

RESTRICTION OF USE OF HAZARDOUS SUBSTANCES (ROHS) IN ELECTRICAL AND ELECTRONIC EQUIPMENT

At EU level, Directive 2011/65/EU is the Directive that lays down the rules on the restriction of the use of hazardous substances (RoHS) in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

Directive 2011/65/EU applies to different categories of EEE, categories 1 to 11, which are listed in Annex I to that Directive. It shall be ensured that EEE placed on the market shall not exceed the maximum concentration values on the restricted substances as listed in Annex II of that Directive. However, certain equipment is excluded from the scope of the Directive, as indicated in Article 2; while a number of exemptions are granted, as listed in Annexes III and IV of the same Directive.

Information on **Directive 2011/65/EU of the European Parliament and of the Council** on the restriction of the use of hazardous substances in electrical and electronic equipment can be accessed through the following link:

http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm

Directive 2011/65/EU and subsequent amendments, have been transposed into local legislation by **Subsidiary Legislation 427.57** (S.L. 427.57), Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations, which can be accessed through the following link:

<https://legislation.mt/eli/sl/427.57/eng/pdf>

S.L. 427.57, the national RoHS Regulations, had been amended by several Legal Notices (L.N.). The Legal Notices that had been published since 2019 are:

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| <u>L.N. 119 of 2019</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2019 |
| <u>L.N. 185 of 2020</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2020 |
| <u>L.N. 361 of 2020</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2020 |
| <u>L.N. 388 of 2021</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2021 |
| <u>L.N. 93 of 2022</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2022 |
| <u>L.N. 239 of 2022</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2022 |
| <u>L.N. 68 of 2023</u> | Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2023 |

<u>L.N. 195 of 2023</u>	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2023
<u>L.N. 77 of 2024</u>	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2024
<u>L.N. xxx of 2024</u>	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2024
<u>L.N. xxx of 2024</u>	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 3) Regulations, 2024

The above links provide information on the EU Delegated Directives that the respective Legal Notices had transposed into the national regulations.

L.N. 119 of 2019 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2019

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Directive (EU) 2017/2102 of the European Parliament and of the Council:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355459011&uri=CELEX:32017L2102>

- removes the prohibition of secondary market operations of non-compliant EEE,
- provides an exclusion for pipe organs,
- provides an exclusion for non-road mobile machinery with a traction drive powered by an external power source, and
- provides conditions for the exemption of reused spare parts recovered from EEE.

Commission Delegated Directive (EU) 2018/736:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355505173&uri=CELEX:32018L0736>

- provides an exemption for certain electrical and electronic components containing lead in glass or ceramic.

Commission Delegated Directive (EU) 2018/737:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355545660&uri=CELEX:32018L0737>

- provides an exemption for lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors.

Commission Delegated Directive (EU) 2018/738:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355590393&uri=CELEX:32018L0738>

- provides an exemption for lead in cermet-based trimmer potentiometer elements.

Commission Delegated Directive (EU) 2018/739:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355590393&uri=CELEX:32018L0739>

- provides an exemption for lead as an alloying element in steel.

Commission Delegated Directive (EU) 2018/740:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355590393&uri=CELEX:32018L0740>

- provides an exemption for lead as an alloying element in aluminium.

Commission Delegated Directive (EU) 2018/741:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355590393&uri=CELEX:32018L0741>

- provides an exemption for lead as an alloying element in copper.

Commission Delegated Directive (EU) 2018/742:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549355590393&uri=CELEX:32018L0742>

- provides an exemption for lead in high melting temperature solders.

Commission Delegated Directive (EU) 2019/169:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549454501633&uri=CELEX:32019L0169>

- provides an exemption for lead in dielectric ceramic in certain capacitors.

Commission Delegated Directive (EU) 2019/170:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0170>

- provides an exemption for lead in PZT based dielectric ceramic materials for certain capacitors.

Commission Delegated Directive (EU) 2019/171:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0171>

- provides an exemption for cadmium and its compounds in electrical contacts.

Commission Delegated Directive (EU) 2019/172:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0172>

- provides an exemption for lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages.

Commission Delegated Directive (EU) 2019/173:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0173>

- provides an exemption for lead and cadmium in printing inks for the application of enamels on glasses.

Commission Delegated Directive (EU) 2019/174:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0174>

- provides an exemption for lead bound in crystal glass as defined in S.L. 427.04.

Commission Delegated Directive (EU) 2019/175:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0175>

- provides an exemption for lead oxide in seal frit used for making window assemblies for certain laser tubes.

Commission Delegated Directive (EU) 2019/176:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0176>

- provides an exemption for lead in the plating layer of certain diodes.

Commission Delegated Directive (EU) 2019/177:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0177>

- provides an exemption for lead as activator in the fluorescent powder of discharge lamps containing phosphors.

Commission Delegated Directive (EU) 2019/178:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549446876652&uri=CELEX:32019L0178>

- provides an exemption for lead in bearings and bushes applied in certain non-road professional use equipment.

The objectives of each Directive whose provisions are transposed by the above Legal Notice are:

Directive (EU) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- Directive 2011/65/EU contains a request that the Commission examine the need to amend the scope of that Directive in respect of the EEE covered therein and, if appropriate, present a legislative proposal with respect to any additional exclusions related to that EEE.
- Secondary market operations for EEE, which involve repair, replacement of spare parts, refurbishment and reuse, and retrofitting, should be facilitated to promote a circular economy in the Union. Any unnecessary administrative burden on market operators should be avoided. Directive 2011/65/EU allows EEE that fell outside the scope of the previous Directive 2002/95/EC, but which would not comply with Directive 2011/65/EU, to continue to be made available on the market until 22 July 2019. After that date, however, both the first placing on the market and secondary market operations of non-compliant EEE are prohibited. Such prohibition of secondary market operations is inconsistent with the general principles underlying Union measures for the approximation of laws relating to products and should therefore be removed.
- Certain niche product groups should be excluded from the scope of Directive 2011/65/EU as their inclusion would bring negligible environmental or health benefits and introduce unresolvable compliance problems or market distortions that cannot effectively be addressed through the exemption mechanism provided for in that Directive.
- One type of such niche market is, pipes in organs, that are built using a specific type of lead-based alloy, for which no alternative has been found so far. Most pipe organs are kept in the same place for centuries and their turnover rate is negligible. Pipe organs should therefore be excluded from the scope of Directive 2011/65/EU as their inclusion would bring negligible benefit in terms of the substitution of lead.
- Directive 2011/65/EU does not apply to non-road mobile machinery with an on-board power source, which is made available exclusively for professional use. However, for certain types of non-road mobile machinery, two versions are produced in the same production line, with the power source (either on-board or external) being the only difference. Those versions should be treated in the same way under that Directive. Non-road mobile machinery with a traction drive powered by an external power source should therefore also be excluded from the scope of Directive 2011/65/EU.
- For all relevant EEE categories, as set out in Annex I to Directive 2011/65/EU, the conditions for the exemption of reused spare parts, recovered from EEE, should be clearly specified. Likewise, since exemptions from the restriction of the use of certain hazardous substances should have a limited duration, the maximum validity period for existing exemptions should also be clearly specified for all relevant EEE categories, including for category 11.

Commission Delegated Directive (EU) 2018/736 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for certain electrical and electronic components containing lead in glass or ceramic.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- In ceramics, lead provides particular dielectric, piezoelectric, pyroelectric, ferroelectric,

semiconductor, magnetic properties over a wide use ranges in terms of temperatures, voltages or frequencies. In glass, lead provides crucial properties such as lowering the melting and softening points, improving workability, machinability, and chemical stability and others. Lead-containing glass can be used over a wide range of applications, including insulation, protection, resistance, bonding or hermetic sealing.

