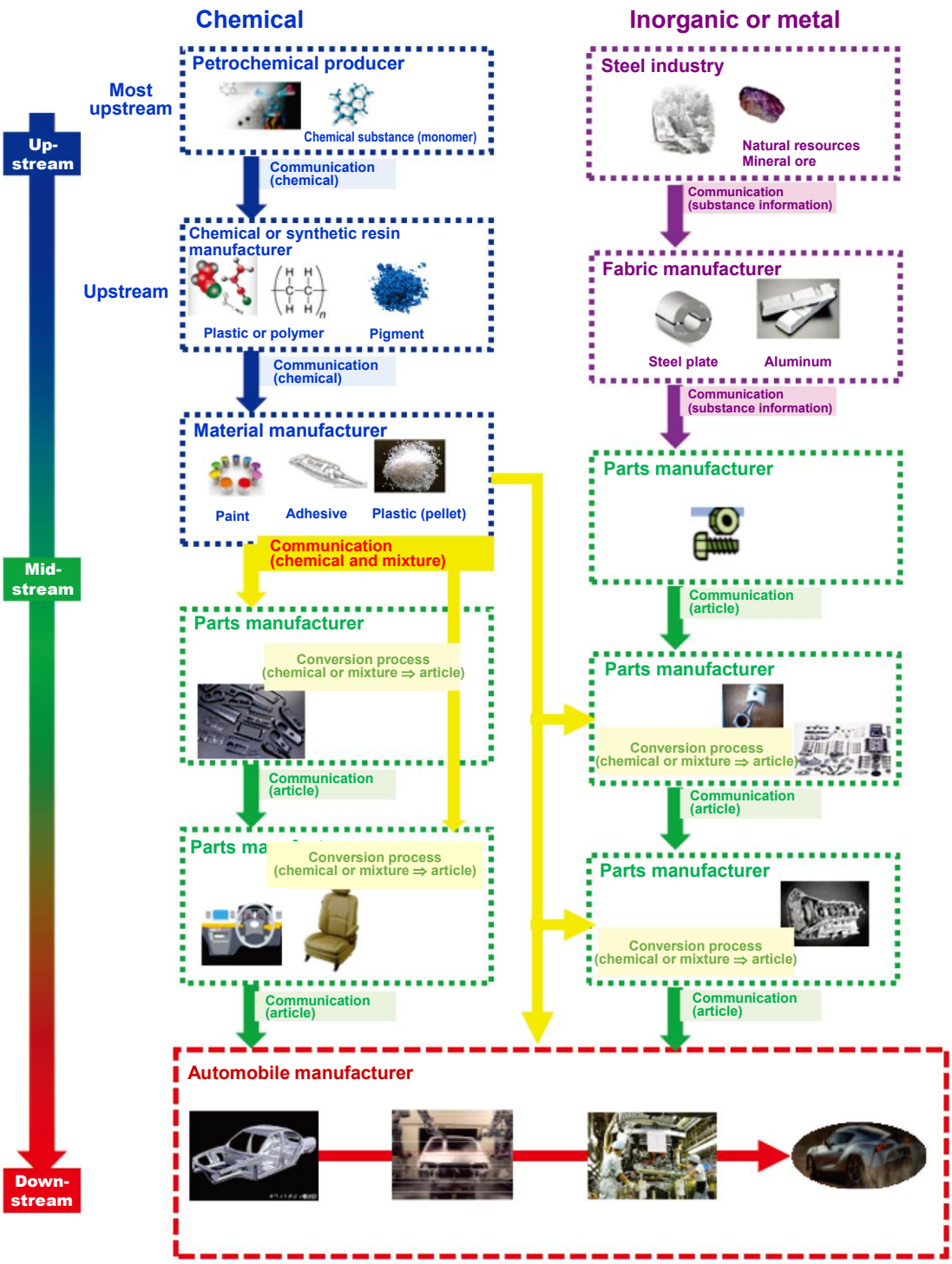

Figure 4.5 Communication of chemical substance information in the automobile manufacturing supply chain (from upstream to downstream)

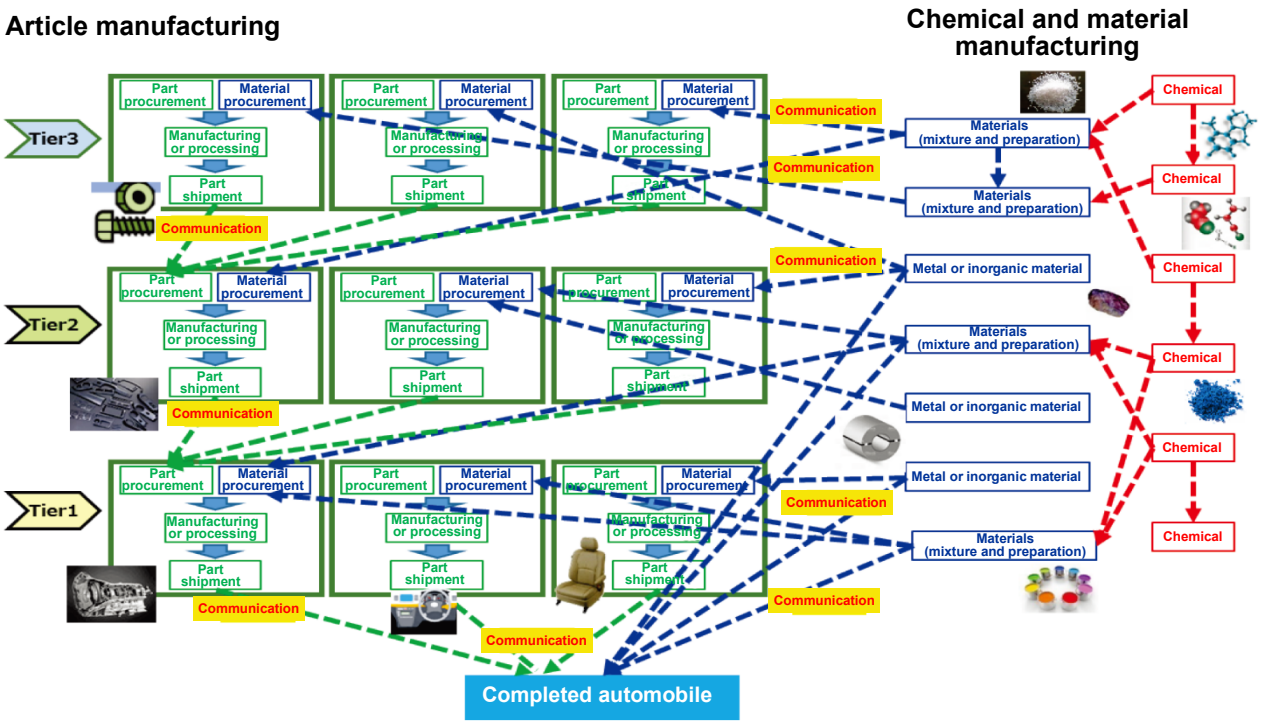

Figure 4.6 Communication of chemical substance information in the automobile manufacturing supply chain (from article to chemical)

Table 4.2 Examples of articles the composition of which changes in the conversion process and articles the composition of which does not change in the conversion process

Major examples where material composition changes in the conversion process (surface treatment, paint, adhesive, and thermoset resin)

Conversion process	Chemical used (input to the conversion process) (chemical substance or mixture)	Target of the process (article)	New article resulting from the conversion process	Phenomenon What happens in the conversion process
Manufacturing and shaping of rubber parts	Rubber and cross-linker		Rubber part	Vulcanization (heating and pressurization using a mold)
Plating	Plating solution	Metal part Plastic part	Plated part made of the base material shown on the left	Metal film resulting from electrochemical reaction
Chemical conversion coating	Chemical conversion coating solution	Metal part Automobile body	Product shown on the left with chemical conversion coating • Chromate • Phosphate • Alkaline black coating, etc.	Oxidation, reduction, displacement, precipitation
Painting	Paint	Metal part Plastic part Automobile body	Painted part Painted automobile body	Volatilization of solvent Hardening of plastic component in paint
Adhesion	Adhesive	Metal part Plastic part Automobile body	Junction piece Automobile body	Volatilization of solvent Hardening of plastic component in adhesive

Manufacturing and shaping of plastic parts	1. Polyol, (di)isocyanate, blowing agent 2. Unsaturated polyester, epoxy, toughening agent (continuous fiber)	1. Shaping of urethane foam 2. FRP formed parts	1. (Expanded) polyurethane foam part 2. FRP part	1. Chemical reaction (polymerization), hardening 2. Hardening of plastic component

Major examples where material composition does not change in the conversion process (metal and thermoplastic resin)

Conversion process	Chemical used (input to the conversion process) (chemical substance or mixture)	Target of the process (article)	New article resulting from the conversion process	Phenomenon What happens in the conversion process
Press molding, casting, or forging of metal part	Steel plate (iron or aluminum) Cast iron, cast aluminum alloy Special steel, wrought aluminum alloy		Press part Cast part Forged part	Plastic deformation Melting and solidification Plastic deformation
Cutting work of metal or plastic	Metal part or plastic material	—	Cut metal or plastic part	
Injection molding of thermoplastic resin	Thermoplastic resin pellets PP, PE, PVC, ABS, PS, PA, PC, etc.		Plastic part	Melting and hardening (solidification) of plastic

4.6 Consolidation of information on chemicals in products in the automotive industry

Each company in the automobile supply chain must consolidate information on chemicals in products and provide downstream customers with it based on rational information at each stage assuming that information on chemicals in products is managed at each of the design, development, procurement, manufacturing, and delivery stages in the company as shown in Figure 4.7.

