

Chemical Global Market Access for Small Appliances



Do you know the key chemical regulations and standards that apply to your products?

Chemical regulations for electrical and electronic products are complex. It can prove challenging for stakeholders along the value chain to track and manage their compliance. As regulatory requirements vary widely from state to state and country to country, the challenge becomes global.

Different regulatory bodies around the world have established regulatory frameworks addressing how to manage hazardous chemicals. Some of these frameworks specifically address chemicals related to electrical and electronic products, while others generally address chemicals and chemical management.

UL Solutions empowers you to navigate this complexity that can help you better understand global market access for your products. This document maps relevant global regulatory frameworks and activities to help you identify chemicals of interest to the electronics sector, including a special section on food contact materials.

For more information, contact us at smallappliances.na@ul.com

European

- Restriction of Hazardous Substances (RoHS) Directive
- Waste Electrical and Electronic Equipment (WEEE) Directive
- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation, substances of very high concern (SVHC), total cadmium, polycyclic aromatic hydrocarbons, phenylmercury compounds, etc.
- Persistent Organic Pollutants (POP) Regulation (EU) 2019/1021
- Battery Directive
- Packaging Directive

United States of America (USA)

- Toxic Substances Control Act (TSCA)
- Batteries – Federal Regulation
- California Proposition 65
- Various State RoHS
- Packaging
- Restricted Substances in Children's Products
- Chemicals of High Concern to Children

United Arab Emirates (UAE)

- UAE RoHS

Saudi Arabia

- SASO RoHS



EU – U.K. RoHS Directive

On July 1, 2011, the European Union adopted the Directive 2011/65/EU, which came into effect starting July 21, 2011, replacing the previous Directive version 2002/95/EC.

Directive 2011/65/EU is commonly known as the Directive on the Restriction of Hazardous Substances (RoHS) in Electrical and Electronic Equipment. It restricts the use of certain harmful substances (lead, cadmium, mercury, hexavalent chromium, polybrominated diphenyl ethers, polybrominated biphenyls and phthalates) in these articles.

The EU RoHS Directive covers a wide range of products: almost all electronic, electrical, medical, communications, toys, information technology and telecommunication equipment, and other electrical and electronic products.

The directive's inclusion of complete machine products as well as parts and raw materials involves the entire production chain.

The EU RoHS Directive prohibits the following substances in homogeneous materials of electrical and electronic equipment (EEE) above the limits established in the same directive:

- Lead (0.1%)
- Mercury (0.1%)
- Cadmium (0.01%)
- Chromium (VI) (0.1%)
- Polybrominated biphenyls (PBB) (0.1%)
- Polybrominated diphenyl ethers (PBDE) (0.1%)
- Phthalates: DEHP, BBP, DBP, DIBP (0.1%)

These substances can be verified using specific test methods that the International Electrotechnical Commission (IEC) has

developed and which are part of the IEC 62321 - Determination of certain substances in electrotechnical products series.

In addition to test methods used for analytical testing, the EU RoHS Directive includes a harmonized standard necessary for preparing the technical documentation requested according to the EU RoHS Directive: the IEC EN 63000:2018 Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances.

Recall example of an electrical or electronic product

A recalled headset contains lead (measured value up to 58.4% by weight) in the solder. The product's plastic material contains an excessive amount of bis (2-ethylhexyl) phthalate (DEHP) (measured value: 0.13% by weight). Lead poses a risk to the environment. DEHP may harm children's health and cause possible damage to their reproductive systems.

The product does not comply with the commission's RoHS Directive in electrical and electronic equipment.

The EU RoHS Directive requests that manufacturers draw up technical documentation. Moreover, where manufacturers have demonstrated EEE compliance with the applicable requirements, they draw up an EU declaration of conformity and affix the CE marking on the finished product.

As for other requirements, noncompliance with the EU RoHS Directive may result in notification via the Safety Gate, the EU rapid alert system for dangerous non-food products.

What happens in the U.K.?

