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Software Is Our Business
Sustainability Is Our Passion

PCN Vefahren Automatisieren

Herausforderungen und Lösungen bei der Umsetzung

Automate PCN Notifications

Challenges and Solutions for Implementing Automation

Markus Pogrzeba, opesus AG

Berlin, 5. November 2024

Operative Sustainability

We complement and extend SAP Sustainability solutions

Agenda

About Us

46 Employees

12 Years

5 Locations

4 Countries

Competency
great skills and talents

Culture
proud of our team and our work

Commitment
sees every job to its success

Character
honorable, honest, humble

Experts At What We Do

Sustainability Topics

RoHS
Chemical Regulations
Product Compliance
Substances in Articles
Sustainability Reporting
REACH
Life Cycle Assessments
Circular Economy
Carbon Footprint
CLP
Global Harmonized System

Technical Knowledge

SAP S/4HANA
SAP ECC
ABAP
Business Technology Platform
SAP Product and REACH Compliance
CDS Views
ABAP Restful Application Programming
IPC1752A
Data Exchange Formats
Fiori
IUCLID
IMDS
CDX
Data Exchange Platform
Integration
Silicon Expert
ECHA Portal

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opesus makes SAP Sustainability Solutions work!

Consulting

Strategy
Design
Implementation
Knowledge Transfer

Software Development

Our unique strength: deep SAP software development expertise

Solutions

Solutions to complement and enhance SAP sustainability solutions

BASF
KÄRCHER
Biesterfeld
Unilever
arxada
FUCHS
BRENNTAG
BAYER
Lubrizol
MERCK
OKYA
Givaudan
ASKCHEMICALS
We advance your casting
metabo
Werner & Mertz Professional
DeLonghi
AlzChem
Roche
FRANKE

Customers

160 Customers
3 million employees combined
1,4 trillion € turnover combined

SAP Partner

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Why automation?

High Number of New or Changing Mixtures

Industries with seasonal products, like, flavors and fragrances.

Industries with high volume of individual customer mixtures (one-off)

Legal Changes

Classification changes of components

New hazard classes (e.g. endocrine disruptors for human health)

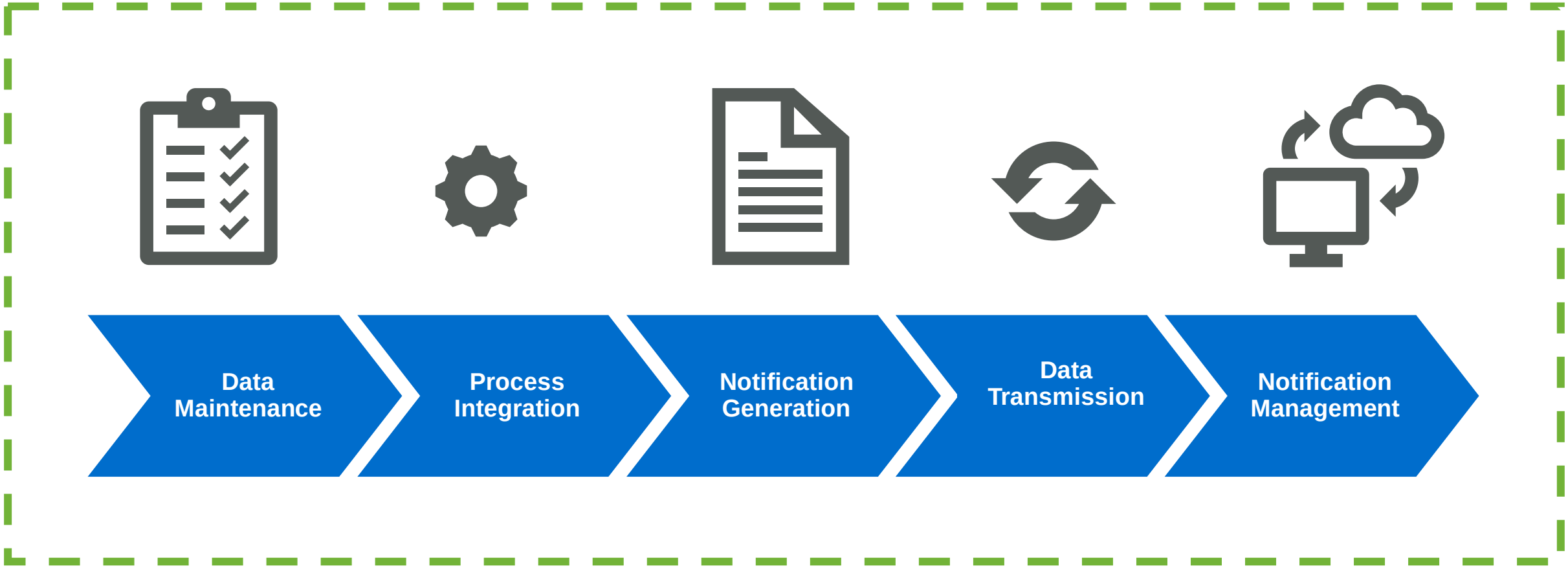
Raw Material Changes

Raw material changes (e.g. supplier UFI, components, classification)

