Innovation for Biocides: a Supplier’s Perspective

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DuPont Microbial Control

Preservation of Paints & Detergents: Workshop on Innovation & Industry challenges
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www.aise.eu
Content

• What is innovation in the biocides industry?
• What are the Incentives for Innovation?
• What are the Challenges for innovation?
• What way forward?
What is Innovation in the Biocides Industry?
Biocide Industry Objectives

• Our purpose is to provide means to kill or control harmful organisms in order to protect products, people and the environment

• Our goal is to continuously innovate to reduce risk and ensure safety for man and the environment
How to Innovate in Biocides? The Industry is Taking a Holistic Approach to Solving Today’s Challenges

- New Microbial Control strategies
- New active substances
- New formulations (end-use biocides)
- New dosing systems
- New packaging
New Microbial Control Strategies are being Explored by Industry Participants Due to Pressure on Existing Technologies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>New techniques</th>
<th>Comments/Limitations</th>
</tr>
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<tbody>
<tr>
<td>Reduce contamination</td>
<td>Enhanced plant hygiene</td>
<td>Need efficient biocides:</td>
</tr>
<tr>
<td></td>
<td>Advanced diagnostic</td>
<td>• Disinfectants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Fast kill preservatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Long-term preservatives</td>
</tr>
<tr>
<td>« Non-synthetic chemical »</td>
<td>Biologically-derived chemicals</td>
<td>Not different from synthetic chemicals</td>
</tr>
<tr>
<td>control (non petrol-based)</td>
<td>Microorganisms</td>
<td>Still conceptual</td>
</tr>
<tr>
<td></td>
<td>Pasteurization, UV, ...</td>
<td>Technical issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cost, energy consumption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No persistence of action</td>
</tr>
<tr>
<td>Optimize efficacy of preservatives</td>
<td>Boosters</td>
<td>Regulatory uncertainty</td>
</tr>
<tr>
<td></td>
<td>Blends of actives</td>
<td></td>
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</table>

Efficacy is key, we cannot jeopardize the protection needed or favoring resistances ... which would negatively impact health and environment.
New Biocidal Active Substances Are Demanding more Specificity and Selectivity for Target Organisms.

• Active options can originate from chemical synthesis or biological derivation
• Phenotypic or target based exploratory screening for new chemicals requires extensive investment
• New substances require earlier screening for toxicity and sensitization as part of selection process
• More simple option is to look at variations of existing chemical families or sourcing from adjacent markets (like eg. Plant Protection)
New Formulations and Innovative Delivery System May Help Leverage Existing Active Technologies More Effectively

<table>
<thead>
<tr>
<th>New biocides formulations</th>
<th>New packaging</th>
<th>Advanced dosing systems</th>
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<tbody>
<tr>
<td>Reduced bioavailability</td>
<td>Reduce industrial worker exposure</td>
<td></td>
</tr>
<tr>
<td>Controlled-release</td>
<td>No impact on end-users</td>
<td></td>
</tr>
<tr>
<td>Precursors of actives</td>
<td></td>
<td></td>
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<tr>
<td>Blends of actives</td>
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What are the Incentives for innovation?
Key drivers and expectations for innovation

• **Societal demand**
  • Hygienic and healthy environment
  • Safe and environmental friendly products
  • Quality and long lasting products

• **Industry demand and market expectations**
  • Efficient use of energy and raw materials, reduction of waste
  • Efficient control of harmful organisms, protection of products and processes
  • Protection of workers, consumers and the environment
Regulatory framework as an incentive for innovation

• Since 2000 more than 2/3\textsuperscript{rd} of the active substances have disappeared

• Exclusion/substitution criteria will impact > 30% of remaining substances

• The most efficient substances are expected to be banned or severely restricted

• Multiple market gaps have been appearing, ... but ...