- Currently, substitution or elimination of lead in glass and/or ceramic is still scientifically or technically impracticable.
- Since for the applications concerned in categories 1 to 7 and 10, no reliable alternatives are available on the market or are likely to be available on the market in the near future, a renewal of the exemption with a validity period until 21 July 2021 is justified. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2018/737 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Discoidal and planar array capacitors are derivations of multi-layer ceramic capacitors. They are specialist capacitors used in electromagnetic interference filters and electromagnetic interference filtered connectors for high end applications, where the elimination of electrical interference is critical. Typical applications for assemblies incorporating those components include professional audio equipment, maritime monitoring and video surveillance systems.
- Lead-containing solders used in discoidal and planar array capacitors provide the combination of a suitable melting point and ductility. The ductility of that solder avoids cracking of the ceramic layer during and after soldering due to thermal mismatch between the ceramic capacitor and the copper pin.
- Currently, the substitution of lead is scientifically and technically impracticable.
- Since for the applications concerned in categories 1 to 7 and 10, no sufficiently reliable alternatives are available on the market or are likely to be available on the market in the near future, validity period until 21 July 2021 is justified. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2018/738 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in cermet-based trimmer potentiometer elements.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Trimmer potentiometers are variable resistors. They work with a wiper to adjust the resistance of the circuit. They are applied in a wide range of products like, e.g. audio-visual equipment, communication equipment, toys and measuring devices, electrical household appliances. They contain lead as lead oxide in resistive inks where it acts as a bonding agent.
- Currently, there are no reliable lead-free alternatives available so that substitution of lead is still scientifically and technically impracticable.
- Since for the applications concerned in categories 1 to 7 and 10, no sufficiently reliable alternatives are available on the market or are likely to be available on the market in the near future, validity period until 21 July 2021 is justified. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2018/739 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element in steel.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead is added to steel as a machinability enhancer for industrial production. It has a lubrication effect that eases deep drilling and high speed operations. Galvanisation is the process of applying a protective zinc coating to steel in order to prevent corrosion.
- Though lead-free steel is available for some specific applications, the substitution in the remaining applications is currently scientifically and technically impracticable. A further narrowing of the scope of the exemption has proven to be currently not feasible due to the high complexity of the supply chain.
- Among galvanised steels, lead is still necessary only in batch hot dip galvanised steel and in a lower concentration due to progress in technology.
- Since for the applications concerned in categories 1 to 7 and 10, no sufficiently reliable alternatives are available today or are likely to be available on the market in the near future, and in case of hot dip galvanised steel, the lead content results from impurities from recycled zinc, validity period until 21 July 2021 is justified for both applications. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2018/740 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element in aluminium.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.

- Lead is intentionally added to aluminium as a machinability enhancer for industrial production. Certain lead-free alternatives have been recently made available on the market. The technical practicability and reliability of these alternatives are still unclear.
- Furthermore, while lead-bearing aluminium scrap recycling is environmentally advantageous, the elimination of this unintentionally introduced lead from the aluminium recycling stream is not yet technically practicable.
- In case of unintentional presence of lead stemming from lead-bearing aluminium scrap recycling, the impracticability of lead elimination and the lower environmental impact of recycled aluminium justifies granting an exemption until 21 July 2021 for categories 1 to 7 and 10. Regarding lead in aluminium alloys for machining purposes, where lead is added to obtain certain properties, an exemption for categories 1 to 7 and 10 with the duration of 3 years after the publication of this Directive should be granted to allow the industry to carry out necessary assessments of the performance of lead-free alternatives available on the market and adapt to possible changes. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2018/741 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element in copper.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead in copper alloys acts as chip breaker and lubricant, gives copper alloys a favourable machinability, and provides the finished component also with other properties, such as corrosion resistance.
- Currently, alternatives to the use of copper alloys containing lead up to 4 % by weight cannot be identified as scientifically or technically practicable.
- For categories 1 to 7 and 10, the exemption should be renewed until 21 July 2021 to allow performing a comprehensive survey of the supply chain in order to narrow the scope of the exemption at the time of the next review. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2018/742 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in high melting temperature solders.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead gives solders crucial properties such as high melting point, electrical conductivity, thermal

conductivity, ductility, corrosion-resistivity, appropriate oxidation nature, and wettability.

- Currently, substitution or elimination of lead in high melting temperature solders is still scientifically or technically impracticable. Neither is it currently possible to narrow the scope of the exemption due to the high diversity of the applications concerned.
- Since for the applications concerned in categories 1 to 7 and 10, no reliable alternatives are available on the market or are likely to be available on the market in the near future, a renewal of the exemption with a validity period until 21 July 2021 is justified. For categories other than categories 1 to 7 and 10, the existing exemption is valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/169 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in dielectric ceramic in certain capacitors.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Discrete ceramic capacitors for a rated voltage of 125 V AC or 250 V DC or higher bear the capability of storing and releasing electric charges (electrostatic capacitance) and are incorporated into high voltage circuits in a wide variety of EEE. They are used in all types of markets and applications, for example social infrastructure systems, industry automation, oil and mineral exploration, power conversion, high power supplies, telecommunication, and medical devices.
- The function of lead in the dielectric ceramic is to obtain high dielectric constant at high operating voltage, high energy storage capability (also at high temperatures), low leakage at high voltage and high temperatures, and low loss at high current, frequency, and temperatures.
- A substitution or elimination of lead is still scientifically and technically impracticable for certain ceramic capacitors due to the lack of reliable substitutes.
- Since, for the applications concerned, no reliable alternatives are yet available on the market, the exemption for categories 1 to 7 and 10 should be renewed for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.
- Applications covered by entries 7(c)-I and 7(c)-IV are excluded from entry 7(c)-II.

Commission Delegated Directive (EU) 2019/170 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in PZT based dielectric ceramic materials for certain capacitors.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Ceramic capacitors which are part of integrated circuits or discrete semiconductors use dielectric ceramic materials based on PZT (lead-zirconium-titanate) ceramics. Lead containing PZT ceramics offer high piezoelectric effect, high dielectric constant, pyroelectric behaviour and ferroelectric properties.
- A complete substitution or elimination of lead in such capacitors is still scientifically and technically impracticable due to the lack of reliable substitutes.
- Since, for the applications concerned, no reliable alternatives are available today or are likely to be available on the market in the near future, the exemption for categories 1 to 7 and 10 should be renewed for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/171 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and its compounds in electrical contacts.

- Directive 2011/65/EU lists cadmium as a restricted substance in Annex II.
- Electrical contact materials containing cadmium are used in many electromechanical devices as components which can carry current intermittently through contact surfaces. Devices concerned are in particular power switching of electric motors, relays and contactors, switches for power tools, appliance switches, circuit breakers for switching equipment, power packs, occupancy/time delay sensors, and lighting control panels.
- Cadmium in electrical contacts provides essential properties such as superior performance, arc-quenching, higher conductivity, less contact erosion and relatively easy manufacture compared to the alternatives.
- For certain applications covered by the current exemption, a substitution or elimination of cadmium is still scientifically and technically impracticable due to the lack of reliable substitutes or requires more time to ensure the reliability of the available substitutes.
- For all other applications currently covered by the exemption, the conditions for renewal are not fulfilled. The exemption for those applications should continue to apply for 12 months after the date of entry into force of this Delegated Directive in accordance with Article 5(6) of Directive 2011/65/EU.
- Since, for the applications concerned by that renewal, no reliable alternatives are available on the market or more time is needed to ensure the reliability of such alternatives, the exemption

for those applications should be renewed for categories 1 to 7 and 10 for the maximum duration validity period of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/172 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Leaded solders are used in flip chip connections as bumps and solders for attaching the die to the chip carrier. The solders must be resistant to electromigration failure at the extremely high current densities required and able to create a solder hierarchy that allows staged assembly and rework of components in the manufacturing process. They must also have high ductility to reduce thermo-mechanical stress in under bump metallurgy structures, in particular in larger dies.
- For certain applications covered by the current exemption, a substitution or elimination of lead is still scientifically and technically impracticable due to the lack of reliable substitutes.
- For all other applications currently covered by the exemption, the conditions for renewal are not fulfilled. The exemption for those applications should continue to apply for 12 months after the date of entry into force of this Delegated Directive in accordance with Article 5(6) of Directive 2011/65/EU.
- Since, for the applications concerned by that renewal, no reliable alternatives are available on the market, the exemption for those applications should be renewed for categories 1 to 7 and 10 for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/173 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in printing inks for the application of enamels on glasses.

