

**IMPLEMENTING THE NEW  
MACHINERY DIRECTIVE (MD)  
IN THE UNITED KINGDOM**

**BERR Response to its  
Public Consultation**

**APRIL 2008**

**URN 08/817**

## Introduction

BERR issued a consultation document on 25 September 2007 entitled 'Implementing the new Machinery Directive 2006/42/EC in the United Kingdom'. The document sought views on a draft set of Regulations to transpose the provisions of the Directive into UK law.

The consultation closed on 18 December 2007. Twelve responses were received in total. These included businesses, trade associations, and trading standards organisations.

BERR is grateful to those who responded for their time and their views. The views expressed have been carefully analysed and have been of help in finalising the draft Regulations to implement the Directive.

This document provides an overview of the responses received to the consultation and addresses the issues they raised. A list can be found at Annex A and copies of the original responses are available on request.

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If you have any comments, concerns or reservations about the way this consultation has been conducted, or suggestions of ways in which BERR's consultation process could be improved, these should be sent to:

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## Background

The current Machinery Directive (98/37/EC) has been in existence for almost 20 years – the original 1989 Directive was consolidated in 1998 after a series of small amendments, hence the reference number. It is one of a family of European Union Directives that use the 'New Approach' regulatory model to effect a single market in several product areas, basically by removing non-tariff barriers to trade through the harmonisation of national safety requirements. The product area covered by the Machinery Directive is very wide and ranges from relatively small consumer items, such as power tools at one extreme, to heavy construction and lifting equipment at the other.

Over a period of several years leading up to 2006 the Directive was re-negotiated. The end result was a thorough overhaul and modernisation of the original Directive although the basic features and principles remained intact. The transposition of this new Directive (2006/42/EC) into UK legislation was the subject of the consultation. Member States' authorities are under an obligation to have enacted suitable implementing provisions in their own legislation by 29 June 2008 and to bring these into force on 29 December 2009. The consultation document contained a draft UK Statutory Instrument to illustrate how this might be accomplished.

The background to this exercise and the specific issues it raises are explained in greater detail in the consultation document (reference URN 07/1215 – see especially pages 4-7).

## Responses to the consultation and BERR's response

Those consulted were invited to respond to 10 specific questions about the proposals and to add any other comments they might have. The analysis below summarises the responses received to the questions and then gives a view from BERR including any action BERR has taken as a result. Responses that were specifically about the Directive rather than our transposition of it have generally not been included with a few exceptions, e.g. the various points about interpreting Annex I of the Directive that were raised under Question 2.

**Question 1: Do the draft Regulations transpose accurately all of the provisions of the Directive that require to be transposed into UK legislation? If not please say which provisions you consider have not been properly transposed.**

### *Responses*

From those who expressed a view there was complete agreement that the provisions had been accurately transposed.

In addition this was an opportunity to raise issues of transposition that were not raised specifically in the other questions.

A representative association pointed to a discrepancy between the texts of the Directive and the draft Regulations concerning the Declaration of Conformity. Article 5(1)(e) implies that the original must accompany the product whilst draft regulation 7(2)(e)(i) seems to allow for a copy. The respondent welcomed the greater flexibility in the draft UK Regulations but wanted there to be robust guidance to back it up.

Another representative organisation also expressed general concerns about the requirements for the Declaration of Conformity. The same respondent noted that references to the Official Journal of the European Union (“OJ”) had been omitted. A consultant enquired about the transposition of the penultimate sentence of Article 1(2) of the Lifts Directive as inserted by Article 24 (2) of the Machinery Directive, i.e. the one beginning ‘Lifting appliances moving along a fixed course ..... etc.’ as arranged by the amendments to the Lifts Regulations 1997 in Schedule 6 to the draft Regulations. The consultant also noted that the directive’s usage of ‘Where the lift.....etc.’ in the statement of the essential requirements for the ‘carrier’ (Article 24(2) final paragraph) had not been carried through to the relevant part of Schedule 1 to the Lifts Regulations (where the usage ‘In the case of lifts .....’ was proposed to be retained).

