Poison Centre Notifications (CLP Art. 45)
Huntsman's Simple & Efficient Solution using SAP EHS Product Safety

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Agenda

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Huntsman

HUNTSMAN

Enriching lives through innovation

- Global manufacturer of chemicals you use every day. Markets served include: transportation, home life, construction, energy and fuels, clothing and footwear

- 50 years, located in more than 100 countries

- 4 Divisions:
  - Polyurethanes
  - Performance Products
  - Advanced Materials
  - Textile Effects

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Huntsman businesses

POLYURETHANES	PERFORMANCE PRODUCTS	ADVANCED MATERIALS	TEXTILE EFFECTS
MDI	Amines	Composites	Dyes
Polyols	Surfactants	Adhesives	Chemicals
PO/MTBE	Maleic Anhydride	Resins	Inks
TPU	Upstream Intermediates		Apparel
PU Systems			Home & Institutional
			Technical Textiles

Huntsman

HUNTSMAN

Enriching lives through innovation

Operating >75 Manufacturing, R&D and Operations Facilities in ~30 Countries[1]

Europe 26%

U.S. & Canada 34%

Asia Pacific 27%

Rest of World 13%

~10,000 Employees[1]

Rest of World 9%

U.S. & Canada 28%

Europe 28%

Asia Pacific 35%

Map Key
- Polyurethane
- Performance Products
- Advanced Materials
- Textile Effects
- Shared Facility
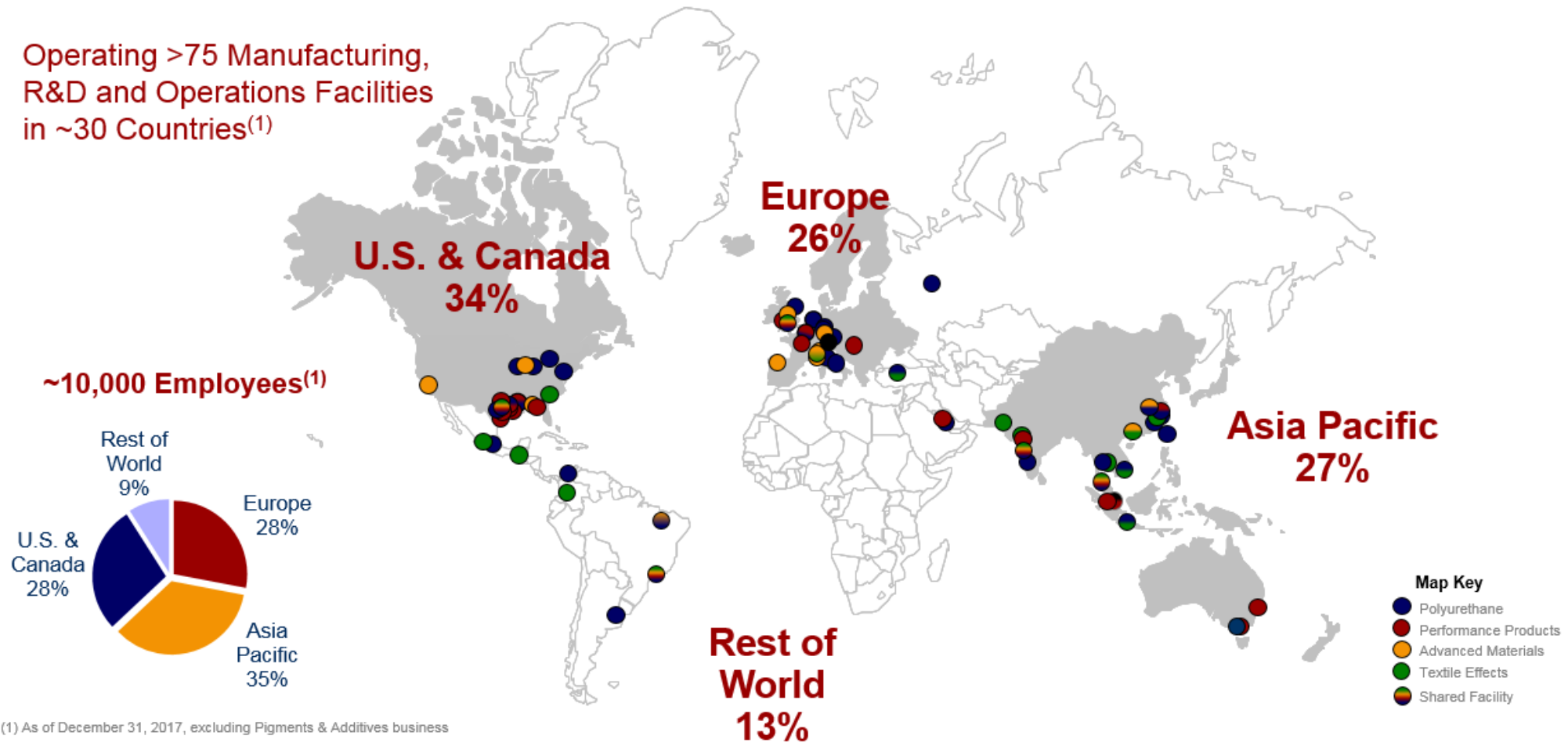
(1) As of December 31, 2017, excluding Pigments & Additives business

