IT implementation of the SCIP database

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Key points

- Overall timelines
- Who is contributing
- An overview of what we are building
- The IUCLID format for SCIP

09:30—10:30 IT implementation of the SCIP database (30 min. + 30 min. Q&A)
- IUCLID format
- Data preparation and submission (ECHA Cloud)
- Dissemination
- IT user group – state of play
Tom Uotila, IT project manager, ECHA

ECHA — EUROPEAN CHEMICALS AGENCY

	2018		2019				2020				2021	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2

LEGAL MILESTONES

- 07/2018 WFD entry into force
- 01/2020 Establish SCIP DB
- 07/2020 Transpose WFD
- 01/2021 Submit to SCIP DB

STAKEHOLDER ENGAGEMENT

- 10/2018 1st WS & draft scenario
- 05-06/2019 Consultation on info req.
- 11/2019 2nd WS
- 10-12/2019 IT user grp meetings
- 2020 IT user grp meetings TBA

IT TOOLING MILESTONES

- 09/2019 Info req. published
- 10/2019 IUCLID 6.4 SCIP format
- Q1/2020 SCIP DB 1st prototype UC: Data preparation
- 10/2020 SCIP DB v1 enhancing prototype to production level use
- Q1-Q2/2021 SCIP DB v2 UC: make data available

SCIP IT user group participants

- ACEA
- ASD
- Apple
- APPLiA
- Assent Compliance Inc
- Boeing
- BOMcheck
- DXC Technology
- ECD Compliance
- EDRA
- EUPC
- EuroCommerce
- Euromot
- IBM
- Intel
- iPoint-System GmBH
- Kemi
- Kingfisher
- Lear Corporation
- Opesus AG
- ORGALIM
- Papros Inc
- PFA
- Philips
- Siemens
- SMEunited
- LIFE AskREACH project

Revised Waste Framework Directive Art 9(2)

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.

Prepare and submit the data

A *database* is an organised collection of data

Provide access to the data
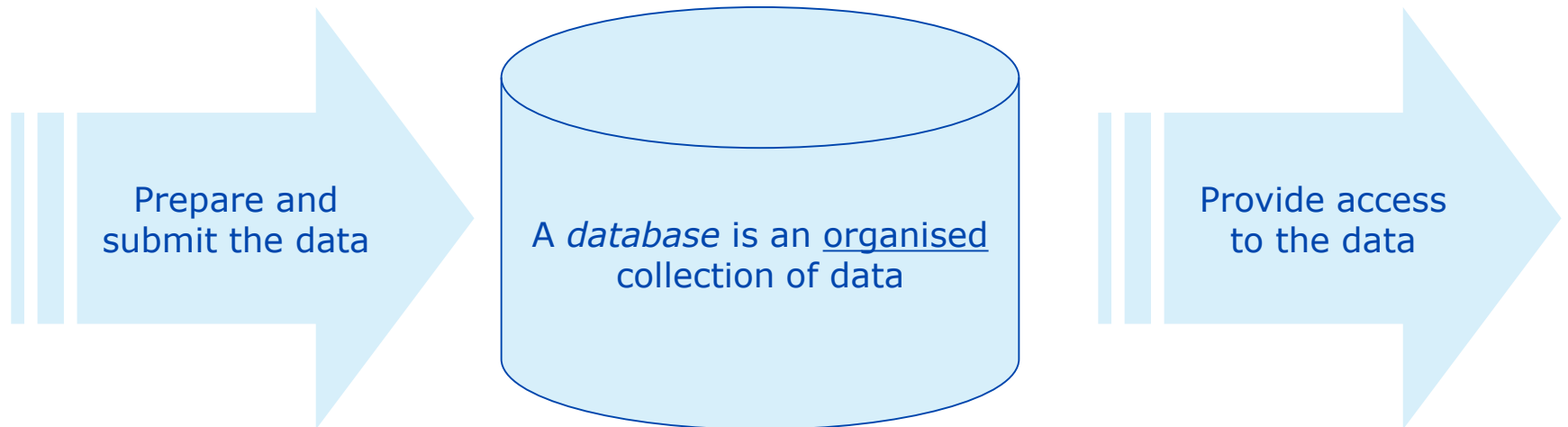
Underlying design considerations

