JSC Newsletter

We wish you Season's Greetings and a very Happy New Year and look forward to the opportunity to work with you in 2015.

During 2014 we have been busy on agrochemical projects, both at EU and National level, and our work on biocides and REACH continues to expand.

JSC staff spotlight

We have welcomed Ewa Karas, Alex Gledhill and Ben Bolton to the team this year. This has further strengthened our biocides and metabolism expertise and introduced efficacy to our portfolio – meet all of our team on the website!

JSC office move

In May JSC moved to The Exchange, the tallest building in Harrogate, situated right next to the railway station. We are on the fifth floor and have marvellous views of the town and surrounding countryside. The new office will give us much needed space and enable more efficient organisation for client meetings.

The Tour de France comes to Harrogate

Harrogate took centre-stage when the Tour de France came to Yorkshire in July. All the towns and villages on the route were decorated with yellow painted bicycles and yellow, green and "spotty" bunting. It was a very exciting weekend, even though it brought the town to a standstill. The weather was fine and Yorkshire was showcased on the TV by numerous helicopter shots showing the lovely villages and beautiful countryside.

REGULATORY HIGHLIGHTS

AGROCHEMICALS

Zonal authorisations and re-registration: Delays are being experienced within Member States due to workloads, leading to long lead times for booking evaluation slots. This situation is unlikely to improve in the short term due to the numbers of plant protection products coming up

for re-registration. In the longer term it is expected that changes to the dRR template and better co-operation between Member States will bring about improvements. We encourage potential applicants to make sure they plan well ahead.

Comparative assessment and substitution: A guidance document was noted at Standing Committee meeting in October and will apply for applications for product authorisation from 1 April 2015. Comparative assessment and substitution will be applied at national level. However, the Commission has yet to present final proposals for a list of candidates for substitution. An initial proposal included around 80 substances approved up to 2012. This was subsequently withdrawn. Currently there is no indication of when a new proposal can be expected.

Endocrine disruptors: the Commission launched a public consultation in late September calling for data to support the impact assessment. Work was started in November on the methodology to screen for candidate substances under the various options. This will be used to screen a selection of plant protection products, biocidal products (BPs), cosmetics, general chemicals and substances of concern under the water framework directive (WFD). The delay in finally agreeing the criteria for identifying potential endocrine disrupting substances is leading to issues where the interim criteria apply.

Data requirements: certain member states are causing difficulties for applicants where they are refusing to accept waivers allowed in the guidance in instances where there are no validated test methods and guidelines available. Commission Guidance document (SANCO/10181/2013 rev 2.1) states that: "In some cases, agreed test methods or guidance documents are not yet available for particular data requirements. In these cases, waiving of these particular data requirement points is considered acceptable as long as no test methods or guidance documents are published…". The Commission has brought this issue to the attention of member states.

Review of Regulation 1107/2009 and Regulation 396/2005: JSC supports the efforts being made by industry to encourage the European Commission to ensure that there is a more 'joined up' approach in the procedure for the authorisation of plant protection products and the establishment of MRLs. In particular the regulatory process should be refocused to provide thorough risk-based assessments rather than defaulting to a hazard-based approach.

BIOCIDES

BPR Review Regulation: this has been published and identifies which active substances are supported under the Review Programme; it also provides a process for companies to take over the support for active substances that may have been redefined.

Article 95 List: this list is now available on the ECHA website. The obligation that biocidal products must be based upon active substances from suppliers that appear on this list will take effect on 1 September 2015. The latest version of the Article 95 list and guidance can be found on the ECHA website.

Product families: ongoing discussions are approaching completion meaning that product family development can proceed. This provides industry with options to significantly reduce product authorisation costs. Additional information on Product families can be found in the Finalised document on implementing the BPF concept on the CIRCABC website (finalised CA documents).

In-situ biocides: following many years of discussion there has now been an agreement made on how in-situ biocides should be regulated under the BPR. The latest Commission Proposal is available from the November 14 CA meeting on the CIRCABC website.

Treated articles: new guidance has been agreed and published; this clarifies both the scope and obligations for labelling placed on suppliers of treated articles. More information is available on the ECHA website.

GENERAL CHEMICALS

REACH 2018: ECHA launched its campaign for the final phase-in registration timeline of 2018 for substances manufactured or imported in low volumes, between 1-100 tonnes per year. A new webpage dedicated to the 2018 submission is now available to help and encourage registrants to start the dossier preparation process as early as possible due to the complexities of the technical dossier preparations. ECHA has generated a simplified procedure indicating the principles of seven steps to REACH 2018.

New Compliance Check Strategy: ECHA is changing how it checks the compliance of registration dossiers. The main focus will be to check information on those substances that matter most for the protection of people and the environment. This means high-tonnage registrations with data gaps in human health or environment endpoints and with high potential for exposure; and substances or mixtures that are widely used by workers or the general public. Most dossiers will be chosen because of these concerns but some dossiers will still be picked up randomly so that no registrant can be certain that their dossier will not be selected.

New eGuide for Safety Data Sheets and Exposure Scenarios: a new eGuide has been launched by ECHA to help users navigate their way around safety data sheets and exposure scenarios. The guide contains 'quick look' pages and short video tutorials to help users understand the key information in the dossier and how to utilise and understand this information to ensure they are a compliant downstream user of a REACH registered substance.

CLP Campaign: from 1 June 2015, the Classification, Labelling and Packaging (CLP) Regulation will apply to both substances and mixtures. This means that suppliers of mixtures on the market in the EU will need to re-classify their products in accordance with the CLP criteria. ECHA has provided a dedicated webpage providing campaign materials, leaflets, guidance and a questions and answer section.

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