EXPLANATORY MEMORANDUM TO

THE
BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2005

2005 No. 2451

1. This explanatory memorandum has been prepared by the Health and Safety Executive and is laid before Parliament by Command of Her Majesty.

2. Description

2.1. The instrument corrects a defect in the scheme under which an annual levy is charged to the biocides industry. Suppliers of products currently on the market should have been made liable to pay the levy, but they were inadvertently excluded.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None.

4. Legislative background

4.1. The Biocidal Products Regulations 2001 and the Biocidal Products Regulations (Northern Ireland) Regulations 2001, as amended by the Biocidal Products (Amendment) Regulations 2003, transpose the Biocidal Products Directive 98/8/EC. They set up a product approval system for non-agricultural pesticides, disinfectants and preservatives. Once a product is brought within the framework of the new legislation it will be illegal to market it unless it has been authorised.

4.2. Authorisation 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.

4.3. There are transitional provisions in the Directive and Regulations under which existing products are gradually assimilated into the new regime. The active substances used in them are to be reviewed in a programme 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 and accepted.

4.4. The Directive (article 25) requires that member states recover the costs they incur in operating the system. 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). In accordance with the Directive it was 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.

4.5. The disapplication referred to at para.4.3 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. Transposition of article 25 of the Directive is incomplete while this state of affairs persists.

4.6. The Transposition Note for the 2003 Regulations, which introduced the charging provisions now being corrected, is attached to this memorandum at annex 1.

5. Extent

5.1. This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

7.1. The two-component charging regime which will be completed by this instrument was fully consulted on when the 2001 and 2003 regulations were introduced. It mirrors the one operated in the UK since the mid-80s, under the Food and Environment Protection Act (and NI equivalent). Until the error now being corrected was spotted it was assumed by both regulators and duty-holders that the intended scheme was in fact in place.

7.2. There are about 390 people in the excluded group and the annual levy they were meant to pay is currently about £300. The policy significance of the proposed amendment is that: (i) the Directive is incompletely transposed until it comes into force; and (ii) the system is invidious as it is because some of the people who should be liable to pay the levy are being charged and some are not.

7.3. Because the amendment corrects an error in the scheme set up by the 2003 regulations, the new SI containing the correction will be issued free to those who bought the earlier one (2003 No.429).

8. Impact

8.1. A Regulatory Impact Assessment (consisting of the Regulatory Impact Assessment prepared for the 2003 Regulations and a supplement to it) is attached to this memorandum at annexes 2 and 3.

8.2. The impact on the Public Sector is nil.

9. Contact

Stuart Smith
Health and Safety Executive
020 7717 6298
stuart.smith@hse.gsi.gov.uk

Annex 1 (of ex memo)

TRANSPOSITION NOTE FOR ARTICLE 25 OF THE BIOCIDAL PRODUCTS DIRECTIVE, IMPLEMENTED BY THE BIOCIDAL PRODUCTS REGULATIONS 2001; THE BIOCIDAL PRODUCTS REGULATIONS (NORTHERN IRELAND) 2001; AND THE BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2003

DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market		
Main elements of the Directive		
Article		**Transposed by**
25	Requires Member States to put into place systems by which they may seek full recovery of the cost of operating the biocides regime established by the Directive	As regards Great Britain: Regulation 3 and Schedule 1* As regards Northern Ireland: Regulation 4 and Schedule 2**

* These provisions complete the implementation as regards Great Britain of Article 25, and begun by Regulation 39 and Schedule 12 of the Biocidal Products Regulations 2001

** These provisions complete the implementation as regards Northern Ireland of Article 25, and begun by Regulation 39 and Schedule 11 of the Biocidal Products Regulations (Northern Ireland) 2001

Annex 2 (of ex memo)

BIOCIDAL PRODUCTS REGULATIONS: GENERAL INDUSTRY CHARGE REGULATORY IMPACT ASSESSMENT FOR 2003 AMENDMENT

Title of the regulatory proposal

1. This regulatory impact assessment (RIA) covers the introduction of a General Industry Charge (GIC) associated with the implementation of the Biocidal Products Directive(**1**) (BPD). It supplements the RIA already produced for the Biocidal Products Regulations 2001(**2**)(BPR) and the Biocidal Products Regulations (Northern Ireland) 2001(**3**)(BPRNI).

