Health and Safety Executive Board			HSE/13/48
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Update – Chemicals Regulation Directorate

Purpose of the paper

1. The Chair considered that it was timely for the Board to have an information paper on Chemicals Regulation Directorate (CRD) and its work.

Background

2. CRD was formed in 2009 when the Pesticides Safety Directorate, a former Defra agency that had been taken into HSE in the previous year, was merged with the pre-existing Chemical Assessment Schemes Unit, to create a new HSE directorate.

3. CRD has responsibility for managing and delivering key aspects of the following chemical regimes which are largely governed by EU legislation:

- Plant protection products (ppps)(essentially agricultural pesticides)
- Biocides (non-agricultural pesticides)
- REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)
- Classification, labelling and packaging (CLP)
- Prior Informed Consent (for import/ export)
- Detergents

4. In addition CRD provides scientific advice to the whole of HSE on the health effects of chemicals; and the secretariat for the independent Advisory Committee on Pesticides and the “WATCH” scientific subcommittee of the Advisory Committee on Toxic Substances.

5. A list of the relevant EU legislation is attached at Annex 1. It is worth noting that this legislation aims to regulate both human and environmental safety.

6. For each of these regimes CRD’s functions are slightly different. Further details are given in Annex 2 but broadly for the main regimes:

- For ppps CRD do both the policy and delivery work, with Defra holding the strategic policy lead and reporting through to Defra Ministers.
- For bioicides and CLP CRD do the delivery work. Policy is done by the International Chemicals Unit in HSE’s Cross Cutting Interventions Directorate reporting to DWP Ministers.

- For REACH CRD do the delivery work with Defra doing the policy work and reporting to their Ministers.

7. CRD's operating costs are currently about £16 million and are recovered from various sources:

		£ millions (2012/13)
Industry (50%)	ppp fees	4.1
	biocides fees	0.9
	ppp annual charge	2.7
	biocides annual charges	0.7
Defra (33%)	Defra ppp policy	4.2
	Defra REACH	1.3
EC (4%)	Contracts	0.6
	ECHA fees	0.075
HSE (8%)	HSE Grant in Aid	1.2
Other (2%)		0.3

8. CRD currently employs 219 full time equivalent (fte) staff - a further breakdown by discipline is provided in Annex 3.

Argument

9. Key developments and challenges on each of the major regimes are:

9.1. Plant protection products.

a. EU ppp legislation has been in place since 1991. Updated legislation was introduced in 2009 consisting of:

- a new authorisation regulation. This retains a two tier approach with active substances being approved at EU level and products containing those substance then authorised by Member States before they can be marketed or used. However a number of new features have been introduced including hazard based criteria for substance approval, comparative assessment and substitution and a geographical three zone system for product authorisation.
- a Directive for sustainable use of pesticides requiring Member States to implement training and certification systems for users, requirements for application equipment testing, measures to protect specific areas such as water, integrated pest management (IPM) and indicators. Each Member States has to prepare a National Action Plan to reduce risks and impacts of pesticides.
- a regulation on statistics

b. In addition another EU regulation deals with Maximum Residue Levels in food (MRLs) which sets trading limits for food and feed of plant and

animal origin. These levels are critical for the import and export of food.

c. CRD has led in implementing these requirements in the UK including the national implementing legislation and preparation of the National Action Plan which was published in February 2013. Some implementation work is ongoing and key issues are the hazard criteria, comparative assessment and IPM (integrated pest management). UK Government did not favour hazard triggers when they were proposed since they take no account of exposure in deciding risk and one in particular, 'endocrine disruptors' is still very much a live issue since the detailed criteria are still to be agreed. Defra is leading across Government on this issue, with CRD playing a pivotal role. This definition will be applicable to a number of pieces of EU chemical legislation.

d. CRD is regarded by both industry and more widely as one of, if not the, leading Member State authority. Demand for both our regulatory and policy work remains high and we are often the authority of choice because of a track record of predictability, accessibility and transparency, with decisions based on robust science and evidence. However this demand has placed significant strain on CRDs resources in the last two years. Section 10 discusses future demands and resourcing issues.

