Update on Major EU Chemical-related Regulations

TURI 2019
Norwood, MA

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Agenda- Part 1

- **EU REACH Overview**
  - Registration obligations and Supply Chain concept
  - REACH controls, active Evaluation and list changes
- **Classification and Packaging Regulation (CLP)**
  - CLP Annex VI- Harmonized Classifications
  - Poison Control Center Notification Submission- Mixtures
  - TiO_2 Classification Update
- **EU RoHS**
  - Current substance list and documentation/certification requirements
- **Waste Framework Directive**
  - SVHC in Articles Database ("SCIP")

Agenda- Part 2

Tools and References

- ECHA website
- SIN List
- BOMcheck (electronics)
- GADSL (Automotive)
- EU Rapid Alert System

Questions:

Are you involved with exporting to the EU:

- "Pure" chemical substances?
- Chemical mixtures (paints, solutions, plastic compounds (pellets, etc.), etc.?
- Articles- molded products, solid complex products, solid components, etc.?

Do you regularly follow ECHA's regulatory activities?

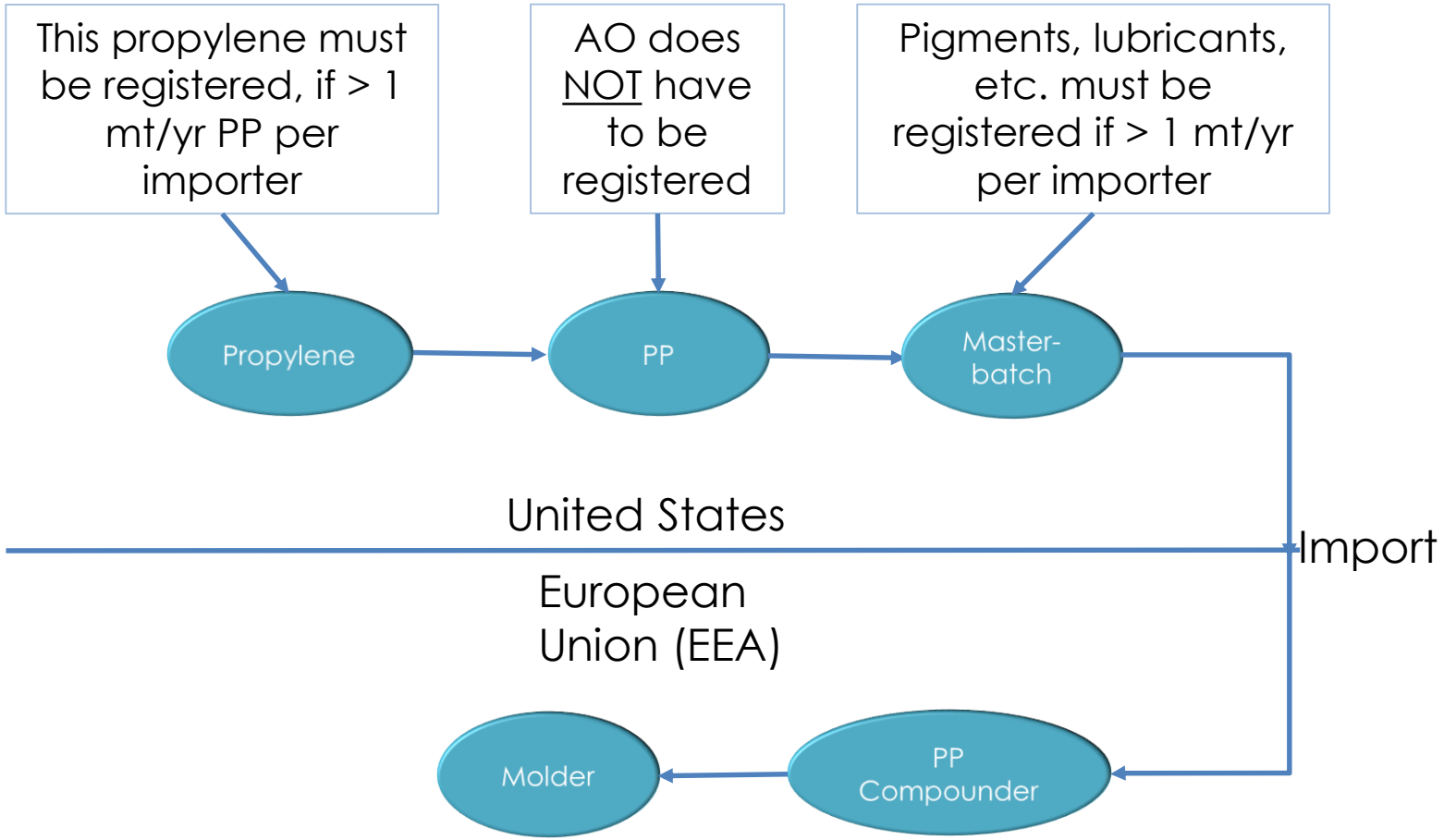
REACH Regulation- Registration

- Substances produced or imported into EEA > 1 mt/EU legal entity (manufacturer or importer) must be registered
- Only EU legal entities can register
- Polymers are exempt, but monomers used to produce polymer must be registered in the Supply Chain
  - "Stabilizers" to protect the polymer do not need to be registered (i.e. antioxidants, heat stabilizers, UVIs), but other additives DO (lubricants, coupling agents, pigments, etc.)
  - Plastic compounds (pellets, dry blends, masterbatches, etc.) are considered chemical mixtures, thus the substances in the compounds are subject to registration obligation
- Some exemptions or reduced data requirements for research and market development

Supply Chain

- The specific "provenance" of a substance from initial production site
- I.E.- Although nearly 300 companies have registered propylene, "your" propylene supplier's propylene must be registered if used to produce your polypropylene imported into Europe at > 1 mt/yr.
- Track the registration obligation

REACH Registration Obligations



