SCIENTIFIC INSTRUMENT NEWS

INTERVIEW

11

Four types of phthalate esters have been added to the substances restricted under the European RoHS directive, bringing the total regulated substances to 10 together with the six that were previously restricted.
We asked Miyuki Takenaka, who serves as the International Vice Chairman of the TC (Technical Committee) 111 (Environmental Standardization for Electrical and Electronic products and systems) of the International Electrotechnical Commission (IEC), which is the international standards organization for the field of electrical and electronics technology, regarding the background of these 4 phthalates additions to the European RoHS directive.
We also discuss the future trends in regulations on chemical substances contained in products and how companies should approach chemical substances.

Expansion of restricted substances in the RoHS directive and trends in international standards

Consideration on chemical substances contained in products from the perspective of sustainability

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1. Characteristics of phthalate esters, and points should be focused on when making products compliant with RoHS 2

[Q] Please tell us about the background to the new addition of four types of phthalate esters to the banned substances under the European RoHS directive.

[Takenaka] The European RoHS directive (*1) was first enacted on 1st July 2006, and since then regular studies have been conducted into additional substances. Although various substances were presented as candidates this time, ultimately four types of phthalate esters (*2), which are contained mainly in electrical and electronic devices and which are known to be reproductive toxicity as well as endocrine disruptors, were added. From July 22, 2019, their usage will be restricted in all electrical and electronic devices (excluding medical devices and supervisory control devices) sold in the EU, with a maximum permitted concentration of 0.1% each in homogenous material. This restriction on usage will be applied to medical devices including in-vitro diagnostics devices and supervisory control devices including those for industrial purposes from July 22, 2021. Since the European RoHS directive is often generally called that RoHS 2 to distinguish it from the old RoHS directive, we also refer to it as the RoHS 2 in the rest of this manuscript.

Endocrine disruptors are substances that act on living organisms in a way similar to hormones and are either harmful to health or have the possibility of being harmful to health. As such, the use and manufacture of many have already been restricted. Phthalate esters were restricted from sale in the EU in childcare and toy products when the total content of DEHP, BBP, and DBP was 0.1 wt% (1,000 ppm) or more under Entry 51 in Annex XVII (restricted substances) of the European REACH regulations (*3). From July 2020, Entry 51 in Annex XVII of the REACH regulations will be enacted to add DIBP and to expand the restriction to articles (excluding some exceptions). Restrictions on phthalate esters are thus becoming extremely strict around the world.

[Q] What kinds of products are phthalate esters used in?

[Takenaka] Phthalate esters are mainly used as plasticizers to give flexibility to materials such as resin and rubber and make them easier to process by molding. They are also added to extremely familiar materials such as polyvinylchloride. Since polyvinylchloride is used as a cable coating in electrical and electronic devices, phthalate esters are commonly found in products such as electrical cords, wiring material, adapters, connectors, insulators, and flexible resin parts. Furthermore, they are included in a wide range of parts that make up electrical and electronic devices such as paint, adhesive, and rubber parts.

In the preparation period that has been ongoing since the pending addition of phthalate esters to RoHS 2 was announced in 2015 up to now, progress has been made with switching to substitute materials in industry. Since electrical and electronic devices are made up of a wide variety of parts, sometimes in excess of several hundred thousand pieces, this requires careful handling throughout the entire supply chain. I think that the collation and publication of guidelines related to phthalate esters, along with the assistance provided across all related industries by the four electrical instruments and electronics groups (*4) that were fully active in RoHS 1 in order to promote smooth handling with the supply chain switchover process, can serve as a significant reference.

[Q] Please tell us what points should be focused on when making products compliant with RoHS 2.

[Takenaka] The major difference between phthalate esters and substances that have been previously restricted is the high transferability. Even when not used in the parts or products themselves, if phthalate esters are contained in resin or rubber parts built into the production line, or in packaging materials used in transport or storage processes, there is the possibility of contamination by contact. This, therefore, requires thorough risk management including not only the product itself, but also the surrounding materials and equipment.

Furthermore, the RoHS directive only applies to products sold in the EU, and the phthalate esters that have been added to the restricted substances at this time are not banned domestically within Japan. However, I think that material procurement, product design, and specifications are also becoming increasingly common at many companies as globalization becomes more widespread. Accordingly, if parts, etc. that continue to use phthalate esters are handled inside the same factory, the construction of management systems for preventing mixing and contamination will be required.

