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## HEALTH AND SAFETY EXECUTIVE

### Senior Management Team

**BIS (formerly: BERR)<sup>1</sup> proposal for a Statutory Instrument (SI) to give extra enforcement provisions to HSE and other authorities to meet the requirements of the EU Regulation N° 765/2008 on Accreditation and Market Surveillance (RAMS)**

**A Paper by Phil Papard**

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### Issue

1. To enable the UK to apply a new over-arching and direct-acting EU Regulation (Accreditation and Market Surveillance (RAMS)) on market surveillance of products covered by Community harmonisation legislation, HSE inspectors (and other market surveillance authorities (MSAs)) will require additional enforcement powers. BIS has formally offered to take the lead in drafting and enacting a new Statutory Instrument to clarify enforcement arrangements for this Regulation. The SMT is asked to consider the implications and accept the BIS offer.

### Timing

2. For decision at the 29 June SMT meeting to secure subsequent Board approval and allow drafting and clearance of the necessary legislation to proceed to meet the implementation date of 1 January 2010.

### Recommendation

3. To agree to advise the Board to agree to BIS legislating to provide HSE with the necessary powers.

### Background

6. HSE has long enforced legislation concerning the supply of products and substances for use at work. Legal provisions include section 6 of the Health and Safety at Work Act (HSW Act) and the Supply of Machinery

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<sup>1</sup> As a result of the recent Government reshuffle, BIS (Department for Business, Innovation and Skills) has replaced BERR (Department for Business, Enterprise and Regulatory Reform).

(Safety) Regulations 1992, as amended. Other HSE supply legislation includes regulations on the supply of explosives (POMSTER<sup>2</sup>), and DfT-sponsored law on cableways, enforced by HSE (FOD for ski type tows and gondolas/chair lifts and the Mines Inspectorate for rail-mounted cableways (funicular railways)).

7. HSE inspectors enforcing current supply legislation use the provisions of the HSW Act, in particular the general powers of Inspectors and the power to issue Prohibition and Improvement Notices. However, these are limited in scope for dealing with some aspects of a supply regime (e.g. there are no powers to recall products or require them to be withdrawn from the market).
8. The EU is becoming increasingly concerned at the level and disparity of market surveillance between Member States. During the development of RAMS, the UK was successful in maintaining a policy line that market surveillance should remain risk based.
9. HSE work in this area is mainly spread between FOD (both inspector and administrative staff), HID and the Sectors. FOD traditionally expects around 1% of its inspector time to go on reactive and proactive product safety work (which would equate to around 4.3 staff-years in 2009/10). Time on product supply aspects of incident investigations is difficult to distinguish and will vary, but at least five major investigations in 08/09 included very significant product supply elements.
10. Further, under a Service Level Agreement (SLA) with BIS, HSE deployed around a third of a staff year of proactive effort on this work in 2008/09, including engagement at EU Level. Staff costs of £28,500 and travel and subsistence costs of £17,600 were recovered. In addition, HSE supports BIS in taking forward Safeguard Actions against defective work products and Formal Objections to defective Harmonised Standards (currently around 2 to 4 such actions each year).
11. For 2009/10 and beyond, a revised SLA and improved internal tracking will allow us to recover a greater proportion of staff costs, to around £60,000, including testing/examination work with HSL. All proactive work under the SLA must be agreed between HSE and BIS, and the SLA limits this to 1.5 staff years (£122,000 in staff costs). Reactive work (e.g. follow up to incidents and complaints) is part of HSE's normal enforcement remit and is not currently cost recoverable.
12. The new (RAMS) legislation will not of itself result in any additional demand for market surveillance work (although the profile of such work is increasing generally in the EU).

