Understanding the Proposed TSCA Inventory Reset and Preparing for the Next TSCA Reporting Cycle

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- On September 29, 2009, Lisa P. Jackson (EPA Administrator) announced a plan to strengthen the federal chemical management programs
  - One revision that has already been considered is the Toxic Substances Control Act (TSCA) Chemical Substance Inventory Reset

- The next TSCA Inventory Update Reporting Cycle will address chemicals manufactured during 2010
  - Tracking of information must occur throughout 2010; reports will be due in 2011
OUTLINE

• Overview of Toxic Substance Control Act (TSCA) and the TSCA Chemical Substance Inventory

• Revisions Planned for TSCA (TSCA Reform)
  – Companies will need to provide more data to the EPA on chemical risks/health impacts
  – TSCA Inventory Reset Initiative

• Upcoming TSCA Inventory Update Reporting Cycle
  – Contents of Report
  – Expected Changes to Reporting Rules
Toxic Substances Control Act (1976)

- Prior to TSCA: “…the government had no power to require that chemicals, with the exception of those used as pesticides, drugs, and food additives, be tested before they were put into commerce.”

- In 1971, the President’s Council on Environmental Quality stated that: “…we should no longer be limited to repairing damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory.”

From “The Toxic Substances Control Act: History and Implementation” (EPA)
Toxic Substances Control Act (1976)

- TSCA gave the EPA the authority to:
  - require testing of chemicals, and,
  - regulate the production, use, and disposal of new and existing chemicals

- Purpose of TSCA:
  - to ensure that chemicals used in commerce are safe and do not endanger public health and welfare, or the environment
Toxic Substances Control Act (1976)

- Regulates all organic and inorganic chemical substances and mixtures not covered by other legislation

- **Does not regulate:**
  - Food products or additives, drugs, or cosmetics (Federal Food, Drug, and Cosmetic Act)
  - Pesticides (Federal Insecticide, Fungicide, and Rodenticide Act)
  - Nuclear materials (Atomic Energy Act)
  - Tobacco or tobacco products (The Bureau of Alcohol, Tobacco, Firearms and Explosives)
Toxic Substances Control Act – Status in 2009

• In a memo to employees in January 2009, Lisa P. Jackson (EPA Administrator) stated that:
  
  “More than 30 years after Congress enacted the Toxic Substances Control Act, it is clear that we are not doing an adequate job of assessing and managing the risks of chemicals in consumer products, the workplace, and the environment. It is now time to revise and strengthen EPA’s chemicals management and risk assessment programs.”
Toxic Substances Control Act – Status in 2009

- On September 29, 2009, the EPA Administrator announced the Obama Administration’s “Essential Principles for Reform of Chemicals Management Legislation”

- These principles are intended to aid Congress during the legislative process required to:
  - Strengthen and update the existing programs; and,
  - If necessary, prepare a new chemical risk management law, to address issues not covered by TSCA.
TSCA Chemical Substance Inventory
TSCA Chemical Substance Inventory

TSCA Section 8 – Reporting and Retention of Information

• Section 8(b) of TSCA requires the EPA to compile, keep current, and publish the TSCA Inventory

• Toxicity is not a criterion used to determine whether the chemical belongs on the Inventory

• The Inventory contains chemicals used in the United States for commercial purposes from January 1, 1975 to the present
TSCA Chemical Substance Inventory

• The Inventory now includes over 80,000 chemicals, and consists of the:
  – Publicly-available list; and,
  – CBI list (confidential list)

• The Chemical Substance Inventory is a list of chemical substances manufactured, imported, or processed in the United States for commercial purposes
  – Includes substances manufactured as intermediates for use by the manufacturer
TSCA Chemical Substance Inventory

- New chemical substances are added to the Inventory after:
  - Companies have submitted Premanufacture Notifications (PMNs) to the EPA; and,
  - The EPA has approved the PMN; and,
  - The companies have subsequently notified the EPA that the manufacture or importation of the chemical substance has commenced. [via a Notice of Commencement of Manufacture/Import (NOC)]
TSCA Section 5 – Manufacturing and Processing Notices

• Section 5(a) – Premanufacture Provisions
  EPA has the authority to regulate new chemical substances prior to their manufacture or import.

• Section 5(a) – Significant New Use Rules
  EPA can restrict the use of a chemical substance to identified acceptable uses.
TSCA Reform
TSCA Reform – Toxicity and Exposure Data

Revisions to the PMN Process:

• Currently, during the PMN process, “companies have no legal obligation to develop new information, only to supply data that may already exist”

• “Manufacturers must develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals are safe.”

Lisa P. Jackson, EPA Administrator, 9/29/2009
TSCA Reform – Toxicity and Exposure Data

Existing Chemicals:

- EPA plans to complete the work started under the High Production Volume (HPV) Challenge Program in which companies were challenged to submit basic screening level hazard data on HPV chemicals.

