Best Practices in (M)SDS Authoring in SAP EH&S

Betty Hicks, United States Authoring Operations Manager

Alex Ortiz, Director of Ariel Integrated Content

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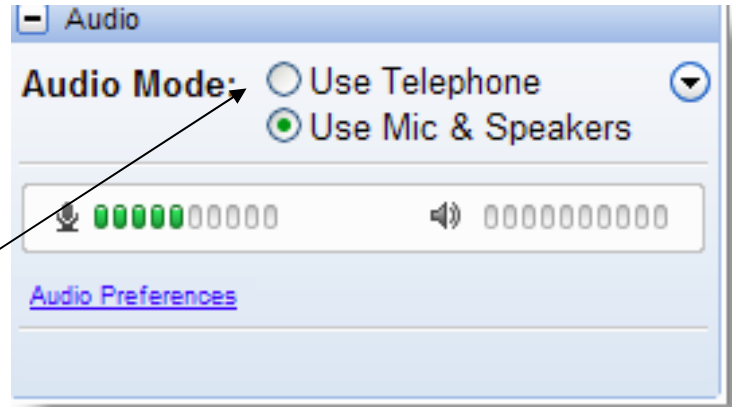

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Web Seminar Instructions

- Click Q&A button to submit your questions. Questions will be answered at the end of the presentation.
- This web seminar will be recorded. The audio and visual presentation link will be sent to you after the web seminar

Guest Speakers

Betty Hicks, US Authoring Operations Manager, 3E Company

- 2003 to 2007 participated as a Senior (M)SDS author responsible as Project Manager for several clients providing global compliant (M)SDSs
- Since 2007 has served as US Authoring Operations Manager for 3E

Alex Ortiz, Director of Ariel Integrated Content

- Manages the production and maintenance of Ariel Regulatory Data, Phrase Library, Rules & Template
- Participated in more than 50 SAP EH&S Implementations

SAP

Getting Started

- Initial Setup: Considerations!
- Who should be involved?
- What tools can I utilize for maximum output?
- Considerations
- Building Blocks

SAP

- SAP implementation of the software, such as EH&S module, is a massive operation which changes how the organization works together.

  Your GOAL is to make the changes work for YOU!

- The resulting changes that the implementation of SAP generates are intended to reach high level goals, such as:
  - *improved communication and*
  - *increased return on investment.*

- SAP is modular and fully customizable. EH&S is comprised of several modules that optimize the use of data to perform EH&S functions.

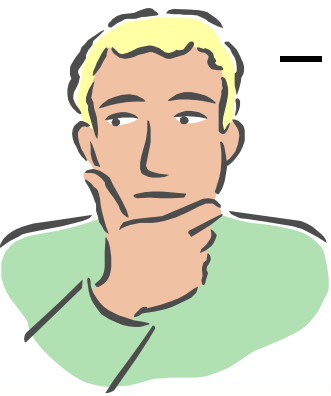
- One customer's SAP does not necessarily mirror another SAP EH&S setup. The system is defined by it's utilization as specified by the owner.

- SAP is as ROBUST as the information and set up

SAP

Before you get started:

- THINK! THINK! THINK!
- Identify goals and expectations early.
  - What is your end goal for SAP EH&S output for authoring?
  - What are your expectations from the system once up and running?
- Make the system work for you!
- Most popular feedback: “If we had only thought this through, we would have done things differently.”



SAP

Explore the opportunities SAP provides to complete work faster, smarter!

- Develop in-house expertise
  This expertise can provide support later down the road
- Have the right people working together
- Consider cleaning up your data before you migrate to SAP
- DON'T settle for "*We've always done it this way*".
- Don't try to recreate your legacy system
- Streamline your process
- Eliminate as much customization as possible – Helps other building blocks fit
- Document your processes
- Spend the manpower to invest in fully loading SAP with data.

SAP

If you decide to move forward to get SAP EH&S up and running!

Who should be involved?

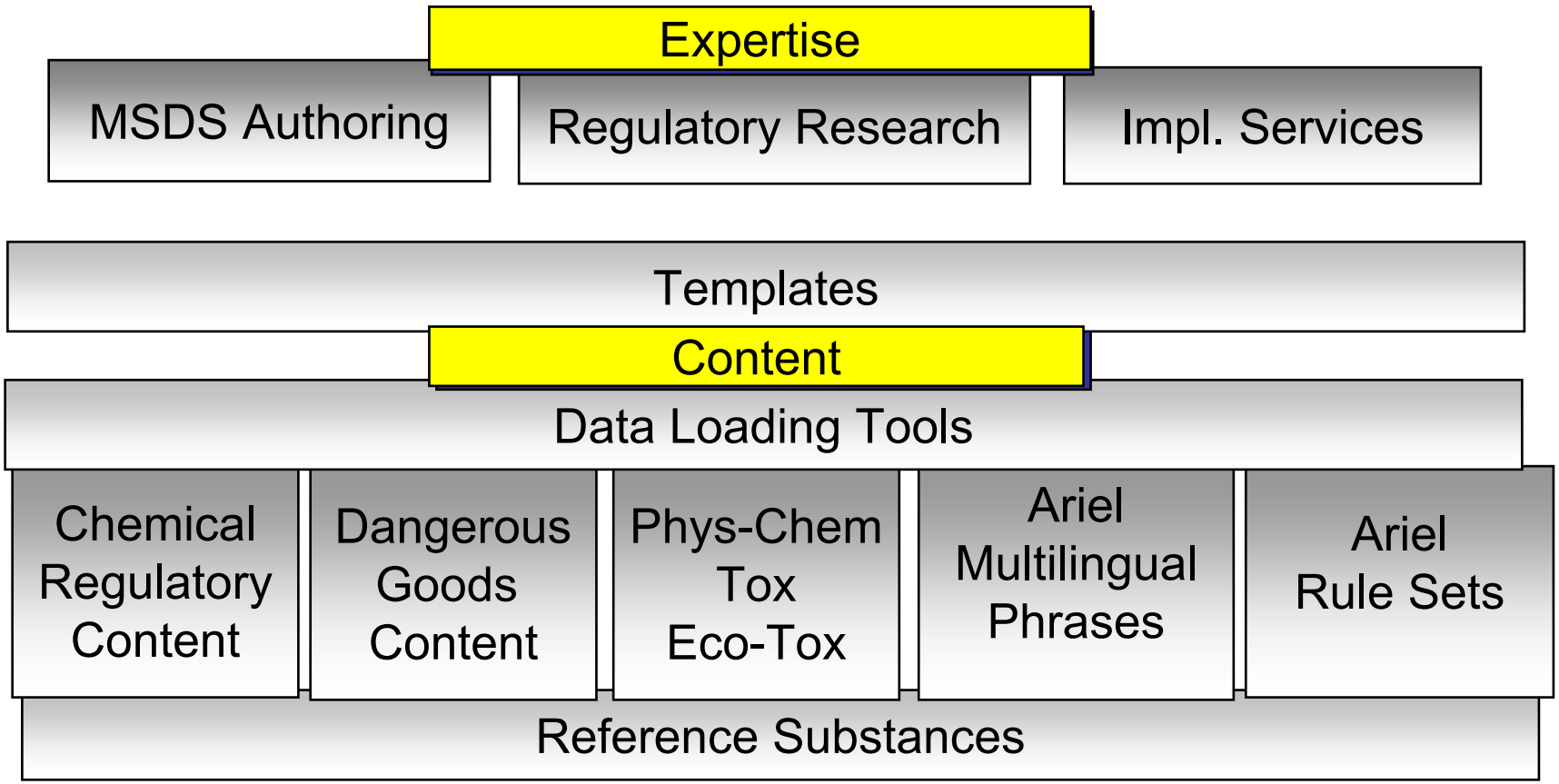
IT person(s)
Author(s)

An author is aware of the regulations/compliance [illegible] be followed.

IT can push the buttons to make it work.

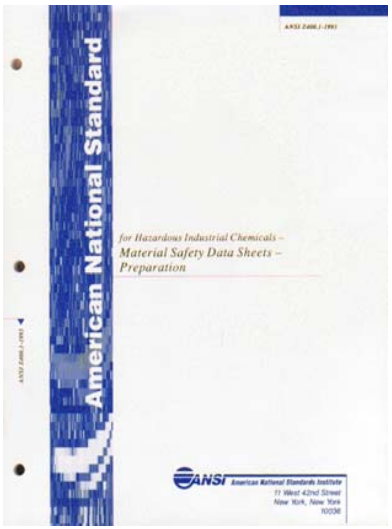
Use as many available tools/building blocks as possible to optimize the implementation

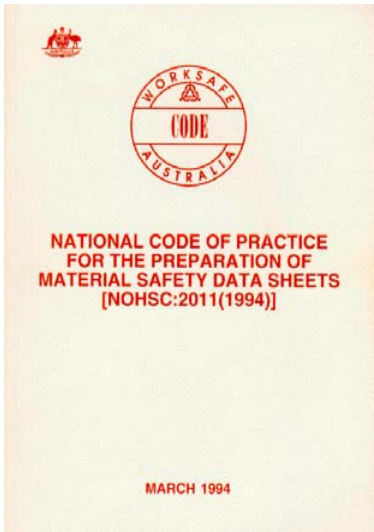
Elements of Authoring in SAP EH&S

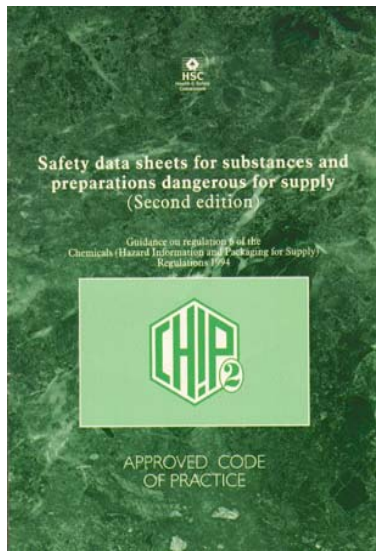


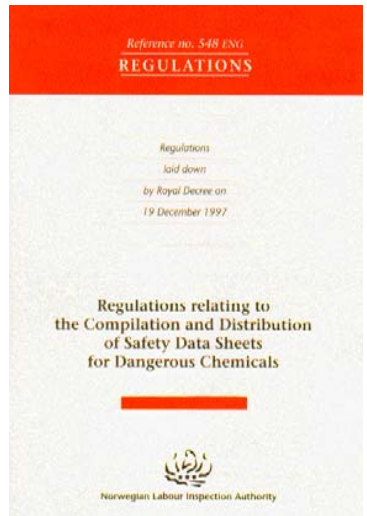
Understanding Global (M)SDS Regulatory Requirements

Know your target!







