HSC/05/86 **ANNEX 2**

To: Lord Hunt
PUS (Lords) cc: [list]

From: Stuart Smith
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Policy Group/Disease Reduction Division

Date: [date]

PROPOSED BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2005

SUMMARY

The Biocidal Products Directive 98/8/EC establishes an EU system for the approval of non-agricultural pesticides, disinfectants and preservatives. It requires that member states recover their costs from the industry. In the UK legislation implementing this requirement some of the people who should be contributing to those costs have been accidentally left out. The draft amending regulations accompanying this submission correct the defect.

Issue

1. A proposal from the Health and Safety Commission (Chairman's letter: annex ...) that the Biocidal Products Regulations 2001 and the Biocidal Products Regulations (Northern Ireland) 2001 should be amended, to correct an error in the arrangements under which an annual levy is imposed on the industry.

Recommendation

2. That you approve the amending regulations.

Timing

3. Routine

Background

4. The Biocidal Products Regulations transpose the Biocidal Products Directive 98/8/EC. They prohibit the supply of a biocidal product (broadly speaking, a non-agricultural pesticide, disinfectant or preservative) unless it has been authorised. Authorisation is in two stages. First, active substances are assessed and included on a central list at Community level.Then, products containing listed active substances are authorised by member states.

5. The Directive requires that member states recover the costs they incur in operating the authorisation system. The Regulations implement that requirement by setting up a two-component charging system. Individual fees are charged to applicants for the work done in processing their active substance or product dossiers. The balance of costs is covered by means of an annual general industry levy. Two groups of people should be liable to pay the levy now: those supplying biocidal products and those supporting active substances for inclusion on the Community list.

6. There are transitional provisions under which existing products will be gradually brought into the new system. The Regulations do not immediately apply to products containing existing active substances, but are switched on for products containing a particular active substance when it has been reviewed. This temporary disapplication should have affected only the authorisation procedure, but it has been inadvertently allowed to cover the part of the Regulations that makes product suppliers (though not active substance supporters) liable to pay the levy. Contrary to what was intended they are therefore *not* liable to pay it during the transitional period.

7. The proposed amendment of the Regulations remedies the defect.

Argument and legal issues

8. The cost-recovery provisions of the Directive will be incompletely transposed as long as the present state of affairs persists. Retrospective amendment of the Regulations – so that the intended charging regime would be deemed to have existed all along – is not feasible. It would require primary legisation, as the Regulations are made under the European Communities Act (ECA) which does not permit such a step. It would be legally challengable on the grounds that it would be an attempt to subvert the purposes of the ECA in order to remedy our own mistake.

9. The people in the excluded group paid the levy for the year 2003-4. There were 391 of them and each paid £301. The error means that that money was taken unlawfully and it has been repaid. They cannot be charged for 2004-5, but can be charged for the 2005-6 provided that the correcting amendment comes into force during that year.

10. The levy provisions were inserted into the Regulations by amendment in 2003. They were set up UK-wide by simultaneously altering the principal regulations for both Great Britain and Northern Ireland, making use of the authority conferred on the Secretary of State as designated Minister for the purpose of section 2(2) of the ECA. The designated Northern Ireland Department (DETINI), and both the Northern Ireland and Scotland competent authorities (Scotland being separate within Great Britain for this purpose), wish the present amendment to be dealt with in the same way. The draft regulations do so.

Consultation and communication

11. Formal external consultation is not called for, as the proposal merely establishes the charging regime extensively consulted on during the preparation of the 2001 Regulations and 2003 amendment, and indeed assumed by everyone to exist until now. Besides, we have no option but to make the correction if we are not to remain in breach of the Directive.

12. People in the excluded group have been told direct about the proposal, in the course of having their money returned (see para.9 above). The remainder of the biocidal products industry has been informed by way of a widely-distributed factsheet

produced by HSE. More detailed and technical consultation with the industry takes place in a standing Charging Review Group set up for the purpose.

13. Other government departments (at official level) and the devolved administrations are content. Para.10 above deals with the special status of Northern Ireland and Scotland.

Costs and benefits

14. There are no significant costs associated with this proposal in itself. In putting in place the intended charging regime it provides for the annual transfer of the missing part of the levy from suppliers of biocidal products to the government, and achieves compliance with the charging provisions of the Directive.

15. The regulatory impact assessment prepared for the 2003 amendment to the Regulations is still applicable. A supplementary one has been prepared for the present proposal. Both are attached to the draft explanatory memorandum at annex ....

Commencement

16. The amending regulations should come into force as soon as possible, and in any case during 2005-6, so that full cost recovery can begin.

Clearance

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