

**EXPLANATORY MEMORANDUM TO
THE SUPPLY OF MACHINERY (SAFETY) (AMENDMENT)
REGULATIONS 2005 (the “Amendment Regulations”)**

2005 No. 831

1. This explanatory memorandum has been prepared by the Department of Trade and Industry and is laid before Parliament by Command of Her Majesty.

2. **Description**
 - 2.1 This instrument has been made to effect further amendments to the Supply of Machinery (Safety) Regulations 1992, as amended, (the “principal Regulations”) which transpose Directives which have been consolidated in Directive 98/37/EC. The Amendment Regulations primarily extend the range of penalties available for offences created by the principal Regulations by introducing liability on conviction on indictment in addition to liability on summary conviction (regulation 2(1)(f) and implement Article 21(1) of Directive 98/79/EC (regulation 2(1)(g)).

 - 2.2 The Amendment Regulations also update the provisions in the principal Regulations to reflect the consolidation of Directives into Directive 98/37/EC with ancillary arrangements (regulation 2(1)(a) and regulation 2(2)), the consolidation of Directive 83/189/EEC into Directive 98/34/EC and also, as regards approved bodies for the purposes of the conformity assessment procedures in the principal Regulations, the possibility of recognition in mutual recognition agreements and similar agreements (regulation 2(1)(c) and (d)). The opportunity has been taken to update references, in the principal Regulations, to enforcement in Northern Ireland (regulation 2(1)(b) and (h)) and correct an error in regulation numbering following an earlier amendment of the principal Regulations (regulation 2(1)(e)). Finally, in regulations 3, 4 and 5, some consequential changes are made to other legislation.

3. **Matters of special interest to the Joint Committee on Statutory Instruments *or* the Select Committee on Statutory Instruments**
 - 3.1 It will be noted that regulation 2(1)(g) implements Article 21(1) of Directive 98/79/EC, the remainder of which has been implemented in S.I. 2002/618. Article 21(1) makes a change to the wording of one of the exclusions to Directive 98/37/EC implemented in Schedule 5 to the principal Regulations (by way of a substituted reference to “medical devices”); that Article does not, however, attribute any meaning to

“medical devices” and an element of elucidation has been provided, in the substituted wording in regulation 2(1)(g), based on the meaning ascribed in Directive 98/79/EC as transposed in S.I. 2002/618. This instrument was identified as being suitable to implement that change but, unfortunately, the progression of this instrument has been delayed which has meant the late implementation of Article 21(1) into the principal Regulations. The Department is not, however, aware of any difficulty caused by that late implementation. Steps will be taken to draw the attention of relevant stakeholders to this amendment in particular by way of publication on the Department’s website relating to the Amendment Regulations.

- 3.2 Attention should also be drawn to the last three lines of the wording of the substitution for regulation 17 of the principal Regulations (as amended). These words were omitted from the principal Regulations at the time of the amendment made by S.I. 1994/2063 but, on further reflection, the Department is of the view that the words should be reinstated to reflect more accurately the requirements of the Directive and for consistency with other Regulations that implement the corresponding provision in other Directives; reference is made to “EEA State” rather than “member State”, at this point, for the reasons set out in the Explanatory Note to S.I. 1994/2063.

4. Legislative Background

4.1 As indicated in paragraph 2, the Amendment Regulations further amend the principal Regulations which implement what is now the consolidated Directive 98/37/EC. The principal Regulations have been amended on one occasion previously in 1994 to implement amendments to the original Directive which has now been consolidated. As in the case of the principal Regulations, the power to make the Amendment Regulations is contained in section 2(2) of the European Communities Act 1972. The Committees’ attention has been drawn to the late implementation of Article 21(1) of Directive 98/79/EC and the explanation in paragraph 3. The reasons for the other further amendments are set out in the Policy background (paragraph 7 below); since these further amendments are not specifically required by the consolidated Directive 98/37/EC, the scrutiny history of that Directive is not relevant for the purposes of the consideration of the Amendment Regulations.

5. Extent

- 5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

- 6.1 Not applicable.

7. Policy background

- 7.1 This instrument effects various amendments to the principal Regulations, some of which regularise and/or update text in the principal Regulations as indicated in paragraph 2.
- 7.2 As regards the amendments made by regulation 2(1)(f) of the Amendment Regulations, following a review of several Regulations which implemented product safety Directives, certain sets of Regulations were identified where it was considered appropriate to increase the range of penalties available for offences under those Regulations, bearing in mind the possible severity of consequences to the health and safety of people and damage to property which might arise in the event of such an offence. Those Regulations included the principal Regulations. Consultation, as regards the proposed increase of the penalties, then took place in 2002 alongside similar proposals concerning other Regulations but without any substantive comments being received.
- 7.3 It is now considered appropriate to progress the amendment to the principal Regulations relating to the increase in range of penalties as well as the other amendments being made. The other amendments being effected by the Amendment Regulations are, in many cases, matters of formality and reflect Community obligations; in that connection, relevant amendments are being made to the Regulations, for which this Department is responsible, which implement product safety Directives as and when a suitable opportunity occurs.

8. Impact

- 8.1 Since it is only Article 21(1) of Directive 98/79/EC which is being implemented, no Transposition Note has been prepared.
- 8.2 The question of a Regulatory Impact Assessment does not arise as the only impact will be on those who are in breach of the principal Regulations. In addition, it is not considered that there will be any additional costs to the Exchequer arising from the Amendment Regulations.

9. Contact

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