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Views on Success and Future Directions

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**American
Chemistry
Council**



American Chemistry Council

- 130 chemistry companies and 70 partners employing nearly 1 million people
- ACC supports research and performance programs to improve health, safety, and environmental performance, through:
 - Responsible Care[®], LRI, and HPV
- Founding partner in HPV Challenge and the parallel SIDS program

ACC Performance

Responsible Care®:

- Signature ethic of the chemistry industry
- Management systems to improve health, safety, and environmental performance and engage with stakeholders

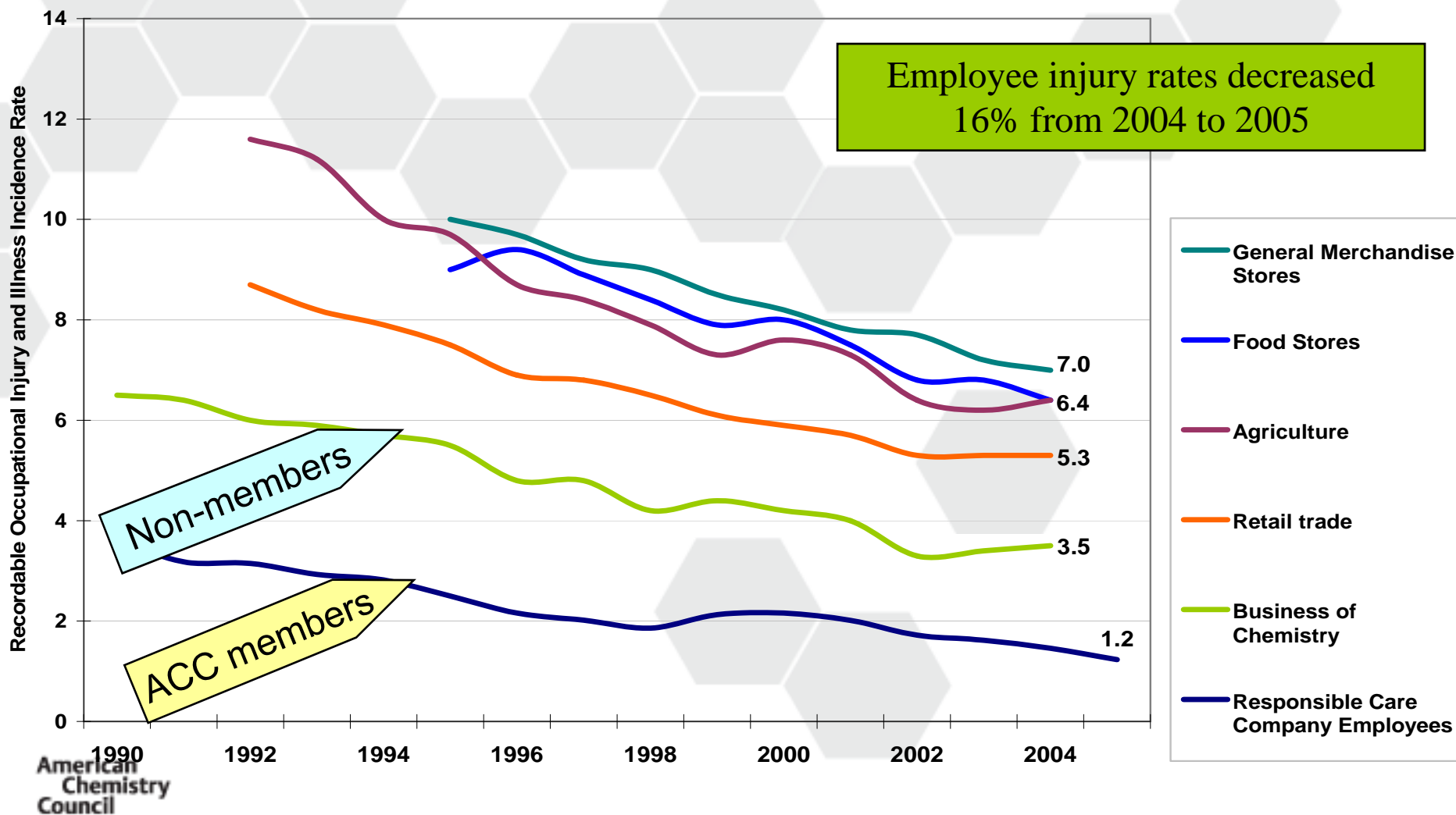
Long-Range Research Initiative (LRI):