Since Brexit, the EU Withdrawal Act 2018 preserves the U.K.'s RoHS Regulation for electrical and electronic equipment of 2012 applies in Great Britain (England, Scotland and Wales) and allows for amendments so it can continue to function effectively now that the U.K. has left the EU.



WEEE Directive

On July 24, 2012, the European Union adopted the Directive 2012/19/EU of the European Parliament and of the Council of July 4, 2012, on Waste Electrical and Electronic Equipment (WEEE), which came into effect on Feb. 15, 2014, replacing the previous WEEE Directive 2002/96/EC.

The WEEE Directive requires manufacturers to bear the responsibility of collecting, recycling and properly disposing of electrical and electronic equipment waste to better recycle and/or reuse electronic and electrical products. The EN 50419 standard specifies the labeling requirements to ensure compliance with the WEEE Directive (WEEE symbol as shown below). They apply to all electrical and electronic equipment manufacturers in the European Union.

The WEEE Directive covers 10 electronic and electrical product categories:

- Large household appliances
- Small household appliances
- IT and telecommunications equipment
- Consumer equipment and photovoltaic panels
- Lighting equipment
- Electrical and electronic tools (with the exception of large-scale stationary industrial tools)
- Toys, leisure and sports equipment
- Medical devices (with the exception of all implanted and infected products)
- Monitoring and control instruments
- Automatic dispenser



What happens in the U.K.?

The WEEE Regulations 2013 (as amended) continues to be the underpinning U.K. legislation after Brexit.

REACH Regulation (SVHC, total cadmium, polycyclic aromatic hydrocarbons, phenylmercury compounds)

The EU REACH Regulation covers the European Union's regulations of the registration, evaluation, authorization and restriction of chemicals, i.e., (EC) No. 1907/2006. It officially came into effect on June 1, 2007, and was officially implemented on June 1, 2008.

Along with the REACH requirements, electrical and electronic equipment must also meet the restrictions of the REACH Annex XVII, such as total cadmium, polycyclic aromatic hydrocarbons, phenylmercury compounds and others.

For example, REACH Annex XVII restricts the use of polycyclic aromatic hydrocarbons (PAHs): a product shall not be placed on the market for supply to the general public if any of its rubber or plastic components coming into direct, prolonged or repetitive short-term contact with the human skin or the oral cavity (under normal or reasonably foreseeable conditions of use) contain more than 1 mg/kg (0,0001% by weight of this component) of any of the listed PAHs.

Such articles include, among others:

- Household utensils, trolleys and walking frames
- Tools for domestic use
- Watch straps, wristbands, masks and headbands

Toys, including activity toys and childcare articles, shall not be placed on the market if any of their rubber or plastic components that come into direct, prolonged or repetitive short-term contact with the human skin or the oral cavity, under

normal or reasonably foreseeable conditions of use contain more than 0.5 mg/kg (0.00005% by weight of this component) of any of the listed PAHs.

The PAHs subject to the restriction are:

- Benzo[a]pyrene (BaP) CAS No 50-32-8
- Benzo[e]pyrene (BeP) CAS No 192-97-2
- Benzo[a]anthracene (BaA) CAS No 56-55-3
- Chrysen (CHR) CAS No 218-01-9
- Benzo[b]fluoranthene (BbFA) CAS No 205-99-2
- Benzo[j]fluoranthene (BjFA) CAS No 205-82-3
- Benzo[k]fluoranthene (BkFA) CAS No 207-08-9
- Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3

These PAHs are present in plastic and rubber parts. They are impurities in raw materials used in the production of certain parts and products including extender oils and in carbon black. They don't perform specific functions as constituents of the parts and aren't added intentionally during the production process.

When electrical and electronic products have a plastic/rubber component in contact with skin that contains an excessive amount of PAHs, they can be withdrawn from the market and notified in the Safety Gate of the European Commission.