- Directive 2011/65/EU lists lead and cadmium as restricted substances in Annex II.
- Lead and cadmium in printing inks applied to glass provide a durable product marking, especially on the glass bulb of lamps. The marking serves several purposes such as European conformity (CE) and Waste Electrical and Electronic Equipment (WEEE) marking, identifying the producer and the

lamp type and wattage, which is relevant for safety, correct lamp replacement and recycling. The durability of the marking is important to maintain the legibility of product markings throughout product-lifetime, as required by legislations and product safety standards.

- Lead provides essential properties such as good adhesion, lower enamelling temperatures, higher durability and opacity.
- Cadmium is used to achieve certain hues of the enamel in various application areas, including applications for safety and warning purposes where certain hues are considered to increase visibility. It also provides important filtering functions.
- The substitutions or eliminations of lead or cadmium are still scientifically and technically impracticable for certain applications covered by the current exemption with regard to categories 1 to 7 and 10 due to the lack of reliable substitutes.
- For all other applications currently covered by the exemption, the conditions for renewal are not fulfilled. The exemption for those applications should continue to apply for 12 months after the date of entry into force of this Delegated Directive in accordance with Article 5(6) of Directive 2011/65/EU.
- Since for the lead or cadmium containing applications concerned by the renewal, no reliable alternatives are available on the market, the exemption for those applications should be renewed for categories 1 to 7 and 10 for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/174 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead bound in crystal glass as defined in Directive 69/493/EEC.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead bound in crystal glass is defined in Annex I (Categories 1, 2, 3 and 4) to Directive 69/493/EEC; which Directive is transposed to local Subsidiary Legislation 427.04.
- Lead oxides (PbO or Pb₃O₄) are used as an intermediate for the chemical synthesis of lead crystal glass (LCG). LCG is used in EEE because its unique combinations of processing (cooling time, working range), optical (refractive index, dispersion) and decorative (Vicker's hardness) properties allows the manufacturing of electrical and electronic articles which could not be produced otherwise, such as specific luminaires and chandeliers, electrified mirrors, clocks and watches, digital photo frames and building materials (illuminated blocks).
- A substitution or elimination of lead in crystal glass is still scientifically and technically impracticable due to the lack of reliable substitutes.

- Since reliable alternatives for the applications concerned are not yet available on the market or are likely to be available on the market in the near future, the exemption for categories 1 to 7 and 10 should be renewed for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/175 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead oxide in seal frit used for making window assemblies for certain laser tubes.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead-containing laser products are used as coherent light sources in a broad range of critical scientific and industrial applications, such as spectroscopy, microscopy and holography. Lead oxide-based material in Argon and Krypton laser products provides a critical thermo-mechanically stable and vacuum-tight seal between the optics and laser tube.
- A substitution or elimination of lead is still scientifically and technically impracticable for Argon and Krypton laser tubes due to the lack of reliable substitutes. The exemption for the use of lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes should therefore be renewed for categories 1 to 7 and 10.
- Since, for the applications concerned, no reliable alternatives are available today or are likely to be available on the market in the near future, the exemption for categories 1 to 7 and 10 is renewed for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/176 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the plating layer of certain diodes.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- High voltage diodes (HVD) are used in external power supplies of IT and telecommunication equipment and for automotive applications. During the manufacturing process of HVD, lead contained in the glass beads dissolves into the plating solution, which results in approximately 2,5 % of lead content in the plating layer of the diodes. Thus, the lead is not added intentionally but is the result of the contamination from the lead-containing glass.
- Avoiding the contamination of the plating layer of HVD is scientifically and technically

impracticable and no reliable substitutes are available on the market. The exemption for the use of lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body should therefore be renewed for categories 1 to 7 and 10.

- Since eliminating lead by avoiding lead contamination for the applications concerned is still impracticable and no reliable substitutes are available on the market, the exemption for categories 1 to 7 and 10 is renewed for the maximum duration of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2019/177 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as activator in the fluorescent powder of discharge lamps containing phosphors.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead activator in the fluorescent powder is required to allow the barium silicate phosphor to fluoresce. It transforms the 254 nm radiation to the designed UV (290 nm - 400 nm) radiation and it is used in over 95 % of the indoor low pressure mercury vapour fluorescent lamps in tanning and certain medical applications. It provides UV intensity at the wavelength of 350 nm that is crucial in order to initiate skin pigmentation.
- Tanning equipment is strictly regulated in the Union and any possible alternative to lead would have to fulfil criteria on reliability, safety and health risk concerns. Currently, there are no such alternatives available.
- Due to the lack of reliable substitutes, a substitution or elimination of lead is still scientifically and technically impracticable for certain discharge lamps containing phosphors. The exemption for the use of lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP ($\text{BaSi}_2\text{O}_5:\text{Pb}$) should therefore be renewed.
- Since, for the applications concerned, no reliable alternatives are yet available on the market, the exemption for categories 1 to 7 and 10 is renewed for the maximum validity period of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation. For categories other than 1 to 7 and 10, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.
- A new sub-entry 18(b)-I is added for discharge lamps when used as phototherapy lamps (medical equipment) containing phosphors. An assessment showed that it is mechanically possible that a lamp intended for medical use can fit in tanning equipment and vice versa, hence the new sub-entry. This sub-entry is specific to medical applications except for those covered by entry 34 of Annex IV. This sub-entry should apply to categories 5 and 8 and be valid until 21 July 2021.

Commission Delegated Directive (EU) 2019/178 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in bearings and bushes applied in certain non-road professional use equipment.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead containing bearings and bushes are necessary to achieve satisfactory reliability in terms of seizure resistance, conformability, embedability and debris resistance in large size engines and those operating in harsh or demanding environments to be used in professional use non-road equipment, such as mobile air compressors, mobile welding equipment and mobile cranes.
- Currently, there are no lead-free alternatives available on the market which would provide sufficient level of reliability for application areas of professional use non-road equipment engines.
- Due to the lack of reliable substitutes, a substitution or elimination of lead is scientifically and technically impracticable for certain professional use non-road equipment engines. The exemption for the use of lead in bearings and bushes of certain diesel or gaseous fuel powered internal combustion engines applied in non-road professional use equipment should therefore be granted, adding a new entry 42 to Annex III.
- Since, for the applications concerned, no reliable alternatives are yet available on the market or are likely to be available on the market in the near future, the exemption for category 11 is granted for the maximum validity period of five years starting from 22 July 2019, which is the date that category 11 enters into the scope of Article 4(1) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Provisions from Directive (EU) 2017/2102 shall apply as from 12th June 2019;
provisions from Directives (EU) 2018/736 to 2018/742 shall apply as from 1st July 2019;
provisions from Directive (EU) 2019/178 shall apply as from 22nd July 2019; while
provisions from Directives (EU) 2019/169 to 2019/177 shall apply as from 1st March 2020.