Nanoform Substances

- Substances in particle form can be also be in nanoform
  - REACH defines nanoform as a substance with ≥50% particles with at least one dimension ≤100 nm (number size distribution)
- New or existing REACH substance registrations must be updated by 1 January 2020 with required characterization and safety information for the nanoform of the substance.
- Several EU Member States also have registration requirements for products containing nanoform substances (some for substance alone, some include mixtures containing, and some including articles containing)

ECHA Lists 1/2

Each list can be "filtered" or searched on attributes

- Candidate List (**S**ubstance of **V**ery **H**igh **C**oncern)
  - Registry of SVHC intentions until outcome
- Authorisation List (Annex XIV)
  - Submitted recommendations- SVHCs for Authorisation
- Restriction List (Annex XVII)
  - Registry of restriction intentions until outcome
- Community Rolling Action Plan (CoRAP)

ECHA Lists 2/2

- **C&L Inventory (CLP/GHS classifications- Harmonised and self-classified)**
  - CLP Annex VI- only harmonised (mandatory) classifications
  - Registry of CLH intentions until outcome
- **Biocidal Products Regulation**
  - Biocidal Active Substances
  - Biocidal Products
  - Several subsidiary lists on activities- registration, renewal, etc.
- **PIC- Prior Informed Consent**
- **POPs- Persistent Organic Pollutants**
- **CAD/CMD- Chemical Agents Directive/Carcinogens and Mutagens Directive (EU-level OELs)**

Refresher- Major REACH Controls Authorisation and Candidate List

- **Authorisation**
  - Substance cannot be manufactured or used within the EU (EEA) without specific authorisation from ECHA
  - Some limited exclusions (including if Registered as an "Intermediate" and handled under "strictly controlled conditions", fuel component, etc.)
- **Candidate List (SVHC)**
  - Substances which are "candidates" to be placed under Authorisation
  - If present in "articles", must be disclosed down the supply chain, and should be notified to ECHA
  - Currently 201 substances- substances added ~ every January & July, so list needs to be checked often!

