SCIP Introduction Presentation for AEM
(June 25, 2020)

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What Are EU REACH 1907/2006?, SVHCs? and obligations to report data?

Under the EU Registration, Evaluation and restriction of CHemicals (REACH) regulation (EC) no 1907/2006, Substances of Very High Concern (SVHCs) are identified as those which are considered to be the most hazardous to humans and the environment.

Following a structured review process under the Community Rolling Action Plan (CoRAP), substances are listed on the ECHA Candidate List of substances of very high concern for Authorisation, which is essentially a watch list of substances which require specific reporting actions. Under Article 33(1) of EU REACH, manufacturers of articles (products) have a legal obligation to report data:

Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

There are numerous references under EU REACH, where it was assumed this data would flow down to waste stream operators.
EU REACH Regulation
“Once an article, always an article!”

- Important concept: “article” definition
  - REACH Article 3(3) “article... means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”

- European Court of Justice judgment of September 10, 2015 in case C-106/14:
  - In assemblies (complex products/objects), each component fulfilling the criteria of REACH Art. 3(3) is an “article” and remains an “article” when incorporated in the (complex) object “Once an article, always an article!”

Further information: ECHA Guidance on Requirements for Substance in Articles, Version 4.0 (June 2017)

Objects can be very complex...

... but principles remain the same.

- Calculation of 0.1% threshold per individual “article” (component AND below). There is no de minimis, 5 grams or otherwise.
Users of The SCIP Database

- **Consumers.**
  - Raise concerns
  - Inform

- **Non-Governmental Organisations.**
  - Retrieve data on products containing hazardous substances

- **Waste Stream Operators.**
  - Consume secondary raw materials

- **Article Manufacturers.**
  - Provide data
  - Create / update records
  - Create / update records. Retrieve data on mixtures, materials and products procured from supply chain

- **Member State Competent Authorities (MSCAs).**
  - Retrieve data / Enforce reporting

- **European Commission.**
  - Assemblies
    - Products
    - Materials
    - Mixtures
    - Substances

- **European Chemical Agency (ECHA).**
  - Create and maintain the database

- **Academia.**
  - Retrieve data.

- **Distributors.**

- **Importers.**
  - Provide data

- **Non-EU Article Manufacturers.**
  - Provide data

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EU SCIP Database Article 9 Requirements

Article 9(2) - Legal Text requirement for ECHA to generate database as per their own discretion.

2. The European Chemicals Agency shall establish a database for the data to be submitted to it pursuant to point (i) of paragraph 1 by 5 January 2020 and maintain it. **The European Chemicals Agency shall provide access to that database to waste treatment operators.** It shall also provide access to that database to consumers upon request.

Article 9(i) - Current legal requirement to report data:

(i) promote the reduction of the content of hazardous substances in materials and products, without prejudice to harmonised legal requirements concerning those materials and products laid down at Union level, and ensure that any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (\(^5\)) **provides the information pursuant to Article 33(1)** of that Regulation to the European Chemicals Agency as from 5 January 2021

The legal text for 9(i) is being updated to clarify the obligation that data will be required using tools and templates provided by ECHA - this has been agreed by member states and will be published in an amendment to EU WFD 2018/851 in July 2020.

"Any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council provides the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021 using the format(s) and submission tool(s) provided by this Agency for that purpose.”
EU revised Waste Framework Directive (WFD) 2008/98/EC

Implementation timeline for Article 9(1)(i)&(2) of the revised WFD


Entry into force: 4 July 2018

5 January 2020

Establish database (‘SCIP’)

SCIP prototype

5 July 2020

Prepare notifications

5 January 2021*

Notify ECHA

Provide access

Scary paranoia. Support database development

Enforce

*ECHA: The legal duty kicks in on 5 January 2021, meaning also that for every article placed on the market still on that day or the next, a notification would have had to be made by that time (provided that REACH Article 33(1) applies!). If supply occurs later on, the notification has to be done by that later time.

Official list of transposed WFD regulations
SCIP Reporting: Who can report data?

Legal Obligation to Report Data

- ECHA REACH-IT Accounts are supposed to be created by EU Based Legal entities where you provide a valid address and business information for an EU location.

- The expectation is that whoever completes the documentation for a product imported into the EU which contains an SVHC has the legal obligation to report data.

Non-EU?

- You are expected to collect (i) EU REACH data to identify SVHC content; (ii) Additional EU SCIP data.

