Opportunities for companies under the new Biocidal Products Regulation

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Cefic – European Biocidal Products Forum

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Overview

• Aim of the new BPR

• Opportunities offered by the new BPR

• Conclusion and outlook
New regulation on biocides

• **Shared Aim (all stakeholders):**
  - identify and undertake efforts to improve the regulation of biocidal products

• **Industry seeking efforts to identify and realise:**
  - Clarity, Predictability, Consistency, Efficiency in process
  - Measures to reduce administrative burden and time to market
  - Harmonisation in implementation and application
Opportunities offered by the BPR

Simplification and Streamlining

• Procedures & Authorisation options

• Mutual Recognition of authorisations - *in parallel or in sequence*

• Union Authorisation

• Biocidal Product Family

• Same Biocidal Products

• Simplified Authorisation Procedure

• Changes to authorised products
Union Authorisation

Objective: Facilitate access to the entire EU market

Opportunities:

• “One-stop shop” for companies to the EU market
• Address all concerns at once
• Widely applicable

• But:
  • Phased approach, high fees
Biocidal Product Family

Objective: Facilitate authorisation of closely-related products

• One authorisation for a group of biocidal products containing the same active substance(s) with similar uses

• Composition variations or replacement of non-active substances

• Individual products are defined

• Improvement on frame formulation concept
Biocidal Product Family

*Opportunities:*

- Possibility to change composition without new application and new authorisation (within permitted ranges)
- Easier to quickly comply with market demands
- Saves time and resources

*But:*

- All products need to have the same classification
2011 Industry survey

Objective: Assess impact of Union Authorisation and the Biocidal Product Family concept

- Joint exercise A.I.S.E – EBPF
- Questions about portfolio, intentions, expectations
- Approx. 90 companies, 8000 products, all PTs
- Contribution to the BPR second reading
Biocidal product family

71% of products could be grouped in families
(1980 dossiers)

Future

Family vs. individual

5423

823

1157
Market size

% of dossiers in different MS bands

- Regional (6-10): 33%
- Sub-regional (3-5): 19%
- Local (1-2): 16%
- European (>11): 32%
Union Authorisation

56% of dossiers for Union authorisation

<table>
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<th>Year</th>
<th>All Dossiers</th>
<th>UA</th>
<th>NA+MR</th>
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Same biocidal product authorisation

Objective: facilitate the easy authorisation of an existing product by a second company

• Regulation EU 414/2013, based on Art 17(7) of BPR
• Establishes the system of derived/duplicate authorisations, currently in place under many national systems
• Allows companies easy entry into the market based on existing authorisation of the same product
• “Mutual recognition between companies”
Same biocidal product authorisation

Opportunities:

• Companies can complement their portfolio and service with biocidal product without the heavy regulatory burden

• Focus of operation remains on providing best solutions
Simplified authorisation procedure

Objective: facilitate the marketing of products with lower concern – better profile with regard to HH and ENV

• For products with:
  • Active substances listed on (new) Annex I
  • Do not contain substances of concern, nor nanomaterial
  • Sufficient efficacy
  • No need to wear PPE
Simplified authorisation procedure

Opportunities:

• Faster process: evaluation within 90 days
• No requirement for Letter of Access to active substance dossier
• Once authorised in one Member State, notification to other Member States is sufficient
• But:
  • Concrete data requirements remain unclear
Conclusion and outlook

• The EU biocides regulatory scheme – BPD – places a heavy burden on industry and authorities

• The BPR introduces new opportunities and challenges

• A pragmatic use of the biocidal product family concept remains the best opportunity to decrease the regulatory burden

• Union Authorisation offers promise of streamlining and speed to market but there may be some constraints over its applicability
Conclusion and outlook

• Implementation is key
• There remains much work to be done in terms of providing guidance and clarity of processes in new areas
• Pragmatism and practical considerations need to prevail
• Continued dialogue among all stakeholders
Thank you for your attention

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