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Huntsman – SAP EHS implementation

Why SAP EHS? The implementation story…

- Project GAIA (Huntsman's project name) was a strategic project to replace Product EHS IT systems with SAP EHS for
  - Hazard communication and label printing
  - Regulatory compliance (Substance Volume Tracking)
  - Dangerous goods transport compliance

- The project leveraged standard work processes and standard SAP functionality to maximize efficiency of PEHS services
  - Provided a foundation for future EHS initiatives
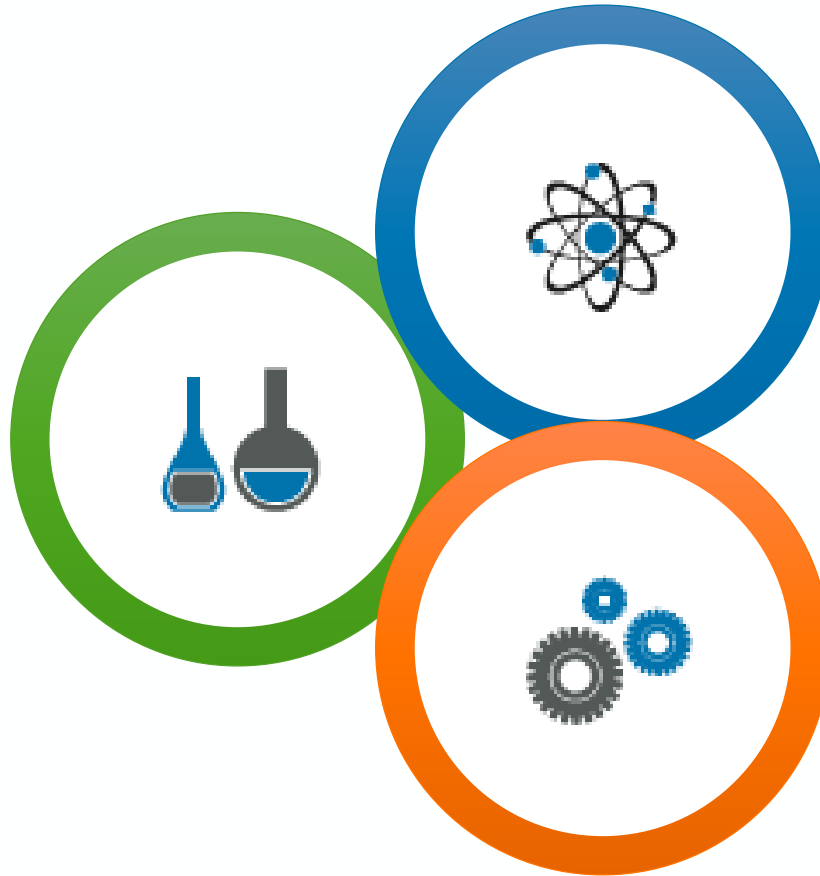 - Stay close to standard – minimal bespokes

Data implementation

- 30,000+ Real substances
- 9,000 Pure substances

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Current Situation and Key Issues

Poison Centre Data + EU = Many Formats!

– Different formats and ways to report in almost every member state

– Formats include XML, Excel, CDs, PDFs, and Word forms…

– Companies have to report similar information multiple times

– Different information is required: e.g. exact composition, only hazardous components, additional product data in some countries required