- Created by chemical industry in 1999
- Conduct “basic” research (e.g., endocrine disruption, mechanisms of action) to address potential chemical impacts
- Invested more than \$100 million since 1999

CHEMSTAR:

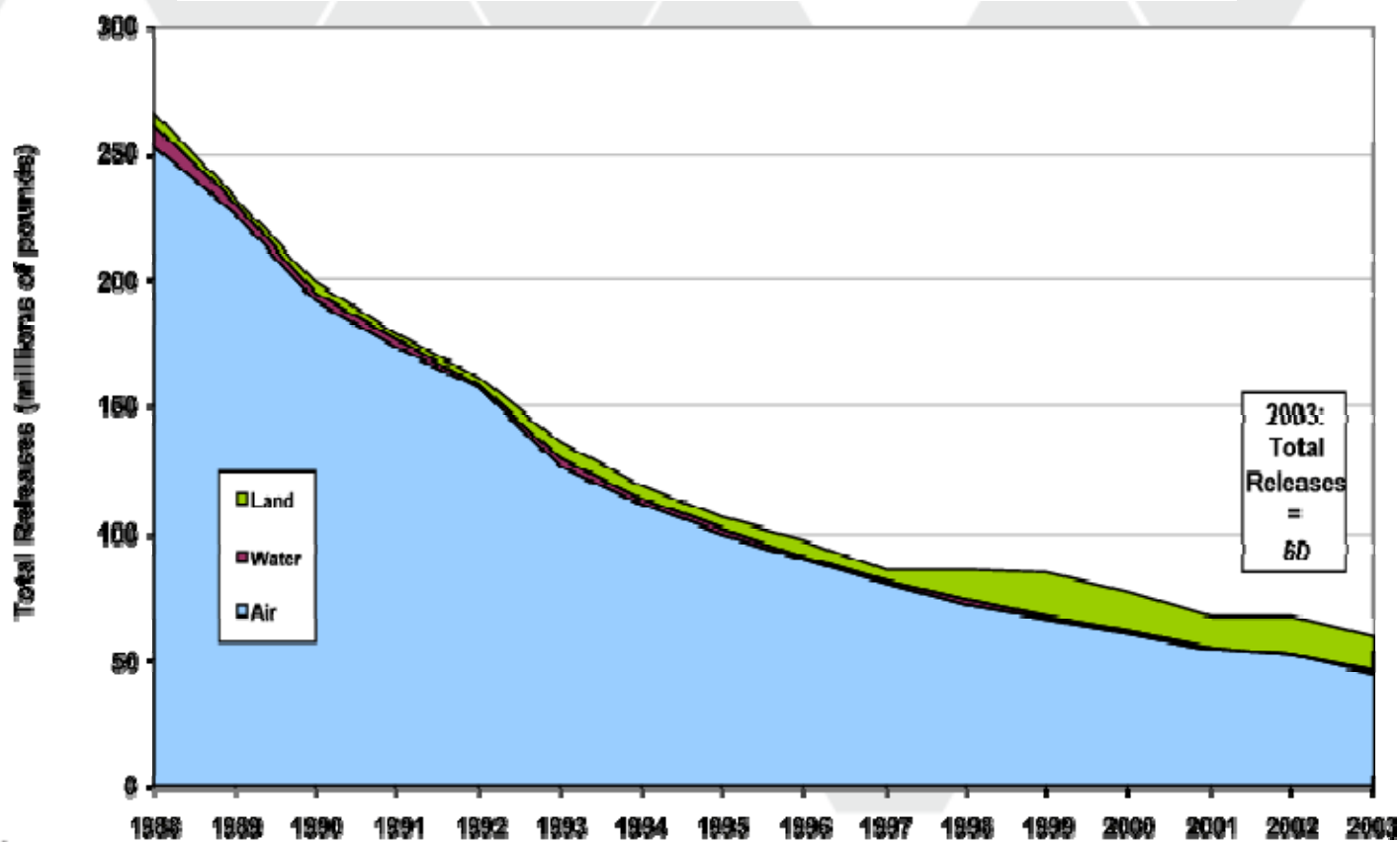
- For 25 years more than 70 groups have conducted chemical-specific testing and research, with test results made public

Commitment to Results: Recordable Occupational Incidence Rates



Commitment to Results – TRI Data

TRI data for Responsible Care® companies



Before the Challenge ...

- Electronic databases just coming of age
- Full study reports generally treated as proprietary – could be used by competitors
 - Robust summaries solved that problem
- Lack of standardized formats for sharing test information
 - Hundreds of pages, making comparisons difficult and cumbersome
- “Negative” data not published in journals, or routinely submitted to EPA

Data Availability Studies

Why did studies find so little data?