Purpose and intended effect of the proposal

2. The BPR and the BPRNI implement BPD in the United Kingdom. This is an Article 95 Directive and establishes a European Union (EU) wide authorisation scheme for placing biocidal products on the market. Broadly speaking 'biocidal products' are non-agricultural pesticides, disinfectants and preservatives. The regime established by the legislation operates at two levels. Active substances for use in biocidal products must be entered on a list maintained at Community level (Annex I of BPD). The products themselves must be authorised at Member State level. Both active substance entries and product authorisation are granted only after risk assessment on the basis of a substantial data package submitted by the applicant. There are mutual recognition provisions to ensure that a product authorised in one member state may not be excluded from others without good reason.

3. Under a 10 year programme established by a series of European Commission Review Regulations biocidal products already on the market will gradually be brought within the new regulatory framework. In the UK the new system will gradually supersede the existing one based on the Food and Environment Protection Act 1985 and the Control of Pesticides Regulations 1986 (and Northern Ireland equivalents.)

4. It is planned that Ministers in England and Wales, Scotland and Northern Ireland will delegate most of their functions under the Regulations to the Health and Safety Commission (HSC) and thence to the Health and Safety Executive (HSE).

5. Article 25 of BPD requires "Member States [to] establish systems obliging those having placed or seeking to place biocidal products on the market and those supporting entries for active substances onto Annex I to pay charges, corresponding as far as possible to their costs in carrying out all the different procedures associated with the provisions of this Directive". "Their costs" refers to the costs of the Member State Competent Authority. "Those supporting" Annex I entries include applicants seeking inclusion of new active

---

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.
2 SI 2001 No 880.
3 SR 2001 No 422

substances and those who have undertaken to provide the required information on existing active substances under the review programme.

6. The UK has partly implemented Article 25 by establishing a system of fees under schedule 13 of BPR and schedule 11 of BPRNI. However there are some ongoing costs, associated with running the system as a whole, that cannot be attributed fairly and once and for all to application-specific fees. Ministers agreed when BPR and BPRNI were introduced that recovery of these general costs would be by way of a 'General Industry Charge' (GIC). The arrangement of application-specific fees supplemented by a general levy mirrors the one currently used under domestic pesticide approval legislation. The GIC is intended to recover the costs of:

   a) monitoring the effects of biocides;
   b) research directly related to the authorisation of biocides;
   c) UK input into the EU level work of other Member States;
   d) establishing and maintaining the technical competence of the people who will carry out the assessments as required by BPD;
   e) providing information to applicants and dutyholders under the regulations; and
   f) maintaining an authorisation system and procedures that are efficient and operate well.

   The amending Regulations will enable HSE to collect a single charge from each liable person within the UK, whether the product is first placed on the market in England, Wales, Scotland or Northern Ireland or a combination of those.

Risk Assessment

Options

7. Article 25 requires that the UK government recovers the costs referred to in Article 25 in full. Failure to do so would result in:

   a) possible infraction proceedings for failure to transpose the BPD fully;
   b) a financial burden on the UK government to the extent that Competent Authority costs were not recovered;
   c) incomplete harmonisation of the Community market.

8. HSE considers that there are three possible ways of charging the GIC. These are based on:
   a) turnover on biocidal products;
   b) a fixed charge per company; or
   c) a fixed charge per product.

   HSE also considers that, as the chargeable work is largely related to permission to place a product on the market, the charge should be paid by those first placing biocidal products on the UK market (regardless of any

subsequent supply chain) and those supporting entries for active substances onto Annex I.

Information sources and background assumptions

9. HSC held a public consultation exercise on these 3 options in summer 2000(**4**) (see Appendix 1). Further information was sought from industry in late 2000. The compliance costs have been estimated from information received from these consultations. They measure the additional costs to Industry of preparing to comply with the GIC together with the annual costs of compliance, but not the GIC itself (which represents operational and administrative Competent Authority costs transferred to the industry. The GIC itself was considered in the regulatory impact assessment (RIA) for the principal Regulations.

