

March 27, 2019

Subcommittee on Electronic Components Environment

ESG Committee of Electronic Components Board

Japan Electronics and Information Technology Industries Association (JEITA)

## **Guideline on Contamination Prevention Measures concerning Specific Phthalates in a Compliance Assurance System for the EU RoHS Directive**

### **Legal Notice and Disclaimer**

This document aims to assist users in complying with their obligations under the EU RoHS Directive.

However, users are reminded that the text of the EU RoHS Directive is the only authentic legal reference and that the information in this document does not constitute legal advice.

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### **1. Introduction (Foreword)**

Four types of specific phthalates, namely, di(2-ethylhexyl)phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) (hereinafter, “specific phthalates”) were added as restricted substances to the EU RoHS Directive by the EU Commission Delegated Directive (EU) 2015/863 published in the EU Official Journal on 4 June, 2015.

As specific phthalates generally present a good functionality balance when used as plasticizers for resins and rubber, they are widely employed to give flexibility and workability to those materials. On the other hand, these specific phthalates are also well known for their migration properties, and contamination caused by this migration may lead to violation of the EU RoHS Directive regulations. In face of that, measures to prevent contamination by migration become necessary in order to assure conformity to the EU RoHS Directive.

Electric and electronic component manufacturers have been requested to establish management systems for the originally restricted substances in order to make their products conform to the EU RoHS Directive. As a matter of course the establishment of the same type of management system is also required for the specific phthalates. However since the specific phthalates present high levels of migration compared to the originally restricted substances, inclusion of risk assessment and management with consideration to migration also becomes necessary from a contamination prevention perspective.

If these specific phthalates could be eliminated from the supply chain, the likelihood of inclusion by contamination could be reduced. However, specific phthalates are widely used and there may be cases when parts and materials including the specific phthalates have to be used in manufacturing processes and transport/storage operations. Therefore, when considering migration of the specific phthalates, efforts must be taken towards an adequate management aiming to reduce product contamination risk by migration of the specific phthalates (mixing and contamination prevention, change control management, etc.). This must also include equipment, fixtures and package materials that do not directly constitute the product.

This guideline was prepared to be used as guidance for electrical and electronic component manufacturers to understand the requirements of the EU RoHS Directive and properties of the specific phthalates and conduct adequate risk management for prevention of product contamination by migration of the specific phthalates in order to ensure conformity of their products to the EU RoHS Directive.

### **2. An Outline and Requirements of the EU RoHS Directive**

#### **Outline of the EU RoHS Directive**

The EU RoHS Directive (Recast Directive 2011/65/EU published on July 1, 2011) regulates the inclusion of hazardous substances in electrical and electronic equipment. The hazardous substances for restriction and their maximum concentration values (by weight in homogeneous materials) are determined in Annex II of the Directive. The restriction for the specific phthalates (4 substances) that were added to Annex II by the Delegated Directive (EU) 2015/863 of June, 2015 comes into force on July 22, 2019.

The EU RoHS Directive requires implementation of internal production control as set in Module A of Annex II of Decision 768/2008/EC in order to check and assure that inclusion of hazardous substances does not exceed the established maximum concentration values, more concretely, management in accordance with EN50581:2012 is required.

#### **Why electrical and electronic component manufacturers must conform to the RoHS Directive**

The EU RoHS Directive is applicable to manufacturers placing their electrical and electronic equipment in the EU (and EEA (European Economic Area)). However, in order to conform to the EU RoHS Directive, all the components and materials that constitute electrical and electronic equipment must be checked concerning the non-inclusion of hazardous substances on a homogeneous material basis. Hence, electrical and electronic component manufacturers

also must assure conformity to the EU RoHS Directive in some form and share that information based on the agreements signed with their customers in the supply chain.

### 3. Noteworthy points concerning the specific phthalates

The specific phthalates are substances mainly used as plasticizers for (organic) polymeric materials.

#### What are plasticizers?

We call plasticizers those substances that have the function of providing adequate plasticity (“plasticizing”) and softening stiff, brittle (organic) polymeric materials. Plasticizers do not directly bond with the (organic) polymers; plasticization occurs through the decrease of intermolecular forces of the polymer chains in the (organic) polymeric materials which happens when the plasticizer molecules diffuse and penetrate into the (organic) polymeric materials, spacing the polymer chains apart. This can be compared with the similar principle of making a load moveable by inserting rollers underneath it. By this principle, for a substance to present useful properties as a plasticizer, it must have compatibility with the (organic) polymeric material for diffusing into it, as well as a bulky structure for increasing the space between the polymer chains. In addition, from a practical use perspective, among other properties the substance must be chemically stable over a wide range of use conditions.

