# After REACH 2018 - What's Next?

Tuesday, March 19, 2019

**Premise:** The deadline for the registration of existing chemicals in EU commerce has now passed. What can you expect from ECHA under REACH in the future? ECHA dossier reviews and updates? Authorization and Restriction activities? Substances in Articles?

**General Session Notes:**

- Update to the Waste Framework Directive will impact REACH and require notification into ECHA database for substance of concern in articles - keep an eye on that for article manufacturers and mixtures.
- *Topic for next SCHC: Extended SDSs for REACH

**REGISTRATION:**

**Question/Prompt/Concern:**

- Registration - how are you evaluating now what is new, what tonnages may change, how are you being active and keeping track of your registrations, etc.?

**Response:**

- 1 - switch OR to someone in the EU (was in the UK)
- 2 - watching tonnage bands to ensure staying within registration limit but may need to increase bands to next level as sales grow -- for companies that do not have a lot of new products right now can do this manually.

**Question/Prompt/Concern:**

- What do you look for when verifying REACH registration status - are you ok with registration # on supplier SDSs? Is that good enough? Do you check the registration numbers to make sure they are valid?

**Response:**

- 1 - most customers are happy with that
- 2 - customers may come back to verify their use
- 3 – statement that all substances in this mixture are verified by REACH, please contact our OR for additional information (see section 15)
    - For items that are proprietary
    - Supply distributors with a letter that says the same thing
    - OR can then provide certificates/documentation to customers who reach out

**EVALUATION:**

**Question/Prompt/Concern:**

- Evaluation of substances and registrations

**Response:**

- REACH is not done once registrations are in - they will continue to be looking at substance and registrations that need evaluation -to try to remove harmful substance/ products from the market
    - Started with "low hanging fruit"
    - Start with dossiers and pick through the data and look at classification and exposure pattern.

**TONNAGE:**

**Question/Prompt/Concern:**

- If you switch/up tonnage bands, EU says to notify "without undue delay"

**Response:**

- Unclear as to what "undue delay" means and what the expected timeline associated with it is
- Best to submit quickly, may need an internal company timeline

**Question/Prompt/Concern:**

- Customers who want to be included in your tonnage band - how can you keep the customer happy without going above your own tonnage band

**Response:**

- 1 – monitoring to keep track of own sales
- But a lot of companies may assume that they are being covered, important to check

**Tonnage Notes:**

- Tonnage - if registered in 2010 and were over 1,000 tonnes per year then good to go as that is the upper tonnage band.
- Use - need to know how sales/customers are using the substance. You can cover you in our tonnage BUT depends on how you are using it
    - *REACH is all about use and thus exposure standpoint
    - if getting information from a customer, get info as to what their use is or what category it falls under
    - important to ensure you have the information on hand from the customer verifying how they said they are using it so that if they provided incorrect details, you have documentation to back it up

**<u>DOWNSTREAM USERS:</u>**

**Question/Prompt/Concern:**

- Downstream user obligations

**Response:**

- Shared experience with an extended SDS authoring
    - If greater than 10 tonnes, safety assessment and exposure scenarios and amend to a SDS
    - Substances - lengthy, difficult
    - Electronic systems to assist with creation, help simplify process
    - Mixtures - performed with OR assistance, added to the end of current EU REACH SDS
- For simple mixtures: could look to integrate some of the extended SDS info stuff into regular 16 sections. ECHA has some options in their guidance on this.
    - Also consider use of SUMIs (sector use maps) when available

**Question/Prompt/Concern:**

- Downstream user requirements

**Response:**

- Is it registered? Registered for your use?
- Follow obligations provided in extended SDS or confirm equivalent level of controls
- If not, then may need to create own downstream user report (submit to ECHA) to evaluate and fit company needs

**<u>SDSs:</u>**

**Question/Prompt/Concern:**

- SDSs - on ECHA's enforcement radar

**Response:**

- Pushed out to member states (MS) to enforce
- May see some differences with enforcement
  But the MS will meet regularly to set campaigns as to what they want to see, important changes, etc. Next enforcement priority-focus :
  - Focus on things with nickel, cadmium, lead in consumer products (imported products comply with certain restrictions under REACH)
  - They are also verifying that chemical products are labelled with the required safety information
  - Tighter collaboration with customs

**Question/Prompt/Concern:**

- Different languages for extended SDSs - how are people approaching that? expensive, long, etc.
- How to translate, how to be practical about it

**Response:**

- 1 - google translate (for shorter ones to fewer countries/languages)
- 2 - software services for SDS authoring

**Question/Prompt/Concern:**

- Extended SDS Phrases

**Response:**

- chemical safety assessments
- Set phrases but can put in free text based on how the chemical may be used - to explain daily release amount for example so there are some set phrases and others that are not set/up to SDS company
  - Try to give qualifying factors so people can appropriately scale
  - Difficult to do with translations
- Recipient can use the extended SDS info to do internal scaling to try to meet recommendations, exposure parameters with what company requires
- Extended SDS phrase incorporation into SDSs
  - Risk management measures, PPE - section 8
  - Uses - section 1
  - Some in section 15
  - May be difficult to prove/demonstrate that you have included all information from extended part into SDS