### *BERR Comments*

Annex 2 of the Directive provides for the Declaration of Conformity to be retained by the manufacturer and so, by implication, Article 5 must be speaking of a copy which is why the transposition has been undertaken in this way. The change in the draft Regulations reflects a difference between Annex II of Directive 2006/42/EC and the corresponding provisions of Directive 98/37/EC.

BERR assumes that the comment about OJ references relates to references in the Directive to harmonised standards. In the Directive, these are often referred to either as harmonised standards, the references to which have been published in the OJ (Article 7(2)) or as “harmonised standards...referred to in Article 7(2)”. Given the quite large number of references which need to be made to harmonised standards in transposing the Directive into UK Regulations, it seemed neater to avoid frequent repetition of these rather long-winded phrases by adopting the defined term “published harmonised standard” (defined in regulation 2(2) to mean a harmonised standard, the references to which have been published in the OJ). We propose to retain this basic approach in the final Regulations, but we have taken account of this comment by inserting a reference to the OJ in the key provision on presumption of conformity (draft regulation 7(4)) and making that provision the reference point for the defined term. It is hoped that readers will find this more user-friendly and more consistent with the drafting of the Directive.

On the point about the transposition of Article 24(2), BERR considers that although sub-paragraph (b) of the existing definition of a ‘lift’ in the Lifts Regulations 1997 already transposes the words which appear in the penultimate paragraph of Article 1(2) of the Lifts Directive, as amended, it may be better to follow the format of the definition in the Directive more closely and the draft Regulations will be amended accordingly. The usage of ‘Where’ instead of ‘In the case of’ is also to be adopted in the Statutory Instrument as a drafting improvement.

**Question 2: Do the draft Regulations deal appropriately with any other legal or practical issues raised by the implementation of the Directive in the UK context? If not please explain your response as fully as possible.**

### *Responses*

A representative association pointed out that the new Directive contains two definitions of the concept of ‘machinery’. These are firstly the ‘narrow’, core definition set out in the five indents at Article 2(a) and secondly the wide definition introduced by the preamble to Article 2 that includes the core definition but also extends it to all of the products, except (of course) for ‘partly completed machinery’, laid out in Article

1.1. The draft UK Regulations in the consultation document did not attempt to distinguish the two definitions and effectively treated all references to “machinery” in the Directive as relating, by default, to the wider definition (although some suggestions were made to change the wording *itself* of the narrow definition in Article 2(a) and the issue of whether these changes were desirable or not was addressed directly by Question 5 – see discussions of responses to that question below).

A representative organisation placed on record a number of issues of interpretation concerning the new set of essential requirements (Annex I of the Directive) that had come to its attention. In doing so it acknowledged that the draft Regulations had simply converted Annex I *verbatim* into Schedule 2 and so the comments did not affect the consultation directly. They are therefore not discussed here but BERR gives its assurance to this and all other stakeholders, *especially those who raised other issues in the course of this consultation exercise that are purely concerned with 2006/42/EC*, that a comprehensive body of guidance is being developed for the Directive under the stewardship of the European Commission. The UK authorities (i.e. BERR and HSE together) are playing, and will continue to play, a full part in this exercise in the run-up to the enforcement of the new Directive in 2009, and beyond if necessary. They will, furthermore, ensure that the requirements for guidance that are expressed to them by UK stakeholders, including the ones that have already been expressed in the course of this consultation, receive due attention.

Another representative organisation asked for the draft Regulations to make it clearer that they apply to all ‘new’ products in their scope, i.e. newly placed on the UK market or put into service in the UK, and especially that this would include products already in service that had undergone what were considered to be ‘major’ modifications.

Finally a consultant wished to see the principle of gender neutral drafting embodied in the draft Regulations.

### *BERR Comments*

BERR has already raised the very basic issue about the clarity of the Directive – i.e. the two ‘parallel’ definitions of ‘machinery’ – with the European Commission at the earliest available opportunity and in the most appropriate forum, which is the periodic stakeholders’ Working Group. The Commission has subsequently made an initial statement to clarify the legislative intention behind this apparent drafting problem in an official Working Group paper and this will be incorporated into the comprehensive body of guidance that is being developed for the Directive referred to above. BERR has subsequently decided that the Regulations would benefit from a slight adjustment to reflect the Commission’s statement and put into a clearer context how the two definitions are to be understood.