Refresher: Major REACH Controls Restriction and Evaluations

- **Restrictions**
  - Substance(s) cannot be present in certain (or all) uses
- **Evaluation of registrations submitted**
  - ECHA can require additional testing by registrants to decide whether additional controls are appropriate

Restrictions- In force 1/2

Currently 73 Restrictions in force, plus many more proposed. Currently in force:

- As of July 2020, DEHP, DBP, DIBP and BBP are further restricted from general use (all indoor and all skin/mucous contact uses) (Entry 51)
- Cadmium compounds for use in polymers/plastics (Entry 23)
- Various organotin compounds in various end uses (Entry 20)

Restrictions- In force 2/2

- MDI in Consumer Products (general public) (Entry 56)
  - Package must include gloves and special labelling
- Toluene in adhesives or spray paints for Consumer (Entry 48)
- 1-methyl-2-pyrrolidone (NMP)- certain conditions and Risk Mgmt measures required- from May 2020 (May 2024 for wire coating) (Entry 71)
  - DMF is proposed for similar Restriction
- Several Restrictions on substances classified as Repro, Carc, Muta, or ED

Restrictions- Pending 1/2

- Pending broad restriction on **lead in PVC** products (max 0.1% qs Pb). Effective 2 years from approval- some additional extensions. The Commission notified the WTO. (Acts as amendment to Entry 63).
- ECHA has proposed a broad restriction on **"microplastics"** (<5mm dimensions) in consumer and professional-use products, plus labelling and reporting requirements for all end uses (includes plastic pellets)
- Pending restriction on **diisocyanates** in Industrial and Professional products- would require extensive training and warnings to workers

Restrictions- Pending 2/2

- Carefully check all **brominated flame retardants**
- Carefully check all **per/polyfluorinated** substances
- Carefully check all **heavy metal** substances
- Pending Restriction on **formaldehyde** and **"formaldehyde releasers"** (typically adhesives, resins) Biocides and textiles are already controlled
- Pending Restriction on **chlorophosphate FRs** in childcare and PUR foam consumer furniture and mattresses

Hypothetical Situation #1

My coating formulation's solvent blend includes 2% DMF.

Do I need to do anything?

Hypothetical Situation #1

- CLP Annex VI shows a harmonised classification for DMF which must be used for EU classification:

  Acute Tox 4 (skin and inhalation)

  Eye Irritation 2

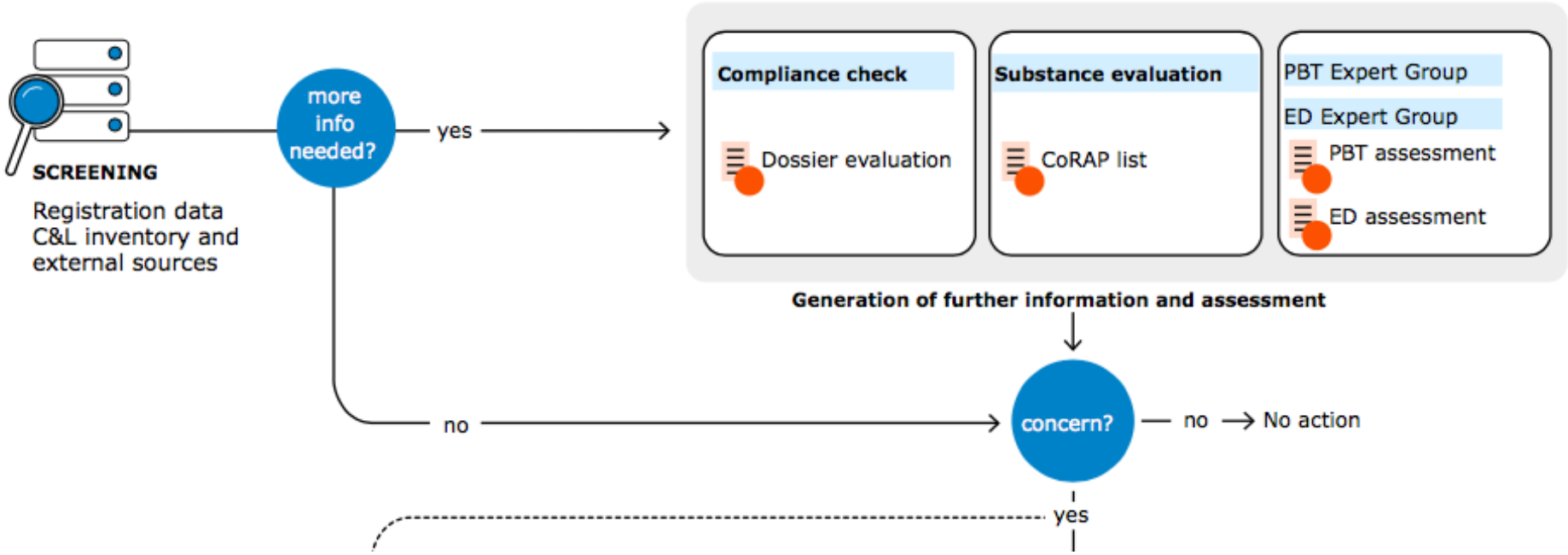
  Repro 1B (H360D)