- You should consider creation of SCIP data, either internally or via a third party.
  - Noting if you send products from a non-EU location to different distributors in different EU member states, multiple SCIP submissions may be required unless agreements to share data exist between different suppliers.
### SCIP Reporting: Duty Holder vs Foreign User Roles

**Duty Holder**

- Obligation to report data.
- Requires ECHA REACH-IT Account [EU Legal Entity].
- Assign third-party consultant/solution provider as a foreign under ECHA REACH-IT Account [EU Legal Entity].
- Need to collect additional SCIP specific data from the supply chain.
- Create complex/single article datasets.
- Submit dossiers.

**Foreign User**

- Third-party consultant/solution provider aiding the duty holder.
- Requires ECHA REACH-IT Account [EU Legal Entity]. Assigned foreign role under duty holder REACH-IT account.
- Perform actual data collection activities on behalf of the duty holder.
- Article dataset and dossier creation, including the validation of data.
- Use S2S interface to submit data to SCIP system once validated and approved by the duty holder.

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**NOTE** - ONLY EU based legal entities can submit data into the ECHA SCIP system.

You will need to have either (i) a business unit based in the EU or; (ii) appoint a third party to act as your legal entity.
SCIP Reporting: Datasets & Dossiers?

Article Datasets

- Individual product/complex product information.
- Compiled using SCIP mandatory and/or optional data reporting fields.
- Updated as new data is known (additional SVHCs/products containing SVHCs/SVHCs removed from products).
- Once data compiled:
  - SCIP Article Notification submission freezes data and generates .i6z file for article(s) record.

Dossiers

- Snapshot of a Article dataset at a point in time (based on SCIP Article Notification submission .i6z file created.
- Not linked dynamically to dataset.
- Created to generate final .i6z package, which is then submitted to ECHA submission portal as a dossier.
- Unique submission ID generated per dossier submitted.
- New SCIP Number field tracks submission of dossier IDs → part numbers

IUCLID (Cloud)
# EU REACH (typical) vs EU SCIP Data Fields

<table>
<thead>
<tr>
<th>EU REACH</th>
<th>EU WFD SCIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact details [Supplier detail]</td>
<td>[ECHA REACH IT Account (LE Manager) + defined SCIP Public Prototype Environment Users] First name, Last name, Email, Username, password [Company specific - identify legal entity address which generates the UUID] DUNS number, Vat Number, Business address, Name, UUID [Auto generated after legal entity created]</td>
</tr>
<tr>
<td>Part number, candidate list version, compliance statement, substance data (CAS, EC etc), concentration (optional) safe use information (basic).</td>
<td>[Article Record - Part Record] Article Name*, Other Name Type, Other Name Value, Primary article identifier type*, Primary article identifier value*, Other Article Identifiers, Article Category*, Production in EU*, Picture, Height Type, Width, Diameter, Density, Weight, Volume, Colour, Other characteristic, Value, <strong>No need to provide safe use information beyond the identification of the Candidate List substance</strong>*, Safe use instruction [inserted where supplier safe use instructions go beyond data stored in ECHA system], Disassembling instructions - Language, Disassembling instructions - attached document, <strong>If complex product article record Article</strong>*, Number of Units (Now optional)</td>
</tr>
<tr>
<td></td>
<td>[Chemical of Concern Record] Candidate list version*, Candidate list substance*, Substance name, EC number, CAS number [Auto-generated from selected substance], Concentration range*, Material Category*, Mixture Category* <strong>mixture or material category must be selected</strong>, Candidate list substance no longer present.</td>
</tr>
<tr>
<td></td>
<td>[Reference Substance] Currently 300 unique substance ID’s (expanded list of EU REACH candidate list substances in .i6z format - need to be attached with chemical of concern - specific to reported chemical substance).</td>
</tr>
<tr>
<td></td>
<td>[Dossier] Dossier name (given by user)<em>, Dossier subject</em> [Name*, Submitting legal entity*, Dossier creation date/time <em>, version</em> - Auto-Generated]</td>
</tr>
</tbody>
</table>

**BOLD = Mandatory, BOLD* = Mandatory with drop down list, all other fields are optional.**
SCIP reporting follows both EU REACH 1907/2006 Article 33(1) reporting and the European Court of Justice (ECJ), September 2015 ruling on ‘Once An Article Always An Article’.