e. CRD works closely with both the European Commission and the European Food Safety Authority (EFSA), who are responsible for EU risk assessment, to develop EU processes and procedures so that they are effective and efficient. CRD chair, on the Commission's behalf, a Post Approvals Issues group dealing with product authorisation issues and are very active on EFSA's Pesticides Steering Committee.

f. More widely there is increasing concern within industry and government circles about the impact of the authorisation regulation on the availability of plant protection products and the consequent impact on security and price of food. The number of substances approved in the EU has reduced from just over 1000 to 428 (including around 180 new substances) since 1991. It is notable that compared to other regimes such as biocides and REACH there is no socio-economic element built into decision making where need can be balanced against risks. Various initiatives are underway to address this issue and within them IPM (using the available tools and techniques in the most effective way) is likely to be pivotal. CRD are currently discussing with Defra how we fit into this wider picture since as pesticides regulator we only hold a proportion of the policy levers for this. In this broader context CRD organise on Defra's behalf the main stakeholder group in the UK, the Pesticides Forum[1], and act as liaison point for a well developed industry Voluntary Initiative[2] for pesticides which works to raise industry standards.

[1] http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/pesticides-forum
[2] http://www.voluntaryinitiative.org.uk/default.aspx

g. CRD are responsible for a number of monitoring programmes for pesticides including the Wildlife Incident Investigation Scheme[3], a residues monitoring programme supported by a Defra Expert Committee on Pesticides Residues in Food (PRiF)[4], Pesticides Usage Surveys and a formulations monitoring programme.

9.2 Biocides

a. EU biocides legislation has been in place since 1998. An updated biocides regulation will apply in September this year. Its basic features mirror those for ppps. Key differences are:

- The wide range of product types covered, in widely different situations, some of which have been lightly regulated in the past.
- A more harmonised approach to product authorisation where environmental conditions between Member States are much less relevant than for ppps.
- A different approach to sustainable use requiring that the Commission report in 2015, on the basis of experience gained with the application of the regulation, how it is contributing to sustainable use of biocides and the need to introduce additional measures.

b. The regulation also includes a new role for the European Chemicals Agency (ECHA) akin to that EFSA plays for ppps. However overall the regime relies on the same model as ppps, drawing on the expertise of Member State authorities. Legislative implementation is being led by International Chemicals Unit but a range of other changes are required which fall to CRD.

c. Demand for product authorisations is also high for biocides. CRD has received 37% of all lead applications submitted in the EU and has granted 52% of all lead EU authorisations that have been finalised.

d. For both biocides and ppps it has been necessary to review all of the authorisations that pre-existed at a national level when the EU regimes were introduced. For ppps this was completed in 2008 after an initial (very) slow start. For biocides progress has remained slow and the Commission has recently extended the deadline for its completion until 2024. To achieve this will still require a significant annual resource commitment from Member States.

9.3 REACH

a. REACH has been implemented progressively since 2006. It superseded and expanded the scope and demands of earlier industrial chemicals legislation. It differs fundamentally from the pesticides and biocides regimes in that it is not a general permissioning scheme, but rather is focussed on the provision of clear and reliable information throughout the supply chain to allow for the safe use of chemicals.

[3] http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/reducing-environmental-impact/wildlife/wildlife-incident-investigation-scheme.htm
[4] http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PRiF

Furthermore its core processes are managed directly by ECHA and do not rely on the expertise of Member States in the same way. It deals with substances through registration (in 3 groups determined largely by tonnage bands (over 1000 tonnes per annum by 2010, 100 tpa by 2013 and 1 tpa by 2018)). It is expected to cover about 30,000 substances in total including evaluation of a proportion of those and authorisation and restriction of those considered to be of the greatest concern.

b. CRD is responsible for human health aspects of REACH and works closely with the Environment Agency (EA) who deal with the environmental aspects.

c. One of our key duties as the UK REACH Competent Authority is to deliver a Helpdesk function. This has been in great demand by UK companies since it was established in 2007-08, particularly in the run-up to the first registration deadline. A high proportion of registrations overall were from the UK which is evidence that awareness of REACH is high in the UK. The second and third registration deadlines may present additional challenges with substance in lower tonnage bands being supported by smaller companies.

d. 2012-13 saw the first year of substance evaluation, CRD and EA completing three of these. We have also been working on several Restriction proposals, some from the UK and more from other Member States.

e. CRD provide the UK members for ECHA's Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) and the REACH Enforcement Forum. Wider stakeholder engagement is through Defra's Chemical Stakeholder's Forum[5] in which CRD participate.