Downstream companies such as automobile manufacturers must clarify criteria required for delivered products and properly communicate them based on legal information, etc. suitable for the selling area, applications, and other characteristics of end products to suppliers.

Each company shall consolidate information on chemicals in products based on information on chemicals in purchased parts acquired from suppliers as well as scientific insights and manufacturing information related to your manufacturing process. The companies at the midstream of the automobile supply chain must consolidate information on chemicals in articles to be delivered. In particular, companies that have the conversion process from chemicals to articles shown in section 4.5 must take extra care because the composition or concentration may change in the manufacturing stage.

According to article 33 of the REACH Regulations, automobile manufacturers are obliged to disclose and provide information. In addition, the European Chemicals Agency (ECHA) made it mandatory to register substances of very high concern in products (SCIP) in January 2021 as described in section 4.1. As a result, each company needs more accurate data creation and management than ever before.

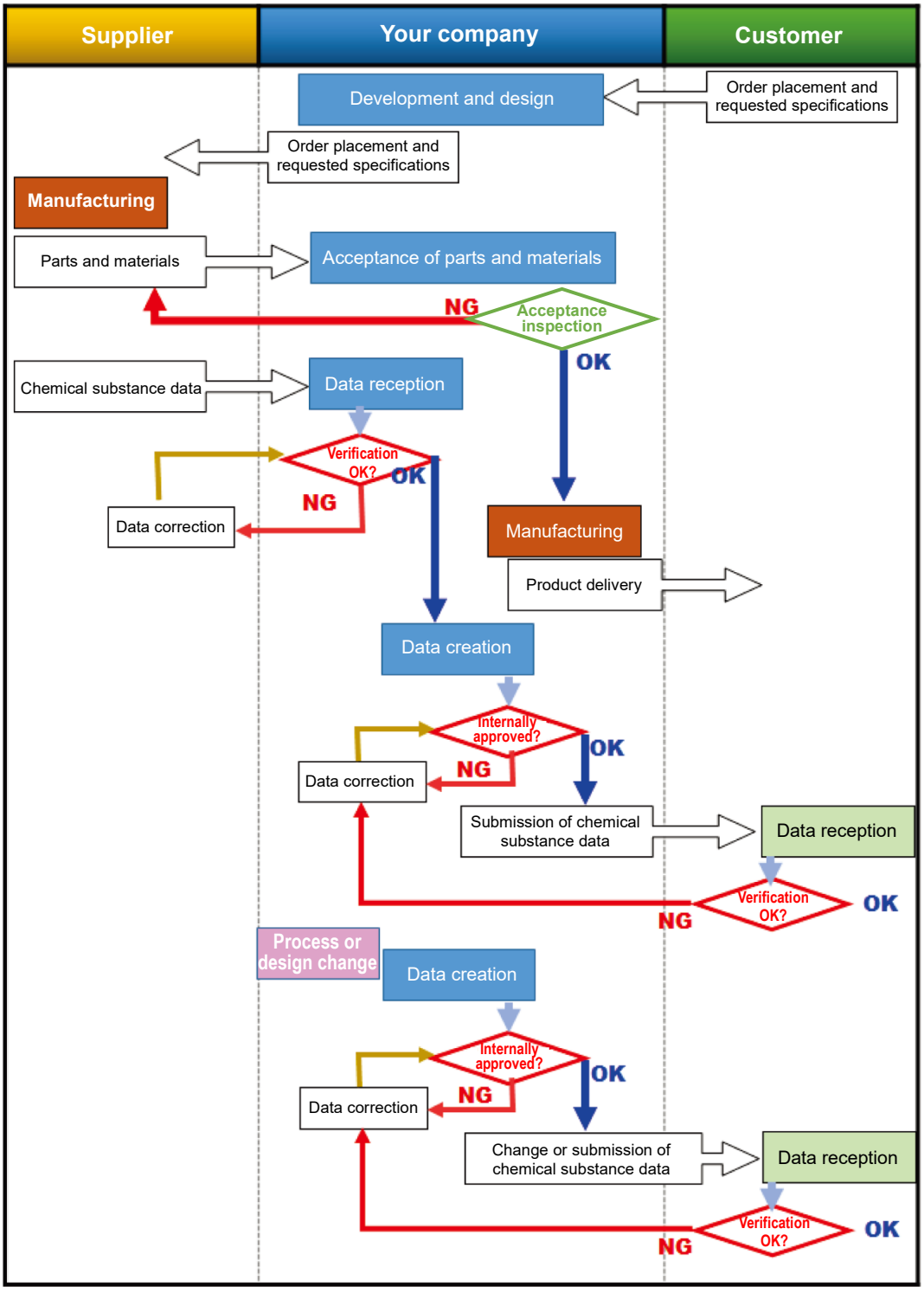

Figure 4.7 Procedure to manage chemicals in products

4.7 Proper time to communicate information on chemicals in products

Information on chemicals in products in the automobile supply chain shall be mainly communicated in the following cases:

(1) When a new model of vehicle is developed

To verify the type approval of a new model of vehicle and conformity with laws and regulations on chemical substances in each country, automobile manufacturers shall ask suppliers to submit IMDS data at the time of prototyping or mass production (as instructed by each automobile manufacturer). Automobile manufacturers and suppliers shall discuss and determine the submission deadline of IMDS data, sufficiently considering the lead time required for communication in the supply chain.

(2) When part or material specifications are changed

If the weight or constituent materials of a part that makes up their product are changed, apply for changes to 4M (man, machine, method, and material) to customers and update IMDS data or promptly submit the JAPIA sheet.

(3) When laws, regulations, or GADSL is revised

When laws, regulations, or GADSL is revised, update IMDS data or verify data on the JAPIA sheet and modify and resubmit submitted information as needed.

4.8 Consideration of trade secrets

Although information on chemicals in products required to comply with domestic and overseas laws must be disclosed, it is also important to secure confidential corporate information to maintain company competitiveness. In particular, disclosing information on chemicals in chemical products or articles could create major business problems for suppliers.

In the automotive industry, it is agreed as IMDS operation rules that substances not restricted according to laws and regulations can remain unpublicized to secure confidential corporate information as long as the total amount of substances classified as confidential or highly confidential information is within 10% of all the materials.

In addition, you must sufficiently recognize that information communicated using the IMDS and JAPIA sheets itself is also confidential information that contains the expertise of each supplier in the supply chain and handle the information with great care.

4.9 Support for organizations that have difficulty achieving autonomous management

It is important that all the organizations in the supply chain properly manage chemicals in products for the product manufactured throughout the supply chain to comply with laws, regulations, and other rules related to chemicals in products.

However, in reality, many organizations have difficulty autonomously managing chemicals in products including data and chemical reactions. This tendency is particularly strong in midstream companies, which should be the core of communication of information on chemicals in products.

Therefore, it is also critical that downstream and upstream organizations provide support so that all the organizations in the supply chain understand the requirements for managing chemicals in products in the Guidelines and implement proper management.

5. Implementation Items for Proper Management of Chemicals in Products in the Automotive Industry

Chapter 5 is related to the check sheet entry form in *Self-assessment sheet in Appendix A.*

Sections 5.1 to 5.6 show specific items that each company in the automobile supply chain must implement to properly manage chemicals in products.

