



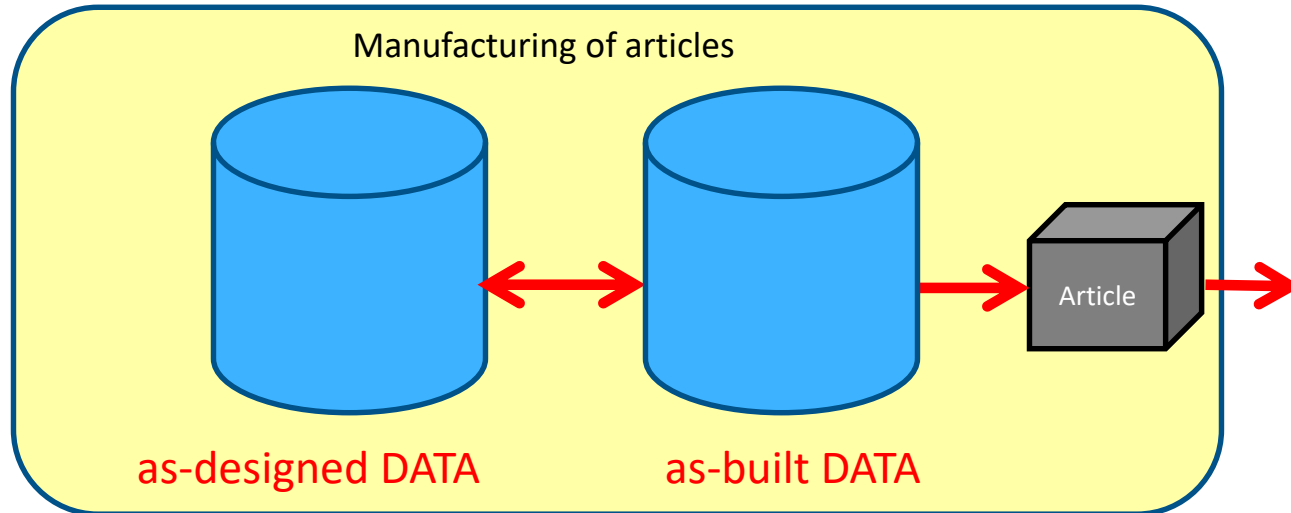
Enforcement issues at manufacturers of articles, whilst no EU IT infrastructure is in place for codification and distribution of SDSs

ECHA Forum for Exchange of Information on Enforcement Open Session,
Pascal Frou, SAFRAN, on behalf of ASD

Context

- The REACH and CLP Regulations and Waste Framework Directive create obligations to Manufacturers of Articles (as Downstream Users):
 - ❑ Use of mixtures and substances according to Safety Data Sheets provided by suppliers
 - ❑ Use of substances covered by a REACH Authorisation application according to the relevant CSR and Risk Management Measures
 - ❑ Reporting substances (SVHCs) in articles
 - ❑ Substitution of substances (SVHCs), when viable alternatives are available