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<sup>2</sup> Placing on the Market and Supervision of Transfer of Explosives Regulations 1993

13. The RAMS Regulation is over-arching and, as a Regulation, directly acting. It was made in July 2008 and is now in force. It mainly deals with:
  - a. accreditation arrangements, including of Notified Bodies;
  - b. market surveillance provision including at the EU Borders; and
  - c. an information system to facilitate these activities.
14. The market surveillance articles of RAMS apply from 1 January 2010 and require arrangements, including enforcement, to be in place for:
  - a. Recall of defective products from end customers
  - b. Withdrawal of defective products from the supply chain
  - c. Destroying of dangerous products or making them inoperative
  - d. Stopping non-conformant products being offered for supply or put into use, together with
  - e. General powers such as right of entry, examining documents, taking samples etc
15. Under RAMS, a product which is unsafe or does not conform to applicable requirements can be withdrawn, restricted or prohibited. If a product presents a “serious risk requiring rapid intervention”, it may be recalled, withdrawn or prohibited.
16. BIS, in its capacity as the UK Competent Authority, has taken the view that, although RAMS could in theory be applied directly in the UK, supporting domestic legislation is necessary:
  - to ensure that the law is comprehensible to the persons to whom it is addressed; and
  - to provide for enforcement powers, remedies for breach and sanctions.
17. Also, certain provisions of RAMS can be interpreted as requiring member states to implement them specifically to ensure that their market surveillance authorities have the powers necessary to fulfil their obligations. HSE Legal Advisers concur with all these views.
18. BIS has formally approached HSE with a proposal to include in their implementing SI provision of powers to enable HSE inspectors to have access to the full range of enforcement tools – i.e. to ensure that HSE has sufficient powers to recall, withdraw, restrict or prohibit products.
19. BIS is approaching other MSAs similarly.

## **Argument**

20. HSE inspectors have hitherto used the provisions in HSWA section 6(1)(d) to require suppliers to inform their customers of risks/defects in

the equipment they have supplied which may give rise to a serious risk to health or safety. With careful drafting of Notices and their Schedules, inspectors have generally successfully obtained satisfactory responses from suppliers to correct serious problems with equipment they have supplied.

21. However, although HSE has usually been able to obtain this outcome to date, it could be open to challenge and is not equivalent to the requirements of RAMS to be able to insist on withdrawal or recall. HSE inspectors also cannot use S.6 where they are unable to prove there is a “serious risk to health or safety” - for example for higher risk products such as safety components for lifts and cableways found not to have the required third-party accreditation, where lack of action by HSE could undermine this system.
22. There is no power to destroy products in our current Supply legislation. HSWA section 20(2)(h) includes a power to destroy an article or make it inoperative but only in the course of examining or testing it and only insofar as is necessary for carrying into effect the relevant statutory provisions. Also the power is limited to where there are grounds for regarding the article as dangerous. Thus more powers for this provision of RAMS seem likely to be needed and this is to be resolved with BIS.
23. Therefore, there are gaps in HSE inspectors’ current enforcement powers when compared to those required by RAMS. (A similar situation affects other MSAs, including MHRA<sup>3</sup>, HSE NI, ORR, NWML<sup>4</sup>, and VCA<sup>5</sup>). There seems to be no way around this. Detailed consideration was given to the possibility of invoking the “lex specialis”<sup>6</sup> given in RAMS, the argument being that the existing product safety Directives contained more specific provisions than RAMS and therefore HSE inspectors would require no new powers. However, it was later accepted that there were real enforcement gaps to be filled by RAMS. Ongoing reliance on only HSWA powers is therefore not considered tenable and new UK legislation is needed to give the additional powers.
24. Taking no, or incomplete, action to fill these legal “gaps” would risk the UK being found to be in contravention of RAMS and so risk infraction proceedings, with the added resource implications of EU Commission scrutiny of HSE’s market surveillance work.
25. Adopting the BIS proposal would help to maintain the good relationship HSE has with BIS, which has been vital on those occasions when HSE has had to take safeguarding action in Europe against defective products and EU Standards. It would also give better transparency to

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<sup>3</sup> Medicines and Healthcare products Regulatory Agency

<sup>4</sup> National Weights and Measures Laboratory

<sup>5</sup> Vehicle Certification Agency

<sup>6</sup> Lex Specialis - the principle that where two or more competing laws apply in the same circumstance, the more specific law (the lex specialis) should apply in place of the more general

the way product safety legislation (of all kinds) is applied in the UK, both to stakeholders and the EU Commission.