The text following Check Item: can be used for self-assessment of how each company or organization manages chemicals in products as well as assessment and verification with business partner (suppliers or customers). Actual evaluations can be reviewed using *Self-assessment sheet in Appendix A.*

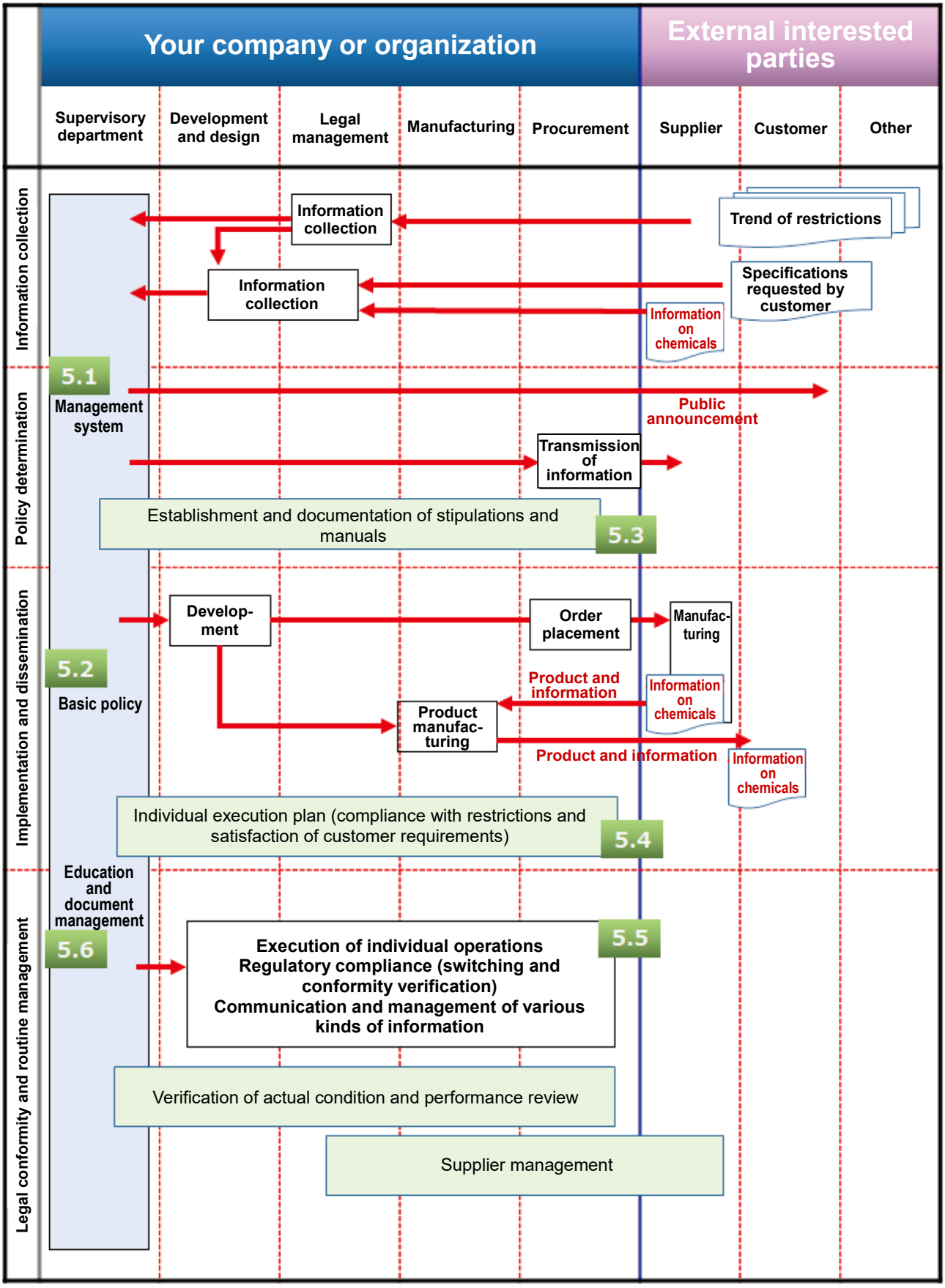

Figure 5.1 Examples of implementation items for management of chemicals in products

5.1 State of the organization and management system

5.1.0 State of the organization

(1) Understanding of the organization and its situation (no related questions)

The organization shall clarify their external and internal issues to impact their ability to achieve the intended result of management of chemicals in products related to their goals.

Note

Issues are changing circumstances that can impact the organization that works on management of chemicals in products. Examples include the following:

a) External issues include domestic and overseas legal, technical, and economic situations related to chemicals in products and the awareness and values of external interested parties.

b) Internal issues include the characteristics or situation of the organization such as governance and organization framework, products, and abilities (those engaged in management of chemicals in products as well as knowledge and processes). It is important that all the departments involved in design, development, procurement, manufacturing, and delivery recognize the necessity of management of chemicals in products.

(2) Understanding of the needs and expectations of interested parties (no related questions)

The organization shall clarify the following matters to understand the needs and expectations of interested parties.

a) Interested parties closely related to the management of chemicals in products
b) Requirements closely related to the management of chemicals in products by these interested parties

Note

Examples of external interested parties related to the management of chemicals in products include customers, suppliers, subcontractors, and government.

(3) Determination of the scope of management of chemicals in products (no related questions)

The organization shall determine the proper scope of management of chemicals in products, considering the following matters:

a) External and internal issues of the organization defined in 5.1.0 (1)
b) Requirements by interested parties defined in 5.1.0 (2)
c) How the organization uses chemical substances
d) Products that are handled by the organization and provided from or delivered to outside

Note

Consider the following items when determining the scope of management criteria for chemicals in products.

a) Products to which the provisions apply (external purchase, supplied products, external delivery, products that the organization supplies)

b) Customer requirements

c) Requirements by related departments in the company

d) Products that the internal organization that supervises management of chemicals in products handles include the

following products that could cause contamination even if contained components are not restricted. Take preventive measures against contamination of these products.

- Indirect packaging materials (e.g., packaging materials and protective materials for parts)
- Secondary materials (e.g., grease and mold release agent)
- Jigs and tools

5.1.1 Management system

(1) Acquisition of management system certifications

It is important that the organization that manages chemicals in products has a management system to continuously plan, do, check, and act and be reviewed by a third party to acquire certifications. Typical certifications are the ISO14001 environment certification (or simplified EMS) and the ISO9001 quality certification.

You must also perform operations in line with the system of these management systems and tools, go through internal audits and external reviews, and maintain the management systems to manage chemicals in products in the automotive industry.

Check Item: 5.1.1.1 Acquisition of management system certifications (acquisition of ISO14001 or other environmental certification (simplified EMS)) and operation of it

Each company or organization shall acquire these management system certifications and take action according to the acquired certifications.

It is best to conduct internal and external audits on a regular basis to maintain the management systems.

Note

(1) The ISO14001 standard defines the framework for environment management systems. This standard is useful as the base of a management system for management of chemicals in automobiles as well as automobile parts and materials. The ISO9001 standard may be applied as part of quality management in terms of quality assurance activities.

(2) The Guidelines focus on how the product chemical management system is maintained. It is particularly important that the design, development, procurement, acceptance, manufacturing, inspection, and delivery processes go through internal audits on a regular basis and are subject to external reviews.

5.2 Basic policy and management framework

5.2.1 Basic policy on management of chemicals in products

The organization shall define the basic policy on management of chemicals in products approved by the chief executive or the top management of the organization that supervises management of chemicals in products. The defined policy shall be disseminated within the company, understood by internal related parties, and be available to interested parties.

Check Item: 5.2.1.1. Existence of policy on management of chemicals in products and dissemination in and outside the company (organization)

The company (organization) shall have provisions for the management framework for chemicals in products in the company (organization) and perform relevant operations.

In addition, it is best to review and update the policy on a regular basis and announce details publicly as well as in the company (organization).

Note

(1) It is important for the policy to include legal compliance and conformity with industry standards such as GADSL and customer requirements.

(2) For example, you can gather related parties and explain the policy or post the policy on an information sharing system such as an education system or intranet to disseminate the policy in the company (organization).

(3) For interested parties, you can, for example, include the policy in the environment report, CSR report, or other document issued by each company, individually gather external related parties and explain the policy, or widely announce the policy by posting it on each company's website, etc.

5.2.2 Management framework for chemicals in products

You shall establish a framework where the responsibilities and authorities for relevant roles are clarified to reliably manage chemicals in products according to the basic policy.