- There is a proposed restriction requiring use of Derived No Effect Levels of 3.2mg/m^3 inhalation, and 0.79 mg/kg bw/day skin (2 year transition)

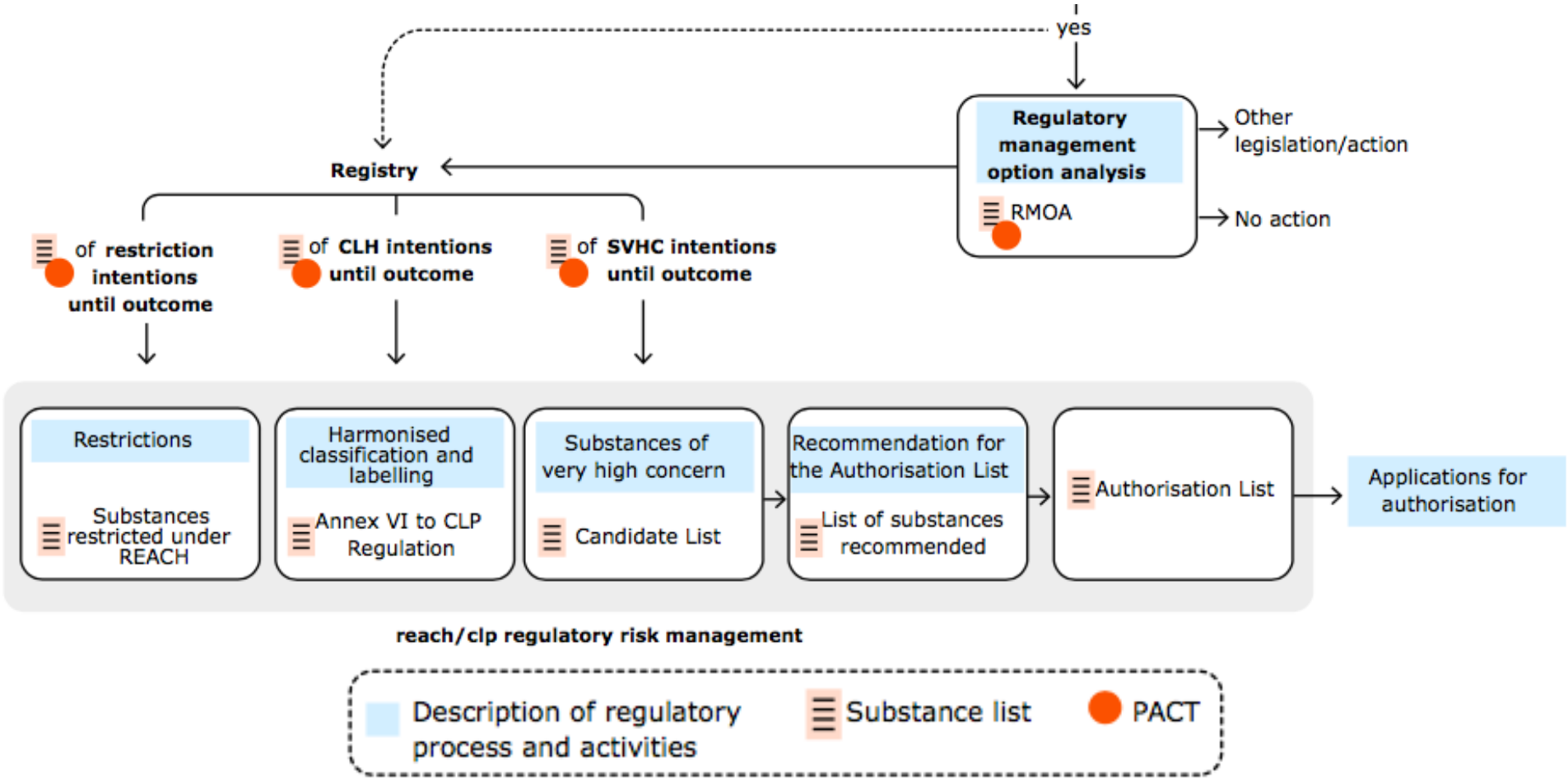
REACH Evaluation Programs

- Can be initiated by Commission or Member State Authority
  - May result in "no action needed", or additional regulatory controls (classification, Restriction, SVHC listing, etc.)
  - **Co**mmunity **R**olling **A**ction **P**lan (CoRAP)
    - Can require additional testing data on substances
    - 376 substances have been or are currently under CoRAP evaluation
  - Evaluations for Endocrine Disruption or PBT/vPvB
- IF evaluation results in concern, then:
  - **R**egulatory **M**anagement **O**ption **A**nalysis (RMOA)
- Check ECHA often
  - **P**ublic **A**ctivities **C**oordination **T**ool (PACT)
    - Lists status of evaluations- CoRAP, ED, PBT/vPvB, RMOA, etc.
    - Will also show if substance has been "cleared"

ECHA Evaluation Processes



Possible Evaluation Outcomes



CoRAP Evaluation of TOTM

Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate

EC / List no: 222-020-0 **CAS no:** 3319-31-1

Data generation and assessment

DEv - Dossier evaluation

DEv 1

SEv - Substance evaluation (Community Rolling Action Plan (CoRAP))

SEv 1

Evaluating Member State	Austria
Co-Evaluating Member State	
Initial grounds for concern	Suspected PBT/vPvB High (aggregated) tonnage Wide dispersive use
Year	2012
Status	Ongoing

Checked with Austrian authorities- still ongoing as of October 2019!

EU RoHS 1/4

- Key changes in past few years:
  - "The Four Phthalates" (DEHP, DBP, DIBP, BBP) were added to the prohibited list- prohibition takes effect 22 July 2021
    - In June 2018, Swedish Authorities proposed medium-chain chlorinated paraffins to be added. No action thus far
  - EN IEC 63000:2018 specifies the technical documentation required to demonstrate compliance with RoHS (IPC 1752A can be used to obtain declarations from upstream suppliers)