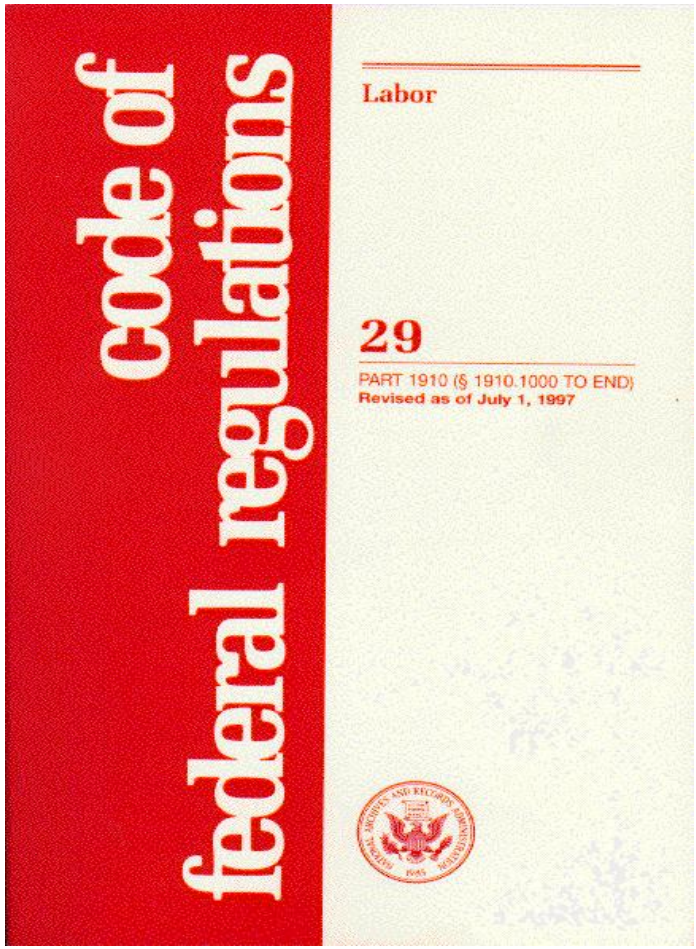


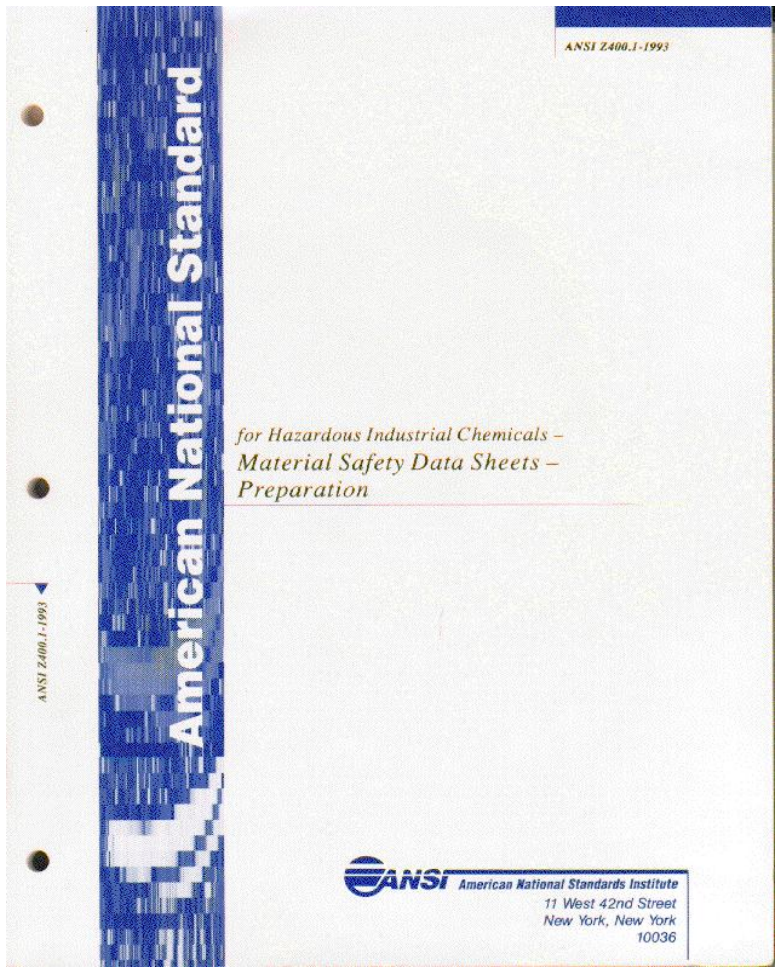
Lack of Standardization

Despite GHS, (M)SDSs lack global standardization

- Variation in national regulatory information to be included in the (M)SDS
- Variation in language
- Variation in requirements and headings

USA: Requirements





USA: Requirements

CFR Regulatory Data Requirements

- Sec. 2: composition/information on ingredients
  - For untested mixtures:
    - Chemical and common name of ingredients at health hazards ≥ 1%
    - Chemical and common name of ingredients which are physical hazards
    - Chemical and common name of ingredients which are listed carcinogens at ≥ 0.1%
- OSHA, ACGIH, or company exposure limits (and/or in Sec. 8)

USA: Requirements

CFR Regulatory Data Requirements (Cont'd)

- Sec. 3: Hazards Identification
  - OSHA, IARC or NTP carcinogen listings
- Sec. 8: Exposure Control/Personal Protection
  - OSHA, ACGIH, or company exposure limits (and/or in Sec. 2)

USA: Requirements

ANSI Additional Recommended Data

Sec. 13: Disposal Considerations

- Classification under applicable laws (*RCRA*, 40 CFR 261- Hazardous Wastes)
- Identification: US EPA Waste Nos. and descriptions

USA: Requirements

ANSI Additional Recommended Data (cont'd)

- **Sec. 15:** Regulatory Information
  - Federal Regulations (e.g., OSHA, TSCA, CERCLA, SARA III, etc.)
    - OSHA - State whether material is OSHA-hazardous
    - TSCA - Provide status of material under various sections of TSCA, e.g.:
      - § 5(a)(2) SNURs
      - § 5(e) Final Consent Orders
      - § 5(h)(3) R&D limitations
      - § 8(b) TSCA Inventory
      - § 12(b) Export notification

USA: Requirements

ANSI Additional Recommended Data (cont'd)

- CERCLA - RQ or a statement that there is no RQ
- SARA III - Provide information on the material which may include:
  - § 302 Extremely Hazardous Substances (Chemical ID, Threshold Planning Quantity and RQ)
  - § 311/312 Hazard Classes
  - § 313 Toxic Chemicals (Chemical ID, CAS RN, percent by weight)

USA: Requirements

ANSI Additional Recommended Data (cont'd)

- State Regulations
  - Many states have adopted the HCS, but some may have additional requirements - Consult the regulations of the states in which you do business
    - Inclusion of State-listed substances at or below HCS concentrations (e.g., Mass., Penn., R.I., Ca.)
    - Specialized data requirements (VOCs in Ca., environmental effects in Vt.)

Korea - MSDS

- Fully adopts the *16 sections of the UN Purple Book*
- Must comply with the GHS standards
  - Pure substances: July 1, 2010
  - Mixtures: July 1, 2013
- Should be prepared in the *Korean language*
- The test data conducted in compliance with GLP (Good Laboratory Practice).
- Should be prepared for all substances and mixtures *containing more than 1%* of physical, health, and environmental hazards.

Overview – GHS

Hazard Communication – MSDS

Sixteen section MSDS required

1. Substance identity and company contact information
2. Hazards identification
3. Chemical composition and data on components
4. First aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls and personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

MSDS Requirement – Korea specific

- Section 9 – Physical and chemical properties

  - 17 properties (from Appearance to Viscosity) are identical to the ones of UN Purple book.

  - Korea *added Molecular Weight* as No. 18 property

- Section 14 – Transport Information

  - Korea MSDS *does not require No. 7* information of Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

MSDS Requirement – Korea specific (cont.)

- Section 15 – Regulatory Information
  - Restrictions under the *Industrial Safety & Health Act*
  - Restrictions under the *Toxic Chemicals Control Act*
    - **Observational** chemicals
    - **Prohibited** chemicals
    - **Restricted** chemicals
  - Restrictions under the *Safety Control of Dangerous Substances Act*
  - Restrictions under the *Wastes Control Act*
  - Restrictions under other foreign or domestic laws

Japan

MSDS

- PRTR
  - Any suppliers required to provide MSDS
  - Concentration cut-off (≥ 1% or ≥ 0.1%)
  - Content must be indicated to two significant figures (e.g. 1.6%)
- ISHL
  - Industrial chemicals
  - Content % with range
  - Introduced GHS (GHS Implementation)
- PDSCL
  - Required for all specified chemicals, specified and poisonous substances
  - Prescribed concentration cut-off
  - Exact content % must be provided on MSDS

Japan

GHS Implementation

- SDS (JIS Z 7250:2005) – Dec. 31, 2010
  - 16 sections
  - Identification
  - Hazard identification (GHS classification and label elements)
  - Composition/information on ingredients
  - Pictograms (pictograms may be in white and black diagrams, or may be replaced with the name of pictogram)
  - Toxicological information (aligned with that of GHS; route of exposure)

Country variation

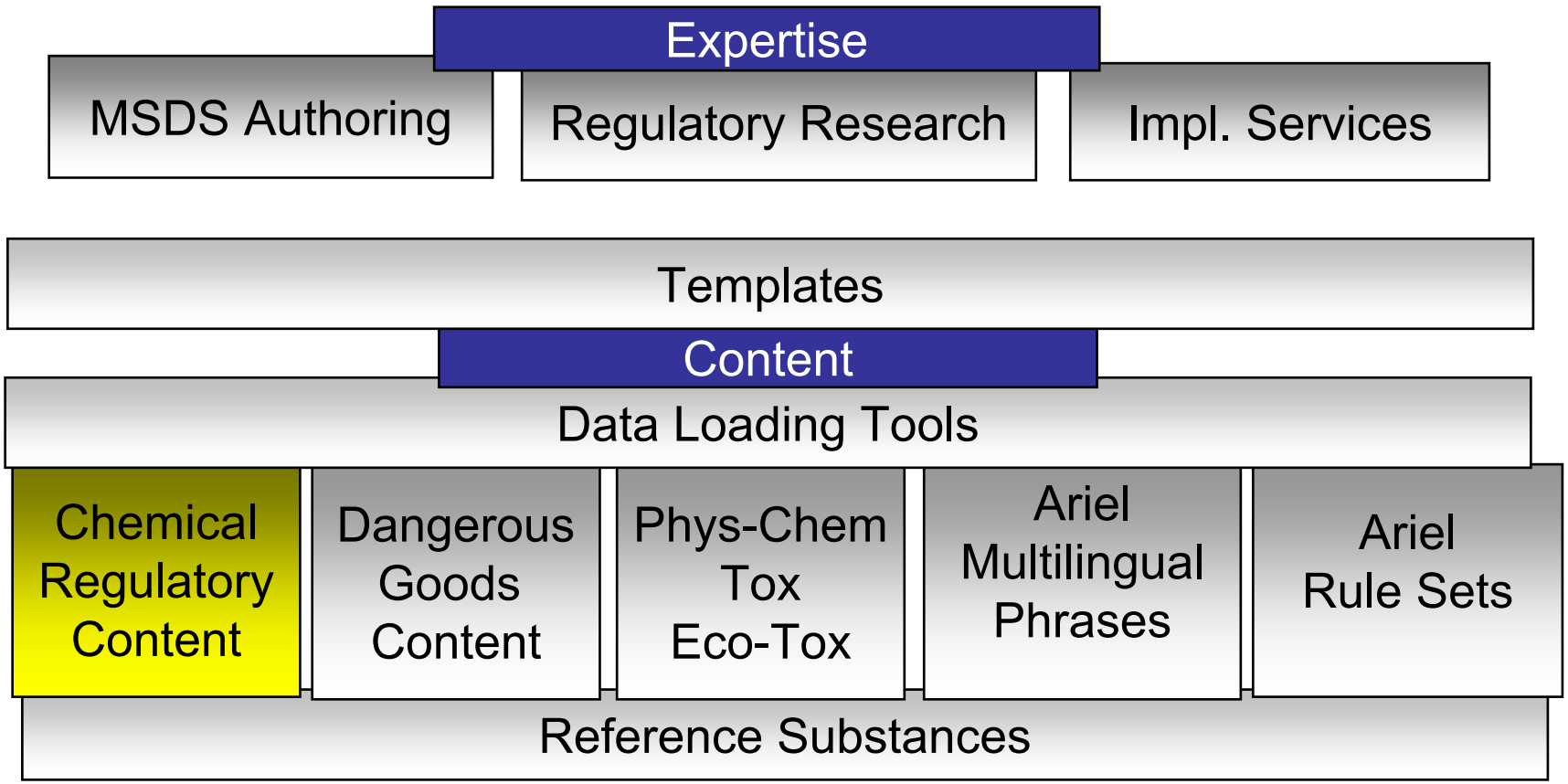
Therefore:

Understand regulatory requirements with regard to:

- Content
- Language
- Format

So you can align these with your content, phrase library and template implementation requirements!