- Usefulness of the SCIP DB vs. burden on industry
- Transparency vs. legitimate confidentiality concerns
- One size, fits all
- Keep it simple
- Reuse existing data structures
- Reuse ECHA IT resources
- Prototyping

SCIP database - system overview
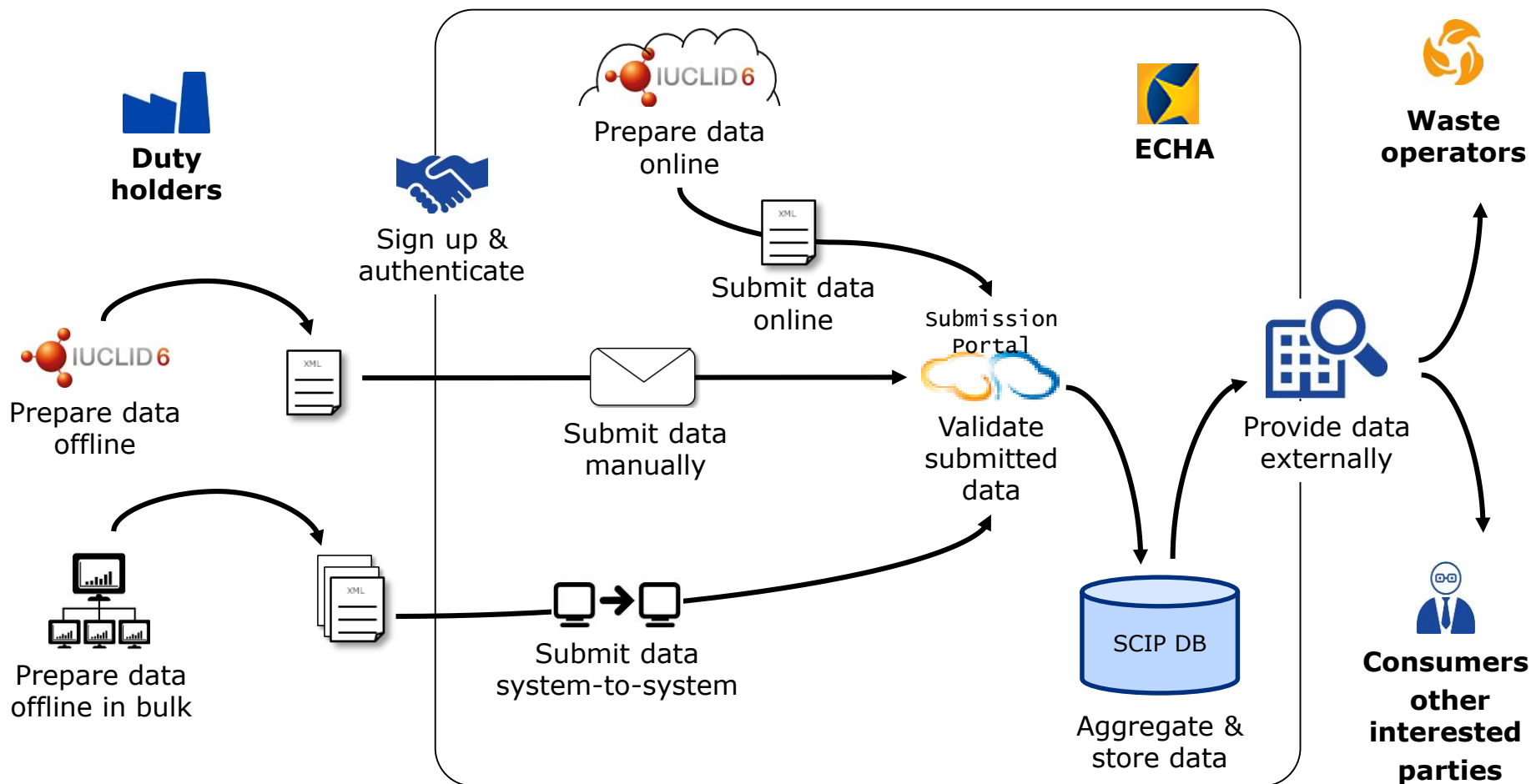
IUCLID6 – format and application

- IUCLID6 formats provide the pre-established layouts for data on chemicals in a regulatory context

- IUCLID6 application is a suite of tools supporting the processing of this data

- Some of these tools include

  - Data preparation tool

  - Validation assistant

  - Report generator

IUCLID format for SCIP

- Technically, the format is a set of XSD (XML schema definition) files

- From a business perspective, these XSD files implement the information requirements