L.N. 185 of 2020 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2020

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2019/1845:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1576751717084&uri=CELEX:32019L1845>

- provides an exemption for bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems

Commission Delegated Directive (EU) 2019/1846:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1576751816997&uri=CELEX:32019L1846>

- provides an exemption for lead in solders used in certain combustion engines

The objectives of each Directive whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2019/1845 of 8 August 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems.

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP) as restricted substance in Annex II.
- An exemption was requested for the use of DEHP in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use.
- DEHP is added to rubber material as plasticiser in order to provide flexibility. The rubber components are used as flexible connections between parts of engine systems and assure prevention of leakage, sealing of engine parts and protection from vibration or dirt and fluids over the lifetime of the engines.
- Currently, there are no DEHP-free alternatives available on the market which would provide sufficient level of reliability for applications in engines where long life and special properties such as resistance to any contact material (e.g. fuel, lubricant oil, coolants, gases, or dirt), temperature and vibration are required.
- Due to the lack of reliable alternatives, a substitution or elimination of DEHP is still scientifically and technically impracticable for certain rubber parts used in engine systems. It is therefore, appropriate to grant the requested exemption, by including the applications covered by it, as a new entry 43 in Annex III to Directive 2011/65/EU, with respect to electrical and electronic equipment of category 11 of Annex I to the same Directive.
- The exemption is granted for the maximum validity period of 5 years starting from 22 July 2019. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2019/1846 of 8 August 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders used in certain combustion engines.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- An exemption was requested for the use of lead in solders of sensors, actuators and engine control units that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers.
- Each engine within scope of the requested exemption is equipped with specific types of sensors, actuators and engine control units that monitor and control its emissions to ensure compliance with Regulation (EU) 2016/1628 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery.
- The conditions experienced in and close to such engine and an exhaust system can be so severe in terms of elevated temperatures and vibration levels that they may cause early failure of solder bonds.
- Currently, for the applications of lead covered by the requested exemption, additional time is needed for testing to ensure the reliability of available lead-free substitutes.
- Due to the lack of reliable alternatives, a substitution or elimination of lead is scientifically and technically impracticable in certain combustion engines. It is therefore, appropriate to grant the requested exemption, by including the applications covered by it, as a new entry 44 in Annex III to Directive 2011/65/EU, with respect to electrical and electronic equipment of category 11 of Annex I to the same Directive.
- The exemption is granted for the maximum validity period of 5 years starting from 22 July 2019. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Provisions from Directives (EU) 2019/1845 and 2019/1846 shall apply as from 1st May 2020.

L.N. 361 of 2020 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2020

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2020/360:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1584520666503&uri=CELEX:32020L0360>

- provides an exemption for lead in platinized platinum electrodes used for certain conductivity measurements;

Commission Delegated Directive (EU) 2020/361:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1584520724673&uri=CELEX:32020L0361>

- provides an exemption for hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators;

Commission Delegated Directive (EU) 2020/364:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1584520768392&uri=CELEX:32020L0364>

- provides an exemption for the use of cadmium in certain radiation tolerant video camera tubes;

Commission Delegated Directive (EU) 2020/365:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1584520789923&uri=CELEX:32020L0365>

- provides an exemption for lead in solders and termination finishes used in certain hand-held combustion engines;

Commission Delegated Directive (EU) 2020/366:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1584520823388&uri=CELEX:32020L0366>

- provides an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

The objectives of each Directive whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2020/360 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for certain conductivity measurements.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead-containing platinized platinum electrodes are used in specialised instruments for measurements which require certain measurement qualities such as wide range, high accuracy, or high reliability for high concentration of acid and alkali.
- The Commission had granted an exemption for the use of lead in platinized platinum electrodes used for conductivity measurements where certain conditions apply, by Delegated Directive 2014/73/EU; which was to expire on 31st December 2018.

- Due to the lack of reliable alternatives, a substitution or elimination of lead in the applications concerned is currently scientifically and technically impracticable for certain measurement instruments. It is, therefore, appropriate to grant the renewal of the exemption.
- The exemption should be renewed for the maximum duration of 7 years until 31st December 2025. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2020/361 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators.

- Directive 2011/65/EU lists hexavalent chromium as a restricted substance in Annex II.
- Hexavalent chromium (Cr(VI)) acts as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators. It is used to create a layer on the interior surface of the steel tubes to protect them from the cooling solution that contains corrosive ammonia.
- An exemption from the restriction for the use of hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution is included in Annex III to Directive 2011/65/EU. For categories 1 to 7 and 10, the exemption was to expire on 21st July 2016.
- The evaluation led to the conclusion that the current exemption with regard to categories 1 to 7 and 10 is to be divided into two sub-entries with wording clearly reflecting the scientific and technical progress as regards to substitution of hexavalent chromium, which differs depending on the type of application.
- For applications with power input $\geq 75\text{W}$ and for systems fully operating with non-electrical heaters (corresponding to high boiler temperature applications), a substitution or elimination of hexavalent chromium is still scientifically and technically impracticable due to the lack of reliable substitutes. It is, therefore, appropriate to grant the requested renewal for applications using high boiler temperatures until 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- For applications with power input $< 75\text{W}$ (corresponding to low boiler temperature), the conditions for renewal are no longer fulfilled and therefore, the renewal request should be rejected. The exemption for those applications should expire 12 months after the date of entry into force of this Directive.
- For categories 8, 9 and 11, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2020/364 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of cadmium in certain radiation tolerant video camera tubes.

- Directive 2011/65/EU lists cadmium as a restricted substance in Annex II.
- Cadmium in video camera tubes is necessary to achieve satisfactory radiation tolerance and optical performance of video cameras operating in environments with high radiation exposure, such as nuclear power plants and nuclear waste reprocessing facilities.
- Currently, there are no cadmium-free alternatives available on the market which would provide the necessary combination of optical performance and sufficient radiation resistance.
- Due to the lack of alternatives, a substitution or elimination of cadmium is scientifically and technically impracticable for certain video camera tubes. It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 9.
- The requested exemption should be granted for a duration of 7 years starting from 5th March 2020. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2020/365 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes used in certain hand-held combustion engines.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead is a common alloying element in solder material to control the melting point. Alternative materials to replace the restricted substance have been successfully tested. However, additional time is needed to confirm the reliability of the lead-free products.
- The Commission had granted an exemption for the use of lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, that for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC), by Delegated Directive (EU) 2014/72/EU; which exemption was to expire for categories 1 to 7 and 10 on 31st December 2018.
- Currently, there are no lead-free alternatives available on the market which would provide sufficient level of reliability for the applications covered by the exemption.
- Due to the lack of reliable alternatives, a substitution or elimination of lead is currently scientifically and technically impracticable for certain hand-held combustion engines. It is, therefore, appropriate, to renew the exemption.

- The exemption for categories 1 to 7, 10 and 11 should be renewed until 31st March 2022. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- For categories 8 and 9, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU.

Commission Delegated Directive (EU) 2020/366 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain *in-vitro* diagnostic medical devices for the analysis of blood and other body fluids and body gases.

