

## **SUPPLEMENTARY REGULATORY IMPACT ASSESSMENT**

### **BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2005**

#### **STATUS**

1. Full. But note: (i) this RIA is supplementary to the one prepared for the Biocidal Products (Amendment) Regulations 2003, signed on 26 February 2003 (attached); (ii) no additional external consultation is proposed.

#### **PURPOSE AND INTENDED EFFECT**

##### **Issue**

##### *Summary*

2. The proposed amendment is to correct a defect in the scheme under which we impose an annual levy on the biocides industry. Some of the people who should be liable to pay the levy have inadvertently been exempted from it. As a result we have taken money unlawfully from the excluded group for 2003-4, and we are currently unable to charge them at all.

##### *Background*

3. The Biocidal Products Regulations 2001 and the Biocidal Products Regulations (Northern Ireland) 2001 (as amended) transpose the Biocidal Products Directive 98/8/EC. They set up a product approval system for (broadly speaking) non-agricultural pesticides, disinfectants and preservatives. Approval under the new system 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.

4. There are transitional provisions in the Directive and Regulations under which existing products are gradually assimilated into the new regime. They establish a review programme for active substances lasting until 2010. The Regulations deal with this by disapplying themselves in respect of products containing existing active substances, and switching themselves on again for products containing a particular active substance when that active substance has been reviewed.

5. The Directive (art.25) requires that member states recover the costs they incur in operating the procedures it creates. The Regulations implement this 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 a general industry levy, called the 'General Industry Charge' (GIC). The original 2001 regulations contained arrangements for fees. The GIC provisions were added by the Biocidal Products (Amendment) Regulations 2003, which covered both Great Britain and Northern Ireland.

6. The GIC is charged at a flat rate in arrears. We intended that two groups of people should be liable to pay the GIC immediately: people supplying biocidal products and those supporting active substances in the review programme.

#### *The problem*

7. The disapplication referred to at para.4 above has been inadvertently allowed to cover the part of the Regulations that makes product suppliers (*not* active substance supporters) liable to pay the GIC. Contrary to what was intended they are therefore *not* liable to pay it. Not having intended or noticed this we have charged them for the year 2003-4. There were 391 of them and we have charged each £301.54, making a total of £117,902. We have had to decide what to do with this money and what to do about charging for 2004-5 and beyond.

#### **Objective**

8. The proposed amendment corrects the error and instates the charging regime that was intended and believed to exist from the coming into force of the 2003 amendment.

#### **Risk assessment**

9. The proposal addresses the twofold risk of legal challenge: from the European Commission for incomplete transposition of the Directive and domestically for an inequitable charging regime.

#### **OPTIONS**

10. As regards the defect in the regulations, there are three options. Each has implications for the handling of the money taken from the excluded group for 2003-4:

(i) leave it as it is. This would be a breach of Community law, as we should have failed to fully transpose art.25 of the Directive. Within the UK charges under the GIC would fall only on some of those who should be paying them, which would be grossly unfair and legally challengeable. The advice of both Cabinet Office and HSE lawyers is that the money taken from the excluded group for 2003-4 would have to be repaid. It was taken unlawfully and to retain it would constitute maladministration;

(ii) amend the regulations retrospectively, so that the intended charging regime would in effect have been in place from the beginning. The money collected so far could be retained. But the amendment would have to be done by means of primary legislation, as s.2.2 of the European Communities Act, under which the regulations were made, does not permit retrospective legislation. DWP and not HSE would have to take on the task. It would take a long time, during which we should continue to be in breach of the Directive, and be correspondingly costly. There is a high probability of legal challenge on the grounds that it would be an attempt to subvert the intentions of the ECA in order to remedy our own mistake;

(iii) amend the regulations as proposed, so that the GIC can be charged to the excluded group as soon as possible. As for option (i) above, the money taken so far would be refunded.

11. Option (iii) is the only realistic one. The amount of uncollected levy is much too small to justify attempting option (ii).

## **EQUITY AND FAIRNESS**

12. See above. Uncorrected, the charging regime would unfairly burden people who support active substances in the review programme.