The specific phthalates combine many of the above properties. In particular, the representative phthalate DEHP, has been employed as plasticizer in a wide range of uses due to its good compatibility with polyvinyl chloride (PVC), nitrocellulose, methacrylic acid and chlorinated rubber.

#### Items containing the specific phthalates and their applications

Items containing the specific phthalates are almost limited to organic materials such as resins, rubber, etc. Specific phthalates are not included in inorganic materials such as metals, glass, ceramics, etc. except for limited intentional uses or by contamination. For the main uses and applications of the specific phthalates please see the “Important Notes concerning the Phthalates Restricted by the EU RoHS Directive - Detailed Version (Second Edition)” (only available in Japanese: title is a free version of the original Japanese) by the Four Japanese Electrical and Electronic Associations.

It should also be noted that as the specific phthalates were only regulated for limited applications (toys, food packaging) so far, items where they are included may be found everywhere throughout the supply chain.

#### Migration

Migration is a noteworthy characteristic of the specific phthalates.

Migration is the characteristic of a substance to move from one article to another. As mentioned above, specific phthalates have the characteristic of diffusing within organic materials. Therefore, specific phthalates that moved to the surface through molecular motion can migrate to another article.

Migration is dependent on contact conditions such as, contact temperature and pressure (mechanic stress), contact time (duration), etc. As temperature rises and molecular motion is intensified it becomes easier for the specific phthalates to bleed in the surface; also if contact pressure is high it becomes easier for specific phthalates to be extruded onto the surface: these conditions promote migration. For cases of prolonged contact or contact accompanied by a sliding motion, migration amounts are increased due to the increase of migration conditions. Moreover, if oils or organic solvents are present on the contact surface, migration is promoted as specific phthalates are leached and attracted to the surface.

Even when there is no contact, albeit small, specific phthalates show volatility at normal temperature and migration may occur due to volatilization within narrow enclosed spaces such as packages.

(Reference: “Appendix: Table of Physical Properties of the Specific Phthalates”)

### 4. Approach to contamination prevention management concerning the specific phthalates

Companies in the supply chain must investigate the possibility of product contamination by specific phthalates and take contamination prevention measures (steps) suited to their actual conditions.

Existing management systems for substances in products can be used when setting mechanisms for contamination prevention measures concerning migration of specific phthalates. Specifically, risks concerning contamination by specific phthalates are identified based on the risk assessment approach defined in IEC63000:2016 and a control plan must be prepared and conducted.

When conducting the risk assessment, first the scope must be reviewed. Items containing specific phthalates may be present in every place (manufacturing sites, warehouses, transport equipment, etc.) and process (manufacturing processes, transport and storage operations, etc.), and migration risk occurs by simply coming into contact. Hence, it is necessary to include all items that come into contact with the product or which are placed nearby the product within narrow enclosed spaces in the assessment scope. If new risks are discovered as a result of the assessment, the necessary contamination prevention processes (implementation items) will have to be added to the existing management system.

In order to maintain the contamination prevention management system, it will be necessary to make efforts for the continual improvement of contamination prevention processes. As in the case of contamination measures for other restricted substances, in order to keep the conditions for non-contamination of the product by the specific phthalates,

adequateness of the risk assessment conducted as well as need for further improvement must be verified. Not only one's own company but supply chain as a whole must become involved with these measures concerning contamination by migration. Therefore, conditions of the contamination prevention measures for the specific phthalates at the supplier must be checked as necessary.

### **5. Risk Assessment Procedures for the Prevention of Contamination by Specific Phthalates**

In this section, basic procedures are described for electrical and electronic component manufacturers to assess risk of contamination risk by specific phthalates and implement prevention measures.

A process for securing and maintaining conformity assurance to the EU RoHS Directive can be established by referencing to these risk assessment procedures, adapting them to one's own processes and enforcing them.

The basic concept for the prevention of contamination by migration is as follows:

Collecting, organizing and checking basic information for risk assessment implementation

- Refinement of assessment scope (Procedure 1)

- Identification of -items that may cause contamination (Procedure 2)

Elimination of specific phthalates from process to avoid risk (Procedure 3)

(In case elimination from process is not possible), In order to reduce risk,

- Avoidance of contact between product and items containing specific phthalates (Procedure 4)

- Verification of method for risk reduction of contamination by contact and implementation of contamination prevention measures (Procedure 5)

After measures to prevent contamination by migration are clarified, the determined contamination prevention process is included in the relevant management system of the company.