Check Item: 5.2.2.1 Existence and operation of a management framework for chemicals in products in the company (organization)

The company (organization) shall have provisions for the management framework for chemicals in products in the company (organization) and perform relevant operations.

In addition, it is best to implement a system to evaluate and verify the actual management and operation of relevant operations in the company according to the latest provisions (e.g., upper-level organization that receives reports and internal audit).

Note

(1) Regarding the management and operation framework, the departments responsible for necessary operation, their roles, and an organization chart that includes these must have been approved by the chief executive or top management and disseminated within the company (organization) for effective and reliable management of chemicals in products.

(2) The top management of the management framework for chemicals in products shall ask for regular reports to reliably manage chemicals in products in order to evaluate and improve the actual management and carry out all related operations.

5.2.3 Governance over domestic and overseas subsidiaries and subcontractors

Each company that has domestic or overseas subsidiaries shall establish a governance and management framework and provisions related to its management and operation framework for the

domestic or overseas subsidiaries as the parent company to properly manage chemicals in products. Each company that has subcontractors shall have provisions for subcontractors including the management and operation framework and shall carry out all related operations according to the provisions to properly manage chemicals in products.

Check Item: 5.2.3.1 Establishment and operation of a governance and management framework for domestic and overseas subsidiaries and subcontractors

Each company shall have provisions for the management framework for domestic and overseas subsidiaries and subcontractors and perform relevant operations.

In addition, it is best to implement a system to evaluate and verify the actual management and operation of relevant operations in the company according to the latest provisions.

Note

(1) For proper governance over domestic or overseas subsidiaries in terms of management of chemicals in products, it is important to establish governance and verify the environmental management framework by asking domestic or overseas subsidiaries and subcontractors to establish transparency and accountabilities and seeking the understanding of the chief executive or top management.

(2) It is important to verify regular and proper operation and management by domestic or overseas subsidiaries to evaluate the actual operation.

5.3 Management of chemicals in products

It is important to establish management criteria and management provisions suitable for the business and products of the company (organization) to manage chemicals in products based on the basic policy and management framework described in the previous section (section 5.2).

This section describes the importance and details of the management criteria for chemicals in products and the method of and provisions for management of chemicals in products.

5.3.1 Management criteria for chemicals in products

You shall create and establish the criteria for the types and management level (threshold) of managed chemicals in products (parts and materials) of the company (organization) (management criteria for chemicals in products) and apply them to management operations of chemicals in products.

Check Item: 5.3.1.1 Existence of management criteria for chemicals in products (laws and regulations to be observed in one's own products, restricted substances, and management methods)

The company (organization) shall have criteria agreed on throughout the company (organization) and have them disseminated within the company (organization), and publicly announced them.

In addition, it is best to have verified that all the internal and external related parties take action according to the latest version of the criteria.

Note

(1) Note the following items to establish management criteria for chemicals in products.
   a) The management criteria for chemicals in products are defined based on the laws, regulations, and industry standards related to chemicals in products. It is important to maintain the latest information.
   b) Multiple management criteria may be defined depending on the product field, destination, and other factors.
   c) For customer requirements, refer to section 5.3.4, "System related to the management of chemicals in products by customers."
(2) It is important to identify applicable laws and regulations even for consignment production. It is also important that the organization that receives the order of consignment production clarifies management criteria for chemicals in products.
(3) It is important to review the management criteria on a regular basis with the internally defined frequency and accurately keep review records. It is also important to properly review management criteria in addition to periodic reviews in line with changes to laws, regulations, customer requests, etc.

5.3.2 Provisions for division of roles and work procedures to reliably manage chemicals in products

The company (organization) shall define division of roles, operational provisions, or work procedures based on the framework documented in section 5.2.2 and perform operations according to them to properly manage chemicals in their products.

Check Item: 5.3.2.1 Provisions for division of roles and work procedures to manage chemicals in products and their operation

The company (organization) shall have provisions for the roles and work procedures of the department in charge based on the framework described in section 5.2.2 and a council to verify how operations are performed according to the management framework for chemicals in products.

In addition, it is best to have a council to verify provisions and how operations are performed and implement a system to have council meetings on a regular basis to evaluate and verify their actual operation.

Note

(1) It is important to clarify the following items for the framework in the company (organization).
   a) General manager
   b) Department that mainly supervises operations in the company (organization)
   c) Roles of each department in the company involved in management of chemicals in products
   d) Clarification of external and internal issues of the company (organization)
(2) The management method includes documented procedures, operation rules, and manuals for management operations according to the management criteria.
(3) It is important to note the following items to establish the management method and documented procedures.
   a) Clarification of input (resources and information) and expected output (deliverables including information) acquired at each of the design, development, procurement, manufacturing, and delivery stages
   b) One of the outputs at delivery is communication of information on chemicals in products to customers using the IMDS or JAPIA sheet
(4) It is important to note the following items to clarify the management method.
   a) Consider information shown to suppliers, how to acquire information on chemicals in products, data formats (such as IMDS and JAPIA sheets and SDS), frequency, and other factors.

b) If you have determined that your own products are free from the possibility of containing chemical substances restricted according to laws, regulations and customer requests based on scientific grounds (such as chemical analysis data), retain information that documents these results.

5.3.3 Goals and action plan

Each company shall have goals related to the management of chemicals in products and an action plan to achieve the goals and perform relevant operations according to the action plan.

Check Item: 5.3.3.1 Existence of goals and an action plan to achieve the goals as well as how operations are performed according to the plan

The company (organization) shall implement goals and an action plan established by the department that mainly supervises the management of chemicals in products and that is approved by the top management of the organization.

In addition, it is best to manage goals, an action plan to achieve them, and how operations are performed and report them to the upper-level organization and obtain approval.

5.3.4 System related to the management of chemicals in products by customers

Communication with customers is important to reliably apply various information from customers to the operations of the company (organization) and take action to satisfy customer requests. Therefore, the company (organization) shall create work procedures, rules, etc. related to how to maintain communication with customers and how to utilize acquired information, etc. and perform operations according to them.

Check Item: 5.3.4.1 Contact department for operations related to the management of chemicals in products (e.g., IMDS, criteria, and studies), maintenance of person-in-charge information, and how they are communicated to customers

The company (organization) shall have provisions for communication of contact department and person in charge information to customers for smooth communication with customers and communicate them to customers.

In addition, it is best to communicate contact department and person in charge information to customers according to provisions and manage how they are communicated.

Check Item: 5.3.4.2 Compliance with customers' provisions for management of chemicals in products

The company (organization) shall individually comply with customers' provisions for management of chemicals in products and apply them to the provisions or criteria related to the management of chemicals in products in the company as needed.

In addition, it is best to apply customers' provisions for management of chemicals in products to the provisions or criteria related to the management of chemicals in products in the company and verify compliance.

Note

(1) Examples of customer information include the following:
Customer's policy, management criteria, management method, and applicable laws and regulations

(2) It is important to apply acquired customer information to internal information and review it. Apply the

information to the internal policy once a year and take necessary actions until then.

5.4 Operation of management of chemicals in products

To properly manage chemicals in products and operate the management system, the company (organization) shall take proper actions for their business and products.

This section describes matters related to management provisions and the state of operations at each step of the operation processes for each company to manage chemicals in products more specifically though the basic policy on management of chemicals in products, the management criteria for chemicals in products, and the method of and provisions for management of chemicals in products described in sections 5.2 and 5.3 provide implementation items across the target organization (and affiliated companies under governance based on the criteria).

If the organization does not have operations or functions described in each item below or if the product is not within the scope, the organization does not have to implement specifications for target matters.

5.4.1 Management of chemicals in products during design and development

The department responsible for the relevant operations and the department that mainly supervises the management of chemicals in products in the organization shall clarify work procedures and provisions to properly manage chemicals in products at each of the procurement, manufacturing, and shipment stages, make documented information available, perform relevant operations, and maintain related provisions in a way suitable for their products and business categories to realize products that satisfy the management criteria for chemicals in products at the design and development stages in the organization (and affiliated companies to which the provisions apply).

Specifically, they shall define matters to be implemented, criteria, and procedures for proper management at the design and development stages in the management criteria for chemicals in products and the method of and provisions for management of chemicals in products in section 5.3, or create manuals or other documents based on these provisions and perform operations according to these provisions.

When managing products (parts or materials) that go through the conversion process described later in section 5.4.3.2, clarify their management criteria to realize products that satisfy the management criteria for chemicals in products in the product state after the conversion process.