Change in sourcing/supplier

→ Workload to high to handle PCN notifications manually

Automated PCN Notification Process



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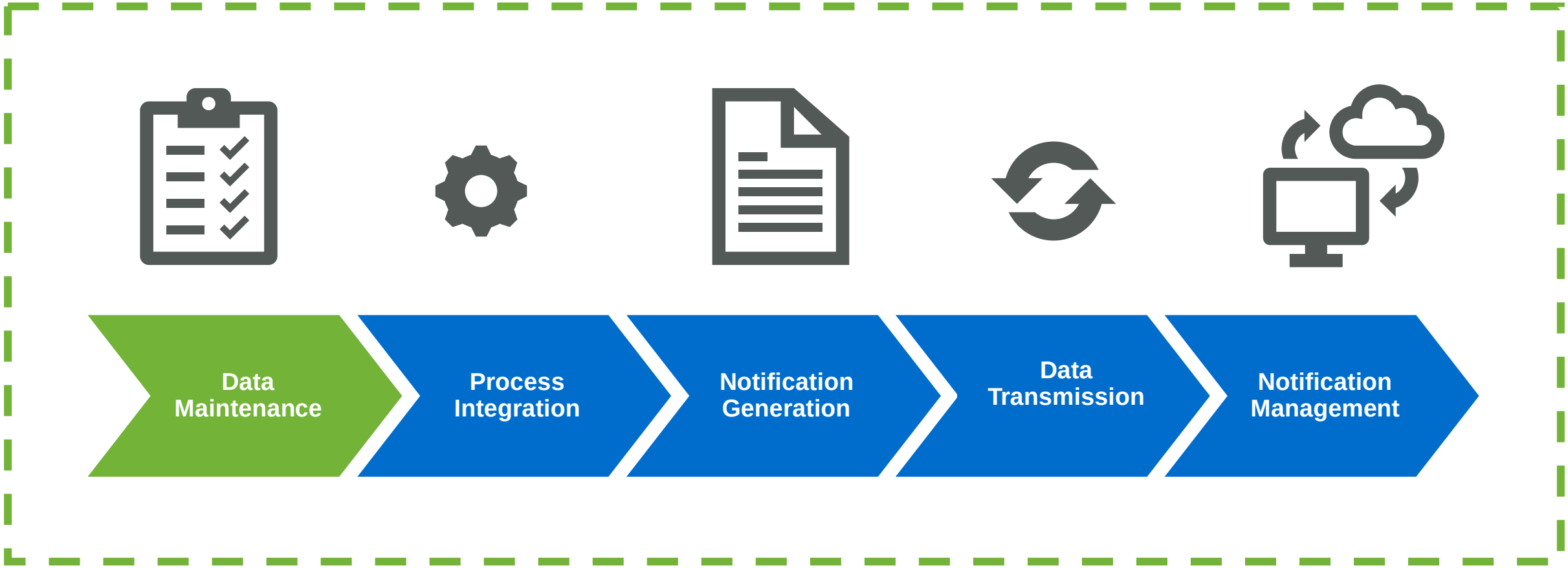
Automated PCN Notification Process



Data Maintenance

Challenge:

Required PCN notification data must be available and complete to automate the notification process.

Companies required to do notifications typically have a product compliance/SDS authoring system and most of the data for PCN notifications available.

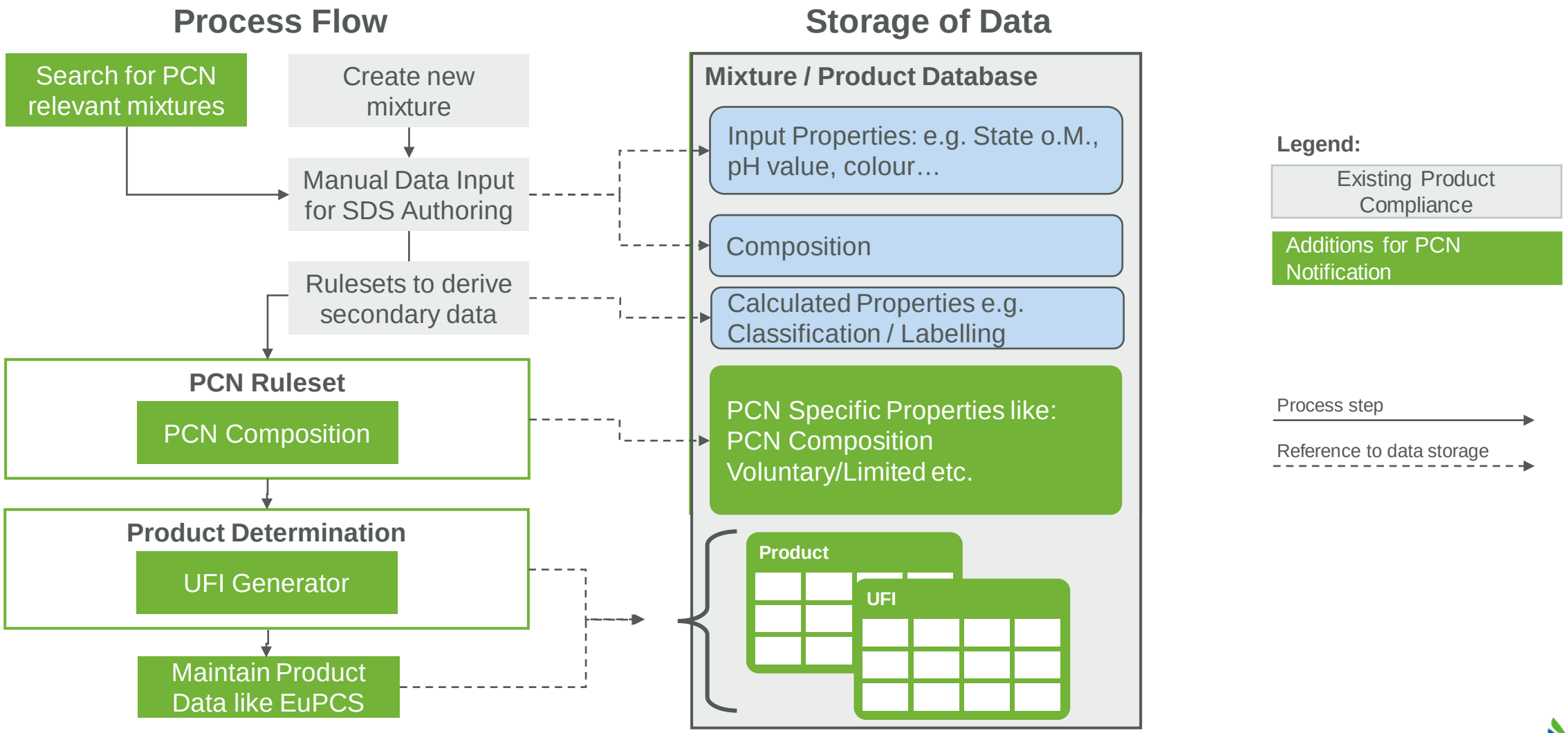
Possible Solution:

Extend the data maintenance process for mixture/product in your existing product compliance system to include additional data required for PCN.