This means you cannot list your finished complex product with a list of SVHC’s underneath it for a SCIP submission.
EU REACH Regulation
Component-level reporting (*according to ECHA*)

The information to be communicated down the supply chain must follow each component (or “sub-assembly”) as placed on the market.

Source:
3rd workshop on REACH regulation and its impact on space sector, 16.10.2019, Paris; [link](#)

Further information: [ECHA Guidance on Requirements for Substance in Articles, Version 4.0 (June 2017)](#)
SCIP Reporting: How an Article Notification Should Look Like

- Motor vehicle (passengers)
  - Article category
  - Reference number: 2345678900098
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- Combustion engine
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- Water pump
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- O-ring, 15x2.08, 20x3.5B, 20x5.0B
  - Article category
  - EC:276-158-1, CAS:71888-89-6, 1,2-Benzenedicarboxylic acid
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- Distributor
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- O-ring, 20x3.5G
  - Article category
  - EC:276-158-1, CAS:71888-89-6, 1,2-Benzenedicarboxylic acid
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- 0-ring_2
  - Article category
  - EC:276-158-1, CAS:71888-89-6, 1,2-Benzenedicarboxylic acid
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- Tyre
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- Tyre valve
  - Article category
  - + safe use instructions, disassembling instructions and characteristics

- Tyre valve cap
  - Article category
  - EC:271-084-6, CAS:68515-42-4, 1,2-Benzenedicarboxylic acid
  - Article category
  - + safe use instructions and characteristics
In this scenario a supplier of an article containing the SVHC would perform their Article Dataset creation and Dossier submission, first, providing their downstream users with a SCIP number.

The downstream user would then use the IUCLID interface and reference the suppliers SCIP number in their own Article datasets and dossiers.
Emerging Themes: Referencing (ii)

- This would logically work if you were able to get:
  - All your suppliers with SVHC content on Articles to perform ECHA SCIP submissions (if they are based in the EU).
  - You perform SCIP notifications on behalf of Non-EU suppliers (via an EU Based Legal Entity)
Emerging Themes: Referencing (iii)

**Basic principles**

1. **No change on the physical form nor composition on the reference article is allowed.**
2. The article referenced will become a component of a more complex object.
3. You cannot add additional components or other information to a referenced article.
4. By using referencing you are linking your notification to the upstream suppliers article notification and its updates.

**KEY - You are not making changes to referenced articles.**
Emerging Themes: Simplified Submission Numbers (SSN)

- **Supplier Part B**
  - Create Article Dataset

- **Submission Portal**
  - Submits a Dossier → Gets a SCIP Number
  - Product in as supplied state remains untouched across a supply chain.
  - Supplier exports .xls for all submissions from ECHA Submission Portal.
  - Edits the file.

- **Your Organization**

  Submit .xls file into the Submission portal to identify you merely resell a product as received from a supplier.

- **AS YOU ARE NOT** absorbing the article into your own products, you merely **PASS** them along.
### Emerging Themes: Part Families Overview

**Example: O-rings**

*(Our view; Illustration purposes only)*

<table>
<thead>
<tr>
<th>Diameter:</th>
<th>15mm</th>
<th>15mm</th>
<th>20mm</th>
<th>20mm</th>
<th>20mm</th>
<th>20mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness:</td>
<td>2.0mm</td>
<td>2.0mm</td>
<td>3.5mm</td>
<td>3.5mm</td>
<td>5.0mm</td>
<td>5.0mm</td>
</tr>
<tr>
<td>Colour:</td>
<td>Black</td>
<td>Grey</td>
<td>Black</td>
<td>Grey</td>
<td>Black</td>
<td>Grey</td>
</tr>
<tr>
<td>Item No.:</td>
<td>15x2.0B RJ</td>
<td>15x2.0G RJ</td>
<td>20x3.5B RJ</td>
<td>20x3.5G RJ</td>
<td>20x5.0B RJ</td>
<td>20x5.0G RJ</td>
</tr>
<tr>
<td>Brand:</td>
<td>Rubber joints RJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAN:</td>
<td>994455667 7801</td>
<td>994455667 7812</td>
<td>994455667 7823</td>
<td>994455667 7834</td>
<td>994455667 7845</td>
<td>994455667 7856</td>
</tr>
<tr>
<td>Article Category*:</td>
<td>4016 93 00 90</td>
<td>4016 93 00 90</td>
<td>4016 93 00 90</td>
<td>4016 93 00 90</td>
<td>4016 93 00 90</td>
<td>4016 93 00 90</td>
</tr>
<tr>
<td>Candidate List substance</td>
<td>CAS No. 71888-89-6</td>
<td>CAS No. 71888-89-6</td>
<td>CAS No. 71888-89-6</td>
<td>CAS No. 71888-89-6</td>
<td>CAS No. 71888-89-6</td>
<td>CAS No. 71888-89-6</td>
</tr>
<tr>
<td>Concentration:</td>
<td>8% w/w</td>
<td>8% w/w</td>
<td>8% w/w</td>
<td>8% w/w</td>
<td>8% w/w</td>
<td>8% w/w</td>
</tr>
<tr>
<td>Material:</td>
<td>SBR, vulcanised</td>
<td>SBR, vulcanised</td>
<td>SBR, vulcanised</td>
<td>SBR, vulcanised</td>
<td>SBR, vulcanised</td>
<td>SBR, vulcanised</td>
</tr>
</tbody>
</table>