Check Item: 5.4.1.1 Existence of provisions for operations management and how operations are performed and managed according to the provisions

The company (organization) shall have provisions to manage chemicals in products at the design and development stages and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

Management both at the design and development stages

(1) The design and development stages include not only operations in the design development department, etc. but also operations in related departments that are performed by the time production starts.

(2) For example, an organization that selects products to be procured is considered to have the design function even if it is not a design-related department. Accordingly, this guideline item is applicable to this organization.

(3) It is important to define design conditions, purchase conditions, manufacturing process, manufacturing conditions, delivery conditions, etc., considering chemicals in purchased products and chemical substances added, reproduced, or removed in the manufacturing process in order to consider risks in terms of management of chemicals in products and ensure that the product satisfies the management criteria for chemicals in products. Manufacturing conditions include prevention of misuse and contamination and management in the reaction process.

(4) It is important to define the time, range, and other details of the acquisition and verification of information on chemicals in products provided from outside and verification of how suppliers manage information on chemicals in products from experiment to prototyping through to mass production depending on the products to be manufactured. Products provided from outside are broken down into supplied products and specified products. It is important to recognize and properly manage the respective products as follows.

Supplied products: Parts and materials supplied from the product shipment destination to be incorporated into the product the company manufactures

Specified products: Parts and materials specified by the product shipment destination to be incorporated into the product the company manufactures

(5) The management criteria related to chemicals in products at each stage clarified during design and development can be shown in the specification document, drawing sheet, manufacturing instructions, work instructions, and criteria, for example.

(6) It is important to fully identify risks and define and operate a management method when using recycled materials.

Management at the design and development stages when manufacturing articles using chemicals

(1) Examples of manufacturing articles from chemicals include plastic shaping, surface treatment such as plating, painting, and printing, and joints using solder, adhesive, etc. For example, note that the concentration (amount) and types of chemicals in products may change due to the hardening (drying) reaction between before hardening (drying) and after hardening (drying) in the case of adhesion.

(2) When manufacturing articles from chemicals, it is important to verify information on chemicals in products about the chemicals to be purchased.

(3) If the concentration and types of chemicals in products may change in the manufacturing process, it is important to identify the changes and verify that the product conforms to the management criteria for chemicals in products. For example, low-molecule-weight components in coatings may volatilize in the baking finishing process. In the hardening and shaping process of hardening resin, monomers, hardening agents, and hardening accelerators may be involved in the hardening reaction and change the chemical composition due to bonding or incorporation into cured resin, polymerization, or other phenomenon.

(4) If the organization that manufactures articles from chemicals cannot identify the change in the chemical composition, it is important to contact the supplier of the chemicals or take other action.

(5) When the manufactured article comes with chemical products, it is important to verify information on chemicals in chemical products. Examples include refrigerants, greases, lubricants, and rust preventive oils.

(6) Pay attention to notes related to management during design and development in the same process because they may be performed at the same time as the process to manufacture a new article from articles in many cases.

(7) It is best to use the communication method for information on chemicals in products standardized in the automobile field such as the IMDS and JAPIA sheets to verify information on chemicals in chemical products. Information on the SDS alone may be insufficient.

Management at the design and development stages when manufacturing articles using articles

(1) Examples of manufacturing a new article from articles include combination of parts and machining on a part converted for the first time from chemicals such as plastic and metal.

(2) When manufacturing a new article from articles, it is important to verify information on chemicals in procured products and verify that the products conform to the management criteria for chemicals in products.

(3) When solder, adhesive, paint, ink, or other material is used, the process of manufacturing the article using chemicals is performed at the same time. Therefore, pay attention to the description in "Management at the design and development stages when manufacturing articles using chemicals."

(4) It is best to use the communication method for information on chemicals in products standardized in the automobile field such as the IMDS and JAPIA sheets to verify information on chemicals in articles.

5.4.2 Management of chemicals in products at time of purchase and acceptance of parts and materials

The department responsible for the relevant operations and the department responsible for management of chemicals in products in the organization shall create work procedures and provisions to properly manage chemicals in products, make documented information available, perform relevant operations, and maintain related provisions in a way suitable for their products and business categories to realize products that satisfy the management criteria for chemicals in products at purchase and acceptance of parts and materials by the organization (and affiliated companies to which the provisions apply).

Specifically, they shall define how to purchase parts and materials from suppliers, how to acquire information on chemicals in products in the acceptance process and information from suppliers including requests to create and submit information for suppliers, and actions for the verification result of acquired information.

(1) Acquisition and verification of information on chemicals in products from suppliers

The department responsible for the relevant operations and the department responsible for management of chemicals in products in the organization shall provide the management criteria related to chemicals in products and management method to suppliers and verify that necessary information is accurately acquired according to provided details at purchase and acceptance of parts and materials by the organization (and affiliated companies to which the provisions apply).

Check Item: 5.4.2.1 Existence of provisions for acquisition and verification of information on chemicals in products from suppliers and how operations are performed according to the provisions

The company (organization) shall document people in charge of acquiring, verifying, and managing information on parts and materials to be managed and how to acquire, verify, and manage such information in provisions and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

(1) It is important to clarify the verification method at acceptance. For example, the company (organization) can clarify the assessment method (such as verifying actual goods against information and assessment by a specialized department on an as-needed basis), how to document information on assessment results, and identification management method.

(2) Verify that acquired information satisfies the management criteria for chemicals in products. If not, it is

important to ask the supplier to verify, correct, and resubmit information to acquire information that satisfies the management criteria.

(3) Information acquired from suppliers must be retained as documented information or a database.

(2) Management of chemicals in products at the first and routine acceptance of products

The department responsible for the relevant operations and the department responsible for management of chemicals in products in the organization shall clarify the management method and rules related to chemicals in products at the first and routine acceptance of products, provide them to suppliers and the department in charge of the relevant operation in the organization, and ensure management at purchase and acceptance of parts and materials by the organization (and affiliated companies to which the provisions apply).

Check Item: 5.4.2.2 Existence of provisions for management of chemicals in products at the first and routine acceptance of products and how operations are performed according to the provisions

The company (organization) shall have a documented system to manage chemicals in products at the first and routine acceptance of products from suppliers in the provisions and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

(1) It is important to clarify the verification target, criteria, method, frequency, and other details at acceptance depending on risks in terms of management of chemicals in products including the likeliness that chemical substances restricted according to the management criteria for chemicals in products are contained, the supplier's management level of chemicals in products, past results, and whether recycled materials are used for verification at acceptance.

(2) Verify consigned goods as well at acceptance.

(3) When procuring items from multiple companies (multiple sources), use the verification method suitable for the risks of each supplier.

(4) If there are risks in terms of the management of chemicals in products, verify packing materials such as tapes, cushioning materials, tying materials, shock-absorbing materials, secondary materials (indirect materials), etc. used for the product (including those attached to the product) as well.

(5) You can match information such as the order number and model number as an acceptance check when accepting a product that conforms to the management criteria related to chemicals in products from the supplier.

(6) Complete acquisition and verification of information on chemicals in products when ordering or during procurement by the deadline separately determined with the customer based on the submission deadline of the automobile manufacturer.

5.4.3 Management of chemicals in products in the manufacturing process in the company

(1) Management provisions for management criteria in the manufacturing process

The department responsible for the relevant operations and the department that mainly supervises the management of chemicals in products in the organization shall create work procedures and provisions to properly manage chemicals in products, make documented information available, perform relevant operations, and maintain related provisions in a way suitable for their products and business categories to manufacture and ship products that satisfy the management criteria for chemicals in products in the manufacturing process of their own products in the organization (and affiliated companies to which the provisions apply).

Check Item: 5.4.3.1 Existence of management provisions for management criteria in the manufacturing process and how operations are performed according to the provisions

The company (organization) shall have provisions to manage chemicals in products in the manufacturing process and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

(2) Management of chemicals in products that go through the conversion process

It is important to correctly understand the details of and changes in the conversion process in the manufacturing process of products that go through the conversion process in the manufacturing process in the company (organization), particularly products that go through chemical changes to properly manage chemical substances in product at shipment.

Specifically, the department responsible for the relevant operations and the department that mainly supervises the management of chemicals in products in the organization shall make work procedures and provisions to properly manage chemicals in products in each of the procurement, manufacturing, and shipment processes available as documented information, perform relevant operations, and maintain related provisions in a way suitable for their products and business categories to realize products that satisfy the management criteria for chemicals in products.