Data Maintenance – Typical Data Gaps

Information	Available	ERP / SDS System	Comment
Mixture Composition	New	PCN Composition	Full composition required!
UFI	New	Mixture or Product	Strategy on product and labelling required
EuPCS Category	New	Product	New, can be mapped in some cases
Product, Trade Names	Yes	Product	Must be aligned with labelling strategy
Submitter Details	Yes	Company	Can typically be derived from Company
Packaging	Indirect	Product	Can typically be mapped to Product Information
Classification	Yes	SDS Authoring	Typically available in SDS Authoring System
Label Elements	Yes	SDS Authoring	Typically available in SDS Authoring System
Toxicological Information	Yes	SDS Authoring	Typically available in SDS Authoring System
Use Type	Yes	SDS Authoring	Typically available in SDS Authoring System
Colour	Yes	SDS Authoring	Typically available in SDS Authoring System
Physical State	Yes	SDS Authoring	Typically available in SDS Authoring System
pH-Value	Yes	SDS Authoring	Check if pH is detailed enough!

Example of Data Maintenance Process in ERP System

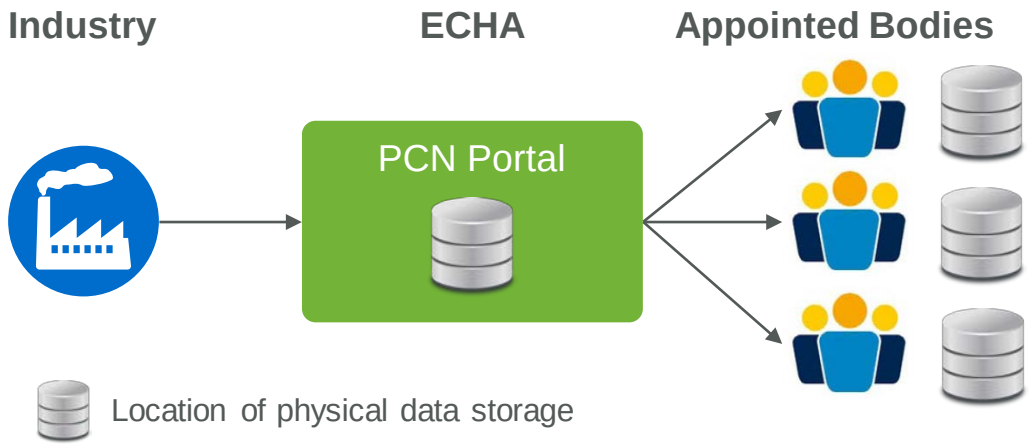


Maintaining the PCN Composition

Data Security Is Central

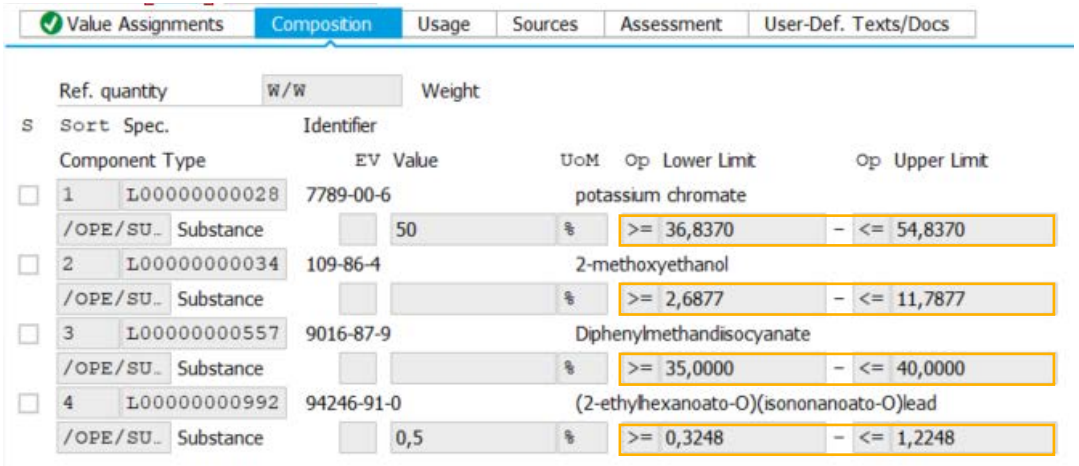
- Exact composition is highly confidential business information
- Potential risk of data breach
- CLP regulation allows stating concentration ranges within specific widths*

** See Regulation 1272/2008 (CLP), Annex VIII, Part B, Chapter 3.4*



Possible Solution

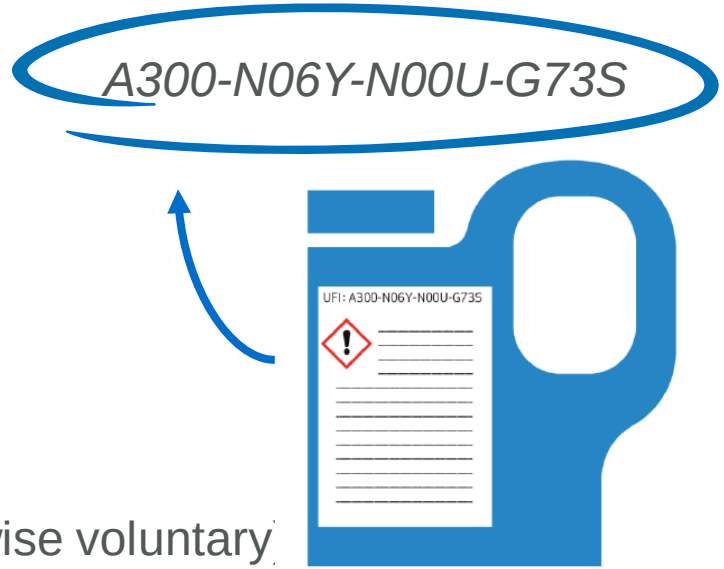
- Ruleset that validates, calculates and writes PCN composition
- Randomize composition within allowed ranges
- Integrate ruleset into SDS authoring process



Unique Formula Identifier (UFI)

Recap on UFI

- 16 character alphanumeric code in 4 blocks
- **Link between product** and **formulation**
- Carrier of compositional information in supply chain
- Where?
  - » **On label** and included in **poison centre notification** or
  - » **On packaging** (proximity of label and clearly visible)
  - » **On SDS** in section 1.1 (industrial use, not packaged products, otherwise voluntary)



Source: ECHA Workshop "Implementation of CLP Annex VIII", Feb 1st 2018

Required data to generate the UFI

- VAT Id or company key and formulation number

Available tools

- ECHA Online UFI Generator
- Other implementations, e.g. **opesus UFI Generator in SAP**

