Society for Chemical Hazard Communication / General Meeting
17-18 March 2015 San Francisco (CA)

eSDS Use and Development: Meeting the Challenges

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Table of contents

2

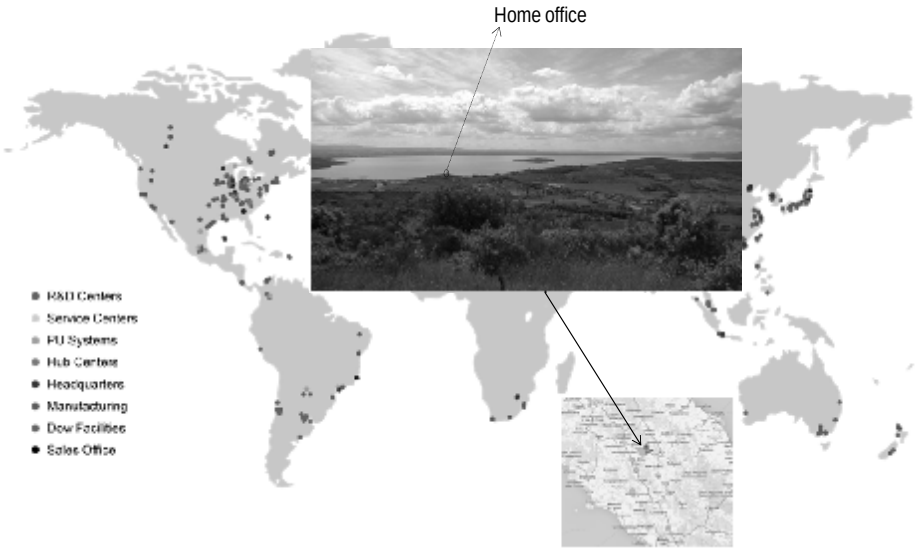
About Dow

Table of contents

- Delivers a broad range of technology-based **solutions** to customers in approximately **180** countries
- **Integrated value chain** aligned to high-growth sectors such as packaging, electronics, water, coatings and agriculture
- **$57 billion** annual sales in 2013
- **53,000** approximate employees worldwide
- **6,000** products manufactured at **201** sites in **36** countries across the globe

3

Dow locations



4

Focus on key markets

Developing innovative solutions aligned with attractive end markets

As part of Dow's accelerated strategy, the Company is narrowing its focus – selecting into high-margin, high-growth end-use markets, while reducing exposure to commoditizing markets. Collectively, these actions are driving sustainable long-term growth.

5

Table of contents

6

Sustainability goals

7

Table of contents

- **q** About Dow
- **q** Sustainability and product Safety at Dow
- **q** Managing the complexity
  - » A wealth of information, too much of a good thing? The case of Exposure Scenario and eSDS
- **q** What is an Exposure Scenario (ES) and what is an eSDS
- **q** Managing ESs/eSDS at Dow
- **q** Conclusions

8

Managing the complexity: the case of Exposure Scenario and eSDS

Why is this complex? Something to do with complexity...

Ø Complexity science is defined as the study of the phenomena which emerge from a collection of interacting objects

Objects like regulations, voluntary initiatives, best practices, public perception, etc.

Ø Complexity has also a lot to do with wealth of information and the easiness to read and retrieve it

Is wealth of information a good thing?

YES as far as you have a good map and a good kompass...such as:

- Clear understanding of the legislation (what is binding, what is recommended, what is good practice)
- Awareness that interpretations are embedded in the text of the law
- Understanding data and the fact that data need some sort of judgement
- Applying common sense

9

Table of contents

10

The eSDS/ES: regulatory definitions I

An Exposure Scenario is a set of conditions that describe how a substance (as such, in a mixture or in an article) is manufactured or used during its life-cycle and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment

Article 3.37 of the REACH Regulation

q Exposure Scenario(s) have to be documented and communicated to the downstream users.

Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI

Article 31(7) of the REACH Regulation

The eSDS/ES: regulatory definitions II

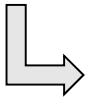
….in an annex to the safety data sheet…

Article 31(7) of the REACH Regulation

So the relevant exposure scenarios go in an annex to the SDS making it an Extended Safety Data Sheet: eSDS

Is this applicable to all products? Substances and Mixtures?

The ES (or ESs) as presented in this presentation is applicable to both.



However: ESs were developed in Dow only for substances so far ; for mixtures only ES info has to be presented (not necessarily using an ES template)

The eSDS/ES: from legal language to "reality"

In simpler terms…

Exposure Scenario (ES): Describes how a substance may be handled to control exposures to both human health and the environment.

"Handling" means activities and since there are many possible activities a new concept was introduced:

Contributing Scenario (CS): An activity (for example spraying, brushing, mixing, etc) that may contribute to exposure

Since both humans and the environment can be exposed, we refer to:

- Environmental Contributing Scenario
- Worker Contributing Scenario
- Consumer Contributing Scenario

Connecting the dots

The Exposure Scenario describes the life cycle phase being assessed (e.g. substance manufacture), breaking it down into individual process steps (Contributing Scenarios), identifying the degree to which humans or the environment are exposed to the substance at each step and finally how that exposure can be controlled by applying appropriate Operational Conditions and Risk Management Measures.

Key ES terms

When introducing new concepts…we need a new vocabulary. So the SU, PC, PROC, ERC and AC terms (use descriptors) were introduced

• Sector of use category (SU): Describes the area of use (e.g. manufacture, public domain, private use, etc.) and also the type of industry (e.g. large scale chemical manufacture)

• Product category (PC) describes in which types of chemical products (= substances as such or in mixtures) the substance is finally contained when it is supplied to end-uses (by industrial, professional or *consumer users*).

• Process category (PROC) describes the *application techniques or process types* defined from the *occupational* perspective

• Environmental release category (ERC) describes the broad conditions of use from the environmental perspective.

• Article category (AC) describes the type of article into which the substance has eventually been processed. This also includes mixtures in their dried or cured form (e.g. dried printing ink in newspapers; dried coatings on various surfaces).

Meeting the challenges: what is needed

- Define and agree (inside and outside Dow) on the new format
- Define and agree (inside and outside Dow) on a common set of phrases to be used across all industries
- Develop a new technology to develop ESs
- Develop an efficient and effective work process

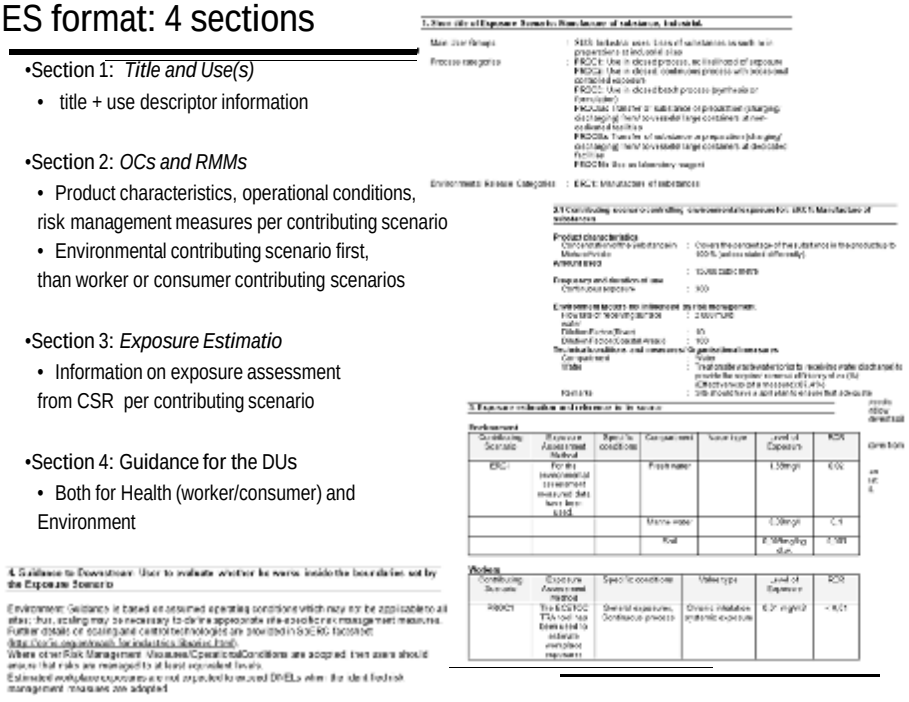
The ES format

So now that we have introduced new concepts, translated these into new technical terms…we need a framework, a container where to put all these new things. *However:*