On the status of major modifications all New Approach Directives, including all generations of the Machinery Directive, have as their objective the creation of a Single Market across the EU in *new* products (and new products alone). This principle is carried through to all of the implementing Regulations for such Directives in the UK, past, present and future and specifically in these draft Regulations by regs. 4(1)(c) (machinery) and 5(d) (partly completed machinery). BERR does not see a need for further enunciation. The principle is also stated clearly in the European Commission’s ‘Guide to the Implementation of Directives based on the New Approach and Global Approach’ (typically known as the ‘Blue Guide’).

The final version of the Statutory Instrument will incorporate appropriate gender neutral drafting.

**Question 3: Do you consider the draft Regulations as framed to be ‘business-friendly’? If not, and the problem is one of drafting, please state which ones are not and suggest a form of words for each that would make them clearer.**

#### *Responses*

Two representative organisations and one local government organisation specifically criticized the clarity, including in comparison with the Directive, with one of the former questioning the need for the transposition exercise at all, although acknowledgment was made of the inherent difficulty of avoiding this problem totally.

One trade association considered the drafting of draft regulation 27 very clumsy.

#### *BERR Comments*

It is in the nature of EC directives (as opposed to regulations) that they generally need to be transposed into the domestic legislation of Member States. In the present case, those provisions of the Machinery Directive which confer rights or impose obligations on businesses and individuals must be transposed into UK legislation. Otherwise they will not form an effective part of UK law and the UK will be failing in its EU obligations.

In transposing the Directive, we have followed the actual wording of the Directive as closely as possible unless there is a good reason not to do so (for example, to introduce greater clarity where we think the Directive text is hard to follow, even if this means using more, rather than fewer words). We have also attempted to preserve the formatting of Annex I, which makes up the bulk of the Directive, in Schedule 2. However, the constraints of the statutory instrument template, which applies to all UK secondary legislation, do not permit us to mimic the formatting or heading conventions used in EU legislation any more closely than we have done, even if we had wanted to. Readers who find the format (rather than the substance) of UK statutory instruments generally is not sufficiently user-friendly should express their views to HMSO in the Office of Public Sector Information.

The comment about regulation 27 gave us cause to look again at the very need for this provision. Our conclusion was that regulation 27 was unnecessary given paragraph (k) of Schedule 3 and the replacement of Directive 73/23/EEC by Directive 2006/95/EC, so it will not appear at all in the final version of the Regulations.

**Question 4: Do you consider the Regulations as framed make it clear to a manufacturer what he needs to do to bring his products into conformity? If not, please explain why.**

#### *Responses*

Responses here were essentially intertwined with the responses to other questions or raised issues that concerned difficulties with the underlying Directive which BERR has noted and will need to be addressed by guidance, although two representative organisations commented specifically that the Regulations were clear in this respect.

One representative organisation enquired about the partial revocation of the All Terrain Motor Vehicles (Safety) Regulations of 1989 in Schedule 1 to the draft

Regulations. The organisation went on to assume, correctly, that the reason for this is that such vehicles, commonly referred to by the shorthand expression ATVs, are covered by the Machinery Directive, and hence these draft Regulations (with the exception of those designed and placed on the market specifically for competitive use), but it was concerned that the change needed to be highlighted to avoid confusion for manufacturers.

#### *BERR Comments*

On ATVs BERR accepts the need for explicit confirmation of the coverage issue and will provide this in the guidance literature for UK users that it will be issuing in the run-up to the enforcement date. It is hoped that this will avoid the risk of confusion and overall will deliver a safer and clearer regulatory regime for ATVs in the longer term.

**Question 5: Article 2 (a) of the Directive defines “machinery” and is transposed by regulation 4 (2) (a) in a slightly different format. Do you prefer how it has been transposed, or would you prefer to see the text of the Directive reproduced here? If neither, what text do you think would provide greater clarity?**

#### *Responses*

A large corporation alongside several trade and local government organisations preferred the text of the Directive both because it was intrinsically clearer in their view and also because having a UK version that departed from this text (even if only in form, not substance) caused scope for confusion amongst regulators, industry and other users.