– As a result different information available for medical personal in case of an emergency
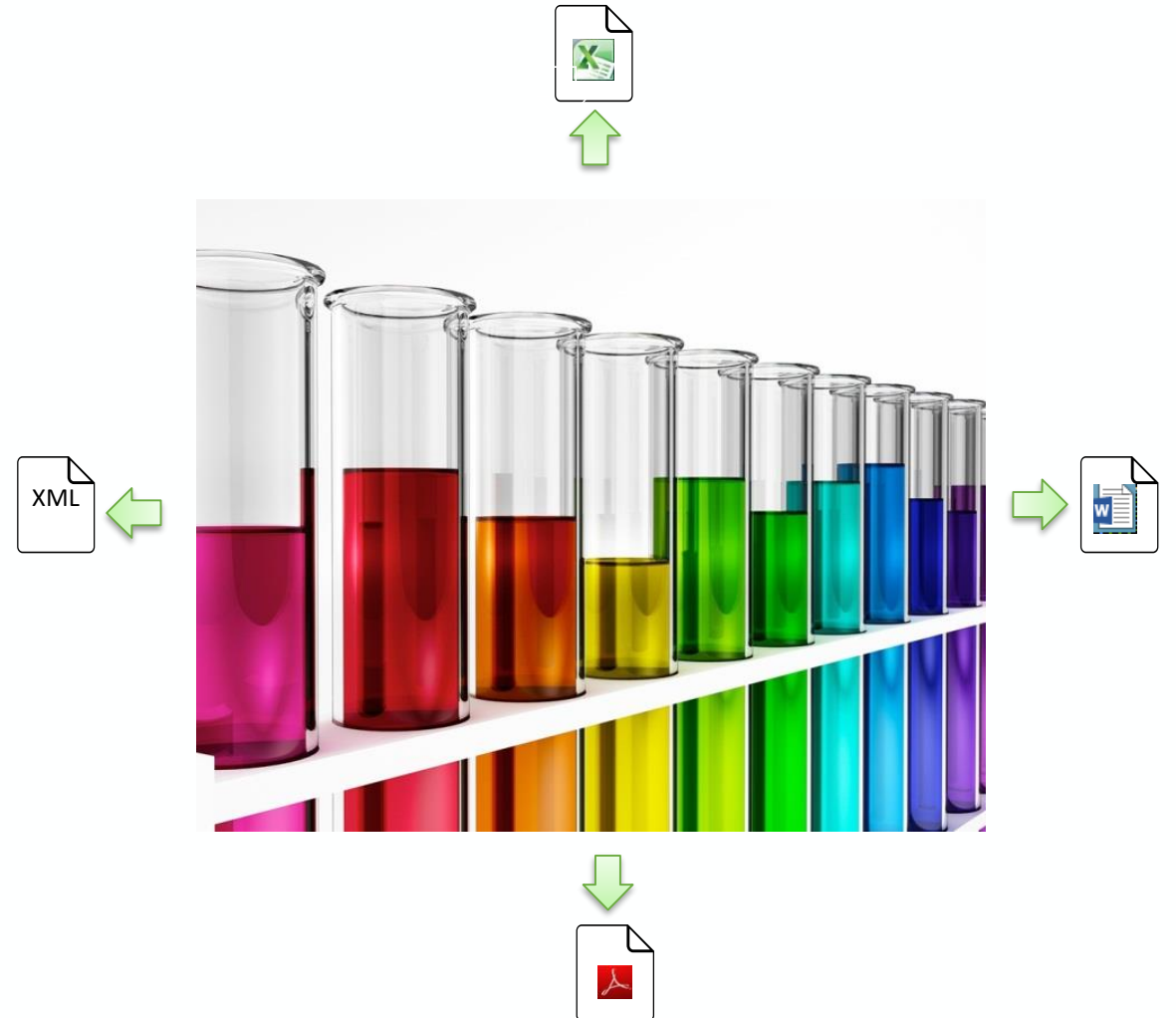
EU Poison Centre Notification – PCN Format

CLP Regulation (EC) No. 1272/2008 – Article 45

- Member states shall appoint bodies that receive information relevant for emergency health response

- Affects *"importers and downstream users"* that place **hazardous mixtures** on the market

- Establish a "***common format** for the electronic submission"*
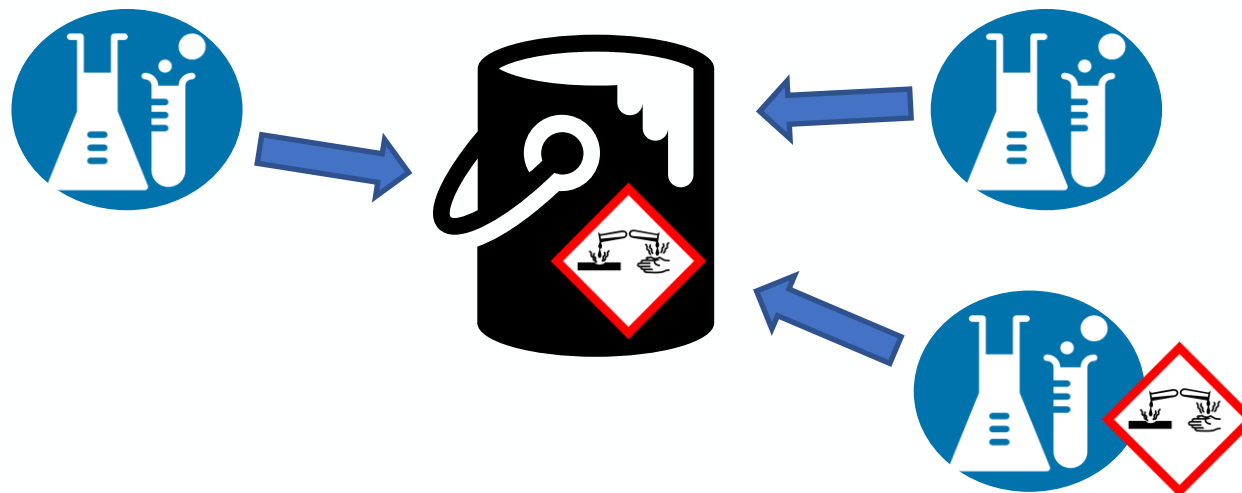
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What needs to be notified?