- The REACH legislation does not provide a specific format for the ES for communication
- The format implemented by Dow takes into account:
  - The recommendations from ECHA
  - The latest template from SAP (our IT provider), which is aligned to ECHA recommendations for the format
- The template is not fixed in stone: it may be refined/improved in the future, reflecting the latest insights from industry/ECHA

ES format: 4 sections

- Section 1: *Title and Use(s)*
  - title + use descriptor information
- Section 2: *OCs and RMMs*
  - Product characteristics, operational conditions, risk management measures per contributing scenario
  - Environmental contributing scenario first, than worker or consumer contributing scenarios
- Section 3: *Exposure Estimatio*
  - Information on exposure assessment from CSR per contributing scenario
- Section 4: Guidance for the DUs
  - Both for Health (worker/consumer) and Environment



Consistency: SDS and ES

For several types of data, REACh Annex II states:

"The information in this section of the safety data sheet shall be consistent with ….. in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet."

=> This is relevant to data in SDS sections 7 / 8 /13 and section1 (identified uses / uses advised against)

Example section 8 / DNEL & PNEC:

8.1.4. Where a chemical safety report is required or a DNEL as referred to in Section 1.4 of Annex I or a PNEC as referred to in Section 3.3 of Annex I is available, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

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Why use of standard phrases?

Facilitation of:

- Upload of ES information in SDS systems
- Translations in all EU languages
- Standardized extended SDS can be sent to customers electronically
  - Communication between SDS systems (exchange of ES information in the supply chain): ESCom XML
- Development of ES for mixtures prepared by formulators

*Dow will align as much as possible with the industry developed and ECHA endorsed ESCom Standard for ES phrases and XML for electronic data exchange in the supply chain!**

**Dow is actively participating and driving the effort in ESCom XML and Standard Phrases Catalogue activities!*

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Meeting the challenges: the IT view

- The ESs are generated from SAP
- The need to have multiple ESs and the concept of the Contributing Scenarios lead us to implement a new data model - provided by SAP and adapted to our needs
- The ESs are an integral part of the SDS and of its authoring process (additional 'section')

Meeting the challenges: the IT view, the data model

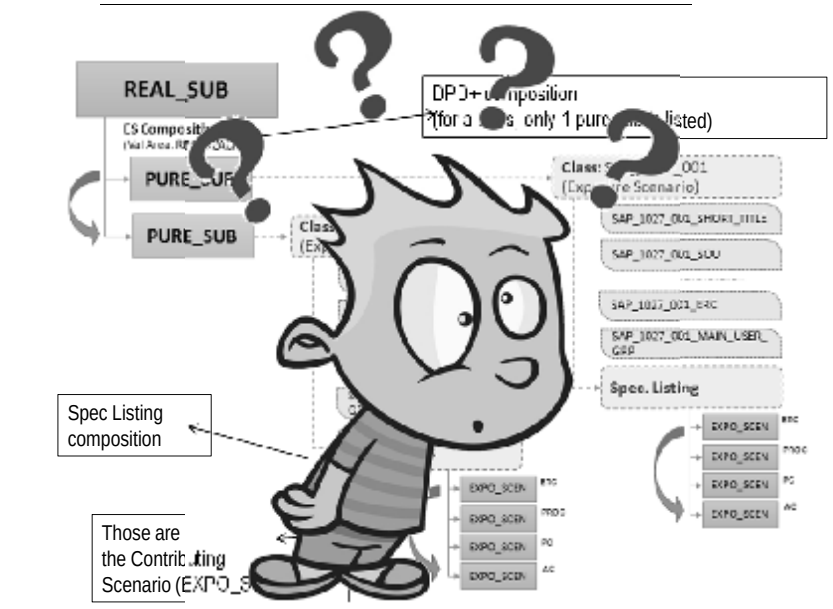
The ES data model reflects standard practices in the product EHS Area:

