



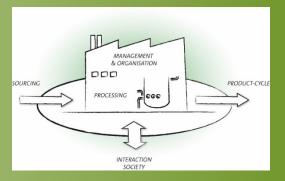
SEVESO versus REACH: "two faces of the same coin"





EPSC Webinar 23 October 2020

Nico Mulder & Jean-Marc Abbing **Open**



Seveso & REACH legislation in force for over 10 years, still their focus area is very much alive these days



Brussels, 14.10.2020 COM(2020) 667 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

 $\{SWD(2020)\ 225\ final\} - \{SWD(2020)\ 247\ final\} - \{SWD(2020)\ 248\ final\} - \{SWD(2020)\ 249\ final\} - \{SWD(2020)\ 251\ final\} - \{SWD(2020)\ 251\$

EU COMMISSION: TOXIC FREE STRATEGY

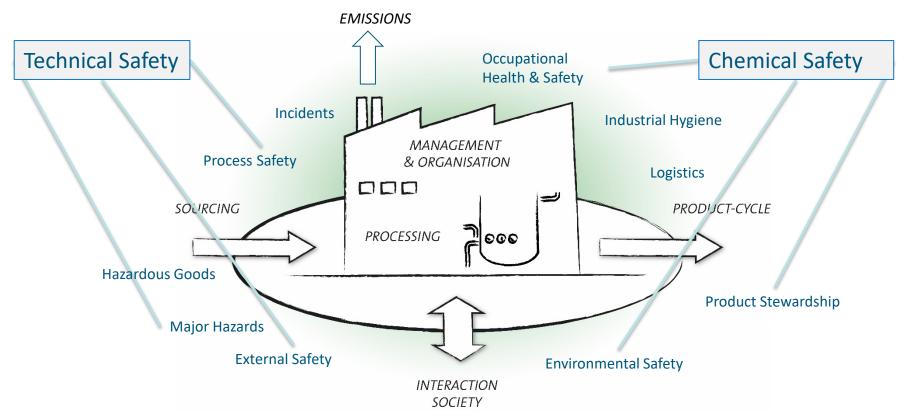
Likely result:

- More substances to be identified as having endocrine disrupting properties
- Speeding up the existing REACH processes

Likely consequence:

 more restrictive measures for substances with long term effects on humans and/or the environment

Industrial Safety focus areas within RHDHV



Todays moderators

Jean-Marc Abbing

Training: Geology, Environmental Sciences, Industrial Hygiene

Experience: 30 years, mainly in consultancy

Current role: Sr consultant EHS management

■ Focus area: Chemicals based industry (manufacturing and downstream users)

Languages: NL, EN, FR

Nico Mulder

Training: Chemical Engineering, HSE management

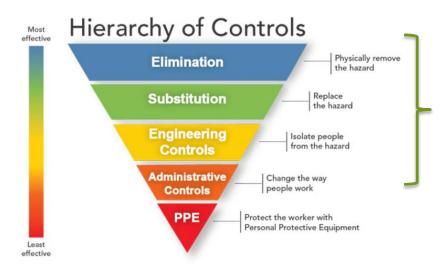
Experience: 30 years, mainly in industry

Current role: Sr consultant process safety management

Focus area: Chemical and (bio-)pharmaceutical industry

Languages: NL, EN, FR

Common grounds, separate domains?



Focus area of both REACH and SEVESO legislation:

Protect workers, public and the environment from exposure to harmful substances by taking measures at the source (i.e. at the processing installations)

Ref: The National Institute for Occupational Safety and Health (NIOSH)

Still they seem to be separate domains/disciplines:

- REACH → Toxicology, environment, occupational safety
- SEVESO → Process safety management, technical safety



Agenda

□ REACH essentials: approach for risk reduction of SVHC □CLP essentials 1 Reach & CLP \square Reach & CLP \rightarrow 3 main categories of substances □SEVESO essentials: prevention and mitigation 2 SEVESO and Process ☐ Process safety in practice **Safety Management** □Risk management approach: onion model and BowTie model □ Compare classifications **3 REACH and SEVESO:** ☐ Example of substances that may in near future be classed as SVHC differences & overlaps □ Case study of substance already phased out: timelines then and now 4 To what extent will ☐ Inherent safety: Process safety versus SVHC Control □ Options for Inherently Safer Design in CAPEX projects Reach & CLP influence □ Discussion process safety?