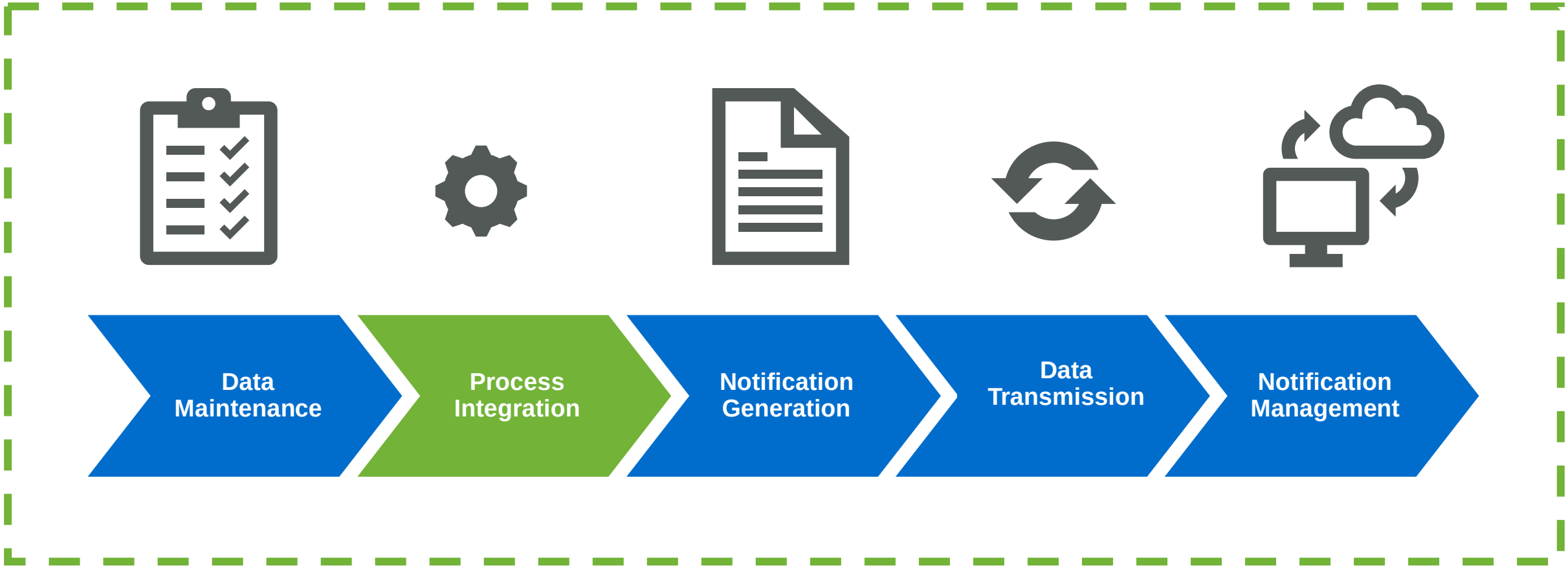
Recommendation:

- Always print UFI on SDS to communicate UFI in the supply chain.
- Use company key(s) instead of VAT Id to protect CBI – UFI can be decoded.

Product Determination Strategies

	Mixture	Product	Customer	Considerations
Product	▪ Product is defined by mixture itself	▪ 1 to n relation between mixture and product name ▪ Product is defined by mixture and product name	▪ Product is defined by mixture and customer specific product name	▪ Different approaches for different business units ▪ Grouping by product names (trade names), disregarding packaging size
EuPCS	▪ EuPCS stored mixture level	▪ Uses additional product table to store several product categories for one mixture		
UFI	▪ UFI stored on mixture level	▪ Uses additional UFI table to store different UFI per product for same mixture		

Automated PCN Notification Process



Process Integration: PCN Notification Triggers

Market Placement: Sales Order

Monitor and Evaluate Sales Orders:

Sales Orders are a very good indicator for maket placements.

- Check if market is of relevance (only EEA)
- Check if product/related mixture is hazardous according to Annex VIII or voluntary submission is wished for.
- Check if notification already exists
- In case of update, check if update is required based on Annex VIII update requirements (new/changed product identifiers, classification change, toxicological data change)

Update Notification: New Safety Data Sheet

Evaluate Mixture data at release of a new SDS for a Mixture

The release of a new SDS confirms that new and completely maintained SDS data is available. This is a good indication that an updated PCN notification might be required.

- Check if update is required based on Annex VIII update requirements (new/changed product identifiers, classification change, **toxicological data change - over 200 fields**)
- Send updates to all legal entities/countries where previous notifications exists

Market Placement: Delivery

Monitor and Evaluate Deliveries:

In build to order scenarios, the Sales order might is too early in the process. The mixture details are not known at this point. In this case the delivery is a good alternative indicator for market placement

Evaluation is the same as for the Sales Order.

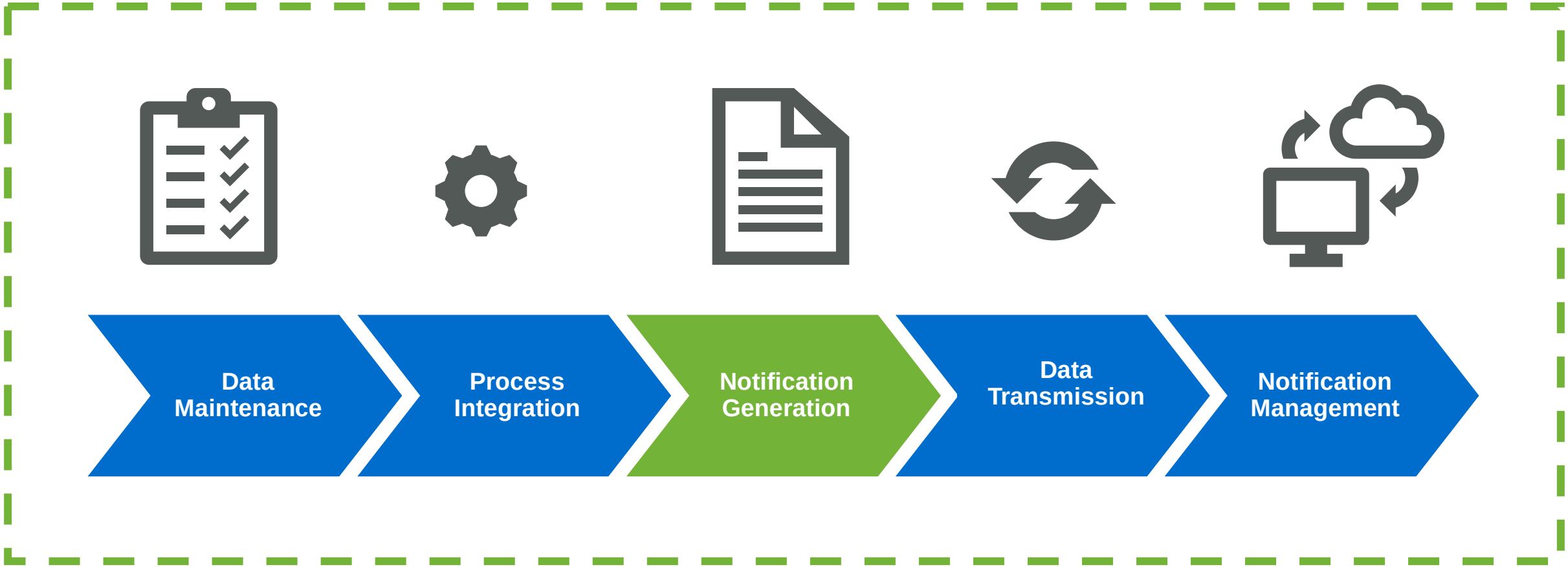
Significant Change: Mixture Composition Changed