Check Item: 5.4.3.2 Existence of provisions for management of products associated with conversion processes (manufacturing processes in which the composition of chemical substances changes due to oxidation reaction, reduction reaction, or other phenomenon or manufacturing processes in which the concentration of chemical substances changes due to condensation, evaporation, or other phenomenon) and how operations are performed according to the provisions

The company (organization) shall have provisions to manage chemicals in products in a way suitable for products that go through conversion processes and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

(1) Identify manufacturing processes that require priority management. For example, identify manufacturing processes in which the composition of chemical substances changes due to oxidation reaction, reduction reaction, or other phenomenon or manufacturing processes in which the concentration of chemical substances changes due to condensation, evaporation, or other phenomenon and perform proper management.

(2) It is important to manage chemical substances restricted according to the management criteria for chemicals in products so that they do not remain or are not generated above the management criteria related to chemicals in products in the manufacturing process due to changes in the composition and concentration.

(3) Because chemical compositions may change in the process of changing chemicals into an article (conversion

process), it is important to verify whether the chemical composition has changed and identify the new chemical composition if changes have occurred. For example, low-molecule-weight components in coatings may volatilize during baking finishing. In the hardening and shaping process of hardening resin, monomers, hardening agents, and hardening initiators may be involved in the hardening reaction and bond with or get incorporated into the cured resin or be polymerized. For the conversion process, refer to section 4.5, "Specific actions and points to be noted on management of chemicals in products in the automotive industry," and Table 4.2, "Examples of articles the composition of which changes in the conversion process and articles the composition of which does not change in the conversion process."

(4) Identify chemical substances the contained amount of which should be monitored, determine the monitoring method (measurement method and measurement frequency), and perform proper management in each process.

(3) Provisions for operations management related to traceability in the manufacturing process

The company (organization) shall have work procedures and a system to manage the traceability of information on chemicals in products and reliably manage traceability according to them to identify information on chemicals in their own products, promptly use, disclose, and communicate the information.

Check Item: 5.4.3.3 Existence of provisions for operations management related to traceability and how operations are performed according to the provisions

The company (organization) shall have provisions related to traceability to manage records for information on the management of chemicals in their own products and perform operations according to the provisions. (For example, the company (organization) records and stores purchase and usage records of materials, secondary materials, etc. and maintains their traceability.)

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

(1) The following information is important for traceability management, for example, to identify the range in case of nonconformity or provide information in case of change.
- Component materials of respective products and their manufacturing time and location
- Information on chemicals in the component materials, manufactured product, etc.

(2) It is also important to establish a system to relate the above documented information that should be retained, identify the information according to risks in terms of management of chemicals in products, and promptly use, disclose, and communicate it.

(4) Management when changing processes and materials

When changing processes or materials in the manufacturing process in the company, the company (organization) shall identify the possibility that the change will impact the management of chemicals in products and its details and take proper action regardless of the reason.

As specific examples, the company (organization) can properly verify changes in chemicals in products resulting from the changes, perform a review according to the management criteria for chemicals in products before making the changes, and retain documented information that describes the review result of the changes, the responsible person who formally permitted the changes, and actions resulting from the review.

Check Item: 5.4.3.4 Existence of management criteria and provisions for changes in processes and materials and abnormalities in processes (including misuse and entry of foreign matter) and how operations are performed according to the provisions

The company (organization) has provisions to change processes and materials and perform operations according to them.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

(1) Changes include change or addition of supplier and change of purchased product, part weight, part composition, and manufacturing process.

(2) Manage changes made by suppliers, subcontractors, and other related parties in the supply chain as well as changes made in the company (organization). It is important to clarify the communication flow with suppliers, subcontractors, and customers in case of change.

(3) It is important to reliably acquire information on changes made by suppliers in advance. It is also important to reliably show the change management procedure to suppliers (including secondary, tertiary, and subsequent suppliers) at this time.

(4) Verify conformity to the management criteria for chemicals in products before making changes.

(5) It is important to inform customers of changes in advance. In other words, it is important to promptly submit updated information on chemicals in products and provide customers with the lot information and identification information of the product using the IMDS and JAPIA sheets if chemicals in products change.

(6) Generally, changes to be managed include changes to four production factors (4M), that is, man, machine, material, and method. In addition, the measuring method (Measurement) should be also taken into consideration. Refer to Table 4.2, "Examples of articles the composition of which changes in the conversion process and articles the composition of which does not change in the conversion process."

5.4.4 Management of chemicals in products in the shipment process in the company

(1) Work procedures and provisions in the shipment process

The department responsible for the relevant operations and the department that mainly supervises the management of chemicals in products in the organization shall make work procedures and provisions to properly manage chemicals in products available as documented information, perform relevant operations, and maintain related provisions in a way suitable for their products and business categories to realize products that satisfy the management criteria for chemicals in products in the shipment process of the products of the organization (and affiliated companies to which the provisions apply) with the same position as quality management conditions at product shipment.

Check Item: 5.4.4.1 Existence of work procedures and provisions in the shipment process and how operations are performed according to the provisions

The company (organization) shall have provisions to manage chemicals in products in the shipment process that are applied to the shipment criteria and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Note

(1) It is important to verify that all the predefined points have been verified in the manufacturing process. Examples of points to be verified at shipment include the following:

a) Purchased products verified at acceptance have been used for manufacturing.
b) The product has been manufactured according to the management criteria related to chemicals in products at each stage.
c) Records for changes have been saved if changes were made.
d) Proper actions have been taken if a nonconformity occurred.
e) The products have been sampled for verification as needed.

(2) Examples of verification methods include the following:
a) You can identify the management situation in the manufacturing process from identification tags.
b) You can identify management data in the manufacturing process from the production management system.

(3) Manage products to be shipped in warehouses as well to prevent shipment errors and contamination.

(4) It is necessary to establish and implement management criteria for delivered products in light of the laws and regulations applicable to management criteria for chemicals in products, GADSL, customer requirements, feedback, nonconformities, and other factors.

(2) Traceability in the shipment process (no related questions)

The company (organization) shall reliably manage the traceability of information on chemicals in products in the shipment process as in the manufacturing process described in section 5.4.3 (3).

To manage the traceability in the shipment process, you can record and store the details of the management of chemicals in products related to products to be shipped as evidence, for example.

Note

(1) It is important to record and store the following information and maintain the traceability of products to be shipped.
a) Purchase and usage records of materials, secondary materials, etc.
b) Evidence of conformity to the management criteria for chemicals in products (e.g., IMDS and JAPIA sheets)
c) Person (people) who formally permitted delivery

(2) It is also important to establish a system to relate the above documented information that should be retained, identify the information according to risks in terms of management of chemicals in products, and promptly use, disclose, and communicate it.

(3) Change management in the shipment process (no related questions)

The company (organization) shall record and store the details of changes made to processes and materials in the shipment process as in the manufacturing process described in section 5.4.3 (4) because they impact chemical substances in products.

5.4.5 Management of suppliers

To properly manage chemicals in products in the company (organization), it is important to take proper action for each supplier to ensure reliable management of chemicals in products in the supply chain. For this purpose, the department responsible for supplier management operations and the department that mainly supervises the management of chemicals in products in the organization shall provide requirements for managing chemicals in products to the suppliers of all the parts and materials that should be managed and reported and thoroughly implement the requirements.

Meanwhile, it is also important that restricted suppliers properly manage chemicals in products. To achieve this, take action to verify, evaluate, and enhance how suppliers manage chemicals in products, also referring to *the Guidelines for Green Procurement Promotion (Provisional Edition)—Promotion of value chain management*—issued by the Ministry of the Environment in 2012.

Check Item: 5.4.5.1 Existence and operation of a system to provide suppliers with management requirements for chemicals in products

The company (organization) shall have provisions to provide each supplier with management requirements to ensure compliance with their management criteria for chemicals in products and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to manage how operations are performed in the organization.

Check Item: 5.4.5.2 Existence of provisions for verification of suppliers' management framework for chemicals in products and how operations are performed according to the provisions

The company (organization) shall have provisions to verify the management frameworks for chemicals in products of all the suppliers of the parts and materials that should be managed and reported and perform operations according to the provisions.

In addition, it is best to verify on a regular basis according to the provisions how all suppliers manage relevant chemicals, secure evidence, conduct verification in which the top management of both organizations is engaged, and perform improvement activities according to the actual situation.