REACH & CLP essentials



REACH: Goals and tools

WHAT:

- European regulation, effective since 2007
- Phased approach (registration deadlines in 2010, 2013, 2018)

WHY:

- Safe use of all substances
- Reduce (possibly phase out) the use of the most dangerous substances (identified as the "so called" Substances of Very High Concern SVHC)
- Innovation

HOW:

- Safe use of all substances => REGISTRATION DOSSIERS
- Reduce (of the SVHC) => RESTRICTION and AUTHORIZATION of SVHC
- Innovation as result of substitution efforts

WHO

Industry and European Chemicals Agency (ECHA, Helsinki)



CLP: goals and tools

WHAT:

- European regulation, effective since 2007
- Fully implemented now

WHY:

- Reduce differences between chemical substances hazard classification and the transport classification
- Global Harmonisation of hazard classes.

HOW:

 Hazard classification based on physical/chemical & toxicity data (environment and human): (in dossier REACH registration)





















Hazard symbols

Physical











Health









Environment





Hazard classes CLP and REACH: SVHC (long term effects)



PHYSICAL

- Explosives
- Flammable gas and aerosol
- Flammable liquid and solid
- Oxidizing gas, liquid and solid
- Gasses under pressure
- Self-reactive substances and mixtures
- Self-heating substances and mixtures
- Pyrophoric liquid and solid
- Water reactive
- Organic peroxide
- Corrosive to metals



HEALTH

- Acute Toxicity
- Corrosive to skin
- Eye Damage
- Skin- / Eye irritation
- Sensibilization
- Carginogenic, Mutagenic & Reprotoxic (CMR)
- Specific Target Organ Toxicity (STOT)
- Aspiration
- Endocrine disruptors



ENVIRONMENT

- Acute Toxicity
- Chronic Toxicity
- Hazards to ozone layer
- Endocrine disruptors

Result REACH & CLP: qualitative

REACH results in 3 main clusters of substances:

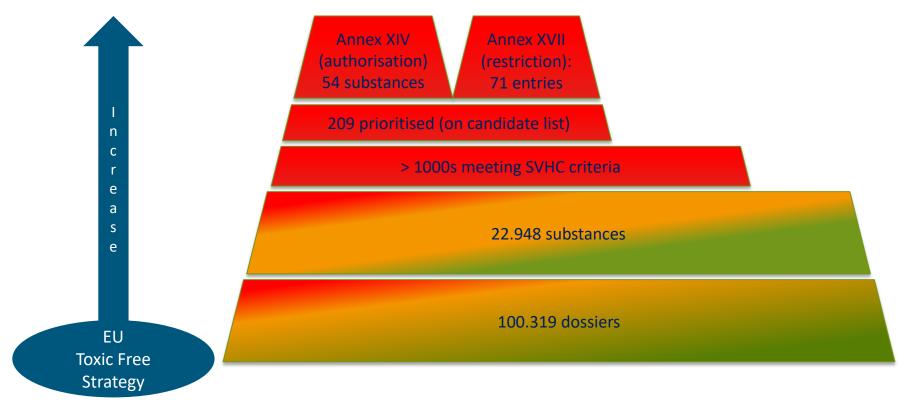
Non hazardous substances (green);

All hazardous substances,
 not meeting SVHC classification (orange);

Substances of Very High Concern (red);



Result REACH & CLP: quantitative (Sept 2020)



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Seveso: Goals and tools

WHAT:

European Directive, original version1982 (Seveso I) updated in 1996, 2008 and 2012

WHY:

- To prevent major accidents that may have an acute impact outside sites' boundaries (e.g. toxic cloud, fire, explosion, environmental release)
- To ensure appropriate preparedness and response should such accidents nevertheless happen.

HOW:

- Operators of facilities handling quantities of hazardous materials over certain tresholds are to:
 - Notify the competent authority about the inventory of dangerous substances
 - Compile a major accident prevention policy (MAPP)



- Provide information to the competent authorities to identify the risks for domino effects
- Produce a safety report
- Produce internal emergency plans

Upper tier facilities only



Seveso legislation: origin = environmental concerns

Major incidents with large environmental impact:

Year	Location	Type of installation	Incident	Environmental implications
1976	Seveso, Italy	chemical plant	A runaway reaction in a chemical plant released 2,3,7,8- tetrachlorodibenzo- p-dioxin (TCDD)	Contamination of locally grown food, widespread death of animals; emergency slaughtering of animals to prevent chemical entering the food chain
1984	Bhopal, India	chemical plant	An uncontrolled chemical reaction released methyl isocyanate gas and other chemicals	Broad-scale death of plants and animals created food shortages in the short term; long-term effects still impact plants, animals and people 30 years later
2010	Macondo, Gulf of Mexico	upstream oil	Blowout of wellhead and release of an estimated 650 million L of oil into Gulf of Mexico	Described as the "worst environmental disaster in American history" by the US Natural Resources Defence Council (NRDC), the oil and dispersants had a devastating impact on marine plants (including death of seaweed beds), animals and birds, and severely impacted fishing and tourism

Ref: Kerin, T. (2019). Managing Process Safety. In *The Core Body of Knowledge for Generalist OHS Professionals*. 2nd Ed. Tullamarine, VIC: Australian Institute of Health and Safety.