In industry, conformity assessment is already performed using EN 50581 (technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances), which is a harmonized standard with the RoHS directive, and IEC 63000:2016, which is the equivalent international standard. Hence, companies that use these directives have already been performing thorough management of the chemical substance contents of related products. The restrictions on phthalate esters are only just beginning, and it is important to understand the content risks and maintain compliance in the manufacturing and procurement of parts in your company in the same manner as was expected with RoHS 1.

[Q] You were appointed the international vice chairman of the IEC TC111 on October 25, 2018. What kinds of activities does IEC TC111 perform as an organization?

[Takenaka] The IEC is an institution for promoting international standards in the fields of electrical and electronics technology, and has established a number of what are called technical committees (TCs) in order to develop international standards for each of the wide variety of technical fields. Among these, TC111 was kicked off in October 2004 as TC for formulating various environmental standards for electrical and electronics devices and systems. This is because the RoHS directive had been announced at that time and the REACH regulations were being investigated, so there was a strong demand for a common international framework to circulate environmentally friendly products in international markets. Since its establishment, Japan has served as the international chairman, and there are currently 25 member nations with voting rights as well as 10 nations participating as observers. Furthermore, the Japan Electronics and Information Technology Industries Association (JEITA) operates the Japanese domestic committee of IEC TC111 as the trustee deliberation body.

The environment faces various problems from hazardous chemical substances that have an effect on biological organisms, including greenhouse gases related to climate change and the depletion of water and mineral resources, and so our target scope extends from products to systems and services. Figure 1 shows the international standards that are currently being developed by IEC TC111. For example, in the field of chemical substances, we work on developing standards in areas such as formulating a framework and common format for manufacturers in order to ensure that parts do not contain hazardous substances, conveying this information throughout the supply chain, and on developing methods for measuring regulated substances. Furthermore, we also work on developing standards based on the basic policies of international standardization activities in various fields including environmentally conscious design, methods for calculating emissions of greenhouse gases, and material efficiency (recyclability).

