

## ANNEX II

### House Bill – Toxic Chemicals Safety Act of 2010

- Inclusion of mixture in declaration testing and other provisions. Text refers to “chemical substances and mixtures”
- Aggregate and cumulative exposures to be considered
- Aggregate exposure to include natural sources, background sources, etc
- Definition of persistence and bioaccumulative to be derived from Category for Persistent, Bioaccumulative and Toxic New Chemical Substances, 64 FR 60194. As noted in that notice:

*The key is how persistence and bioaccumulation potential are determined in the PMN process, and by implication, how bioavailability is determined. This policy statement leaves unspecified how EPA intends to do this, but the Agency will consider all available and relevant data, and will use its professional judgment in considering issues like bioavailability of metals. ....It is the policy of the TSCA New Chemicals Program that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity, and by extension, to bioaccumulate. If the intact metal compound is not toxic and the metal is not available from the metal compound, then such a chemical would not be a strong candidate for regulation under TSCA section 5(e).*

- A minimum data set will be required. NAMC members have noted that given the large amount of data available on metals, therefore, this provision should not be critical for metals.
- Legislation provides for order authority in addition to test rule option for PEA on data collection and data generation.
- The presences of the chemical substance in human tissues (e.g., biomonitoring data) will be critical factor in determination of test generation and/or safety review.
- Bioaccumulation and persistence will also be critical factors.
- Manufacturers will be required to provide declarations of hazard, exposure and use information.
- Unclear if a new use identified by one entity could trigger data generation for all other manufacturers or just the single entity

### Senate – Safe Chemicals Act of 2010

- Nano materials will be regulated as new substances
- Cumulative and aggregate exposure –including natural and background levels
- Same definition as bioaccumulative and persistence as TSCA
- Negligible risk to vulnerable populations
- Minimum data set to include uses
- Test order for information collection and data generation

- May need to develop information regarding presence in human tissue and epidemiology studies
- No criteria, limits or parameters on when or how EPA can use the order authority
- Consideration of reimbursement for data generation or reliance, but then data will be posted on public website?
- Thresholds on Section 5 for safety standard – if less than 1,000,000 pounds production, 100,000 pound releases and not PBT, CMR, etc
- Metal and metal substances likely to get captured in Section 5 criteria
- Safety determination on chemical or chemical in particular use? Will listing be of allowable uses or just the substance?