

# Achievements – one year after entry into operation

## Biocides Stakeholders' Day

24 September 2014

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## Overview

- Applications
- IT tools
- Communication, guidance and support
- Cooperation with stakeholders
- Biocidal Products Committee and Working Groups
- Coordination Group

## Where are we now?



- Starting point: one year before entry into operation
- Opening doors: 1 September 2013
- Complex and evolving framework ...
- ...but it works
- Improving



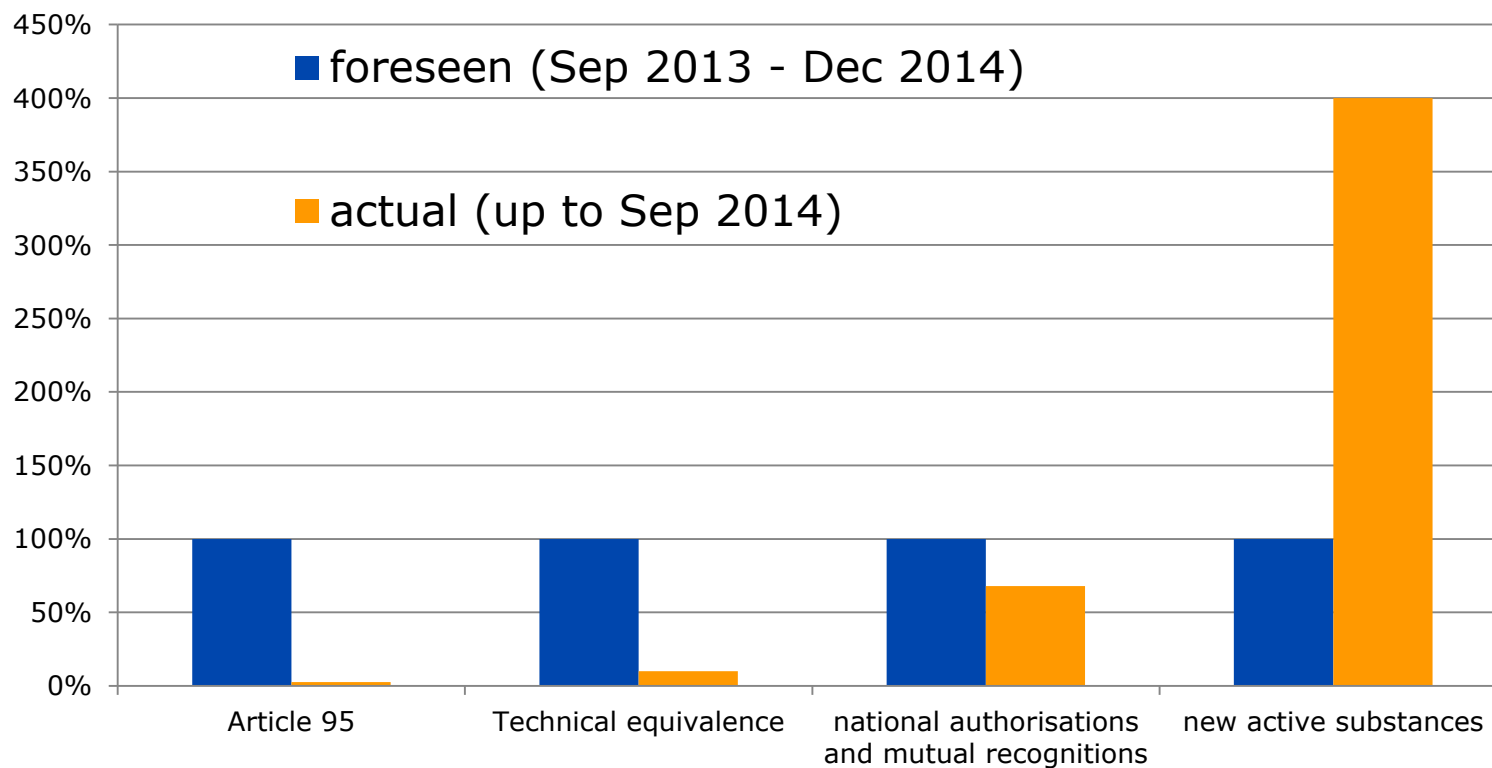
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## **3000 applications processed since 1 September 2013 (1500 in 2013)**

- Large majority for national authorisations and mutual recognitions
- Active substances:
  - New active substances: 8
  - Annex I inclusion: 1
  - Renewals: 2
- Article 95: 11
- Technical equivalence: 9
- Union authorisation: expected in 2015
- Data sharing: 47 inquiries; 5 disputes

