AmCham EU position on the Customs Union Technical Regulation RoHS

Call for greater synergy between EU and Customs Union regulatory environment

POSITION PAPER

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) has been closely following the development of the Customs Union Technical Regulation RoHS (CUTR RoHS). While the current draft takes positive elements from the EU RoHS directive, some of its provisions may need to be revised in light of the experience accumulated in the EU, notably with regards to EU RoHS cables, medical devices (category 8), monitoring and control equipment (category 9) and provisions related to the proof of compliance in TR RoHS (article 7).

We invite the authorities of the Customs Union Member States (Russia, Belarus and Kazakhstan) and the Eurasian Economic Commission to take into account the comments and recommendations included in this position paper during the stakeholder consultations that will run until 20 May 2014.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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15 May 2014

Introduction

In 2010, the Customs Union (CU) of Belarus, Kazakhstan and Russia (the Member States) launched a process for developing a CU legislation building on the EU's in environmental regulation. Technical Regulations (TR) were chosen to be the main legal instruments for harmonisation.

The restriction of hazardous substances in electrical and electronic equipment (RoHS) was listed among the priority areas for TRs. In 2011, the Belarus State Agency on Standardisation (Gosstandart) was assigned with developing the relevant draft (hereinafter TR RoHS), which was made available to stakeholders in December 2013 and submitted for a 60-day consultation between 18 March and 20 May 2014. On the basis of the comments received, the draft will be updated in June and submitted for interstate consultations during the Summer- and Autumn of 2014 and is expected to be adopted in the fourth quarter of 2014, with the earliest date of entry into force foreseen for summer 2016.

TR RoHS aims to restrict the presence of certain heavy metals (lead, mercury, cadmium, hexavalent chromium, polybromebephinyl, PBDE) in electrical and electronic equipment while simultaneously taking into account the European experience and adapting it to the Customs Union market realities.

AmCham EU is pleased to provide its comments to the on-going stakeholder consultations.

General remarks

The EU RoHS directive is a result of a long decision-making process that included extensive interaction between the EU institutions, stakeholders and third-party consultants. Moreover, the process that lasted for more than ten years revealed a need to establish different transition periods for specific categories of equipment.

AmCham EU understands that TR RoHS is designed to use certain elements from the EU RoHS Directive while adapting it to the Customs Union cultural and legal realities. AmCham EU welcomes the efforts of the Customs Union authorities to align particular provisions and the structure of TR RoHS with EU RoHS.

However, a number of TR RoHS provisions are either less clear or stricter than those in EU RoHS. As a result, we strongly encourage further alignment of TR RoHS to avoid the inability for non-Customs Union manufacturers to supply products to the local market.

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
1.	Article 1 - Scope	2. This Technical Regulation of the Customs Union shall not apply to: - Spare parts and accessories to the Electrical and Electronic Equipment released to circulation in the uniform customs territory of the Customs Union before this Technical Regulation of the Customs Union enters into force;	To ensure consistency across geographies, provisions for spare parts need to **address repair and upgrades** to allow for the extension of the lifetime of EEE or updating functionalities. Therefore, relating repair and upgrades to the spare parts provision is key in terms of legal certainty and compliance to extend the lifetime of products on the CU market. **We therefore propose to include the following text:** 2. This Technical Regulation of the Customs Union shall not apply to: ***Spare parts and components for the repair or upgrade of:*** • ***Electrical and Electronic Equipment released to circulation in the uniform customs territory of the Customs Union before the date of the entry into force of the Technical Regulation.*** • ***Electrical and Electronic Equipment which benefited from an exemption specified in Appendix 3 to this Technical Regulation of the Customs Union and which was released to circulation in the uniform customs territory The Customs Union before the expiry of that exemption.***
2.	Article 1, p.2 – Scope	2. This Technical Regulation of the Customs Union shall not apply to:	EU RoHS provides for specific exclusions from the scope of the legislation. We understand that the intention of the legislator is to also exclude such equipment from the scope of TR RoHS. Although we understand the legislator provides for a an exhaustive list of EEE in Appendix 1, for the purposes of clarity, we would still invite the legislator to include definitions in the relevant part of the TR RoHS with explicit provisions stating that they are outside the scope.