SEVESO is applicable to many sites all over the EU



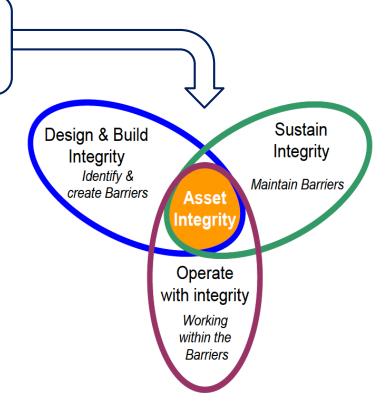


Process Safety – Definition

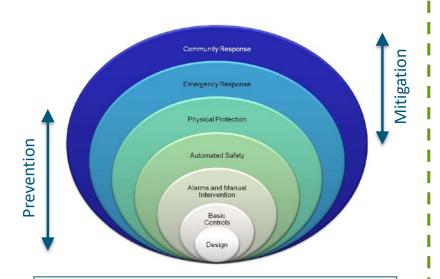
Process safety is about managing the integrity of operating systems by applying inherently safer design principles, engineering and disciplined operating practices.

- It deals with the **prevention and mitigation** of incidents that have the potential for a loss of control of a hazardous material or energy.
- Such loss of control may lead to severe **consequences** with fire, explosion and/or toxic effects, and may ultimately result in loss of life, serious injury, extensive property damage, environmental impact and lost production with associated financial and reputational impacts.

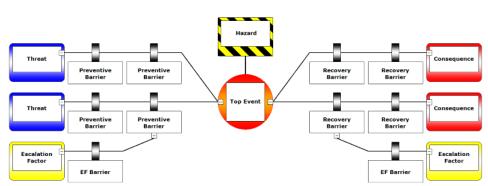
Ref: Kerin, T. (2019). Managing Process Safety. In The Core Body of Knowledge for Generalist OHS Professionals. 2nd Ed. Tullamarine. VIC: Australian Institute of Health and Safety.



Process safety to a large extent relies upon installing and managing successive (technical) barriers



Layers of protection: onion model

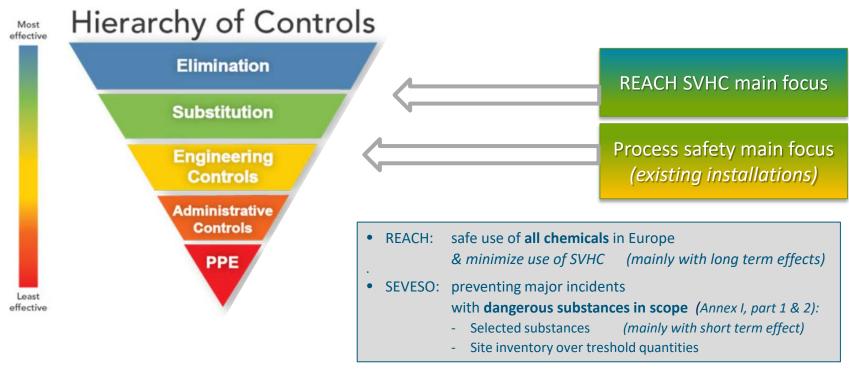


BowTie model

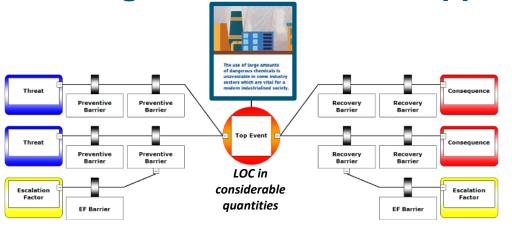
Hazard = the processing of a toxic or highly energetic material in an industrial plant Top Event = loss of containment of such material



Common grounds, however:

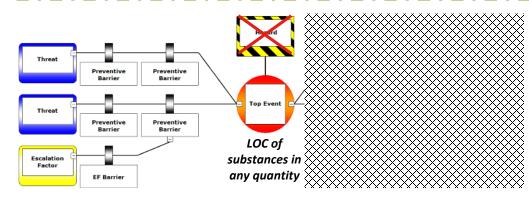


Plotting Seveso & REACH approach on a Bow-Tie diagram



Process safety / PSM philosophy:

 given the hazard, focus on preventive as well as mitigating barriers



Reach philosophy:

- for SVHC
 - → eliminate the hazard
- for other hazardous substances
 - → focus on preventive barriers

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Hazard classes CLP: SVHC



PHYSICAL

- Explosives
- Flammable gas and aerosol
- Flammable liquid and solid
- Oxidizing gas, liquid and solid
- Gasses under pressure
- Self-reactive substances and mixtures
- Self-heating substances and mixtures
- Pyrophoric liquid and solid
- Water reactive
- Organic peroxide
- Corrosive to metals



HEALTH

- Acute Toxicity
- Corrosive to skin
- Eye Damage
- Skin- / Eye irritation
- Sensibilization
- Carginogenic, Mutagenic & Reprotoxic (CMR)
- Specific Target Organ Toxicity (STOT)
- Aspiration
- Endocrine disruptors



ENVIRONMENT

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Hazard classes CLP: SEVESO



PHYSICAL

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HEALTH

- Acute Toxicity
- Corrosive to skin
- Eye Damage
- Skin- / Eye irritation
- Sensibilization
- Carginogenic, Mutagenic & Reprotoxic (CMR)
- Specific Target Organ Toxicity (STOT): Single Exposure
- Aspiration



ENVIRONMENT

- Acute Toxicity
- Chronic Toxicity
- Hazards to ozone layer

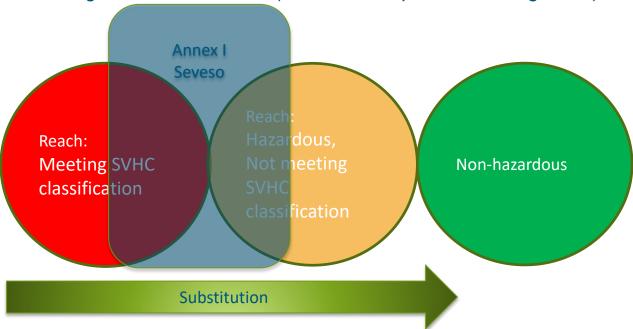
Some named dangerous substances

Substances on the production site

Meeting classification of a SVHC (only)

Meeting classification Annex I Seveso (only)

Meeting both classifications (i.e. within scope of both obligations)



Examples of substances currently under evaluation

Substance	CAS /	Actual classification	Concern in the RMOA
	EINECS nr		
Benzyl Alcohol	100-51-6 / 202-	H332, H302	Carcinogenic H350
(As one of the solvents in pure or	859-9		Mutagenic H340
technical form, or as UVCB or as			Toxic for reproduction H360
impurity.			Respiratory sensitiser, STOT RE
Others are: xylenes etc.)			(under development in 2020)
Vinyl Acetate	108-05-4/	H225, H351, H332, H335	Carcinogenic
	203-545-4		Mutagenic
			(under development in 2020)

In order to remain aware (and ahead) of such evaluations and their outcomes one can monitor:

- Ongoing dossier evaluations ECHA on the CORAP list,
- RMOA list (Risk management option analysis)
- Harmonised classification and labelling consultations



Regulatory management option analysis

The regulatory management option analysis (RMOA) list includes substances for which an RMOA either is under development or has been completed since the start of the implementation of the SVHC Roadmap in February 2013.

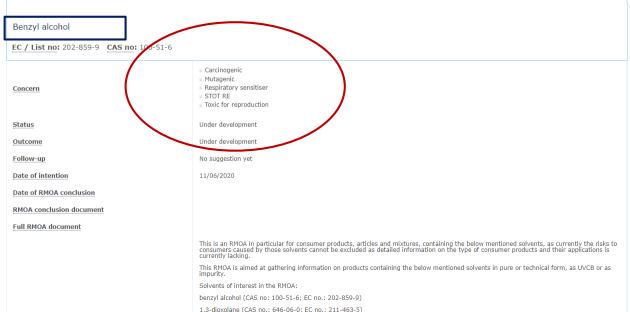
For each substance, the table shows the assessing Member State (submitter), the concern, the outcome and the suggested follow-up from the RMOA, and the date of the latest update to the list entry.