A. Designated compositions

- Composition at real substance level.
  - → To list the pure substances of relevance for the ES(s)
    - for substances, it will list exclusively the pure substance representing the substance registered
- Composition at pure substance level
  - → To list the contributing scenarios for environment and worker/consumer

B. Designated specification types, which are recipients of different kinds of data

Data model in our ERP



Summary of Data Model

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Meeting the challenges: what is needed

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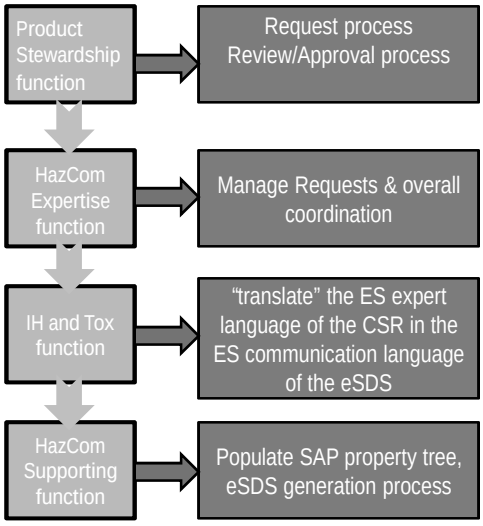
The Work Process: the big picture for ES



The generation of ESs requires:

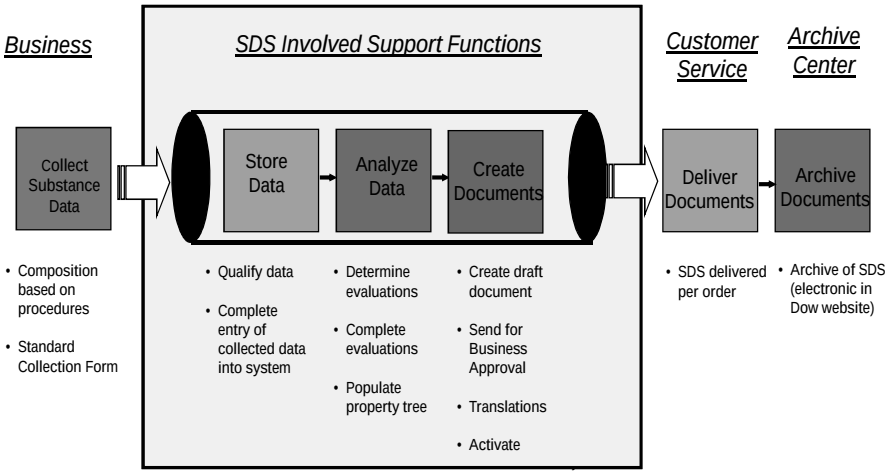
-The expertise of several functions

- Reliable IT platform

- Solid work process to put all pieces together and ensure integration with the SDSs' authoring process (please see next slide)

The Work Process: the big picture for eSDS

At Dow SDS work process involves Product Stewardship, Expertise and support function activities, maintaining a steady dialogue throughout the process.



29

Conclusions

- The introduction of ES/eSDS in the community territory is an opportunity for the Chemical Industry
- It is an important switch from a hazard based approach to a risk/exposure based approach
- Its implementation was challenging overall
  - In Dow it was also an opportunity for challenging the status quo, internal re-organization & data clean up
- It is a moving target: a learning by doing process, both for the Industry and for the Authorities

30

Thanks to my colleagues:

Dook Noij, Pawel Papuga, Otto van Ruiten, Celine Bruny, Ryan Kozar, Katie Dinninger...and many others!

31

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32