- Directive 2011/65/EU lists lead as a restricted substance in Annex II.
- Lead in the PVC sensor card of concerned *in vitro* medical devices (blood analysers) enhances sensor performance which is necessary for the optimum performance of the device in terms of analytical reliability claimed in product publications and thus for fulfilment of requirements laid down in Directive 98/79/EC on *in vitro* diagnostic medical devices.
- The Commission granted an exemption for the use of lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors that are used in *in vitro* diagnostic medical devices for the analysis of blood and other body fluids and body gases, by Delegated Directive (EU) 2015/573; which exemption was to expire on 31st December 2018.
- While lead-free technologies are available on the market for certain analysers of other manufacturers, reliability testing of substitutes for the specific application subject to the current renewal request requires additional time.
- Discontinuation of the exemption is expected to avoid a total of 157kg of lead being placed on the Union market. At the same time, however, it will result in the need to replace the entire diagnostic device, and consequently, is expected to lead to a premature generation of 112,000kg of waste electrical and electronic equipment. Furthermore, significant socioeconomic impacts on health providers using the devices concerned would be incurred.
- Considering the restriction process on lead in PVC provided for in Regulation (EC) No 1907/2006 (REACH), the exemption should be granted for a short validity period of 2 years to ensure full alignment with that Regulation once the relevant restriction process is concluded.
- Therefore, it is appropriate to grant the renewal of the exemption, for category 8, and it should be renewed for the duration of 2 years starting from 5th March 2020. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Provisions from Directive (EU) 2020/364 shall apply as from 1st September 2020, while provisions from Directives (EU) 2020/360, 2020/361, 2020/365 and 2020/366 shall apply as from 1st April 2021.

L.N. 388 of 2021 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2021

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2021/647:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L0647>

- provides an exemption for the use of certain lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) use.

Commission Delegated Directive (EU) 2021/884:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L0884>

- provides an extension to the validity period of an exemption for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems.

The objectives of the Directives whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2021/647 of 15 January 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of certain lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) use.

- Directive 2011/65/EU lists lead and hexavalent chromium as restricted substances in Annex II.
- Certain lead and hexavalent chromium compounds are used in essential parts of electric and electronic initiators (EEI), such as electric fuseheads, primary explosive charges and pyrotechnic delay charges. EEI are a part of electric and electronic detonators that are primarily used for mining of minerals, construction and demolition activities, as well as in components of integrated rescue systems.
- Currently, there are no alternatives for lead diazide, lead styphnate, lead dipicramate, orange lead (lead tetroxide), lead dioxide in EEI and for barium chromate in long time pyrotechnic delay charges of EEI available on the market which would meet all essential requirements in order to ensure safe operation of EEI.
- Due to the lack of alternatives, a substitution or elimination of lead diazide, lead styphnate, lead dipicramate, orange lead (lead tetroxide), lead dioxide and barium chromate is scientifically and technically impracticable in certain EEI components. It is, therefore, appropriate to grant the requested exemption for the use of lead and hexavalent chromium compounds in EEI of explosives for civil (professional) use in Annex III to Directive 2011/65/EU with respect to electrical and electronic equipment of category 11.
- The requested exemption is to be granted for a duration of 5 years starting from 20 April 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2021/884 of 8 March 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards the validity period of an exemption for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems.

- Directive 2011/65/EU lists mercury as a restricted substance in Annex II.
- Mercury is used in electric rotating connectors of intravascular ultrasound imaging systems which provide the electrical conduction path between the rotating transducer and stationary electronic equipment. The use of mercury enables, among other things, higher frequency operation which allows obtaining higher resolution imaging beneficial for patients.
- The Commission had previously granted an exemption for the use of mercury in intravascular ultrasound imaging systems, by Delegated Directive (EU) 2015/574, by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 30 June 2019.
- Due to the lack of alternatives, a substitution or elimination of mercury in the applications concerned is currently scientifically and technically impracticable. It is, therefore, appropriate to grant the renewal of the exemption.
- The exemption is to be renewed for the maximum duration of 7 years until 30 June 2026. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Provisions from Directive (EU) 2021/647 shall apply as from 1st November 2021, while provisions from Directive (EU) 2021/884 shall apply as from 1st July 2022.

L.N. 93 of 2022 **Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2022**

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2021/1978:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1978>

- provides an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices.

Commission Delegated Directive (EU) 2021/1979:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1979>

- provides an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils.

Commission Delegated Directive (EU) 2021/1980:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1980>

- provides an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids.

The objectives of the Directives whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2021/1978 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices.

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) as restricted substances in Annex II, applicable from 21st July 2021.
- Currently, the restriction of DEHP, BBP, DBP and DIBP is not to apply to spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of medical devices, including *in vitro* medical devices, placed on the market *before* 22nd July 2021.
- Hence, a request was made for an exemption for the use of DEHP, BBP, DBP and DIBP in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, that are placed on the market *after* 21st July 2021.
- The request was evaluated and concluded that the total negative environmental and health impacts of substituting refurbished parts containing DEHP, BBP, DBP and DIBP with new substance-free refurbished parts are likely to outweigh the total environmental and health benefits.
- It is, therefore, appropriate to grant the requested exemption, in Annex IV to Directive

2011/65/EU. But, in order to ensure a high level of protection for the environment, health and consumer safety, reuse should take place in auditable closed-loop business-to-business return systems and reuse of spare parts should be notified to the customer.

- The requested exemption is granted for a duration of 7 years starting retroactively from 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2021/1979 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils.

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP) as a restricted substance in Annex II, and it is not to be used, from 22nd July 2021, in medical devices, including *in vitro* medical devices, above a maximum concentration value of 0,1% tolerated by weight in homogeneous materials.
- The evaluation of the requests for an exemption for the use of DEHP in plastic components in MRI detector coils, which took into account the availability of technically practicable and reliable substitutes and the socioeconomic impact of substitution, concluded that no suitable alternatives to DEHP are sufficiently available on the market and that not granting the exemption is likely to result in total negative environmental, health and consumer safety impacts caused by substitution, which outweigh the benefits.
- It is, therefore, appropriate to grant the requested exemption, for the use of DEHP in plastic components in MRI detector coils, in Annex IV to Directive 2011/65/EU.
- The requested exemption is granted until 1st January 2024, starting retroactively from 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2021/1980 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids.

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP) as a restricted substance in Annex II, and it is not to be used, from 22nd July 2021, in medical devices, including *in vitro* medical devices, above a maximum concentration value of 0,1% tolerated by weight in homogeneous materials.
- DEHP is used as a membrane solvent of ion selective electrodes applied in point of care analysers which help to measure the concentration of ionic substances in human body fluids and/or in dialysate fluids.

- The evaluation of the request for an exemption for the use of DEHP in ion-selective electrodes for analysing human body fluids and/or dialysate fluids, concluded that alternatives to DEHP are currently not sufficiently reliable and that the substitution of DEHP in specific applications would result in negative environmental and health impacts that outweigh its benefits.
- It is, therefore, appropriate to grant the requested exemption, for the use of DEHP in ion-selective electrodes for analysing human body fluids and/or dialysate fluids, in Annex IV to Directive 2011/65/EU.
- The requested exemption is granted for a duration of 7 years starting retroactively from 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

Provisions from Directives (EU) 2021/1978, 2021/1979 and 2021/1980 shall apply retroactively from 21st July 2021.

L.N. 239 of 2022 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2022

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2022/274:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L0274>

- provides an exemption for the use of mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps for special purposes.

Commission Delegated Directive (EU) 2022/275:

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32022L0275>

- provides an exemption for the use of mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes.

Commission Delegated Directive (EU) 2022/276:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0276>

- provides an exemption for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes.

Commission Delegated Directive (EU) 2022/277:

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32022L0277>

- provides an exemption for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes < 30W with a lifetime equal to or above 20,000h.

Commission Delegated Directive (EU) 2022/278:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0278>

- provides an exemption for the use of mercury in metal halide lamps.

Commission Delegated Directive (EU) 2022/279:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0279>

- provides an exemption for the use of mercury in other discharge lamps for special purposes.

Commission Delegated Directive (EU) 2022/280:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0280>

- provides an exemption for the use of mercury in other low pressure discharge lamps.

Commission Delegated Directive (EU) 2022/281:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0281>

- provides an exemption for the use of mercury in single capped (compact) fluorescent lamps for special purposes.

