

Following the decision for the UK to leave the European Union, the UK Government are trying to make a deal with the EU to leave in a controlled manner, however, are also planning for a 'No Deal' Brexit. Exit day is intended to be 29 March 2019, however Ministers may decide that a different date will be applied. More information can be found on www.gov.uk.

This article discusses UK Marking, intended to replace CE Marking when the UK leaves the EU. It was written in January 2019, before any final decision is made, and before the leaving terms are fully known, so depending on when it is read, may be out of date. It is intended to provide updates as the situation becomes clearer. Each version is numbered and dated. The subject is 'Machinery', however many of the points apply to other Regulations as well, including Outdoor Noise, LOLER, ATEX, EMC etc. The updates will be published on the Safe Machine website at <https://www.safemachine.co.uk/press-articles/>.

The proposals affect all manufacturers of machinery supplying into the UK from either within the UK or from outside the UK. Manufacturers should already be CE marking machinery and should hold Technical Files explaining how they meet the Essential Requirements of relevant Directives, along with detail of how machinery is built and what safety measures are implemented. This will still be required for machinery being exported into the EEA and Turkey.

Where equipment is subject to Notified Body inspection or testing, it is recommended that this is discussed with the Notified Body currently appointed, as soon as possible.

This article is intended to identify changes or additions that may be required to be implemented to machinery, instructions, manufacturers plates and Declarations to enable supply into the UK seamlessly.

EU Directives and UK Law

For many years, Directives have been produced in the EU and adopted in each Member State as laws. Laws in the UK pass through Parliament in the form of bills. Once bills have progressed through all their stages, they become Acts of Parliament. Acts of Parliament often confer powers on Ministers to make more detailed orders, rules or regulations by means of Statutory Instruments (SI's). The scope of these powers varies greatly, from the technical (e.g. to vary the dates on which different provisions of an Act will come into force, to change the levels of fines or penalties for offences or to make consequential and transitional provisions) to much wider powers such as filling out the broad provisions in Acts. Often, Acts only contain a broad framework and SI's are used to provide the necessary detail that would be considered too complex to include in the body of an Act. The

Department for Business, Energy and Industrial Strategy is the relevant Government Body, with the [Secretary of State](#) for Business, Energy and Industrial Strategy being the Minister responsible for the legislation. (At the time of writing this post is held by Greg Clark MP).

STATUTORY INSTRUMENTS	
2008 No. 1597	
HEALTH AND SAFETY	
The Supply of Machinery (Safety) Regulations 2008	
Made - - - -	19th June 2008
Laid before Parliament	23rd June 2008
Coming into force - -	29th December 2009
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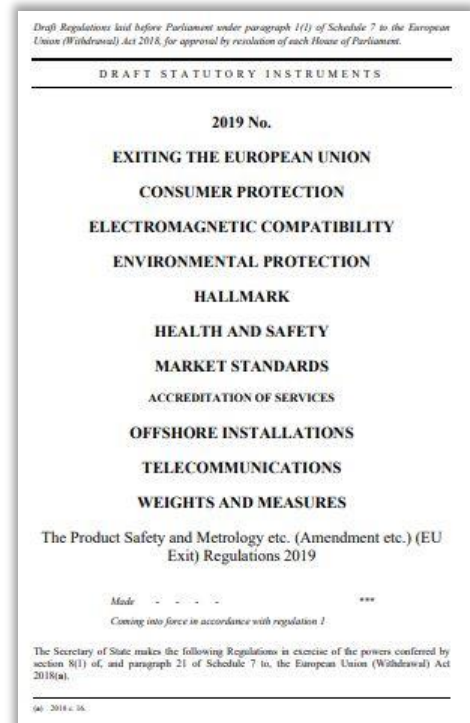
Contents of the Draft SI and their Implications on the Machinery Sector

In December 2018 the UK Government published a draft [Statutory Instrument](#), undated and not numbered. This covers numerous changes to several UK Regulations including Machinery. The text in *italics* is from the draft document. The link is provided in full at the end of this article.

The Regulations are aimed at changing from requiring CE Marking on machinery supplied into the UK, to a new 'UK Mark'. The form of this marking has not been published at the time of writing. Clearly the text of the SI may change before being implemented. There will be changes to other legislation also to support this.