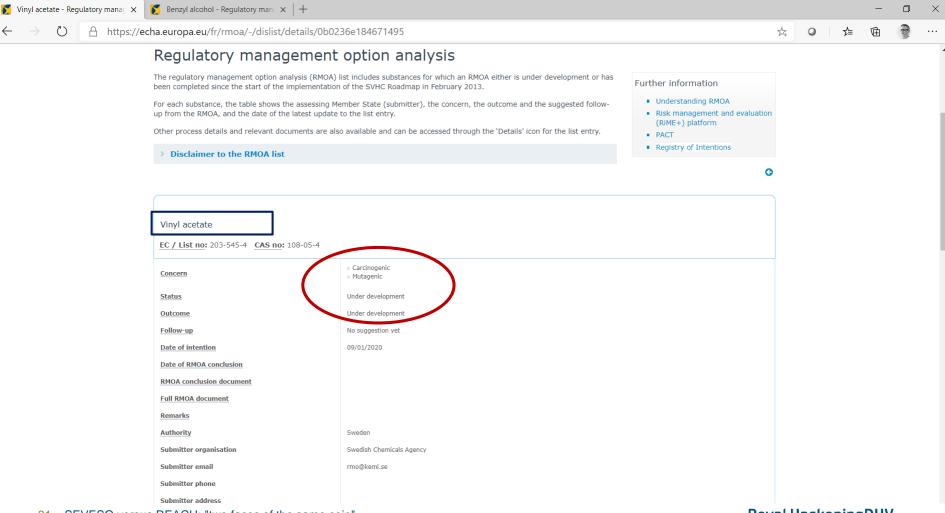
Other process details and relevant documents are also available and can be accessed through the 'Details' icon for the list entry.

> Disclaimer to the RMOA list

Further information

- Understanding RMOA
- Risk management and evaluation (RiME+) platform
- PACT
- Registry of Intentions





Vinyl acetate

From Wikipedia, the free encyclopedia

Vinyl acetate is an organic compound with the formula CH₃CO₂CH=CH₂. This colorless liquid is the precursor to polyvinyl acetate, an important industrial polymer.^[3]

Production [edit]

The worldwide production capacity of vinyl acetate was estimated at 6,969,000 tonnes/year in 2007, with most capacity concentrated in the United States (1,585,000 all in Texas), China (1,261,000), Japan (725,000) and Taiwan (650,000), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers include China Petrochemical Corporation (7%), Chang Chun Group (6%), and LyondellBasell (5%), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers include China Petrochemical Corporation (7%), Chang Chun Group (6%), and LyondellBasell (5%), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers include China Petrochemical Corporation (7%), Chang Chun Group (6%), and LyondellBasell (5%), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers include China Petrochemical Corporation (7%), Chang Chun Group (6%), and LyondellBasell (5%), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers include China Petrochemical Corporation (7%), Chang Chun Group (6%), and LyondellBasell (5%), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers in the largest producer (5%), In The average list price for 2008 was \$1600/tonne. Celanese is the largest producer (ca 25% of the worldwide capacity), while other significant producers in the largest producer (ca 25% of the worldwide capacity), while other significant producers in the largest producer (ca 25% of the worldwide capacity), while other significant producers in the largest producer (ca 25% of the

It is a key ingredient in furniture glue.[5]

Polymerization [edit]

It can be polymerized to give polyvinyl acetate (PVA). With other monomers it can be used to prepare various copolymers such as ethylene-vinyl acetate (EVA), vinyl acetate-acrylic acid (VA/AA), polyvinyl chloride acetate (PVCA), and polyvinylpyrrolidone (Vp/Va Copolymer, used in hair gels). ^[8] Due to the instability of the radical, attempts to control the polymerization via most 'living/controlled' radical processes have proved problematic. However, RAFT (or more specifically MADIX) polymerization offers a convenient method of controlling the synthesis of PVA by the addition of a xanthate or a dithiocarbamate chain transfer agent.

Other reactions [edit]

Vinyl acetate undergoes many of the reactions anticipated for an alkene and an ester. Bromine adds to give the dibromide. Hydrogen halides add to give 1-haloethyl acetates, which cannot be generated by other methods because of the non-availability of the corresponding halo-alcohols. Acetic acid adds in the presence of palladium catalysts to give ethylidene diacetate, CH₃CH(OAc)₂. It undergoes transesterification with a variety of carboxylic acids.^[9] The alkene also undergoes Diels-Alder and 2+2 cycloadditions.

With an iridium catalyst, vinyl acetate can undergo transesterification, giving access to vinyl ethers:[10][11]

ROH + CH2=CHOAC → ROCH=CH2 + HOAC

Toxicity evaluation [edit]

Tests suggest that vinyl acetate is of low toxicity. For rats (oral) LD50 is 2920 mg/kg.[3]

On January 31, 2009, the Government of Canada's final assessment concluded that exposure to vinyl acetate is not harmful to human health.^[12] This decision under the Canadian Environmental Protection Act (CEPA) was based on new information received during the public comment period, as well as more recent information from the risk assessment conducted by the European Union.