Data control in the manufacturing of articles

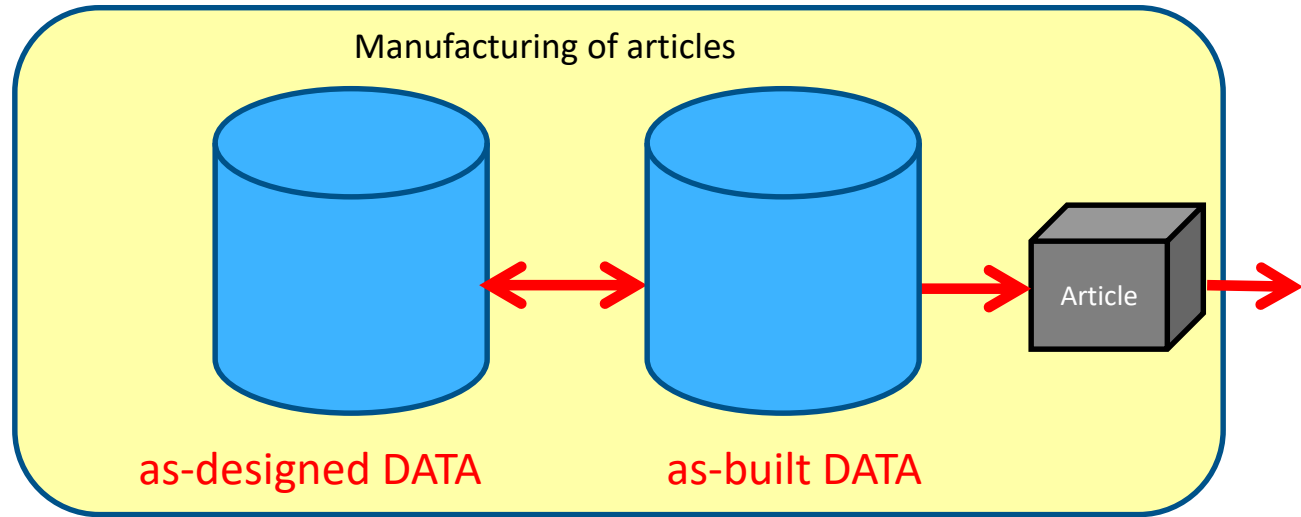
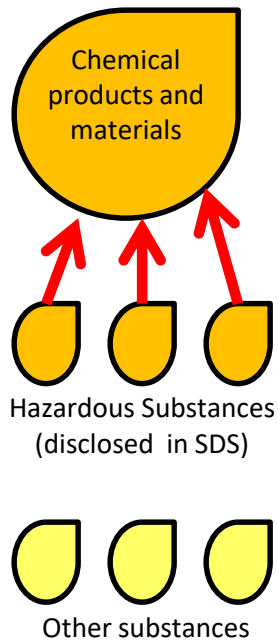


- Design control (drawings, certified configuration)
- Qualified chemical products and materials
- Manufacturing processes approved list (development and qualification)

- Production control (route sheets, planning,)
- Manufacturing and assembling,
- Traceability, SVHC in articles,
- Health-safety and environment management
- Inspection and delivery to customers

Article Manufacturer's IT (Information Technology) Infrastructure, supporting evidences for enforcement inspections

