2nd ECHA Biocide Stakeholder day

Union Authorisation

Analysis of Benefits and Risks – Industry Perspective

Ludger Grunwald

Regulatory Affairs EMEA

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Agenda

- Introduction
- Objectives
- Benefits and Expectations
- Risks and Challenges
- Possible Next Steps
- Summary

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Objectives & Criteria

Union Authorization (UA)

- Harmonisation
- To facilitate access to the entire EU market
- One Authorisation valid across EU*
- Products with similar conditions of use
- Not open to substances fulfilling the exclusion criteria, rodenticides or antifouling products (Article 42(1))
- Progressive phase-in period for workability until January 2020

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* Unless explicitly restricted

Timeline

Union Authorization

- Pre-defined phase-in periods according to Article 42(1): Dossier Submission possible before!

1. Step

1 September 2013:

PT 1, 3, 4, 5, 18 and 19

Or a BP containing new active substances

2. Step

1 January 2017:

PT 2, 6 and 13

3. Step

1 January 2020:

All remaining PTs (beside those excluded)

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Source: echa.europa.eu

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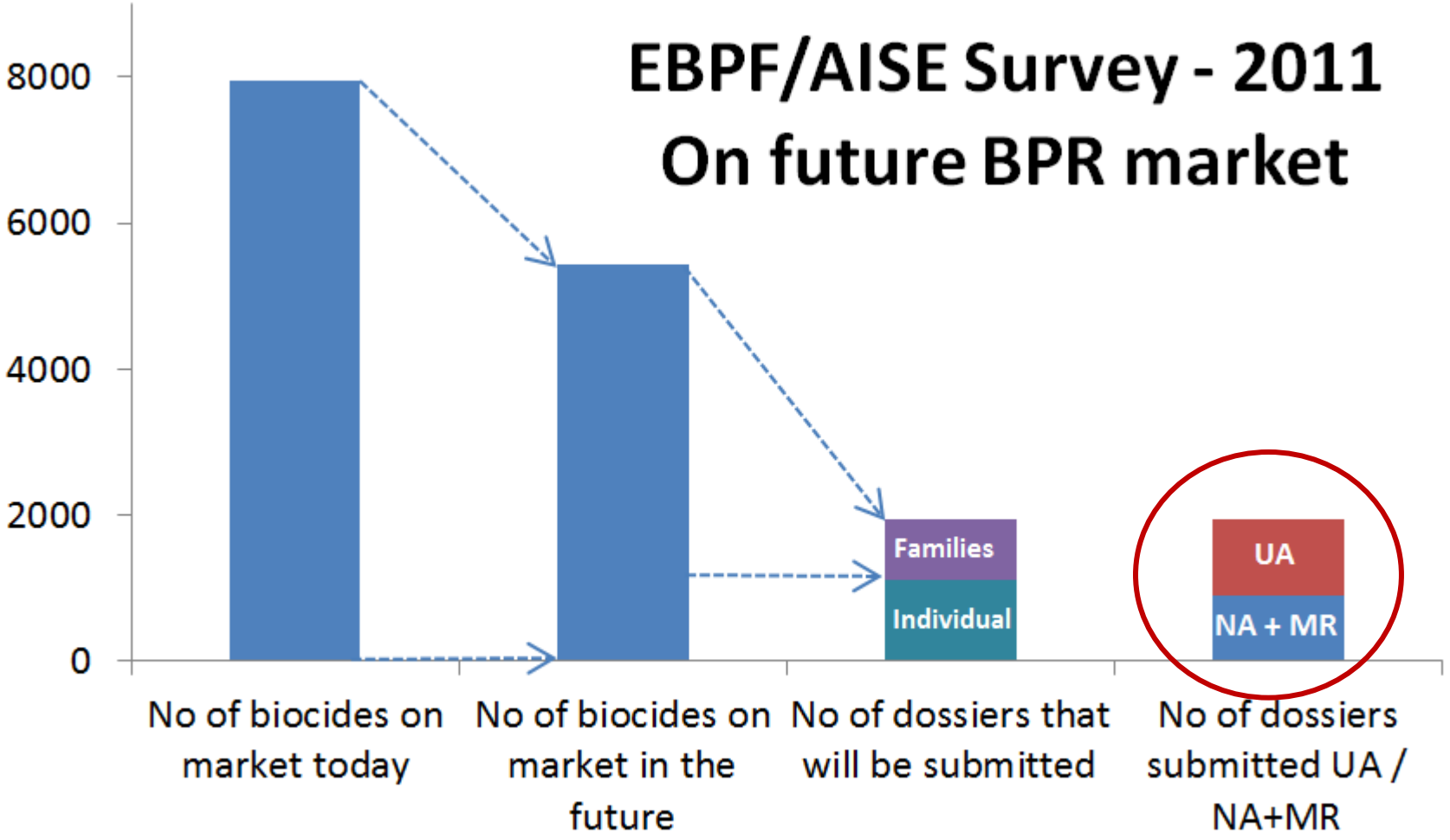
Benefits and Expectations