Mixtures that are **placed on the EU market** and classified as *hazardous* based on their *health* or *physical* effects
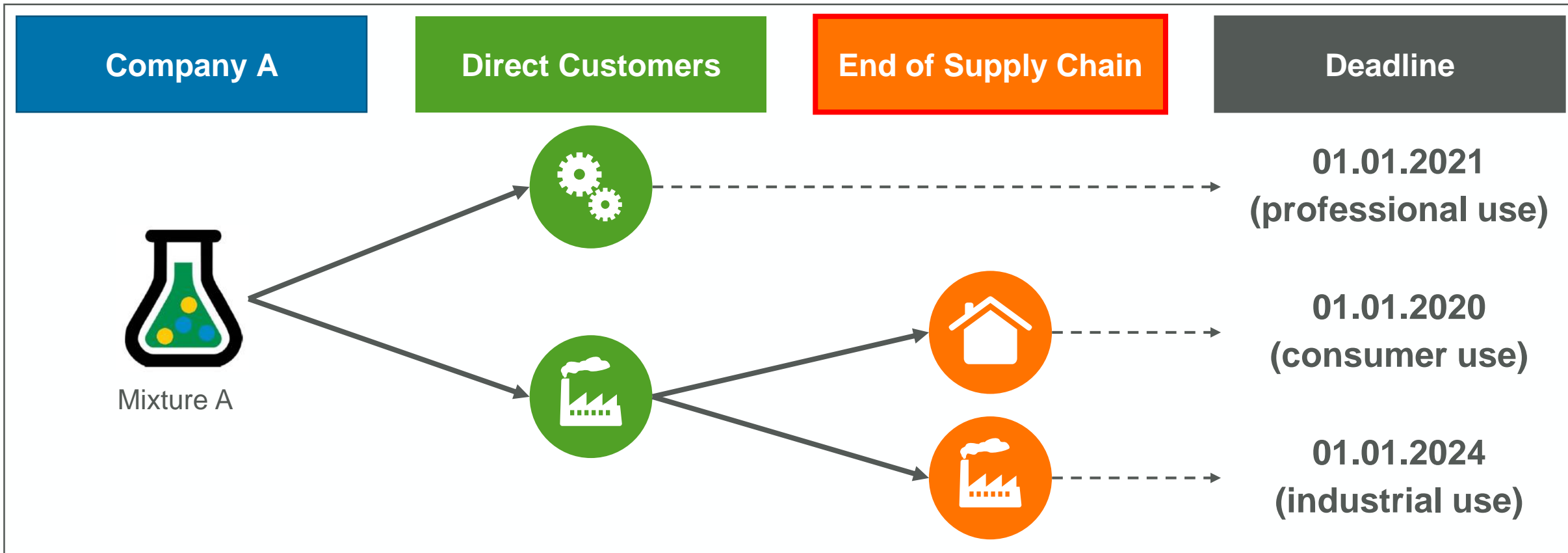
      Exemptions: R&D, mixtures only classified as gases under pressure or explosives

Unique Formula Identifier (UFI) required for notification for each mixture and must be printed on the safety data sheet and on the product label