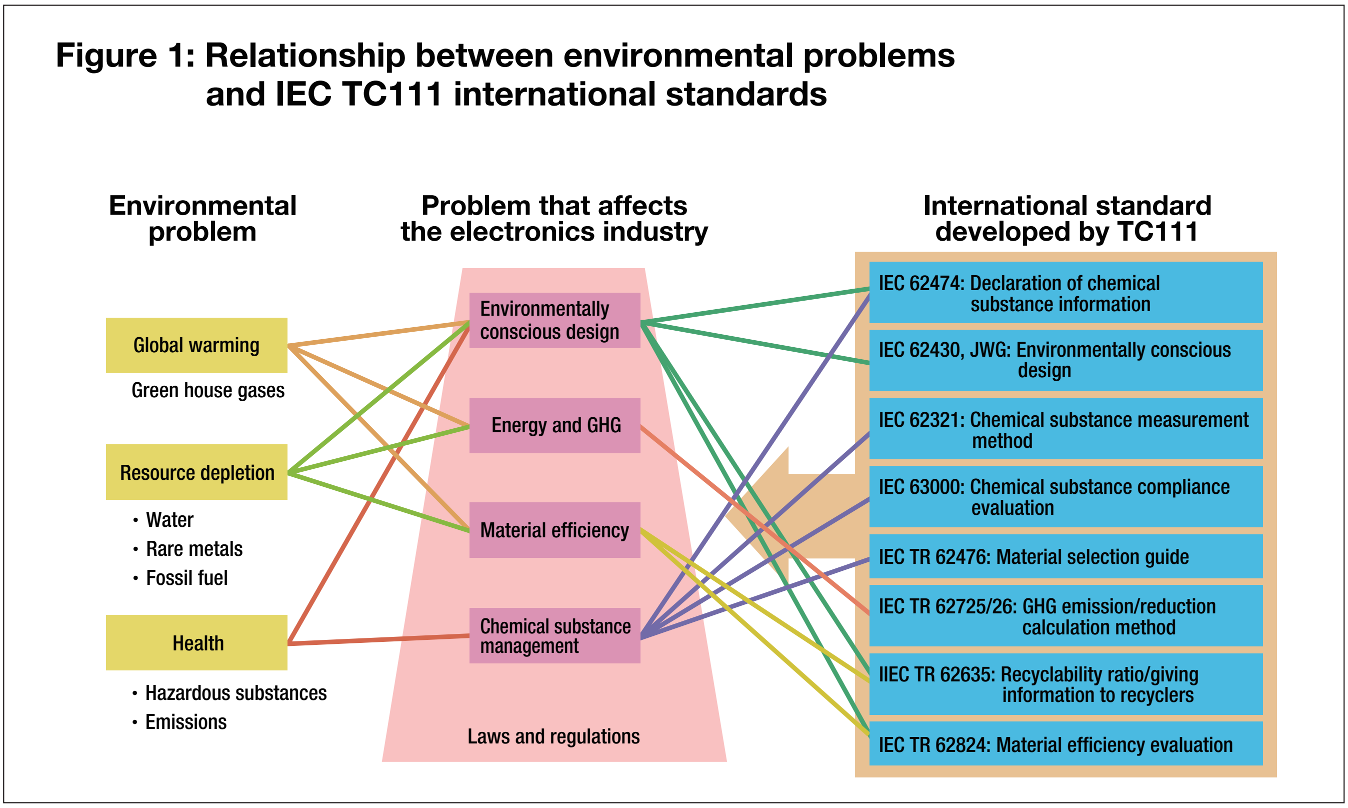

Figure 1: Relationship between environmental problems and IEC TC111 international standards

2. Taking advantage of Japan's advanced technologies and systems for the development of international standard

[Q] Please tell us about the significance of promoting international standardization for environmental standards. Furthermore, please tell us how you would like to contribute to standardization and environmental support by companies as the international deputy chairman.

[Takenaka] Environmental problems are not the problems of a single country, but are global problems, as shown by global warming and the problem of plastic in the ocean. In an age where economic globalization is progressing and the value chain spreads across national borders, there are demands to not only consider the profit or convenience for our own company or country, but to share value widely. However, I think that we must not create a situation where the industry in some particular country suffers a significant loss due to the regulatory system, or where there is some excellent technology that could contribute to the world but which cannot be utilized. From this perspective, the importance of creating a framework and rules where the major countries in the world can deliberate and everyone can participate with a clear understanding is continually growing. In particular, for the technical and optional standards referenced by compulsory regulations in each country, the basic principle is that if an international standard already exists, the domestic standard is to be formulated based on the international standard. Because of this, many experts from each country participate actively in IEC TC111 to promote international standards that are beneficial to their own countries. Japan has excellent environmental technology and environmentally friendly products. Actively proposing this kind of approach is also necessary in terms of maintaining industrial competitiveness.

For example, IEC TC111 has developed an international standard (IEC62474) governing the procedures for declaring information about the contained chemical substances in the supply chain for electrical and electronic devices, and maintains and manages a related substance database

(VT62474). In Japan, practical utilization of "chemSHERPA", which complies with IEC62474, started in 2018. As the standardization of information declaration tools spreads both domestically and internationally, parts manufacturers who are positioned in the middle of the supply chain are able to significantly reduce their administrative workloads because the format used to disclose information to customers is unified.

Furthermore, when testing chemical substances in products, it is necessary to apply internationally common measurement conditions and testing methods, and IEC TC111 has developed international standards (IEC62321) related to such testing methods. Among the biggest features of the IEC62321 testing methods are that they maintain the required precision based on a two-stage method consisting of a screening analysis method and a precision analysis method, and that provides a rational and practical method in terms of both time and cost. For the six substances that were already regulated, a screening measurement using a fluorescent X-ray fluorescence analysis (XRF) that resulted from a development led by Japan has been adopted as an international standard, and is now widely used for on-site management in factories. Many excellent Japanese technologies relating to phthalate esters were also actively proposed to IEC TC111, including adopting Pyrolysis gas chromatography (Py/TD GC), and screening technologies such as Fourier-transform infrared spectroscopy (FT-IR), high-performance liquid chromatography (HPLC), and thermal desorption mass spectrometry (TD-MS).

