PRODUCT COMPLIANCE UPDATE

2020 Issue 3

Headlines

New amendments to Harmonised Standards lists published in the OJEU:

RoHS Directive (2011/65/EU)

Details of changes: (EU) 2020/659   15 May 2020

Standards being withdrawn (see standards watch)

- **within 1 year**
  - European Standards   6 standards
- **within 2 years**
  - European Standards   11 standards

Note: Where references are made to expiry dates these are the dates published in the standards, and not necessarily the dates published in the OJEU

Standards Watch

Changes to standards and EU Directives that impact on product compliance

European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking: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 Aug 2020	EN 62321-4:2014	RoHS	EN 62321-4:14 + A1:17
08 Sep 2020	EN 61000-4-5:2014	EMC	EN 61000-4-5:04 + A1:17
29 Aug 2020	EN ISO 14006:2011	Quality Systems	EN ISO 14006:2020
20 Dec 2020	EN 60950-1:2006 +A2:2013	LVD	EN 62368-1:2014 + A11:2017
	EN 60065:2014 + A2:2014		
27 May 2021	EN 61010-2-201:2013	LVD	EN IEC 61010-2-201:2018

Within 2 years

Date	Old standard	Subject	New standard
31 Aug 2021	ETSI EN 301 489-1 V2.1.1	EMC	ETSI EN 301 489-1 V2.2.3
14 Sep 2021	EN 60204-1:2006 + A1:2009	Machinery	EN 60204-1:2018
31 Oct 2021	ETSI EN 300 328 V2.1.1	Radio	ETSI EN 300 328 V2.2.2
18 Nov 2021	EN 50581:2012	RoHS	EN IEC 63000:2018
14 Jan 2020	EN 62474:2012		EN IEC 62474:2019
22 Feb 2022	EN 61010-1:2010	LVD	EN 61010-1:2010 + A1:2019
	EN 61000-6-1:2007	EMC	EN IEC 61000-6-1:2019
	EN 61000-6-2:2005		EN IEC 61000-6-2:2019
01 Mar 2022	EN 61000-3-2:2014		EN IEC 61000-3-2:2019
12 Apr 2022	EN 60730-1:2011	LVD	EN 60730-1:2016 + A1:2019
	EN 60730-1:2016		

> European harmonised standards are regularly updated
>
> Care should be taken to make sure product compliance is kept up to date

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.

Directive	Original list		Amendments	
	OJEU Ref	Date	OJEU Ref	Date
EMC	2018/C 246/01	06 Aug 2019	(EU) 2019/1326	08 Aug 2019
LVD	2018/C 326/02	14 Sep 2018	(EU) 2019/1956	27 Nov 2019
RED	2018/C 326/04	14 Sep 2018	(EU) 2020/167	06 Feb 2020
			(EU) 2020/553	21 Apr 2020
Machinery Directive	2018/C 092/01	09 Mar 2028	(EU) 2019/436	19 Mar 2019
RoHS Directive	2012/C 363/05	23 Nov 2012	(EU) 2020/659	15 May 2020

Sustainability - REACH

Nothing new, just a reminder and some useful information

REACH Guidance from the ECHA

Under REACH "downstream users" are companies or individual workers who use chemicals. This includes companies who manufacture goods or offer services where chemicals are not the main element of their business, such as food, construction or cleaning companies. The chemicals used typically include paints, metals, adhesives, solvents and cleaning agents. There are several guidance documents from the ECHA:

- Guidance and tools for downstream users
- Guidance in a Nutshell - Downstream users
- Guidance for downstream users

UK REACH CA information leaflets

The UK Competent Authority (CA) for REACH is the Health and Safety Executive.
To support UK industry they have produced a number of information leaflets on REACH:

No	Date	Title
1	Jul 2016	REACH is here
2	Jul 2016	What REACH means for manufacturers
3	Jul 2016	What REACH means for EU importers
4	Jul 2016	What REACH means for users of chemicals
5	Jul 2016	REACH - The basics
8	Jul 2016	REACH - Exemptions
9	Jul 2016	REACH - Articles
11	Jul 2016	REACH - Creating an inventory for downstream users
12	Jul 2016	REACH - Substances of very high concern (SVHCs)
13	Jul 2016	REACH - Safety data sheets (SDS)
16	Jul 2016	REACH - Registration
17	Jul 2016	REACH - (Substance Information Exchange) SIEF
19	Jul 2016	REACH - Authorisation
20	Jul 2016	REACH - Restrictions
21	Jul 2016	REACH - Annex III - low volume registration

The full list can be found at: https://www.hse.gov.uk/reach/bitesize.htm

There is more information on the UK HSE REACH site: https://www.hse.gov.uk/reach/index.htm

How many Chemicals are identified in REACH?

