

LEV Systems & SMR08, etc

Compliance with UK product law

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Key UK product safety law

- **Supply of Machinery (Safety) Regulations 2008 (SMR08)**
- Electromagnetic Compatibility Regulations 2016 (**EMC16**)
- Radio Equipment Regulations 2017 (**RER17**)
 - *all one time duties on the relevant economic operator*
- **Section 6(1) Health & Safety at Work etc Act 1974 (HSWA S6)**
 - HSWA S6(1)d: retrospective duty to provide information
- R10 PUWER 1998: purchaser duty linking to SMR, EMC, etc
 - ***also relevant and important:***
 - HSWA S6(3): duty to safely install work equipment
 - **HSWA Section 3: duty to non-employed persons**

UK product law comes from

- UK's implementation of EU single market law, eg:
- Machinery Directive (89/392/EEC, 98/37/EC & 2006/42/EC)
 - SMR08 replaced, with only minor evolution, SMR92
 - SMR92 mandatory since 1995, revised in 1994 & 2005
 - similarly EMC16 & RER17 implement EU Directives
- All sit alongside existing domestic law: HSWA S6
 - *and continue in essentials unchanged on EU-Exit (deal or no-deal)*

Main Requirements of Product Law



Products in scope must when placed on the market

- meet all relevant essential requirements (EHSRs)
- show this in the product's technical file (& kept for 10+ yrs)
- be accompanied (in English) by comprehensive:
 - Information/Instructions, and a
 - Declaration of Conformity (to indicate who is responsible)
- be appropriately marked: CE marking continues

Scope of SMR08

- Not just classical **‘machinery’**,
 - an assembly, fitted with *or intended to be fitted with a drive system* other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

(this is a very wide definition)

Machinery also in Scope

- also an assembly as referred to in the previous slide, *missing only the components to connect it on site or to sources of energy and motion;*



Machinery also in Scope

- an assembly as referred to in the previous slides, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or structure;



Machinery also in Scope

- assemblies of machinery as referred to previously which, in order to achieve the same end, **are arranged and controlled so that they function as an integral whole;**



Machinery also in Scope

- an assembly of linked parts or components, at least one of which moves and which are joined together, **intended for lifting loads and whose only power source is directly applied human effort;**



Machines & 'machinery'



- *The following products are also in scope of SMR08:*
 - interchangeable equipment
 - **safety components**
 - lifting accessories
 - chains, ropes and webbing
 - removable mechanical transmission devices

and to be treated in same way as machinery
- *& Partly Completed Machinery (NB: PCMs are not machinery)*

Interchangeable machinery

- devices which, after the putting into service of machinery or of a tractor, are assembled with that machinery or tractor by operators themselves in order to change its function or attribute a new function, in so far as they are not tools



Safety components

- (i) which serve to fulfil a safety function;
- (ii) which are independently placed on the market;
- (iii) the failure or malfunction of which endangers the safety of persons; &
- (iv) which are not necessary in order for the machinery to function, *or for which normal components may be substituted in order for the machinery to function;*



Lifting accessories

- **lifting accessories**
 - are not attached to lifting machinery;
 - allow a load to be held;
 - are placed between the machinery and the load or on the load itself, or are intended to constitute an integral part of the load; and are independently placed on the market
- **Chains, ropes & webbing**
 - designed and constructed for lifting purposes as part of lifting machinery or lifting accessories



Removable mechanical transmission devices



- *means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing.*

When it is placed on the market with the guard it shall be regarded as one product;



Within scope, but not *machinery*: Partly Completed Machinery (PCM)



- drive systems and other assemblies which:
 - are almost machinery;
 - cannot in themselves perform a specific application; and
 - are *only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery.*



Partly Completed Machinery: SMR08



R8(1) Before partly completed machinery (PCM) is placed on the market, the RP (responsible person) must ensure that:

- the relevant technical documentation is prepared and made available
- assembly instructions are prepared
- a ***declaration of incorporation (DoI)*** has been drawn up and that a copy of it accompanies the PCM; and the original is retained

R8(2) The **assembly instructions** and the **DoI** shall accompany the PCM until it is incorporated into machinery (*DoI becomes part of final machine's technical file*)

PCMs do not have to meet any essential health & safety requirements (EHSRs), but any EHSRs which they do meet should be declared on the DoI and covered by the product's technical file

Note: PCMs do not have CE marking under SMR08/MD, but may be CE marked under other legislation

Relevance of CE marking

- Required by various product law, ***but***
- Must not be placed on a product unless product complies with all relevant CE marking legislation
- Not a quality or safety guarantee, but a sign of compliance by person placing product on market
- Checking for it is part of purchaser's due diligence
 - see also checklist in free HSE leaflet 'Buying new machinery'

