Where we are on biocides

Biocides Day
24 October 2018

Erik van de Plassche
Chair, Biocidal Products Committee
European Chemicals Agency
Biocides characteristics

Very complex

High workload

Limited capacity / resources

Limited political visibility

Small is beautiful – freedom
Luuk van Middelaar in *The Passage to Europe*:

“Thus far, the European Union has been able to “muddle through” on a middle ground that keeps the multitude of nations integrated, though still independent.”
Five years of operation: 2013 to 2018

- **IT**: R4BP, IUCLID, SPC Editor, EUSES
- **Guidance**: volumes I to IV
- **Transition** periods over
- **First Union** authorisations
- **Appeals**, court case and Ombudsman case
Data sharing: disputes and inquiries

- **2013:**
  - Inquiries: 20
  - Disputes: 0

- **2014:**
  - Inquiries: 80
  - Disputes: 10

- **2015:**
  - Inquiries: 160
  - Disputes: 10

- **2016:**
  - Inquiries: 60
  - Disputes: 20

- **2017:**
  - Inquiries: 40
  - Disputes: 0

- **2018:**
  - Inquiries: 40
  - Disputes: 0

Legend:
- **Inquiries**
- **Disputes**
## Data sharing: disputes and appeals

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List of active substances and suppliers (Article 95)
Technical equivalence applications

- Tier I
- Tier II
- TE
- not TE
Review Programme: 39% finalised

priority lists with product-types

I (PT 8; 14; 16; 18; 19; 21)
II (PT 3; 4; 5)
III (PT 1; 2)
IV (PT 6; 13)
V (PT 7; 9; 10)
VI (PT 11; 12; 15; 17; 20; 22)
Speeding up the Review Programme

Commission  Biocidal Products Committee
Approval of active substances

- **Approved**: 255 active substance and product-type combinations (144 active substances, of which 6 micro-organisms)

- **Non-approval decisions** based on evaluation and peer review: 15 active substance and product-type combinations

- Of all active substances for which an opinion adopted by Biocidal Products Committee: 19% meet the exclusion criteria and 12% are candidates for substitution
Review Programme workload: 377

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Renewal of active substance approvals: 5 active substance/product-type combinations not supported
Impact of endocrine disruptor criteria

• From now on, no Commission decision without an assessment against the new ED criteria (except for non-approval proposals)

• Commission approval decisions on hold for 11 active substances for 33 active substance and product-type combinations, due to ED assessment

• Two evaluations received by ECHA from Member State authorities since August 2017

• Co-formulants for product authorisation
Approval of *in situ* active substances

- Additions to the Review Programme: **55** active substance and product-type combinations for **28** active substances (Article 93 and 94; redefinitions)
- Majority for *in situ* generated active substances
- Do we make it too complex?
New actives substances

• **Biocidal Products Directive**: 3 active substances for 13 active substance and product-type combinations under evaluation by authorities

• **Biocidal Products Regulation**: limited number of applications

  ➢ almost no new chemistries
Product authorisation

- **National** authorisations: granted for **7 900** biocidal products (families)

- **Union** authorisations: granted for **2** biocidal product families and **2** for the same biocidal product family

- **Simplified** authorisation: **82** biocidal product authorisations granted

- Renewals for rodenticides and wood preservatives

- National regimes for product authorisation
National authorisations by product-type
Coordination Group: referrals

- Informal
- Formal

ECHA
European Chemicals Agency
Referrals by product-type

- 8
- 14
- 18
- 19
- other
Referrals: success

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National authorisation: changes

Year:
- 2013
- 2014
- 2015
- 2016
- 2017
- 2018

Categories:
- Administrative
- Minor
- Major
- Clas
## Union authorisation

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Same biocidal products for Union authorisation

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## Access to documents

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<tr>
<th>Year</th>
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| 2015 | 10       | • 7 active substance related  
• 2 product related  
• 1 for meeting documents |
| 2016 | 9        | • 7 active substance related  
• 2 product related |
| 2017 | 18       | • 11 active substance related  
• 4 product related  
• 2 for meeting documents  
• 1 for internal procedures (Article 95 list) |
| 2018 | 50       | • 4 active substance related  
• 46 product related: 35 documents available and disclosed, 33 product assessment reports and 2 SPCs |
Conclusions

• Review Programme did speed up but we have to keep the momentum

• Union authorisation: prevent formation backlog

• MSCAs need to focus on the Review Programme → this will free up resources used in national regimes

• Need to reduce complexity → in-situ, ED and SPC
Thank you
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