#### *BERR Comments*

BERR and our HSE enforcement colleagues, as regulators, find, at a professional level, that our engagement is more with the various wordings of the Directive rather than the UK Regulations and so the points expressed struck a chord. We would be conscious too that creating a deliberate distinction between the Directive concepts and those in the Regulations, however well intentioned this may be, would carry with it the danger of confusion in the discussions over interpretation of the Directive we have with our European partners.

This means that the case for altering the Directive text in the UK Regulations must be a clear and decisive one. In other words, if there are definite reasons for *not* altering there must be not just equally good arguments on the opposite side of the argument but a clear overall added value for change. There was no positive support at all in the consultation for either the principle of altering this aspect of the Directive’s wording or for the specific drafting suggestions we had made. BERR has therefore decided that such alteration should be avoided and that the text of the UK Regulations should not depart from the text of the Directive in this area. The final version of the Statutory Instrument will reflect this policy.

**Question 6: Article 2 (g) of the Directive introduces the new concept of “partly completed machinery”. Regulation 5 transposes this in a slightly different format. Is this helpful, and does it work? If not, what wording would make it clearer?**

## *Responses*

Although the same underlying principle as in Question 5 applies the responses to Question 6 did not follow entirely the same pattern with the re-drafting that BERR had performed on this concept getting a good reception in some quarters. It should be added that the nature of the re-drafting under Question 6 was more a case of re-formatting a rather dense paragraph of text in the Directive into an arguably more digestible series of indents in the draft Regulations, i.e. there was less of a creative element than with Question 5.

The sole response that was entirely critical was that of the large corporation which re-stated under this heading the comment it had made to Question 5. At the other end of the spectrum two of the trade associations that were critical under Question 5 were entirely content with the drafting of regulation 5. In the middle of the spectrum a local government organisation and two trade associations that had been critical of the Question 5 re-wording were prepared in principle to accept a different text in the UK Regulations but offered some alternative drafting or posed specific questions and one of this sub-group also registered its support for placing this concept in a separate regulation from the definition of 'machinery'. The re-drafting that was suggested concerned reg. 5(a) and (d).

## *BERR Comments*

BERR was satisfied that in the case of 'partly completed machinery' there was, to refer back to the reasoning under Question 5 above, a 'clear overall added value for change'. The definition that will appear in the Regulations that are eventually made will therefore not copy the exact wording of Article 2(g) of the Directive.

The question then became a subsidiary one of deciding whether any of the alternative pieces of drafting that had been put forward, and for which BERR is very grateful, were preferable to the draft that had been offered in the course of the consultation. BERR was attracted towards one idea put forward of, in effect, separating the aspects of regulation 5 that are to do with the intrinsic characteristics of 'partly completed machinery' from those concerned with its deployment. This would see regulation 5 being divided into sub-paragraphs along the following lines:

5.(1) Subject to paragraph (2), provisions of these Regulations which refer to "partly completed machinery" apply to assemblies (including drive systems) which—

- (a) are almost machinery;
- (b) cannot in themselves perform a specific application; and
- (c) are only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery.

(2) Paragraph (1) does not apply to assemblies of the kind described in paragraph (1) which—

- (a) are placed on the market or on or after 29th December 2009; and
- (b) are not intended to be incorporated into or assembled with other products to form a product which falls into one of the descriptions of products specified in Schedule 3.

One trade association expressed some impatience with the apparently vacuous concept of 'almost machinery'. The UK Regulations will need to adopt this concept but it may well be necessary for the Guidance that is being prepared to develop it to some degree or other. Alternatively it is perfectly possible that this aspect of the definition will come to play no practical part in the interpretation of the Directive. This situation will need to be monitored.

Another trade association pointed out that the concept of 'putting into service' had no application to 'partly completed machinery'. BERR acknowledges its error and has removed it from what will now be regulation 5(2)(a) of the Statutory Instrument (see above).

**Question 7: The draft Regulations use the terms “manufacturer” and “authorized representative” as defined in the Directive, but also employ the term “responsible person” in cases where the Directive refers to manufacturers and authorized representatives together. Do you agree with this approach? If not, please provide reasons.**

#### *Responses*

Two representative organisations and one local government organisation explicitly supported the approach taken without qualification but it also attracted some criticism.