Note

(1) The management of chemicals in products by suppliers refers to a system to properly manage chemicals in products at each of the design, development, procurement, manufacturing, and delivery stages. The main management factors according to the implementation items in the Guidelines are as follows:

a) Situation of improvement

b) Changes in internal and external issues related to the management of chemicals in products

c) Information on the performance and effectiveness of the management of chemicals in products including the tendencies of the following items:

- Relevant communication with external interested parties (such as suppliers, customers, and subcontractors)
- Goal achievement level
- Conformity to the management criteria for chemicals in products
- Cases of nonconformity and countermeasures
- Result of performance evaluation
- Performance of suppliers and subcontractors

d) Validity of resources input to promote the management of chemicals in products

e) Effectiveness of efforts on risks and opportunities

f) Improvement plan

When excluding factors, clarify the reasons and actions taken.

(2) For example, you can see the documentation or visit the site to verify how chemicals in products are managed. It is advisable to utilize the *Self-assessment sheet in Appendix A* in the Guidelines.

(3) When procuring items from multiple companies (multiple sources), it is important to include each supplier in the target scope.

(4) You can determine the risk level in terms of management of chemicals in products by a supplier based on acquired information on chemicals in products, the possibility that the purchased products could contain unintended chemical substances (such as the existence of conversion processes or parallel production and types of chemicals and articles), the degree of conformity to the Guidelines, existence of an environment or quality management system, past results, etc.

(5) Examples of actions for verification results include adoption, transaction continuation, direction, and transaction suspension.

5.4.6 Points to be noted on management of chemicals in products in other processes in the company

(1) Prevention of misuse and contamination (no related questions)

The organization shall implement preventive measures against the misuse of and contamination from chemical substances restricted according to the management criteria for chemicals in products in each process in the company, particularly in the manufacturing and shipment processes.

Note

(1) As a specific example, you can separate the manufacturing processes that require priority management and other manufacturing processes.

(2) It is important to properly separate used equipment, jigs, tools, etc. and store parts, works in progress, and end products (including storage in warehouses) in manufacturing processes that require priority management.

(3) Examples of contamination here include unintended inclusion of chemicals in products.

(4) Specific examples of preventive measures against chemical contamination include thorough washing when changing chemical raw materials and thorough washing to remove mold release agents or rust preventive agents required only in intermediate processes.

(5) It is important to properly implement preventive measures against contamination from packaging materials and protective materials that do not make up the product as well depending on the possibility of contamination.

(2) Identification and traceability (no related questions)

The organization shall reliably manage the traceability of information on chemicals in products in processes other than the manufacturing process described in section 5.4.3 and the shipment process described in section 5.4.4 with proper means to identify information on chemicals in products and promptly use, disclose and communicate the information.

Note

You can ensure traceability by mutually associating documented information that is retained, referring to the Guidelines.

(3) Change management (no related questions)

The organization shall properly verify changes in chemicals in products, review the changes according to the management criteria for chemicals in products in advance, and retain documented information that describes the review result, person (or people) who formally permitted the changes, and necessary actions resulting from the review for any changes related to chemical substances restricted according to the management criteria for chemicals in products in processes other than the manufacturing process described in section 5.4.3 and the shipment process described in section 5.4.4.

Note

(1) Changes include change or addition of a supplier and change of purchased product and manufacturing process.

(2) It is important to acquire information on changes made by suppliers in advance. It is also important to inform customers of information on changes in advance.

(4) Action in case of abnormality or nonconforming product

If some nonconforming products are found as a result of a problem in the management operations of chemicals in products in the company (organization), the department responsible for the relevant operations and the department that mainly supervises the management of chemicals in products in the organization shall take action such as prompt notification or emergency action (identification of the affected range and prevention of spread).

Check Item: 5.4.6.1 Existence of procedures and rules in case of an abnormality or nonconforming product and how operations are performed according to the rules

The organization shall have provisions for actions (including internal reporting and measures) in case of an abnormality or nonconforming product related to chemicals in products and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to verify and evaluate the situation, report it to the upper-level organization, and manage it.

(5) System for recurrence prevention and lateral dissemination

If some nonconforming products are found as a result of a problem in the management operations of chemicals in products in the company (organization), the company (organization) shall locate causes, take temporary and permanent countermeasures, implement recurrence prevention measures, and laterally disseminate them after taking emergency actions.

Check Item: 5.4.6.2 Existence of a system for recurrence prevention and lateral dissemination and how operations are performed

The company (organization) shall have provisions to locate causes, take temporary and permanent countermeasures, implement recurrence prevention measures, and laterally disseminate them in the company (organization) as well as to affiliated companies and organizations after proper emergency actions for nonconforming products and take action according to them.

In addition, it is best to perform all operations without omission according to the latest provisions and implement a system to verify and evaluate the situation, report it to the upper-level organization, and manage it.

Note

(1) Nonconforming product here is defined as below.

- Products (parts or materials) that do not or may not conform to the criteria, provisions, and rules applicable to the management of chemicals in products are acquired, manufactured, or shipped or restricted chemical substances are detected in one or more processes in the company (organization).

(2) It is best to determine the following matters in advance in relation to actions against nonconformity.

a) Internal report route in case of a nonconformity
b) Identification of affected range and prevention of spread
c) Determination of temporary and permanent countermeasures and actions against the nonconformity that occurred (was detected) and means to implement them
d) Rules related to reporting to customers, etc.
e) Cause location, recurrence prevention, and lateral dissemination

(3) The above documented information can be limited to matters related to chemicals in products. However, it is better to incorporate the information in the ISO management system to audit and review it.

5.5 Management of information and data on chemicals and operation of conformity check operations

For proper management of chemicals in products and operation of the management system, information and data related to chemicals in products communicated in the supply chain is particularly related to compliance. It is important to understand the information correctly, communicate it accurately, and establish, operate, and manage various provisions and manuals to ensure management.

To achieve this, this section describes important implementation items related to the management of information and data on chemicals and the operation of conformity check operations as part of the management operations of chemicals in products in each company more specifically.

5.5.1 Overall operation

The company (organization) shall document the details, procedures, roles, sharing of responsibility of all operations related to the communication of information on chemicals in products with suppliers and customers and information and data management in the company in form of the management provisions, manuals, and other documentation that clarify them and perform operations according to them.

Check Item: 5.5.1.1 Existence of provisions for the operation of data management and conformity check operations related to the management of chemicals in products in general and how operations are performed

The company (organization) shall have provisions in line with the workflow in the organization and perform operations according to them.

In addition, it is best to perform all operations without omission according to the provisions and implement a system to manage how operations are performed in the organization.

Note

The following matters are important in relation to these individual management provisions and manuals.

(1) The management provisions and manuals are related to or included in upper-level internal provisions that are documented and managed to manage chemicals in products in the organization.

(2) The management provisions and manuals are thoroughly understood by related departments in the company and disseminated to related external suppliers and customers to reliably perform operations according to them.

5.5.2 Acquisition of data from suppliers and verification of acquired data

The company (organization) shall have clear procedures and rules for all of the operations related to acquiring information and data from suppliers—from data submission requests to suppliers to data acquisition through verification of acquired data. The company (organization) shall disseminate and thoroughly implement them in related departments in the company and suppliers and perform operations according to these provisions and rules.

Check Item: 5.5.2.1 Existence of rules for data exchange with suppliers (request for submission and acquisition) and how operations are performed according to the rules

The company (organization) shall have rules in line with the workflow in the organization and process acquired data on main suppliers and parts.

In addition, it is best to have rules in line with the workflow in the organization, process all acquired data according to the rules, and manage evidence.

Check Item: 5.5.2.2 Existence of rules for conformity checks of data received from suppliers and actions in case of a nonconformity and how operations are performed according to the rules

The company (organization) shall have rules in line with the workflow in the organization and process main acquired data.

In addition, it is best to have rules in line with the workflow in the organization, process all acquired data according to the rules, and manage evidence.

Note

(1) Information on chemicals in products that should be acquired refers to all information on chemicals defined in the management criteria for chemicals in products (section 5.3.1) and provided to suppliers (e.g., whether chemicals are present, their amounts, concentrations, and applications).

(2) It is important that the procedures and rules for verifying the conformity of acquired data include the following matters.

- The information on chemicals in products acquired from the IMDS and JAPIA sheets contain all the information on chemicals described in (1) without omission.
- The management criteria for chemicals in products and the rules of IMDS and JAPIA sheets in the company are complied with.
- Customer requests are also considered during assessment.

(3) It is important to use identification numbers specific to respective chemical substances such as CAS number to identify chemical substances.