It is classified as an extremely hazardous substance in the United States as defined in Section 302 of the U.S. Emergency Planning and Community Right-to-Know Act (42 U.S.C. 11002), and is exbject to strict reporting requirements by facilities which produce, store, or use it in significant quantities [13]

See also [edit]

- · Polyvinyl alcohol
- · Vinyl propionate

· Acetic acid ethenyl ester 1-Acetoxyethylene Identifiers CAS Number 108-05-4ॡ ✓ CHEBI:46916 № X ChEBI ChemSpider 7616₺ 🗸 100.003.224₺ 🗸 ECHA InfoCard FC Number 203-545-4 KEGG C19309 េ ✓ MeSH C011566 @ PubChem CID 7904륜 L9MK238N77 ₽ X CompTox DTXSID3021431 € 2 Dashboard (EPA) InChi [show] SMILES [show] Properties Chemical formula C₄H₆O₂ 86.090 a·mol-1 Molar mass Appearance Colorless liquid Odor Sweet, pleasant, fruity; may be sharp and irritating[1] 0.934 g/cm3 Density -93.5 °C (-136.3 °F; Melting point 179.7 K) 72.7 °C (162.9 °F: 345.8 K) **Boiling point** -46 4-10⁻⁶ cm³/mol Magnetic susceptibility (x) Hazards Safety data sheet ICSC 0347 € R-phrases (outdated) S16, S23, S29, S33 S-phrases outdated) NFPΔ 704 (fire diamond) Flash point -8 °C (18 °F; 265 K) 427 °C (801 °F; 700 K) Autoignition

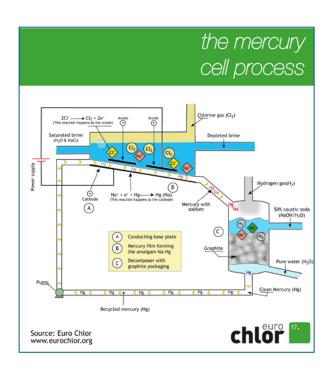
Case study

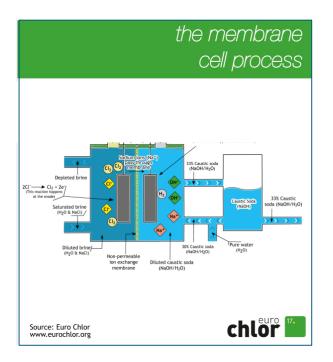
Phasing out mercury cell electrolysis in Europe

Mercury						
	Hazards					
GHS pictograms						
GHS Signal word	Danger					
GHS hazard statements	H330, H360D, H372, H410					
GHS precautionary statements	P201, P260, P273, P280, P304, P340, P310, P308, P313, P391, P403, P233 ^[92]					
NFPA 704 (fire diamond)	200					

Case study: chlor alkali electrolysis process





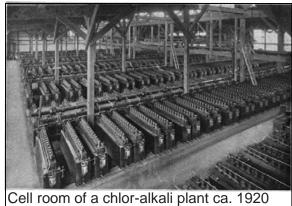


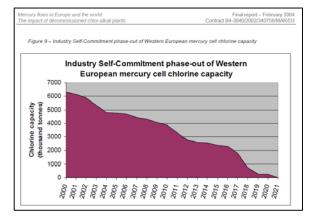
Case study: mercury cell electrolysis

The phasing out of the mercury cell electrolysis process in the EU took decades:

- Patented in 1892, industrial scale production since approx. 1900
- Side-effect: environmental releases of mercury
- The diaphragm process was developed from 1950 onwards. Commercial scale production was operational in Japan since 1975. This process was regarded a superior method both in its energy efficiency and lack of harmful chemicals.
- "In 2001, the European chlor-alkali sector voluntarily committed to phase-out of mercury cell technology by 2020. Meanwhile, however, under the Industrial Emissions Directive, the BAT conclusions (Best Available Techniques) became legally binding. This meant that, by 11 December 2017, mercury-based production technology should cease"
- "As a result, European chlor-alkali producers using the mercury technology converted or dismantled such facilities. Any resulting mercury-containing wastes were also addressed."

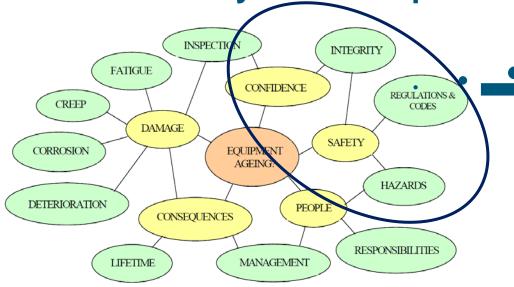
"....": Ref: EuroChlor website





Conclusion:

Reach & CLP may result in "premature" plant retirement



Plant ageing

Management of equipment containing hazardous fluids or pressure

Prepared by TWI Ltd, ABB Engineering Services, SCS (INTL) Ltd and Allianz Cornhill Engineering for the Health and Safety Executive 2006 ageing