It is important to note that also after the contamination prevention process is included, risk assessment of the manufacturing process must still be continually implemented taking into consideration the occurrence of new risks of contamination by the specific phthalates.

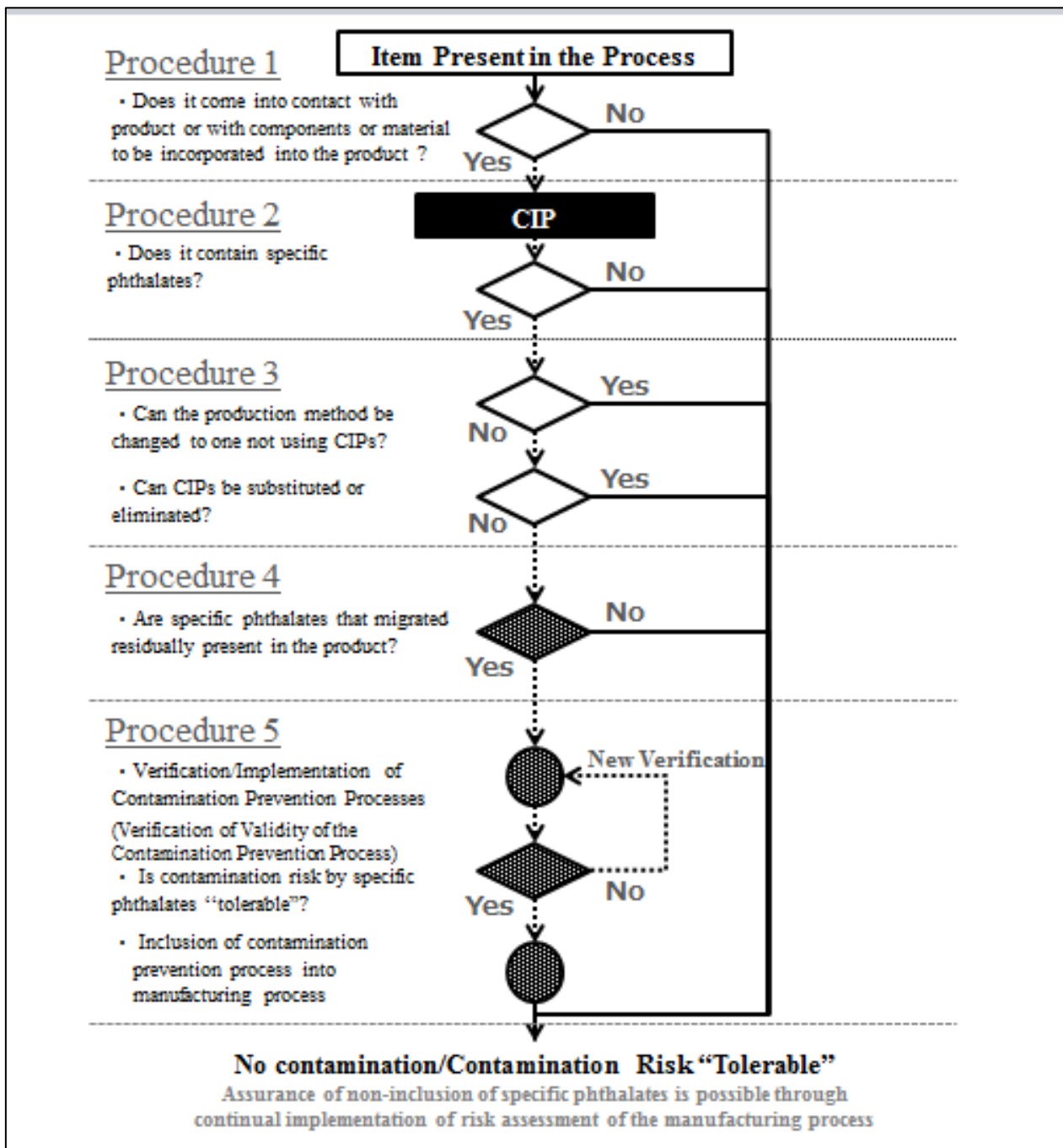


Figure Work Flow of Risk Assessment for the Prevention of Contamination by Specific Phthalates

### **Procedure 1: Identify the items that may come into contact with the product**

Refinement of the items (with possibility to cause contamination) that must undergo phthalate risk assessment is done.

What to do:

- (1) Identify items of the manufacturing process and transport/storage operations with the following possibility:
  - Contact with the product,
  - Non-contact with the product inside narrow enclosed spaces
- (2) For the items identified in (1) above, advance to the next procedures.
 