Monitor and Evaluate Composition Changes

Not every composition change resulst in a new SDS. Therefor its advisable to also monitor composition changes.

- Check if composition changed beyond the allowed changes defined in Annex VIII
- Generate new UFIs and send updates

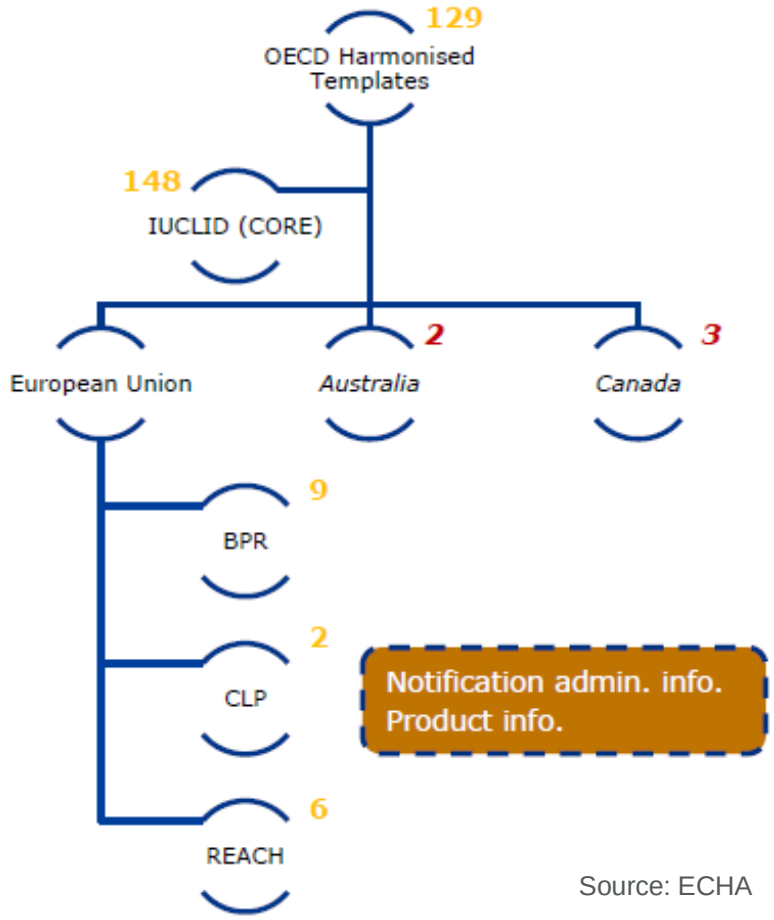
Automated PCN Notification Process



Map Data and Generate PCN Format

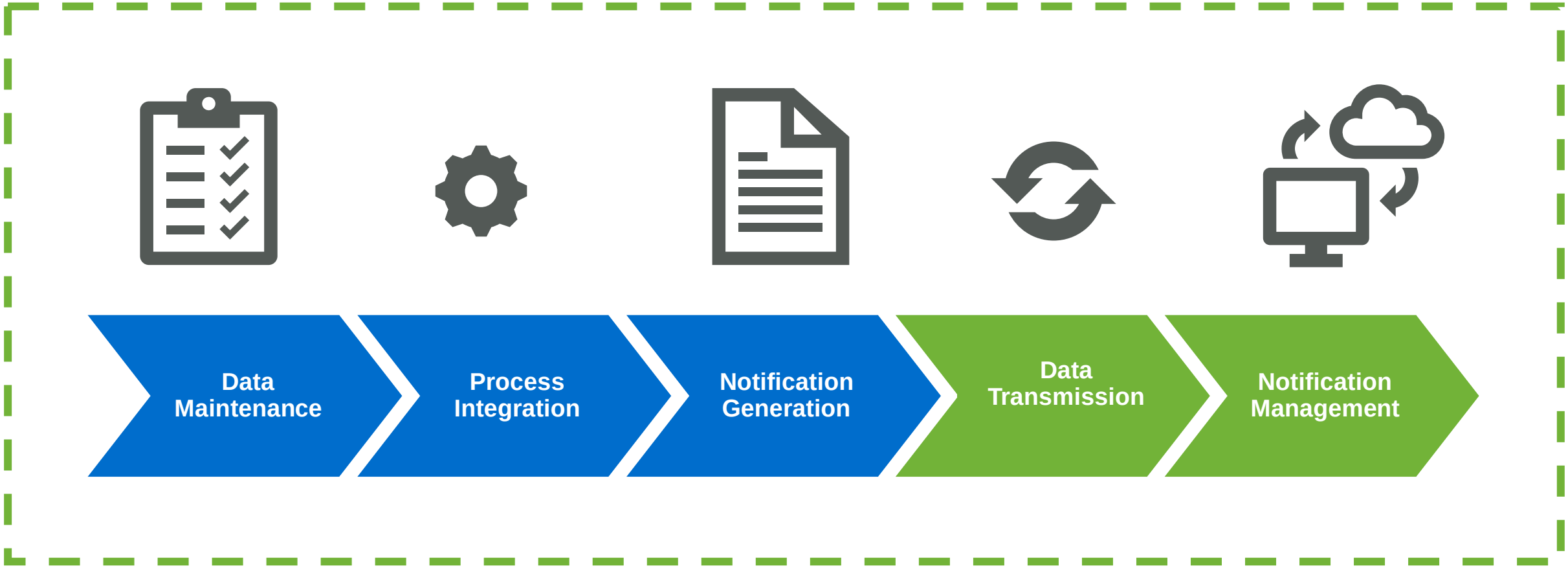
PCN format is based on the IUCLID XML format