 Plant ageing is not only a matter of lifetime in service and technical integrity

Regulatory

- When risk acceptance criteria as held by society and authorities change, a technically healthy production process/installation may soon become "outdated"
- In such case, economical payback period of the original investment will hardly be considered

Royal Haskoning DHV

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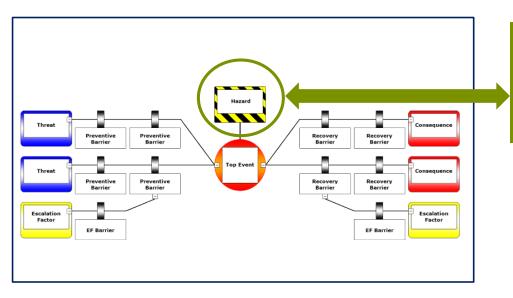
Should we adapt our PSM approach and put more emphasis on Inherently Safer Design?

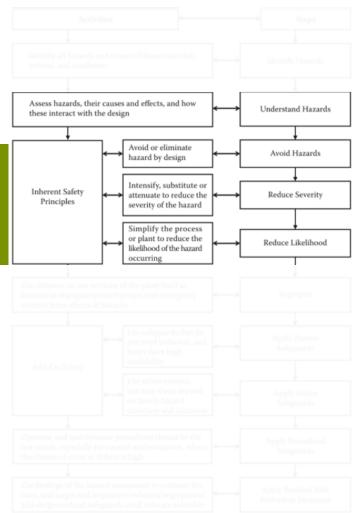
Origin of the notion inherent safety: lecture by Dr. Trevor Kletz (ICI), 1977: "What You Don't Have Can't Leak"

Inherently safer design summarised in four main strategies:

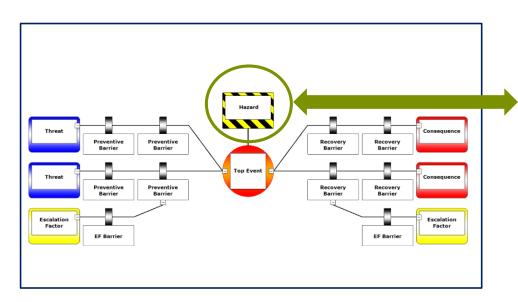
Keyword	Description	Alternative Keyword	
Minimise	Using or having smaller quantities of hazardous substances	Intensification	
Substitute	Replacing a chemical/material with a less hazardous substance or Replacing a process or processing technology with a less hazardous one		
Moderate	 Using: less hazardous or energetic processing or storage conditions, a less hazardous form of material, or facilities that minimise the impact of a release of hazardous material or energy 	Attenuation and Limitation of effects	
Simplify	Designing facilities which eliminate unnecessary complexity and make errors less likely, and which are forgiving of errors that are made	Error tolerance	

Incorporating inherent safety into process risk management

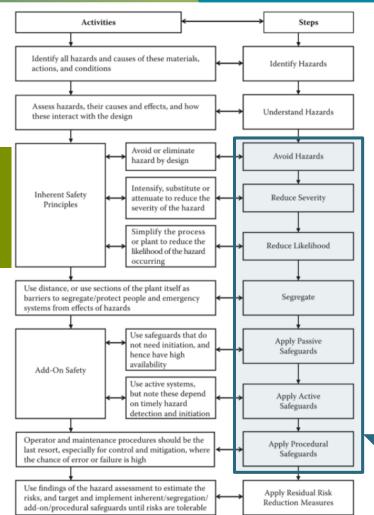




Incorporating inherent safety into process risk management



Ref: Kletz, T.A., Amyotte, P., 2010. Process Plants: A Handbook for Inherently Safer Design. CRC Press.

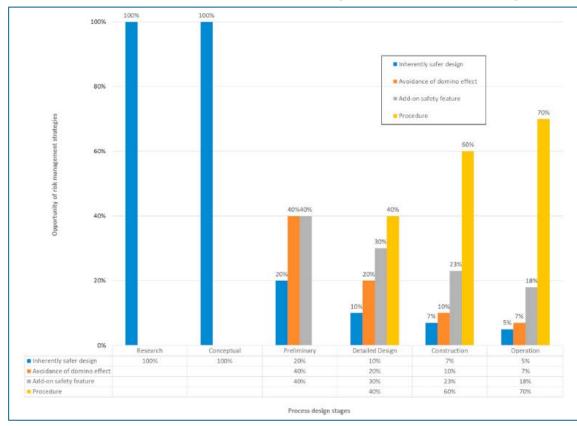


Inherently safer design serves both REACH & Seveso However, hierarchy aspects still to be bridged