Many of the proposed amendments simply replace terms such as EEA, EU and Community with UK or United Kingdom, terms such as Directive with 'enactments', and have little effect on the physical changes that manufacturers need to make.

The following items are where changes may be required, however these do not appear to be onerous. It is intended that there will be a transition period of probably eighteen months to allow changes to be made.



Authorised Representative

It is not essential for non-UK or non-EU companies to have an Authorised Representative, but where this course is taken, there will be some changes.

Anyone based in the UK who immediately before exit day acts as Authorised Representative in an EEA state will be accepted as authorised representative for the UK but will lose the ability to be Authorised Representative in the EEA, as the requirements as article 2 of the Machinery Directive 2006/42/EC requires the authorised representative to be a natural or legal person¹ established in the Community.

Companies based outside of the EU with an Authorised Representative prior to exit day in the remaining 27 EU states will be able to continue to use that Authorised Representative. Companies who appoint an EU Authorised Representative after exit day will require a UK Authorised Representative also.

Manufacturers don't need an authorised representative, however, do need someone identified as the person to compile the technical file on the Declaration. This person must be based in the EU. UK based companies exporting to the EU should ensure this is done before exit day to ensure that exports can continue. It is not clear whether there will be a transition period allowed by the EU. It is not clear whether market surveillance will be increased on imports from the UK following Brexit.

It would make sense to hope for the best, but plan for the worst.

¹ A natural or legal person can be a legal entity such as a company, not necessarily an individual.

Standards

The Regulations accept that existing EN or ISO Standards will continue to be able to be used to support compliance, however, will in future be known as ‘designated standards’.

A “designated standard” means a technical specification which is -

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations: -

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

The Secretary of State may remove from publication the reference to a standard which has been published. Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

It is assumed that this will be done in association with BSI, and a list of Standards that support the Essential Requirements be provided, but at present it is not clear where this will be published, probably the [BEIS](#) website.

Obligations re Annex IV Machinery

There is an additional Regulation 12A relating to machinery listed in Annex IV which references CE marking and the Directive. For manufacturers using Notified Bodies for Annex IV machinery conformity assessment, it is recommended to consult the Notified Body for more details.

Marking

Equipment supplied in the UK will have to carry a new UK marking symbol. If a Technical File has been prepared for CE marking to the Machinery Directive 2006/42/EC, then there are relatively minor changes, or additions required to apply the UK marking as well, these are indicated later. However, these will have to be addressed in the Technical File. It is expected that a single Technical File will be acceptable, with minor changes identified for the UK Marking requirements.

If a Technical File does not exist, then it will have to be created in the same way that a Technical File is required for CE marking machinery. It may identify situations where CE marking is not being carried out at present on assemblies of machinery and ensure that marking is provided.

End users need to ensure their purchase requirements are updated to consider the new provisions.

It is expected that the Health and Safety Executive will police the new Regulations.

Notified Bodies/Approved Bodies

The term 'Notified Body' will be replaced by 'Approved Body'. A UK Notified Body (NB) that existed on or immediately before exit day will automatically be an Approved Body. A new register of Approved Bodies will be set up, presumably identified on the [BEIS website](#), however this is not yet in place.

It is expected that any UK manufacturer relying on a UK NB, that either the NB will continue being an EU Notified Body and become a UK Approved Body. In cases where this does not happen, it is expected that it will be possible to transfer files to EU NB's.

Transition

There will need to be a transition period to ensure goods keep moving. A new Regulation 30 suggests that product (defined as 'machinery to which these regulations apply'), which was made available between 29th December 2009, when the present Machinery Directive 2006/42/EC came into force, and immediately before exit day will still be able to be supplied into the UK for a limited time.

Machinery being supplied into the European Economic Area (EEA) will still need to carry CE marking and nothing should change, other than there should be an EU person identified as the person to compile the Technical File on the Declaration of Conformity or Incorporation. As the UK won't be in the EU, then companies exporting to the EEA should ensure the Technical Files are able to be provided on request by relevant authorities by an EU person.

If a machine is currently on the market and CE marked, then it appears that it will be able to be supplied into the UK for a period of 18 months beginning with exit day before changes are required.

If a machine is supplied that has not been placed on the market before exit day, then it must comply with the UK Marking requirements from exit day, or when it is placed on the market.