Japanese companies can also be said to have constructed the most rigorous chemical substance content management systems in the world, such as those created for the RoHS directive. Because of this, it is important to clearly propose and lead fair discussions in order to ensure that Japan's excellent technology and systems are actually utilized in the development of international standards. By doing this, I hope that we will support corporate initiatives for the environment and contribute to the industry overall.

3. It is essential that regulations on chemical substance content of products be strengthened in the future

[Q] Are regulations about the chemical substance content of products, including the RoHS directive, expected to become stronger in the future? How do you think companies should face this?

[Takenaka] In Europe, the seven substances that are being investigated as the next additional substances for the RoHS directive are tetrabromobisphenol A (TBBPA), medium-chain chlorinated paraffins (MCCPs), antimony trioxide (Sb_2O_3), beryllium (Be) and its compounds, nickel compounds ($NiSO_4$, Ni_2SO_3), cobalt compounds ($CoCl_2$, $CoSO_4$), and indium phosphate (InP). There is no doubt that regulations on the chemical substance content of products, including the REACH regulations, will become stronger.

Furthermore, with the aim of building a recycling-based economic system, the European Commission adopted the "Circular Economy Package" as a new sustainability strategy for the entire EU in 2015. As part of this, a critical raw materials (CRM) list was created, and it was envisioned that a system would be created that would oblige producers to declare information about the content of these materials in products. As of 2017, 27 minerals (*5) have been selected for inclusion on the CRM list. These measures create the requirement to not only ensure that hazardous substances are not used, but to also consider the recycling usage of raw materials contained in products. However, since raw material information is also related to corporate secrecy, I expect that mechanisms for sharing information while maintaining confidentiality will be investigated in the future.

In the world of today, where a variety of environmental problems have arisen, the handling of sustainability affects corporate value and whether or not a business succeeds. The chemical substance is related to many of the United Nations Sustainable Development Goals (SDGs), and is particularly deeply related to goal 12 related to "responsible consumption and production". Not only meeting regulations, but also actively taking measures that give consideration to environmental value leads to increased company value.

Building a sustainable recycling society not only demands that manufacturing does not emit hazardous substances into the environment, but also demands the development of products that give consideration to material reuse and recycling from the design stage (Figure 2). I expect that companies will need to have a higher awareness than ever before about the usage of chemical substances and selection of raw materials. We at IEC TC111 are aiming to support all of the companies working to create community and environment values, with a focus on sustainability through the development of appropriate international standards.