Elements of Authoring in SAP EH&S



Product Safety

Use a service provider if possible. 3E maintains –

- Staff to tracking regulations, maintaining data providing Updates every quarter
- Standard implementation and Update process that includes customizing and phrases
- Built-in regulatory expertise (generics)
- Rigorous quality process for data maintenance
- Reference and integrated content

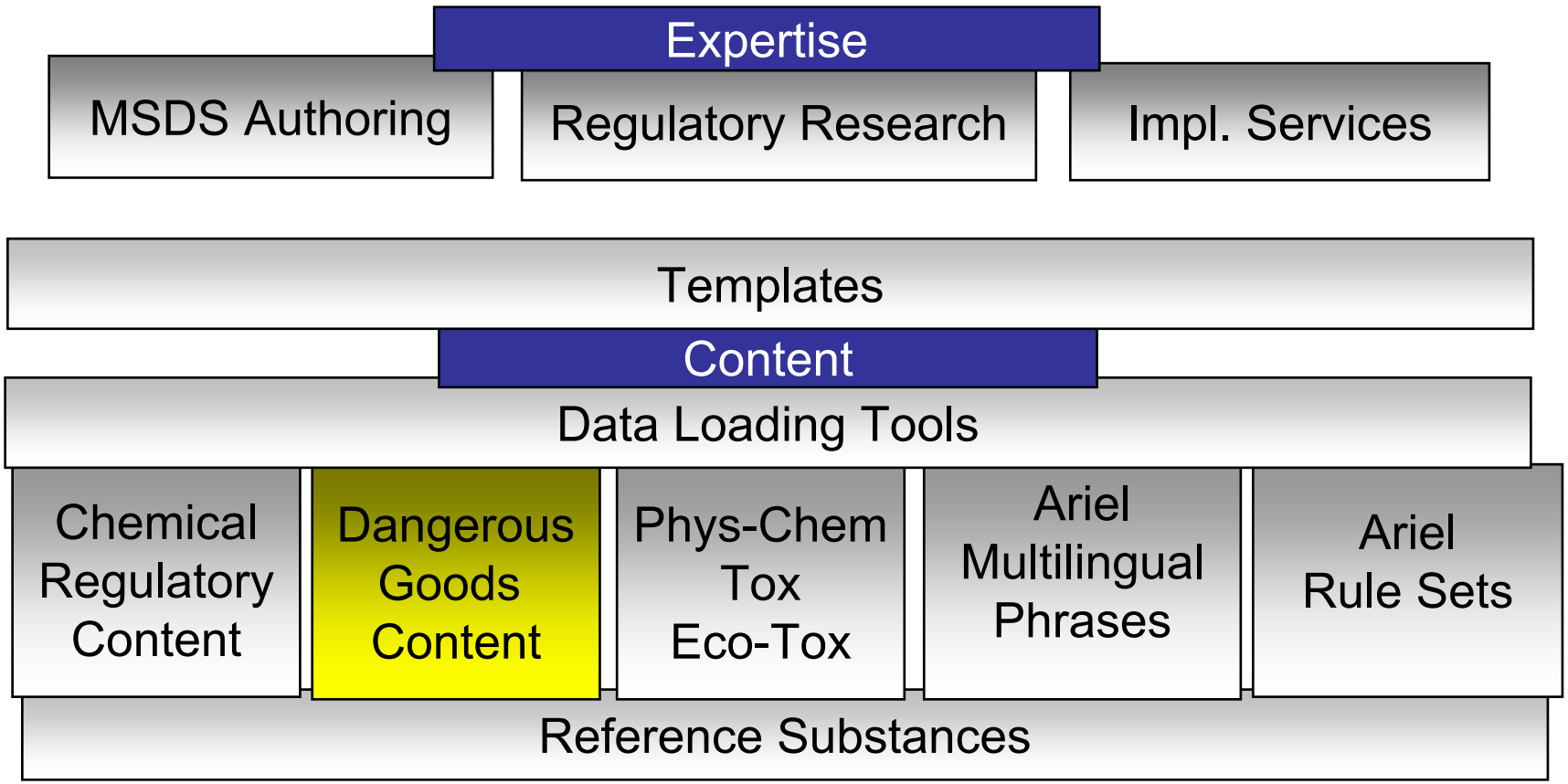
  300,000+ unique CAS RNs

  700+ regulatory lists covering:

  - North and Latin America
  - Western and Central/Eastern Europe
  - Global Inventories
  - Asia Pacific
  - Mid-East/Africa

Allow your company regulatory experts to focus on compliance rather than data-entry

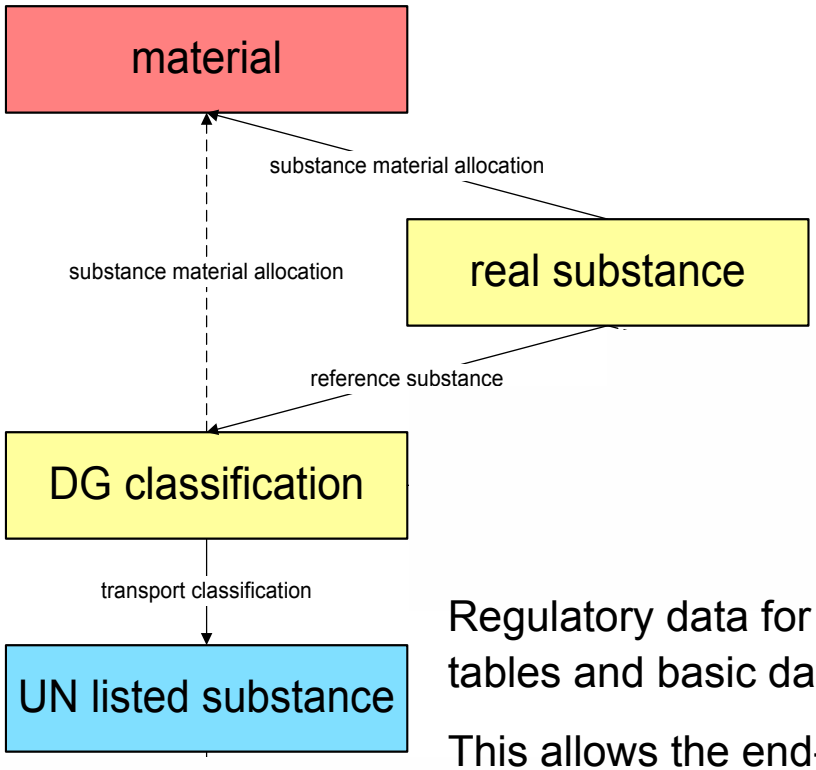
Elements of Authoring in SAP EH&S



DG Data

Regulations for All Modes of Transport
ADR: European agreement on the international carriage of dangerous goods by road
RID: Regulations concerning the International carriage of dangerous goods by rail
ADNR: Regulations Concerning the Transport of Dangerous Goods on the Rhine
IATA: International Air Transport Association (IATA) Dangerous Goods Regulations
IMDG: IMO International Maritime Dangerous Goods Code
49CFR: US Department of Transportation Hazardous Materials Regulations
TDG: Canadian DG Regulations
Mexico: List of Dangerous Goods
China: List of Dangerous Goods
Australia: Australian Code for the Transport of Dangerous Goods by Road and Rail
Japan: coming in 2009

DG Data for SAP EH&S



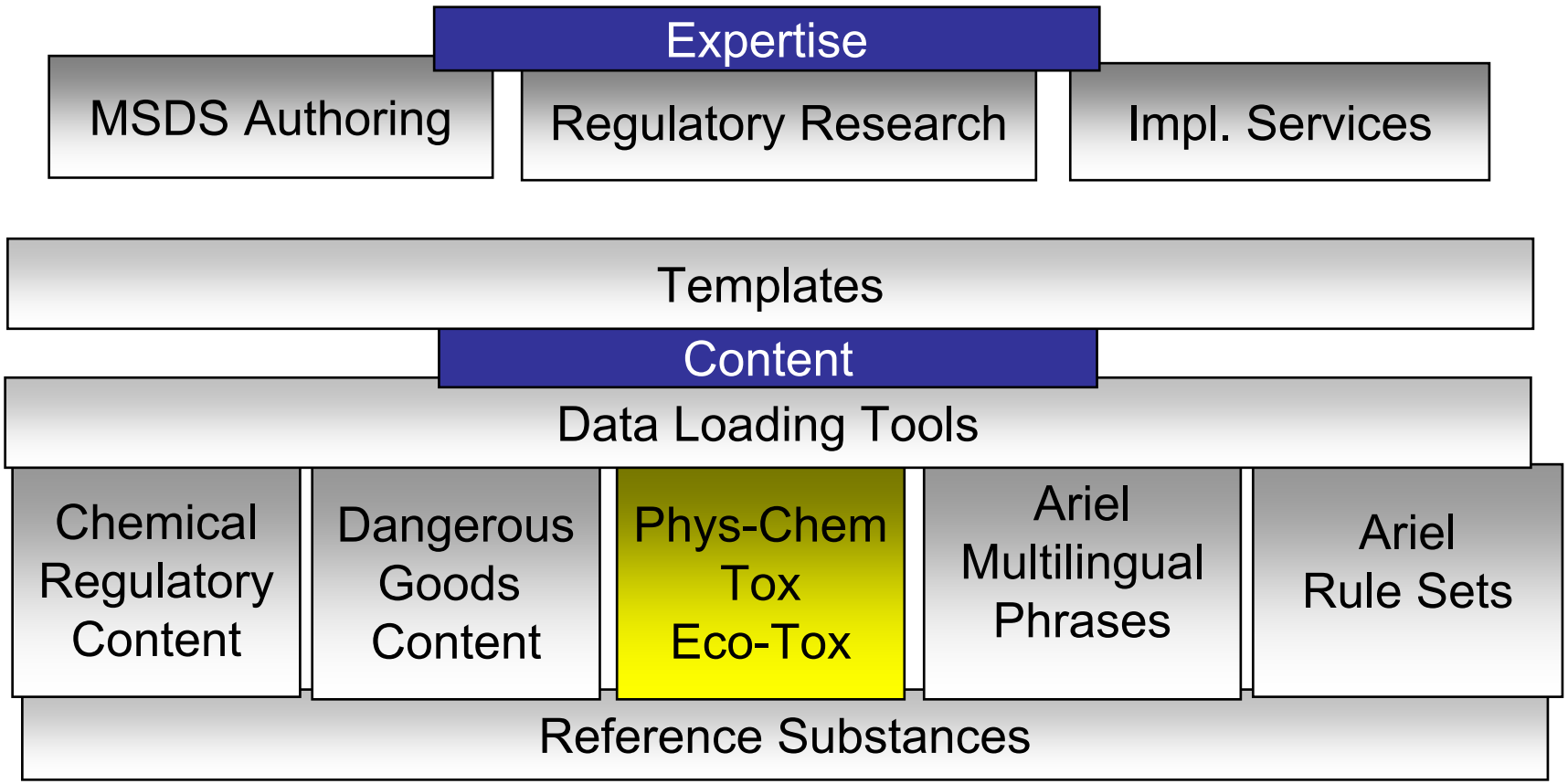
All modes of transport:

- Road
- Rail
- Inland Waterway (Rhine)
- Air
- Sea

Regulatory data for the transport of dangerous goods fills customizing tables and basic data related to UN List substances.