The large corporation re-stated under this heading the comment it had made to Question 5. One representative organisation believed that the two sub terms, precisely because they are closely related to each other *but* different in their meanings, should never be brought together under the single umbrella term of 'responsible person'. Another representative organisation believed that the 'responsible person' concept in the draft Regulations failed to cover all of the facets which the same concept covers in the *existing* Regulations (and that this was partly due to a gap in the coverage of Article 5 of 2006/42/EC). Finally, a further representative organisation feared confusion with the way in which 'responsible person' is used in other sets of UK Regulations (e.g. the EMC Regulations).

#### *BERR Comments*

On the issue of whether the term 'responsible person' should be used *at all* in the UK Regulations it should be understood that Question 7 is slightly different in principle from Questions 5 and 6. Existing UK Regulations that transpose New Approach Directives, including the 'Supply of Machinery (Safety) Regulations 1992', typically use the concept of 'responsible person' to denote the body to which the obligations of the Directives apply and which the Directive usually describes as 'manufacturers' or 'authorised representatives'. Apart from the fact that these Directive terms have hitherto not been further defined, it has been the view that 'manufacturer' in particular has a narrow meaning in English, i.e. closely integrated with the production process, and that the rather wider meaning it has under the Directive would not be fully appreciated by users of the UK Regulations unless it were changed in transposition.

The difference brought about by 2006/42/EC is that the two component parts of 'responsible person' are now defined in the Directive (and these definitions have been incorporated, with minor presentational differences, into the draft Regulations). The question therefore arises as to whether the UK term was required any more, given this stronger foundation for the respective meanings of 'manufacturer' and 'authorised representative', and especially that the definition of the former explicitly includes a 'catch-all' provision that extends it beyond its 'traditional' design and production base. BERR has concluded that, on balance, 'responsible person' still has some value as a familiar piece of 'shorthand' drafting for transposing the 40 or so provisions of the Directive which refer to "the manufacturer or his authorised representative" (which in gender neutral drafting would otherwise become "the manufacturer or the manufacturer's authorised representative").

On the question of a potential gap in coverage it is BERR's contention, contrary to what might be thought at first sight, that neither 2006/42/EC nor the draft UK implementing Regulations change the role or duties of the authorised representative. It still remains the case that a manufacturer based outside the EU has the choice of whether to appoint one. However, there *is* a new requirement that a manufacturer based outside the EU must appoint a person based in the EU, to be responsible for providing the technical file to the national authorities if so requested. This person *may* also be an authorised representative, but does not have to be one, and could, for example, be a lawyer or accountant instead – the key point is that such a person does not have to actually *draw up or produce* the technical file, only to be responsible for providing authorities with *access* to it. In other words it is the view of the UK authorities that the concept of *compiling* the technical file as it is used in Annex II part A2 of the Directive does not necessarily mean constructing it from first principles.

On the point about confusion with the EMC Regulations the concept as it used in the machinery context is the mainstream 'New Approach' one that has no application beyond the point of first placing on the market/putting into service. This is true of the existing 'Supply of Machinery (Safety) Regulations' and will remain so in the new set, i.e. the relationship with the EMC Regulations will not change and so the risk of confusion will neither increase nor decrease as a result.

**Question 8: Is it clear in the draft Regulations when, and for what purpose, a manufacturer needs to use the services of a Notified Body? If not, please provide reasons.**

#### *Responses*

Three representative organisations specifically agreed that the situation was clear.

A representative of local government called for an 'or' to be placed between each of the items in the listing of conformity assessment procedures in draft regulation 11(3).

#### *BERR Comments*

Whilst the insertion of an emphatic 'or' is not absolutely necessary in its present context the criticism of regulation 11 was nevertheless considered a reasonable one and also prompted a re-think about its structure (and the structure of regulation 12). The version of these provisions that will appear in the final form of the Regulations will therefore incorporate the 'or', as suggested, and also adopt a slightly altered structure.