9.4 Classification and Labelling (C&L)

a. CRD has continued the long history of HSE regulatory science input to EU C&L activity, generating some proposals ourselves and commenting on proposals of other Member States. The driving purpose of C&L has always been to transmit, via pictograms and short phrases, simple messages to recipients of chemicals about the potential threats the chemical poses to human health and/or the environment.

b. However, regulatory regimes, including pesticides, biocides and REACH, and other legislation such as EU workplace regulations and those covering Major Hazards, have incorporated mechanisms to deal with substances classified in particular ways – for example for carcinogenicity or reproductive effects. Consequently C&L decisions have an increasing impact on the ability to market and use chemicals.

10. Other activities

[5] https://www.gov.uk/government/policy-advisory-groups/uk-chemicals-stakeholder-forum

10.1. CRD has been active in the EU Twinning programme for prospective new Member States and over many years has provided about 5 % of all UK Government twinning work. In addition to meeting wider Government policy objectives and delivering influence across Europe (particularly in accession states), this work provides an excellent development opportunity for staff and adds variety and a wider perspective to our work. An overview is at Annex 4.

10.2. CRD also has an active external training programme running a range of chargeable events dealing with aspects of the regimes we operate. Last years programme is also at Annex 4. These events are well received and generally oversubscribed.

11. Governance

11.1 In addition to the HSE management chain, because the strategic policy lead for two of our key regimes is held by Defra and a number of other departments and the devolved administrations have a direct interest in our work, there are a number of regular points at which CRD's work is reviewed. The keys ones are:

- A quarterly management monitoring meeting with Defra
- A quarterly Interdepartmental Pesticides Committee chaired by Defra
- The REACH steering group with all departmental interests.

11.2. There has also been a review of the pesticides policy arrangements by Defra which concluded an overall success that is meeting expectations and increasingly delivering the anticipated benefits. The arrangements for governance are fundamentally sound and fit for purpose. Recommendations were made in the report for some modest improvements to the structure and processes.

12. Cross cutting issues

12.1 Regulatory Science

a. Regulatory science is clearly at the core of CRD's activities. Broadly the head of each of the specialist teams is responsible for assuring and maintaining the quality of our scientific output. This output is also subject to rigorous peer review through the processes developed by EFSA and ECHA at EU level. Nationally for pesticides the independent ACP also examines our work and one of the roles of the ACP chair is to provide an annual quality review.

12.2 CRD's Regulatory Strategy Programme

a. This is essentially our regulatory change management programme which has been conceived as a rolling programme of projects. Key projects currently underway are:

- submission handling to achieve greater consistency between ppps and biocides

- zonal harmonisation for ppps to achieve a higher level of harmonisation with other Member States as required by the new zonal authorisation system.
- performance measures examining how CRD's performance is measured and reported across the board.

12.3 Compliance

a. CRD has a small compliance team of about 10 FTEs. CRD's primary role is enforcement of marketing and registration related issues for ppps, biocides and REACH and to provide operational support to other enforcers (whether within or outside HSE). Ppp and REACH enforcement activities are included in the Defra budget. One of the key benefits of creating CRD has been the opportunity to align the enforcement approaches around HSE standard models and to harness together the wide enforcement expertise of HSE inspectors with the specialist expertise of CRD colleagues on chemicals legislation, through for example the virtual National Pesticides Enforcement Team. Enforcement of marketing provisions is of great interest to industry and remains an area where demand is likely to continue to exceed resources.

b. For REACH enforcement CRD has proved to be highly influential on the REACH Enforcement Forum run by ECHA and has pressed consistently for a proportionate, risk based and targeted approach.