**<u>ENFORCEMENT:</u>**

**Question/Prompt/Concern:**

- Enforcement

**Response:**

- Will vary by country/member state
- ECHA is training Customs to be their eyes and ears
  - What do you hear from your customers….
    - Section 15 concerns from customers (depends on what member state they are in) -- two level communication - different regulations to put but are not clear about instructions
  - *Biggest is managing business risk, supplier risk, customers

**DOCUMENTATION:**

**Question/Prompt/Concern:**

- Systems for documentation and verification

**Response:**

- 1 - SharePoint
- 2 - product stewards for each product line, they handle documentation for all regulations for those lines
- ECHA wants dossier updates every 3 years - make sure you have your original files otherwise you have to use IUCLID and re-enter manually ALL data - make sure all documentation is in place and have a system to attach documentation
    - IUCLID is constantly being updated to new versions
    - If you entered in 2010 to version 4 and then need to update and they are on version 6, cannot get back in - make sure you always have a way to access newest version and have updated info/files

**RESTRICTED MATERIALS:**

**Question/Prompt/Concern:**

- Restricted Materials - have you been involved with restrictions, micro-plastics issue

**Response:**

- Micro-plastics are not just plastics, it is misleading, look at definition

**Microplastics Definition:**

The request to ECHA from the European Commission6 referred to microplastic particles as 'synthetic water-insoluble polymers of 5mm of less in any dimension'. After discussing with the Commission, ECHA subsequently adopted a 'working definition' for microplastic particles for its call for evidence as 'any polymer7, or polymer-containing, solid8 or semisolid9 particle10 having a size of 5mm or less in at least one external dimension'. The intention was that all four of the criteria in the definition (substance, state, morphology, dimensions) would need to be fulfilled concurrently for a material to be considered as a 'microplastic' and, therefore, for its uses to be of interest to ECHA. The ECHA working definition did not distinguish between synthetic (i.e. artificial), naturally occurring or modified naturally occurring polymers or between water soluble and water insoluble polymers. However, these elements are recognized to be important for risk assessment and information on these aspects were specifically requested in the call for evidence. Source: https://echa.europa.eu/documents/10162/13641/note_on_substance_identification_potential_scope_en.pdf/6f26697e-70b5-9ebe-6b59-2e11085de791

**OTHER:**

**Authorization:**

- Ensure that your chemical CAN be used
    - – watch indirect impact from supply chain or discontinuation of substance in EU from your supplier.
- Have to prove to ECHA its safe to use
- Only get approved for a certain time then have to come back to them for re-approval to continue to use
- Show complete control or safe use/safe use level or that you are going to switch it out

**Other Countries that implement something similar:**

- China - for trade reasons

- K-REACH
- To be part of OECD, have certain benchmarks
- Big market, want to have control or visibility of market
- European Commission used to do risk assessments, could not get enough completed, pushed out to industry

**Brexit:**

- If UK OR have to find a new OR in EU
- May not know for awhile
- Does your company have a plan and resources in place

**Question/Prompt/Concern:**

- Naming differences between EU & US - don't want to confuse customers

**Response:**

- 1 - divided ingredient into jurisdictional standard you would ship it to so you do not have to worry about removing inapplicable information for one document to another for the same thing -- ship to EU so remove Prop 65, change CAS #s? (remembering to change)
- 2 - US document and EU document (think GHS hazards)

**Question/Prompt/Concern:**

- Medical directive and how it plays into REACH - especially with SVHCs

**Response:**

- Medical devices are regulated now by a new regulation and included a piece about restricted substances – CMR
- Linked it to CLP but that list is constantly growing
    - Phthalates
    - Have to do a benefit risk analysis if it will come in contact with the human body, fluids, to show it can be used without harm
        - First have to know if it is in your medical device -- go down multiple levels -- down to suppliers… that can be difficult
        - New and existing EU medical devise will require some type of benefit risk documentation analysis, if falls into a set of categories, if it is at a certain percentage >0.1%
        - Guidance to how to in Sept (specifically phthalates first){post meeting issued recently from SHEER]
        - EU - notified bodies are the ones who approve them
        - *Purely looking at this in regard to patients and human health

**LINKS:**

- REACH: https://echa.europa.eu/regulations/reach/understanding-reach
- Latest News: https://echa.europa.eu/reach-2018
- Keep your registration up-to-date: https://echa.europa.eu/reach-2018/keep-your-registration-up-to-date
- IUCLID: https://iuclid6.echa.europa.eu/
- DCG Call for Continued Compliance: https://echa.europa.eu/-/call-for-companies-to-continue-their-cooperation-after-the-deadline
    - https://echa.europa.eu/documents/10162/13559/180531_dcg_recommendation_continued_cooperation_en/35fc05b0-13ba-0e94-b069-2e0ea19dc0f3

- How to make changes to join submissions: https://echa.europa.eu/changes-to-joint-submissions
- How to improve your dossier: https://echa.europa.eu/support/how-to-improve-your-dossier
- Dossier Evaluation Status: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status
- Decision under dossier evaluation: https://echa.europa.eu/decision-under-dossier-evaluation-recommendations
- Decision under substance evaluation: https://echa.europa.eu/decision-under-substance-evaluation-recommendations
- Public Activities Coordination Tool: https://echa.europa.eu/pact
- Brexit: https://news.bloombergenvironment.com/environment-and-energy/2019-outlook-more-scrutiny-in-chemical-regulation-in-european-union