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema xmlns="http://iuclid6.echa.europa.eu/namespaces/manifest/v1"
    xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:xlink="http://www.w3.org/1999/xlink"
    attributeFormDefault="unqualified" elementFormDefault="qualified"
    targetNamespace="http://iuclid6.echa.europa.eu/namespaces/manifest/v1">
    <xs:annotation>
        <xs:appinfo>Manifest XML Schema Definition</xs:appinfo>
    </xs:annotation>
    <xs:import namespace="http://www.w3.org/1999/xlink" schemaLocation="xlink.xsd"/>

    <!-- General Information -->
    <xs:complexType name="general-informationType">
        <xs:annotation>
            <xs:documentation>Holds the elements under the "general-information" section</xs:documentation>
        </xs:annotation>
        <xs:sequence>
            <xs:element type="xs:string" name="title">
                <xs:annotation>
                    <xs:documentation>The name that should be displayed as a first element, once opening the XM
                </xs:annotation>
            </xs:element>
            <xs:element type="xs:string" name="created">
                <xs:annotation>
                    <xs:documentation>The creation date of the i6z file</xs:documentation>
                </xs:annotation>
            </xs:element>
            <xs:element type="xs:string" name="author">
                <xs:annotation>
                    <xs:documentation>The IUCLID user (i.e. concatenation of "First name " and "Last name") tha
                </xs:annotation>
            </xs:element>
            <xs:element type="xs:string" name="application">
                <xs:annotation>
                    <xs:documentation>It is by default "IUCLID6" and in a parenthesis the release version and b
                </xs:annotation>
            </xs:element>
            <xs:element type="xs:string" name="submission-type">
                <xs:annotation>
                    <xs:documentation>The submission type of the dataset. The list of valid submission types is