10. The total costs to a company comprise (i) the above compliance costs and (ii) the annual GIC itself. At the time of the public consultation in summer 2000 the total costs likely to be attributed to the GIC, and paid by the industry as a whole, increased from £400,000 in 2001/2 to plateau at £700,000 in 2003/4 and beyond. From these figures it was estimated that each company would contribute from £330 (2001/2) to £580 (2003/4) with a per company option and from 0.13%-0.20% (2001/2) to 0.23%-0.29% (2003/4) of turnover with a turnover option. Current estimates, given that the implementation of the regime in the EU is progressing more slowly than anticipated, are that the GIC will be around £400,000 per year for the first few years from 2003/4.

11. A total of forty-five replies were received to the Commission's Consultative Document. Twenty-five respondents stated that they would prefer a flat rate charge per company. One respondent stated a preference for a tiered charge per company depending on the size of the company. Thirteen respondents preferred the turnover option. Six respondents made no comment on which charging option they preferred. Of the eight companies identifiable as small or medium-sized, three ($1 < 15$, $1 < 30$ and $1 < 60$ employees) preferred a flat rate per company and three ($2 < 2$ and $1 < 50$ employees) preferred the turnover option.

12. Unless otherwise stated, all cost data are in 2000/01 prices. Since the costs are essentially staff time, costs over 10 years are uprated by 1.8 per cent per year to allow for real increases in earnings. These projected costs are then discounted using the Treasury recommended discount rate of 3.5 per cent.

Benefits and costs

Benefits

13. There are benefits:

    a) In having a properly funded authorisation system for biocides in the UK so that it can discharge the functions listed in paragraph 4 efficiently; and

4 Consultation on options for charging the general industry charge (GIC) to enable the Health and Safety Executive to recover costs of activities under the Biocidal products Regulations 2000, CD 162. HSE Books, 2000.

b) In that costs are met by those first placing biocidal products on the market and supporting entries of active substances onto Annex I of BPD rather than by the taxpayer.

Costs

14. We assume that there are no or minimal additional compliance costs to that part of the industry currently regulated under the Control of Pesticides Regulations (CoPR), as the effort devoted to the existing system can be transferred to the new . However, adopting a per company option will result in companies with a low turnover paying more under the GIC than they do under the CoPR levy. Companies with a high turnover will pay less. From information gathered in an HSE in-house research project we estimate that there are 1000 companies that will be subject to the new charging regime that were not subject to the current CoPR regime, and that 200 of these are 'large' (turnover greater than £1M) and 800 'small' or 'medium-sized'.

Option 1 - Per Company Option

15. For this option, a company, in the first year, is required to inform HSE of its name and address, the name of the person to whom payment requests should be sent and whether they are supplying products to the market or supporting active substances for entry onto Annex I. In subsequent years it will only be necessary to inform HSE if the existing entry is incorrect and to provide the correct information.

Costs to Industry

16. As an average we assume that both large and small and medium-sized companies need 1 hour manager time (£48/h) to establish the system in the first year and insignificant time to complete the annual return form.

First year

17. The cost in the first year is £48 per company. This gives a total cost in the first year of £48,000 (£9,600 for large and £38,400 for small and medium-sized companies).

Subsequent years

18. Recurrent costs are considered to be insignificant.

Costs to HSE

19. We estimate that 20 days administrative staff time(**5**), at an average cost of £120 per day, is needed in the first year to establish the procedures and database and 110 days annually to collect the relevant information, prepare

5 Assumes the majority of time is spent by clerical and junior executive grades (job bands 5 and 6 with some time allowed by a more senior executive grade (job band 3). The midpoints of HSE's pay ranges for administrative staff at these bands were used, plus an allowance of an additional 30% in non-wage labour costs. The daily cost of these staff was calculated by dividing their annual pay by the number of working days in a year (220).

and issue invoices, record payment and handle queries. It should be noted that this will ultimately be paid by industry through the charge.

First year

20. The costs are £15548.

Subsequent years

21. The costs are £13200 per year.

22. The total implementation and compliance costs over ten years for Option 1 are about £166804 in present value terms. Rounded undiscounted annual costs are shown in Table 1 below.

