BPR – new processes

Biocides Stakeholder's Day

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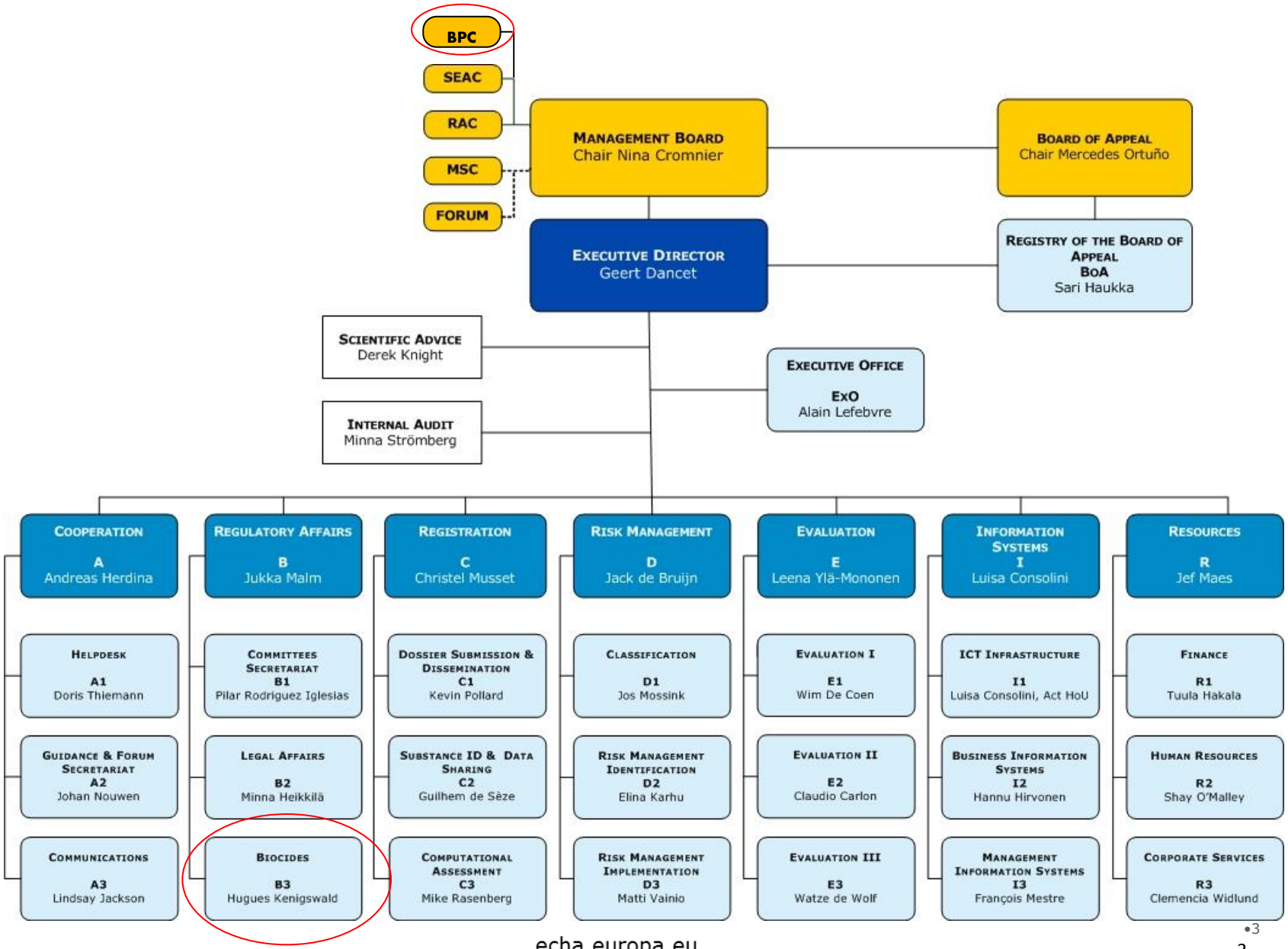
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