	#		SEVESO - PSM	REACH SVHC	
	1	Identify hazards	Major accident resulting in LOC (> threshold hold-up on site)	→ Any LOC of SVHC	
Inherently Safe Design	2	Avoid hazards	Through alternative process design <	→ Through alternative substances	
	3.1	Reduce consequence severity	Intensify, Substitute or Attenuate process or plant	Puts priority on reducing likelihood of release over reducing	
	3.2	Reduce likelihood	Simplify process or plant	consequences of release	
	4	Segregate facilities	 Segregate people and emergency systems from hazards within the plant Avoid impact of incidents in plant A on adjacent plant B 	 Avoid impact of fugitive emissions on surroundings → double containment, mag drive pumps, minimum # flanges 	
Layers of Protection	5.1	Passive safeguards	Blow-off to safe location	 Safe the surroundings from any blow-off 	
	5.2	Active safeguards	Measure T, p → flanges & fittings automated block valves	See item 4	
	6	Procedural safeguards	Operating & maintenance procedure	Operating & maintenance procedure	
	7	Residual risk reduction	Iterate steps 1-6 until acceptable risk ◀-	→ Aim for no residual risk	

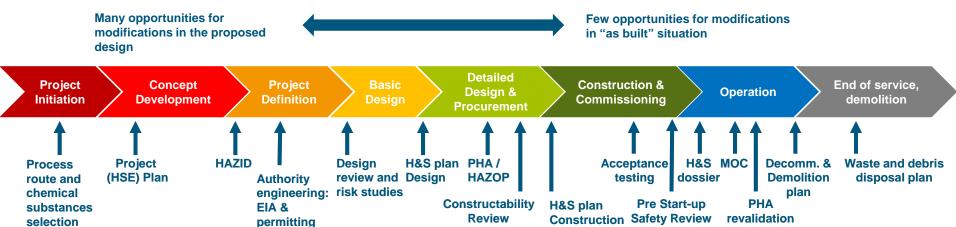


Opportunities of risk management strategies during CAPEX projects

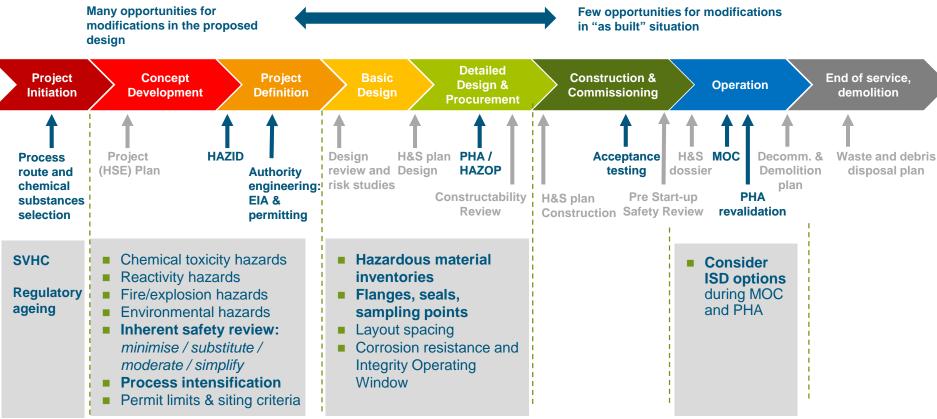


Ref: Park, Xu, Rogers, Pasman, El-Halwagi Journal of loss prevention in the process industries 63 (2020) 14040

CAPEX project lifecycle & inherent safety options



CAPEX project lifecycle & inherent safety options



Inherent safety guideword matrix - example

	Eliminate	Minimise	Substitute	Moderate	Simplify
Raw material					
In-process storage					
Product inventory					
Process chemistry					
Process controls					
Process piping					
Process equipment					
Process conditions					
Maintenance					
Siting					
Transportation					



Summary

- REACH has known a long ramping-up period (2007 2018), but is now in full swing
- Substances in common use in process industries are or may one day become SVHC
- For substances classified as SVHC, two 'flavours' exists as per REACH:
 Phasing out unless authorised (now > 50 entries) or restricted use (now > 70 entries)
- In case of SVHC additional layers of protection ("add-on safety") may not suffice
- Inherent safety and process intensification therefore deserve renewed attention
- Whereas previously timelines for implementation of phasing out could span decades (i.e. amortisation period), some 5 years now seems more probable
- EU Commission toxic free strategy is likely to give a boost to the above observations



REACH and process safety (Seveso) seem to be largely independent, however they merit being regarded as two faces of the same coin, the side of which could bear the inscription: toxic free strategy

We thank you for your participation



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