Commission Delegated Directive (EU) 2022/282:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0282>

- provides an exemption for the use of mercury in non-linear tri-band phosphor lamps.

Commission Delegated Directive (EU) 2022/283:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0283>

- provides an exemption for the use of mercury in High Pressure Sodium (vapour) lamps with improved colour rendering index for general lighting purposes.

Commission Delegated Directive (EU) 2022/284:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0284>

- provides an exemption for the use of mercury in double-capped linear fluorescent lamps for general lighting purposes.

Commission Delegated Directive (EU) 2022/287:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0287>

- provides an exemption for mercury in fluorescent lamps for other general lighting and special purposes.

The objectives of the Directives whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2022/274 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps for special purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- The exemption covers a heterogeneous group of lamps of different shapes, technologies, applications, and purposes. Mercury is used in the discharge tube, which is essential to convert electrical energy to light.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned is currently technically impracticable. However, that evaluation highlighted that mercury-free substitutes in the form of light emitting diodes lamps (LED) are available, and that they are used as lighting sources in new equipment coming on the market.
- CCFL and EEFL in many applications have been replaced by mercury free substitutes, but some applications still require such lamps to ensure their functionality and to avoid a premature generation of electrical and electronic waste.
- It is, therefore, appropriate to grant the renewal of the exemption, for the use of mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes, for a period of 3 years, only for those lamps used in the electrical and electronic equipment that was placed on the market before the adoption of this Directive, 24th February 2022.

- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation.

Commission Delegated Directive (EU) 2022/275 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in High Pressure Sodium (vapour) lamps for light colour and colour rendering properties.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned is currently technically impracticable. The evaluation also concluded that the content of mercury allowed in those specific applications should be reduced to correspond to the changes in the market for the specific lamps types.
- It is, therefore, appropriate to grant the renewal of the exemption, for the use of mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes, for a maximum period of five years, as no reliable substitutes are currently available.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/276 of 13 December 2021 amending, for the purpose of adapting to technical and scientific progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in single capped (compact) fluorescent lamps to produce ultraviolet light, which

is then converted into visible light by the fluorescent coating on the lamp bulb.

- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that sufficiently reliable mercury-free substitutes for the lamp types covered by the exemption are already widely available and that the substitution of mercury in these lamps is scientifically and technically practicable. Furthermore, that evaluation concluded that the benefits of substitution will clearly outweigh any negative impact.
- It is, therefore, appropriate to reject the renewal of the exemption, for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes, since the exemption conditions are no longer fulfilled. An expiry date with the earliest possible date of 12 months from the Commission decision to revoke the exemption is set, given that there are no practical circumstances that would justify a longer expiry time, in particular considering that many of the lamps in question are also covered by the Ecodesign Light Sources Regulation which sets minimum energy efficiency requirements to be respected in order for the products to be placed on the market, which will imply that those lamps will not *de facto* be placed on the market since 1 September 2021.

Commission Delegated Directive (EU) 2022/277 of 13 December 2021 amending, for the purpose of adapting to technical and scientific progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes < 30 W with a lifetime equal to or above 20000 h.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted an exemption for the use of mercury, with a maximum content of 3.5 mg, in single capped (compact) fluorescent lamps for general lighting purposes < 30W with a lifetime equal or above 20,000h, by Delegated Directive 2014/14/EU; which exemption was to expire on 31 December 2017.
- Mercury is used in single capped (compact) fluorescent lamps to produce ultraviolet light, which is then converted into visible light by the fluorescent coating on the lamp bulb.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that sufficiently reliable mercury-free substitutes for the lamp types covered by the exemption are available and that the substitution is scientifically and technically practicable. Furthermore, that evaluation concluded that the benefits of substitution will clearly outweigh any negative impact.
- It is, therefore, appropriate to revoke the exemption, for the use of mercury, with a maximum content of 3.5 mg, in single capped (compact) fluorescent lamps for general lighting purposes < 30W with a lifetime equal or above 20,000h, since the exemption conditions are no longer fulfilled.
- A small share of the lamp types covered by this exemption are subject to the ecodesign criteria

laid down in the Ecodesign Light Sources Regulation, which are applicable as of 1 September 2021, and will hence not be placed on the market any longer, but the vast majority of lamps covered by the current exemption are not affected by the criteria under the above-mentioned Ecodesign Regulation. Consequently, the maximum possible expiry date of 18 months following the decision is set with regard to the entire exemption entry in order to avoid unnecessary high socio-economic costs by market participants directly linked to the substitution of the latter category.

Commission Delegated Directive (EU) 2022/278 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in metal halide lamps.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in metal halide lamps, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in metal halide lamps to improve the colour, efficiency, lifetime, and the stable operation of those specific lamps.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned is currently technically impracticable.
- It is, therefore, appropriate to grant the renewal of the exemption, for the use of mercury in metal halide lamps, for a maximum period of five years.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/279 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in other discharge lamps for special purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in other discharge lamps for special purposes not specifically mentioned, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- The function of mercury in gas discharge lamps for special purposes is related to the light generating process to convert electricity into light.

- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned by the exemption is currently technically impracticable. The evaluation also concluded that it is possible to further define the applications that qualify for a renewal of the exemption because of their specific functionality and application area, namely high pressure mercury vapour lamps used in projectors, used for horticulture lighting and emitting light in the ultraviolet spectrum.
- It is, therefore, appropriate to grant the renewal of the exemption for the use of mercury in other discharge lamps for special purposes not specifically mentioned, for a period of 3 years, given the prospects of substitution and limiting the exemption in the future. For those specific applications, high pressure mercury vapour lamps used in projectors, used for horticulture lighting and emitting light in the ultraviolet spectrum, the exemption is renewed for a maximum period of 5 years.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/280 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in other low pressure discharge lamps.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in other low pressure discharge lamps, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in low pressure discharge lamps to produce ultraviolet light used for ultraviolet germicidal or bacterial disinfection and/or purification of air, water and surfaces.
- The evaluation of the renewal application, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the elimination of mercury in the applications concerned or its substitution by a substance of comparable performance is currently technically impracticable. That evaluation further concluded that the current scope of the exemption can be limited to low pressure discharge lamps that are not phosphor-coated and emit light in the ultraviolet range.
- It is, therefore, appropriate to grant the renewal of the exemption for the use of mercury in other low pressure discharge lamps, with a revised wording, setting out the limited scope of the exemption, for a maximum period of 5 years, and an expiry date of 12 months is set for the current exemption.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental

and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/281 of 13 December 2021 amending, for the purpose of adapting to technical and scientific progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in single capped (compact) fluorescent lamps for special purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in single capped (compact) fluorescent lamps for special purposes, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in single capped (compact) fluorescent lamps (CFL) for special purposes to produce ultraviolet light, which is then converted into visible light by the fluorescent coating on the lamp bulb.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the elimination of mercury in the applications concerned or its substitution by a substance of comparable performance is currently technically impracticable. Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, the assessment also concluded that, on one hand, the scope of the exemption should be narrowed to further specified applications and, on the other hand, the duration of the current broad exemption can be shortened.
- It is, therefore, appropriate to grant the renewal of the exemption for a maximum period of 5 years, for CFL lamps for special purposes designed to emit light in the ultraviolet spectrum, as no reliable alternatives are currently available. For all other types of CFL lamps falling into the category of CFL lamps for special purposes, the exemption is renewed for 3 years, to allow the industry to prepare detailed information to justify the continuation of this exemption for specified special lamp categories.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/282 of 13 December 2021 amending, for the purpose of adapting to technical and scientific progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in non-linear tri-band phosphor lamps.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in non-linear tri-band phosphor lamps with tube diameter > 17mm (e.g. T9), by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in non-linear tri-band phosphor lamps to produce ultraviolet light, which is then converted into visible light by the fluorescent coating on the lamp. The composition of the coating, which contains the mercury, determines light colour and colour rendering.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned is currently technically impracticable. That evaluation further concluded that the mercury concentration limit in the lamp categories covered by that exemption can be lowered from 15mg to 10mg per lamp.
- It is, therefore, appropriate to grant the renewal of the exemption, with a revised wording, setting out the limited scope of the exemption, for a period of 3 years, to collect further data related to the availability of substitutes for the specific lamp types covered by that exemption. While an expiry date of 12 months is set for the current exemption.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/283 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in High Pressure Sodium (vapour) lamps with improved colour rendering index for general lighting purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in High Pressure Sodium (vapour) lamps for light colour and colour rendering properties.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned was scientifically and technically practicable as concerns parts of the entries. The evaluation concluded nevertheless that the exemption should be renewed for the part of entry which concerns lamps with a high colour rendering higher than 80, equal to or lower than 105W and that, whilst the use of mercury

is still necessary, that can be further lowered.