- EPA intends to require that companies submit information to fill the remaining gaps in health and safety data.

(HPV chemicals are chemicals manufactured and/or imported in quantities of > 1,000,000 pounds/year)
TSCA Reform – Toxicity and Exposure Data

The planned revisions are joint efforts:

• “Industry too, has called for action. Chemical producers...want the US to lead the world in chemical risk management, not fall further behind” (Jackson – 9/29/2009)

• “In the end, the costs will be justified and we will have a consistent regulatory regime that is protective of the public and does not impede the manufacturing competitiveness” (Dan Borne, LCA President, “The Advocate”, 10/11/2009)
TSCA Reform – Reset Initiative

• The TSCA Chemical Substances Inventory currently includes over 80,000 chemicals

• However, that number may be inflated due to:
  – chemical nomenclature issues resulting in redundant entries; and,
  – the inclusion on the list of chemicals that were manufactured in (or imported into) the United States in the past, but are now no longer in commercial use
TSCA Reform – Reset Initiative

• Importance of the Inventory:
  – Serves as the basis for all TSCA Programs
  – An accurate TSCA Inventory is an essential component of EPA’s efforts to set priorities for determining which chemicals should be the focus of health and safety studies.
TSCA Reform – Reset Initiative

- The EPA has proposed to reset the TSCA Chemical Substances Inventory to remove outdated chemicals.
- A process was proposed in which companies would certify which chemicals had been manufactured or imported within a specified timeframe.
- A public meeting was held on December 8, 2008.
TSCA Reform – Reset Initiative

Benefits of the reset:

– Redundant entries would be removed;
– Outdated entries would be removed; and
– Would result in a streamlined list containing only the chemicals currently in commerce in the United States.
Who's Reporting What?
A Look at the "Petroleum Process Streams"
[§710.46(b)(1)] Reported in 2006

- Process streams with 0 facilities reporting, 221
- Process streams with 1 facility reporting, 58
- Process streams with 6-10 facilities reporting, 55
- Process streams with 2-5 facilities reporting, 140
- Process streams with more than 10 facilities reporting, 117
TSCA Reform – Reset Initiative

Risks of the reset:

• Unfortunately, the removal of a chemical from the Inventory eliminates the authorization for any production (or import) of that chemical in the United States.

• Small manufacturers are not required to submit TSCA inventory update reports; therefore, there is a risk of specialty chemicals being inadvertently deleted from the list.
TSCA Reform – Reset Initiative

- Chemical processors would also need to be included in the reset process.

- In general, the comments from industry groups supported the TSCA Reset Initiative; however, there were concerns regarding:
  - The need for complete participation to prevent the inadvertent deletion of chemicals from the list.
  - Each facility needs to be concerned about the chemicals manufactured on-site and the raw materials/additives purchased from other facilities.
  - The timing of the initiative.
TSCA Reform – Reset Initiative

• EPA has reviewed the comments submitted during the comment period and is currently considering the next steps (per Jim Alwood – EPA – Chemical Control Division)

• It is possible that the Reset Initiative could be timed to occur simultaneously with the upcoming reporting cycle
TSCA Inventory Update Reporting

• The next TSCA Inventory Update Reporting cycle will address chemicals manufactured (or imported) during calendar year 2010

• Reports must be submitted between June 1, 2011 and September 30, 2011

• Each facility should confirm that required information is being tracked from January 1, 2010 through December 31, 2010
TSCA Inventory Update Reporting

- Reporting is required for chemical substances that were manufactured or imported:
  - For a “commercial purpose”
  - At a single plant site in quantities at or above the threshold quantity

- Last reports were for calendar year 2005, with reports due in 2006
  - Reporting threshold was 25,000 pounds/year for 2005
  - Reporting threshold for earlier reports was lower
TSCA Inventory Update Reporting

• Reporting includes substances manufactured as intermediates for use by the manufacturer
  – Referred to as ‘site-limited’ production
  – Does not include ‘non-isolated intermediates’ (compounds generated and consumed within the process and not isolated or stored)
The Top 10 States by Production Volume and the Number of Chemicals They Report (only Non-confidential 2006 IUR Records Presented)

<table>
<thead>
<tr>
<th>State</th>
<th>Total Production Volume (billion lbs)</th>
<th>Number of Chemicals</th>
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<tbody>
<tr>
<td>LA</td>
<td>12,000</td>
<td>0</td>
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<tr>
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<td>0</td>
</tr>
<tr>
<td>OH</td>
<td>0</td>
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</tr>
</tbody>
</table>

From EPA Document - "2006 Inventory Update Reporting: Data Summary"
What does a Pulp Mill Report?