This allows the end-user to create Dangerous Goods Classifications that may then be linked to either real substances or materials and which then fill the material master. The completion of this process enables the end-user to take advantage of a broad set of functionality, including document generation and dangerous goods checks.

Elements of Authoring in SAP EH&S



PCTEC Data

- Phys-Chem, Tox and Eco-Tox data is difficult to manage
  - Migration of company-specific data
  - Too much data from some sources
  - Not enough data from other sources
  - Expert judgment involved

PCTEC Data

Available data includes

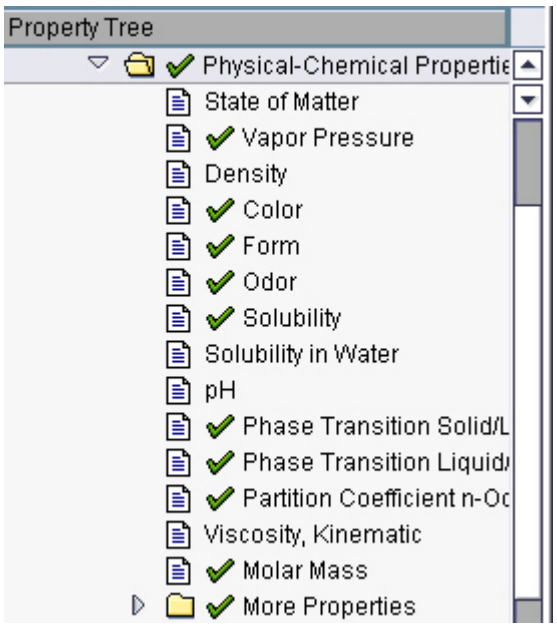
~ 120,000 data records for ~ 8,000 unique CAS RNs

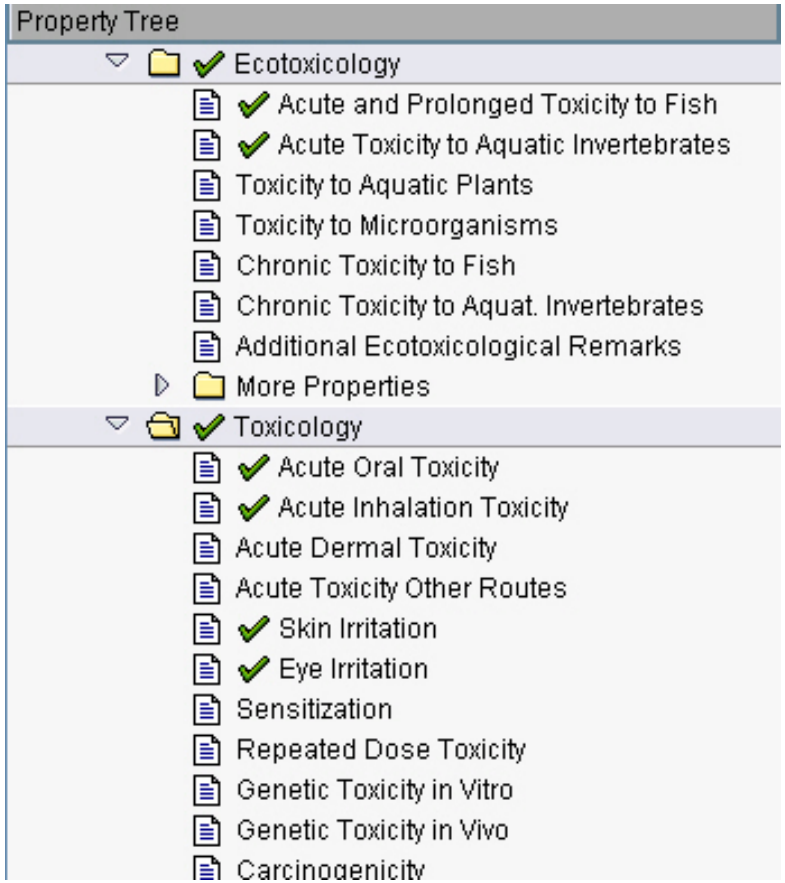
Primary sources for this data are:

- HSDB (Hazardous Substances Data Base)
- AQUIRE (Aquatic Toxicity Information Retrieval)
- ACGIH: Critical Effects
- EC Annex1: Sensitizers
- EPA: EPISuite Database