There are five lists of substances relevant to REACH, each serving a different purpose. When preparing these lists the European Chemicals Authority, (ECHA), often refers to "unique" substances, however each of these could include a number of subservient substances – greatly increasing the totals

List	No of "unique" substances	Total No. of substances
Register of substances	22857	??
Registry of intentions	38	1116
Candidate List	209	310
Authorisation List	54	97
Restriction List	70	893

ECHA Newsletters

A quarterly newsletter from the European Chemicals Agency

- [Issue 2, May 2019](#)
- [Issue 3, September 2019](#)
- [Issue 4, November 2019](#)
- [Issue 1, February 2020](#)
- [Issue 2, May 2020](#)

EU Regulations, Directives and other acts

The aims set out in the EU treaties are achieved by several types of legal act.

Some are binding, others are not. Some apply to all EU countries, others to just a few.

Below are the main methods that the EU uses to convey the compliance requirements that affect our products

Regulations

A "regulation" is a binding legislative act. It must be applied in its entirety across the EU.

For example, when the EU wanted to make sure that there are common safeguards on goods imported from outside the EU, the Council adopted a regulation.

eg Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Directives

A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals.

One example is the EU consumer rights directive, which strengthens rights for consumers across the EU, for example by eliminating hidden charges and costs on the internet, and extending the period under which consumers can withdraw from a sales contract.

eg The Low Voltage Directive, (LVD)

Decisions

A "decision" is binding on those to whom it is addressed (e.g. an EU country or an individual company) and is directly applicable.

For example, the Commission issued a decision on the EU participating in the work of various counter-terrorism organisations. The decision related to these organisations only.

Recommendations

A "recommendation" is not binding. When the Commission issued a recommendation that EU countries' law authorities improve their use of videoconferencing to help judicial services work better across borders, this did not have any legal consequences. A recommendation allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

Opinions

An "opinion" is an instrument that allows the institutions to make a statement in a non-binding fashion, in other words without imposing any legal obligation on those to whom it is addressed.

An opinion is not binding. It can be issued by the main EU institutions (Commission, Council, Parliament), the Committee of the Regions and the European Economic and Social Committee. While laws are being made, the committees give opinions from their specific regional or economic and social viewpoint.

For example, the Committee of the Regions issued an opinion on the clean air policy package for Europe.

Update on Harmonised Standards Lists
What's changed in the recent lists published in the OJEU

RoHS Directive (2011/65/EU)

Last full list published:	2012/C 363/05	23 Nov 2012
Details of changes:	(EU) 2020/659	15 May 2020

Annex	Purpose	No of standards
I	harmonised standards added	**1**
II	harmonised standards to be removed	**1**

EN IEC 63000:2018 has now been added, and will replace EN 50581:2012 from 18 Nov 2021

New Standards Published
National and international standards of interest published in recent months

May 2020

BS EN IEC 61000-4-11:2020	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase
BS EN IEC 62368-1:2020 + A11:2020	Audio/video, information and communication technology equipment. Safety requirements

June 2020

BS EN IEC 61293:2020	Marking of electrical equipment with ratings related to electrical supply. Safety requirements
BS EN IEC 62368-3:2020	Audio/video, information and communication technology equipment. Safety aspects for DC power transfer through communication cables and ports
BS EN ISO 14063:2020	Environmental management. Environmental communication. Guidelines and examples
BS EN ISO 22313:2020 Expert Commentary	Expert Commentary for BS EN ISO 22313:2020. Security and resilience. Business Continuity Management Systems. Guidance on the use of BS EN ISO 22301
BS ISO 10018:2020	Quality management. Guidance for people engagement
PD IEC TR 62998-2:2020	Safety of machinery. Examples of application
PD IEC/TR 63212:2020	Harmonization of environmental performance criteria for electrical and electronic products. Feasibility study
PD ISO IWA 31:2020	Risk management. Guidelines on using ISO 31000 in management systems

Compliance Calendar

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

May 2020

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

June 2020

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 **A**	23	24	25	26	27	28
29	30					

A New EMC standard must be used:

- EN 61000-4-11:2004 + A1:2017, (replaces EN 61000-4-11:2004)

July 2020

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			

August 2020

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 **B**	30
31						

A New RoHS related standard must be used:

- EN 62321-4:2014 + A1:2017, (replaces EN 62321-4:2014)

B New Environmental related standard must be used:

- EN ISO 14006:2020, (replaces EN ISO 14006:2011)