

Final Stages of REACH, EU HazCom, Brexit

Gill Pagliuca
Denehurst Chemical Safety Ltd
gill.pagliuca@denehurst.co.uk
www.denehurst.co.uk



31 May 2018 – not the end of REACH, but the end of the beginning ...

- Approx. 21 500 chemicals registered as of 1 June 2018 in approx. 90 000 registrations
 - Earlier estimates were around 30 000 chemicals requiring registration - where are the missing ones?
 - Some substances removed from market
 - Some substances being managed to keep below 1 ton threshold
 - Some still not registered yet ...
 - Many registrations still taking place (approx. 1600 since end of May!)
 - Late changes in Lead Registrant
 - Data sharing disputes still ongoing
 - Late availability of test results
 - Just didn't get it done in time

How to register now

- If a valid pre-registration is in place, can still use pre-registration number and contact Lead Registrant through the pre-SIEF pages in REACH-IT
 - Commission expected to issue an Implementing Regulation with finite deadline (31st December 2019?) on use of pre-registration numbers
 - Will also introduce a finite deadline for use of 3 year rolling averages to calculate tonnage – in future will all be based on calendar year (Jan-Dec)
- If no valid pre-registration, Inquiry is needed

Inquiry process

- Need clear information on substance identity, including good quality analytical data
- If all this is in place, Inquiry dossier is simple to prepare (~ 1-2 hours) and submit, and response back from ECHA within a couple of weeks
- If poor analytical data/unclear substance ID, expect dossier to be rejected and delays while you sort out or get additional data and resubmit

Enforcement

- REACH-EN-FORCE 7 (REF-7) in 2019 will focus on checking duties related to registration and registrations of intermediates
- Enforcement will include co-operation with customs authorities for imported goods and checks of strictly controlled conditions for intermediates
 - Some carriers starting to ask for proof of registration from Only Representatives (OR) and importers

Compliance

- Registration is not the end of the road – legal obligation to keep dossiers up to date
 - 67% of dossiers have never been updated
 - ECHA's REACH 2018 Roadmap - Phase 7 Keeping registrations up to date
 - New initiatives to be launched this Autumn
 - Companies need to make sure structures in place for updating Joint Submissions
 - Some Member States (MS) calling for an Implementing Regulation to clarify obligations to keep dossiers up to date

Compliance checks

- Prioritisation likely for substances that are high hazard (i.e. concerns for long-term health/environmental hazards) and high exposure
 - Shift by regulators to evaluation of groups of substances
- Dossiers that are rarely updated also likely to be a target for future compliance checks
- ECHA publish list of substances likely to be targeted <https://echa.europa.eu/regulations/reach/evaluation/compliance-checks>
 - List updated several times per year
 - Opportunity to update your dossier before the evaluation process starts



REACH - Where next?

2nd REACH review (published March 2018)

- No major legislative changes
- Key actions identified were:
 - Improvements in compliance of registration dossiers
 - Simplification of requirements for extended Safety Data Sheets, evaluation, authorisation
 - Ensuring a level playing field with non-EU companies through effective restrictions and enforcement
 - Clarity on interface between REACH and other EU legislation, in particular OSH and waste

Notification of substances in articles

- Current notification obligations set out in REACH Article 7(2)
 - Applies to articles produced or imported that
 - contain >0.1% w/w SVHC and
 - total tonnage of SVHC >1 tpa,
 - unless already registered for that use or exposure can be excluded

Notification of substances in articles

- Obligations extended by Directive (EU) 2018/851 amending Article 9 of the Waste Framework Directive
 - Aims to facilitate recycling of materials and also allow consumers to make more informed choices
 - Requires all suppliers, including producers, importers, distributors and retailers to make notifications
 - Requires ECHA to establish database to receive notifications
 - Requires Member States to adopt the necessary implementing legislation by 5 July 2020

New substances in articles notifications

- Notification will be required for all articles that contain SVHC > 0.1% by 5 Jan 2021
 - No minimum volume thresholds for notification
- Information to be available to waste treatment operators and to consumers upon request
- Will need to provide information required by REACH Article 33, i.e. information necessary to allow safe use, including as a minimum the name of the substance



New substances in articles notifications

- Many questions still to be resolved:
 - As requirements will be implemented by MS, will they be harmonised?
 - Will notification still be required if notified further up the supply chain? In a different MS?
 - What information will be confidential, particularly in relation to consumer requests?
 - What will be considered to be sufficient information to allow safe use?
 - Will regulators use this information to identify need for new legislation, e.g. new REACH Restrictions, amendments to ROHS, etc.