Notification must be accepted before product can be placed on the market

How to Create Poison Centre Notifications
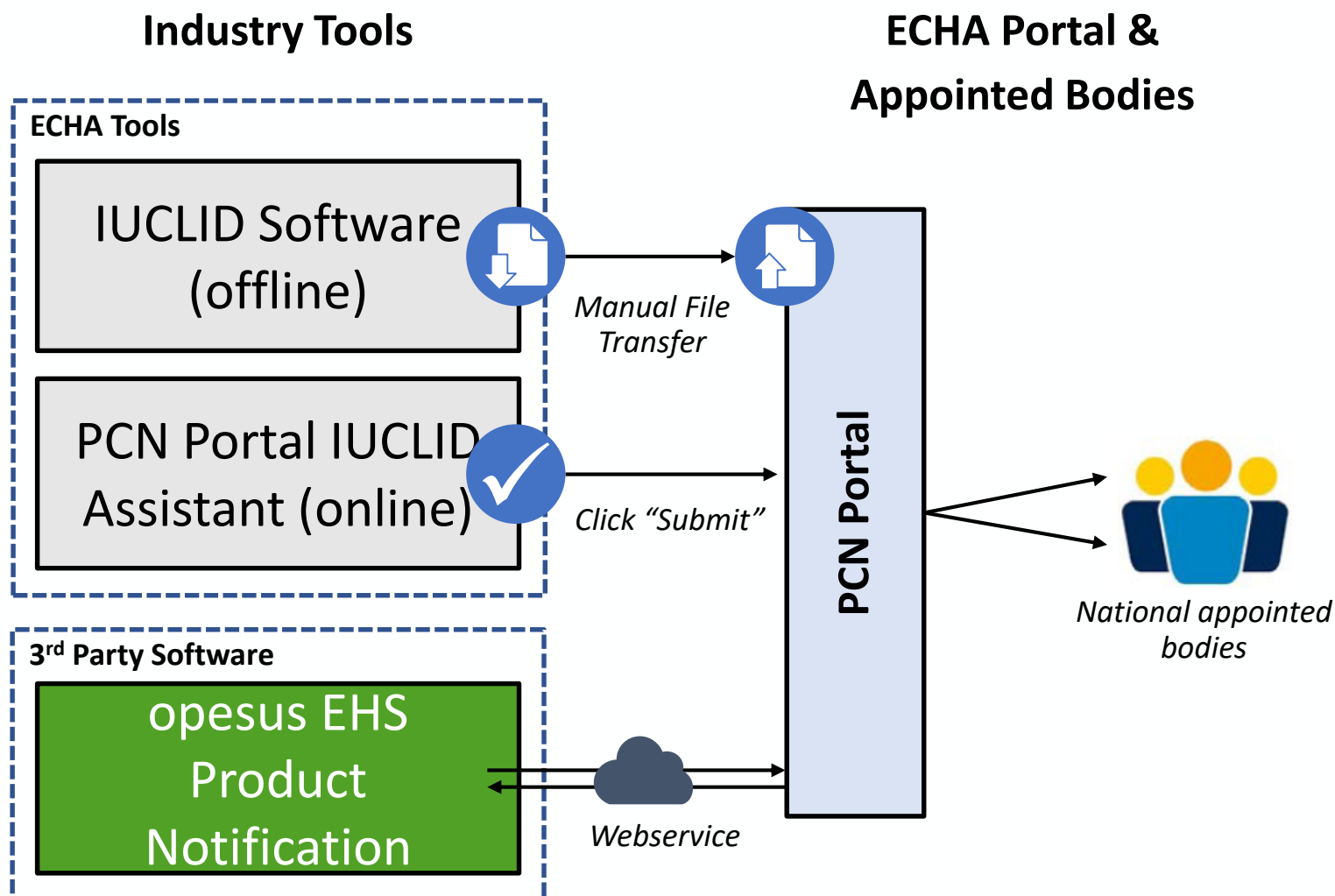
Industry Tools

ECHA Portal &
Appointed Bodies

ECHA Tools

IUCLID Software (offline)

Manual File Transfer

PCN Portal IUCLID Assistant (online)

Click "Submit"

PCN Portal

3rd Party Software

opesus EHS Product Notification

Webservice

National appointed bodies

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Challenges: Old (BfR) Format vs. New (PCN) Format

|	BfR-Format	PCN-Format
Templates / Format Definition	1 xsd	27 xsd (17 represent IUCLID documents)
# Files in one Notification	One XML	> 10 XMLs, packed as .i6z file
Lines of XML Code for simple* example	~ 150	~ 1,500

* Two substances; no "special" cases

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Required Information in SAP EHS System

Information	Available		SAP System	Comment
Mixture Composition	**New**	✗	PCN Composition	Full composition required!
UFI	**New**	✗	Spec. Property / EPN	Strategy on product and labelling required
Product, Trade Names	Yes	✓	Spec. / Material	Multiple sources e.g. Sales Text, Short Text.
Packaging	Indirect	▶	Material, BOM, others	Can be determined from different sources
Classification & Labeling	Yes	✓	Spec. Property	Typically available in SAP EHS
Toxicological Information	Yes	✓	Spec. Properties	Typically available in SAP EHS
Color	Yes	✓	Spec. Property	Typically available in SAP EHS
pH-Value	Yes	✓	Spec. Property	Check if pH is detailed enough!

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Maintaining the PCN Composition