Recall example of an electrical or electronic product

For example, the Safety Gate notified an electric nose hair trimmer with skin-contacting plastic/rubber that contains an excessive amount of PAHs — notably, benzo(a)pyrene, benzo(a)anthracene and dibenzo(a,h)anthracene (measured values: 20 mg/kg, 81.5 mg/kg and 2.3 mg/kg by weight respectively). These PAHs may cause cancer and are mutagenic and toxic for reproduction. The product does not comply with the REACH Regulation.



Moreover, according to REACH, enterprises producing products containing substances of very high concern (SVHC) are required to fulfill report and information transfer obligations under REACH regulation.

Substances that may seriously affect human health and the environment fall under the SVHC category. These are primarily carcinogenic substances, mutagenic or toxic to reproduction, and substances with persistent and bio-accumulative characteristics. Other substances of equivalent concern include endocrine-disrupting chemicals.

The classification of a substance as an SVHC and its inclusion in the European Chemicals Agency (ECHA) Candidate List can trigger certain legal obligations for the importers, producers and suppliers of an article that contains such a substance, e.g., notification and information along the supply chain and the need to submit a notification through the ECHA SCIP database.

The ECHA publishes an updated Candidate List every six months. This official list of the EU's SVHCs comes from proposals made by national authorities or ECHA, broad public consultation and scientific rigor in decision-making.

Any supplier of an article containing an SVHC on the Candidate List for Authorisation in a concentration above 0.1% weight by weight (w/w) on the EU market must submit information on that article to ECHA, as of Jan. 5, 2021.

The SCIP database ensures that the information on articles containing Candidate List substances is available throughout the products' and materials' entire life cycle, including at the waste stage.

Consumers and waste operators can then access the information in the database from the submitted SCIP notifications.

The following suppliers need to submit a SCIP notification to ECHA if needed according to indications shared above:

- EU producers and assemblers
- EU importers
- EU distributors of articles and other actors who place articles on the market

The duty to provide information to ECHA does not cover retailers, excluding importers and/or producers, and other supply chain actors supplying articles directly and exclusively to consumers.



What happens in the U.K.?

The U.K. REACH is part of the U.K.'s chemicals regulatory regime. If you are based in Great Britain (England, Scotland and Wales), you will need to follow the U.K.'s REACH regulation to manufacture, import, sell or distribute chemical substances or mixtures. If you sell or distribute chemicals in the U.K. and the EU, you will need to follow both the U.K.'s and the EU's REACH requirements.

POP Regulation

POP is the acronym for Persistent Organic Pollutants Regulation (EU) 2019/1021.

This regulation aims to protect human health and the environment from certain pollutants by prohibiting, phasing out or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants or the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants.

Chemical substances identified as POPs include:

- Pesticides (such as DDT)
- Industrial chemicals (such as polychlorinated biphenyls widely used in electrical equipment)
- Unintentional byproducts formed during industrial processes, degradation or combustion (such as dioxins and furans)
- Alkanes C10-C13, chloro (short-chain chlorinated paraffins (SCCPs))

According to the POP Regulation, the production, placing on the market and use of articles containing SCCPs in concentrations higher than 0.15% by weight shall not be allowed.

SCCPs function as plasticizers and flame retardants in a variety of applications, including paints, adhesives and sealants, leather fat liquors, plastics, rubber, textiles and polymeric materials.

Recall example of an electrical or electronic product

Recently, an increased number of Safety Gate notifications have dealt with SCCPs in plastic parts in electrical and electronic products.

The product cables' plastic material contains an excessive amount of SCCPs and lead (measured values up to 0.87% and 0.26% by weight, respectively). SCCPs are toxic to aquatic organisms at low concentrations and bioaccumulate in wildlife and humans, posing a risk to human health and the environment.



What happens in the U.K.?

Since Brexit, the U.K.'s Restrictions on POPs are regulated by the Persistent Organic Pollutants Regulations 2007 (U.K. Statutory Instruments 2007 No. 3106), as amended, which had implemented the EU POP Regulation in the U.K.

Battery Directive

On Sept. 26, 2006, the European Union issued Directive 2006/66/EC of the European Parliament and of the Council on Batteries and Accumulators and Waste Batteries and Accumulators, which officially replaced 91/157/EEC on Sept. 26, 2008.