## Options

26. Assuming that the “no action” option is considered undesirable, there are essentially two options for providing the necessary powers to HSE inspectors:
  - a. HSE to amend its own legislation to extend inspectors powers, that are given in HSWA and in POMSTER (which is HSE legislation) and possibly also for HSE’s Biocidal Products Regulations and Plant Protection Products Regulations if these are considered by BIS/the Commission to be within scope of RAMS (we are awaiting views from BIS on this).
  - b. To agree to BIS’s suggestion for them to enact a Statutory Instrument to give MSAs, including HSE, these extra powers and for POMSTER, and if needed, Biocidal and Plant Protection Products Regulations to be included in this.

## Discussion of options

27. Virtually all the legislation affected by RAMS is sponsored by BIS who would necessarily be in the lead for amending or adding to their legislation.
28. HSE amending its own legislation separately would require significant resource from legal and policy teams. It could risk placing HSE at the centre of adverse media interest around the issues of “trying to expand our powers at a time of recession” and “more European health and safety burdens”. Similar work would also be needed by BIS and/or the other MSAs to give these powers to all the relevant inspection bodies. Besides the wasteful duplication of effort, this could result in different “Notices” being applicable to the same products and companies. For example the same machine may be enforced under the Machinery Directive by HSE and HSE NI, its environmental noise by VCA; its electromagnetic compatibility by Ofcom, and construction products by DCLG <sup>7</sup>.
29. Whichever route is taken, it is likely to require updated warrants for inspectors, but this could be mitigated by only issuing them in the first instance to the FOD/HID Product Safety Team members, staff doing product safety projects and new inspectors. Other inspectors could then be issued with updates when they are required for other reasons.
30. The advantages of BIS developing the legislation include: coordinated and efficient legislative drafting with less resource input required by HSE, less risk of adverse media interest directed at HSE and the same legislative powers being used across MSAs. This latter advantage also

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<sup>7</sup> Department for Communities and Local Government

could assist in better liaison with Trading Standards on products that are on the boundary between industrial and consumer products (e.g. power tools) and the development of a more flexible legal boundary.

31. No additional product safety work will be generated by the legislative change alone. With new powers, we believe that the risk-based work that HSE takes forward through targeted proactive work and in response to serious incidents will potentially be more efficient, with less need for Inspectors to operate at the limits of their HSWA powers.
32. Following discussions between HSE and DfT policy teams dealing with the Cableways Regulations we understand DfT will ask BIS to include the Cableways Regulations in the RAMS Statutory Instrument, so HSE inspectors can use the same Notices and powers for enforcing this SI.

### **Recommended Option**

33. We respond agreeing to BIS's proposal, and further that POMSTER should be included in the SI conferring the enforcement powers.

### **Consultation**

34. Among those consulted were: Legal Advisers Office (Chris Hales and Caroline Croft); HID (explosives inspectorate); C-CID (David Pascoe re POMSTER); FOD (David Sowerby, Andy Gay and Terry Rose); CRD (Dave Bench); ND (Mike Weightman); HID (Peter Baker and Ian Whewell) and PFPD (Sarabjit Purewal) have been consulted. All supported the option recommended by this paper, with some useful comments on points of detail..
35. Most significant of these comments related to the new powers and the proposed Statutory Corporation for ND. We will discuss this issue with BIS and ND as the work develops to ensure that the amending order accommodates this change. Based on their comments, we will also explore with CRD whether the warrants would be needed for their staff

### **Presentation**

36. If the BIS option is agreed presentational issues will be discussed with BIS and is likely to be done at the UK Industry/stakeholder forum and with a press release. Regarding internal communications, once the legislation is agreed, besides general awareness-raising articles (for instance in FOD Briefing), the Product Safety Teams would be briefed at their annual update seminar. It is suggested that the Board could be informed via the Chief Executive's monthly briefing.