Management of chemical products when manufacturing articles

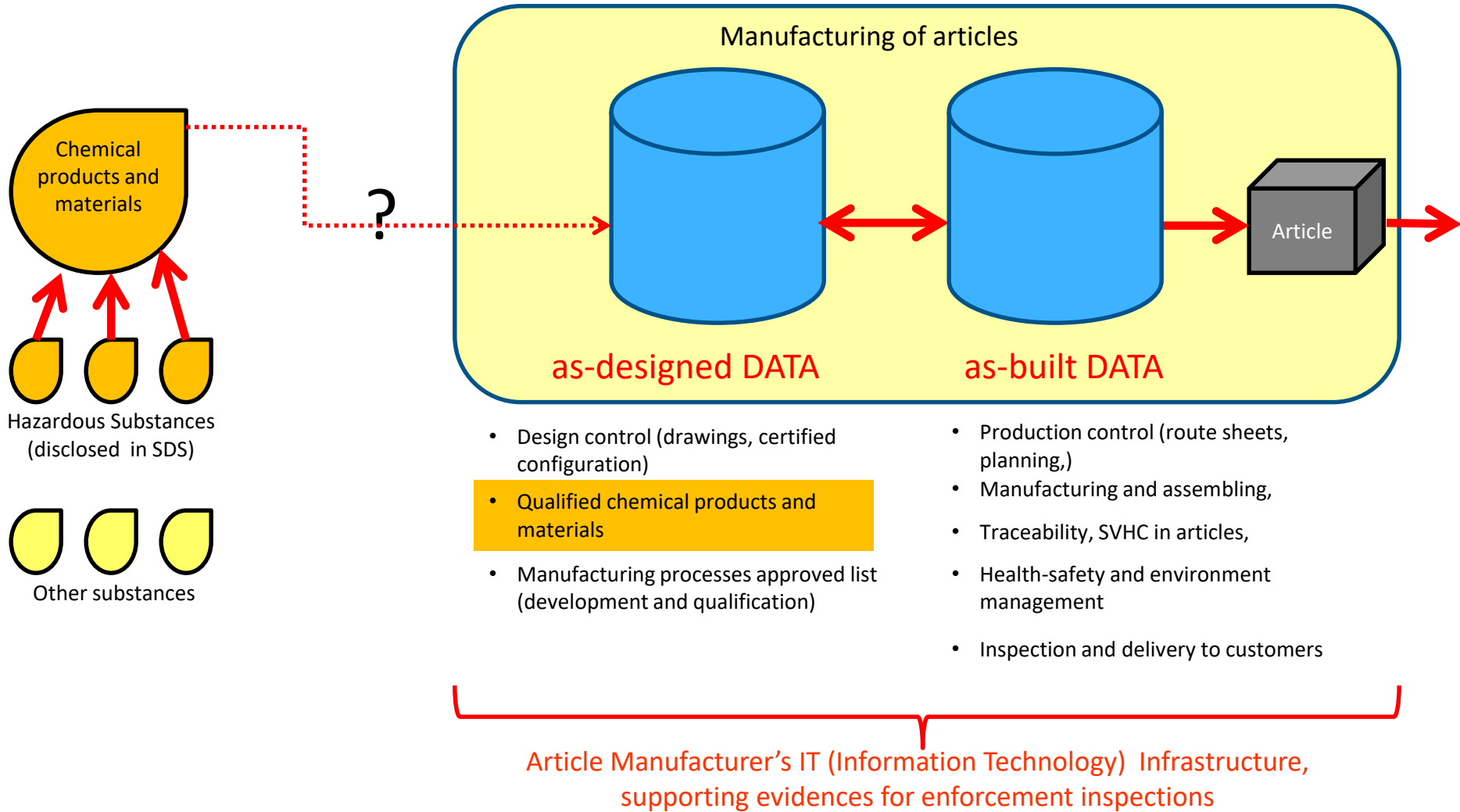


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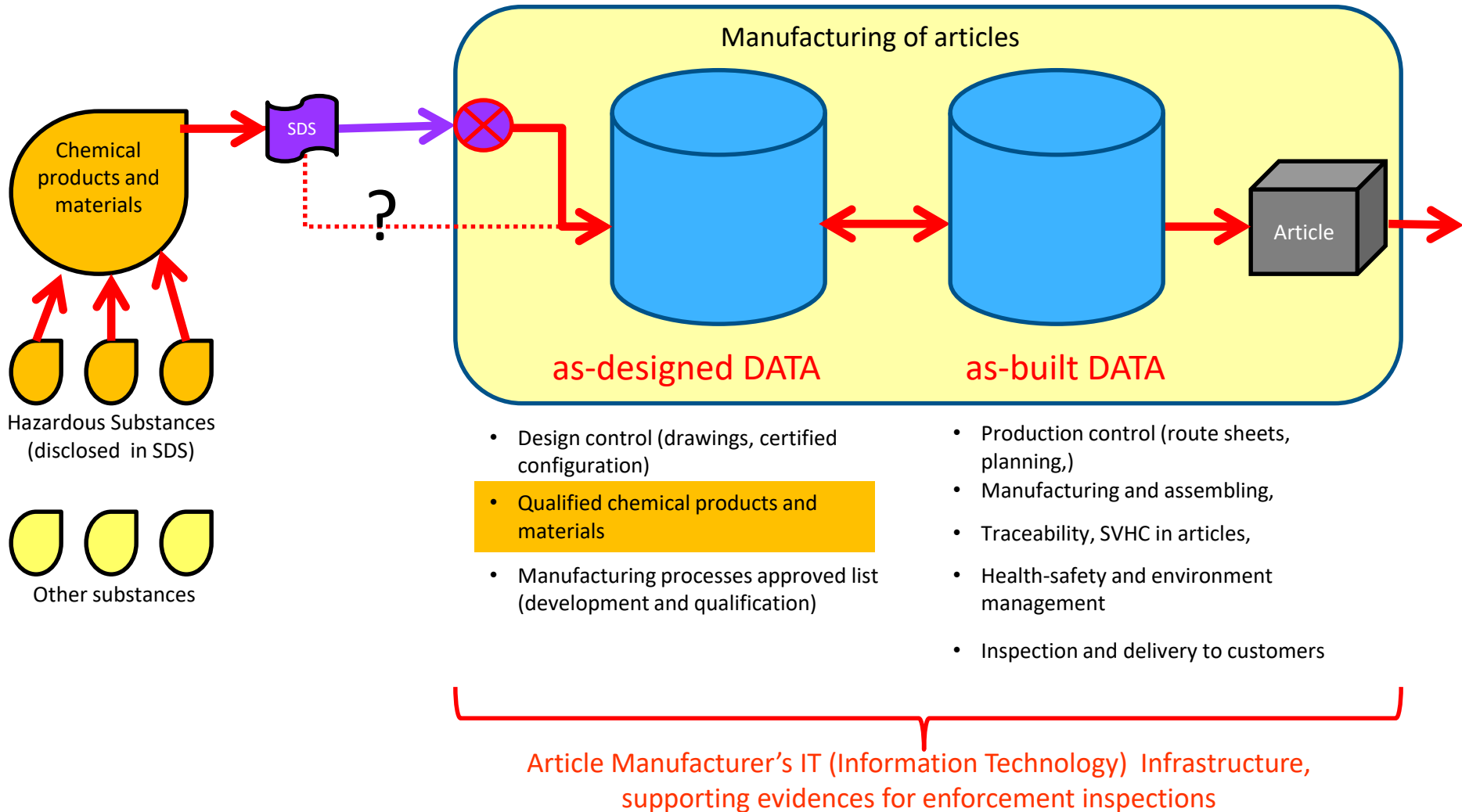
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Management of chemical products when manufacturing articles



