

**Draft covering letter and background note to Lord Hunt**

**Proposals for the Biocidal Products (Amendment) Regulations 2007**

At its meeting on 5 December, the Health and Safety Commission agreed to recommend to you proposals for the Biocidal Products (Amendment) Regulations 2007. I am now writing to ask you to make the Regulations so that they can come into force on the next common commencement date (6 April 2007).

Many of the changes introduced by the amending Regulations arise from the need to address the issues raised by the European Commission in an Article 226 Reasoned Opinion on what it considers to be defective implementation of the Directive, which is transposed in Great Britain by the Biocidal Products Regulations 2001, and in NI by the Biocidal Products Regulations (Northern Ireland) 2001. Should you agree to make the Regulations, a response will be sent to the European Commission indicating that we will have addressed the outstanding issues by 6 April 2007.

Other changes introduced by the amending Regulations will:

- for certain classes of products, activate the provisions in the Directive;
- update and correct other references in the existing Regulations;
- take account of developments with the Directive and the Commission Regulations arising since the consultation ended that require further amendment to the existing Regulations.

I attach a background note summarising the main changes introduced by the amending Regulations (**Annex A**). The draft Regulations are at **Annex B**. They apply only to Great Britain. Northern Ireland (NI) is carrying out its own consultation based closely on the GB exercise and will be making separate Regulations. 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.

BILL CALLAGHAN  
Chair, Health and Safety Commission

## Background Note

### Introduction

1. In April 2006 the Health and Safety Commission (HSC) published widely a Consultative Document (CD) on proposed revisions to the Biocidal Products Regulations 2001. The CD set out our plans to fulfil the commitments made in a holding reply to an Article 226 Reasoned Opinion to complete implementation of the Biocidal Products Directive 98/8EC, to bring about other changes necessary to comply with an EC Review Regulation and to make some other minor corrections. These changes were to be brought about via the Biocidal Products (Amendment) Regulations 2006.

2. The consultation did not attract a high level of interest, with 29 replies 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.

### Draft Regulations – main changes and consultation responses

3. Most of the proposed amendments consulted on are relatively minor and of low impact, but the consultation responses raised two issues:

- 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 the European industry group; 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.

5. 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.

6. Following a meeting and a subsequent exchange of correspondence between HSE and DG Environment, HSE decided to defer the original proposed implementation date from 1 October 2006 to 6 April 2007 to allow time to resolve these issues.
7. The draft Regulations attached at Annex B include amendments to address these issues, mainly by changing the definition of “existing active substance” in line with the Directive and removing several of the problematic amendments for provisional authorisations/registrations and data protection.
8. The draft also introduces a new provision to deal with the approval of “essential use” products that have been brought about by recent amendments to the EC Regulations governing the review programme for existing active substances and the biocidal products containing them.
9. 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.