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	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
			We therefore propose to exclude from the scope the following definitions: - ***Large-scale stationary industrial tools;*** - ***Large-scale fixed installations;*** - ***Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis;*** - ***Equipment that is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;*** - ***Equipment designed to be sent into space;*** - ***Equipment designed to be part of another piece of equipment falling outside the scope of RoHS;*** - ***Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;*** - ***Non-road mobile machinery made available exclusively for professional use;*** - ***Active implantable medical devices; and*** - ***Photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications.***
3.	Article 2 – Definitions	NONE	Annex I of EU RoHS defines industrial monitoring and control instruments as 'monitoring and control instruments including industrial monitoring and control instruments'. In other words, the European legislator made a clear distinction between the equipment designed for consumer and those specifically for industrial and professional use. TR RoHS refers to category '11. Household and laboratory measuring devices'. From the proposed definition it is not clear whether the intention is to cover all category 9 monitoring and control equipment or include category 9 industrial in particular.

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
			We urge the Customs Union authorities to exclude industrial and professional equipment from the scope of TR RoHS that was already foreseen under EU RoHS I directive. This can be done by merely deleting the word 'laboratory' from the definition so that the final definition reads: ***11. Household measuring devices.*** **Should this option not be acceptable, we propose to include the following definition:** ***'Industrial monitoring and control instruments' means monitoring and control instruments designed for exclusively industrial or professional use;***
4.	Article 2 – Definitions	NONE	Similar to the first EU RoHS directive (Directive 2002/95/EC), we believe the TR is not an appropriate tool to regulate medical equipment on the Customs Union market. The TR lacks exemptions and provisions specific to medical devices (MD) and in vitro diagnostic medical devices (IVD) and provides too-short certification validity times that are not in line with the much longer expected useful lifetime of medical equipment. Many MDs and IVDs typically remain on the market for 10 to 20 years or even longer. The use of well-maintained or refurbished equipment is a viable alternative for keeping costs under control in hospitals and clinical laboratories and providing reliable results for the safe management of patients in the healthcare system. TR RoHS also provides for stricter and costly certification requirements that will be burdensome for the medical technologies sector to comply with. **Therefore, we propose to exempt medical devices and IVDs from the TR altogether would ensure a continued supply of medical equipment to the Customs Union at current pricing structures.** Alternatively, if excluding the medical devices and in-vitro medical devices from the scope of TR is not possible, we invite the authorities to amend the definitions, foresee application dates, list of exemptions and validity period of exemptions in line with the provisions of EU RoHS (see points 10, 12 AND 14).

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
			We propose including the following text: ***'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*** - ***Diagnosis, prevention, monitoring, treatment or alleviation of disease;*** - ***Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*** - ***Investigation, replacement or modification of the anatomy or of a physiological process;*** - ***Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; and*** - ***Which is also EEE.*** ***'In vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*** - ***Concerning a physiological or pathological state;*** - ***Concerning a congenital abnormality;*** - ***To determine the safety and compatibility with potential recipients; or*** - ***To monitor therapeutic measures.*** ***Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles` are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.***

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
			Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination. ***'Active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.***
5.	Article 3 – Rules on the circulation on the market	NONE	Non-RoHS compliant medical devices should be maintained on the market today or prior to the entry into force of the specific requirements as set out in Appendix 3 until their end-of-life. Furthermore, medical devices that remain property of a company, but are supplied to hospitals and replaced in case of defect that were marketed prior to the ban date, should be allowed on the market until end-of-life. **We therefore propose to include the following definitions:** ***2a. Non-compliant medical devices can be maintained on the market or prior to the entry into force of the specific requirements as set out in Appendix 3 until their end-of-life.*** ***2b. Medical devices that remain property of a company, but that are supplied to hospitals and replaced by another one from the existing in case of defect that were marketed prior to the ban date, shall be allowed on the market until end-of-life.***
6.	Article 6 – Compliance with Restriction of Hazardous Substances	2. The Electrical and Electronic Equipment research (tests) and measurements methods shall be established in the standards included in the List of Standards containing the methods of research (tests) and measurements, including the sampling procedures necessary for application and meeting the	Article 6(2) 'Compliance with Restriction of Hazardous Substances' refers to the 'List of Standards'. It is understood that this list contains EN 50581:2012 'Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances' that specifies the technical documentation that the manufacturer may compile in order to declare compliance with the applicable substance restrictions. (Within the EU, compliance with this EN Standard confers a presumption of conformity with the corresponding requirements of the EU RoHS Directive). The approach described in EN 50581 is essential for RoHS as the substance restrictions apply at the