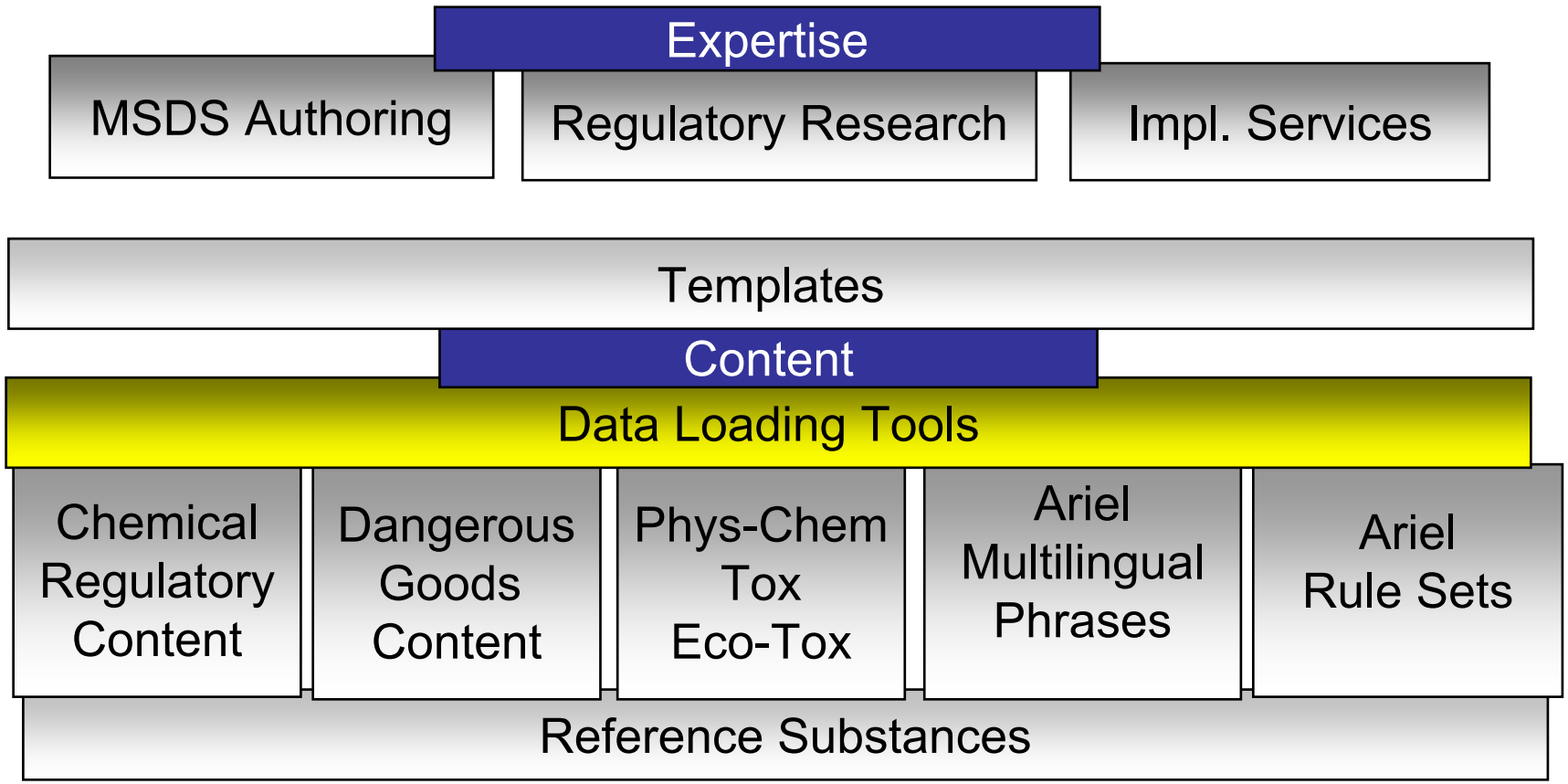
PCTEC Data

Data as it appears in SAP EH&S Property Tree

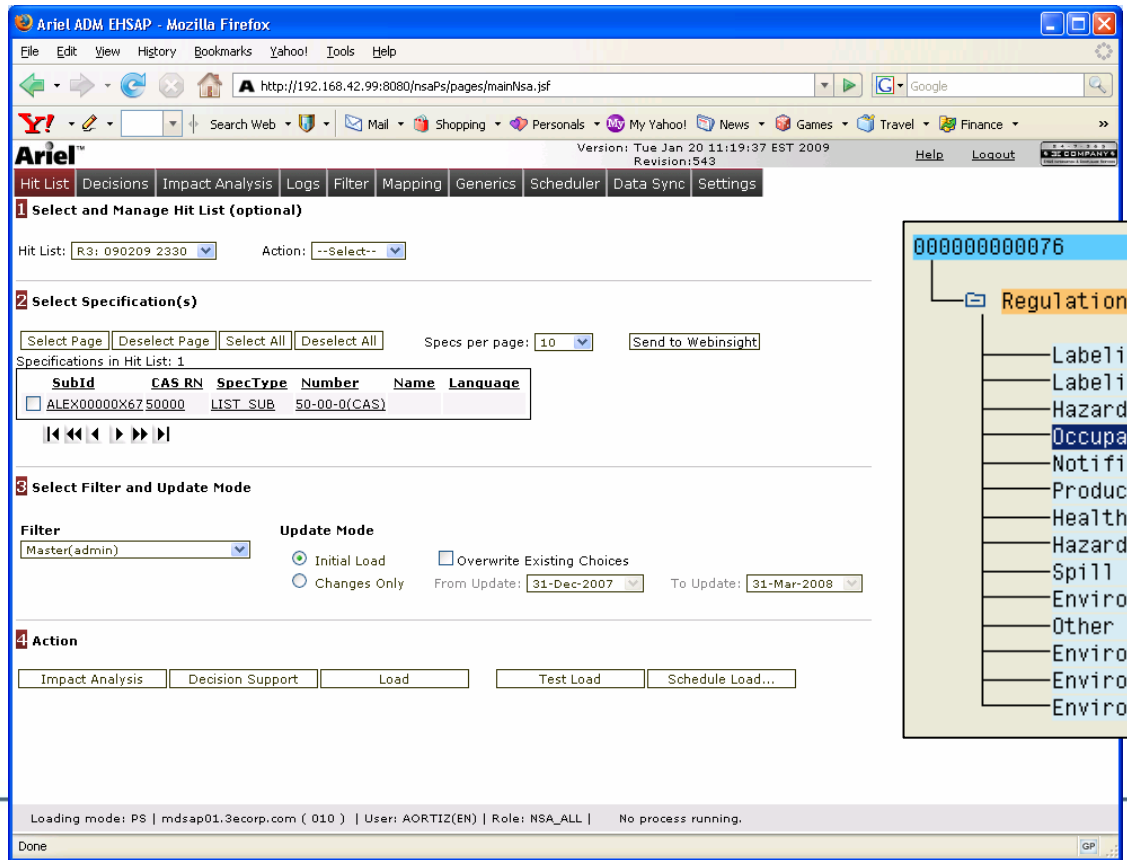




Elements of Authoring in SAP EH&S



ⓘ ADM-EHSAP


Ariel ADM EHSAP - Mozilla Firefox
File Edit View History Bookmarks Yahoo! Tools Help
http://192.168.42.99:8080/nsaPs/pages/mainNsa.jsf
Search Web Mail Shopping Personals My Yahoo! News Games Travel Finance
Ariel™
Version: Tue Jan 20 11:19:37 EST 2009
Revision:543
Help Logout
Hit List Decisions Impact Analysis Logs Filter Mapping Generics Scheduler Data Sync Settings
1 Select and Manage Hit List (optional)
Hit List: R3: 090209 2330
Action: --Select--
2 Select Specification(s)
Select Page Deselect Page Select All Deselect All
Specs per page: 10
Send to Webinsight
Specifications in Hit List: 1
SubId CAS RN SpecType Number Name Language
ALEX00000X67 50000 LIST_SUB 50-00-0(CAS)
3 Select Filter and Update Mode
Filter
Master(admin)
Update Mode
Initial Load
Changes Only
Overwrite Existing Choices
From Update: 31-Dec-2007
To Update: 31-Mar-2008
4 Action
Impact Analysis Decision Support Load Test Load Schedule Load...
Loading mode: PS | mdsap01.3ecorp.com (010) | User: AORTIZ(EN) | Role: NSA_ALL | No process running.
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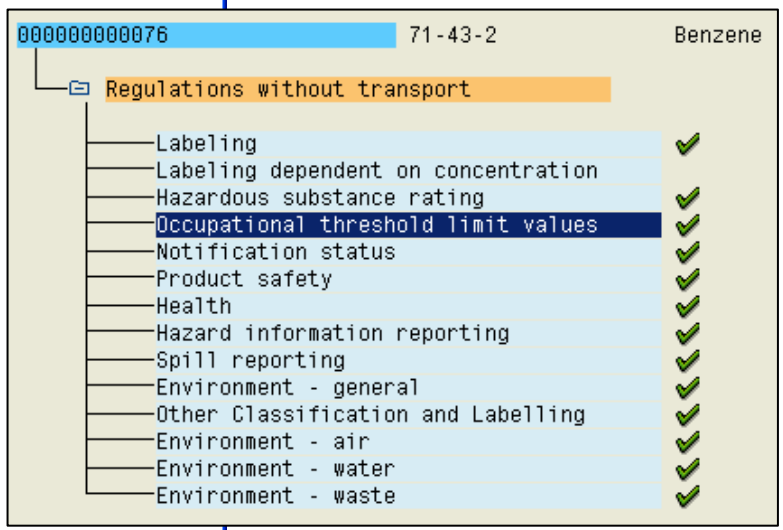
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71-43-2
Benzene
Regulations without transport
Labeling
Labeling dependent on concentration
Hazardous substance rating
Occupational threshold limit values
Notification status
Product safety
Health
Hazard information reporting
Spill reporting
Environment - general
Other Classification and Labelling
Environment - air
Environment - water
Environment - waste

Data Load Workflow

Decision Support Process

- Data service should allow a very high degree of automation (e.g. scheduling data updates or loading overnight), but . .
- Data service is not just data pump!
- Service should provide the user an opportunity to review data and make decisions
  - What decisions do users make?
  - How do users make them?

Decisions Workflow

Typical User Decisions

1. Is a Generic group relevant?
    - e.g. Arsenic and its compounds, except when present in metals or alloys (S~AS~C)
2. Which of two or more generics groups is most relevant?
    - e.g. Barium zinc sulfate sulfide, CAS RN 1345-05-7
        - For the same regulations, different entries apply to
            - » Barium Compounds
            - » Zinc Compounds

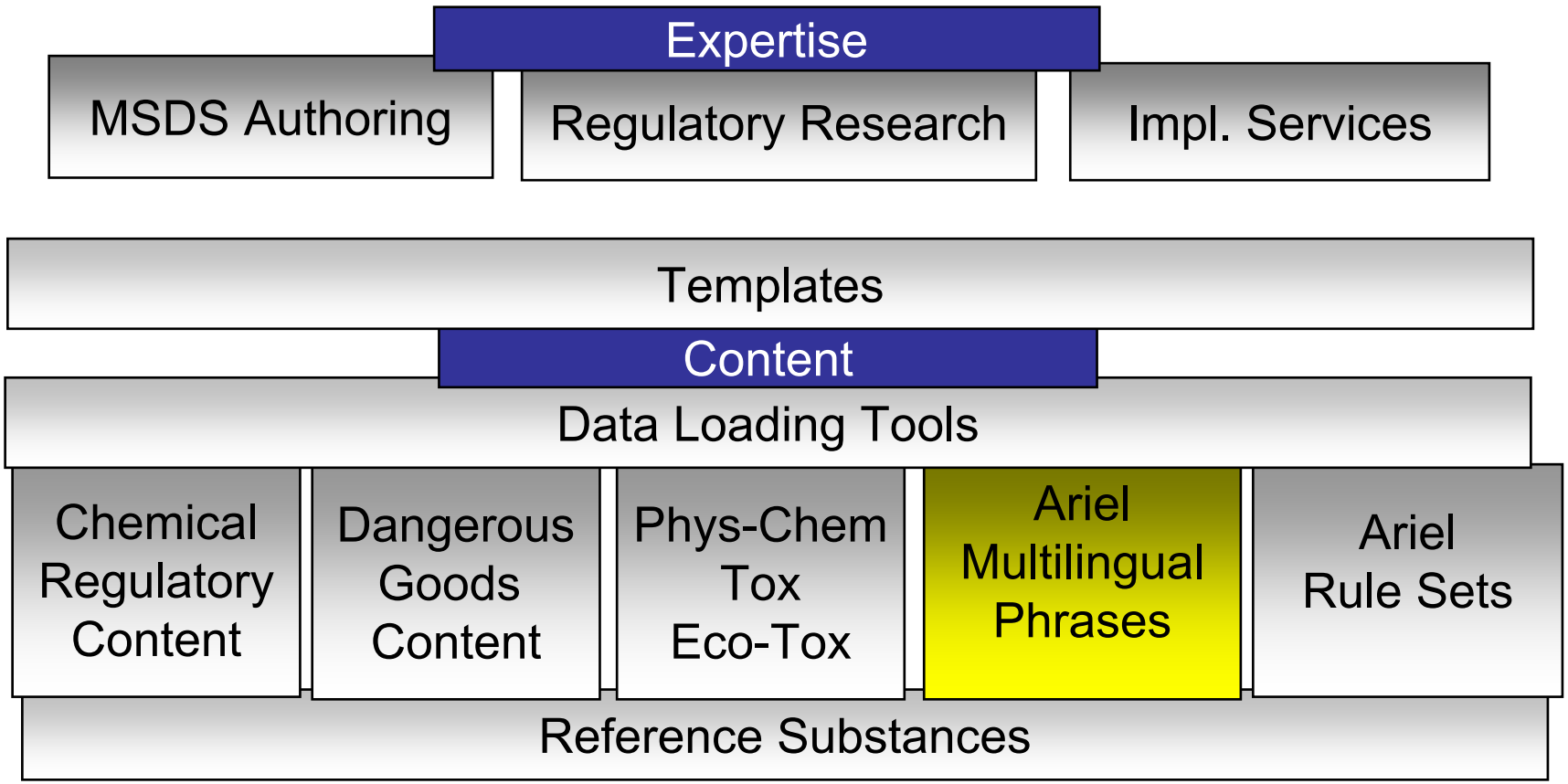
Decisions Workflow

Decisions Support Workflow

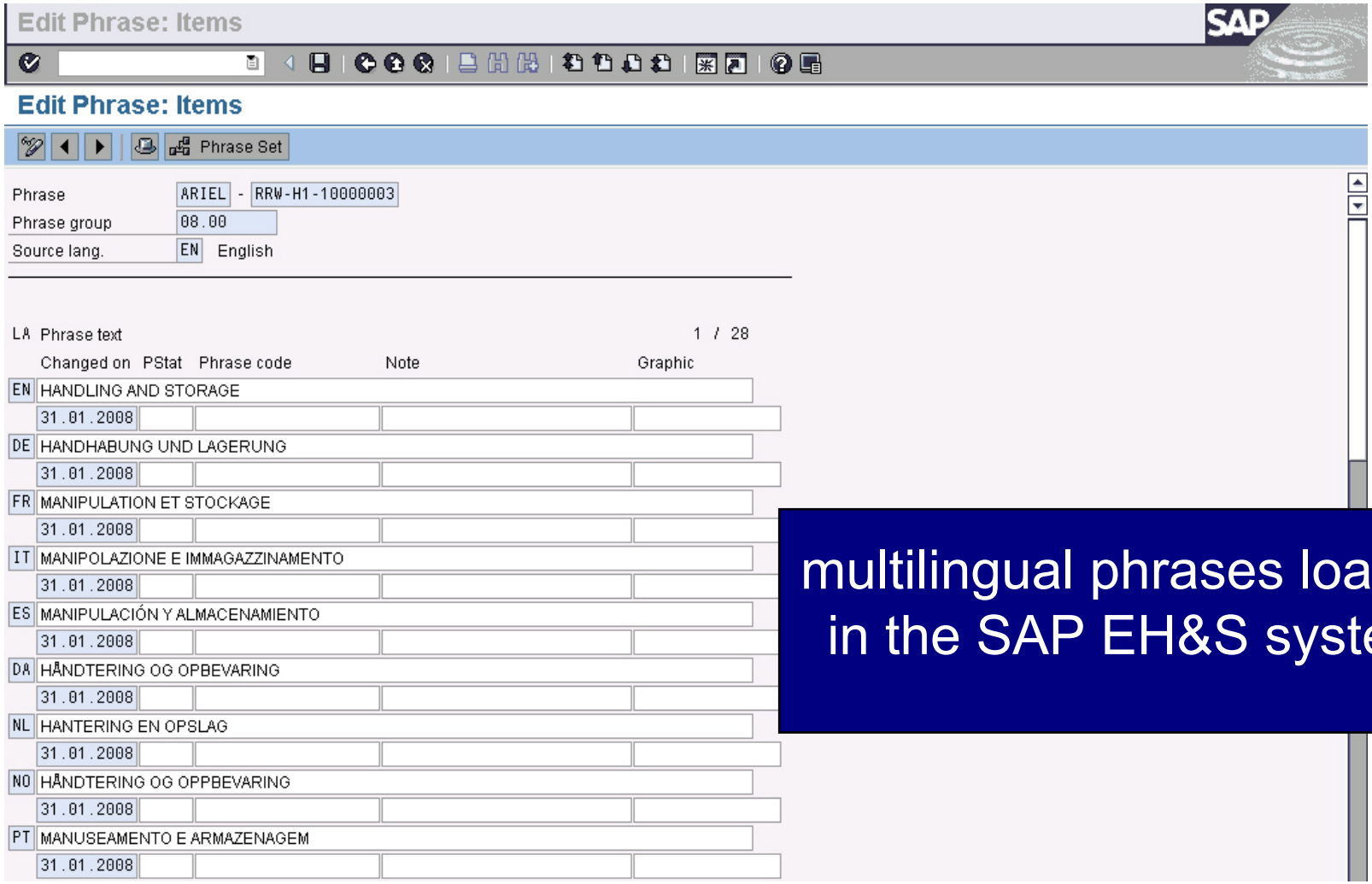
ADM allows users to schedule data loads, to load data for thousands of substances at a time or review data substance by substance

