Health and Safety Executive Senior Management Team Paper			HSE/SMT/09/61
Meeting Date:	29 June 2009	**FOI Status:**	Partially closed (Annex A of attached Board paper)
Type of Paper:	For discussion	**Trim Ref:**	2009/239710
Exemptions:	Section 35 of the Freedom of Information Act		

HEALTH AND SAFETY EXECUTIVE

Senior Management Team

Consultation and Negotiating Strategy for a Draft European Regulation on Biocides

A Paper by Steve Coldrick

Advisors: Robin Foster and Bethan Slater

Cleared by Jane Willis on 19 June 2009

Issue

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

Timing

2. For clearance at the 29 June 2009 SMT meeting prior to the HSE Board meeting on 22 July 2009.

Recommendation

3. That SMT approves the attached paper for submission to the HSE Board.

Background

4. The draft Regulation referred to in this paper runs into 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). Also available on request, in draft form, are the Explanatory Memorandum and initial Regulatory Impact Assessment, which are currently under preparation for submission to parliamentary scrutiny. These will have been finalised by the time of the July Board meeting.

5. For further detailed background, see attached draft paper.

Argument

6. See attached draft paper.

Health and Safety Executive Board			Paper No: HSE/09/
Meeting Date:	22 July 2009	**FOI Status:**	Partially closed (Annex A)
Type of paper:	Above the line	**Exemptions:**	Section 35 of the Freedom of Information Act
Trim reference:			
CONSULTATION AND NEGOTIATING STRATEGY FOR A DRAFT EUROPEAN REGULATION ON BIOCIDES			

Purpose of the paper

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

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.

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).

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.

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 may not be 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.

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. 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.

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.

We anticipate that the Swedish presidency will aim to make significant progress on the Regulation starting in July 2009. We understand 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 2 July 2009 [*by the time the paper is received by the Board this will have happened so the date can be inserted*]. The intentions of the subsequent Spanish presidency are less clear to us at this time, but we believe they will continue what Sweden has started, assuming reasonable prospect of a first reading deal between the Council and Parliament around June 2010.

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.

Another key 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.

Argument

<u>Negotiating Strategy</u>

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) harmonising the fee structure across Member States (but not the fees themselves).

The Commission has estimated that although (a) above would increase costs by between €194 and €706 million over 10 years, the total cost savings from (b) to (e) above are between €2.7 and €5.7 billion across Europe over 10 years. We are presently doing our best to estimate figures for the UK for the initial RIA. Although we anticipate savings will exceed costs, the ratio may not be as large as the Commission estimates.

HSE has developed a high-level negotiating strategy from which further negotiating lines will be developed. Discussion of our negotiating strategy is contained in an Annex to this paper, which is fully-closed due to Freedom on Information (FOI) considerations, specifically Section 35 of the Freedom of Information Act which provides exemptions for formulation of government policy.

Consultation

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.

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) and the NIHSE. Direct contact has already been established with Better Regulation Executive (BRE) within Department for Business Innovation and Skills (BIS).

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.

ICU has started to make contact with key players. 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.

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

Presentation

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

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 support from CRD, LAO, EAU and other colleagues. The necessary resources are included as part of the Long Latency Health Risks Division (LLHRD) work programme.

The resources necessary to operate the existing biocides regime comes from HSE 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.

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.

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

The Board is invited to:

a) endorse the strategy in Annex A (paragraph 13 refers)
b) agree the slightly shortened period of 10 weeks for public consultation (paragraph 16)
c) agree that Jane Willis can clear the consultative document (paragraph 16) on behalf of the Board.

Paper clearance

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

Contact

Bethan Slater, International Chemicals Unit
Email: bethan.slater@hse.gsi.gov.uk Tel. 020 7227 3828

Dr Robin Foster, International Chemicals Unit
Email: robin.foster@hse.gsi.gov.uk Tel. 020 7227 3814

European Biocides Regulation – proposed UK negotiating strategy

► ◄

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