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		requirements of the Technical Regulation of the Customs Union and verification (confirmation) of the product compliance.	homogeneous material level and a final product cannot be 'tested' for RoHS - the Introduction to EN 50581 states: 'For those restrictions that apply at the 'homogeneous material' level, it is impractical for manufacturers of complex products to undertake their own testing of all materials contained in the final assembled product. Instead, manufacturers work with their suppliers to manage compliance and compile technical documentation as evidence of compliance. This approach is well recognised by both industry and enforcement authorities.' In complying with EN 50581, the manufacturer of a finished product will compile Technical Documentation (a 'Technical File') which will typically comprise many different documents including: • Supplier declarations and/or contractual agreements; • Material declarations; and • Analytical test results. In most cases, these documents will be stored electronically - there is no requirement in EU RoHS for these documents to exist as a physical file. Furthermore, this information is only provided to the EU authorities in the event of a challenge to the compliance of the product - it does not have to be provided to a certification body before the product is placed on the market.
7.	Article 7 – Confirmation of compliance	*NONE*	We understand that both TR and EU RoHS directive are seeking to restrict the same substances in the same products. It would be advisable that the Customs Union accepts products that are CE-marked in compliance with the EU RoHS legislation or, alternatively, minimise as far as possible local requirements. Should companies be required to comply with new and different certification, testing and labelling requirements in the Customs Union, the cost to industry could be significant and result in delays of product to the local market. Similarly, consumers and governments will be faced with additional higher costs.

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			Therefore, we propose to amend the text to ensure that products CE-marked in compliance with EU RoHS directive are deemed compliant with the TR.
8.	Article 7 – Confirmation of compliance	6. The declaration of conformity shall be subject to registration according to the laws of the Customs Union. The declaration validity shall start from the date of its registration. The validity of the declaration of conformity for the Electrical and Electronic Equipment manufactured on industrial scale shall not exceed 5 years, for a batch of the Electrical and Electronic Equipment (separate product) the validity of the declaration of conformity shall not be fixed.	We understand that the declaration of conformity must be provided for individual instruments at the time they are placed on the market, based on the data received from sourced components and possibly additional tests for individual questionable parts. The present text is unclear in terms of consequences in case if the EEE is still used or resold. Medical devices can have a lifetime exceeding 15-20 years, which means that specific products might need to be tested again for a new declaration. ***Therefore, we propose to make the Declaration unlimited in time OR clarify the entity that will be responsible, whether new data of the sourced components should be collected and documented, and the timeframe it should cover.***
9.	Appendix 1, p. 10 – The List of the Electrical and Electronic Equipment Covered by the Technical Regulation	10. Medical equipment, with the exception of implantable and biologically active (infected) products and medical equipment made for beam introscopy and radiotherapy	Similar to the first EU RoHS directive (Directive 2002/95/EC), we believe the TR is not an appropriate tool to regulate medical equipment on the Customs Union market. The TR lacks exemptions and provisions specific to medical devices (MDs) and in vitro diagnostic medical devices (IVDs) and provides too-short certification validity times that are not in line with the much longer expected useful lifetime of medical equipment. Many MDs and IVDs typically remain on the market for 10 to 20 years or even longer. The use of well-maintained or refurbished equipment is a viable alternative for keeping costs under control in hospitals and clinical laboratories and providing reliable results for the safe management of patients in the healthcare system. TR RoHS also provides for stricter and costly certification requirements that will be burdensome for the medical technologies sector to comply with. Therefore, exempting medical devices and