  - Note that continued use of CE marking indicates that the supplier confirms RoHS compliance
- Substance concentration based on "homogeneous material"

Current RoHS Prohibited List 2/4

Lead (0.1%	Mercury (0.1%)
Cadmium **(0.01%)**	Hexavalent Chromium (0.1%)
Polybrominated diphenyl ethers (0.1%)	Polybrominated biphenyls (0.1%)
Bis (2-ethylhexyl) phthalate (0.1%)	Butyl benzyl phthalate (0.1%)
Dibutyl phthalate (0.1%)	Diisobutyl phthalate (0.1%)

EU RoHS 3/4

Some exemptions:

- Heavy industrial installed tools or fixed installations
- "Means of Transport" for persons or goods
  - But does apply to electric non-type-approved 2 wheel vehicles
- Off-road heavy equipment for professional use
- Photovoltaic installations
- Active implantable medical devices
- Equipment solely for R&D- only provided business-to-business

EU RoHS 4/4

Some Exemptions (cont'd)

- Repair of medical devices and monitoring & control instruments placed on the market prior to effective dates of substances
- Certain exemptions for medical devices and monitoring & control instruments utilizing or detecting ionizing radiation and other specific applications in these products- some with expirations
- Annex II and III list specific substance/end use exemptions

Classification, **L**abelling and **P**ackaging Regulation ("CLP")

- EU's Implementation of GHS
- CLP implementation of GHS differs from US HCS
  - A few different classes (i.e. CLP : no Flammable Liquid 4, Combustible Dust, etc. US: no Eye Damage 2B, etc.)
  - English wording of some H and P statements differ between CLP and HCS. EU has additional "EUH" statements
  - A few different threshold values for classification
  - CLP mandates environmental classes
- CLP Annex VI
  - Lists "harmonised" mandatory minimum substance classifications which must be used within the EU (EEA)
- Substance or mixture evaluations under CLP may result in classifications differing from US HCS classifications