Data Security is Central

- Exact composition is highly **confidential business information**
- Potential risk of data breach
- CLP regulation allows stating **concentration ranges** within specific ranges
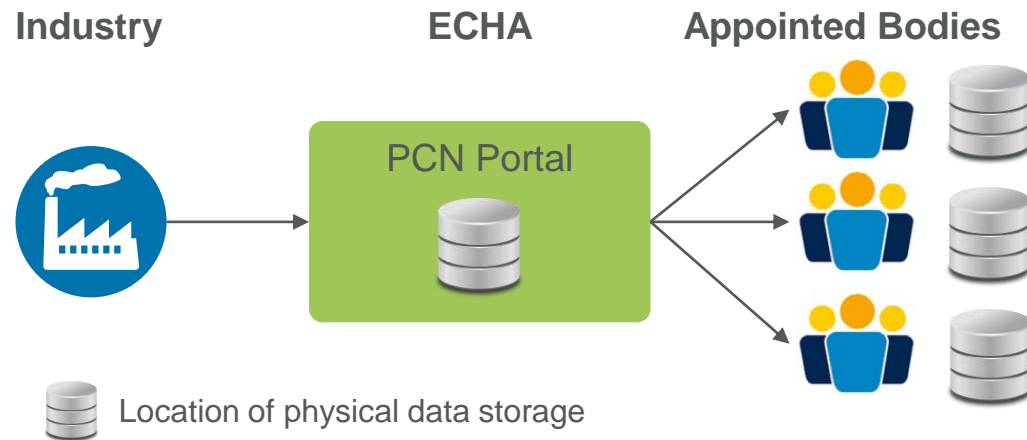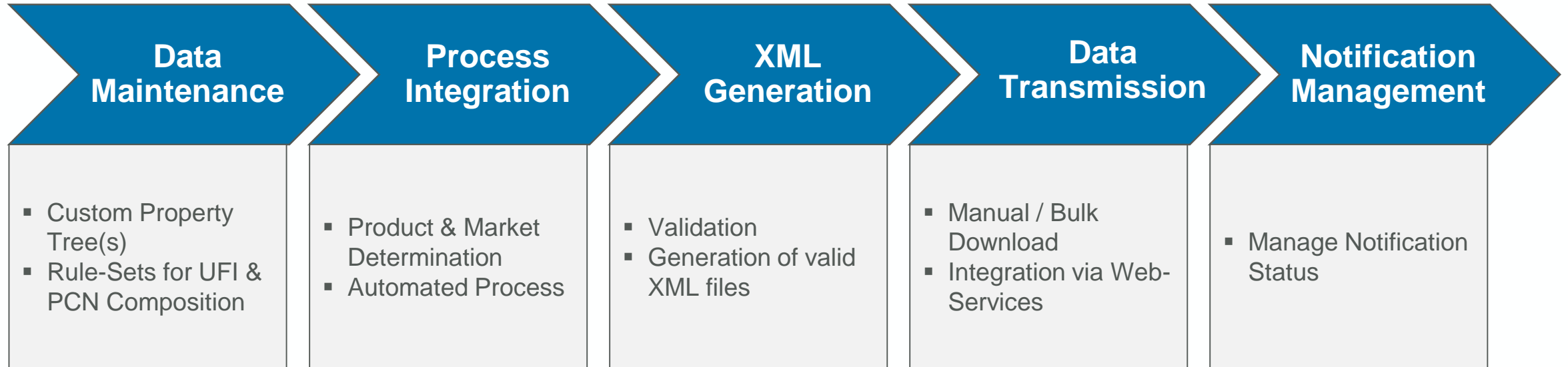
Solution:

- Basic concept: ABAP **Ruleset** that validates, calculates and writes PCN composition
- Highly configurable
- Can **automatically randomize** a composition within allowed ranges
- Can be triggered together with standard rulesets

Industry ECHA Appointed Bodies

PCN Portal

Location of physical data storage

✓ Value Assignments	Composition	Usage	Sources	Assessment	User-Def. Texts/Docs

	Ref. quantity	W/W		Weight			

S	Sort	Spec.		Identifier					
	Component Type		EV	Value		UoM	Op Lower Limit		Op Upper Limit
☐ 1	L00000000028		7789-00-6			potassium chromate			
	/OPE/SU… Substance			50		%	>= 36,8370	–	<= 54,8370
☐ 2	L00000000034		109-86-4			2-methoxyethanol			
	/OPE/SU… Substance					%	>= 2,6877	–	<= 11,7877
☐ 3	L00000000557		9016-87-9			Diphenylmethandiisocyanate			
	/OPE/SU… Substance					%	>= 35,0000	–	<= 40,0000
☐ 4	L00000000992		94246-91-0			(2-ethylhexanoato-O)(isononanoato-O)lead			
	/OPE/SU… Substance			0,5		%	>= 0,3248	–	<= 1,2248

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Functional Overview

EPN covers the end-to-end Process of Product Notifications

Data Maintenance	Process Integration	XML Generation	Data Transmission	Notification Management
▪ Custom Property Tree(s) ▪ Rule-Sets for UFI & PCN Composition	▪ Product & Market Determination ▪ Automated Process	▪ Validation ▪ Generation of valid XML files	▪ Manual / Bulk Download ▪ Integration via Web-Services	▪ Manage Notification Status

Additional Benefits

Inside SAP EH&S
Product is delivered entirely in customer's SAP EH&S

Out-of-the Box Customizing
Initial installation to fit customer-specific needs

High Flexibility
Enabling customer specifics without modification of software

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Why opesus EHS Product Notification tool for PCN?