Waste batteries accumulators also appear on the control list, making it applicable to battery packs, portable batteries, car batteries, industrial batteries and others. With a few exceptions, the Battery Directive 2006/66/EC and the subsequently amended Directive 2013/56/EU cover all batteries and accumulators, regardless of their chemical nature, size or design.

The Directive minimizes negative effects of batteries and accumulators and their wastes. It regulates substances like lead, cadmium and mercury in batteries and accumulators and establishes labeling requirements and measures to achieve collection and recycling goals.

What happens in the U.K.?

The 2008 batteries and accumulators regulations continue to be the underpinning legislation for batteries (after Brexit). The regulation still aligns with the EU Directive and has the same substance restrictions and labeling requirements.

Packaging Directive

Packaging for electrical and electronic products placed on the EU market is also subject to certain chemical requirements and those horizontally applicable under regulations such as REACH and POP.

In Europe, the Directive 94/62/EC on packaging and packaging waste establishes limits for certain heavy metals — specifically that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight.

EU battery label



Cd
(if cadmium
content > 0.002%)



Pb
(if lead
content > 0.004%)

Toxic Substances Control Act (TSCA)

The Toxic Substances Control Act (TSCA) of 1976, i.e., 15 U.S.C. §2601 et seq. (1976) provided the United States Environmental Protection Agency (EPA) the authority to define reporting, record-keeping and testing requirements and restrictions relating to chemical substances and/or mixtures for covered products.

As required under the TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the EPA issued five final rules on Jan. 6, 2021 to reduce exposure to the following chemicals that are persistent, bioaccumulative and toxic (PBT):

- DecaBDE
- Phenol, isopropylated phosphate (3:1) (PIP (3:1))
- 2,4,6-TTBP
- Hexachlorobutadiene (HCBD)
- Pentachlorothiophenol (PCTP)

Three of these substances (DecaBDE, PIP (3:1), PCTP) are restricted in various products and articles; they may be present in plastic or rubber articles and the first two substances are known to be present in various electrical and electronic equipment.

This restriction may affect the electrical and electronic industry if the company manufactures (including import), processes, distributes in commerce or uses:

- Phenol, isopropylated phosphate (3:1) (PIP (3:1)), or PIP (3:1)-containing articles, especially plastic articles that are components of electronics or electrical articles
- Decabromodiphenyl ether (decaBDE) and decaBDE-containing products and articles, especially wire and cable rubber casings, textiles, electronic equipment casings, building and construction materials and imported articles such as aerospace and automotive parts

For PIP (3:1), the EPA proposes to extend the compliance date applicable to the processing and distribution in commerce of certain PIP (3:1)-containing articles, and the PIP (3:1) used to make those articles until Oct. 31, 2024, along with the associated recordkeeping requirements for manufacturers processors and distributors of PIP (3:1)-containing articles.

Meanwhile, the restriction for decaBDE has been applied since March 2021 with different steps of adoption in the upcoming months and years.



USA

In the United States, electrical and electronic products must comply with a range of similar regulations and standards.

Batteries – Federal Regulation

The United States has some of the most stringent legislation on waste battery pollution management. The legislation aims to prohibit the use of mercury in batteries and facilitate the collection and recycling of nickel-cadmium rechargeable batteries, small, sealed lead-acid rechargeable batteries and other regulated batteries.

Additionally, the U.S. has established a complete waste battery recycling system and several waste battery treatment plants. The Mercury-Containing Batteries and Rechargeable Batteries Management Act (U.S. Public Law 104-142) was implemented on May 13, 1996. The law has laid out rules for labeling, production, collection, transportation, storage and more for waste nickel-cadmium batteries, waste small-sealed lead-acid batteries and other waste rechargeable batteries.

California Proposition 65

In 1986, California residents passed California Proposition 65, also known as the Safe Drinking Water and Toxic Substances Act of 1986.

Proposition 65 requires businesses to warn Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm.