13. <u>Future size and shape</u>

13.1 CRD has recently concluded a future size and shape exercise which concluded that, based on legal requirements and industry intelligence, demand for industry funded work will grow and be sustained at a significantly higher level than is currently being delivered. There are clear business, legal and reputational risks if CRD is unable to deliver this work, including delayed access to market for UK businesses and availability of important products for UK users. The conclusion is that CRD will need to recruit further regulatory scientists to meet this demand, in addition to replacing those that will leave either through retirement or the furnish a relatively high external demand within companies and consultancies for trained regulatory scientists familiar with the regimes we operate. We would also expect to be able to expand our EU twinning activity to a higher level than it is running at present.

13.2 With respect to Government funding for ppps we have taken the opportunity to reduce numbers of staff to levels that are consistent with our budget expectations at the end of the current spending review round. If further reductions are required we are examining the balance between government and industry funding for some activities including the monitoring programmes. For REACH we expect to meet any shortfall by increasing ECHA funded evaluation work. For HSE Grant in Aid this is already a relatively small proportion of our funding and opportunities for further reductions are limited.

14. <u>High profile issues</u>

14.1 A number of issues have been of high political or media profile recently and serve to highlight some of the difficult decisions that are involved in the regulation of chemicals.

- Copper. Copper was not supported by industry through the biocides review programme and was consequently was not approved by the European Commission. However it is widely used in water systems for *Legionella* control. The UK has now made an essential use application for this use. Until the outcome of the application is known, HSE's primary concern is that *Legionella* control is not compromised and HSE and Local Authority inspectors will take a sensible and proportionate approach to enforcement if they come across these systems in use.

- Outdoor use of rodenticides. The standard risk assessment procedure for second generation anticoagulant rodenticides for uses other than indoors indicates a high risk to birds. However outdoor use of these products is important for the control of rat populations with consequent public health implications. CRD have been consulting all stakeholders including Defra, who have an overall interest in rodent control and in the protection of birds, users and interested NGOs. There are strong and opposing views and concerns amongst different stakeholder groups about where the correct balance lies and one of the objectives of the consultation is to gather evidence to support a long term position. None of the regulatory options available will satisfy all the lobbying parties. This issue has been relatively widely reported in the media.

- Neonicotinoid insecticides and bees. Neonicotinoids are a class of insecticide that have been implicated by some in the decline of bee and other pollinator populations. Recently the EU voted on restrictions on the use of these substances, which the UK did not support. CRD has been heavily involved in examining the evidence and briefing Defra Ministers on this issue, dealing with the intense media, parliamentary and stakeholder scrutiny and supporting Defra in providing evidence to an Environmental Audit Select Committee enquiry. Work is now ongoing on the follow up to the EU action.

- Bystanders and residents. The risk to bystanders and residents (those living near sprayed land) has been an area of controversy for some years. Campaigners have argued that the approach taken by CRD was not sufficiently precautionary. In 2005 the Royal Commission on Environmental Pollution produced a report on the issue and in 2006 a campaigner, Georgina Downs, brought a judicial review against the policy then in place. This challenge was initially successful although the Court of Appeal subsequently overturned the High Court ruling. In the light of these and other developments the Bystanders Risk Assessment Working Group (of the ACP and Committee on Toxicity) undertook a review of the scientific evidence concerning bystanders exposed to pesticides. Their report has been published and Defra Ministers are considering how to take the recommendations forward.

Action

15. This paper is intended to inform the Board about CRD. No specific action is required.

Paper clearance

16. This paper has been cleared by Dave Bench and Geoffrey Podger. In order to assist with managing the agendas at forthcoming Board meetings SMT clearance has not been obtained. An SMT discussion is envisaged after the Board meeting.

Annex 1

Key relevant legislation

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L309/1 24.11.2009)

Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework of Community action to achieve the sustainable use of pesticides (OJ L309/71 24.11.2009)

Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides (OJ L324/1 10.12.2009)

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70/1 16.03.2005)

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the markets and use of biocidal products (OJ L 167, vol 55, 27 June 2012)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive [etc] (OJ L396/1 30.12.2006)

Regulation (EC No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and Regulation (EC) No 1907/2006 (OJ L 353/1 31.12.2008)

Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L104/1 8.4.2004)