- Support for Poison Centre Notification
    - SAP did not have the intention to build a tool to support this
    - Huntsman also did not have intention to develop bespoke tool
        - Stay as close as possible to SAP standard
        - Additional module from SAP/SAP partner

- opesus EHS Product Notification
    - Plug-in for SAP EHS Substance Workbench
    - Close to SAP standard - uses existing data in SAP EHS to create notifications with minimal effort
    - Good fit out of the box
        - Various configuration possibilities offered, to fit your customer specific data model (commercial product name, compositions, phrases, ..)
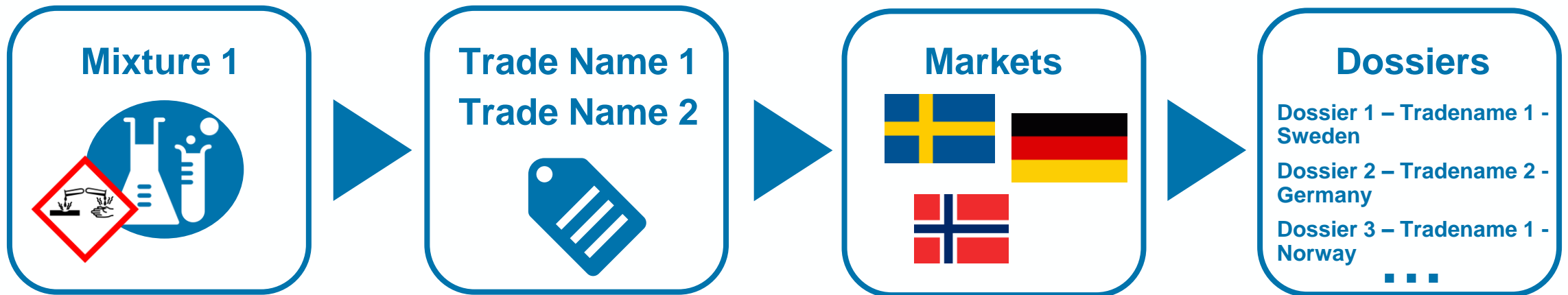
- Commitment from opesus to continuously maintain and update EHS Product Notification tool, and support new features in the future
    - E.g. automated submission from SAP to ECHA PCN Portal

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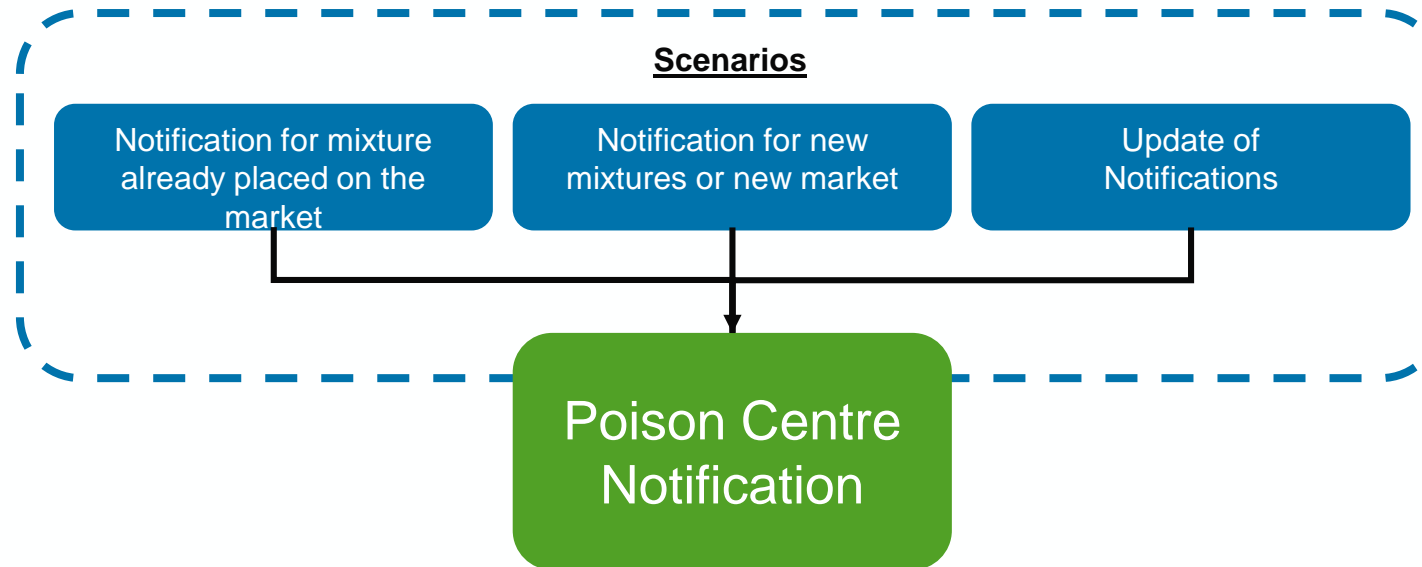# Best Practices Along the Notification Process
Confidentiality: Communication and Submission Strategies

- **Communicate UFI instead of Composition**
  - Communicate UFI of your mixture to your customers instead of disclosing full composition

- **Consider 'on behalf' Submission**
  - Consider 'on behalf' submission as distributor to protect your market insight

- **Submit Country Specific**
  - Country specific submissions help to control submission costs

Mixture 1

Trade Name 1
Trade Name 2

Markets

Dossiers

Dossier 1 – Tradename 1 - Sweden

Dossier 2 – Tradename 2 - Germany

Dossier 3 – Tradename 1 - Norway

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Best Practices Along the Notification Process
Notification Update Scenarios – when to notify?