It also requires California to publish a list of chemicals known to cause cancer, birth defects or other reproductive harm. This list, required to be updated at least once a year, has grown to include approximately 1,000 entries including individual substances and generic entries, such as Nickel compounds.

Since its adoption, California Proposition 65 has led to numerous lawsuits requiring formula reconstitution for consumer products containing listed chemicals. As a result, it has reduced the use of carcinogenic and reproductively toxic chemicals in California.

California Proposition 65 warning requirement for exposure to listed chemicals applies to all consumer products, including electrical and electronic products.





Various state RoHS

The following states have regulations that follow the European Union's RoHS Directive's model: California, Connecticut, Florida, Hawaii, Iowa, Maine, Maryland, Michigan, Minnesota, New Hampshire, New Mexico, New York, Rhode Island, Vermont, Virginia, and Washington. Many of these states prohibit the sale of electronic devices that are approved for sale in the European Union based on the RoHS directive. This means that if one or more of the heavy metals exceeds a specific total concentration, it cannot be sold in that state. An example of the California RoHS regulation follows:

The California Electronic Waste Recycling Act (SB20 and its Amendment SB50), issued in 2003, stipulates the requirements for restricted substances (lead, mercury, cadmium and hexavalent chromium) in video display devices, regulating nine categories of specific electronic equipment with the screen diagonal length greater than four inches, including manufacturer-refurbished products for retail:

- Cathode ray tubes (CRTs)
- Cathode ray tube containing devices (CRT devices)
- Computer monitors containing CRTs
- Laptop computers with liquid crystal display (LCD)
- Desktop monitors containing LCDs
- Televisions containing CRTs
- Televisions containing LCD screens
- Plasma televisions
- Portable DVD players with LCD screens

Packaging

Not only are electrical and electronic products subject to chemical requirements before they can reach the U.S. market, but so is their packaging.

In July 2020, the Toxics in Packaging Clearinghouse (TPCH) published an announcement to seek comments on the update related to perfluoroalkyl and polyfluoroalkyl substances (PFAS) and phthalates or ortho-phthalates as regulated chemicals.

On Feb. 16, 2021, the TPCH updated their Model Toxics in Packaging Legislation to include these chemicals and prohibit packaging and packaging components containing intentionally added PFAS at non-detect limit, and the restriction of packaging and packaging components containing ortho-phthalates greater than the sum of 100 ppm or 0.01% by weight. Additionally, a new requirement states that manufacturers must be able to produce a certificate of compliance at either the authorities' or public's request. The existing legislation enacted in 19 U.S. states prohibits the intentional use of cadmium, lead, mercury and hexavalent chromium in any finished package or packaging component.

The laws also limit any heavy metal contaminants at 100 ppm. However, it will now be up to each state to decide to adopt these changes to their existing regulations or adopt a new law to address toxins in packaging.

Restricted Substances in Children's Products

In 1972, the Consumer Product Safety Act became part of U.S. legislation. The law established the Consumer Product Safety Commission (CPSC) and defined its purpose as protecting the public against unreasonable risk of injury associated with consumer products. It assists consumers in evaluating the safety of consumer products, develops safety standards and promotes research and investigation into causes and prevention of product-related deaths, illnesses and injuries.

In August 2008, the United States president signed into law the Consumer Product Safety Improvement Act of 2008 (CPSIA). On Aug. 12, 2008, Public Law 112-28, August 12, 2008, was signed. The law provides the CPSC with new regulatory and enforcement tools. The CPSC restricts the total concentration of lead and phthalates found in accessible components of children's products. Specific to children's products and components of children's products, the CPSC restricts lead content to 100 ppm with few exceptions. Additionally, it restricts paint or surface coatings on such products to 90 ppm.

Section 108 of CPSIA restricts the use of phthalates (DEHP, DBP, BBP, SINP, DIBP, DPENP, DHEXP and DCHP) at a concentration greater than 0.1% in childcare articles.

The CPSIA requires every manufacturer or importer of children's products to certify that the products comply with all relevant product safety rules by issuing a Children's Product Certificate (CPC) supported by testing through a CPSC-accredited third-party testing laboratory.