- It is, therefore, appropriate to renew part of the exemption for a maximum period of 5 years. This renewed exemption has a revised wording setting out the further limited scope of the exemption. While as the conditions for the renewal of the exemption are no longer fulfilled for the applications listed in the remainder of the entry, the exemption for those applications is revoked with an expiry date of 12 months.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Commission Delegated Directive (EU) 2022/284 of 16 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in double-capped linear fluorescent lamps for general lighting purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.
- The Commission has granted, among other things, an exemption for the use of mercury in double-capped linear fluorescent lamps for general lighting purposes, by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- Mercury is used in double-capped linear fluorescent lamps for general lighting purposes to produce ultraviolet light, which is then converted into visible light by the fluorescent coating on the lamp.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that sufficiently reliable mercury-free substitutes for the lamp types covered by the exemption have become available and that the substitution of mercury in these lamps is scientifically and technically practicable. Furthermore, that evaluation concluded that the benefits of substitution would clearly outweigh any negative impact.
- It is, therefore, appropriate to reject the renewal of the exemption, for the use of mercury in double-capped linear fluorescent lamps for general lighting purposes, since the exemption conditions are no longer fulfilled, and set expiry dates.

Commission Delegated Directive (EU) 2022/287 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in fluorescent lamps for other general lighting and special purposes.

- Directive 2011/65/EU lists Mercury as a restricted substance in Annex II.

- The Commission has granted, among other things, an exemption for the use of mercury in other linear fluorescent lamps for other general lighting and special purposes (e.g. induction lamps), by Decision 2010/571/EU; which exemption was to expire on 21 July 2016.
- The exemption covers an inhomogeneous group of lamps of different shapes, technologies, applications, and purposes. Mercury is used in the discharge tube, which is essential to convert electrical energy to light.
- The evaluation of the renewal applications, received by the Commission, which took into account the availability of substitutes and the socioeconomic impact of substitution, concluded that the substitution or elimination of mercury in the applications concerned is currently technically impracticable.
- It is, therefore, appropriate to grant the renewal of the exemption for a limited period of 3 years, in order to allow for a timely reassessment of the availability of mercury-free replacement lamps for the wide variety of lamp types covered by this exemption. However, for specific lamp categories, namely lamps emitting light in the non-visible spectrum and emergency lamps, there is sufficient information that substitution is technically impracticable in the next years and for those categories of lamps, a validity period of 5 years is justified.
- The exemption is consistent with REACH Regulation and thus does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation, in view of the results of the ongoing efforts to find a reliable substitution.

Provisions from Directives (EU) 2022/274 to 2022/284 and 2022/287 shall apply from 1st October 2022.

L.N. 68 of 2023 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2023

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2022/1631:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L1631>

- provides an exemption for the use of lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections.

Commission Delegated Directive (EU) 2022/1632:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L1632>

- provides an exemption for the use of lead in certain magnetic resonance imaging devices.

The objectives of the Directives whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2022/1631 of 12 May 2022 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections.

- Directive 2011/65/EU lists Lead as a restricted substance in Annex II.
- In March 2019, the Commission received an application for an exemption to be listed in Annex IV to the RoHS Directive, for the use of lead in bismuth strontium calcium copper oxide (BSCCO) superconductor for use in cables and wires and lead in related electrical connections to other EEE components.
- The evaluation of the requested exemption included a technical and scientific assessment study, whereby it was concluded that the addition of lead to BSCCO provides technical and functional advantages which cannot be achieved without the use of lead. Those technical and functional advantages consist in higher resolution images for medical diagnosis or for research and innovation and allow a more stable operation mode of the relevant applications.
- Therefore, it is currently not possible to substitute or otherwise eliminate lead in superconducting material and related solders with the same technical performance, nor is it expected to be so in the foreseeable future. Therefore, the requested exemption is being granted, for an extensive validity period.

Commission Delegated Directive (EU) 2022/1632 of 12 May 2022 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in certain magnetic resonance imaging devices.

- Directive 2011/65/EU lists Lead as a restricted substance in Annex II.

- The Commission has granted an exemption for the use of lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors that are used in certain medical magnetic resonance imaging (MRI) equipment, by Commission Delegated Directive 2014/7/EU, which exemption was to expire on the 30th of June 2020.
- The evaluation of the renewal application, received by the Commission, included a technical and scientific assessment study, whereby it was concluded that old design MRI devices depend on lead-containing MRI components and are highly limited in their compatibility with new lead-free MRI components. Also, a distinction should be made between MRIs with integrated coils and MRIs with non-integrated coils.
- Thus, in view of the above, as regards newly designed MRI devices with lead-containing integrated coils, additional time is required for the technical development of lead-free solutions, thus requiring an exemption for the use of lead. On the other hand, the use of lead in newly designed non-integrated MRI coils and in upcoming lead-free MRI devices with integrated coils should be excluded from the exemption.
- However, the renewed exemptions apply only for a specific period and therefore MRI devices cannot be placed on the market after the dates specified in the exemption if they contain lead.
- Therefore, by not granting the renewal request may result in premature wastage of MRI devices due to a lack of compatible components or redesigning options. This could result in a supply gap of MRI equipment, which could in turn adversely affect health care for patients.
- The total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. Therefore, in order to provide compatible MRI equipment for health services and to allow time for the development of lead-free alternatives, the renewal of the exemption is being granted, with a revised scope, for the maximum duration of 7 years until the 30th of June 2027.

Both exemptions are consistent with REACH Regulation and thus do not prejudice the environmental and health protection afforded by them, while the duration of the exemptions are unlikely to have adverse impacts on innovation, owing to the results of the ongoing efforts to find a reliable substitution.

Provisions in Directives (EU) 2022/1631 and 2022/1632 shall apply from 1st March 2023.

L.N. 195 of 2023 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2023

Overview of and link to the Directive whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2023/171:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023L0171>

- provides an exemption for hexavalent chromium as an anticorrosion agent in gas absorption heat pumps.

The objectives of the Directive whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2023/171 of 28 October 2022 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium as an anticorrosion agent in gas absorption heat pumps.