- In IUCLID information is organized in IUCLID documents. A document is technically one XML-File. Currently IUCLID has approx. 300 documents
- For the PCN-Format 17 documents are relevant, **two of the documents have been specifically introduced for PCN-data.**
- The **documents** will form one dossier that equals one notification. Technically a notification is a **zip file containing the xml files** with file extension .i6z.
- **Mapping** of product compliance mixture and product information to IUCLID **XML elements** required
- **Mapping** of product compliance **phrases/values** to IUCLID phrases required
- Validations with business and quality rules

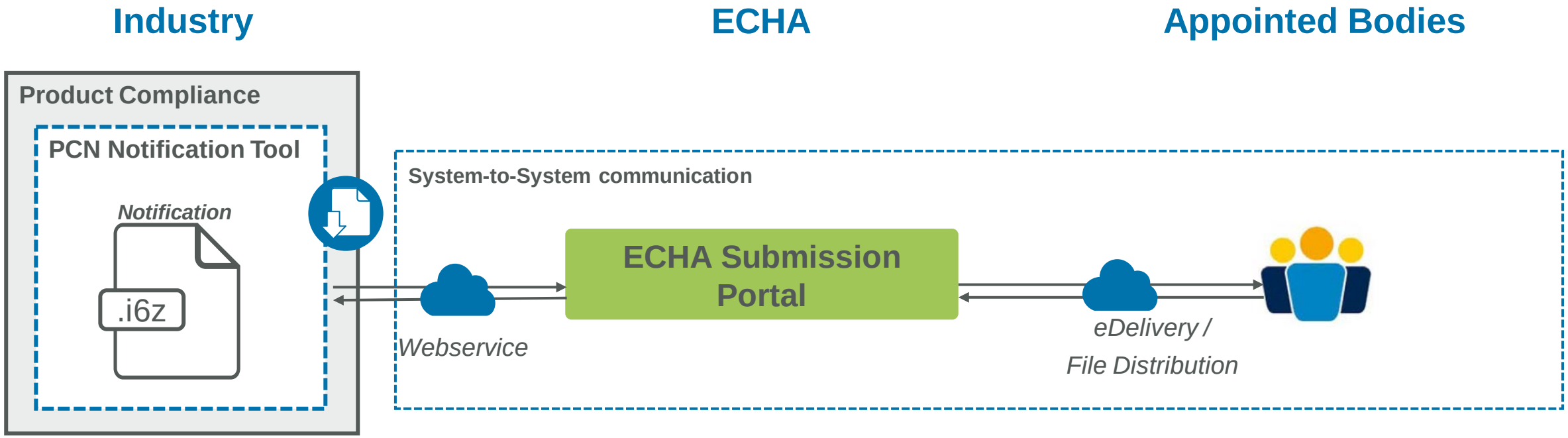


Source: ECHA

Automated PCN Notification Process



Submit notifications via S2S (System-2-System)



Required for Automated Process:

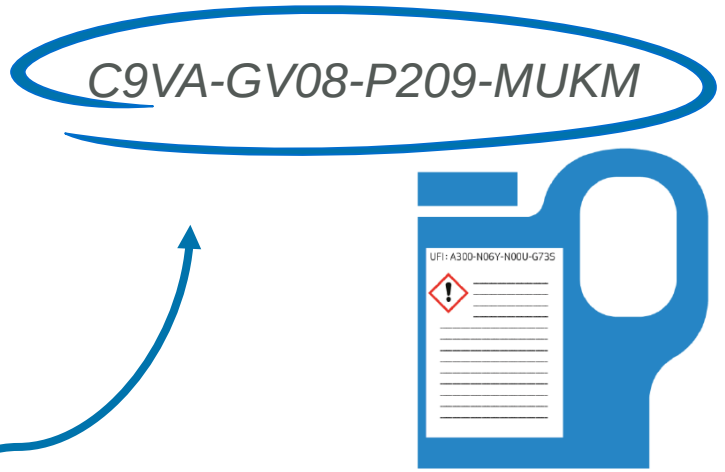
Submit PCN notifications to the ECHA Submission Portal using S2S.

Get submission report via S2S to update status of your notification.

Integrate UFIs on Labels / SDS

For end-to-end automation provide UFIs for:

- Label printing
- Safety Data Sheets



Source: ECHA Workshop "Implementation of CLP Annex VIII"