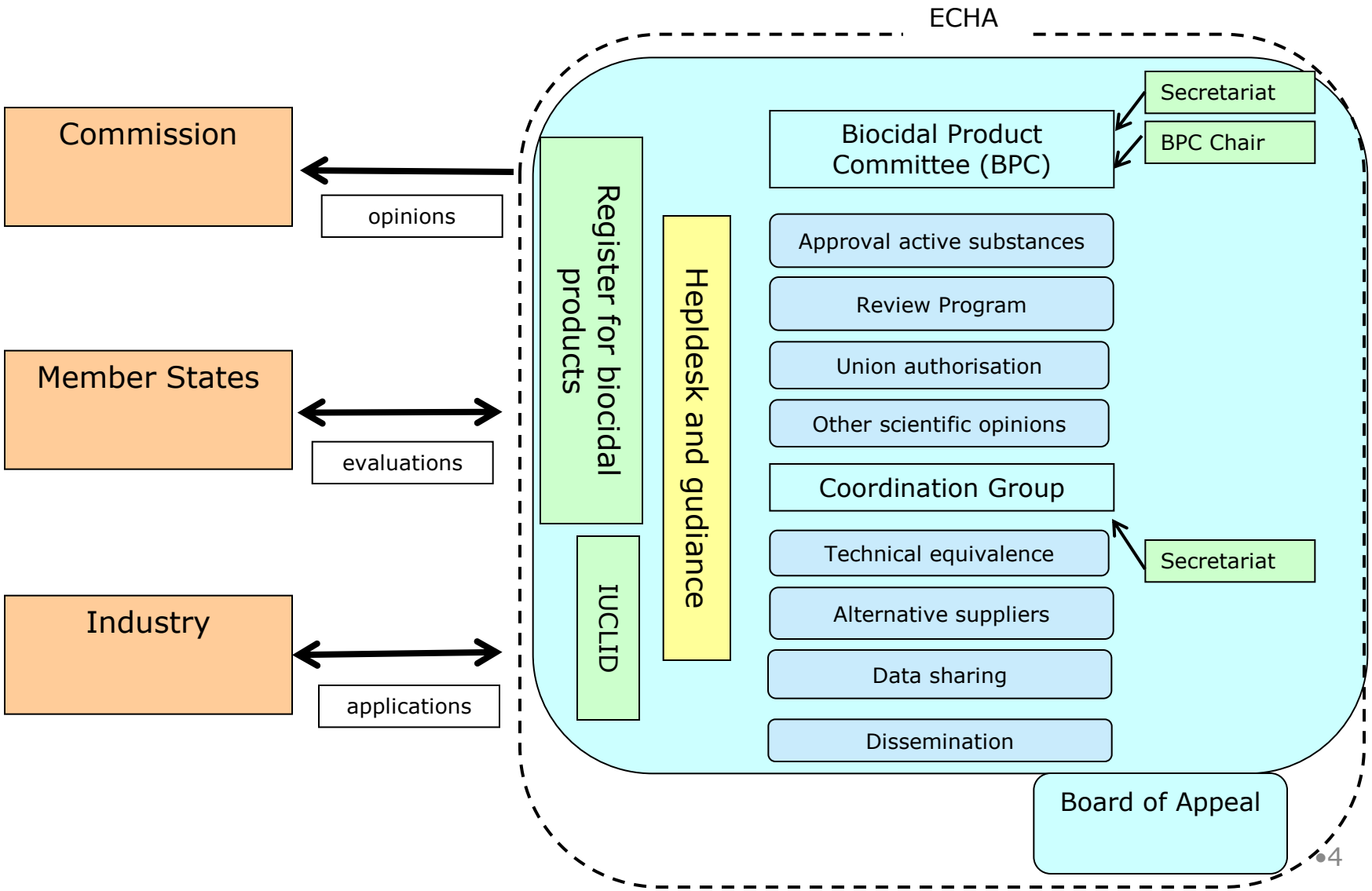
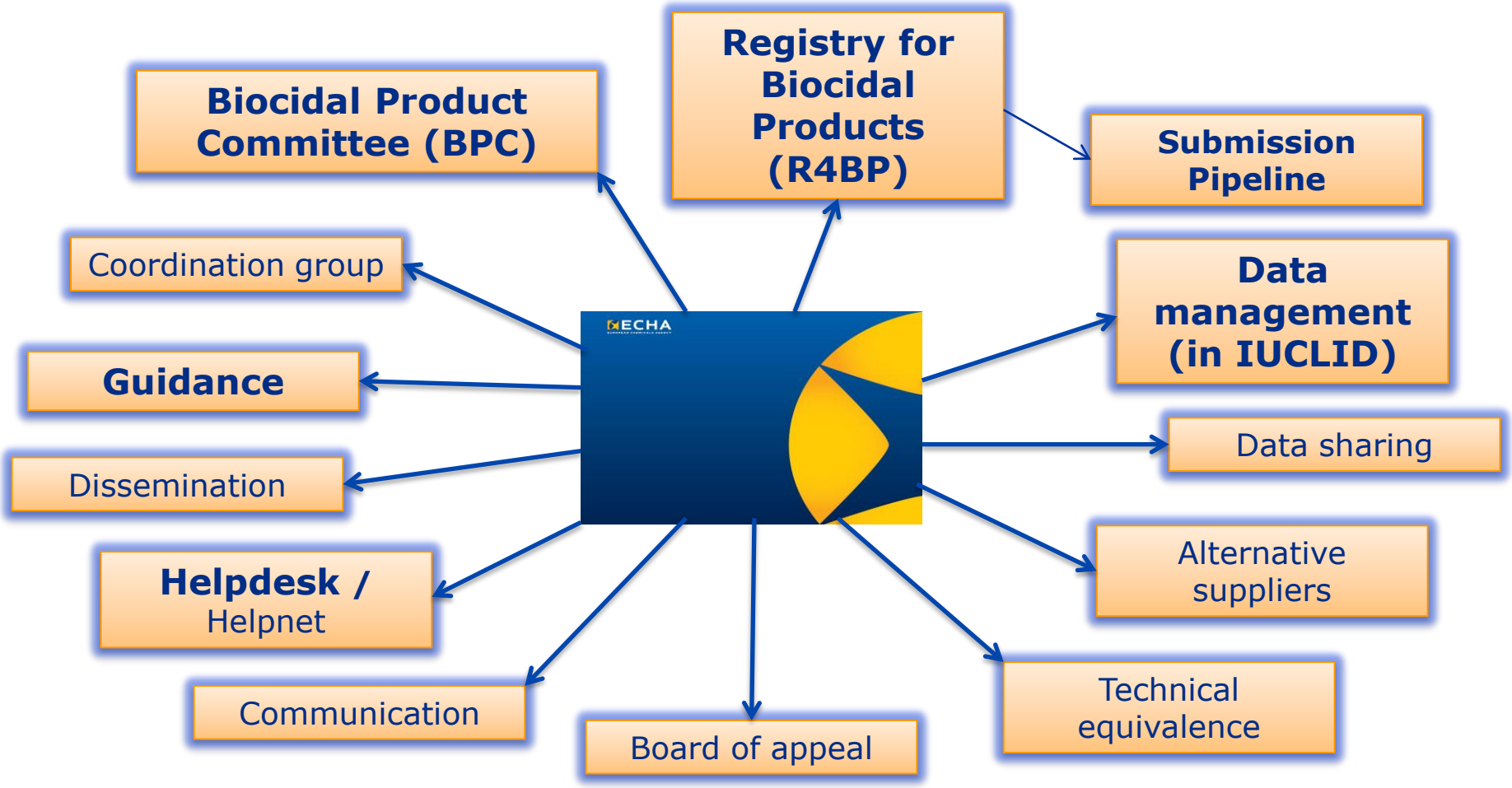
ECHA: a central role