Annex 2

Relative functions of CRD and partners

Regime	CRD functions	Key partners
Plant protection products	- Acting as competent authority - Processing applications - EU technical committees - EU regulatory committees - Policy development and implementation - Monitoring programmes - Management of Defra's pesticides R and D programme - Enforcement (marketing)	Defra hold strategic policy FOD and CRD together form the National Pesticides Enforcement Team (NPET)
Biocides	- Acting as competent authority - Processing applications - EU technical committees - Enforcement (marketing)	HSE International Chemicals Unit (within Cross Cutting Interventions Directorate) have the policy lead FOD for biocides enforcement
REACH	- Acting as competent authority - EU technical committees - Enforcement (registration)	Defra hold strategic policy and do the policy work CRD work with the HSE's Product Safety Teams on enforcement. HSE are a named enforcing authority in the REACH Enforcement Regulations 2008
Classification and Labelling	- Acting as competent authority - Processing applications - EU technical committees	HSE International Chemicals Unit have the policy lead
Prior Informed Consent	- Acting as Designated National Authority - Processing notifications for export	HSE International Chemicals Unit have the policy lead HID and HMRC for enforcement
Detergents	- Acting as competent authority - Dealing with exemption applications	Defra hold strategic policy and do the policy work

Annex 3

Staff numbers (ftes)

Group	Branch	number
Directorate Management Team (and support)		7.8
Planning and Resources	Communication	6.6
	International Development	3.0
	Admin Services Group	8.1
	Registry	6.5
	Regulatory Strategy and Corporate Risk	3.0
	Finance and Business Support	16.7
	IT	10.1
Regulatory Policy	Policy	16.7
	Compliance	10.2
Biocides, Pesticides and Environment	Biocides	12.1
	Pesticides	28.5
	Efficacy	11.1
	Environmental Fate and Behaviour	15.4
	Ecotox	11.8
	Expert Committees	1.0
Chemical Schemes and Human Health	REACH, C&L and PIC	9.2
	REACH Economics	2.0
	REACH Exposure	3.6
	Exposure and Chemistry	27.3
	Toxicology	10.4

Annex 4
Twinning contracts

Country	Contract Number & Date	Title
Serbia	SR/08/IB/AG/01 October 2010 to June 2013	Harmonisation of national legislation with EU legislation for placing on the market and control of PPPs and implementation of new legal provisions
Moldova	MD10/ENP-PCA/AG/06 April 2012 to March 2014	Support to Moldova in the field of norms and standards in food safety for plant origin products
Montenegro	MN10/IB/AG/01 April 2012 to October 2013	Strengthening the administrative capacities of the Phytosanitary Directorate of Montenegro
Croatia	HR2007/IB/AG/02 April to 2010 to July 2011	Further capacity building in the area of PPPs and pesticide residues
Bulgaria	BG/2007/IB/AG/04/UE/TWL Dec 2009 - July 2010	Administration, Co-ordination and Evaluation of Dossiers with Regard to Authorisation of PPPs
Bulgaria	BG 06/IB/AG/03-TL January to July 2009	Improvement of the Plant Protection control system in Bulgaria and implementation of EU requirements related to phytosanitary control on quarantine organisms, biological testing, authorization and control on plant protection products (PPPs)
Croatia	HR2004/IB/AG/01 February 2007 to February 2009	Further development and capacity building in the area of PPPs

Training events 2012/13

Date	Event
Conference and seminars	
Seminar July 2012	**Physical Chemical Properties of Plant Protection Products**
Seminar November 2012	**Biocide Active Substance and Product Processes**
Conference February 2013	**Efficacy Under 1107/2009: A UK View of Current Developments and Experiences**
Workshops (<12 delegates)	
September and October 2012 (x3)	**Technical Fate and Behaviour Assessment of Plant Protection Products**
October 2012 (x2)	**Dermal Absorption Assessments for Plant Protection Products**
December 2012 and January 2013 (x2 –two day workshops)	**Ecotoxicological Risk Assessment of Plant Protection Products**
January 2013 (x1)	**Consumer Risk Assessment Training Day**
March 2013 (x1)	**Pesticides: EU Classification and Labelling of Plant Protection Products**
March 2013 (x2)	**Technical Equivalence Workshop**