

EPA/CPDA Symposium on Inert Ingredients
Carmin Sesa
AgMarketResults
February 3-4, 2010

REACH – DIFFERENCES FROM US LAW – A BUSINESS PERSPECTIVE

2 Major Differences to be discussed

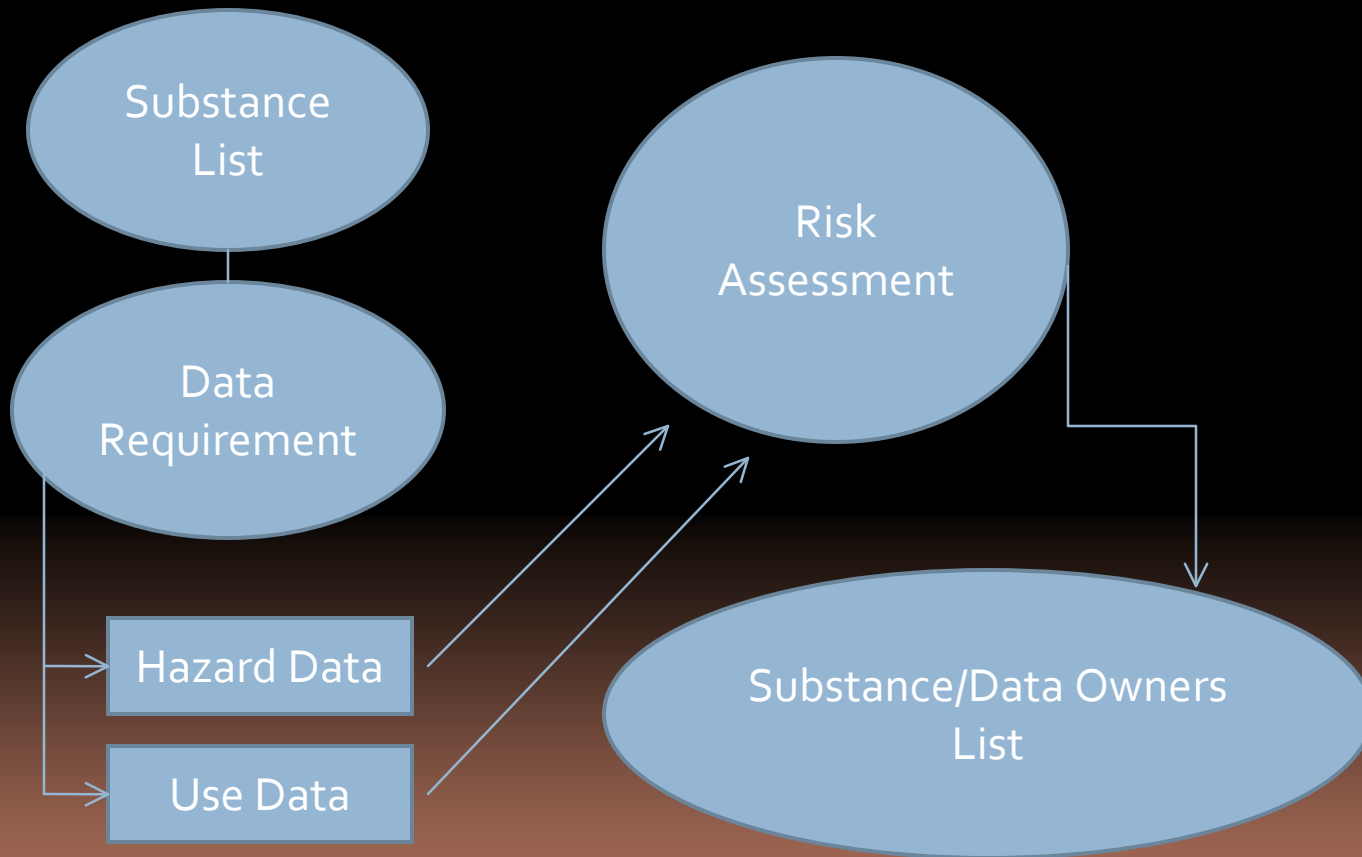
- Data Protection/Data Compensation
- Process
 - Data Evaluation and Risk Assessment
 - Fees and Timeframes

Can Industry and EPA benefit from some of the work that went into the design of the REACH process???