Table 1: per company option, year-on-year implementation and compliance costs (industry and HSE)

Year	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13
Cost (£)	64,000	13,000	14,000	14,000	14,000	14,000	15,000	15,000	15,000	15,000

Option 2 - Turnover Option

23. For this option, in the first year, it is necessary for a company to ensure that they have, or they establish, systems to identify the active substances and/or products that are placed on the market for biocidal purposes and to record the turnover for each. At the end of each year it will be necessary to determine the total turnover on all biocidal products and active substances that are supplied for use in biocidal products and to provide this information to HSE. It is important to note that as active substances may have uses other than as active substances of biocidal products such information may be very difficult to obtain for some companies.

Costs to Industry

24. As an average we assume that a large company needs 2 days manager time (£350/day) to establish the system in the first year and 0.5 days accountant time (£168/day(**6**)) each year to produce the annual turnover figures. Averages are high because of the need in multi-product companies to differentiate between products that are within the scope of the legislation and those that are not, and where products have multiple applications, to partition the turnover accordingly.

25. For a small or medium-sized company the assumptions are 0.5 days manager time in the first year and 1 hours accountant time (£21/h)(**7**) annually.

6 New Earnings Survey 2001 average hourly wage for a chartered/certified accountant is £16.14 x 1.3 (non-wage labour costs) x 8 (hours in working day) = £168.

7 Again, it is assumed that the accounting work required is straightforward, and a chartered accountant is sufficient. 168 / 8 = £21.

First year

26. The cost in the first year is £784 for a large company and £196 for a small or medium-sized company. This gives a total cost in the first year of £313,600 (£156,800 for large and £156,800 for small and medium-sized companies).

Subsequent years

27. Annual costs are £84 for a large company and £21 for a small or medium-sized company. This is £33,600 in total (£16,800 for large and £16,800 for small and medium-sized companies).

Costs to HSE

28. We estimate that 20 days administrative staff time, at an average cost of £120 per day, is needed in the first year to establish the procedures and database and 160 days annually to collect the relevant information, prepare and issue invoices, record payment and handle queries. It should be noted that this will ultimately be paid by industry through the charge.

First year

29. The costs are £21,528.

Subsequent years

30. The recurrent costs are £19,200 per year.

31. The total costs over ten years for Option 2 are about £1.1 million in present value terms. These are all implementation costs. Rounded undiscounted annual costs are shown in Table 2 below.

Table 2: turnover option, year-on-year implementation and compliance costs (industry and HSE)

Year	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13
Cost (£)	335,000	54,000	55,000	56,000	57,000	58,000	59,000	60,000	61,000	62,000

Other options

32. A tiered 'per company' option was considered. The intention of this option would be to reduce the annual GIC for small and medium-sized companies. This option was discounted because of the difficulty in defining (and policing) a 'small' and 'medium-sized' company with respect to the supply of biocidal products. Companies would have to produce the evidence necessary to demonstrate that they were 'small' or 'medium-sized'. HSE would have additional costs in using the information to determine the number of companies in each tier and in calculating the GIC for each. Consequently, the

costs (estimated as up to £2650 in the first year and up to £1325 annually) of this option to both industry and HSE would be greater than for the fixed 'per company' option. Overall, it was considered that these extra costs would be such that any saving in the annual GIC (given its likely low level, see para 10) to small and medium-sized companies in both the first year and annually would be insignificant.

33. A 'per product/per active substance' option was also considered. In this option a company would pay a GIC based on the number of biocidal products/active substances they supplied. This option was also discounted. It was calculated to be more costly to industry and HSE than the 'per company' option, both to establish and in recurrent costs. Initial and recurrent costs were shown to be intermediate between the per company and turnover options. Also, on consultation virtually no respondents favoured this as a way forward.

Conclusion

34. Both in the first year and for recurrent costs, the 'per company' option presents the lowest additional administrative cost over that already incurred through the pesticides levy. It is also easier to understand and to implement. This is our preferred option. However, the total cost to industry will also include the actual annual GIC (see para 10).