Figure 2: Further Challenges for achieving SDGs

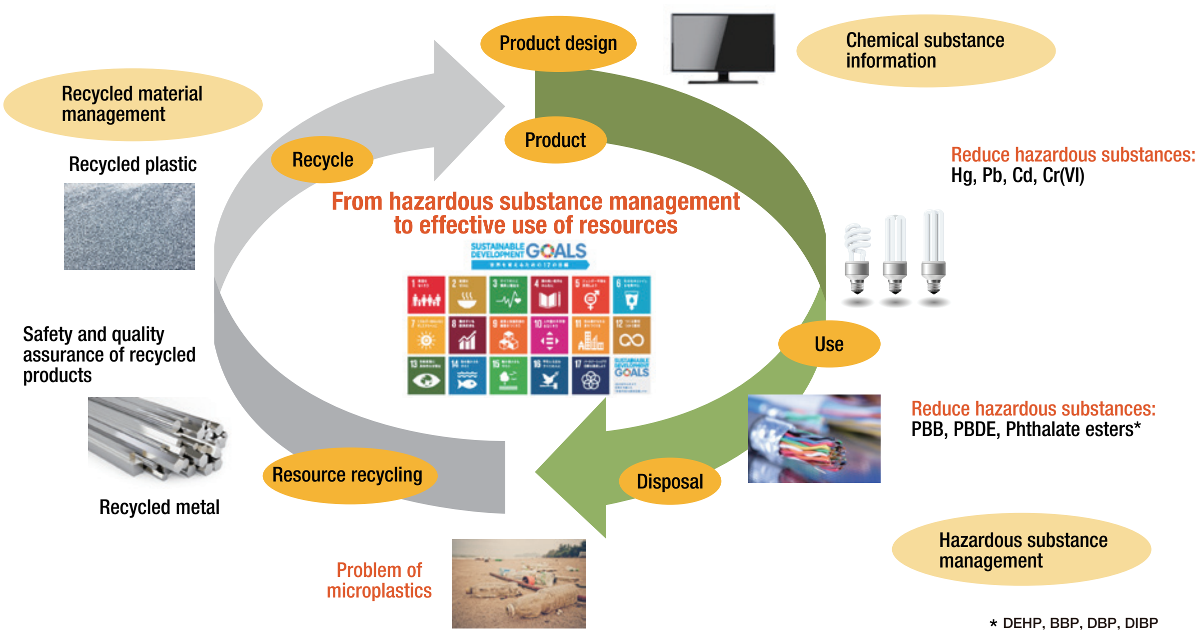

Figure 2: Further Challenges for achieving SDGs

(*1) RoHS directive: RoHS is an abbreviation of Restriction of Hazardous Substances. This was announced in the EU gazette of 13th February 2003 as a directive restricting the use of particular hazardous substances in the electrical and electronic devices in circulation within the EU zone, and was enacted on July 1, 2006. The first amendment, which was made on July 21, 2011, expanded the applicable products and started a system of attaching the CE mark to products. The old RoHS directive (2002/95/EC, commonly RoHS 1) was abolished due to this on January 2, 2013, and was replaced by the amended RoHS directive (2011/65/EU, commonly called RoHS 2) the following day, January 3.

(*2) Four types of phthalate esters: Bis(2-ethylhexyl) phthalate: DEHP, bis(butylbenzyl) phthalate: BBP, dibutyl phthalate: DBP, diisobutyl phthalate: DIBP

(*3) REACH regulations: REACH is an abbreviation of Registration, Evaluation, Authorization and Restriction of Chemicals. This is a system for comprehensive registration, evaluation, certification, and restriction of chemical substances in the EU that took effect on June 1, 2007.

(*4) Four electrical instruments and electronics groups: The Japan Electrical Manufacturers Association (JEMA), the Japan Electronics and Information Technology Industries Association (JEITA), the Communications and Information Network Association of Japan (CIAJ), and the Japan Business Machine and Information System Industries Association (JBMIA)

(*5) CRM list (as of 2017): Antimony, baryte, beryllium, bismuth, borate, cobalt, coking coal, fluorspar, gallium, germanium, hafnium, helium, heavy rare earths, indium, light rare earths, magnesium, natural graphite, natural rubber, niobium, platinum group metals, phosphate rock, phosphorous, scandium, silicon metal, tantalum, tungsten, vanadium

Reference material

Excerpt from RoHS 2: DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF

Excerpt from gazette of additions to European RoHS restricted substances: COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.137.01.0010.01.ENG

Excerpt from gazette of additions to REACH restricted substances: COMMISSION REGULATION (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R2005&from=EN

About endocrine disruptors
http://www.nihs.go.jp/edc/english/edc.html

RoHS related information - JEITA environment division (Japanese)
https://home.jeita.or.jp/eps/euRoHS.html

Cautions related to phthalate esters subject to EU RoHS directive - Four electronic instruments and electronics groups (Third edition) (Japanese)
https://home.jeita.or.jp/eps/pdf/eu20161201.pdf

Guidelines for preventing contamination by designated phthalate esters under management systems for ensuring compliance with the EU RoHS directive - JEITA electronic components division (Japanese)
https://home.jeita.or.jp/ecb/pdf/30-270-1.pdf

IEC TC111
https://www.iec.ch/dyn/www/f?p=103:29:6809014636900::::FSP_ORG_ID,FSP_LANG_ID:1314,25#3

IEC TC111 Domestic Bureau (JEITA) (Japanese)
https://www.jeita.or.jp/japanese/pickup/category/2019/vol28-06.html

About chemSHERPA
https://chemsherpa.net/english

EN50581
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:363:0006:0007:EN:PDF

About RoHS 3 studies
https://rohs.exemptions.oeko.info/index.php?id=288

European Circular Economy, trends in CRM
https://ec.europa.eu/growth/industry/sustainability/circular-economy_en
http://ec.europa.eu/growth/sectors/raw-materials/specific-interest/critical_en
https://www.cencenelec.eu/news/brief_news/Pages/TN-2019-017.aspx