Chemicals of High Concern to Children

Maine, Oregon, Vermont and Washington require manufacturers that sell children's products containing chemicals on their respective lists of Chemicals of High Concern to Children to provide notice to the state prior to sale in that state. State regulations vary in terms of chemicals listed, reporting procedures and whether a chemical must be removed or substituted.



United Arab Emirates (UAE) RoHS

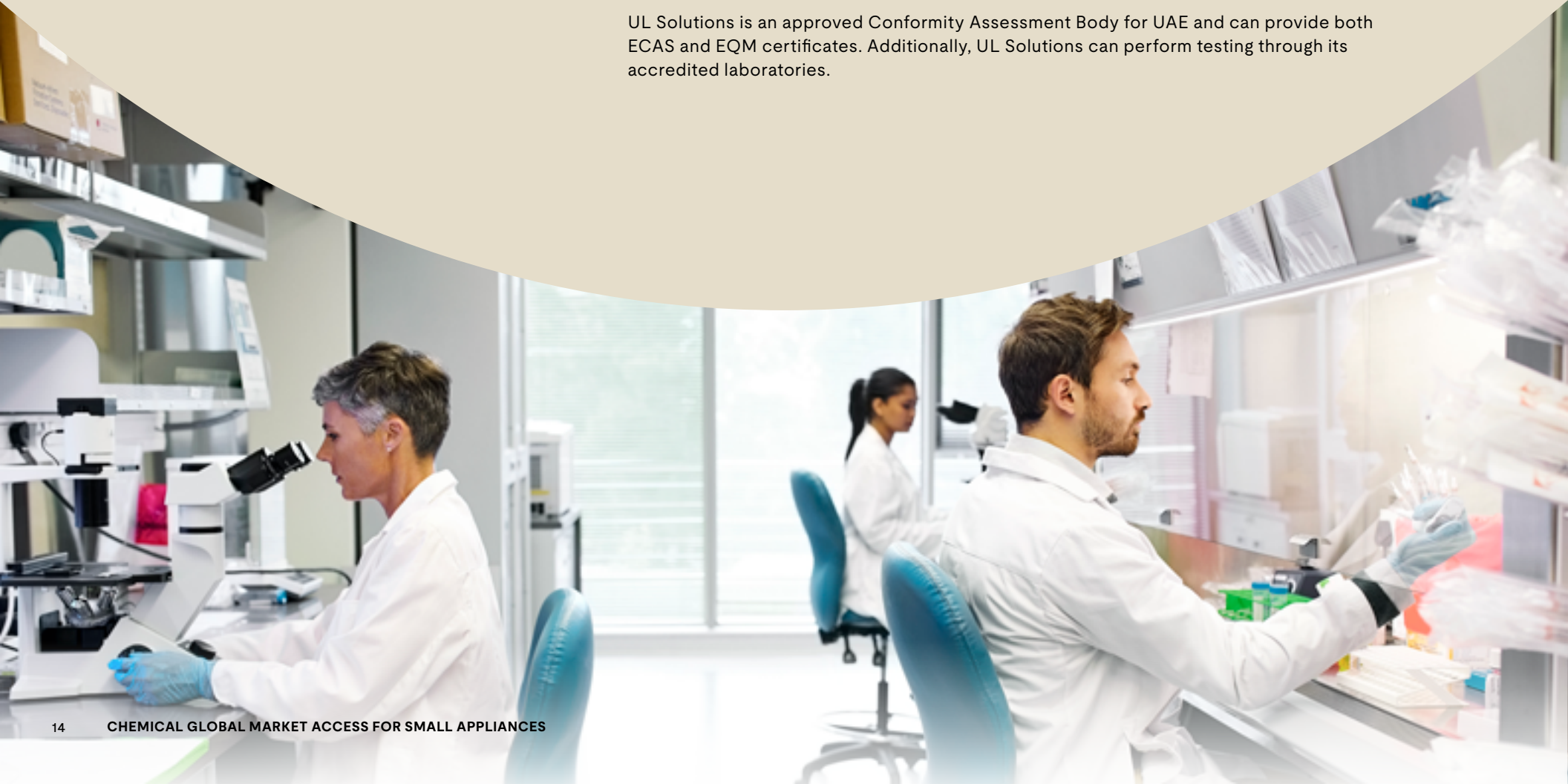
In 2017, the United Arab Emirates issued the UAE Cabinet Decision No. 10 of 2017 (UAE RoHS regulation), which restricted the presence of the following hazardous substances in all EEE: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE) and certain phthalates (DEHP, BBP, DBP, DIBP).

