



Chemicals Regulation and Product Stewardship: Update

November 2014

REACH

Tougher REACH Enforcement

REACH regulators are being encouraged to move from 'soft' regulation, such as advice and guidance, towards fines and criminal penalties, according to the Head of European Chemicals Agency (ECHA) Forum. Speakers at the Chemical Watch Regulatory Summit in Brussels in October supported tougher sanctions and suggested that confidence in REACH would be undermined if businesses saw their competitors 'getting away' with non-compliance. ECHA Forum's REF-3 project had found that only 11% of non-compliances had resulted in fines and criminal complaints. The European Chemical Industry Council (CEFIC) called on regulators to take a harder line and to make more noise about the sanctions and penalties that are being imposed so that the message to the market is clear.

Mike Potts from the Health and Safety Executive (HSE) indicated that there would be a focus on Only Representatives (OR) in the UK. Mr Potts acknowledged that action against ORs would have an impact on the supply chain and downstream users and suggested that downstream users might be allowed a grace period to register as importers in place of non-compliant ORs.

Mr Potts also commented that OR contracts were poorly drafted and failed to include performance criteria that would enable termination for poor performance.

Other matters of interest arising from the Brussels Summit included the following:

- The PIC Regulation will also be the focus of heightened enforcement scrutiny;
- There will be a pilot project looking at restricted substances within products in the market after the sunset dates; and
- Member States are looking to forge greater cooperation between the REACH enforcement agencies and customs departments.

Enforcement is not just an issue for non-compliant businesses: as Mr Potts explained, business continuity could be impacted by enforcement upstream in the supply chain. We are also seeing a greater willingness on businesses to 'shop' non-compliant competitors to the

NEAs. Burgess Salmon's product stewardship team handles corporate defence and dispute resolution and acted on one of the first enforcement investigations under the Restriction of Hazardous Substances Regulations. We can also assist with contractual protections in the supply chain and on OR appointments. For more detail about the conference presentations, please contact Simon Tilling.

Draft CoRAP issued by ECHA

On 30 October 2014, ECHA issued a proposal for a revised and updated Community Rolling Action Plan (CoRAP) to subject 134 substances to review and evaluation by Member States under the REACH Regulation between 2015-2017. This list includes 65 newly selected substances and 69 substances from the plan adopted in March 2014, allocated to individual Member States for evaluation in each of the next 3 years. The EU Member State Committee is expected to issue an opinion on the plan in February 2015, with the final CoRAP adopted by the end of March 2015.

All firms using any of the CoRAP substances should be aware of the forthcoming reviews and evaluations so that they can make preparatory plans for the possible impacts of the process on substance availability for their operations.

2018 Registrations

ECHA "urges all companies to start preparing now for the REACH deadline of 31 May 2018", which concerns substances imported or manufactured in low volumes of 1 – 100 tonnes per year per legal entity.

This deadline is thought likely to involve many more substances than the earlier high volume Registration deadlines, and many more SMEs involved in producing or using the lower volumes.

There is much speculation at present that the 2018 REACH deadline could result in a large number of substances not being supported by smaller companies through the Registration process, and thereby becoming unavailable through the supply chains.

Contingency planning for the impacts of the Registration deadline of 2018 is recommended, both for businesses with direct Registration responsibilities, and those that may be affected by the availability of any substances that may no longer be available.

General Court annuls ECHA's decision on administration charges

ECHA is currently reviewing its administrative charging scheme, following the European's General Court's recently annulment of an ECHA decision to impose an administrative charge on a company. The charge of €20,700 had been levied following ECHA's check of the company's size – it was found to be large and not small as it had self-declared. This had to be paid in addition to the difference in fee payable because of its size.

The General Court found that ECHA's decision in the present case violated the principle of proportionality, where the administrative charge was more than 17 times greater than the registration fee the company had to pay. Whilst the General Court did not expressly rule on ECHA's administrative charging scheme more generally, the court's attitude on proportionality may be implied to have general application.

This matter is on the agenda for the next meeting of ECHA's Management Board in December 2014. Nineteen similar administrative charges have been issued to date and there are other cases pending before the EU Court.

Businesses often assume that regulatory decisions are too difficult to challenge or that the Court will side with public bodies, but this case demonstrates the value of challenging regulatory and administrative decisions in the right circumstances. Burges Salmon has extensive experience both challenging and defending the administrative decisions of regulators and public bodies.