Relevance of Declaration of Conformity



- DoC required by various product law
- Normally should be a single declaration
- Content specified by each product law, indicates:
 - who is responsible for the product (Mft/Installer as mft)
 - on what basis:
 - which Directives/Regulations apply and met
 - conformity with any relevant standards
 - date placed on market (or first put into service)
- Again, checking for it is part of a purchaser's due diligence

The manufacturer's duties also

- Apply to those ***deemed to be manufacturer***, eg:
 - importers of non-compliant goods
 - distributors of own-branded goods
- Under SMR08 duty extends to products when **first put into service** (even if not **placed on the market**), eg to:
 - users who make their own machinery
 - users bringing even existing old machinery into use in the EU for the first time (eg from another site outside the EU, into the UK)
- Also to **substantially modified machinery**, where considered '***new***'

SMR08 uses the defined term 'Responsible Person'

SMR08: the Responsible Person must



- R7(1) place machinery on the market or put it into service unless it is **safe**
- R7(2) ensure that:
 - the applicable **essential health and safety requirements** are satisfied
 - the **technical file** is compiled and made available
 - provide, in particular, information necessary to operate it safely, such as **instructions**
 - follow, as appropriate the **conformity assessment procedure** prescribed
 - draw up the **declaration of conformity** in accordance with Annex II
 - affix the **CE marking** to the machinery visibly, legibly and indelibly
- R7(3) carry out, or procure the carrying out of, **all the necessary research and tests** on components, fittings or the completed machinery to determine whether, by its design and construction, it is capable of being assembled and put into service safely

Conformity Assessment

Unless MD Annex IV, essentially self-certify, no third party is required

Assessment of conformity with internal checks on the manufacture of machinery

1. .. procedure by which the responsible person, who carries out the obligations laid down (see 2 & 3 below), ensures and declares that the machinery concerned satisfies the relevant provisions of the Directive (and UK law: SMR08).
2. For each representative type of the series in question, the responsible person shall draw up the technical file (***evidence to justify the design***)
3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file (***quality and consistency***)

Iterative Risk Assessment is key to the process of risk identification & reduction

Essential Requirements of SMR08



- Vital that product designers and approvers understand the introductory remarks to Annex I on the General Principles:
 - **three EHSRs must always be met: 1.1.2, 1.7.3 & 1.7.4**
- All other relevant EHSRs must be met to ‘state of the art’:
this must be shown in the technical file
 - taking into account ‘state of the art’ it may not be possible to meet the objectives set by the EHSRs. In that event
 - machinery must, **as far as possible**, be designed and constructed with the purpose of approaching these objectives

Some of the key EHSRs for LEV

1.1.2 Principles of safety integration

1.1.3. Materials and products

1.1.5. Design of machinery to facilitate its handling

1.2.1. Safety and reliability of control systems

1.3.4. Risks due to surfaces, edges or angles

1.3.6. Risks related to variations in operating conditions

1.3.7. Risks related to moving parts

1.5.1. Electricity supply & 1.5.2. Static electricity

1.5.6. Fire & 1.5.7. Explosion

1.5.8. Noise (& 1.5.9. Vibrations)

1.5.13. **Emissions of hazardous materials and substances**

1.6. Machinery maintenance

1.7. **Information & Instructions (includes Noise declaration & Sales Literature**

- All relevant EHSRs for your product must be addressed in sufficient detail in your technical file to **justify** your design, and intended uses,
- *to show how EHSR met to the 'state of the art', and*
- **at the manufacturer choice**, referencing specific standards

Technical Files (for each applicable legislation)



- Content is listed in Annex VII (Part 7 Schedule 2 SMR08)
 - much more than just a risk assessment !
 - must be product specific (*like the DoC must also be*)
- Need not be a single physical ‘file’, but
 - all elements must be in place before the product is placed on market, and retained for at least 10 years
 - including evidence of manufacturing - ‘serial conformity’
- *Rapidly made available on request to relevant authorities*

1.5.13. Emissions of hazardous materials and substances



*“Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances **which it produces** can be avoided”*

- **For LEV this covers containment of captured materials and their disposal arrangements (hardware and methods), but not the original ‘dust/fume’ source, BUT**

1.1.2 Principles of safety integration



*“Machinery must be designed and constructed so that **it is fitted for its function**, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also **taking into account any reasonably foreseeable misuse thereof.**”*

Links to EHSR 1.7.3 on description of intended use in sales literature and 1.7.4 on intended use/non-intended uses. Basically: is your LEV suitable for stated purpose?