The definition of EEE and the list of restricted substances is the same of EU RoHS.

To import into the UAE, it is mandatory to obtain a Certificate of Conformity under RoHS Regulation with two possible conformity assessment processes:

- Emirates Conformity Assessment Scheme (ECAS)
- Emirates Quality Mark (EQM)

UL Solutions is an approved Conformity Assessment Body for UAE and can provide both ECAS and EQM certificates. Additionally, UL Solutions can perform testing through its accredited laboratories.





Saudi Arabia

SASO RoHS

On July 9, 2021, the Saudi Standards, Metrology and Quality Organization (SASO) published the Technical Regulations for Limiting Hazardous Substances in Electrical and Electronic Appliances and Equipment with an effective implementation date 6 months after publication, on January 5th 2022. However, SASO communicated the postponement of the implementation on Dec. 16th, 2021. SASO Board approved the gradual implementation of the regulation by category. The new enforced dates are:

n.	Category name	Enforcement date
1-A	Small household appliances	July 4, 2022
1.B	Large household appliances	Oct. 2, 2022
2	Telecommunication and information technology equipment	Dec. 31, 2022
3	Lighting equipment	March 31, 2023
4	Electrical and electronic equipment and tools	June 29, 2023
5	Toys and entertainment tools and appliances and sports equipment	Sept. 27, 2023
6	Tools for monitoring and control	Dec. 26, 2023

This regulation aims to determine the maximum contents of hazardous substances in electrical and electronic equipment and their spare parts and determine the conformity assessment procedures that suppliers must comply with to help ensure the preservation of the environment and the consumer's health and safety.

This regulation's scope applies to all electrical and electronic devices, equipment and their spare parts for the following categories:

- Large and small home appliances
- Information and communication technology equipment
- Lighting equipment
- Electrical and electronic tools and equipment
- Games, entertainment devices and sports equipment
- Monitoring and control tools

Saudi Arabia

Restricted substances and maximum concentration values tolerated by weight in homogeneous material:

Hazardous substances categories	Maximum concentration values allowed
Lead	0.1%
Mercury	0.1%
Cadmium	0.01%
Hexavalent chromium	0.1%
Polybrominated biphenyls (PBB)	0.1%
Polybrominated biphenyls ethers (PBDE)	0.1%

Conformity assessment procedure:

All products in scope of the new Regulation will require a certificate of conformity according to the certification module TYPE A1 of the ISO/IEC 17067. The evaluation must be done by one of the Notified Bodies approved by SASO. RoHS technical evaluation will be required to obtain the product CoC under the main regulation. In order to obtain the final CoC and be ready to access the market, the manufacturers need to comply with all the applicable regulations on their products, not only RoHS but also safety, EE and other.

Suppliers will need to apply for RoHS Product Certification of Conformity (PCoC) through the SABER platform.

RoHS Technical Documentation and Certification will be required as a preliminary step to obtain the Product CoC under the main product regulation.

UL Solutions is an approved Conformity Assessment Body for SASO RoHS and can provide PCoC certifications. Additionally, UL Solutions can perform RoHS testing through its accredited laboratories.



Food Contact



Chemical safety for electrical and electronic products in contact with food

Europe

In the European Union, all materials and articles intended to come in contact with food have to respect the criteria imposed by the Framework Regulation 1935/2004.