Union Authorization



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Benefits and Expectations:

Union Authorization

- One authorization valid across the EU market = **easy market access**
- ECHA driven process with clear deadlines = **predictability**
- Avoiding unnecessary testing due to optimized data requirements = **lower investment in data**

While:

- Effective products while ensuring a high level of protection for human health and the environment
- Reduced uncertainty related to data protection and waiving
- Increasing competiveness and innovation (biocidal family)

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Challenges and Risk:
Union Authorisation

- First risk/challenge: Union Authorisation is a new process,
  - how do you pick the right authorisation strategy for your company
  - how do you justify it financially
- Risks related to the next steps:
  - Finding a eCA to support your application
  - Dossier Preparation and addressing technical questions (e.g. Creating the right Biocide product family)
- While:
  - Ensuring compliance to Art 95
  - Ensuring technical equivalence
  - Time lines and process constraints

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Challenges and Risk:
Union Authorisation – Find a eCA

Evaluating Competent Authority (eCA)

Article 43 and 44

- Capacities
- Experience & Reputation
- Working methods
- Pragmatic
- Total fees
- Communication - language

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Challenges and Risk:

Union Authorisation – New Process and Timelines

Union Authorisation time lines
Article 42, 43, 44

- Role of ECHA Dossier Manager ?
- How to communicate?
- Helpdesk in practice?
- New Requirements
  - Pre-submission form
  - SPC’s
  - Active Dossier (Annex II)
  - Product Dossier (Annex III)
  - Confirmation “similar condition of use”
  - Confirmation of an eCA

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Challenges and Risk:
Union Authorization – Fees

Union Authorization fees

Fee Regulation

- UA Fees (80k€ / 150k€)
- Evaluation fees
- Annual fees UA
- Annual fees MS (?)
- Technical Equivalence fees (depends on AS source)
- Comparative assessment fees (in specific cases)

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Challenges and Risk:

Union Authorisation – Authorisation strategy

Authorisation Strategy
MR: Article 32, 33, 34 UA: Article 42, 43, 44

- UA vs MR or both?
- Simplified procedure possible – new Annex I?
- Same Products Authorisation – pick up list?
- Supplier product / active data (LoA)

Challenges and Risk:
Union Authorisation – Article 95

Approved Suppliers List
Article 95

- Product Supplier?
- Substance Supplier?
- Participant ?
- Every Legal Entity?
- *In-situ* ?

Guidance

Challenges and Risk:
Union Authorization – Technical Equivalence

Technical Equivalence
Article 54

- Responsibility to show TE with formulator but active supplier owns data
- Status of Participant always enough for TE?
- Alternative dossiers submission available?
- Understand data requirements

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Challenges and Risk:
Union Authorization – Technical Questions

Technical Questions
Guidance documents

- Product working acc. to new efficacy guidance?
- Avoid unnecessary data generation (e.g. waiver of Phy.Chem. endpoints in biocidal families)
- Risk Assessments
  - Dietary Risk Assessments
- IUCLID prepared for biocidal familiy

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Possible Next Steps

Steps for Industry

- Confirm your product portfolio
- Decide on authorisation strategy
- Contribute actively to different guidance development

Regulators

- Build guidance according to the new definition of a Biocide Product Family (including practical examples to understand the possible limitations of the concept)
- Need to finalise guidance on Article 95 and efficacy
- Acceptance of (high) number of SPC’s to make it workable for all

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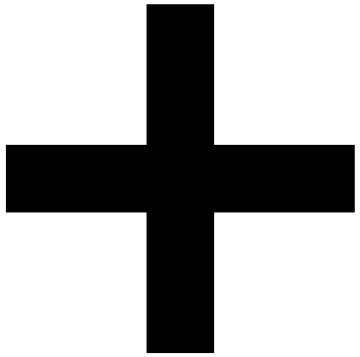
Summary



BENEFITS

- Possibility of Union Authorisation
- ECHA involvement & clear deadlines
- Biocidal Product Family

RISKS

- High authorisation costs
- New and highly complex process
- Remaining uncertainties, lack of guidance

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QUESTIONS AND ANSWERS

Dr. Ludger Grunwald
REGULATORY AFFAIRS EUROPE, MIDDLE EAST & AFRICA
ECOLAB DEUTSCHLAND GMBH Ecolab-Allee 1, D-40789 Monheim am Rhein, ludger.grunwald@ecolab.com