




Styrene Classification and Labelling

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A. Piccinotti

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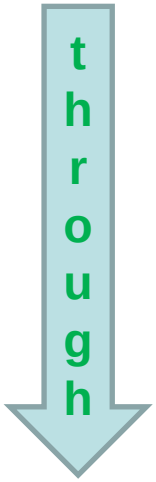
Presentation Goals

- To offer an objective and science based view of actual styrene regulatory status in Europe



- REACH and CLP fundamentals
- Styrene Producer Association (SPA) and Cefic UPR Sector Group Position and activity
- Styrene Classification Process and Timing

Styrene and REACH

- REACH legislation has been in force since June 2007.
- The main aim of REACH is to ensure the safe use of chemicals for workers, consumers and the environment.
- REACH puts the responsibility on industry and imposes obligations on all parties in the supply chain.
- European Styrene manufacturers/importers have registered Styrene and have started to send out the new extended Safety Data Sheet (eSDS).
- Styrene Extended SDS include Exposure Scenarios (ES) for manufacture of UP/VE resins and formulated resins, and FRP manufacturing in industrial and professional settings.

Globally Harmonized System (GHS) for Classification and Labelling of Chemicals

- GHS for hazardous substances and mixtures is being introduced worldwide.
- GHS was implemented in Europe in 2008 by means of the Classification, Labelling and Packaging (CLP) of substances and mixtures regulation.
- CLP introduces revised criteria for hazard classification, new guidelines for safety data sheets, product labels and transport information.
- As a result of REACH and CLP, industry has now entered the phase in which new information must be provided to downstream users.






Styrene Producer Association (SPA) Position

- The SPA, organized in the REACH Styrene consortium, proposed a self-classification for Styrene which resulted in additional risk phrases and hazard statements.
- New risk phrases from the Styrene registration dossier on top of Directive 67/548/EEC Annex I:
  - R48/20 - harmful: danger of serious damage to health by prolonged exposure through inhalation
  - R65 - harmful: may cause lung damage if swallowed
- New hazard statements from the styrene registration dossier on top of CLP Annex VI:
  - H372: Causes damage to hearing through prolonged or repeated exposure by inhalation
  - H335 May cause respiratory irritation
  - H304: May be fatal if swallowed or enters airways






Classification and Labeling of Resins

- As most of UP/VE resins are mixtures containing greater than 10% Styrene, this new classification of Styrene will be directly applied to the classification of UP/VE resins.
- European resin manufacturers are updating their SDS to reflect these changes in Styrene classification.
  - http://www.upresins.org/upload/documents/webpage/styrene-position-paper-en.pdf
- Resin manufacturers will continue to specify risk management measures and operating conditions for safe use of Styrene in UP/VE resin manufacturing and FRP manufacturing in industrial and professional settings based on Styrene Extended SDS from their suppliers.

Styrene DNELs

- The REACH Styrene consortium proposed Derived No Effect Levels (DNELs) for worker inhalation exposure:
  - 20 ppm as an 8-hour time-weighted average (TWA)
- A DNEL is a threshold for safe use of substances and serves as the basis for developing exposure scenarios.
- The REACH Styrene consortium and Cefic UPR Sector Group used the DNELs and ECETOC TRA to perform safe use analyses of UPR/VER manufacturing and use.
- DNELs may ultimately be used for harmonisation of Occupational Exposure Limits (OELs) across the EU:
  - The timing for this process is not yet determined
  - Harmonized OELs help ensure a level playing field

Styrene Exposure Scenario Results

- Styrene exposure during manufacture of UPR, VER, and formulated resins is “safe” under typical conditions of use.
- FRP manufacturing in an industrial setting is also “safe,” but requires careful attention to workplace ventilation.
- FRP manufacturing in a professional setting requires respiratory protection in most cases to ensure “safe” use of styrene.
- Dermal route does not contribute significantly to overall risk.

Styrene OELs

- Currently, Styrene 8-hour TWA limits in the EU vary depending upon the country.
- The exposure scenarios prove that workers can work safely with Styrene-containing resins when using recommended protective equipment and by limiting possible exposure to emissions.
- Extended safety data sheets and Cefic UP/VE Resin Safe Handling Guides (Safe Handling Guides :: The European UP/VE Resin Association) provide relevant information on best practices, operating conditions and risk management measures to control exposure.
- The U.S. Styrene Information & Research Center (SIRC) also recommends 20 ppm as an 8-hour TWA.