Impact on Small Businesses

35. A substantial proportion of suppliers of biocidal products and supporters of entries onto Annex I are small businesses.

36. The total cost of the GIC to a company is made up of two components, these being:

    a) the company's costs in producing the information necessary to comply and in making the annual payment ("compliance costs"); and
    b) the actual annual GIC.

37. With a turnover option, for each small company, the annual compliance costs are likely to be fixed, ie not dependent on turnover (in contrast to the GIC itself). The actual GIC will be low and, if it falls below a particular amount, it may become uneconomic to collect. For most small companies, their GIC may be below this economic minimum. However, they will still incur compliance costs (£196 in the first year and £21 thereafter, per small company). These represent a significant proportion of the total costs to small companies and will be their total costs if the GIC is below the economic minimum.

38. With the per company option the compliance costs are lower (£48 in the first year, insignificant thereafter, per small company) than for the turnover option. However, the GIC is still charged, irrespective of turnover and there will be no minimum that is economic to collect. Consequently, all small companies will pay the GIC. The compliance costs will represent a smaller proportion (13% in

the first year, insignificant thereafter) of their total costs than with the turnover option.

39. Whilst the compliance costs are lower, the total costs (compliance and actual GIC – adding up to £380 in the first year, £580 thereafter) to a small company of the per company option will be greater than for the turnover option. Assuming levy rates as set out in see para 10, and it being uneconomic to collect less than £25, the cut-off under the turnover option would be at a turnover of about £17,000. The total costs for firms close to the margin would be in the region of £140 in the first year and £270 in future years. It is estimated that 30-35% of companies supplying non-agricultural pesticides under the current national regime have a turnover below the cut-off figure.

40. Some small companies, having a very low turnover on biocidal products, could find it uneconomic to supply these products if a per company option were introduced and this were the only cost imposed on them by the new regime. Withdrawing these products from the market could have a significant adverse effect on the viability of individual businesses if they trade in these products alone. However, it should be noted that the data and registration requirements for products are high. Costs, presented in the RIA for the BPR, indicated that, on average, it would cost £78,000 (1998/99 prices) to provide data on each product. This very large disparity means that the marginal effect of the GIC will be insignificant. Low turnover products for which the GIC, other things being equal, would determine their future, will inevitably be withdrawn anyway, and for them the choice of charging basis will unfortunately become immaterial.

Balance of Costs and Benefits

41. The ten year present value costs for option 1 are estimated to be approximately £167,000. The ten year present value costs for option 2 are estimated to be approximately £1.1 million. It has not been possible to quantify in monetary terms any of the potential benefits, largely cost savings, which may be associated with the proposal.

42. However, as noted above, for most SMEs their GIC, based on a turnover option, may be below the economic minimum whereby it is unfeasible to collect. Yet, they will still incur compliance costs, which are considered to represent a significant proportion of the total costs to small and medium-sized companies and will be their total costs if the GIC is below the economic minimum.

Uncertainties

43. There are uncertainties in the cost estimates as it is not known exactly how many companies will be subject to the new charging regime that were not subject to the current CoPR regime. Also, there is uncertainty about the level of costs that will need to be recovered through the GIC and the number of firms with low turnover, affecting the feasibility of collecting the GIC under the turnover option.

Effects on Competition

44. The competition filter was used to assess whether the introduction of a GIC may affect competition.

45. This RIA considers the compliance costs of introducing the GIC. Whichever option is chosen, it is a small additional cost and should be considered against the costs of providing data on products (see para 40). It is not considered to be likely to have an effect on competition given the realities outlined in that paragraph.

46. In the markets currently regulated under CoPR, there are companies with more than 20% of the market share and also, in some areas, where the three largest companies have more than 50% of the market. Given that these markets have been subject to an authorisation procedure for many years, it is not considered that the compliance costs of the GIC will have any further impact on competition in this domain. Any further effect on the market structure is likely to be due to the costs of providing data on products.

47. The remaining markets are not currently subject to an authorisation procedure in the UK. In some areas there may be companies with a substantial share of the market, as there are in those markets regulated under CoPR. However, as with the CoPR markets, it is not considered that the compliance costs of the GIC will have any further impact on the competition in these markets. The major impact, as mentioned above, will be from the costs of providing data on products.