Changes to the Candidate List and Annex XIV of REACH

A consultation for the addition of 10 further substances to the Candidate List for REACH Authorisation closed on 16 October 2014. A consultation on the addition of 22 more substances to Annex XIV on Authorisation is due to close on 30 November 2014, and covers such substances as n-propyl bromide, boric acid and lead compounds.

Derogation for DCM-based paint strippers

The REACH Enforcement (Amendment) Regulations 2014, which have recently been issued, allow the use of DCM-based paint strippers by professionals provided that certain control measures are put in place. The UK has taken advantage of an EU derogation permitting the supply and use of dichloromethane in professional paint stripping activities.

ROHS 2

In July 2014, the Government issued revised and updated guidance on the Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (RoHS 2 Regulation), which implement the revised RoHS Directive of 2011.

The RoHS 2 Regulation place duties on economic operators through the supply chain for Electrical and Electronic Equipment (EEE) placed on the market. In particular, economic operators – and there are differently stated duties for Manufacturers, Importers and Distributors – may not place, or make available on the market, EEE containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in amounts exceeding the established maximum concentration values. Finished EEE must be marked with the EU CE marking.

New categories of products will be brought into the scope of RoHS over a 6.5 year period starting in 2 January 2013.

There are also special provisions about spare parts, detailed provisions for new and future exemptions, and relevant maximum concentration values for homogenous materials.

While some businesses have the matter of RoHS compliance well in hand, we are aware of some significant businesses which have some way to go, and it may be worth recalling that significant contraventions of the RoHS Regulations carry unlimited fines on conviction on indictment, together with the option of remediation orders and payment of the regulator's costs. Furthermore, the Regulations allow for the prosecution of managers and those responsible at a company for the conscious or negligent commission of an offence by the company.

Biocidal products

The European Commission's delegated regulation setting out details of the Review Programme for existing biocidal active substances entered into force on 30 October 2014. The regulation lists all substances and their product-types that are currently supported for review, as well as those that will be withdrawn from legal supply. Companies will have a year from that date to notify ECHA or the Commission if they want to support products that are not covered under the active substances and uses to be reviewed.

Restrictions on the availability of some familiar products for uses such as agriculture are beginning to have noticeable effects, and better information about developments under the Biocidal Products Regulation would give businesses more time in which to plan any necessary adjustments in operations.

CLP Regulation

The Regulation on the Classification, Labelling and Packaging of chemical substances and mixtures (CLP Regulation) will apply significant changes from 1 June 2015. From that date –

- Substances will only have to be classified under the CLP;
- Mixtures must be classified, labelled and packaged according to the CLP, and not under the Dangerous Products Directive; and
- Safety Data Sheets for both substances and mixtures must provide for CLP classification.

It is reported that many suppliers have not yet changed over their classification systems from Dangerous Substances Directive data to the newer CLP system. Formulators and importers of mixtures need to be aware of the changes and plan for implementation, as the deadline is now imminent.

Conflict minerals

As we have noted in earlier briefings, section 1502 of the US Dodd-Frank Act is intended to force disclosure of any financial backing of armed groups in the Democratic Republic of Congo, and of the money made from “conflict minerals”, which include cassiterite, columbite-tantalite, gold and wolframite, and their derivatives, including tin, tantalum and tungsten.

This has resulted in direct reporting obligations being placed by the US Security and Exchange Commission (SEC) on about 6,000 “issuer” companies. Many more companies in the supply chain may already or will in the near future feel the impact of reporting obligations on the source and derivation of these conflict minerals in products.

As issuers directly affected consider whether they need to make Conflict Minerals Reports and “reasonable country of origin inquiries”, companies in the supply chain should consider how they can anticipate and assist with reporting, by deploying information gained from substance inventories and reporting for the REACH Regulation. There may be significant commercial advantages in being able to assist US “issuer” companies to comply with their Dodd-Frank requirements.

Nanomaterials

A large number of products containing nanomaterials are already on the European market. They include batteries, coatings, anti-bacterial clothing, cosmetics and food products. The EU regards nanomaterials as structures which range from about 1 to 100 nm in at least one dimension, although as we have noted in separate briefings, this definition is not without problems and appears to diverge from statements of relevant Standards.

It seems clear that the EU in general and ECHA in particular

are still feeling their way towards the fully effective regulation of nanomaterials, recognising both the scope and potential applications of this technology and its recognised risks in some areas (such as the risk of inhalation of certain types of carbon nanotubes).