Display Accepted UFIs

Product Name	Material	Specification	SOrg.	DChl	Customer Name	Hist. UFI	Leg. Ent.	Country	Unique Formula Identifier	Accepted Date	Valid From (UFI)	Valid To (UFI)
DT4100MP_U01C0001OBI	DT4100MP_U01C	DT4100MP_U01	0001	01	Obi Ravensburg	X	0001	DE	C9VA-GV08-P209-MUKM	09.02.2021 13:37:04	09.02.2021 13:37:04	09.02.2021 17:48:59
						X			6FVA-GVD2-9209-XHRR	09.02.2021 17:49:00	09.02.2021 17:49:00	23.02.2021 09:29:16
						X			NJVA-0V2F-K20S-MVAT	23.02.2021 09:29:17	23.02.2021 09:29:17	17.02.2021 08:47:14
		DT4100MP_U02							RGWA-JVNT-Y207-VMRH	17.02.2021 08:47:15	17.02.2021 08:47:15	31.12.9999 23:59:59
Short Text DT4100MP_U01D SOrg 0001	DT4100MP_U01D	DT4100MP_U01				X			GXT8-E068-7000-VTAD	09.02.2021 13:37:04	09.02.2021 13:37:04	09.02.2021 17:48:59
						X			SXV8-202D-800D-3NQV	09.02.2021 17:49:00	09.02.2021 17:49:00	23.02.2021 09:29:16
									QVW8-M0NR-M00U-CE4K	23.02.2021 09:29:17	23.02.2021 09:29:17	31.12.9999 23:59:59
Sales Text DT4100MP_U01D SOrg 0001			0001	01		X			AMT8-D0EP-0001-7F04	09.02.2021 13:37:04	09.02.2021 13:37:04	09.02.2021 17:48:59
						X			PKV8-109T-100E-F9DM	09.02.2021 17:49:00	09.02.2021 17:49:00	23.02.2021 09:29:16
									UHW8-K0W5-D00V-Q1TA	23.02.2021 09:29:17	23.02.2021 09:29:17	31.12.9999 23:59:59
Short Text DT4100MP_U02B SOrg Indep	DT4100MP_U02B	DT4100MP_U02							07V8-00J6-T00E-TX2C	17.02.2021 08:47:15	17.02.2021 08:47:15	31.12.9999 23:59:59
Short Text DT4100MP_U02C SOrg 0001	DT4100MP_U02C								PAV8-H07M-300X-F8NE	17.02.2021 08:47:15	17.02.2021 08:47:15	31.12.9999 23:59:59
Sales Text DT4100MP_U02C SOrg 0001			0001	01					Y2V8-005E-600F-G7W7	17.02.2021 08:47:15	17.02.2021 08:47:15	31.12.9999 23:59:59

Agenda

opesus EPN Software Supports Various Product Notifications

German BfR Format

- since 2013
- Pilot: ASK Chemicals
- Replaced with EU PCN format in 2021

Swiss BAG Format

- since 2016
- Includes UFI Support
- **31 customers**
- Pilot: SIKA

EU PCN Format

- since 2018
- IUCLID-based submission to ECHA
- **94 customers**
- Pilot: BASF, Biesterfeld
- Collaboration with ECHA and SAP

EU SCIP Format

- since 2020
- IUCLID-based submission to ECHA
- **33 customers**
- Pilot: Baker Hughes
- Collaboration with ECHA and SAP

EU C&L Format

- since 2022
- IUCLID-based submission to ECHA
- **11 customers**
- Development in collaboration with several customers

CMDE Format

- since 2023
- XML-based exchange of marketability data
- Pilot: Lanxess
- Development in collaboration with several customers

EPN Engine

Notification submission via S2S*

Authorization and roles

Process automation triggers

* if supported by authority

Scope of opesus Software for Product Notifications

Covers the End-to-End Process of Product Notifications

Additional Benefits

Inside SAP
Product is delivered entirely in customer's SAP system

Ready-to-use Customizing
Initial installation to fit customer-specific needs

High Flexibility
Enabling customer specifics without modification of software

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Automated Notification Process with opesus EPN

Identify Changes

- Sales Order, Delivery Trigger
- Report to evaluate SDS release
- Report to determin PCN composition changes and new material assignments
- Generic trigger RFC function

Check Relevance

- Check country, check if mixture and if either hazardous or voluntary
- Check if update is required

Approve Request

- Work list: approve notification request / set to not required or re-create in case of error
- Or automatic approval by status, country, legal entity, update type, validation status and authorization group

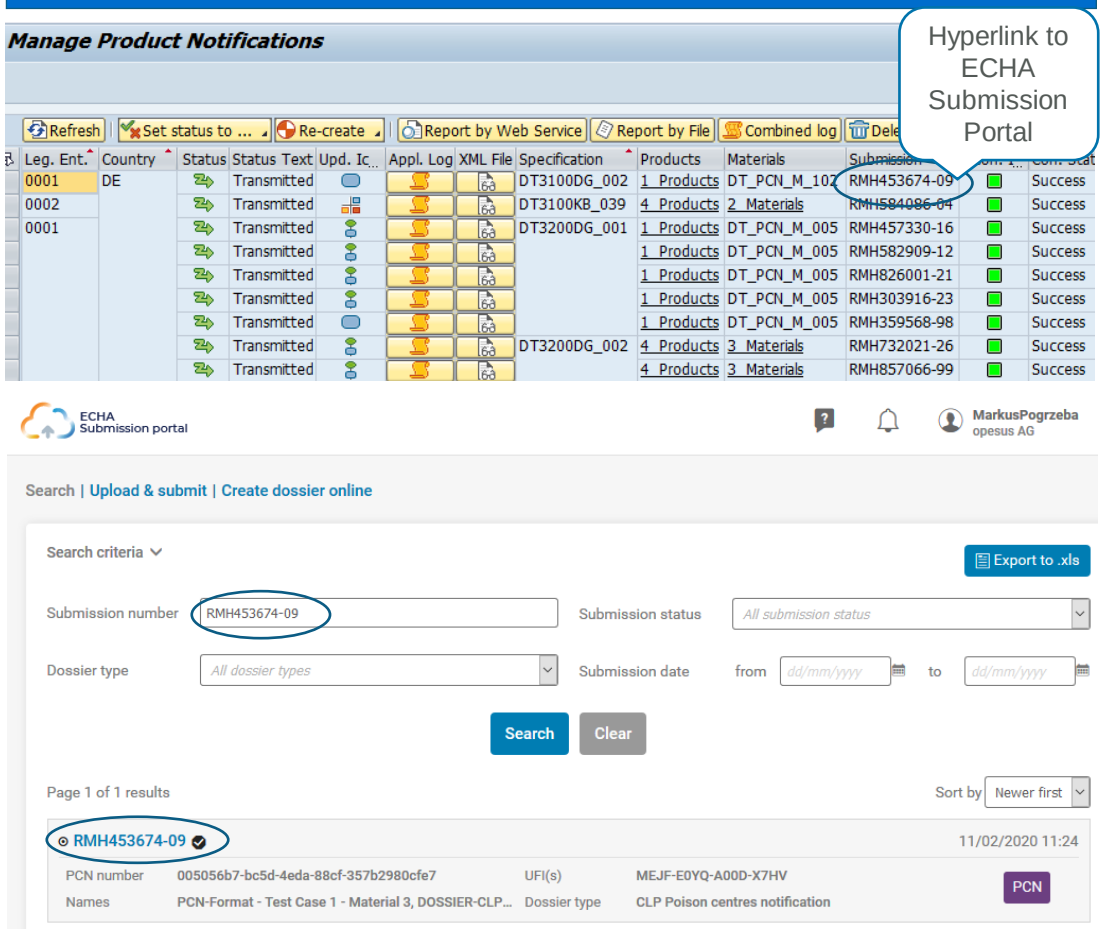
Submission

- Automatic subission of approved notification request via S2S
- Report to automatically get the latest status of your Notification