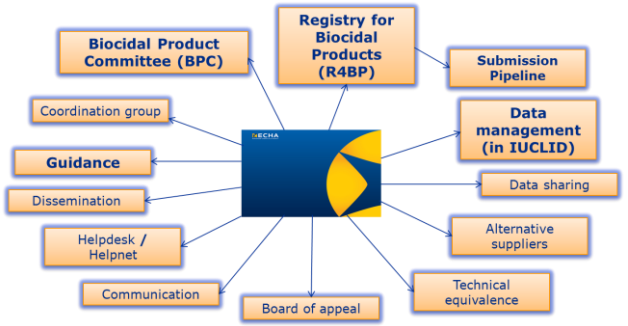


The role of ECHA in biocides



Summary of the role of ECHA in biocides

- **Centralised IT system**
  - Register for Biocidal Products (hub for all applications)
  - IUCLID 5.5 including biocides functionalities.



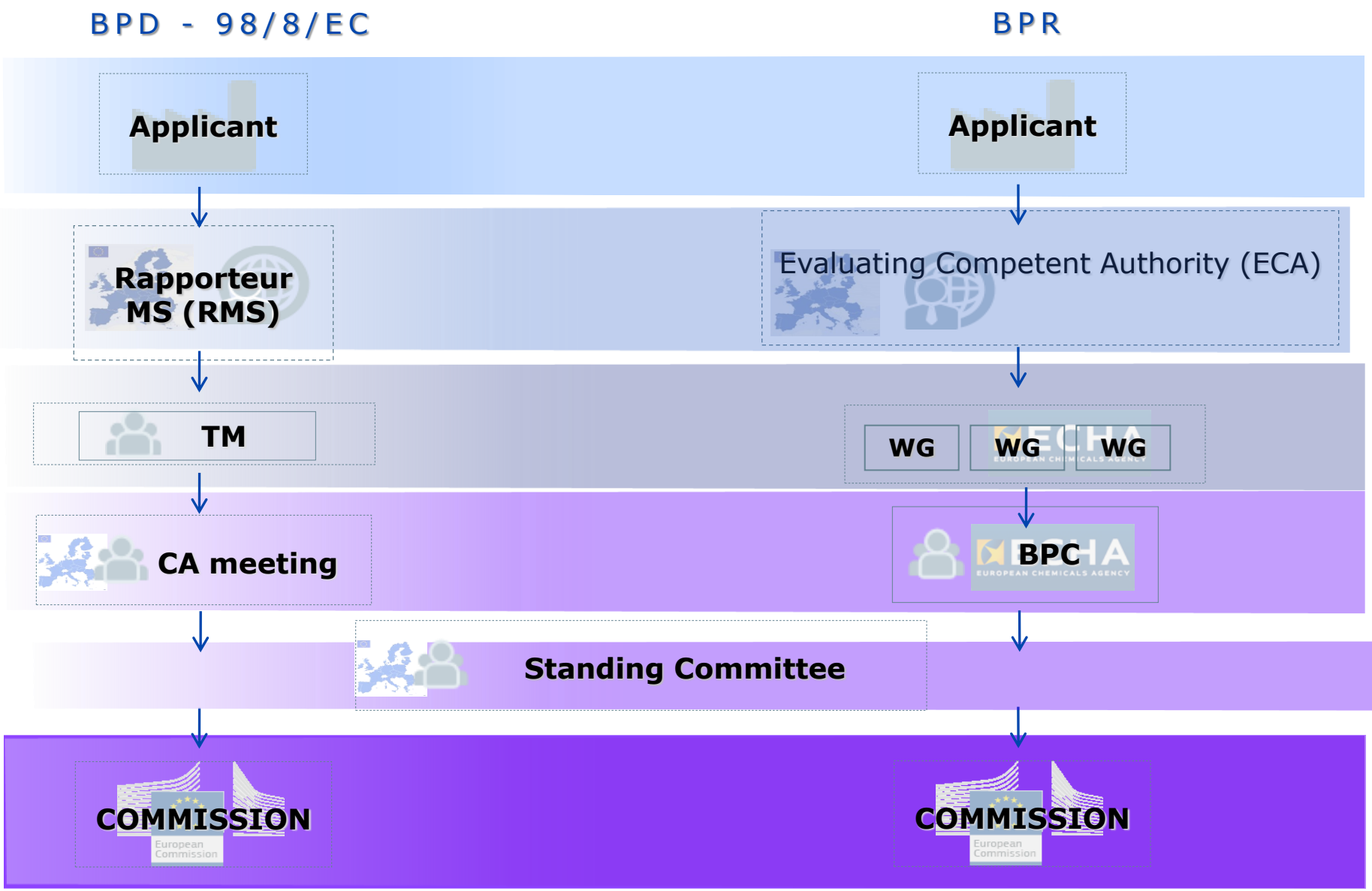
- **Biocidal Products Committee and Coordination Group**
  - Central bodies for an EU-wide approach
  - Scientific and administrative support to members
  - Assure quality, consistency and transparency

- **Support to applicants and Member States**
  - Provide guidance and an ECHA Helpdesk / Helpnet
  - Promote a consistent approach between Member States

- **Data sharing, dissemination and technical equivalence**
  - Benefit from REACH experience

- **Communication**
  - Awareness raising with key actors and stakeholders

Old vs. new system - mapping



Preparatory activities

Building up the operational capacity

- ECHA's capacity still under development
  - Financial constraints due to less fees than planned
  - Prudent approach to recruitment:
    - 44 staff foreseen in end 2013 (-23% vs. planning)
    - More need for administrative staff (interims)
  - Impact on preparations

- Sufficient MS resources?
  - Continuing the approval of applications under BPD
  - Preparing for EiO of the BPR
  - Ability to accelerate the review programme

Operational on 1 September 2013

- But with certain limitations
  - Time constraints
  - Resources constraints
- Priorities:
  - Ensure industry can apply & comply with BPR
  - Ensure MSCAs can operate under the BPR
- Focus on key structures & functionalities

Key structures & Key functionalities

- IT systems
  - IUCLID 5.5: active substances & biocidal products
  - R4BP v3.0: submission of application types necessary on 1 September 2013
- Biocidal Products Committee & working groups
- Coordination Group
- Secretariat: adequate support
- Guidance: essential ones first
- Helpdesk & Communication

R4BP3 and IUCLID 5.5: common hub and paperless system

R4BP v3

- One submission system for all applications
- A major change
  - Electronic submissions
  - European common system
- On the road to automation via further versions

IUCLID 5.5

- Companies can store all info on biocidal substances & products in one IT system
- Endpoint information is structured on international standards (OECD)
- Supports preparation of all biocide applications and notifications
- Database storage system for ECHA & MSCAs

Managing the change together

Conclusions

- Improvement vs BPD
- New opportunities
- New rules and processes
- A challenging situation:
  - Strict and short legal timelines
  - Paperless system
  - Rules and processes change
  - Increased workload and resources constraints

Thank you

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