Denmark Proposal to Reclassify Styrene

In October 2011, the Danish Competent Authority (CA) proposed two new classifications for Styrene under CLP:

- Specific Target Organ Toxicity following repeated exposure (STOT RE 1)
  - Consistent with the Styrene REACH registration dossier
  - Already implemented in styrene suppliers' SDS as self-classification: H372 - Causes damage to hearing through prolonged or repeated inhalation exposure
- Category 1B for reproductive toxicity "a presumed human reproductive toxicant"
  - The SPA undertook a careful assessment of the available scientific data and concluded that the weight of available evidence demonstrates that Styrene **is not selectively toxic to development and hence classification for reproductive toxicity is not warranted.**






What was the previous conclusion on Styrene reproductive toxicity?

- The current Danish proposal does not bring forward any new scientific information.
- Denmark made the same proposal during the TC C&L review in 2007 based on the **same studies**.
- The majority of EU Member States agreed with the UK Rapporteur that the data **was not sufficient** for any classification for reproductive toxicity.
- The UK, as previous Member State rapporteur for Styrene, did not make a new proposal for classification and labelling in 2008 based on extensive review of available data.
- Styrene **is not classified** as a reproductive toxin anywhere else in the world.





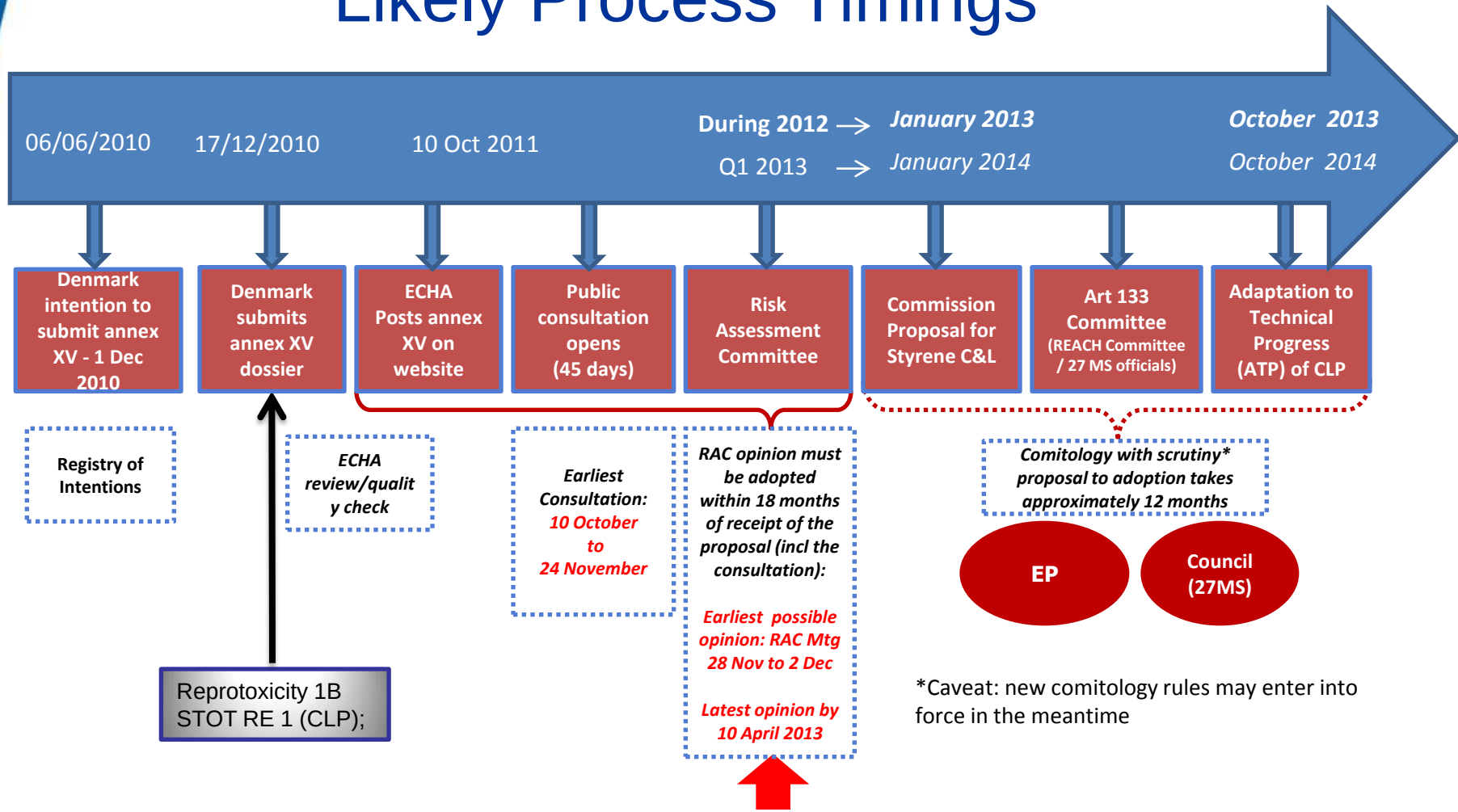

What are the next steps in the classification process?