When viewing data for a substance, it's possible to only see Decisions that must be made

Elements of Authoring in SAP EH&S



Phrases in SAP



multilingual phrases loaded in the SAP EH&S system

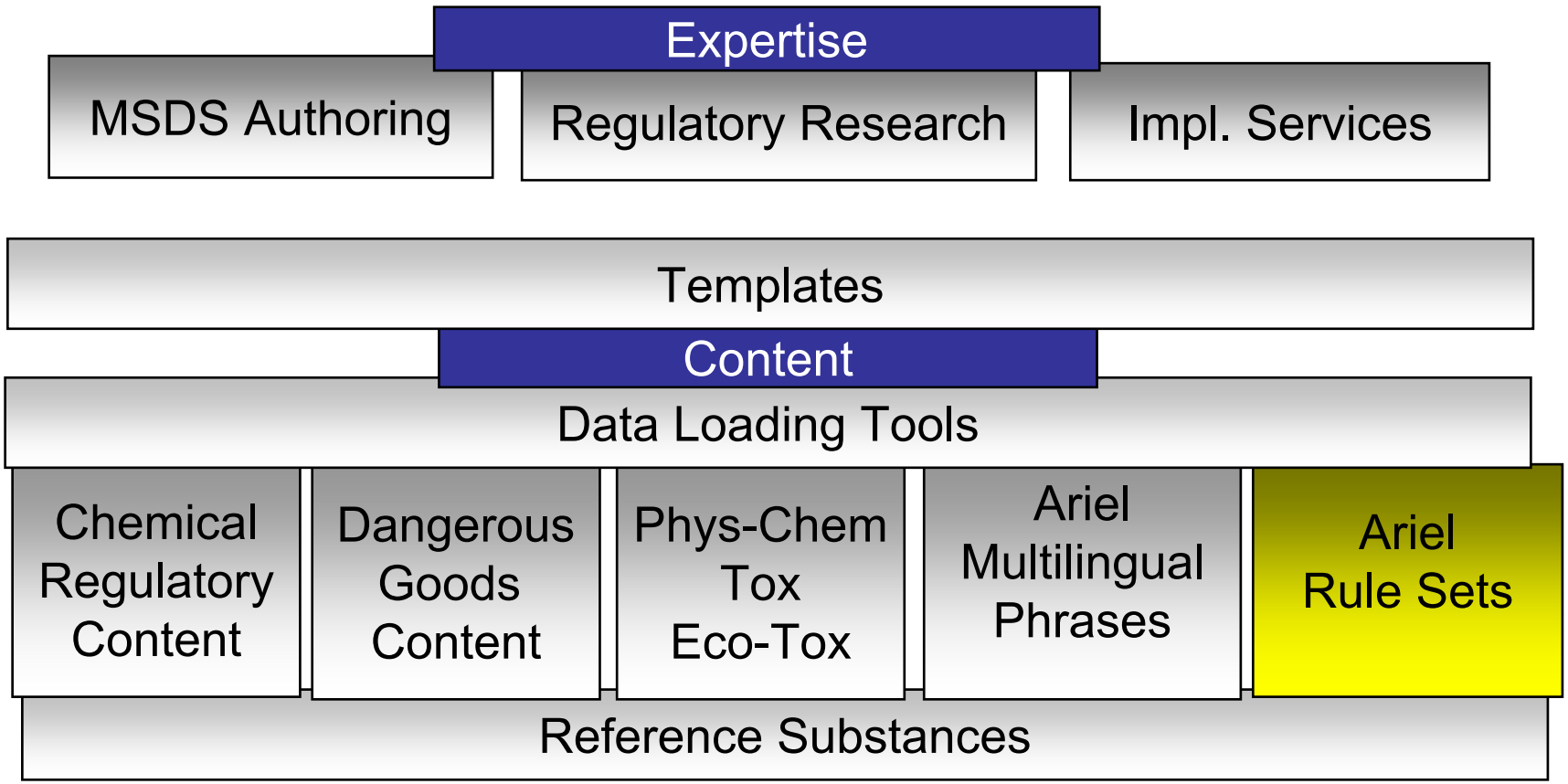
Multilingual Phrases

Phrase Library should be available in all languages in which you do business. Maintaining a phrase library can be a huge task and can have a significant impact on Rules and Templates

3E provides ~6,000 phrases used for the creation of (M)SDSs, including:

- Header and sub-header phrases
- Risk and safety phrases
- GHS hazard and precautionary statements

Elements of Authoring in SAP EH&S



Expert Rules for SAP EH&S

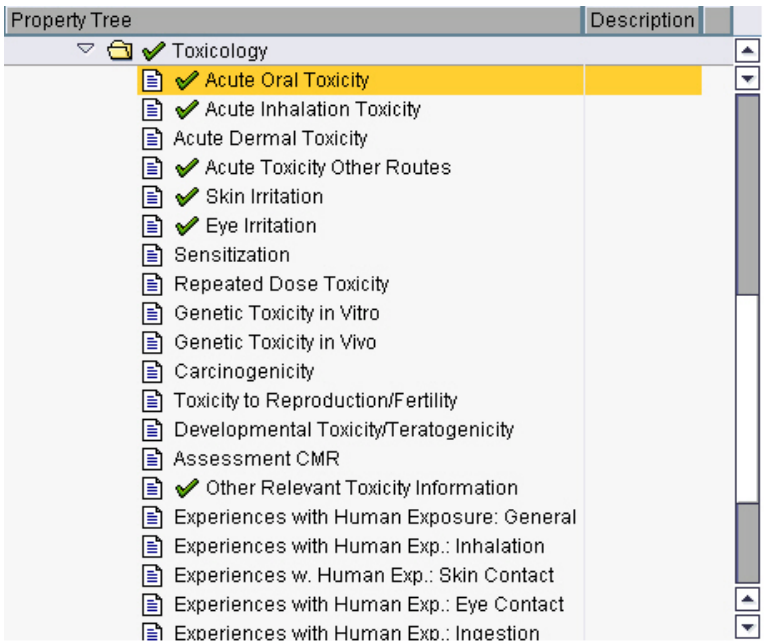
Expert Rules are automated regulatory compliance tools that systematize local country/area regulations for the creation of safety data sheets or product labels

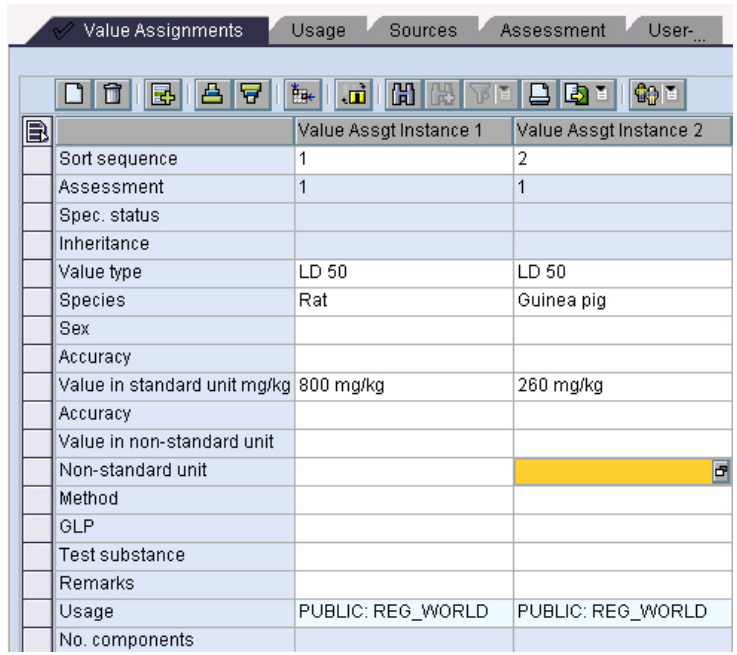
Rules use existing data to make decisions, just as a Product Safety/Dangerous Goods expert would, such as to:

- Use component regulatory data to determine regulatory conclusion about a mixture, or
- Classify a substance based on toxicological test results and evaluations

Expert Rules for SAP

- GHS Rules Example
  - Rule considers data in specific properties to derive the classification of the mixture based on toxicity and/or classification data on mixture or individual substance level





Expert Rules for SAP

- GHS Rules Example
  - End result – GHS Classification

Sort ...	Hazard Class	Hazard Category	Route of Exposure
1	Flammable liquids	Hazard category 4	
2	Self-heating substances and	Classification not possible.	
3	Corrosive to metals	Classification not possible.	
4	Acute toxicity	Hazard category 4	Oral
5	Acute toxicity	Hazard category 3	Dermal
6	Acute toxicity	Hazard category 2	Inhalation - gas
7	Acute toxicity	Classification not possible.	Inhalation - vapour
8	Acute toxicity	Classification not possible.	Inhalation - dust and m
9	Skin corrosion/irritation	Hazard category 2 - Irritant	
10	Serious eye damage/eye irrita	Hazard category 2A	
11	Respiratory sensitizer	Hazard category 1	
12	Skin sensitizer	Hazard category 1	
13	Germ cell mutagenicity	Hazard category 2	
14	Carcinogenicity	Hazard category 1A	
15	Toxic to reproduction	Classification not possible.	
16	Target organ systemic toxicity	Hazard category 1	
17	Target organ systemic toxicity	Hazard category 1	

Expert Rules for SAP EH&S

- **Rules are computer programs**, written in a proprietary language
- **Rules programs are written using the EHS Rules Editor**, but can be modified using Notepad or a similar utility
- **Rules programs reside outside the SAP R/3 system on a Rules server**

Expert Rules for SAP

- Generic rules – applicable to all regional modules:
  - Reportable Composition
  - Chemical Inventory Status
- North America – types of rules included:
  - OSHA reportable hazards
  - Federal and State RTK regulations
  - Special hazards (CMRs)
  - Country specific OEL requirements
- Europe – types of rules included:
  - Classification
  - Components Requiring Label Disclosure
  - Special Hazards (CMRs)
  - Country Specific OEL Requirements
  - Local (WGK – DE, Maladies Professionelles - FR)