- Hexavalent chromium is a restricted substance listed in Annex II to Directive 2011/65/EU.
- In December 2020, the Commission received an application for an exemption to be listed in Annex III to that Directive, (hereinafter referred to as ‘the requested exemption’), for the use of hexavalent chromium as an anticorrosion agent in gas absorption heat pumps.
- Gas absorption heat pumps require electricity for auxiliary functions like pumping a working fluid through the system. The gas absorption heat pumps described in the requested exemption fall under category 1 ‘large household appliances’ of Annex I to Directive 2011/65/EU.
- The evaluation of the exemption application, which included a technical and scientific assessment study, concluded that substitution of hexavalent chromium in the refrigerant solution is currently scientifically and technically impracticable, and other heating technologies eliminating the use of hexavalent chromium in the form of sodium chromate cannot offer equivalent functionality and performance. Gas absorption heat pumps can indeed provide higher energy efficiency than condensing boiler technologies. They can also help to replace those systems and can lead to carbon dioxide emission savings.
- That evaluation thus concluded that the total negative environmental, health and consumer safety impacts of substituting hexavalent chromium in the uses covered by the exemption application are likely to outweigh the total environmental, health and consumer safety benefits.
- Research efforts to find possibilities for reducing the hexavalent chromium content and/or to substitute or eliminate the use of hexavalent chromium are expected to require more than 5 years. Thus, the requested exemption is granted until 31 December 2026, with a maximum concentration of 0.7% hexavalent chromium by weight in the refrigerant solution, and for applications within category 1.

Provisions in Directive (EU) 2023/171 shall apply from 1st September 2023.

L.N. 77 of 2024 **Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2024**

Overview of and links to the Directives whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2023/1437:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023L1437>

- provides an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions.

Commission Delegated Directive (EU) 2023/1526:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023L1526>

- provides an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices.

The objectives of the Directives whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2023/1437 of 4 May 2023 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions.

- Mercury is a restricted substance listed in Annex II to Directive 2011/65/EU.
- In April 2021, the Commission received an application for an exemption to be listed in Annex IV to that Directive, for mercury in melt pressure transducers for capillary rheometers at temperatures over 300 °C and pressures over 1,000 bar.
- The used pressure transducer, incorporated in capillary rheometers, consists of electrical components and is an electrical measurement device falling under category 9 ‘monitoring and control instruments’ of Annex I to Directive 2011/65/EU.
- The evaluation of the exemption application, which included a technical and scientific assessment study, concluded that the substitution and elimination of mercury in these specific applications are currently scientifically and technically impracticable.
- It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 9 and to limit the validity period of the exemption to 31st December 2025.

Commission Delegated Directive (EU) 2023/1526 of 16 May 2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices.

- Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.
- In December 2021, the Commission received an application for an exemption to be listed in Annex IV to that Directive, for lead as a thermal stabilizer in polyvinyl chloride used as base material in

sensors used in *in vitro* diagnostic medical devices.

- The described *in vitro* diagnostic medical devices fall under category 8 ‘medical devices’ of Annex I to Directive 2011/65/EU.
- A technical and scientific assessment study was carried out to evaluate the requested exemption and concluded that the substitution of lead in the specific sensors is not completed yet. The availability of substitutes for such specific devices is not ensured as current lead substitutions are not reliable for all parameters (for example: creatinine and blood urea nitrogen) or have a low accuracy for such parameters. In addition, the evaluation concluded that rejecting the requested exemption would negatively affect the health service.
- Thus, having regard to the overall negative environmental, health and consumer safety impacts and the socioeconomic impacts, it is appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 8 and for a limited validity period until 31st December 2023.

Provisions in Directives (EU) 2023/1437 and 2023/1526 shall apply from 1st February 2024.

L.N. xxx of 2024 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2024

Overview of and link to the Directive whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2024/232:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024L0232>

- provides an exemption for the use of cadmium and lead in plastic profiles in electrical and electronic windows and doors containing recovered rigid polyvinyl chloride.

The objectives of the Directive whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2024/232 of 25 October 2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and lead in plastic profiles in electrical and electronic windows and doors containing recovered rigid polyvinyl chloride.

- Cadmium and lead are restricted substances listed in Annex II to Directive 2011/65/EU. Lead is restricted with a maximum concentration value of 0.1% and cadmium with a maximum concentration value of 0.01% by weight in homogenous materials.
- In December 2015, the Commission received an application for granting an exemption for cadmium and lead in electrical and electronic windows and doors containing recovered polyvinyl chloride (PVC) ('the requested exemption'). Thus, a technical and scientific assessment study, including stakeholder consultations, was carried out to evaluate the requested exemption.
- Cadmium and lead are used in recovered PVC frame material for window and door sets for the purpose of polymer stabilisation of the PVC profiles. While lead-free and cadmium-free virgin PVC is available on the market, the use of recovered PVC requires lower amounts of energy and natural resources (such as water, petroleum, and natural salt) than the amounts that would otherwise be needed for the use of virgin PVC. Therefore, the total negative environmental, health and consumer safety impacts caused by substitution would likely outweigh the total environmental, health and consumer safety benefits thereof.
- Thus, having regard to the overall environmental, health and consumer safety impacts, it is appropriate to grant the requested exemption by including the applications covered by that exemption in Annex III to Directive 2011/65/EU with respect to the electrical and electronic equipment of category 11, for a limited validity period until the 28th of May 2028.

Provisions of Directive (EU) 2024/232 shall apply from 1st August 2024.

L.N. xxx of 2024 Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 3) Regulations, 2024

Overview of and link to the Directive whose provisions are transposed by this Legal Notice are:

Commission Delegated Directive (EU) 2024/1416:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024L1416>

- provides an exemption for cadmium in downshifting quantum dots directly deposited on LED semiconductor chips.

The objectives of the Directive whose provisions are transposed by the above Legal Notice are:

Commission Delegated Directive (EU) 2024/1416 of 13 March 2024 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in downshifting quantum dots directly deposited on LED semiconductor chips.

- Cadmium is a restricted substance listed in Annex II to Directive 2011/65/EU, with a maximum concentration value of 0.01% by weight in homogenous materials.
- Delegated Directive (EU) 2017/1975 provides for an exemption for the use of cadmium selenide in downshifting semiconductor nanocrystal quantum dots for use in display lighting applications. This exemption was to expire on 31st October 2019. However, an exemption remains valid until a decision on any renewal application has been taken.
- Eventually, in September 2017 and April 2018, the Commission received applications to amend this exemption. The received applications were evaluated by taking into account the availability of substitutes and the socioeconomic impact of substitution. It also included a technical and scientific assessment study, a follow-up study and stakeholder consultations.
- The evaluation took into consideration that the current exemption does not distinguish between different configurations regarding the way the cadmium-based material is embedded in the quantum dot. Subsequently, the evaluation concluded that applications with ‘on-edge’ and ‘on-surface’ configurations no longer meet the conditions for an exemption, due to the available substitutes and the negative environmental, health and consumer safety impacts. Thus, the exemption on these configurations is being revoked and a maximum possible expiry date of 18 months is set, until 21st November 2025.
- The evaluation also concluded that even though that the ‘on-chip’ configuration requires the lowest amount of cadmium and shows better performance levels; alternatives to ‘on-chip’ technology applicable in lighting applications are currently available, are reliable and achieve similar performance levels. Thus, the part of the exemption for the ‘on-chip’ technology applicable in lighting applications, is being similarly revoked.
- The evaluation further concluded that many alternatives to ‘on-chip’ technology applicable in display applications are currently available, however, for some specific technologies, such as micro displays, no reliable alternative currently exists. Thus, due to greater energy efficiency and lower use of total cadmium, the environmental benefits outweigh the total negative environmental, health and consumer safety impacts caused by a substitution of cadmium, in such applications. While the limited scope of the exemption, in the form of a maximum concentration of cadmium per device, ensures that less cadmium is placed on the market than under the previous exemption. Consequently, an exemption is granted for cadmium in downshifting

semiconductor nanocrystal quantum dots directly deposited on LED semiconductor chips for use in display and projection applications, until 31st December 2027.

- The exemption is consistent with REACH Regulation and does not weaken the environmental and health protection afforded by it. While the duration of the exemption is unlikely to have adverse impacts on innovation.

The provisions from Directive (EU) 2024/1416 shall apply from 1st January 2025.