UFI Provision

- Provision of UFI Parameter Symbols for SDS and Labelling
- Provision of RFC Functions to read UFIs for remote label printing
- Distribution of UFIs per ALE into logistic systems

Automatic Submission via S2S Web-Service



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Key Success Factors Automated PCN Submissions

- Product and UFI determination strategy that fits with your product portfolio and links to mixture composition.
- Protection of CBI: use of concentration ranges and distribution of notifications only to countries where the product is on the market - PCs in countries get only products they really need
- Early validation (before sending): Validation rule framework that implements pretty much all ECHA BR and validation rules that are relevant. IUCLID value list checks, to ensure only allowed values are submitted within a dossier.
- Consistency checks to ensure the update/significant change of composition chain is correct.
- Only send updates if required. Detailed checks on data endpoint level to determine if an update is legally required. This reduces costs for industry and data clutter for PCs.
- Security Concept: Store S2S keys safely, encryption of data during submission (including composition information)
- Automation: Detect if products are placed on new markets or if updates occur.
- Monitoring Automation Process: Event register and worklist registers to be able to monitor and check if failures occur. Alerts to system administrators if failures occur.

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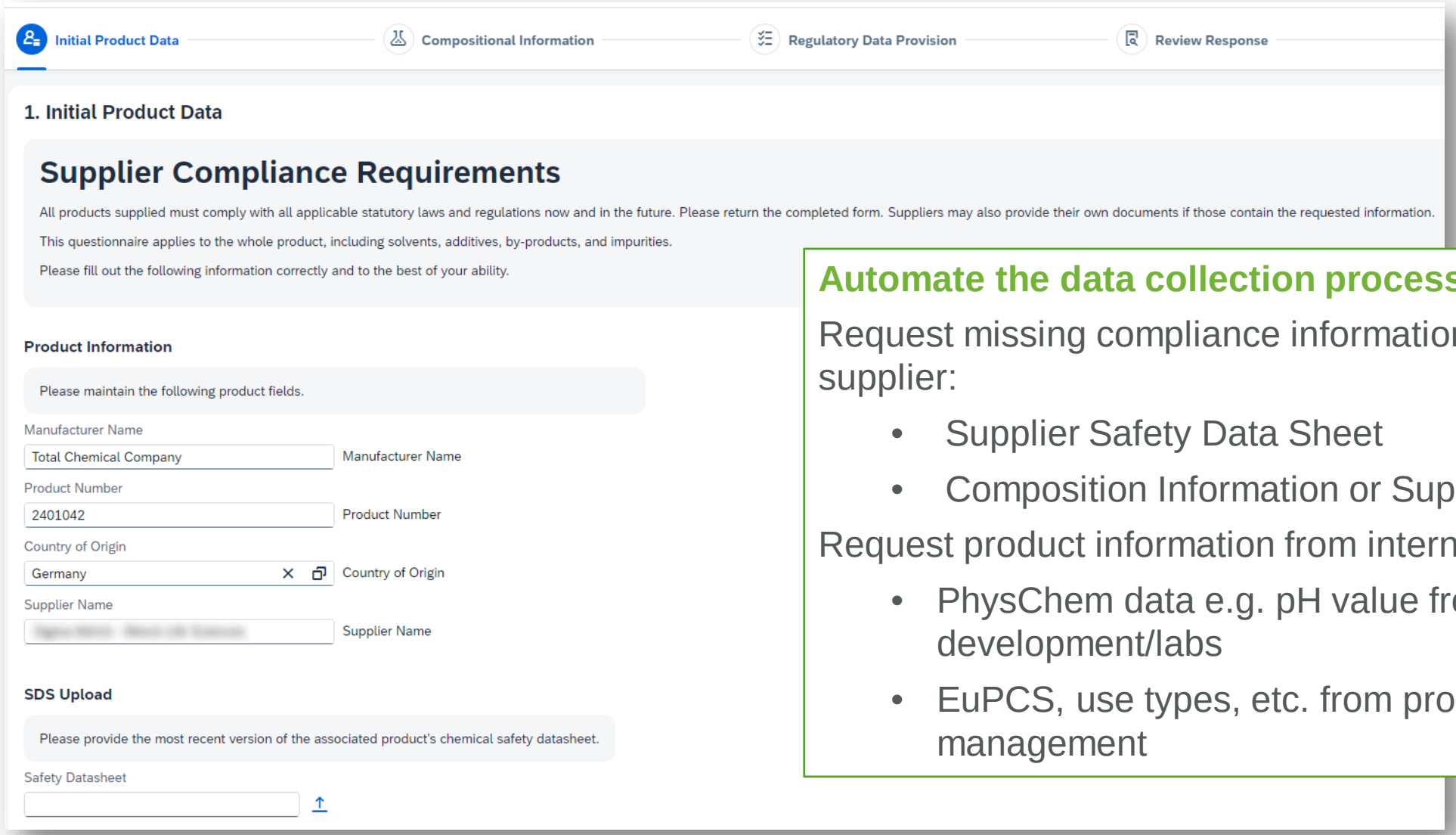
opesus Product Compliance Collaboration

PCC: Request Compliance Data from Suppliers



Automate the data collection process

Request missing compliance information from your supplier:

- Supplier Safety Data Sheet
- Composition Information or Supplier UFI

Request product information from internal department:

- PhysChem data e.g. pH value from product development/labs
- EuPCS, use types, etc. from product management

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Summary

Process automation with System-2-System submission is a huge success. Most companies we are supporting are using process automation and System-2-System submissions.

Large companies (= many mixtures) would either not be able to, or would have a very hard time, to fulfill their legal notification obligations w/o the possibility of automation and S2S.

Collaboration in work groups between ECHA, Commission, PCs/ABs, Industry and IT providers was key to a successful automated S2S solution.

Update Requirements still pose a challenge to industry and PCs. Refinement of update/significant change of composition legal requirements could help.

Do you have any questions?

Get in touch with us!

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