Data Compensation

- REACH
 - Mandatory Data Sharing with Data Protection
 - 12 years from “final action”
- FQPA
 - Same as FIFRA
 - 10 years of exclusive use from the time of “final action”
 - 15 years of data compensation from the time of data submittal
- TSCA
 - Some protections under Section 4 Test Rule process, but it is limited to 5 years from submittal of the data or “the period which the Administrator determines was necessary to develop such data”

What might a “New” TSCA Data Compensation Process Look Like?



Data Evaluation

- Who will evaluate the data and manage the risk assessments?
 - In REACH most of the “Chemical Assessments” will be completed by industry. Very little of the submittals will be evaluated by ECHA. (This is not the case for substances of high concern.
 - In a TSCA process which would require substantial amounts of data, significant added staffing (and added costs) would be required by EPA.

Food-use Inert / REACH

Total Requirement	\$380 K	\$2,450 K
Physical and Chemical Properties	47	73
Eco Tox	19	430
•Fish early life stage/fish bioconc flow through/bird long term repro (\$290)		
Mammalian Tox	267	1600
•Long term repeated dose/carcinogenicity/two gen/Tertatogenicity		
•OECD 422 Study (\$230K)		
Genetic Tox	32	89
Environmental Fate	16	258
•Aerobic/anaerobic transformation in soil/aq.sediment (\$95K)		
•Identification of degradation products (\$50)		

FEES – Let's look at PRIA

- Pesticide Registration Improvement Act
 - Fee for Service:
 - Assume the fee is based on resources required to do the job
 - Inert ingredient fees are exempt from PRIA
 - There are 143 separate line items
 - 47 of the line items are between \$100K and \$600K
 - 15 items are above \$300K
 - 3 items are above \$500K

Time Frames for evaluation of the larger amounts of data range from 12 to 24 months

Assessment Process Pros and Cons

- Industry Assessment:
 - Internal Costs for Risk Assessments – likely much less than potential EPA fees – likely to be duplicative as companies will need to understand the assessment prior to submittal.
 - Time Frames are also likely to be Duplicative
 - Potential risk is higher
- EPA Assessment:
 - Very likely duplication in fees and time frames
 - Liability to industry is lower – can this be resolved?

Why Discuss REACH and TSCA in an AG inerts Conference

- **Statement of Lisa P. Jackson Administrator, U.S. Environmental Protection Agency Legislative Hearing on the Toxic Substances Control Act (TSCA) Senate Committee on Environment and Public Works December 2, 2009:**
 - *"The need for fundamental TSCA reform has been recognized by industry groups..."*
 - *"I too call on Congress to act on this issue..."*
 - *"EPA looks forward to working with this committee on this very important issue."*

Why Discuss REACH and TSCA in an AG inerts Conference

- In my view manufacturers, suppliers and users of inert ingredients need to re-examine their business strategies in light of a changing global landscape involving the creation, the costs, and the availability of data.
 - How will this new data affect the competitive nature of your products in Europe, as well as in the US?
 - What might your data investments look like with or without data protection?
 - How will resource management change?
 - Will you be a data rich company or seek a compensation strategy for specialty markets?
 - How will you manage the relationships through the value chain to enable appropriate risk assessment and continued supply?
 - What will happen to your market if the evaluation process takes 2-3 years?

Why Discuss TSCA in an AG inerts Conference

- I give credit to ACC and other trade associations that are working on the numerous complex issues surrounding the potential for a new US chemicals management system.
- The goal of this presentation is not to argue the scientific reasons for or against such a change, nor to predict the outcome of this change (a REACH Like TSCA).
- The goal of this discussion is to raise new questions within CPDA member companies.
 - Should you be involved in the “Process” as well as the “Science” of Regulation change?
 - With expertise and experience in FIFRA and FQPA, is CPDA positioned to add value to this “Process” question: Data Compensation and Data Evaluation?