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CONSULTATION AND NEGOTIATING STRATEGY FOR A DRAFT EUROPEAN REGULATION ON BIOCIDES			

Purpose of the paper

1. To seek Board approval for the proposed consultation plan and EU negotiating strategy relating to a proposed draft European Regulation, published by the Commission on 12 June 2009, to replace the current Biocidal Products Directive 98/8/EC. HSE will be negotiating on this proposed Regulation on behalf of the UK.

Background

2. Biocides are chemicals or micro-organisms that control harmful organisms. Examples are disinfectants, preservatives for wood and masonry, insecticides, rodenticides, avicides and anti-fouling paints. Biocides are presently subject to regulatory controls in Europe under the Biocidal Products Directive 98/8/EC (BPD), which is implemented in the UK in the Biocidal Products Regulations 2001 (BPR) as amended.

3. BPD requires a detailed assessment of the properties and acceptability of biocidal active substances (the entities that exert the biocidal action), agreed at EU level before inclusion in a positive list (Annex 1 of 98/8/EC). Companies may then apply for authorisation of the biocidal products (the formulations that will be placed on the market) by Member States. The BPD was modelled on the controls agreed in 1991 for plant protection products (pesticides).

4. When adopted in 1998, the BPD envisaged a 10-year programme to review all active substances in biocidal products then available on the market when it came into force on 14 May 2000. Member States would authorise products in their territories, or withdraw products from the market, in line with the outcome of the review of each active at EU level.

5. However, progress has been very slow. To date only some 30 active substances have been agreed for inclusion in the positive list, and no biocidal products have yet been authorised in Member States (although this will change soon). The programme of reviews of actives has been extended until 2014, although the European Commission admits that even this extended deadline is not achievable. In the interim, many existing active substances have been withdrawn from the market, many for economic reasons because the cost of supporting actives through the review process is high. In short, the BPD has not been a success and revision is urgently needed.

6. In response to the difficulties, the European Commission has proposed a new Regulation to replace the BPD. The proposed Regulation would be directly acting on all Member States, requiring no transposition as such but will need national

legislation for other issues (e.g. penalties, fees). Use of a Regulation is in line with REACH and classification, labelling and packaging, where EC regulations were agreed in 2006 and 2008. It is also in line with recent developments in regulating plant protection products and cosmetics, where requirements in directives implemented by Member States have been revised and recast as EC Regulations.

7. The Commission's proposal for a Biocides Regulation, including its impact assessment, runs to over 190 pages including some 85 Articles and several technical annexes. Copies have not been attached to this Board paper, but are available on request from Bethan Slater (International Chemicals Unit). The Explanatory Memorandum and initial Regulatory Impact Assessment that went to parliamentary scrutiny on [DN -*by the time the paper goes to the Board this will have happened and date can be inserted*] are also available on request.

8. We anticipate that the Swedish presidency will aim to make significant progress on the Regulation starting in July 2009. We understand at least six negotiating meetings are scheduled and the Presidency signalled the priority it is giving to this dossier by calling a meeting right at the start of its Presidency on 3 July 2009. The intentions of the subsequent Spanish presidency are less clear at this time, but we understand they will continue what Sweden has started, assuming reasonable prospect of a first reading deal between the Council and Parliament around June 2010.

9. The challenges presented by the prospect of intensive negotiations over the next year are increased by a number of factors, most notably, that close to publication, the Commission was not willing to divulge its working text, though its proposals developed significantly over the 6 months before publication.

10. Another challenge arises from the need to launch a public consultation on the Commission's proposals over the summer, so the feedback can inform the UK's negotiating position in the early Autumn. This is because, once the Regulation comes into force, it acts directly and public consultation at that stage is pointless.

11. To help meet these challenges we will be working closely with colleagues in the Chemicals Regulation Directorate who have recently been through a similar process on the negotiation of the new Plant Protection Products Regulation.

Argument

Negotiating Strategy

12. We understand the main changes in the Commission's proposal compared to the BPD are:

- a) Extending the scope to cover treated materials containing biocides;
- b) Adopting a centralised (EU) product authorisation scheme for products containing new actives and for low risk products;
- c) Requiring mandatory data-sharing of vertebrate animal test data for both active substances assessment and product authorisation;
- d) Reducing the burden of data requirements

- e) The introduction of exclusion (hazard) criteria, though these are qualified by risk-based and other conditions;
- f) Arrangements for comparative assessment and substitution;;
- g) Harmonising the fee structure across Member States (but not the fees themselves).
- h) Requirements on industry for record keeping and making information publicly available
- i) Requirements for compliance and monitoring and reporting to the Commission

13. Although the use of hazard criteria to restrict use of active substances is not new for biocides, they are framed more generally in the proposal. However, they appear to follow existing practice in regulating biocides, recognising that particularly hazardous substances can be used where engineering controls ensure negligible exposure or where use of a particular active substance is necessary to control a serious danger to public health. However, we need to assess the impact of this aspect of the proposal more fully.

14. The cost of some the additional measures such as access to information, compliance, monitoring and reporting to the Commission is likely to fall to HSE.

15. The provision for recovering costs needs to be clarified to ensure that Member States have powers to recover full costs for work carried out within the scope of the regulation where not reimbursed by ECHA. The regulation proposes that reduced fees may be set for SMEs or waived.

16. The Directive on Sustainable Use of Plant Protection Products mentions that it will apply also to biocides. The Commission are clear that they are not pursuing this as part of the present proposal. We will need to explore what additional burdens it might have on biocide regulation when this issue returns in the future.

17. HSE believes that many key proposals will have efficiency and cost benefits to the system. For example, reduced data requirements for some active substances may contribute significantly to the speed with which substances can be approved and reduce the costs of doing so. Mandatory data sharing should decrease the number of repeat tests resulting in lower costs to industry. However, the experience based on data sharing for pesticides has shown little appetite for sharing.

18. The Commission has estimated that the proposal would increase costs by between €194 and €706 million over 10 years, but the total cost savings would be between €2.7 and €5.7 billion across Europe over 10 years. We are sceptical about the magnitude of the Commission estimates, and the Commission impact assessment does not estimate the cost of all the key new provisions. We are presently doing our best to estimate figures for the UK for the initial RIA.

19. HSE has developed a high-level negotiating strategy from which further negotiating lines will be developed. In particular, we need to be assured that the Commission's impact assessment is sound and addresses all significant aspects of the regulation (exclusion criteria, comparative assessment etc) and that provisions are made to allow Member States to recover their full costs. HSE will engage at an early stage to press the UK view with the Commission, Member States and MEPs.

Discussion of our negotiating strategy is contained in an Annex to this paper, which is fully closed due to Freedom of Information (FOI) considerations, specifically Section 35 of the Freedom of Information Act which provides exemptions for formulation of government policy.

Consultation

20. Within HSE a team has been assembled including representatives from International Chemicals Unit (ICU), Legal Advisers Office (LAO), Chemicals Regulation Directorate (CRD) and Economic Analysis Unit (EAU) to pool expertise, test ideas and develop the detailed negotiating brief.

21. Within Government a group has been established including BIS (Department for Business Innovation and Skills, formerly BERR), Defra, EA, the Scottish Environmental Protection Agency (SEPA), Department of Health (DH), Health Protection Agency (HPA) NIHSE and UKREP. Direct contact has already been established with Better Regulation Executive (BRE) within Department for Business Innovation and Skills (BIS).

22. In terms of wider engagement with industry and other interested parties, we plan to launch an internet-based consultative exercise over a 10-week period beginning on 27 July and ending on 5 October 2009. The slight reduction from the usual 12 week period is a compromise which recognises that consultation over the summer holiday period, although not desirable, is necessary in this case to enable views to be fed in to informing the UK negotiating position before negotiations have advanced too far. The CD will encourage respondents to feed in comments well before the close of consultation as negotiations are likely to resume in earnest in September.

23. In addition we plan to hold an open seminar in mid-September on the proposed Regulation. This will provide a further opportunity for industry and other interested parties to air views. Similar events held during the negotiation of the Classification, Labelling and Packaging (CLP) Regulation proved popular and were well received.

24. HSE already holds the details of those who have gone through the approval process under the current system, many of which will be SMEs, and will be writing out to them to alert them to the consultation and seminar. In addition, HSE will use the Small Business Trade Association Forum (SBTAF) to publicise the consultation through e-bulletins and their next meeting on 21 July. HSE will also be contacting local Chambers of Commerce for help with spreading awareness. HSE has contacted the holder of the Small Firms Consultation Database in BIS. Using this database of around 3000 SMEs, Enterprise Directorate, on policy officials' behalf, can contact owners and managers and invite them to respond to targeted consultations about proposed new regulations. HSE will also be looking to push the message out through the trade press, which should also capture small businesses.

25. Although we are sympathetic to the understandable concerns of SMEs, we are also conscious of the wider context. The principle of 'no data, no market' enshrined in REACH reflects the public expectation that chemicals placed on the market have been tested and assessed. The requirements in the regulatory regimes for pesticides, cosmetics, pharmaceuticals, as well as biocides, are deliberately rigorous. The consequence has been a general trend of rationalisation and mergers

in the chemical industry, and in consequence, all SMEs have been squeezed. However, against this background, the new proposed Biocides Regulation does offer some relief to SMEs through benefits such as reduced data requirements, compulsory data sharing and reduced fees. For example, under the proposed Regulation, larger companies will be obliged to share vertebrate animal testing data for reasonable compensation meaning that this information cannot be withheld from SMEs who will also benefit from improved certainty about costs. Nevertheless, the UK is aware that pressures on SMEs may continue through the loss of products and we will explore these and other issues with help from responses to the consultation.

26. The public consultation will be important in developing and refining the initial RIA.

Presentation

27. The regulation of biocides is a specialist area, and it is unlikely that this major review of the BPD will attract significant media attention. Furthermore, we anticipate that broadly the measures proposed will be positively received as a step in the right direction. However, the BPD has understandably attracted a significant amount of criticism from stakeholders, particularly SMEs, who feel that its requirements are onerously expensive and that is complicated and disproportionate with respect to its overall benefits. We can expect that publication of the Commission's proposal will give opportunities for these understandable views to be repeated.

Financial/Resource Implications for HSE

28. The negotiation of the proposed Biocides Regulation is expected to occupy a significant amount of ICU resource over the next year (100% B3, 50% B2, 30% B4, equivalent to a total estimated cost of £152,590 for 2009/10) with significant support from CRD and LAO, EAU and other colleagues. The necessary resources for ICU are included as part of the Long Latency Health Risks Division (LLHRD) work programme. HSE will consider how CRD input will be funded.

29. The resources necessary to operate the existing biocides regime comes from HSE's grant in aid, application fees and a levy, or general charge, paid by industry. The direction of travel is towards full cost recovery whilst also addressing equitability for SMEs. This is a sensitive area in the current economic climate and will inevitably generate a negative response from industry. Any additional burden imposed by the new Regulation may exacerbate that reaction.

30. The introduction of a central system for a limited number of authorisations may reduce somewhat the fee income, as well as the level of work. However, we anticipate change will be slow and limited. In addition there may be opportunities to claw back any lost income by undertaking assessment work on behalf of the European Chemicals Agency.

31. The principle of full cost recovery seems to be implicit in the proposal to harmonise the fee structure, though not the fees themselves. However, this is an area we will need to monitor closely. In line with what has been established in REACH, it is likely that fees for SMEs will be reduced, with larger firms paying proportionately more.

Action

32. The Board is invited to:

- a) endorse the strategy in Annex A (paragraph 19 refers)
- b) agree the slightly shortened period of 10 weeks for public consultation (paragraph 22)
- c) agree that the Chair can clear the consultative document (paragraph 22) on behalf of the Board.

Paper clearance

33. This paper was produced by Dr Robin Foster and Bethan Slater, and was cleared by SMT on 29 June 2009.

European Biocides Regulation – proposed UK negotiating strategy



▶ ◀ *This Annex is withheld under Section 35 of the Freedom of Information Act: Formulation of Government Policy*