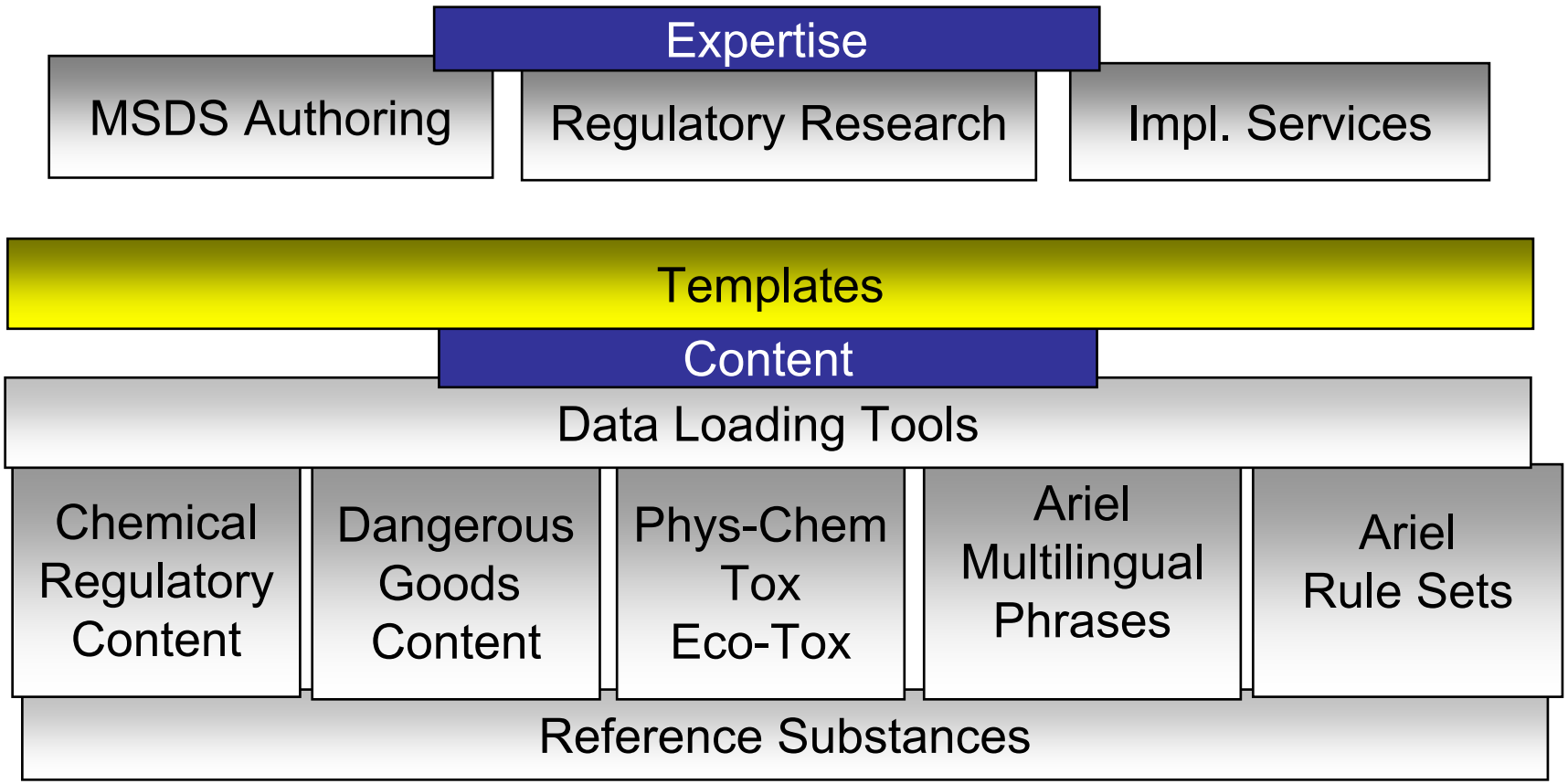
Expert Rules for SAP

- Asia Pacific Rules
  - Identify reportable composition based on country specific regulations
  - Assign hazard classification based on Hazard Symbol, Risk and Safety Phrases
  - Country Coverage:
    - » Australia
    - » Japan
    - » Korea
    - » Malaysia
    - » China
    - » Singapore
    - » Thailand
    - » Taiwan

Expert Rules for SAP

- GHS Rules Module
  - Mixture classification rules based on the UN Purple Book
  - Covers all hazard categories:
    - Physical-chemical, based on transport classification
    - Health, based on toxicity and existing classification data
    - Environmental, based on toxicity and existing classification data
  - Generates labeling elements and hazardous composition
  - Includes country variations for Japan, Korea, Taiwan & EU

Elements of Authoring in SAP EH&S



Templates

Templates are a necessary part of any (M)SDS in SAP EH&S

Template writing can be a messy business, as it requires good familiarity with WWI

Almost every user has his/her own requirements for how an (M)SDS should appear (logo, font, phrasing, content, etc.)

Templates can be created for every SAP EH&S implementation

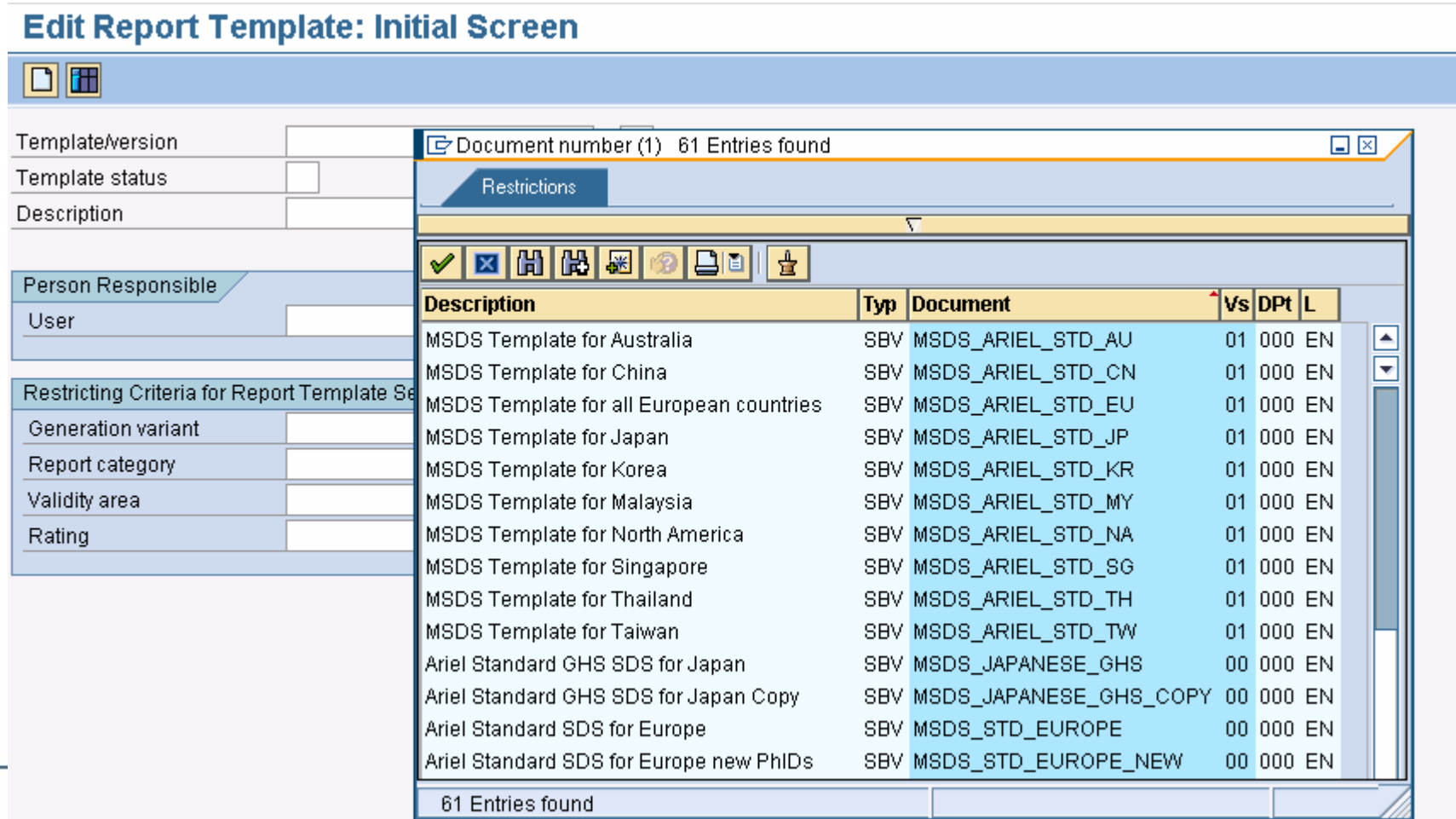
OR

‘Standard’ templates can be licensed and ‘tailored’ to every users needs

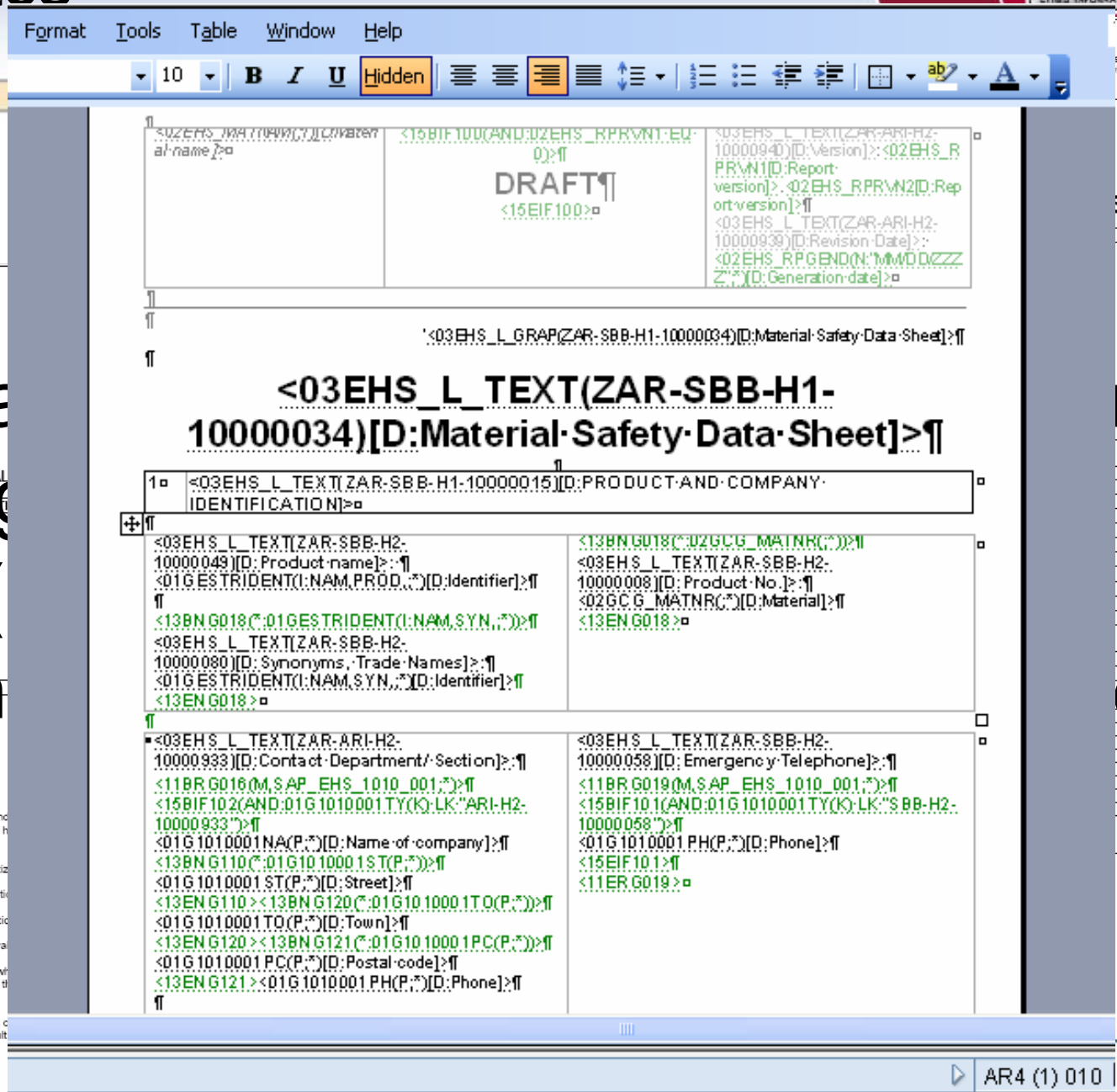
Many companies spend more time than expected creating templates, because there is a lot of ‘experimentation’ between regulatory experts and template writers