### **Costs, Benefits, Financial/Resource Implications for HSE**

37. No new market surveillance (product safety) work will be instigated by the extension of HSE inspector powers; it is required to demonstrate legal compliance with RAMS and may make existing casework easier to resolve in some cases. However it would be true to say that there is an unknown element in taking on new powers and we do not know the

extent to which the power of recall, for instance, may be used or how it will develop in practice, particularly in an operating environment where increasing attention is being paid (not least by the European Parliament and Commission) to market surveillance issues generally.

38. The training and briefing costs attached to these changes will be absorbed in the pre-existing plans for the ongoing briefing and updating of Product Safety Teams, and the ongoing work to update the HSE product supply web pages and Guide to Manufacture and Supply. These costs will be the same whether HSE or BIS makes the legislation.
39. Our recommended option – that we agree to BIS’s proposal for them to enact a Statutory Instrument to give HSE and other MSAs the extra powers required – is the most efficient solution. This option would result in a time cost in the order of 0.05 Staff years (SY) time at B2, 0.05SY at B3 and 0.01SY at B5, equating to a monetary cost of £9247.72<sup>8</sup>. This work will be covered by the existing resource allocation to this specific workstream by STSU (OPSTD) and LAO in particular and, more generally, the resource allocated to machinery safety and ongoing liaison/co-operation with BIS. No additional work will be required, and no other work will be curtailed to take this forward.
40. The second option, whereby HSE amends its own legislation to extend inspectors’ powers, would have a far more significant resource implication for HSE. This option would require a policy team and a high level of LAO and STSU (OPSTD) input to draft and conduct a full external consultation on the SI. This option would result in a time cost in the order of 0.2SY at B2, 0.05SY at B2 LAO, 0.3 SY at B3 and 0.3 SY at B5, equating to a monetary cost of £62574.85. This would be new work over and above the recommended option, with no existing resource allocation.
41. Already inspectors using HSWA Notices for supply legislation including HSWA s6 have to carefully draft and alter the wording on enforcement Notices, as they are worded to apply mainly to “user” legislation and hence to employers. Having a specialised Notice could make the process less time consuming, the wording being directly applicable. This should also make the drafting of schedules easier, clearer and more transparent to the recipients.
42. New warrants for inspectors would be the main cost attached to this proposal, and would be incurred no matter which option is taken. The powers involved will be mainly used by Product Safety Team members, some Sector/Safety Unit staff and a small number of staff on product safety projects run under the SLA with BIS. This group could number

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<sup>8</sup> Staff costs based on the 2008/2009 PFPD ready reckoner, and subject to a 3.5% inflation to give indicative 2009/2010 values.

approximately 50. Other inspectors' warrants could be changed when they are issued for other reasons.

43. Having consulted with HR on this issue, it has become clear that the unit cost of amending and re-issuing a warrant card is currently not readily available as the costs (editing, photography, printing, admin overheads etc.) are borne across a number of different teams and have not been calculated in this sense. An initial best estimate of the unit cost of amending and replacing a warrant card is between £71.40 and £95.20<sup>9</sup>. The basis for this estimate is an assumption of approximately 1.5 – 2.0 hours of staff time at B5 (admin rate of 47.60 per hour for the 09/10 financial year) to cover all aspects of dealing with a one-off request to edit, generate and deliver a warrant card. This equates to a total cost of between £3750 and £4760 to cover warrant replacement for the initial group of 50 staff. Assuming that the initial group of 50 warrants are done in one go or in batches, it is reasonable to assume that the cost would be towards the lower end of this scale.

### **Environmental implications**

44. None

### **Action**

45. SMT is requested to consider and agree the recommendation at paragraph 3 and seek Board agreement so that we can inform BIS of our position and commence drafting and consultation work with them regarding the precise detail of the legislation and its implementation.

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<sup>9</sup> Staff costs based on the 2008/2009 PFPD ready reckoner, and subject to a 3.5% inflation to give indicative 2009/2010 values.