Progress towards a more widely accepted regulatory outcome is being made through advisory groups and industry collaboration with the regulators, such as ECHA's Nanomaterials Working Group (NMWG) and its Group Assessing Already Registered Nanomaterials (GAARN).

The development of nanomaterials is a case study of the way in which industrial and technical developments can run ahead of regulatory capacity to assimilate and assess real regulatory issues, and this process has risk on both sides. There is a need for regulation of real risks, without wanting to stifle innovation or subject nanotechnology to general regulatory rules which are ill adapted to its actual characteristics. For the time being, the industry is well advised to collaborate with and track regulatory developments through the ECHA's stakeholder participation groups.

PIC Regulation

The HSE is currently inviting feedback on a European Commission proposal to amend the EU Prior Informed Consent Regulation (PIC). The United Kingdom signed the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) in 1999, and PIC was implemented in the European Union through Regulation (EU) 649/2012. PIC promotes shared responsibility and allows countries to monitor and control the import of certain dangerous chemicals.

The European Commission proposal adds nine chemicals to Part I of Annex I of PIC, which will then be subject to the export notification requirement, whereby an exporter must notify HSE of their first export to each country outside the EU. Exporters of these chemicals, either as substances or in mixtures, are currently being asked to notify the HSE.

Our Product Stewardship team can help whether you are looking to bring new products to the market or protect exist product lines. We have had substantial experience handling regulatory compliance and investigations.

Pesticides

New guidance issued by the European Food Safety Authority (EFSA) in October 2014 sets out a harmonised methodology for calculating exposure to pesticides. It concentrates on exposures of four main population groups:

- **Operators** – farming professionals who carry out activities linked to the application of pesticides, e.g. mixing and loading of pesticides into machinery, as well as operating, cleaning, emptying or repairing such equipment;

- **Workers** – a person who, as part of their job, enters an area previously treated with pesticides or who handles crops treated with pesticides;
- **Residents** – those living, working or attending school near an area where pesticides are used and who take no protective measures, such as wearing special clothing, to reduce exposure;
- **Bystanders** – those who may be in or next to an area treated with pesticides and who take no protective measures.

The EFSA guidance highlights some uncertainties due to lack of data, particularly in the assessment of resident exposure. EFSA has called on scientists from Member States, research bodies and industry to address these information gaps as the guidance is reviewed.

Water Framework Directive

Present and future aspects of chemicals regulation will have a significant read-across to the continued work to implement the remaining aspects of the Water Framework Directive, which aims to achieve ‘good status’ including ‘good chemical status’ in controlled waters within the EU by 2015.

We are seeing increasing evidence of this read-across in the context of Burges Salmon’s specialist water law work, with companies impacted by developments in the Priority Substances Directive, by the setting of Environmental Quality Standards, and by the development and implementation of River Basin Management Plans.

Contacts

For further information about any of the issues raised in this briefing please contact:



William Wilson
Barrister

+44 (0) 117 939 2289
+44 (0) 7970 577492
william.wilson@burges-salmon.com



Simon Tilling
Senior Associate

+44 (0) 117 902 7794
+44 (0) 7814 703616
simon.tilling@burges-salmon.com

Burges Salmon LLP, One Glass Wharf, Bristol BS2 0ZX Tel: +44 (0) 117 939 2000 Fax: +44 (0) 117 902 4400
6 New Street Square, London EC4A 3BF Tel: +44 (0) 20 7685 1200 Fax: +44 (0) 20 7980 4966

www.burges-salmon.com

Burges Salmon LLP is a Limited Liability Partnership registered in England and Wales (LLP number OC307212) and is authorised and regulated by the Solicitors Regulation Authority. A list of members, all of whom are solicitors, may be inspected at our registered office: One Glass Wharf, Bristol BS2 0ZX.

© Burges Salmon LLP 2014. All rights reserved. Extracts may be reproduced with our prior consent, provided that the source is acknowledged. Disclaimer: This briefing gives general information only and is not intended to be an exhaustive statement of the law. Although we have taken care over the information, you should not rely on it as legal advice. We do not accept any liability to anyone who does rely on its content.

Data Protection: Your details are processed and kept securely in accordance with the Data Protection Act 1998. We may use your personal information to send information to you about our products and services, newsletters and legal updates; to invite you to our training seminars and other events; and for analysis including generation of marketing reports. To help us keep our database up to date, please let us know if your contact details change or if you do not want to receive any further marketing material by contacting marketing@burges-salmon.com.