Case in point- TiO_2

- EU Commission has forwarded to the EU Parliament and Council their recommendation (14th ATP) to classify TiO_2 as Carc 2 (suspected carcinogen by inhalation). Unless either body objects, it will become law by January and the classification in effect from July 2021
  - 300 members of industry have "petitioned" the Commission to conduct an impact assessment of the proposed classification
- Controversial, as the classification is based on small (≤ 10µm) diameter or very small fibers, rather than intrinsic hazard of TiO_2 as a substance- possible precedent
- If alone or present in mixtures in powered form with > 1% TiO_2 particles ≤ 10µm, would require use of Carc 2 in classifying and labelling the mixture
- If present in solid or liquid mixtures, would require special labelling- new EUH phrases 210 and 211 would be required
- The potential effect on waste plastics containing TiO_2 is unclear at this point

CLP Article 45- Poison Center Notification ("PCN") 1/2

- Applies to mixtures classified for human or physical hazards
- Submission deadlines (current):
  - Products for consumer use (delayed to) January 1 2021
  - Products for professional use January 1 2021
  - Products for Industrial use January 1 2024
- Status:
  - There are IT problems with the ECHA database- the submission for consumer products has been delayed from 2020 to 2021
- If your company has SDS software system, check with your provider to be sure that your system will prepare XML file for submission (there is a direct user-portal for manual entry of data, but would seem to be very labor-intensive)

CLP Article 45- Poison Center Notification ("PCN") 2/2

- CLP will require XML submission of product safety data to an ECHA database. The database will only be available to EU poison center professionals.
  - Assigning a product **U**nique **F**ormula **I**dentifier "UFI"
  - Essentially full composition disclosure
  - Tox data from SDS Section 11
  - Product category from standardized EU list: EuPCS
  - CLP Classification
  - Information on submitter, product packaging, appearance, etc.
  - Does not satisfy some Member State product registration obligations

Revised Waste Framework Directive 1/2

- Objectives are to:
  - Reduce the presence of SVHCs in EU waste stream
  - Aid waste industry in safe reuse/disposal
  - Allow authorities to monitor the use of substances of concern in articles
- A new requirement added: ECHA to establish a database – the **S**ubstances of **C**oncern **i**n **P**roducts ("SCIP") database - for hazardous substances in articles
  - Database will be "article-centric", rather than "substance-centric"
    - Articles containing >0.1% SVHC will need to have a Primary Article Identifier for each specific article containing SVHC
    - Companies down the supply chain will be able to incorporate suppliers' Identifiers into their submission to "roll-up" SVHC information down the supply chain for complex products
    - Remember that the "O5A" principle remains- if a complex product contains only one component with >0.1% of a SVHC, the complex product will need to be registered!

Revised Waste Framework Directive 2/2

- Responsible parties for submission:
  - EU producers, importers, assemblers, and distributors
- Information to be submitted
  - Primary Article Identifier for submitted article
  - Description and categorization of submitted article
  - Identifiers of components, if a "complex" article (multiple SVHC-containing component articles)
  - Name and concentration range of SVHC in article
  - Information on safe use of article, including at waste stage
- Timeline:
  - January 2020- database established
  - January 2021- submission deadline

Hypothetical Situation #2

My PVC film that is exported to Europe includes DCHP plasticizer and UV-328 among other components.

Do I need to do anything?

Hypothetical Situation #2

- DCHP (Dicyclohexyl Phthalate) and UV-328 are both on the Candidate List, so you need to inform your EU downstream customer chain.
- You should also submit a notification of "SVHC in Articles" to ECHA, and be prepared to support your importer and downstream submissions to the SCIP database

Questions?

- Please note that Syska Voskian Consulting does not take any position on the scientific basis of Authorities' decisions on any substance
- Our consultancy supports clients' understanding of regulations, and strategies to comply with current and announced future regulations, as well as future regulatory contingencies

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