

COMPLIANCE

2017 Issue 5

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August 2017 September 2017 October 2017

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Headlines



New Harmonised Standards list published in the OJEU for:

Radio Equipment Directive, (2014/53/EU)

Latest publication, 13th October 2017: see 2017/C 344/02

Low Voltage Directive, (2014/35/EU)

Latest publication, 8th September 2017: see 2017/C 298/02

Standards being withdrawn (see standards watch)

within 1 year

European Standards 7 standards Other Standards 1 standard

within 2 years

European Standards 4 standards Other Standards none identified

If you want to know more, contact us



Standards Watch

Changes to standards and EU Directives that impact on product compliance



European harmonised standards are regularly updated

Care should be taken to make sure product compliance is kept up to date

European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking:

Within 12 months

Date	Old standard	Subject	New standard
17 Nov 2017	EN 60065:2002 + A12:11	LVD	EN 60065:2014
26 Jan 2018	EN 50156-1:2004	LVD	EN 50156-1:2015
25 Mar 2018	EN 55014:1997 + A2:08	EMC	EN 55014:2015
05 May 2018	EN 55032:2012	EIVIC	EN 55032:2015
31 Jul 2018	EN 62061:2005 + A1:2013	Machinery	EN 62061:2005 + A2:15
15 Sep 2018	EN ISO 9001:2008	Quality	EN ISO 9001:2015
	EN ISO 14001:2004	Systems	EN ISO 14001:2015

Within 2 years

Date	Old standard Subject		New standard
31 Oct 2018	ETSI EN 301 489-1 V1.9.2		ETSI EN 301 489-1 V2.1.1
	ETSI EN 301 489-17 V2.2.1	EMC	ETSI EN 301 489-17 V3.1.1
15 Feb 2019	EN 55011:2009 + A1:2010		EN 55011:2016
20 Jun 2019	EN 60950:2006 + A2:2013	LVD	EN 62368-1:2014

Other standards being withdrawn

Within 12 months

Date Old standard		Country	New standard
01 Jan 2018	UL 61010-1 2nd Edition	USA	UL 61010-1 3rd Edition

Within 2 years

Date	Old standard	Country	New standard

Lists of European Harmonised Standards

Published in the Official Journal of the EU and giving presumption of conformity with the essential requirements of the relevant Directive.

Further information: Harmonised standards

<u>Directive</u>	OJEU Ref	Date
<u>EMC</u>	2016/C 293/03	12 Aug 2016
LVD	2017/C 298/02	08 Sep 2017
Radio Equipment Directive	2017/C 344/02	13 Oct 2017
Medical Devices Directive	2016/C 173/03	13 May 2016
Active implantable medical devices	2016/C 173/02	13 May 2016
In vitro diagnostic medical devices	2016/C 173/04	13 May 2016
(+ Corrigenda)	2016/C 249/05	08 Jul 2016
Machinery Directive	2017/C 183/02	09 Jun 2017
RoHS Directive	2012/C 363/05	23 Nov 2012



SUSTAINABILITY



REACH – where to get information

Registration, Evaluation, Authorisation & restriction of Chemicals

There are many documents available giving guidance and advice on REACH – a selection is shown below:

UK Information

The UK Competent Authority for REACH is the Health & Safety Executive (HSE), who provide a wealth of information and guidance on their website: http://www.hse.gov.uk/reach/

The HSE produce a selection of "REACH Bitesize advice" information leaflets:

No	Date	Title
1	July 2016	REACH is here
2	July 2016	What REACH means for manufacturers
3	July 2016	What REACH means for EU importers
4	July 2016	What REACH means for users of chemicals
5	July 2016	REACH - The basics
6	July 2016	REACH - Timeline
7	July 2016	REACH - Pre-registration
8	July 2016	REACH - Exemptions
9	July 2016	REACH - Articles
10	July 2016	REACH - Guidance for distributors
11	July 2016	REACH - Creating an inventory for downstream users
12	July 2016	REACH - Substances of very high concern (SVHCs)
13	July 2016	REACH - Safety data sheets (SDS)
14	July 2016	REACH - Substances recovered from waste
15	July 2016	REACH - Guidance on biodiesel
16	July 2016	REACH - Registration
17	July 2016	REACH - SIEFs
18	July 2016	REACH - Minimisation of Animal Testing
19	July 2016	REACH - Authorisation
20	July 2016	REACH - Restrictions
21	July 2016	REACH - Annex III

EU Information

The primary source for information about REACH, including detailed guidance, is the European Chemicals Agency (ECHA)

The ECHA also produce a range of guidance documents:

- Support
- **Guidance**
- **Practical Guides**

Information is also available from the DG Environment REACH website





RoHS - Applications exempted from the restrictions in Annex III

Published Initiatives

The EU Directorate-General for Environment has published several Draft Delegated Directives amending the "applications exempted" in Annex III of the RoHS Directive (2011/65/EU). The comment period has just closed, but some interesting items are:

Exemption 6(a)

"Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight"

Proposed expiry dates:

0	21 July 2021 categories 1-7 and 10				
0	21 July 2021	categories 8	categories 8, (not IVD) and 9, (not industrial)		
0	o 21 July 2023 category 8 (IVD)				
0	21 July 2024	categories 9	(industrial) and 11		
	background	draft Directive	draft Annex	<u>feedback</u>	

No negative comments received.

Exemption 7(a)

"Lead in high melting temperature type solders (i.e. lead- based alloys containing 85 % by weight or more lead)"

Proposed expiry dates:

C	21 July 2021	categories 1-	categories 1-7 and 10		
C	21 July 2021	categories 8	categories 8, (not IVD) and 9, (not industrial)		
C	21 July 2023	category 8 (I	category 8 (IVD)		
C	21 July 2024	categories 9	(industrial) and 11		
	background	draft Directive	draft Annex	<u>feedback</u>	

No negative comments received.

Exemption 7(c)-I

"Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound"

Proposed expiry dates:

0	21 July 2021	categories 1-	·7 and 10			
o 21 July 2021		categories 8,	categories 8, (not IVD) and 9, (not industrial)			
0	21 July 2023	category 8 (I	VD)			
0	21 July 2024	categories 9	(industrial) and 11			
	<u>background</u> <u>draft Directive</u> <u>draft Annex</u> <u>fee</u>					

No negative comments received.





New Standards

National and international standards of interest published in recent months

August 2017	BS EN ISO 9241-112:2017	Ergonomics of human-system interaction. Principles for the presentation of information
	BS EN 55014-1:2017	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission
	BS EN 62321-8:2017	Determination of certain substances in electrotechnical products. Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography mass spectrometry using a pyrolyzer/thermal desorption accessory (Py/TD-GC-MS)
	BS ISO/IEC 20741:2017	Systems and software engineering. Guideline for the evaluation and selection of software engineering tools
	BS ISO 21505:2017	Project, programme and portfolio management. Guidance on governance
	BS ISO 21748:2017	Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation
September 2017	BS EN 55011:2016 + A1:2017	Industrial, scientific and medical equipment. Radio- frequency disturbance characteristics. Limits and methods of measurement
	BS EN 60065:2014 + A11:2017	Audio, video and similar electronic apparatus. Safety requirements
	EN 61000-4-11:— (IEC 61000-4-11:04 / A1:2017)	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
	IEC 62321-4:— AMENDMENT 1	Determination of certain substances in electrotechnical products. Mercury in polymers, metals and electronics by CV-AAS, CV-AFS, ICPOES and ICP-MS
October 2017	BS EN 62087-2:2016	Audio, video, and related equipment. Determination of power consumption. Signals and media
	BS EN 62281:2017	Safety of primary and secondary lithium cells and batteries during transport
	BS EN 62321-7-2:2017	Determination of certain substances in electrotechnical products. Hexavalent chromium. Determination of hexavalent chromium (Cr(VI)) in polymers and electronics by the colorimetric method
	IEC 61000-4-5:—	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test



Compliance Calendar

What's happening in the Compliance world in the next few months

September 2017

MON	TUE	WED	THU	FRI	SAT	SUN
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

October 2017

MON	TUE	WED	THU	FRI	SAT	SUN
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

November 2017

MON	TUE	WED	THU	FRI	SAT	SUN
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17 A	18	19
20	21	22	23	24	25	26
27	28	29	30			

December 2017

MON	TUE	WED	THU	FRI	SAT	SUN
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

A New LVD standard must be used:

EN 60065:2014, (replaces EN 60065:2002 + A12:11)