- Organic by-products (tall oil, turpentine, etc.)
- Substances generated during the kraft liquor cycle and the causticizing cycle
  - Black liquor (or spent pulping liquors) (CAS RN: 66071-92-9)
  - Green liquor (or smelt) (CAS RN: 68131-30-6)
  - White liquor (CAS RN: 68131-33-9)
  - Calcium carbonate (CAS RN: 471-34-1)
  - Calcium oxide (CAS RN: 1305-79-9)
- Ashes, such as fly ash (if sold to a customer)
What does a refinery report?

- Butane, Propane and other pure gas product streams
- Petroleum Process Streams (40 CFR 710.46)
- Sulfur, petroleum coke, and spent caustic (if sold)
What does a Refinery **Not** Report?

- **Crude Oil** – not reportable (naturally occurring)

- **Blended Gasoline Products** – not reported (would be double-counting, as the products are mixtures of the process streams)

- **Fuel gas** - not reportable
  - Do not report by-products disposed as waste or combusted as fuel
  - **Note:** By-products that have commercial purpose must be reported.
Should a Refinery Report....

• Slop oil?
  – Reported as “wastes, petroleum”, CAS RN 68477-26-9
  – Does not qualify as a non-isolated intermediate

• Precious metals in spent catalyst returned for metals reclamation?
  – A monetary credit is received for the metals
  – A metal oxide may have been manufactured during the use of the catalyst
What does a Catalyst Manufacturer Report?

• Catalyst Manufacturers make products that are mixtures of inorganic substances.

• In general, mixtures are not subject to Inventory Update Reporting (exceptions include petroleum process streams and statutory mixtures such as cement and ceramics).

• Instead, the chemical substances comprising the mixture must be reported.
What does a Catalyst Manufacturer Report?

- **Must consider:**
  - What are the components of the catalyst(s)?
  - Which components did the facility actually manufacture?

- **The chemicals reported may include:**
  - Metal oxide(s)
    - Copper oxide, aluminum oxide
  - Aluminate silicate
TSCA Inventory Update Reporting

EXPECTED CHANGES TO REPORTING RULES:

• In early 2010, EPA will propose modifications to the reporting rules. There will be a public comment period for the proposed revisions.
EXPECTED CHANGES TO REPORTING RULES:

- The regulatory agenda states that the modifications will include:
  - “Somewhat minor changes to data reporting requirements”
  - Possible changes to exemptions
  - Changes to reporting of recycled chemical substances and changes to reporting of imported substances
  - A move in the reporting regulations from 40 CFR 710 to 40 CFR 711
TSCA Inventory Update Reporting

INFORMATION REQUIRED ON THE 2006 REPORTS:

• Chemical Information
  – Chemical Identification Number and Code
  – Chemical Name

• Manufacturing Information
  – Manufacturing Activities and Production Volume
  – Number of Potentially Exposed Workers
  – Maximum Concentration
  – Physical Form(s) of the Substance
TSCA Inventory Update Reporting

INFORMATION REQUIRED ON THE 2006 REPORTS:

- Information on Downstream Processing and Uses*
  - Industrial processing
    - Within the facility (on-site) and at other facilities to which the chemical was sold (off-site processing) and associated worker exposure
    - Processing Information reported for domestic uses only
  - Commercial and consumer (end-use) information

*For the 2006 reports, this information was required for chemical substances produced in quantities of 300,000 pounds or more during calendar year 2005, unless the chemical substance qualified as “partially exempt”.

Preparing for the Next Reporting Cycle

• Track 2010 production data for:
  – All materials reported in the 2006 submittal
  – Any new chemical products

• Track 2010 downstream use information for:
  – Chemicals produced at quantities at or above 300,000 pounds/year
    • Petroleum process streams should remain “partially exempt”
    • Inorganic substances will most likely no longer be “partially exempt”
Preparing for the Next Reporting Cycle

• Watch for the new reporting regulations and be prepared to submit comments during the comment period
  – Refer to the EPA Inventory Update Reporting Website (www.epa.gov/oppt/iur)

• Attend EPA Training Workshops
  – Training workshops should commence in the 2nd half of 2010
Preparing for the Next Reporting Cycle

- **Document the Report Preparation Process**
  - This is CRITICAL due to the long time period between submittals
  - Explain any reporting exemptions being used

- **Ensure company-wide report consistency**
  - Review the 2006 reports and identify outliers
  - Review and compare the 2011 reports for all sites prior to submittal
Conclusions
Conclusions

• Review the 2006 Inventory Update Report and supporting documentation for your facility
• Ensure that tracking procedures are in place for 2010
• Watch for the new reporting regulations
  – Refer to the EPA Inventory Update Reporting Website (www.epa.gov/oppt/iur)
• Monitor the progress of the new programs and be prepared to participate in the TSCA Reset Initiative
  – www.epa.gov/oppt
QUESTIONS?