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
			IVDs from the TR altogether would ensure a continued supply of medical equipment to the Customs Union at current pricing structures. **Therefore, we propose that all medical equipment (medical devices and in vitro diagnostic medical devices) should be excluded from the TR. Category 10 should therefore be deleted from the text of the TR.** However, if excluding the medical devices and in-vitro medical devices from the scope of TR, as requested above, is not possible, we invite the authorities to amend the definitions, foresee application dates, list of exemptions and validity period of exemptions in line with the provisions of EU RoHS (SEE POINTS 4, 12 AND 14). **Therefore, we propose to replace the text with the following:** 10. Medical devices.
10.	Appendix 1, p. 11 - The List of the Electrical and Electronic Equipment Covered by the Technical Regulation	11. Household and laboratory measuring devices.	Annex I of EU RoHS defines industrial monitoring and control instruments as 'monitoring and control instruments including industrial monitoring and control instruments'. In other words, the European legislator made a clear borderline between the equipment designed for consumer and specifically for industrial and professional use. TR RoHS refers to category '11. Household and laboratory measuring devices'. From the proposed definition it is not clear whether the intention is to cover all category 9 monitoring and control equipment or include category 9 industrial in particular. We urge the Customs Union authorities to exclude industrial and professional equipment from the scope of TR RoHS which was already foreseen under EU RoHS I directive. This can be done by merely deleting the word 'laboratory' from the definition so that the final definition reads: ***'11. Household measuring devices'.*** Should this option not be acceptable, we invite the authorities to align TR RoHS definition with EU RoHS ***('11. Monitoring and control instruments including industrial monitoring and control instruments.')***, application dates, list of exemptions and validity period of exemptions.

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11.	Appendix 1, p. 12 - The List of the Electrical and Electronic Equipment Covered by the Technical Regulation	12. Cables, wires and cords made for application at 500 V max rated voltage	Article 3 of EU RoHS defines cables as 'all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other'. This definition is based on the current EU practice. Article 2 of TR RoHS does not mention cables in the list of definitions. Instead, the legislator defines cables as a category 12 'cables, wires and cords designed to be used under nominal voltage not higher than 500 V max under alternative and (or) direct current'. Such a definition is wide in its application and could lead to confusion and compliance problems. We recommend the Customs Union authorities to align the TR RoHS definition with the EU RoHS definition. **Therefore, we propose to include the following definition:** ***12. All cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect electrical and electronic equipment to the electrical outlet or to connect two or more pieces of electrical and electronic equipment to each other.***
12.	Appendix 3 – Special Requirements	*Appendix 3* *Special Requirements to the Restriction of Hazardous Substances in Electrical and Electronic Equipment According to the Technical Regulation of the Customs Union - Restriction of Hazardous Substances in the Electrical and Electronic Equipment (TP TC 0__/20__)*	EU RoHS includes annexes of exemptions for particular applications to ensure that companies can continue to place their products on the market beyond the application date. Furthermore, the Commission has amended the annex by means of European bylaws called delegated acts.[1] While TR RoHS Appendix 3 has incorporated the majority of these exemptions, the wording is not fully identical to that of EU RoHS. In addition, the exemptions critically needed for medical devices and monitoring and control instruments are missing from the TR RoHS draft. We strongly encourage full alignment of applicable exemptions or 'Special Requirements' specified in Appendix 3, their numbering ('#') and description ('Special Requirement') with applicable Exemptions, numberings and descriptions in the RoHS2 Directive 2011/65/EU Annex III and IV (as amended) to ensure the continued placement of products on the market where no safe technological alternative exists.

[1] The latest consolidated version of the EU RoHS Directive – http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011L0065-20140129

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<tr><th></th><th>Structural element of the TR</th><th>Text of the Draft TR</th><th>Proposed text and comments (including justification)</th></tr>
<tr><td></td><td></td><td>[TEXT OF EXEMPTIONS]</td><td>
We request this in order to ensure consistency across geographies on applicable Exemptions from the substance restrictions, their numbering (‘#’) and description (‘Special Requirement’), in order to avoid market disruption and significant additional administrative burden for the global electronics industry and supply chains.

Therefore, we propose to adapt Appendix 3 to include the following exemptions:

<table>
<tr><th>#</th><th>Special requirement</th><th>Expiry date of the special requirement</th></tr>
<tr><td>1</td><td>Lead, cadmium and mercury in detectors for ionising radiation.</td><td></td></tr>
<tr><td>1a</td><td>Lead and cadmium in ion selective electrodes including glass of pH electrodes.</td><td></td></tr>
<tr><td>1b</td><td>Lead anodes in electrochemical oxygen sensors.</td><td></td></tr>
<tr><td>1c</td><td>Lead, cadmium and mercury in infra-red light detectors.</td><td></td></tr>
<tr><td>1d</td><td>Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.</td><td></td></tr>
<tr><td>2</td><td>Lead bearings in X-ray tubes.</td><td></td></tr>
<tr><td>3</td><td>Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.</td><td></td></tr>
<tr><td>4</td><td>Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.</td><td></td></tr>
<tr><td>5</td><td>Lead in shielding for ionising radiation.</td><td></td></tr>
<tr><td>6</td><td>Lead in X-ray test objects.</td><td></td></tr>
<tr><td>7</td><td>Lead stearate X-ray diffraction crystals</td><td></td></tr>
<tr><td>8</td><td>Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.</td><td></td></tr>
<tr><td>9</td><td>Cadmium in helium-cadmium lasers.</td><td></td></tr>
<tr><td>10</td><td>Lead and cadmium in atomic absorption spectroscopy lamps.</td><td></td></tr>
<tr><td>11</td><td>Lead in alloys as a superconductor and thermal conductor in MRI.</td><td></td></tr>
<tr><td>12</td><td>Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier</td><td>Expires on 30 June 2021.</td></tr>
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	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)		
				Transform Mass Spectrometer) detectors.	
			13	*Lead in counterweights.*	
			14	*Lead in single crystal piezoelectric materials for ultrasonic transducers.*	
			15	*Lead in solders for bonding to ultrasonic transducers.*	
			16	*Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay.*	
			17	*Lead in solders in portable emergency defibrillators.*	
			18	*Lead in solders of high performance infrared imaging modules to detect in the range 8-14 micrometer.*	
			19	*Lead in Liquid crystal on silicon (LCoS) displays.*	
			20	*Cadmium in X-ray measurement filters.*	
			21	*Cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020.*	
			22	*Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment.*	*Expires on 30 June 2021.*
			23	*Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation.*	*Expires on 30 June 2021*
			24	*Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers.*	*Expires on 31 December 2019.*
			25	*Lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions.*	*Expires on 30 June 2021.*
			26	*Lead in solders on printed circuit boards, termination coatings of electrical and electronic components and coatings of printed circuit boards, solders for connecting wires and cables, solders connecting transducers and sensors, that are used durably at a temperature below -20°C under normal operating and storage conditions*	*. Expires on 30 June 2021.*
			27	*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocenter of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external*	*Expires on 30 June 2020.*

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	surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy.	
28	*Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards.*	*Expires on 31 December 2017.*
29	*Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments.*	*Expires on 30 June 2021.*
30	*Hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020.*	
31	*Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.*	*Expires on 21 July 2021.*
32	*Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment.*	*Expires on 31 December 2019.*
33	*Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators.*	*Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb*
34	*Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors.*	*Expires on 22 July 2021.*
35	*Mercury in cold cathode fluorescent lamps for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017*	*21 July 2024*
36	*Lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments*	*31 December 2020* *Note: May be used after that date in spare parts for industrial*

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)		
					monitoring and control instruments placed on the market before 1 January 2021.
			37	***Lead in platinised platinum electrodes used for conductivity measurements where at least one of the following conditions applies:*** ***(a) Wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0.1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;*** ***(b) Measurements of solutions where an accuracy of +/- 1% of the sample range and where high corrosion resistance of the electrode are required for any of the following:*** • ***Solutions with an acidity < pH 1;*** • ***Solutions with an alkalinity > pH 13;*** • ***Corrosive solutions containing halogen gas.*** ***(c) Measurements of conductivities above 100 mS/m that must be performed with portable instruments.***	***31 December 2018***
			38	***Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in X-ray detectors of computed tomography and X-ray systems***	***31 December 2019*** ***Note: May be***

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)		
					used after that date in spare parts for CT and X-ray systems placed on the market before 1 January 2020.
			39	***Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:*** ***(a) A compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;*** ***(b) A two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies:*** • ***A response time shorter than 25 ns;*** • ***A sample detection area larger than 149 mm2; or*** • ***A multiplication factor larger than 1.3 x 103.*** ***(c) a response time shorter than 5 ns for detecting electrons***	***(a) 21 July 2021 for medical devices and monitoring and control instruments;*** ***(b) 21 July 2023 for in-vitro diagnostic medical devices;*** ***(c) 21 July 2024 for industrial monitoring and control instruments***

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)		
				or ions; ***(d) A sample detection area larger than 314 mm2 for detecting electrons or ions; or*** ***(e) A multiplication factor larger than 4.0 x 107.***	
			40	***Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments.***	***31 December 2020*** ***Note: May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.***
			4g	***Mercury in hand crafted luminous discharge tubes used for signs, decorative or architectural and specialist lighting and light-artwork, where the mercury content shall be limited as follows:*** ***(a) 20 mg per electrode pair + 0.3 mg per tube length in cm, but not more than 80 mg, for outdoor applications and indoor applications exposed to temperatures below 20°C; and***	***31 December 2018***