(4) Because laws and regulations related to chemicals in products, GADSL, and customer requirements may vary depending on the application, show the application to the customer (e.g., Biocidal Regulation, REACH restricted substances).

5.5.3 Creation of data on your own products

The company (organization) shall document and internally share the work procedures and creation criteria that consider customer requests and conform to the management criteria for chemicals in products and the rules of the IMDS and JAPIA sheets in the company for their own products (parts and materials) delivered to customers.

The company (organization) shall create information and data on chemicals in products for all products and materials submitted to customers according to these criteria.

Check Item: 5.5.3.1 Existence of rules and a manual on the creation of data on your own products (to be submitted to customers) and how data is created according to them

The company (organization) shall have rules and manuals in line with the workflow in the organization and process main data.

In addition, it is best to have rules and manuals, process all data according to them, and manage evidence.

Check Item: 5.5.3.2 Whether conversion processes in the manufacturing processes in the company are covered in created data and how data is created

The company (organization) shall have rules and manuals in line with the workflow in the organization and process main created data.

In addition, it is best to have rules and manuals, process all created data according to them, and manage evidence.

Note

(1) When the company exports products overseas, the criteria and procedures related to data creation must include actions to conform to the importing country.

(2) Customers' manuals or the official IMDS manual can be employed.

(3) It is best if the manager verifies the data that the person in charge creates.

(4) These rules and manuals must be disseminated to and thoroughly understood by suppliers.

5.5.4 Submission of data to customers

The company (organization) shall clarify procedures and rules related to the submission of data on chemicals in products created with the procedure in the previous section. The company (organization) shall submit the data by the submission deadline determined with the customer based on the procedures and rules.

Check Item: 5.5.4.1 Existence of rules for submission of data to customers and how data is submitted according to them

For data submission to customers, the company (organization) shall have rules that include decisions made with customers and process data to be submitted to main customers.

In addition, it is best to process data submitted to all customers according to rules and manage evidence.

Check Item: 5.5.4.2 Existence of a system to meet the submission deadline and whether data is submitted by the deadline

For data submission to customers, the company (organization) shall have a system to meet the submission deadline and submit the main data by the deadline.

In addition, it is best to have a framework in line with the workflow in the organization, process all data according to the framework, and manage evidence.

Check Item: 5.5.4.3 Existence of a clear procedure if submitted data is rejected by customers and how the procedure is implemented

For data submission to customers, the company (organization) shall have a manual on actions to take in case customers reject submitted data and process main data.

In addition, it is best to have a manual in line with the workflow in the organization, process all data according to it, and manage evidence.

Note

(1) Schedule management and the framework to meet the deadline are important in addition to the establishment of procedures and rules to submit accurate data by the submission deadline determined with customers.

(2) If some information on chemicals in products cannot be acquired by the deadline determined with customers, take action, considering risks in terms of management of chemicals in products, and inform the customers of the delay.

(3) It is important to clarify procedures and rules for action if customers reject data submitted to them.

5.5.5 Data storage

The company (organization) shall clarify rules and procedures for storing data acquired from suppliers and data submitted to customers in the company and store the data according to them.

Check Item: 5.5.5.1 Existence of rules for storage of acquired data and how data is stored according to them

The company (organization) shall have rules for storage of data acquired from suppliers in line with the workflow in the organization and process main acquired data.

In addition, it is best to have rules in line with the workflow in the organization, process all acquired data according to the rules, and manage evidence.

Check Item: 5.5.5.2 Existence of rules for storage of data submitted to customers and how data is stored according to them

The company (organization) shall have rules for storage of data submitted to customers in line with the workflow in the organization and process main submitted data.

In addition, it is best to have rules in line with the workflow in the organization, process all submitted data according to the rules, and manage evidence.

5.5.6 Data update

The company (organization) shall have work procedures and provisions for updating stored data (that was acquired or submitted) if chemicals in target parts or materials or legal information are changed, update data according to them, submit the data to customers, and systematically store it.

Check Item: 5.5.6.1 Existence of provisions for updating data (creation, submission, and storage) in case of changes in laws, regulations, or customer criteria and how data is handled according to the provisions

The company (organization) shall have provisions for updating stored data (that was acquired or submitted) and process main data.

In addition, it is best to have provisions in line with the workflow in the organization, process all data according to the provisions, and manage evidence.

5.6 Management of human resources as well as documents and information

It is also important to build a system for in-house education and training to properly carry out management of chemicals in products shown in the above sections and perform and continue operations.

5.6.1 Education and human resource development

The company (organization) shall build a system for in-house education and human resource development related to the management of chemicals in products.

It is important to clarify the competence that the person in charge of management of chemicals in products must have at each of the design, development, procurement, manufacturing, and delivery stages in the manual for education and training on the management of chemicals in products and provide education and human resource development according to the manual.

Check Item: 5.6.1.1 Existence and operation of a system to maintain the sustainability of management operations of chemicals in products (ability requirements, passing on experience/knowledge, in-house education)

The company (organization) shall have provisions to maintain the sustainability of management operations of chemicals in products and provide education and perform other activities on a regular basis (according to plan).

In addition, it is best to have provisions and take action with long-term vision to enhance and maintain competencies to manage chemicals in products.

5.6.2 Management of documents (various information and records related to the management of chemicals in products)

The organization that supervises management of chemicals in products shall maintain or retain the documented information recommended in the Guidelines and documented internal provisions that are defined as a requirement for the management of chemicals in products to be effective, review them on a regular basis, and make documented information easily accessible to internal related parties utilizing an intranet, etc.

Check Item: 5.6.2.1 Existence and management of provisions for records management (written procedures and manuals)

To manage chemicals in products, the company (organization) shall document and store the information recommended in the Guidelines, review it on a regular basis, disseminate it to related departments in the company, have provisions that enable these operations, and perform operations according to the provisions.

In addition, it is best to perform all operations without omission according to the provisions and implement a system to manage how operations are performed in the organization.

5.6.3 Evaluation and improvement of how education (5.6.1) and document management (5.6.2) are performed

To manage and maintain management operations of chemicals in products, the company (organization) shall evaluate and improve the implementation status, and report the result to the chief executive or top management. The top management shall review the results of the evaluation and corrective actions.

Specifically, the company (organization) must have a system to evaluate whether all of the operations related to the management of chemicals in products are performed according to provisions and manuals and make improvements and report the evaluation situation to the chief executive (or top management). It is also important to evaluate both internal and external relevant parties (suppliers and customers).

Check Item: 5.6.3.1 Existence and operation of provisions for evaluation and improvement of the implementation status

The company (organization) shall have provisions for the evaluation and improvement of the implementation status and perform operations according to them.

In addition, it is best to perform all operations without omission according to the provisions and implement a system to manage how operations are performed in the organization.

Note

Education

(1) Competence refers to the ability to apply necessary knowledge and skills to achieve the company's goals on management of chemicals in products.

(2) It is important to implement all necessary educational and training items without omission according to plan and verify that attendees have understood.

(3) Examples of general education and training contents include the details of the operations of which each employee is in charge, the concept of management of chemicals in products, laws and regulations in each country, customer requirements, GADSL, IMDS and JAPIA sheets, details and usage of industry standards, applications and risks of restricted chemical substances, cases of misuse and contamination, and analysis methods.

Document management

(1) Documented information refers to information that an internal organization decides to maintain or retain and media that contains such information. Documented information that should be maintained is synonymous with the documents in JIS Z 7201:2012. Documented information that should be retained is synonymous with records. The proper format and media can be selected as needed.

(2) Examples of documented information that should be maintained include the policy for management of chemicals in products, manual on the management of chemicals in products, relevant chemical substance management written procedures, provisions, standards, criteria, rules, written procedures, and document system diagram. The documented information does not necessarily have to be in the form of a manual.

(3) Examples of documented information that should be maintained include relevant information on chemicals in products, acceptance inspection results, shipment inspection results, and internal audit results.

(4) The documented information can be integrated with documented information in the environment or quality management system and managed.

(5) It is important to review the contents of documented information on a regular basis and keep the latest version available when necessary.

Implementation status

(1) It is important that the internal organization that supervises the management of chemicals in products monitors and evaluates compliance with the management criteria for chemicals in products and evaluates the effectiveness of the performance of management of chemicals in products.

(2) It is important that top management reviews documented information, plans to improve the organization and operation, and implements the plan.

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Environmental Technology & Policy Committee Chemical Substances Management Subcommittee

Management Tool Steering Experts Group

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