Context

- The distribution of SDS to DUs (Manufacturers of Articles) is done in pdf files, when not only on paper.
- In order to fulfil their obligations, Manufacturers of Articles:
 - ❑ need the data contained in the SDSs (list of substances contained in the mixture, exposure scenarios)
 - ❑ in order to process this data in their IT system, they have to create their own data base providing in digital formats all the relevant pieces of information, in particular the composition of the mixtures (as identified in the SDS).

Context

- Global reliability of such local data-bases is low :
 - ❑ No unique identifier is presently available for mixtures
 - ❑ Data transfer provides opportunity for transcript errors
 - ❑ Manufacturers of Articles have limited basic skills in chemistry for checking consistency of copied data
 - ❑ For mixtures imported into the EU, particularly mixtures from North America, the SDS often does not meet the REACH Annex II standard and North American suppliers are often reluctant / sometimes refuse to provide an SDS which meets the EU standard

Reasons for addressing this topic during an Enforcement Forum

- Whilst there is work ongoing to improve that situation, including Unique Formula Identifier and electronic data exchange standards (CLP Annex VIII), this will take many years to show significant improvement (Jan 1st 2024 for industrial uses).
- Furthermore the benefit of CLP Annex VIII is presently limited to Emergency Health Bodies, which excludes Manufacturers of Articles, even for non-confidential data.

Reasons for addressing this topic during an Enforcement Forum

- Manufacturers of articles cannot be expected to have perfect information to support their obligations with respect to substances uses due to the imperfect information they get from formulators in SDSs.
- Findings in enforcement inspections at Manufacturers of Articles frequently report non compliant SDSs provided by their suppliers → manufacturers of articles are often instructed to obtain compliant SDS from their suppliers :
 - ❑ Manufacturers of articles have no lever for action for enforcing compliance at their supplier's.
 - ❑ When the manufacturer of a chemical product is outside of EEA, it is moreover difficult to obtain from the importer any effort for providing SDSs, compliant to CLP/REACH.



Thank you for your
attention



AeroSpace and Defence Industries
Association of Europe

ASD

rue Montoyer 10 | 1000 Brussels, Belgium
info@asd-europe.org | www.asd-europe.org