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<tr><td></td><td>(b) 15 mg per electrode pair + 0.24 mg per tube length in cm, but not more than 80 mg, for all other indoor applications.</td><td></td></tr>
<tr><td>41</td><td>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, which for technical reasons must be mounted directly on or in the crankcase or cylinder of handheld combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council)</td><td>31 December 2018</td></tr>
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<tr><td>13.</td><td>Eurasian Economic Commission Council DECISION

On the adoption of the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment.</td><td>2. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment shall enter into force on 15 February 2015

NONE</td><td>EU RoHS article 4 part 3 says that the Directive shall apply to category 9 industrial from 22 July 2017. Should TR RoHS enter into force before that date, and should the legislator choose to include such equipment in scope, it should clearly reflect that these products should comply with TR RoHS no earlier than that date.

Therefore, we propose the following changes to the text of the Council Decision:

2a. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment shall apply to monitoring and control instruments Category 11 that are placed on the market from 22 July 2017.</td></tr>
<tr><td>14.</td><td>Eurasian Economic Commission</td><td>2. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances</td><td>If excluding the medical devices from the scope of TR, is not possible, we invite the authorities to amend the definition, foresee later application dates, list of exemptions and validity period of exemptions (SEE POINTS 4, 9 AND 12).</td></tr>
</table>

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
	Council DECISION *On the adoption of the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment.*	*in the electrical and electronic equipment shall enter into force on 15 February 2015* *NONE*	Any difference in the material and formal requirements between the TR and the EU RoHS directive would enlarge the implementation time needed by all market participants. To adopt the deadlines of EU RoHS unchanged would not be appropriate, even in the case of a complete harmonisation of the material and formal requirements, because electronic devices manufactured within the EU but exclusively intended to be exported (e.g. to Russia, Belarus and Kazakhstan) are currently not required to comply with TR RoHS. In other words, medical devices companies need time to adapt their marketing strategy to the new legislation. The non-availability of products might have an impact on patient safety. Therefore, it is important to ensure that TR RoHS applies to new products that will be marketed after the transition timeframe of the newly adopted text and that it is not applicable to products that are placed on the market already. **Therefore, we propose the following changes to the text of the Council Decision:** ***2c. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment shall apply to medical devices category 10 which are placed on the market from [4 YEARS] of entry into force of the TR.***
15.1	*Eurasian Economic Commission Council DECISION* *On the adoption of the Technical Regulation of the Customs Union*	*2. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment shall enter into force on 15 February 2015* *NONE*	According to article 5 part 2 of EU RoHS, the validity period of exemptions applicable to medical devices and monitoring equipment should be up to 7 years from the enforcement date. A similar provision must be incorporated in TR RoHS to allow medical devices and measurement equipment industry to be compliant with the TR beyond the application date. Similarly, a mechanism needs to be incorporated to enable producers the ability to seek an extension of an exemption prior to the expiry date. **Therefore, we propose the following changes to the text of the Council Decision:**

	Structural element of the TR	Text of the Draft TR	Proposed text and comments (including justification)
	restriction of hazardous substances in the electrical and electronic equipment.		***2d. Decree that the Special Requirements applicable to monitoring and control instruments Category 11 listed in Appendix 3, the maximum validity period, which may be renewed, shall be 7 years from the relevant dates laid down in point 2a to the present Decree, unless a shorter period is specified.***
16.	*Eurasian Economic Commission Council DECISION* *On the adoption of the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment.*	*2. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment shall enter into force on 15 February 2015* *NONE*	It is advisable that the cables are subject to the same timelines as the equipment that they are designed to be used with. A similar approach has already been taken under EU RoHS directive (art. 4 p. 4). Therefore, and to the extent that the legislator chooses to include medical devices and/or industrial monitoring and control instruments at a later date, we would like to propose application dates for cables used with such equipment to be in line with the application dates proposed for these two categories. **Therefore, we propose the following changes to the text of the Council Decision, if applicable:** ***2e. Decree that the Technical Regulation of the Customs Union restriction of hazardous substances in the electrical and electronic equipment shall apply to cables of the following:*** ***- medical devices placed on the market after [4 YEARS OF ENTRY INTO FORCE OF THE TR];*** ***- industrial monitoring and control instruments placed on the market after 22 July 2017.***