• ... in 19 years, < 20 new active substances for all PTs
What are the Challenges for innovation?
From invention to innovation

- Screening efficacy
- Intellectual property
- Application Testing
- Manufacturing process
- Market analysis
- Confirmation of efficacy
- Testing
- Dossier preparation
- Evaluation
- Approval

- Identification of candidate new active
- Scaling up
- Preparation of application for approval
- Approval, product authorization and launch

3 - 5 years
5 - 100* millions €

3 - 5 years
5 - 10 millions €

4 - 7 years
1 - 2 millions €

*Depends on the % of failure/type of application
Market challenges for innovation

• Biocides is a small market:

![](chart.png)

- R&D investments in biocides cannot be compared with other life science industries (pharmaceuticals in EU: € 50 Bn/year), but similar diligence is requested in identifying compounds

• Diverse and fragmented, targeted market often < €50MM

• Not all downstream users sectors are ready to/can pay for innovation
# Technical and regulatory challenges for new actives

<table>
<thead>
<tr>
<th>Technical challenge</th>
<th>Regulatory challenge</th>
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<tbody>
<tr>
<td>Diversity of target organisms</td>
<td>Very long time to the market</td>
</tr>
<tr>
<td>Wide spectrum needed</td>
<td>Very expensive/market size</td>
</tr>
<tr>
<td>Come back to same mode of actions with same toxicological properties</td>
<td><strong>Unstable regulatory environment</strong> (guidances, fees, approval criteria, ...)</td>
</tr>
<tr>
<td><strong>Application Compatibility is a critical parameter</strong></td>
<td>No exclusivity</td>
</tr>
<tr>
<td></td>
<td>High risk and low predictability</td>
</tr>
</tbody>
</table>

High cost, long process, small market and lack of visibility on the return on investment ...

... not so attractive for internal decision makers and external investors ...
A few example of PT6 « new » actives

<table>
<thead>
<tr>
<th></th>
<th>Dossier filed</th>
<th>Approved</th>
<th>Comment</th>
</tr>
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<tbody>
<tr>
<td>MBIT</td>
<td>2009</td>
<td>2018</td>
<td>Isothiazolinone family CLP rules changed in 9 yr =&gt; SCL at 15 ppm for sensitization</td>
</tr>
<tr>
<td>Folpet</td>
<td>2009</td>
<td>2016</td>
<td>Organochlorinated Only fungicide, only in paints (PT6/PT7)</td>
</tr>
<tr>
<td>CIT</td>
<td>2017</td>
<td></td>
<td>Isothiazolinone family</td>
</tr>
<tr>
<td>Sodium azide</td>
<td>2017</td>
<td></td>
<td>Limitation on use (R&amp;D reagents)</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>2018</td>
<td></td>
<td>Limitation on use (R&amp;D reagents)</td>
</tr>
<tr>
<td>Ethanol</td>
<td>2016</td>
<td></td>
<td>Limitation on use (R&amp;D reagents)</td>
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Regulatory challenges for innovation at product level

• Time to the market, cost, uncertainty

• Market dynamic, partly driven by regulation

• Since 2000, all resources are mobilized to support existing products

• Specific uncertainty with mixture toxicity

• Limited possibility to reverse at product level restrictions imposed at substance level (sensitization)
Which path forward?
How can innovation be stimulated?

- Facilitate R&D testing and provisional authorizations
- Fast-track for new active substances
- Regulatory stability (regulations, guidances, ...)
- Science-based transparent decisions
- Accept new products as a way to mitigate risk (mixture toxicity, sensitization, ...)
Possible innovation pathways

• Advanced diagnostic with proper combination of fast kill biocides and long term preservatives

• New biologically-derived actives: numerous candidates from academic R&D, but broad efficacy is challenging and manufacturing process feasibility are key for success

• Advanced formulations: encapsulation, reduced bioavailability, ...

• Mixtures of actives, use of boosters
Conclusion

The biocides industry needs help to reduce risk and accelerate development of new solutions that are necessary for many of the products and processes utilized globally

… an innovation-friendly regulatory environment

… and time to develop these solutions!
Thank you for your attention!

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