- Limited to publicly available, electronically searchable sources
- Design required CAS RN
- Could not possibly count company held data
- Design assumed every endpoint/CAS number intersection was a “data need”
 - Impossible to account for endpoints addressed via categories
 - No exposure derogation
 - No ability to show testing would be impossible or meaningless

Data Availability Studies

Study benefits:

- Catalyze industry understanding that the *public* lacked the same understanding
- Realization that clear action needed

Study drawbacks:

- Hazard (rather than risk) became sole focus
- Left completely inaccurate and lasting impression if data not “publicly available” then it didn’t exist at all

Major Program Achievements

TOTAL OF 11,063 health endpoint studies from first 1,425 Challenge Program chemicals now in public domain!

- More information, on more chemicals, faster than in any regulatory program
- EPA has data to set priorities for further work
- Demonstration of category-based approaches
- Development of RSS templates
 - Can share study results w/o losing value
- Better agreement on data needs, tiered approaches
 - No *in vitro* gentox if *in vivo* available, and no 28-day study if full repro/developmental available, etc.

How Much Data Brought Forward?

Acute fish:	1,505
Acute:	3,178
Genotoxicity:	3,454
Repeat dose:	1,797
Reproductive:	404
Developmental:	634
Combined R/D:	91

Test Plans – The “Bonus Track”

Frequently include:

- Participants, production volumes
- Process descriptions
- Use and sometimes exposure information
- Which studies are relied upon, and why
- Justification for any derogation
- Assessment of endpoint
- Category justification

What HPV is *not* ...

- Finished
 - Some work coming in
 - Relatively little action to date on orphans
 - ICCA path slower, pace not in our control
- The answer to every information need
- A complete risk assessment
 - Intended as a base set of information for an initial hazard assessment and prioritization

Lessons Learned (1)

- More existing data than initial studies predicted
 - Only 313 new studies needed
 - Many chemicals were “data rich”
- “Negative” data not in public databases
- Category approaches:
 - Significant potential to avoid animal testing
 - Process is complex, expensive and time-consuming
- Public comment increases quality, transparency
- Easy to underestimate cost to create/operate consortia, summarize data, draft test plans

Lessons Learned (2)

- Agreeing there could be flexibility helped build support:
 - Challenge/SIDS recognize exposure considerations relevant
- Debate is part of the scientific process – views on data completeness will differ.
 - Important to consider the path and process to address different views on information needs
- Voluntary programs *CAN* produce more usable and publicly available information than you might possibly have imagined

Future Directions – Industry (1)

- Complete work on Challenge and OECD program track chemicals
- Deliver results on EHPV: industry-led extension of work
 - Hazard data on ~574 “new” HPV chemicals
 - Use/Exposure information on current and new HPVs
 - Notable – of those 500 just barely above 1M lbs.
 - “new” HPVs < 5% by volume of chemicals in commerce
- Work with OECD Global Data Portal will enhance data availability, reduce chance for redundant testing

Future Directions – Industry (2)

- Increasing attention to use/exposure information
 - Inventory Update Rule, REACH
- Increasing attention to risk information
 - NPPTAC Screening
 - Industry’s Global Product Strategy
- Explore opportunities to incorporate and expand access to information from other sources:
 - REACH; Canadian DSL categorization; Japan’s HPV
- Discussions on emerging HPVs

Future Directions - EPA

ACC supports EPA action to:

- Quickly complete the NPPTAC-recommended screening process, to:
 - Build public confidence, and
 - Use data in support of risk-based decisions
- Pursue regulatory approaches on “orphans”
- Make risk assessment the objective, not *just* making hazard information available
- Create a meaningful dialogue on role of exposure in the conduct of its assessments
- Greater communication with stakeholders on its views, priorities and outcomes of assessments

HPVIS is just part of the story ...

- HPV Challenge Program: <http://www.epa.gov/hpv/pubs/hpvrstp.htm>
- VCCEP: <http://www.epa.gov/chemrtk/vccep/index.htm>
- TSCATS: http://www.syrres.com/eSc/tscats_info.htm
- OSHA/MSDS: <http://www.epa.gov/enviro/html/emci/chemref/>
- ESIS: <http://ecb.jrc.it/ESIS/>
- OECD HPV Database: <http://cs3-hq.oecd.org/scripts/hpv/>
- UNEP HPV Datasets: <http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html>
- EXICHEM: <http://webdomino1.oecd.org/ehs/exichem.nsf>
- IPCS INCHEM: <http://www.inchem.org/>