## **COSTS AND BENEFITS**

13. The costs and benefits of the charging regime as it should be were considered in the 2003 RIA. The following section assesses only the costs and benefits for the chosen option (iii) of the present proposal. *It is of critical importance to note that all costs and benefits estimated are transfers between biocidal suppliers and the government, which therefore cannot be aggregated.*

### **Assumptions**

14. Costs and benefits are estimated at 2004 prices. In arriving at present value figures, two assumptions are made. First, earnings are assumed to rise by 1.8% a year in real terms, which is equal to the observed increase for the whole economy over the past 25 years or so. Second, costs are discounted to present value using the Treasury-recommended 3.5% discount rate.

### **Sectors and groups affected**

15. The amendment will affect people supplying biocidal products in the UK (391 suppliers) and HSE.

### **Benefits**

16. In accordance with para.10 above, suppliers of biocidal products have been repaid the charge collected for 2003-4. 391 suppliers were charged £301.54 each. As noted at para.7 this represents benefits of around £118,000 transferred to suppliers.

17. Suppliers of biocidal products will also benefit from the delay in putting the new charging regime in place. It is assumed that the correction will come into force halfway through 2005-6. Suppliers will in that case be chargeable for the whole of 2005-6 but will be relieved of the charge for 2004-5. This will transfer cost savings of around around £116,000 in present value terms to the industry.

## **Costs**

18. The costs of the present proposal represent the uncollected levy for 2003-04 and 2004-05 and will be born by HSE. Total costs to HSE transferred to biocidal suppliers are around £234,000 in present value terms.

## **IMPACT ON SMALL FIRMS**

19. The 2003 RIA noted the significant proportion of small businesses in the biocidal products market, and that the sums charged under the GIC are small relative to the costs of data acquisition, dossier preparation and evaluation fees under the authorisation regime established by the Directive. The sums involved in the correction now proposed are correspondingly small (about £300 for each full year in question), though clearly, because they are charged at a flat rate, are more or less significant depending on the size of the recipient company.

## **COMPETITION**

20. The GIC affects two different markets: the one for biocidal product supply and the one for active substances supported under the EU approval system. There is no significant invidiousness in having a period during which some people are charged and not others, because the two groups – product suppliers and active substance supporters – are for the most part not in competition with each other.

21. The amendment is unlikely to have any adverse effect on competition for the market of biocidal product suppliers. The market is not characterized by rapid technological change. The new proposal will not affect some suppliers substantially more than others. The amendment should not have any impact on the market structure. It also does not lead to higher set-up costs or higher recurring costs for new entrants on the market. Moreover the changes are unlikely to restrict the ability of firms to make choices on the market. There are no issues of market concentration.

## **COMPLIANCE, MONITORING AND EVALUATION**

22. As set out in the 2003 RIA.

## **CONSULTATION**

23. The charging regime as it was intended to be was fully consulted upon during the preparation of the 2001 Regulations and the 2003 amendment. A summary of responses to the 2003 GIC proposals accompanies the 2003 RIA. Our legal advice is that it is unnecessary to consult formally on the present proposed correction because it merely institutes the state of affairs already considered and assumed by everyone to exist, and is in any case obligatory to comply with Community law. The biocidal products industry is being informed through normal channels of communication and consultation.

## **IMPLEMENTATION AND DELIVERY PLAN**

24. The charging regime will simply continue to be operated as it has been, but with product suppliers now legitimately included.

## **SUMMARY AND RECOMMENDATION**

25. The Biocidal Products Regulations must be corrected to comply with EU law. We recommend that this is done by a simple amendment under the European Communities Act to come into force as soon as possible. Charges levied unlawfully under the uncorrected regulations have been refunded and that arrangement should stand. It entails a transfer of approximately £118,000 to suppliers of biocidal products. The total cost to the Government of uncollected levy will be approximately £234,000 in present value terms.

## **MINISTERIAL DECLARATION**

I have read the Regulatory Impact Assessment and am satisfied that the benefits justify the costs.

Signed by the responsible Minister:

Date:

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19 May 2005