The goal is to ensure that in every phase of contact between food contact materials (FCM) and food, sufficient inertia is ensured, avoiding any type of negative influence on the quality or nutritional and organoleptic properties of the food. Commission Regulation (EC) No. 1935/2004 provides a harmonized legal EU framework. It sets out the general principles of safety and inertness for all FCMs.

- The principles set out in Regulation (EC) No 1935/2004 require that materials do not:
- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odor in an unacceptable way

Moreover, the framework provides rules on labeling FCMs and on compliance documentation and traceability.

U.S.

In the U.S., the U.S. Food and Drug Administration (FDA) governs the overall regulatory status of FCMs under the FD&C Act and 21 CFR 170-199. Each individual substance in the formulation of an FCM must be evaluated for its regulatory compliance to determine the final item's regulatory status. An FCM complies only if all substances in the formulation are approved for food contact use and required testing meets the regulations in force.

The FDA defines a food contact substance as “a substance intended for use as a component of materials used in the manufacturing, packaging, transporting, cooking or holding food.” It classifies food contact substances that migrate into food as indirect food additives. If a functional barrier prevents a substance from migrating into the food, it is not considered an indirect food additive and is not required to have FDA approval. One of the FDA's categories covers the overall status of each substance expected to migrate to food because of its intended use.

China

In China, the Food Safety Law of the People's Republic of China regulates FCMs. This law prohibits the import, use or purchase of food-related products, including food packaging materials, that do not comply with the applicable Chinese Food Safety Standards promulgated by the National Health Commission (NHC). In November 2016, the NHC published a list of 53 mandatory national standards (FCM GB standards) for food contact materials and articles. With the release of these new standards, a new Chinese FCM GB standards scheme was established. This new scheme includes four major sections: General Standards, Product Standards, Test Methods and General Hygiene Requirement.

Japan

In Japan, the Food Sanitation Law regulates food utensils, containers and packaging. The Food Sanitation Law prohibits the sale of utensils and food container/packaging that contain any toxic or harmful substances. The Ministry of Health, Labor and Welfare (MHLW) has established specifications for various FCMs and their raw materials.

The MHLW has set three different types of specifications:

- General specifications that apply to all food utensils and food packaging materials
- Material-specific specifications and standards
- Specifications applied for some end-use applications that need special consideration

Those specifications include requirements on migration testing to help ensure that finished food contact materials meet various specifications, e.g., heavy metal content and total nonvolatile extractives. Japan is also developing a positive list of substances or materials permitted for use in manufacturing FCMs or articles. In addition, various industry associations such as Japan Hygienic Olefin and Styrene Plastics Association and Japan Paper Association have set voluntary standards for different types of FCMs. Those voluntary industry standards are well respected in Japan.



How UL Solutions can help

UL Solutions, the global safety science leader, has earned worldwide recognition for our expertise in testing and certifying electrical and electronic products. When you factor in our experience in chemical testing, advisory and chemical data management software, it's obvious that UL Solutions is the right partner to support your compliance needs. UL Solutions holistic chemical solutions for electrical and electronic products help you enhance safety across the supply chain, meet sustainability initiatives, and demonstrate regulatory compliance.

We help companies addressing compliance challenges and managing potential risks with different approaches: whether you want to test your products and materials, screening all materials disclosed in products or combine both product testing and material screening, UL Solutions can support you with:

- Testing of products and materials against chemical requirements
- Specific markets certifications
- Chemical data management software that screens material disclosures against global regulations
- Regulatory content and automation software for creating all regulatory compliance documents (SDS authoring, reports, labels)
- Data collection software to gather and manage data on the materials being used in your product development and manufacturing
- Chemical regulatory advisory services and training including technical documents and label reviews, Market Readiness Reports Trainings

Contact us today to learn more.

Visit us at [UL.com/chemical-management-electrical-and-electronic-products](https://www.ul.com/chemical-management-electrical-and-electronic-products) for more information.

i. <https://www.thebusinessresearchcompany.com/report/electrical-and-electronics-global-market-report-2020-30-covid-19-impact-and-recovery>



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