Proposals for securing compliance

48. In the proposed Regulations, a duty will be placed on both those first supplying biocidal products onto the UK market and supporters of entries onto Annex I to inform HSE of their name and address. Once products have been authorised under the new regime, the suppliers of both the product and its active substances can be easily identified.

Monitoring and evaluation

49. A Biocides Charging Review Group, of stakeholder representatives, will be established. It will keep under review the effectiveness, consistency and operation of the Biocidal Products Regulations charging regime's financial and administrative arrangements and their consequences.

50. It is proposed that the method of collecting the GIC be re-evaluated 3-5 years after the Regulations come into force, depending on the rate of transition from the national to the EU regime, with any changes being introduced for the following financial year.

Summary of the Results of the Consultation Exercise

51. A summary of the consultation exercise is presented in Appendix 1.

Recommendations

52. The recommendation is for the GIC to be charged on a per company basis. Some small and medium sized companies have indicated a preference for a turnover option. However, whilst charging on this basis may result in a lower annual GIC for them, sometimes below the level which is economic to collect, the total cost of this option is higher than for the per company option. Additionally, it is considered that, when turnovers are very low, the costs of providing the data to support placing a product on the market (see para 40) is likely to result in these products being withdrawn, independently from of the GIC, as the costs of compliance with BPR are high.

Contact point and date

Graham Bell
Biocides and Pesticides Assessment Unit (HD D4)
HSE, Bootle, L20 3QZ
0151 951 425

APPENDIX 1

Summary of responses to the consultations of summer 2000 and late 2000 on the Biocides General Industry Charge (GIC).

Background

A full public consultation on the charging options took place in summer 2000. At a meeting of the Biocides Charging Review Group on the 8 December 2000 Industry representatives volunteered to provide HSE with factual information on the administrative costs of complying with both a turnover and a per company charging option by 12 January 2001. A letter was sent to interested parties in December 2000, requesting this information and information on how many employees the company had in their biocide businesses.

Information on administrative costs

Little factual information was received. Thirteen replies provided some information about administrative costs of complying with a turnover charge. These costs varied from virtually nil, as the company's accounting package could provide this information, up to £10,000 in the first year for setting up a system to collate the information plus an accountant's fee for verifying that the sales turnover was correct. The only respondent supplying information on the per company option estimated costs as in the region of £50 per cheque paid to HSE.

Small and medium-sized companies

Some companies identifiable as small or medium-sized (3 < 10 employees, 1 with approx 60 employees) voiced concern that their views would be overridden by those of the larger companies and in some cases the Trade Associations. They also pointed out that a turnover charge was fairer to all and there are plenty of proprietary computer packages that can be used to collate the required data.

Other information (on method of charge and who should be charged)

A total of forty-five replies were received. Twenty-five respondents stated that they would prefer a flat rate charge per company. One respondent stated a preference for a tiered charge per company depending on the size of the company. Thirteen respondents preferred the turnover option. Six respondents made no comment on which charging option they preferred. Of the eight companies identifiable as small or medium-sized, three (1 < 15, 1 < 30 and 1 < 60 employees) preferred a flat rate per company and three (2 < 2 and 1 < 50 employees) preferred the turnover option.

Five respondents stated that the draft proposals to implement the GIC did not address the requirement of the Directive to charge the GIC to suppliers of active substances. In the current proposal suppliers of active substances are included. Three respondents voiced concern over what was considered to be in scope of the Biocidal Products Regulations and how this would affect their products.

It should be noted that, of the replies received from individual companies, 13 mentioned that their trade association had requested they write in to HSE to voice their concerns over the GIC. If it were possible to give weightings to the replies then a different picture might emerge.

Declaration

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

Signed by the responsible Minister

.....[Nick Brown].....

.....26 February 2003.....

Annex 3 (of ex memo)

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 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:

CONTACT POINT

Stuart Smith
HSE/DR5
8SW Rose Court
2 Southwark Bridge
London
SE1 9HS

020 7717 6298
stuart.smith@hse.gsi.gov.uk

19 May 2005