More on EHSR 1.1.2 principles ...

In selecting the most appropriate methods, the manufacturer ...
must apply the following principles, in the order given:

- 1. eliminate or reduce risks *as far as possible*** (inherently safe machinery design and construction),
- 2. take the necessary protective measures** in relation to risks that cannot be eliminated,
- 3. inform users of the residual risks** due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment

More on EHSR 1.1.2 principles ...

- When designing and constructing machinery and when drafting the instructions, the manufacturer ... **must envisage not only the intended use of the machinery *but also any reasonably foreseeable misuse thereof.***
- The machinery must be designed and constructed in such a way as to **prevent abnormal use if such use would engender a risk.**
- Where appropriate, the instructions **must draw the user's attention to ways machinery should not be used** - which experience has shown might occur.
- Machinery must be designed and constructed to **take account of the constraints** to which the operator is subject as a result of the **necessary or foreseeable use of personal protective equipment.**

Sales Literature EHSR 1.7.4.3

- Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects.
- Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

Make non-intended uses clear from the outset

Instructions: SMR08 EHSR 1.7.4.2



- *Comprehensive list of contents, all issues to be covered!*
 - intended use, eg systems of work & *non-intended use*
 - transportation, assembly, installation, disassembly
 - use, maintenance, trouble shooting
 - training and PPE requirements, etc
 - also, noise declaration - for worker risk, but note the
 - potential link to the Outdoor Noise Directive (2000/14/EC)
 - the Machinery ADCO NOMAD Noise Guide can help you here
- *All H&S elements should be provided in writing – rest can be electronic*

Relevance of EMC16

- **Electromagnetic Compatibility Directive 2014/30/EU**
- Applies to most electrically powered products
- Concerned with avoiding EM interference between products (not primarily for safety, SMR08 EHSR 1.2 covers that aspect)
- Requires CE marking, DoC, technical evidence
- Likely to apply to LEV machinery alongside SMR08
- *Not enforced by HSE: refer to local trading standards*

Relevance of RER17

- Radio Equipment Regulations 2017 (enforced by trading standards and Ofcom)
- If equipment includes a radio module eg Wi-Fi, Bluetooth, etc RER17 applies alongside SMR08
 - If RER17 applicable they subsume the EMC16 requirements

Note: other CE marking Directives/UK product law, eg: on RoHS, WEEE, other Environmental matters can also apply

Supplier duties: HSWA S6(1)

- If not a 'Responsible Person', eg a 'pure' distributor SMR08 does not apply (*but specific distributor duties exist under other product law: eg EMC16, RER17, etc*)
- And HSWA S6(1) will also apply: supplier duty for health & safety so far as is reasonably practicable (SFARP)
 - SFARP taken as meeting EHSRs and other admin. requirements
 - EU case law: distributors may rely on the 'presumption of conformity' afforded by: CE Marking, the DoC and accompanying Instructions (*but only if no obvious risk, or other evidence of non-conformity*)
- **If not compliant as above, distributors must not supply**

Information requirement of S6(1)d

- No retrospective duties under the current SMR08
 - *unlike EMC16 & RER17, where a ‘recall’ duty exists, but*
- HSWA S6(1)d is an enforceable duty to provide revisions of information, so far as reasonably practicable (SFARP):

“It shall be the duty of any person who designs, manufactures, imports or supplies any article for use at work ... to take such steps as are necessary to secure, SFARP, that persons so supplied are provided with all such revisions of information provided to them by virtue of the preceding paragraph as are necessary by reason of its becoming known that anything gives rise to a serious risk to health or safety.”

A brief introduction to SMR08 etc

- LEV are machinery subject to UK/EU product law
 - some components for safety, or if PCMs, are also subject to SMR08
- Extensive duties apply to those *placing LEV machinery & safety components* on the market, or *first putting a system into use*, or *extensively modifying* an existing system
 - *they will probably not change in essentials with EU-Exit*
- **Each system must** be designed, constructed (assembled in situ) and described/marketed to be *safe for all intended uses*
- Evidence to show this must be complied and kept available

Information/Guidance

- HSE website: [Manufacture and supply of new work equipment](#)
- HSE website: [Local Exhaust Ventilation](#)
- HSE leaflets: [Supplying new machinery](#) & [Buying new machinery](#)
- [Supply of Machinery \(Safety\) Regulations 2008](#) (as amended in [2011](#) to include some environmental EHSRs for only pesticide application machinery)
- [Guide to application of the Machinery Directive 2006/42/EC](#) (Edition 2.2)
- [NOMAD Guide](#) how to report noise emission in instruction manuals



Thank you for your attention