Items other than the ones above are concluded to have "no contamination risk".

Explanation:

As items that may have migration of specific phthalates, first those items that may "come into contact with the product" must be identified and included in the scope. The reason is that in most cases including every item of the factory is considered to be unfeasible in practice. It must be noted that items having "non-contact with the product within narrow enclosed spaces" are treated in the same manner as those having "contact with the product".

First, items in the process (manufacturing processes and transport/storage operations) must be categorized into "items that may come into contact with the product" and "all other items". When categorizing the items, considering the migration properties of specific phthalates, raw materials included in the product and auxiliary materials used in

the manufacturing process, items such as equipment or fixtures used in the manufacturing processes that may come into contact with the product must also be included in the scope together with the raw materials included in the product and auxiliary materials used in the manufacturing process.

### **Procedure 2: Check the presence of specific phthalates**

Presence of specific phthalates is checked for the items identified in Procedure 1 (hereinafter referred as “contact-items in the process” (CIP)) and CIPs that may cause contamination are determined.

What to do:

- (1) Check about the inclusion of specific phthalates for the CIPs identified in Procedure 1.  
Necessary information is obtained through supplier surveys. In case it is difficult to obtain information from a certain supplier, reasonable steps to make up for it must be considered, and implemented.
- (2) If inclusion of specific phthalates is confirmed for a certain CIP, that CIP must be identified.
- (3) For the items identified in (2) advance to the next procedure. All the other items can be considered as “items with no risk of contamination”.

Explanation:

Information on the inclusion of the specific phthalates can be obtained from CIP specifications (non-inclusion reports, material declarations, analytical test results, etc.) based on EN50581:2012 or IEC63000:2016. Appropriate support and guidance to suppliers is recommended when necessary in order to obtain their cooperation.

If information cannot be obtained from a supplier, it is recommended to conduct risk assessment assuming that specific phthalates are present in the item.

It is recommended to necessarily include organic materials in the survey scope of CIPs requiring information on the inclusion of the specific phthalates.

### **Procedure 3: Elimination from the process**

Eliminate CIPs containing specific phthalates from the process. (Elimination of sources of contamination)

What to do:

- (1) Investigate and implement changes to a process that does not use CIPs containing specific phthalates.  
After the changes take place, it is concluded that the process does not present “contamination risks”.
- (2) Investigate and implement substitution to CIPs not containing specific phthalates.  
After the changes take place, it will be concluded that CIPs do not present “contamination risks”.
- (3) If (1) and (2) above cannot be implemented, advance to the next procedure.

Explanation:

The purpose of this procedure is to completely eradicate the possibility of migration by eliminating the specific phthalates from the process. Methods for elimination from the process include, for example, substitution to CIPs that do not include specific phthalates, elimination of the process itself, etc.

After elimination of the specific phthalates is implemented, it must also be checked that the conditions for elimination of the specific phthalates are continually maintained and managed.

### **Procedure 4: Verification and Evaluation of Contamination Impact**

Evaluate the contamination impact by migration of the specific phthalates from CIPs to the product.

What to do:

- (1) Evaluate the contamination impact by migration of the specific phthalates on products concerning the following viewpoints:
  - Existence of contamination,
  - Contamination amount (in case of existence of contamination) (physical properties, contact conditions, etc. can be used as parameters)
- (2) The following viewpoint is used to determine if risk by contamination is “tolerable” or not:
  - Possibility of residual presence in the final product,
- (3) After clarifying concerned standards and grounds for “tolerable contamination risks”, evaluate and consider items meeting those conditions as “tolerable items”.  
In case of existence of CIPs not meeting the determined “tolerable contamination risk” conditions, advance to the next procedure.

Explanation:

The most important point here is to verify and understand “the conditions of the manufacturing process and their relation with contamination by migration of the specific phthalates” through risk assessment.

In Procedures 1 to 3, assessment was implemented based on criteria such as presence/inclusion of the specific phthalates and contact with the product. In this procedure assessment is implemented considering physical properties

of the specific phthalates, contact conditions and possibility of residual presence in the final product. An adequate and objective method for implementing risk assessment is thought to comprise assessment with manufacturing process conditions that present the highest impact of contamination by migration, and when necessary conduction of validation experiments.

When assessing the possibility of residual presence in the final product, final processes must also be included in the investigation. For example, even if contamination by migration actually occurs, in case the specific phthalates that migrated to the product are removed by adequate cleaning, machining, heating, etc. in the final processes, it can be determined that there is no possibility of residual presence of the specific phthalates,.

**Procedure 5: Verification and implementation of contamination risk reduction methods (inclusion of contamination prevention processes)**

Investigate and implement risk reduction methods to prevent contamination by migration from CIPs containing specific phthalates. The processes implemented based on the investigation results are collectively referred to as “contamination prevention processes”.

What to do:

- (1) Investigate and conduct process changes to reduce contamination risks (by change or addition conditions, etc.).  
The result of contamination risk reduction through process change is evaluated as follows:
  - When it is confirmed that specific phthalates are not present in the product, it is concluded that the CIP presents “no contamination risk”.
  - When specific phthalates are present in the product, but it has been determined that the CIP presents “tolerable contamination risk”, it can be concluded that “contamination risk is tolerable” once standards and grounds are clarified.
  - For cases when contamination risk of the product is not tolerable, contamination risk reduction methods must be re-investigated, implemented and an evaluation similar to the above must be performed.
- (2) Add contamination prevention processes whose validity was verified are added to the existing management system.

Explanation:

When there is a change or for verification/evaluation of process conditions, as seen until now physical properties of the specific phthalates and contact conditions must be included and considered with the other process conditions.

Decisions on actual processes, priority management items, etc. will vary depending on the applicable products, processes, etc. of each company. For example, reduction of contamination risk by migration can be considered in terms of contact condition (temperature, contact pressure, contact time, state of contact surface, distance from the source of contamination, etc.) changes in the process.

There may also be cases when it becomes possible to eliminate specific phthalates that migrated to the product by the addition of processes (cleaning, machining, heating, etc.).

For such cases, it must be confirmed that the state of elimination of specific phthalates can be continually maintained by process condition change or inclusion of processes for eliminating the contamination.

For cases when risk reduction of contamination by specific phthalates by process condition change or inclusion of processes for elimination as shown above is evaluated as insufficient, the outflow of products contaminated with the specific phthalates to customers and to the market must be prevented through the addition of control processes such as the measurement inclusion amounts of the specific phthalates in the (final) product, etc.

**Appendix: Table of Physical Properties of the Specific Phthalates**

Substance	Bis (2-ethylhexyl) phthalate	Butyl benzyl phthalate	Dibutyl phthalate	Diisobutyl phthalate
Acronym	DEHP	BBP	DBP	DIBP
CAS RN®	117-81-7	85-68-7	84-74-2	84-69-5
Molecular weight	390.62	312.35	278.35	278.35
Melting point	-50°C	-35°C	-69°C	-37°C
Boiling point	386°C	370°C	340°C	296.5°C
Vapor pressure	6.7.55 <sup>-3</sup> Pa (68°C)	1.1.55 <sup>-3</sup> Pa(25°C) (equivalent)	5.9.55 <sup>-3</sup> Pa(25°C)	1.0.55 <sup>-2</sup> Pa(20°C) (equivalent)
Solubility in water	0.003mg/L(20°C)	0.71mg/L	10mg/100ml(25°C)	
n-Octanol/water partition coefficient	Log Po/w=7.60	Log Po/w=4.73	Log Po/w=4.72	Log Po/w=4.11
Decomposition temperature	approximately 400°C	approximately 430°C	approximately 400°C	approximately 400°C
Appearance	Colorless, oily, slightly viscous liquid	Colorless, oily, slightly viscous liquid	Colorless, oily, slightly viscous liquid	Colorless, oily, slightly viscous liquid

**References**

- “Important Notes concerning the phthalates restricted by the EU RoHS Directive - Detailed Version (Second Edition)” (only available in Japanese) prepared by the Four Japanese Electrical and Electronic Associations
- “Guideline on the Calculation of the Concentration of RoHS Restricted Substances not being Part of the originally designed and manufactured Article” prepared by the Subcommittee on Electronic Components Environment, ESG Committee, Japan Electronics and Information Technology Industries Association (JEITA)
- EN50581:2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- IEC63000:2016 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- Safety Data Sheet: Bis(2-ethylhexyl phthalate) (DOP, DEHP) (Japan Plasticizer Industry Association, 24 March, 2016)
- Safety Data Sheet: Dibutyl phthalate (DBP) (Japan Plasticizer Industry Association, 20 May, 2016)
- Safety Data Sheet: Butyl benzyl phthalate (BBP) (Ministry of Health, Labor and Welfare of Japan, 17 March, 2017)
- Safety Data Sheet: Diisobutyl phthalate (DIBP) (Ministry of Health, Labor and Welfare of Japan, 2 September, 2008)
- Pyrolysis of Bis(2-ethylhexyl phthalate) and dioctyl phthalate (Bulletin of the Chemical Society of Japan, 1982 No.7)