Other hot topics

- Nanomaterials
 - Draft regulation amending REACH Annexes to clarify requirements for nanoforms issued in April
 - Expected to enter into force Jan 2020
 - Guidance being prepared
- 1-10 tons
 - Possibly request CSR for CMRs 1-10 tonne?
- Polymers
 - Registration of some polymers?
- Microplastics

CLP legislation updates

- CLP is updated regularly
 - Annually to adopt new and updated harmonised classifications agreed by the ECHA Risk Assessment Committee (RAC)
 - Every 2 years to adopt changes to the latest GHS
- ATPs published but not yet fully in force
 - [Regulation \(EU\) 2017/776](#) (10th ATP) – amendments to Annex VI including harmonised classification for nicotine, applies from 1 Dec 2018
 - [Regulation \(EU\) No 2017/542](#) Poison Centres ATP – more on this from next speaker!
 - [Regulation \(EU\) 2108/669](#) (11th ATP) – translation of chemical names, applies from 1 December 2019



CLP legislation updates

- ATPs in preparation
 - 12th ATP – update to GHS 6th/7th Rev Ed
[Draft published to WTO](#)
 - Includes updates to flammable gas criteria and desensitised explosives, clarification of health effects definitions and criteria
 - Update to REACH Annex II will also be needed at some point to implement changes to SDS
 - 13th ATP – amendments to Annex VI
 - Will implement 2016 RAC opinions, including MIT and propiconazole
 - 14th ATP – amendments to Annex VI
 - Will implement 2017 RAC opinions, including TiO₂

Brexit

- Possible Brexit scenarios (your guess is as good as mine at this point!)
 - Option 1: UK leaves with “no deal” and is completely out of the EU system on 30th March 2019
 - Transition period to end of 2020????
 - Option 2: UK leaves with some sort of deal covering goods but not services
 - May include “associate membership” of ECHA
 - Or it may not
 - Option 3: UK “exits Brexit” and remains in the EU

Brexit – No deal Option

- ECHA webpages provide a good analysis of the “no deal” situation
 - [ECHA Q&A](#)
- UK making preparations for “no deal” (or a deal that doesn’t include chemicals legislation)
 - [HSE Position statement](#)
 - [UK government paper on impacts on REACH and chemicals legislation](#)

UK Brexit planning

- UK Department for Environment, Food & Rural Affairs (DEFRA) policy lead with UK Health & Safety Executive (HSE) responsible for most of the day to day implementation
- UK Government have stated that all existing EU legislation should continue to apply once the UK has left the EU
 - Draft legislation in preparation
 - IT infrastructure in development

Possible Impacts of BREXIT “No Deal”

- United Kingdom registrations (data from ECHA)
 - Registrations: 12 291 (13%)
 - Second largest after Germany
 - Substances: 5 674 (26%)
 - Of these 29.7% as Importers, 47.5% as OR, 17.4% as Manufacturers, 5.4% as both Manuf + Imp
 - Companies: 1 754 (12%)
 - UK companies are lead registrant for many substances

No Deal Scenario

- If UK becomes “third country” then all UK registrations will be regarded as non-existent
 - For UK manufacturers, possibility to transfer Registration to EU based OR
 - Fees will need to be paid
 - For UK importers, transfer to OR may not be feasible due to wording of Article 8
 - Only manufacturers of substances, formulators of mixtures and producers of articles established outside the EU are able to appoint an Only Representative

No Deal Scenario

- If registration held by UK OR, possible to transfer to another EU based OR
 - many UK OR's considering relocating or setting up an EU company to which registrations could be transferred
 - Again, a fee will need to be paid to transfer registration
 - If transferring to a new OR, co-operation of existing OR is needed
 - Processes for transfer of OR are already well defined under REACH

No Deal Scenario - timing

- ECHA recommending companies set up a contractual agreement to appoint an EU based OR and for the agreement to take effect on the date when the UK leaves the EU
 - 30 March 2019 00:00 hours CET (29 March 2019 23:00 hours GMT), unless a transitional arrangement is agreed
 - ECHA working out practical steps necessary to deal with timing

No Deal - UK Lead Registrants

Options for UK Lead Registrants

- move to the EU
- appoint an EU based Only Representative who takes LR role
- SIEF appoints a new lead registrant

No Deal - Authorisations

- In “no deal” scenario, REACH Authorisations granted to UK companies will no longer apply
- UK suppliers holding Authorisations covering their downstream EU customers can transfer the Authorisation to their OR - if they appoint one
- If no authorisation in place, EU customers will need to seek another supplier whose authorisation will cover them, or to apply for their own authorisation

Classification and Labelling

- EU customers of UK companies will need to submit notifications to the Classification and Labelling Inventory if required
- Labels and SDS for UK products exported to EU will need to be updated with name and address of EU company responsible for placing the product on the market

UK Domestic Impacts of BREXIT

- UK will implement their own equivalent legislation for REACH and CLP
 - No deal paper suggests existing UK registrants will be able to carry across existing registrations
 - Notification within 60 days, full data package to be submitted within 2 years
 - Will be the same data package as REACH
 - “Light touch” notification process for UK companies importing for the first time
 - Notification within 180 days, full registration eventually required
 - Existing authorisations held by UK companies carried through

UK Domestic Impacts of BREXIT

- Many questions still to be answered
 - Will EU companies be able to register in the UK via OR?
 - Will there be fees to pay?
 - Will EU REACH letters of access be valid for UK registrations?
 - Will UK companies relying on authorisations held by EU suppliers be covered?
 - Will the UK remain close to REACH, CLP and other regulations, or will it choose to diverge in future?

Any questions?