Essential Health and Safety Requirements

There are some minor proposed changes to the Essential Requirements: -

1.5.1 The Electrical Equipment (Safety) Regulations 2016 apply instead of the Directive 2006/95/EC, which had been superseded by 2014/35/EU (Low Voltage Directive, or LVD). The UK Regulations were implemented to take account of the changes in LVD 2014/35/EU. It is expected that the Electrical Equipment (Safety) Regulations 2016 will be updated at some point as there are many references to EU Directives and requirements. It is not expected that there will be any physical changes required, other than marking and documentation.

1.5.7 Wording will change from EU Directives to enactments, these being the reference to explosion protection and the ATEX Directive, which is superseded by the SI, however the requirements of requiring protection will not change.

1.7.1 The requirement is for warnings preferably to be understandable pictograms and any text to be in English. The Health and Safety (Safety Signs and Signals) Regulations 1996 are expected to apply, which also refer to EN ISO 7010. Non-EU suppliers should ensure that non-compliant signage should be changed.

1.7.3 Where CE marking is mentioned it is replaced with UK Marking. It is assumed that most manufacturers will produce new plates to incorporate the UK Mark as well as the CE marking.

1.7.4.1 Requires text of Instructions to be in English.

Declarations

Changes to the Declarations are required, including changing the reference from 'EC Declaration' to 'Declaration'. The draft SI refers to the 'name and address of the person authorised to compile the relevant technical documentation' but does not state that this must be in the UK. (The EU require a person to compile the file who is established in the EU). This point will need to be clarified.

Technical Files

Technical Files have the same requirements for documentation as presently, however it must be in English and the wording is changed to reference UK regulations rather than EU.

Annex VIII

Amendments to the requirements for ensuring conformity is assessed to the UK Regulations, rather than the Machinery Directive. It still retains the need for manufacturers to ensure that a conformity assessment is carried out and the machinery is compliant with the Regulations and a Technical File can be made available to demonstrate this.

Conclusion

What it means (in the authors opinion).

1. EN Standards will continue to be used to support machinery safety in the UK for the foreseeable future, however, will be called 'designated standards'.
2. British Standards Institution (BSI) will continue to be involved in developing Standards in Europe and internationally.
3. There will be a new UK mark that will have to be applied either instead of or alongside the CE Marking.
4. There is likely to be a transition period of eighteen months to allow the changes to be put into place.
5. The Essential Requirements that have changed from the Machinery Directive will need to be addressed to allow a Technical File to be created for UK Marking.
6. Declarations will require text changing for UK machinery.
7. If the manufacturer already manufactures CE Marked machinery and has Technical Files and Declarations, there is a small amount of work to update and modify existing documentation to cover the additional requirements for the UK. It does not seem to justify a whole new Technical File for UK machinery.
8. It would seem logical that Declarations could have both EU text and UK text to reduce the administrative burden on manufacturers.
9. Documentation must be able to be provided in English, this may create a burden on EU manufacturers who currently only provide Technical Files in an EU language.

This article was written by Derek Coulson, a Technical Advisor with Safe Machine Ltd., an independent machinery safety consultancy since January 2013. Derek has been working in

the field of Machinery Safety since 1995 and has a lot of experience in CE Marking of Machinery, has been a Senior Engineer with a Laidler Certification LLP, a UK Notified Body number 0870 that became part of TÜV-SÜD BABT, Notified Body number 0168 when Laidler Group became part of TÜV-SÜD Product Services in 2010.

The article is an opinion, it is not advice and has no legal standing whatsoever. E & OE.

Website Links (Current at time of writing).

Safe Machine Website - www.safemachine.co.uk

Draft Statutory Instrument –

http://www.legislation.gov.uk/ukdsi/2019/9780111176368/pdfs/ukdsi_9780111176368_en.pdf

Existing Supply of Machinery (Safety) Regulations 2008 Statutory Instrument –

http://www.legislation.gov.uk/uksi/2008/1597/pdfs/uksi_20081597_en.pdf

Partnership pack: preparing for changes at the UK border after a ‘no deal’ EU Exit –

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/767811/Partnership_pack_prepare_for_no_deal_changes_at_border_Third_edition.pdf

Department for Business Energy and Industrial Strategy –

<https://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy>