Health and Safety Executive Board			HSE/12/27
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7 out, 1 in’ Consolidation for UK Biocides, PIC and CLP Regulations

Purpose of the paper

1. To advise the Board of a proposal to consolidate requirements relating to enforcement and Competent Authorities (CAs) into one Statutory Instrument (SI) covering three directly acting EU Regulations on which HSE leads: Biocides, Prior Informed Consent (PIC) and Classification, Labelling and Packaging (CLP).

Background

2. Article 43 of CLP requires Member States to appoint the CA responsible for proposals for harmonised classification and labelling. In practice, HSE already undertakes this role now with the agreement of other Government Departments and the Devolved Administrations, having done so under the EU legislation that CLP replaced in 2008.

3. The advent of the new EU Biocides Regulation in September 2013 means we can revoke existing national legislation transposing the Biocides Directive. Consolidation of biocides legislation is one of the recommendations in the Löfstedt Report. However, new domestic regulations are required to establish HSE as CA and arrange for enforcement for the new EU Biocides Regulation and for the recast EU PIC Regulation.

Argument

4. Although separate UK regulations with similar provisions could be established for each of these chemical regimes, a more effective and efficient approach would be to achieve the new and existing EU obligations through a single legislative instrument, whilst consolidating the existing related UK regulations into the same instrument. We believe that this approach will be popular with business.

5. The consequence of consolidating these regulations would be a reduction of seven sets of national regulations into one (five from biocides, the existing PIC enforcing regulations and the remnant of CHIP that would otherwise remain after 1 June 2015).

6. In addition to demonstrating consistency and transparency of approach across three directly-acting EU Regulations, there would also be a reduction in the UK Parliamentary/Ministerial activity required. Efficiencies would be achieved as clearance from Ministers, RRC/RPC etc. will only have to be

sought once at each appropriate clearance stage instead of three times if separate projects were undertaken for Biocides, recast PIC and CLP.

7. There are a number of potential problems that could occur by putting all our 'eggs in one basket' in this consolidation project:

- If we run into problems on one of the three aspects we would be vulnerable on three fronts;

- Putting together in one legal instrument the existing regulations will inevitably reveal inconsistencies which will need to be resolved in discussion with OGDs, or otherwise be explained.

8. We have been realistic in what can be consolidated, and although consideration has been given to including Defra-led legislative regimes within this project, it is not proposed to include:

- Enforcement or CA arrangements for the EU Regulation on authorisation of Plant Protection Products. These are in Defra-led legislation and have recently been put in place in a project led by HSE's CRD.

- Enforcement or CA arrangements for the EU REACH Regulation. These are in Defra-led legislation, and are subject to separate consolidation plans under consideration by Defra that also includes Persistent Organic Pollutants and the export of mercury. We will liaise with colleagues in Defra to ensure consistency of approach between the projects.

- Domestic regulations necessary to recover the costs of some types of work, which are needed for Biocides and PIC. These are being taken forward in parallel to this project and, subject to views of legal advisers, we are looking at the possibility of incorporating the necessary provisions in the main HSE fees regulations. This would avoid increasing the number of regulations on the statute book; annual reviews/increases would be taken forward in the same way as other fees.

9. Although the consolidation of the regulatory requirements for the three regimes has some complexity, we estimate that negligible additional resource will be required to deliver a consolidated package and, indeed, some minor efficiencies may be gained. Overall, we believe the consolidated approach offers significant advantages.

10. As chemical safety embraces public safety, as well as protection of the environment, success in this area depends on securing the agreement of relevant Government Departments, Agencies and Devolved Administrations (DAs). Although consolidation may prompt increased scrutiny, early soundings do not indicate this will be problematic. Other Government Departments and Devolved Administrations will continue to be engaged.

11. Treasury Solicitors have received draft instructions.

12. The timescale for this consolidation project is driven by the need to arrange for enforcement and the potential for CA charging when the new EU Biocides Regulation comes into force on 1 September 2013.

13. The provisional timetable at Annex 1 takes into account the process for Route 2 (medium) under the BIS deregulatory guidance. This route has been chosen because the vast majority of the project is to revoke seven pieces of existing legislation on Biocides, PIC and CLP, whilst consolidating the regulatory requirements into a new SI. However, a view on this will be sought from the RRC in May/June 2012, the first critical review point for the project.

Action

14. The Board is invited to note that this project is underway and that members will have the opportunity to comment on the results of the consultation exercise.

Paper clearance

15. The paper was cleared by SMT on 7 March 2012.

Annex 1 – Provisional timetable for the ’7 out, 1 in’ consolidation project:

Draft project timeline & agree with LAO	Policy	1 week	13-Feb-12	20-Feb-12
Draw up instructions	Policy	2 weeks	30-Jan-12	13-Feb-12
Lawyer produces first draft Statutory Instrument (SI)	LAO	4 weeks	13-Feb-12	05-Mar-12
Discussion & agreement of draft SI	Policy & LAO	4 weeks	05-Mar-12	30-Mar-12
2nd & 3rd lawyer checks of draft SI	LAO	3 weeks	02-Apr-12	20-Apr-12
1st draft of Impact Assessment	EAU & Policy	3 weeks	06-Feb-12	24-Feb-12
Finalise project timeline & agree with LAO	Policy	1 week	20-Feb-12	24-Feb-12
Inform BRU of draft SI & timetable	Policy	1 day	24-Feb-12	
Inform SMT of draft SI & timetable	Policy	12 days	24-Feb-12	07-Mar-12
Inform Board of draft SI & timetable	Policy	2 weeks	14-Mar-12	28-Mar-12
Ministerial Scrutiny Stage 1: Planning				
Draft & send Ministerial submission to Secretariat	Policy	6 days	29-Mar-12	06-Apr-12
Ministerial letter to RRC	Policy	10 days	16-Apr-12	27-Apr-12
Reducing Regulation Committee (RRC) considers Minister's information letter ‡	Policy	8-14 days	30-Apr-12	11-May-12
Draft Consultation Document (already underway)	Policy	1 week	27-Mar-12	02-Apr-12
2nd draft Impact Assessment (already underway)	Policy & EAU	3 weeks	27-Mar-12	17-Apr-12
SMT clearance	Policy	2 weeks	20-Apr-12	02-May-12
Fit for purpose SI required before Chair clearance	TSol/Policy			02-May-12
Finalise Consultation Document	Policy	1 week	17-May-12	23-May-12
Finalise Impact Assessment	EAU	1 week +	17-May-12	30-May-12
Clear Impact Assessment with Chief Economist/CE	EAU & Policy	2 weeks	31-May-12	14-Jun-12
Chair to clear CD on behalf of the Board	Policy		03-May-12	16-May-12
Ministerial Scrutiny Stage 2: Consultation				
Ministerial clearance	Policy	10 days	15-Jun-12	25-Jun-12
Home Office Powers of Entry Gateway clearance	Policy	3 weeks	26-Jun-12	16-Jul-12
RRC clearance & European Affairs Committee (EAC) write-round (in parallel) - send IA, CD, project plan, how principle for EU legislation has been applied, options for transposition, dates for transposition & review ‡	Policy	8-14 days	26-Jun-12	16-Jul-12

Consultation	Policy	12 weeks	21-Aug-12	13-Nov-12
Draft EM & TN during consultation	Policy			
MoJ Criminal Offences Gateway clearance (during consultation, when views are emerging)	Policy	4 weeks	01-Oct-12	26-Oct-12
Consultation response: further instructions, finalise EM (inc. consultation details), finalise TN & IA	Policy & EAU	2 weeks	15-Nov-12	29-Nov-12
Final draft of SI, EM, TN, IA	LAO, EAU & Policy	1 week	30-Nov-12	06-Dec-12
Clearance of final IA with Chief Economist & CE ‡	EAU & Policy	2 weeks	07-Dec-12	21-Dec-12
Validation of SI, 2nd/3rd lawyer checks, printing, proofreading	LAO	4 weeks	24-Dec-12	20-Jan-13
Clearance of final draft TM, EN, IA	Policy, BRU, LAO	1 week	21-Jan-13	28-Jan-13
EM clearance by PRU	PRU	3 days	29-Jan-13	31-Jan-13
SMT clearance	Policy	2 weeks	early Feb-13	mtg date tbc
Board clearance (inc. draft SI, TN, Chair's letter, IA, final EM, timetable) ‡	Policy	3 weeks	early Mar-13	mtg date tbc
Send draft SI, TN, Chair's letter, IA, EM, timetable to PRU	Policy	1 day	10-Apr-13	
Draft submission & ministerial response	Policy & LAO	1 week	11-Apr-13	18-Apr-13
Submission & draft response to PO + docs sent to PRU above	Policy & LAO	1 day	19-Apr-13	
Ministerial Scrutiny Stage 3: Final Committee clearance				
Ministerial clearance, inc. response to questions	Policy	10 days (min)	22-Apr-13	10-May-13
RPC opinion on final IA	Policy	10-30 days	13-May-13	11-Jun-13
RRC clearance & EAC write-round (in parallel) ‡	Policy	8-14 days	12-Jun-13	02-Jul-13
Secretariat sends Statement of New Regulation (& possibly draft SI) to DWP Parliamentary Relations Unit (PRU)	Secretariat	8-14 days	12-Jun-13	02-Jul-13
Making & laying of Regulations				
DWP legal approval process: minute to proceed regulatory package	Policy & LAO	2 weeks	03-Jul-13	17-Jul-13
Pass to DWP Parliamentary Relations Unit for signing	Secretariat	2 weeks	18-Jul-13	01-Aug-13
SI laid in Parliament (latest date 10 August 2013)	PRU	30/21 days	02-Aug-13	01-Sep-13
Negative resolution period	Parliament	40 'sitting' days	02-Aug-13	n/a
SI Entry into force	N/A	N/A	01-Sep-13	n/a

‡ critical review points (May 2012; July 2012; December 2012; March 2013 and July 2013)