Templates

Have Templates appropriate to regions, as defined by regulatory requirements and your business rules



Templates


Format Tools Table Window Help
10 B I U Hidden
DRAFT
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1 <03EHS_L_TEXT(ZAR-SBB-H1-10000015)[D:PRODUCT·AND·COMPANY·IDENTIFICATION]>
<03EHS_L_TEXT(ZAR-SBB-H2-10000049)[D:Product·name]>:
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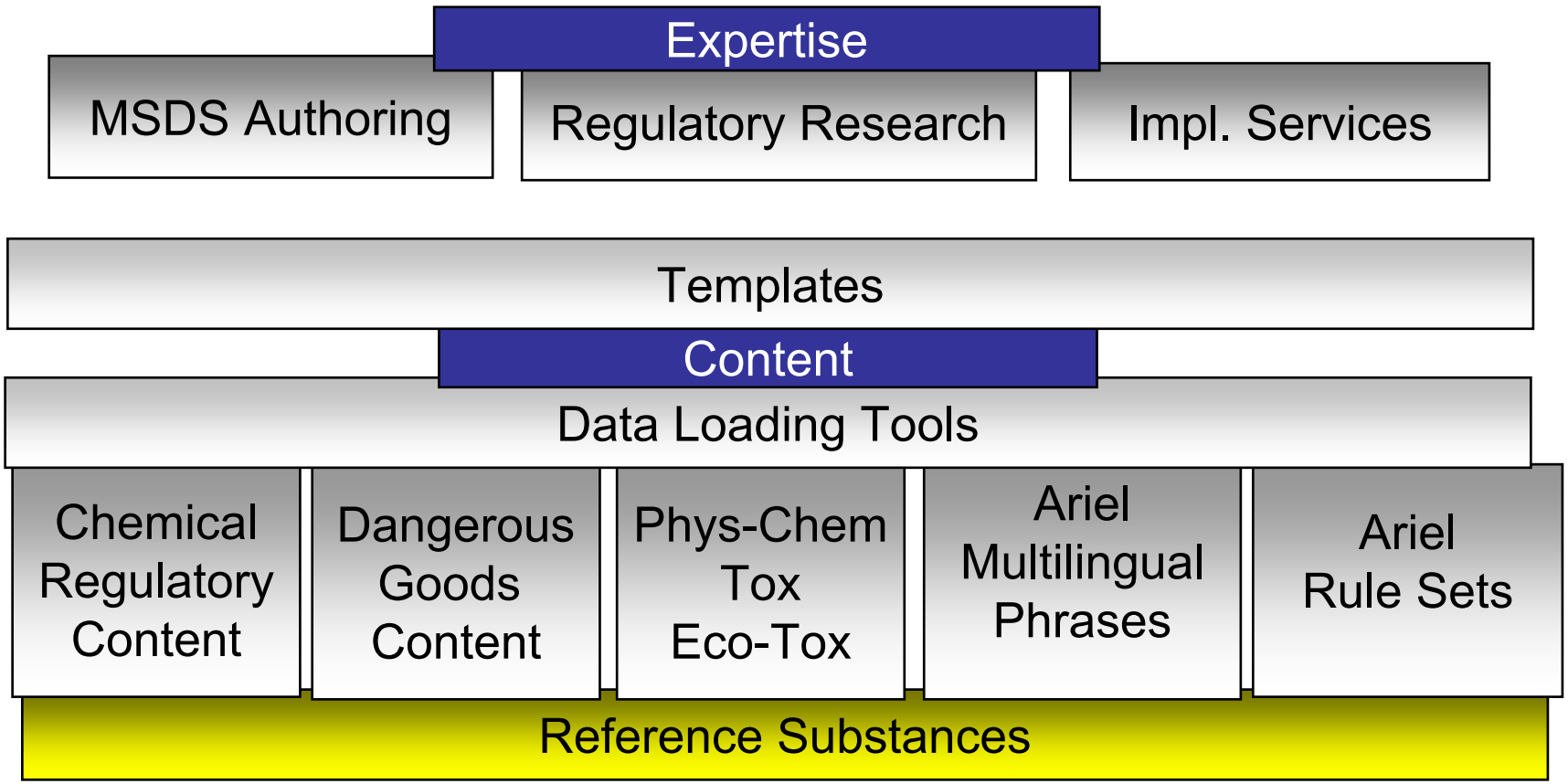
AR4 (1) 010

Elements of Authoring in SAP EH&S



Reference Substance

- Reference Substances

Referencing a substance refers to the ability to **point to data** located in another specification.

The system creates a link from the characteristic values of the reference substance to those of the referencing substance.

This function is performed by utilizing the Reference Tab in the header of the main specification.

Utilizing this function ***greatly*** reduces the amount of data that needs to be manually entered.

Reference Substances need to be created in order to utilize.

Reference Substance

- **Reference Substances (Ref Sub) – Created in the header of your main substance**

- Reference Substances can be created based on:
  - similar hazards,
  - compositions,
  - physical/chemical properties,
  - product lines,
  - just to name a few…….

So, let's look at a couple.

SAP Referencing

Route	Physical	Chemical
Harmful if absorbed through skin (LD50 >100 <1000 mg/kg	Combustible	Cyanide
Sec 4: First Aid Skin: Immediately flush with plenty of water for at least 15 minutes. Get medical attention immediately. Section 7: Handling Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Section 8: Exposure Skin: Wear chemical-resistant gloves and protective clothing appropriate for risk of exposure. Contact glove manufacturer for specific information.	**Section 5:** Fire Fighting – Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide Fire Fighting Further Advice: Wear self-contained breathing apparatus and protective clothing. Use water spray to cool unopened containers. Unusual Fire & Explosion Hazards: Combustible. Material contains a combustible solvent that may accumulate in the container headspace.	**Section 4 First Aid** Inhalation: Remove to fresh air. If not breathing, DO NOT give mouth-to-mouth artificial respiration. Give… Eye: Immediately flush with plenty ……. Skin: Immediately flush with. Call a physical control center immediately… Ingestion: Call a physician or poison control. Hints to Physicians: Symptoms of poisoning… **Section 7: Handling and Storage** Handling: Do not get in eyes, on skin, and clothing. Use only with….. Storage: Keep container closed. Store in a well ventilated place… **Section 8: Exposure Controls** Respiratory: Eye: Skin: **Etc.**

SAP - Referencing

Review your product line!
Where do consistencies exist?

- product line
- chemical family
- route of exposure(s)
- physical hazards

Create Reference Substances to cover

SAP

- SAP systems that maximize output
  - Complete component data
  - Utilize Referencing
  - Utilize the Building Blocks (Rules, Data)
  - Eliminate Manual Input

ACHIEVE TIME SAVINGS AND ACCURACY IN (M)SDS CREATION

SAP – Real Life Instances

- As an authoring service provider for SAP, we have built a knowledge base to “know what works” and “what does not”

- Utilizing the Building Blocks

Building Blocks

Recap for tools that help you utilize your systems capability to remove manual authoring - or Building Blocks

- Regulatory Data
- Rules
- Phrase Library
- Reference Substances
- Template

SAP Set-up Comparisons

4 Case Studies, based on 3E's experience authoring on different companies' SAP EH&S systems

Company A	Company B	Company C	Company D
No Regulatory Data	Regulatory Data	Regulatory Data	Regulatory Data
No Phrase Library	No Phrase Library	Phrase Library	Phrase Library
No Rules	No Rules	Rules	Rules
No Ref. Subs	No Ref. Subs.	No Ref. Subs.	Ref. Subs.
Minimal Templates	Minimal Templates	Minimal Templates	Robust Templates

Company A

- No Regulatory Data
- No Phrase Library
- No Rules
- No Reference Substances
- Minimal Templates

So . . .

- Manual Research
- Manual Calculations on concentration ingredients
- Manual pull of phrases to each section of the Properties Tree
- Manual look up for reportable for Sec 8 (OEL) and Sec 15 (inventory, state rtk, etc)

and . . .

- (M)SDS can take 4 – 8 hrs, plus time for manual maintenance of data

Company B

- Regulatory Data maintained
- No Phrase Library
- No Rules
- No Reference Substances
- Minimal Templates

So . . .

- Company receives regulatory data but it is not utilized by Rules. Similar to Company A, but benefit by having Regulatory data stored on List Sub

and . . .

- (M)SDS can take 4 – 8 hrs, plus time for manual maintenance of data

Company C

- Regulatory Data maintained
- Phrase Library
- Rules Implemented
- No Reference Substances
- Minimal Templates

So . . .

- Rules are utilized to populate OELs, hazard determination, calculation of acute tox data, Section 15 completed

and . . .

- Reduces timeframe to 1 – 4 hours per (M)SDS

Company D

- Regulatory Data maintained
- Phrase Library
- Rules Implemented
- Reference Substances Used
- Robust Templates Used

So . . .

- Other than required information to be manual input, (M)SDS is automated.
- Templates/gen variants are utilized to display data removing need for as many sort sequences

and . . .

- Depending upon complexity of (M)SDS – 15 minutes to 1 hour

Case-Study Summary

A well-configured SAP EH&S environment can result in significant operational time-savings

Company A	Company B	Company C	Company D
No Regulatory Data No Phrase Library No Rules No Ref. Subs Minimal Templates	Regulatory Data No Phrase Library No Rules No Ref. Subs. Minimal Templates	Regulatory Data Phrase Library Rules No Ref. Subs. Minimal Templates	Regulatory Data Phrase Library Rules Ref. Subs. Robust Templates
(M)SDS: 4 – 8 hrs, plus manual maintenance of data	(M)SDS: 4 – 8 hours	(M)SDS: 1 – 4 hours	(M)SDS – 15 minutes to 1 hour

. . . but the goal isn't to remove authors altogether, rather to increase efficiency and quality!

SAP

Something else to Consider:

Does your company want to author on SAP? Invest time and money into bringing authors up to speed on the system

OR

Consider outsourcing to a company that is expert in the SAP arena?

- Clients benefit from professionals who have experience of authoring on numerous SAP EH&S platforms
- No training on the system, just on your processes that you would like to be followed
- Access to experts who know and understand the system.

SAP

- SAP CAN BE A VERY ROBUST SYSTEM…
  - according to how well you build your system and by utilizing the building blocks.

- Let the system work for you!

Questions?