<ul>
<li>ENDP</li>
<li>EXPERIMENTAL_DATA</li>
<li>OECD</li>
<li>OECD_HT</li>
<li>R AUTH APPL</li>
```
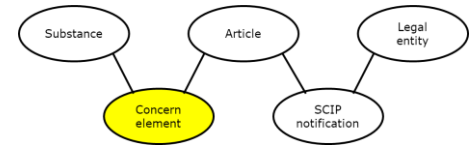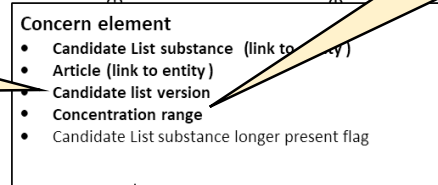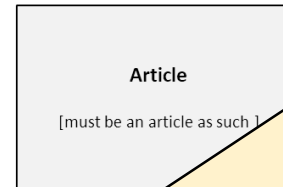
SCIP format core entities
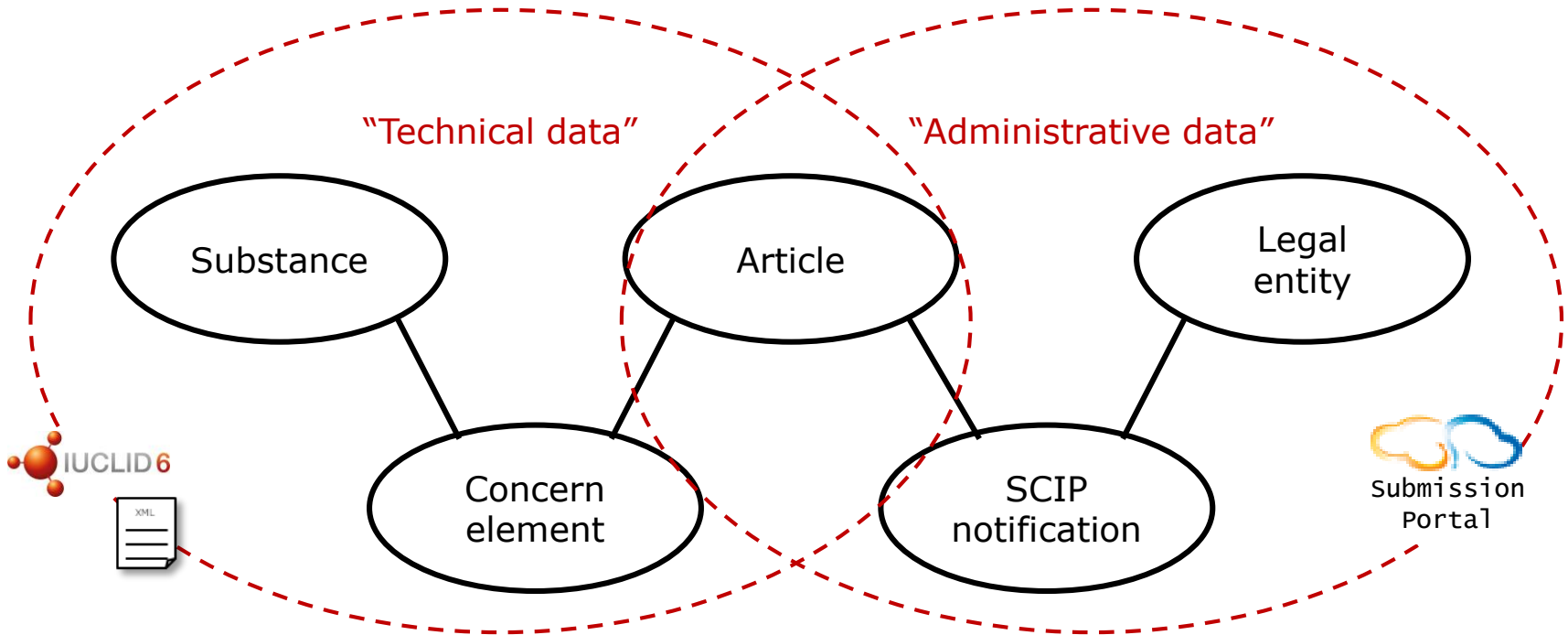
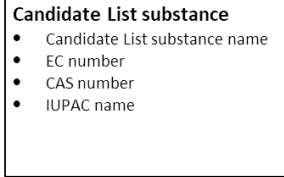# Example: Format defines allowed values

PICKLIST
- 2019/1
- 2019/2
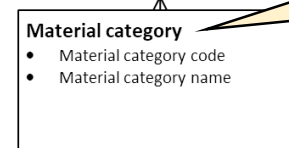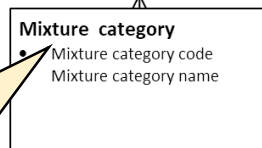- 2019/3
- 2020/1
- 2020/2
- 2020/3
- 2020/4
- 2020/5
- …

Candidate List substance
- Candidate List substance name
- EC number
- CAS number
- IUPAC name

Article

[must be an article as such]

PICKLIST
- > 0.1% w/w and < 0.3% w/w
- ≥ 0.3% w/w and < 1.0% w/w
- ≥ 1.0% w/w and < 10.0% w/w
- ≥ 10.0% w/w and < 20.0% w/w
- ≥ 20.0% w/w and < 100% w/w
- > 0.1% w/w and ≤ 100% w/w

Concern element
- **Candidate List substance (link to entity)**
- **Article (link to entity)**
- **Candidate list version**
- **Concentration range**
- Candidate List substance longer present flag

PICKLIST
- ceramic
- glass
- metal
- …

PICKLIST
- Adhesives and sealants
- Fabric softeners
- Paints/coatings
- Photochemicals
- …

Mixture category
- Mixture category code
- Mixture category name

Material category
- Material category code
- Material category name

Additional material characteristic
- Additional material characteristic code
- Additional material characteristic name
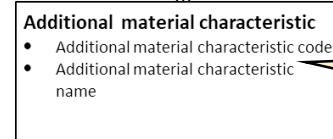
PICKLIST
- coated
- glazed
- unbleached
- …

Allowed values

- The SCIP format also defines and enforces allowed values for certain fields (picklist values)

Concern elements

Candidate list version
2019/1

Concern element + New item

② **Candidate list substance**
Lead styphnate | Lead styphnate | 15245-44-0

Concentration range
> 0.1% w/w and < 0.3% w/w

Material categories + New item

① **Material category**
ceramic > clays / silicate ceramic > clays

Additional material characteristics