Scenarios

Notification for mixture already placed on the market	Notification for new mixtures or new market	Update of Notifications

Poison Centre Notification

Recommendation

Submit to ECHA Portal instead of National Systems

- Only one submission path instead of many national entities
- UFI is known in ECHA system **and** in national system. If you submit only to your national system and your UFI is part of a customer Mixture in Mixture (MiM). Your customers MiM validation would fail in the ECHA portal as the UFI would not be known there
- opesus EPN automates the process for notification updates
    - E.g. update of composition, product name, …

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# Best Practices Along the Notification Process
Notification Generation: Validation Rules

PCN validation rules

- Warning / Error flag: 44 business validation rules → 28 rules could lead to notification submission failure

- Examples:
  - Composition below 70%
  - Invalid UFI

PCN validation rules

Recommendation

- It is advisable to **use a software tool that also checks according to PCN validation rules** to prevent unnecessary submission failures
- **Check data values (e.g. pH)**. You might need to test some of your products to get more accurate pH values. Or request details from your supplier
- The PCN rule set can help you **identify gaps in your composition**.

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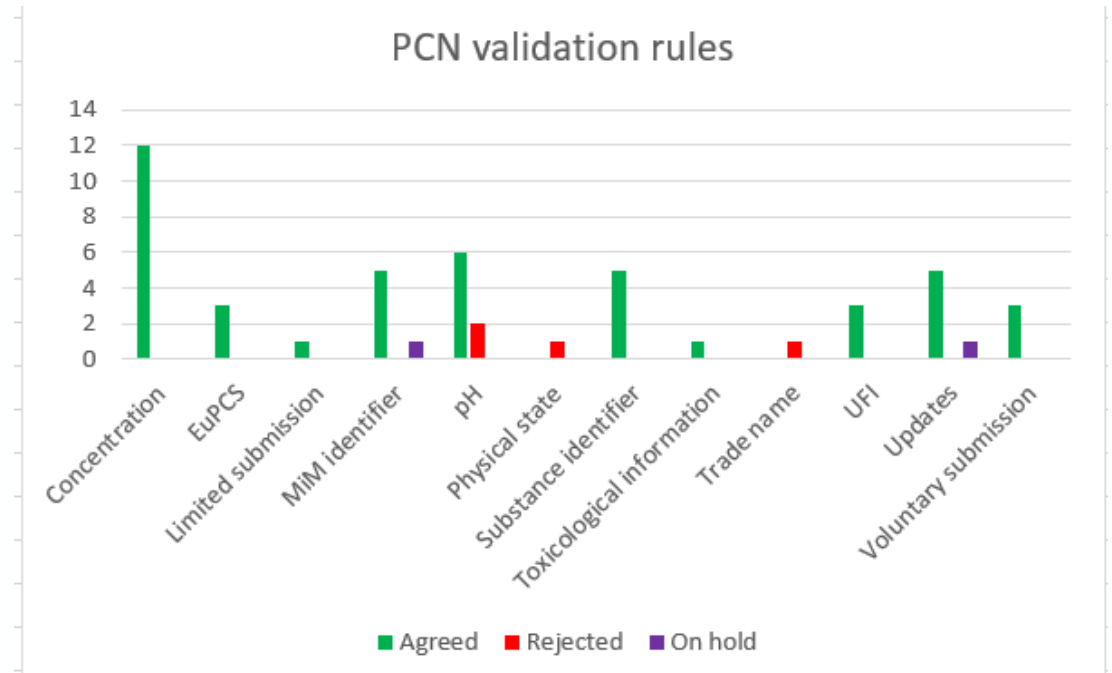
Know Your Obligations
Legal Obligations CLP Article 45 Annex VII

Who is required to submit?
Importer
Downstream User

What is in scope?
Mixtures placed on EEA
market, classified as hazardous
(health or physical effects)

When does it start?
1.1.2020 Consumer Use
1.1.2021 Professional Use
1.1.2024 Industrial Use

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Know Your Obligations Recommendations

Check the roles you have in PCN:

- – Do you have the legal obligation to submit?
- – Which timeline applies to your notification?

Check the data fields for PCN:

- – Do you have all relevant fields?
- – Are they all filled correctly?

Contact your suppliers:

- – Who is in charge and who will make the notification?
- – Challenge to get composition information / UFI from non-EU manufacturers

Contact your customers:

- – Be prepared to notify your products in your supply chain
- – Communicate UFI to your customers

Take the Session Survey.

We want to hear from you! Be sure to complete the session evaluation on the SAPPHIRE NOW and ASUG Annual Conference mobile app.

Presentation Materials

Access the slides from 2019 ASUG Annual Conference here:
http://info.asug.com/2019-ac-slides

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Q&A

For questions after this session, contact us at:
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john.falk@opesus.com