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HEALTH AND SAFETY COMMISSION

Proposed Biocidal Products (Amendment) Regulations: recommendations following consultation

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Issue

1. To report the outcome of the public consultation on proposals for the Biocidal Products (Amendment) Regulations. The proposed Regulations:
 - address the issues raised by the European Commission in infractions proceedings against the UK on what it considers is defective implementation of the Biocidal Products Directive 98/8/EC (BPD);
 - for certain classes of products, activate the provisions in the Directive;
 - update and correct other references in the existing Regulations;
 - take account of developments since the consultation ended, both with the Directive and with the supporting Commission Regulations, that require further amendment to the existing Regulations

Timing

2. Routine. Approval of the proposed Regulations is needed at this meeting if we are to meet the next common commencement date of 6 April 2007.

Recommendation

3. That the Commission:
 - a) Approve the draft Biocidal Products (Amendment) Regulations 2007 at **Annex 1** for submission to the Minister (NB- the draft is subject to final legal checks);
 - b) Approve the draft covering letter and background note from the Chair to Lord Hunt (**Annex 2**).

Background

4. A Reasoned Opinion from the European Commission acknowledges an earlier undertaking by the UK to amend the parts of the UK legislation transposing articles 7(6), 7(8), 8(5), 8(9), 11 and 22 of the Directive. Two points remain: the absence of an explicit reference to the 10 year transitional derogation period referred to in article 16; and the apparent derogation in the UK legislation from the data protection rules, in particular from the requirements of article 12(1)(c).
5. The Consultative Document (CD) was published in April 2006 to seek views on draft Regulations amending the Biocidal Products Regulations 2001 in order to address the issues raised by the European Commission, as well as dealing with the effects of three Commission Regulations in switching on the provisions in the BPD for certain classes of products and updating or correcting other references in the existing Regulations.
6. The consultation did not attract a high level of interest. 29 replies were received, of which 25 were from companies manufacturing and/or marketing biocidal products and industry associations. Neither TUs nor OGDs raised any issues of substance. A summary and analysis of the responses is at **Annex 3**.
7. The draft regulations on which we consulted extended only to Great Britain (GB). HSE Northern Ireland (NI) has consulted separately and the NI Regulations will follow closely those for GB, both in content and timing. A judgement has been made by the European Court that Directives with a legal base under Article 95, which this is, do not have to be implemented in Gibraltar.

Argument

8. Most of the proposed amendments consulted on are relatively minor and of low impact, which might explain the low response rate. The consultation responses raised two areas of contention:
 - the proposal to align the data protection provisions with the European Commission guidance, which was considered premature as the guidance had no legal standing and had not been agreed by industry; and
 - the financial burden on industry of bringing in the advertising requirements with immediate effect – several responses sought a deferral of this requirement to allow producers and distributors to use current stocks of products, labels and other printed material before complying with the changes. This highlighted a misconception about the scope of the advertising requirement. In response a letter was sent to all responders confirming that the provisions do not extend to product labelling or packaging, which are dealt with separately under regulations 30 and 31.
9. A copy of the CD was sent to the European Commission for information. This prompted a response from DG Environment, which has the lead responsibility for the Directive. It appeared that although they were satisfied the draft Regulations addressed the issues set out in the infraction notice, the latest draft had raised new concerns, i.e. that we had:
 - changed the definition of “existing active substance” so that it varied from the Directive definition;
 - introduced new provisions for provisional authorisations/registration of products that went beyond the Directive; and
 - amended the data protection provisions incorrectly. Although this had been done in line with the Commission guidance, this had no legal status and so was not an appropriate document on which to base legislation and, in any case, was subject to change.

Following a meeting and a subsequent exchange of correspondence between HSE policy and legal staff and DG Environment officials, HSE decided to defer the original implementation date from 1 October 2006 to 6 April 2007 to allow time to resolve these issues.

10. The draft Regulations attached at Annex 1 include amendments to address the issues mentioned in paragraph 8, mainly by changing the definition of “existing active substance” in line with the Directive and by removing several of the problematic amendments for provisional authorisations/registrations and data protection.
11. The revised draft Regulations also introduce a new provision to deal with the approval of “essential use” products that have been provided for in recent amendments to the EC regulations governing the review programme for existing active substances and the biocidal products containing them.
12. We do not consider that further consultation on these points is necessary. They mainly mean the original Regulations stand (something many consultees wanted) and the rest are essential for the correct operation of the biocides regime, leaving us no discretion on how this is achieved.

Consultation

The CD was subject to a consultation period of 12 weeks and was distributed widely, as well as being made available on request and via the Internet.

Presentation

13. The proposals set out in the CD have been amended in the light of our exchanges with DG Environment, in many cases in line with respondees’ comments (e.g. the data protection provisions). It is not, therefore, anticipated that the issue will generate a great deal of further interest. The communications strategy is set out in Annex 5 of HSC/06/20. Briefly, phase 1 supported the publication of the CD, and phase 2 will support the introduction of the amendment regulations. We will use similar methods to communicate as those employed in phase 1, i.e. letters, emails and web news, using the existing extensive stakeholder databases; a press release; articles for journals/magazines. The communications strategy will be evaluated to ensure the target audience has been reached.

Costs and Benefits

14. The position has not altered from that set out in HSC/06/20, other than that the amendment Regulations will bring into the fees and charges regime those applying for ‘essential use’ approvals (where they are not already liable under existing criteria), currently expected to affect fewer than five (5) applicants.

Financial/Resource Implications for HSE

15. As set out in HSC/06/20, i.e. none beyond the normal policy staff costs.

Environmental Implications

16. There are likely to be environmental benefits. Biocidal products may have the potential to cause adverse effects in the environment as a result of exposure through use. The regulatory regime aims to ensure a high level of protection for the environment, with risk management in place where appropriate.

Other Implications

17. None.

Action

18. Chair to write to Lord Hunt with HSC's recommendation.