**Question 9: Do you think the partial Impact Assessment (IA) accurately reflects the potential benefits from the draft Regulations transposing the new Machinery Directive in the UK? If not, please explain why, providing, if possible, any evidence or data to support your view.**

#### *Responses*

There were four responses to this question, two of which supported the estimates of the potential benefits outlined in the IA, and two of which disagreed with the estimates.

One representative organisation, whilst not questioning the estimates of the level of potential benefits, did question whether these benefits would materialize in the absence of pro-active enforcement action, in particular with reference to non-

compliant lifting equipment. One representative organisation said that the costs in the IA were under-estimates because of the inclusion in the new Machinery Directive of certain risks relating to tractors.

#### *BERR Comments*

Enforcement of the Machinery Directive across the Internal Market is ultimately a European-wide issue. At a general level the UK enforcement bodies play an active role in engaging with enforcement bodies in other Member States to highlight best practices, exchange information, and introduce systems to reduce the level of non-compliant machinery placed on the European market. This enforcement activity is further underpinned by the development, referred to above, of robust European guidance to establish common and clear interpretations of the Directive.

With regard to lifting equipment, the enforcement situation should be significantly improved by the new Machinery Directive. Currently there are problems dealing with equipment that is claimed not to be a 'lift' in the sense of the 'Lifts Directive' but which includes enough of the features of a 'classic lift' that it ought to be governed by the more stringent essential requirements of that Directive rather than by the Machinery Directive. The new Machinery Directive addresses this problem directly, introducing a clear demarcation between the two Directives, and it also has more detailed essential requirements for lifts/lifting equipment that remain in its scope – these changes will enable more effective enforcement to take place.

Concerning tractors the (partial) inclusion under the new Machinery Directive was only, at worst, to be a stop-gap measure for a very limited period. The European Commission has informed us that revision of the Tractors Directive is on timetable. This will mean that by the time the new machinery Directive comes into force Article 2(e) will no longer apply as all risks relating to tractors will be covered by the new Tractors Directive.

**Question 10: Do you think the partial Impact Assessment (IA) accurately reflects the expected costs from the draft Regulations transposing the new Machinery Directive in the UK? If not, please explain why, providing, if possible, any evidence or data to support your view.**

#### *Responses*

There were five responses to this question, three of which supported the estimates of the potential benefits outlined in the IA, and two of which disagreed with the estimates.

One representative organisation questioned the estimates of the potential costs of implementing the new Directive, and said they could be several times higher than those in the IA due to additional requirements for documentation and testing of products.

One representative organisation questioned the cost estimates on the grounds that costs occurred largely as a result of 'cutting corners' or 'work stress' rather than because of the machinery itself.

#### *BERR Comments*

In terms of the costs of additional requirements for documentation and testing of products, there is no requirement to test every product which falls under the new

Machinery Directive. Testing can be undertaken by sampling, for example from production runs. The UK Government will explain in its own Guidance Notes to the new Machinery Directive how testing can best be undertaken to ensure compliance with the new Directive at least cost to businesses.

In relation to documentation, it is not obvious that the new Machinery Directive will require any significant increase in the volume of documentation needed for machinery over and above what is produced currently.

The requirements of the new Directive in relation to lifting machinery and accessories have not changed significantly from the present Directive. To explain this situation extensive guidance on the application of the new Directive is in the process of being produced by the European Commission with input from both Member State industries and national authorities, including from the UK. This Guidance will, in particular, explain that component parts supplied for the manufacture of complete lifting accessories, whose parts cannot be disassembled and used in different configurations, will not be 'lifting accessories' in the terminology of the new Directive but will rather be 'components'. This Guidance will also address the matter of the testing and use of quality control systems for series produced lifting machinery and accessories.

**List of those that responded to the Machinery Consultation Document  
(URN 07/1215)**

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Anne Humberstone	BEAMA
Yvonne Pearman	British Fluid Power Association
Lisa Peters	Trading Stds Partnership (South West)
Michael Skelding	Door and Hardware Federation
John Tredray	British Industrial Truck Association
Dr Gina Barney	Consultant
Iain Lindsay	Rockwell Automation
Derrick Bailes	Lifting Equipment Engineers Association
Keith Hawken	Agricultural Engineers Association
Ian Unwin	Servomex

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