**Option 1** – Report each O-ring type separately.

**Option 2** – Group O-rings, for example by color.

**Option 3** – Report as a single group for all O-rings.
SCIP Reporting: How Data Goes in
Responsibilities of Duty Holders

DATA SUBMISSION
- Manual Upload of File
- Manual Preparation Online
- System to System

STORAGE
- SCIP Database

DISSEMINATION
- Publication of the Information as Received
  (duty holder responsibility for submitting accurate data)

Immediate Timelines for ECHA SCIP

- ECHA Candidate list updated 25th June 2020.
- ECHA SCIP database updated reference package of candidate list substances will be made available end of July 2020, so you cannot import the latest Candidate List until end of July 2020 into the SCIP system.
- ECHA Submission Portal is updated during the summer to enable SSN.
- October 28th 2020 - you may proceed with real data submissions ahead of 5th January.
Key Differences Between the EU REACH Regulation, EU Waste Framework Directive & EU Market Surveillance Regulations

**EU REACH — Substances, Mixtures, Inform SVHC Presence in Products**
- In case of continuous infringement, a penalty of €100–€1,000 per day of infringement.
- On conviction or indictment, a fine of up to €80,000 or imprisonment not exceeding two years, or both.
- On second/subsequent conviction, a fine of up to €80,000 or imprisonment, not exceeding four years, or both.
- Where applicable, products will be removed from the marketplace.

Published at a time when sustainability and circularity was just a concept.

Information on products containing SVHC not recorded — this becomes known as part of public consultation when substances are proposed for authorization/restricted.

**EU Waste Framework Directive (SCIP Reporting)**
- Currently waste materials containing SVHCs become classified as hazardous materials (POPS/PIC).
- Identifies SVHC content in products placed onto the marketplace.
- Enables waste stream operators and other users to access data.
- Feeds Union Product Compliance Network (UPCN).

**EU Market Surveillance — All Products**
- Included a review of all 69 current product regulations dating back to 1967.
- Standard EU wide product assessment for market enforcement authorities (including customs).
- Introduces a new Union Product Compliance Network (UPCN) - 1st Jan 2021.
- UPCN = regulators with own shared IT systems to check products, share data across EU.
- Enhanced surveillance and enforcement. Websites, products and manufacturers face warnings, unlimited fines and products blocked from being placed onto the EEA.

EU SCIP reporting enables the identification of SVHCs in Products placed onto the EU marketplace.
Not having the information on any SVHCs in products hinders the ability to meeting circular economy goals.
EU SCIP is essentially EU REACH identification of SVHC content in products with extended data fields.
▶ Theoretically EU REACH reporting should have been happening across all sectors since at least 2010.
▶ The additional data fields are likely to be seen as less onerous that a complete new regulation such as EU MDR.
Covid-19 = Delay to SCIP Reporting? (ii)

Unlikely

- European Commission President Ursula von der Leyen, April 15th 2020:
  - “I was aware all through the crisis why the European Green Deal is exactly the right answer,” she said. “We saw there’s a certain dependency on global supply chains. A circular economy means that within the recycling process in the own European area -- we’re way more independent and way more able to produce what is necessary.”
Covid-19 = Delay to SCIP Reporting? (ii)

Unlikely

- European Commission President Ursula von der Leyen, April 15th 2020:
  - “A “circular economy will make us less dependent and boost our resilience,”” European Commission President Ursula von der Leyen told EU lawmakers in Brussels. “This is not only good for our environment but it reduces dependency by shortening and diversifying supply chains.”