- On October 10, 2011, ECHA opened a 45-day public consultation on the Danish proposal.
- The public consultation is the first step in the development of a scientific opinion by the ECHA Risk Assessment Committee (RAC) on this proposal.
  - SPA/Styrene REACH Consortium submitted a common contribution in support of a “no classification” for reproductive toxicity to the RAC as a part of the public consultation.
- The RAC has up to 18 months to form an opinion.
- The RAC opinion has no regulatory impact but will be forwarded by ECHA to the European Commission as a recommendation.

What are the next steps in the classification process?

- The EU Commission may accept the recommendation of the RAC or propose an amendment.
- The estimated earliest possible adoption of such a change to Styrene classification will be late 2013.
- The EU Styrenics industry and Cefic UPR Sector Group (Ashland, CCP Composites, Reichhold and Scott Bader) will continue to work closely with the relevant authorities in support of a “no classification” for reproductive toxicity for Styrene.

Likely Process Timings



*Caveat: new comitology rules may enter into force in the meantime

We are here

Build up of RAC opinion

Conclusions

- A reprotoxic classification for Styrene has been proposed by Denmark as an Annex XV dossier under REACH.
- The SPA evaluation of the science supports the UK rapporteur's opinion in 2007 pointing to a "no reprotoxic" classification.
- Final decision is unlikely to be taken earlier than October 2014.
- The STOT RE 1 self-classification is implemented in the SPA SDS.
- UPR sector group has subsequently informed downstream users.
- The exposure scenarios prove that workers can work safely with Styrene-containing resins when using recommended protective equipment and by limiting possible exposure to emissions.
- SPA recommends a worker OEL of 20 ppm 8-hour TWA.
- A new OEL may be decided after final classification.
- Individual country decisions and OELs will prevail until such time.






U.S. National Toxicology Program (NTP) Report on Carcinogens (RoC)

- On June 10, 2011, Styrene was included in the 12th RoC as "reasonably anticipated to be a human carcinogen."
  - A listing in the RoC only indicates a potential hazard and does not estimate cancer risks to individuals associated with exposures in their daily lives.
- The NTP conclusion is diametrically opposed to the 2007 EU determination that Styrene does not cause cancer in humans.
- Styrene is not classified as a carcinogen at the EU level.
- SIRC is contesting the listing as scientifically unjustified and the result of a flawed process. Lawsuit to be decided in early 2012.
- SIRC will submit additional studies to NTP and likely nominate Styrene for re-review for a future RoC.
- U.S. Congress has proposed $1M for a National Academy of Sciences study of Styrene and cancer.

UPR Sector Group of Cefic

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Back-up Slides

Styrene Exposure Scenarios

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Styrene ES Results for FRP Manufacturing (industrial)

Risk Characterisation				
Manufacturing Activity	**RCR inhalation**	**RCR dermal**	**RCR all routes**	**RMMs**
Open mold - rolling, brushing, etc.	0.75	0.01	0.76	Forced ventilation
Open mold - spray booth or robotic	0.63	0.00	0.63	Local exhaust ventilation
Open mold - spraying on open floor	0.38	0.02	0.40	Forced vent, half mask APR
Putties, bonding pastes (5-25%)	0.45	0.01	0.46	Forced ventilation
Pultrusion / cont. open processes	0.25	0.00	0.25	Local exhaust ventilation
Casting, SMC / BMC / TMC (5-25%)	0.15	0.00	0.15	Local exhaust ventilation
Mixing, blending, formulating	0.75	0.01	0.76	Forced ventilation
RTM, vacuum infusion, sewer relining	0.88	0.00	0.88	Dilution ventilation
High temperature curing (5-25%)	0.45	0.00	0.45	Forced ventilation
Equipment cleaning / maintenance	0.75	0.00	0.75	Forced ventilation
Handling / disposal of waste	0.25	0.00	0.25	Local exhaust ventilation

Styrene ES Results for FRP Manufacturing (professional)

Risk Characterisation				
Manufacturing Activity	**RCR inhalation**	**RCR dermal**	**RCR all routes**	**RMMs**
Open mold - rolling, brushing, etc.	0.35	0.01	0.36	Half mask APR
Open mold - spraying on open floor	0.53	0.05	0.58	Full face APR, time limit
Putties, bonding pastes (5-25%)	0.21	0.01	0.22	Half mask APR
Floor coatings, mastics, etc.	0.35	0.01	0.36	Half mask APR
Transfer, blending, formulating	0.35	0.01	0.36	Half mask APR
Sewer relining (outdoors)	0.18	0.00	0.18	Half mask APR*
Chemical anchoring (5-25%)	0.53	0.00	0.53	
Equipment cleaning / maintenance	0.70	0.01	0.71	natural vent, time limit
Handling / disposal of waste	0.70	0.01	0.71	natural vent, time limit

* During start-up and cutting actions