4th Annual Next Generation Bio-Based Chemicals

Regulatory Challenges & Opportunities in Bringing New Chemicals to Market

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Although “Green” Is Good…

- Biobased products are both encouraged and regulated by the government
  - The U.S. Environmental Protection Agency (EPA) and other agencies encourage innovation in and use of biobased products
  - Ironically, they may receive particular scrutiny due to EPA regulations on “new chemicals”
- Careful preparation and an understanding of EPA and its requirements and approaches can help to avoid problems/delays
“Green is Good” -- But…..

- **Opportunity**
  - Over the past 30 years, governments have recognized the issues with petroleum and to value and encourage more sustainable technologies
  - Markets in many cases have been ahead of governments and recognized the benefits of biobased chemicals

- **Challenge**
  - U.S. regulatory scheme, developed 30 years ago, grandfathered “existing” -- largely petroleum-based -- chemicals
  - “New” chemicals are treated differently, *e.g.*, with upfront, pre-manufacture regulatory requirements
Law of Unintended Effects Can Be Avoided

- **Net Effect**
  - Given the potential scale of the market opportunities for biobased chemistry in the future, EPA’s current distinction between “new” and “old” chemicals is a large potential impediment for commercial development of biobased products.

- **Conclusion**
  - Understanding EPA, its requirements, and operations can help avoid significant hurdles, expenses, or delays.
  - Success sometimes dependent on aggressive representation to break through various standard operating procedures (SOP) and other barriers.
Life at EPA

- Staff (approximately 350 in the chemicals office) are dedicated and see their work as important
- Staff are very pro-environment (it is EPA, not Commerce Department)
  - Science-oriented
  - High expectations for current political leadership
    - Green programs, green chemistry, pro-environment decisions
- Even under Obama II, budget and partisan politics will take a toll
  - Decreased budgets, increased workloads, salary freeze?
  - Increased expectations
  - Increased political pressure/criticisms
Life at EPA: New Chemicals

- Biobased products viewed favorably, but still subject to “chemical regulation” -- including possible delays and controls

- Regulatory decisions generally based on prior decision history with similar cases

  - Highly delegated decision authority
    - EPA review staff have considerable autonomy
    - Can be seen as opportunity to “get it right” at the outset, something which was not possible for petrochemicals
Life at EPA: New Chemicals (cont’d)

- Few decisions involve EPA’s political leadership or even senior leadership in the chemicals office.
- Almost no role for the Office of Management and Budget (OMB) in most decisions.
- Limited oversight by Congress.
- EPA is a relatively large agency but new chemicals are a small part (<1% of total staff).
- Large number of new chemicals reviewed each year:
  - Over 1,000 notices/year
  - Small but increasing number are biobased.
Life at EPA: New Chemicals (cont’d)

- Strict timelines for review
  - But regulated cases invariably take a long time to resolve
- Science is key to EPA’s approach and characterized by:
  - Reliance on structure activity relationship (SAR) and estimated exposures
  - Conservative risk assessment methods and assumptions
  - Large case load results in much default assessment
How to Interact with EPA

- When beginning (e.g., pre-meeting can help)
- When asking for something
  - Understand their perspective/reality
  - Novel issues/products often represent a time sink
- When disagreeing
  - Stand ground politely but firmly
- When threatening
  - Might be needed, elevate issues (and volume) as appropriate
Other Agencies Can Play a Role

- Other agencies can help, but ....
  - Most are not interested -- stove pipe problem
  - Some are more active than others (e.g., OMB/Office of Information and Regulatory Affairs (OIRA))

- If issue is broad or Administration priority, other players may be interested and useful
  - Trade issue -- United States Trade Representative (USTR)
  - Science issue -- Office of Science and Technology Policy (OSTP)
  - Security issue -- Department of Defense (DoD)
  - Energy issue -- Department of Energy (DoE)
  - Agriculture issue -- United States Department of Agriculture (USDA)
Note about Congress

- Many Committees of jurisdiction
- Oversight of EPA programs very “political” at present
- How to use Congress on an issue (carefully)
  - Committees of jurisdiction may be interested
  - Individual members (Representative or Senator) can be helpful
- Influence and role of outside groups (left and right)
  - Pressure on broad issue might affect individual cases
Note about Congress (cont’d)

- Continued budget pressures and skepticism toward EPA resulting in flat or declining resources
  - Some EPA “problems” will worsen as resources decline
    - Contract support, review timeframes, skills-mix may all slip
  - If Congressional dynamic results in decline in EPA resources or staff skills languish …
    - Understanding new technologies or approaches may be viewed less favorably or just not as well understood
    - Time and attention of staff at all levels less able to respond timely or receptively to novel issues
Case Study

- Client starting to make large capital investment and beginning large-scale production of biobased products
- Submissions to EPA caught in “old” vs. “new” chemical snare; new biobased products regulated more aggressively
- Client worked to address EPA issues and to explain more clearly products’ benefits (environmental, performance, etc.); this helped but only to limited extent
- Only after multiple strategic interventions with very senior levels of EPA’s political leadership did EPA recognize the biobased products’ significant benefits and adjust its policies to help level playing field and allow unfettered commercialization
Conclusions

- EPA encourages green products, but regulatory requirements and policies can slow or deter biobased product development.

- EPA is a science driven agency with review requirements and procedures that can lead to more regulatory scrutiny for novel biobased products than for existing petroleum-based products.

- Careful attention before and during planned commercial introduction can avoid regulatory problems that could hinder operations (delay in product introductions, regulatory controls, and related challenges).
Thank You

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