✓ microspheres and particles

Mixture category (EUPCS)
None

① **Candidate list substance**
Lead titanium trioxide | Lead titanium trioxide | 12060-00-3

Concentration range
≥ 20.0% w/w and < 100% w/w

Material categories + New item

Mixture category (EUPCS)
None

Candidate list substance no longer present + New item

① **Candidate list substance no longer present**
Trilead bis(carbonate) dihydroxide | Trilead bis(carbonate) dihydroxide | 1319-46-6

Substance

Article

Legal entity

Concern element

SCIP notification
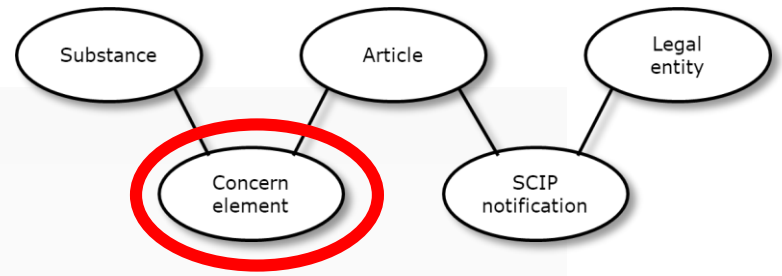
Concern elements

Candidate list version
2019/1

Concern element **+** New item

(20) **Candidate list substance**
Nitrobenzene | Nitrobenzene | 98-95-3

Concentration range

Please select	⌄

> 0.1% w/w and < 0.3% w/w

≥ 0.3% w/w and < 1.0% w/w

≥ 1.0% w/w and < 10.0% w/w

≥ 10.0% w/w and < 20.0% w/w

≥ 20.0% w/w and < 100% w/w

> 0.1% w/w and ≤ 100% w/w ✓

(20) ioni...

Mixture category (EuPCS)
None
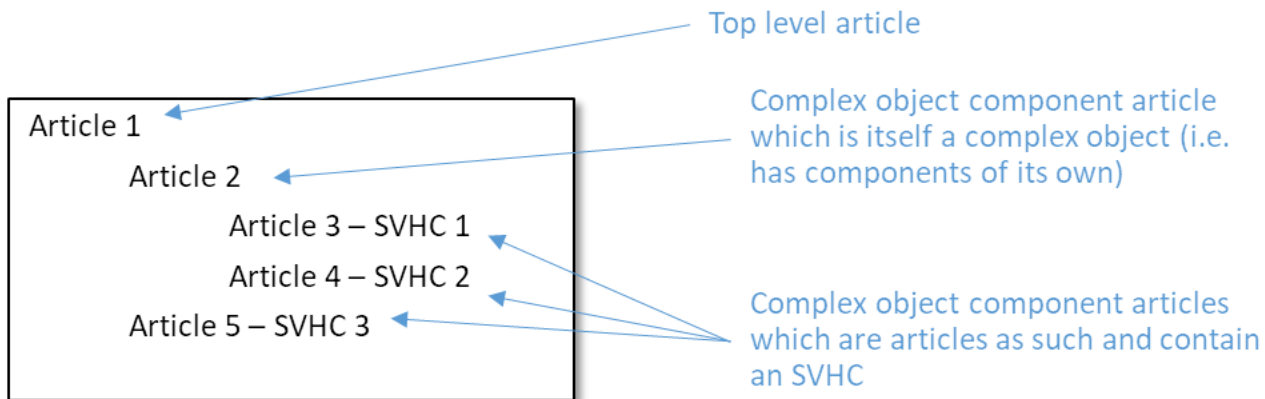
Substance

Article

Legal entity

Concern element

SCIP notification

Using the format comes with responsibility

- The format is intentionally flexible
- A lot of room for discretion lies with the duty holders

  - In particular with how a complex object's hierarchy is reported

Top level article

Article 1

Article 2 — Complex object component article which is itself a complex object (i.e. has components of its own)

Article 3 – SVHC 1
Article 4 – SVHC 2
Article 5 – SVHC 3 — Complex object component articles which are articles as such and contain an SVHC

In conclusion

ECHA EUROPEAN CHEMICALS AGENCY

- Complete
- In the making
- Starting up

Duty holders

Prepare data online

Sign up & authenticate

Prepare data offline

Submit data manually

Submit data online

Submission Portal

Validate submitted data

Prepare data offline in bulk

Submit data system-to-system

SCIP DB

Aggregate & store data

ECHA

Provide data externally

Waste operators

Consumers other interested parties

Questions?