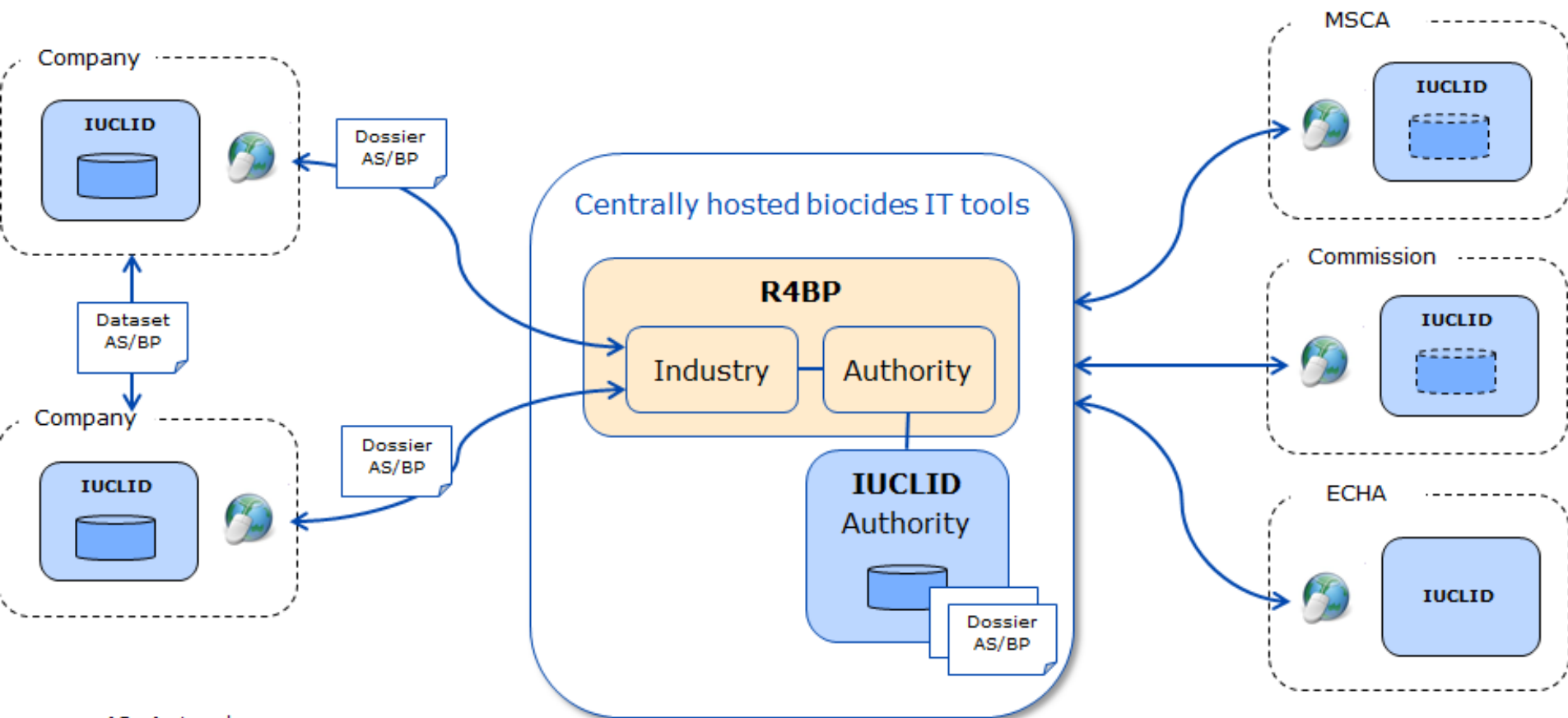
# Applications: forecast vs reality



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# Register for Biocidal Products (R4BP 3.1)



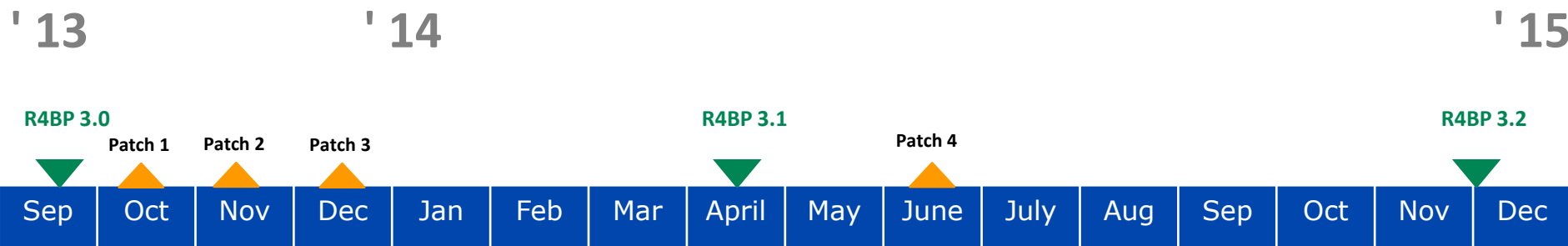
AS = Active substance  
BP = Biocidal product



## IT tools

- R4BP 3 (submission): 2 releases  
3rd release in December 2014 – major improvements
- IUCLID (scientific data): specific tools since v 5.5
- SPC editor: foreseen in October 2014
- Migration R4BP2 – R4BP 3
- Submission manuals + Manual for competent authorities
- Involvement of stakeholders
- Specific Helpdesk support

# R4BP 3



3.0

3.1

**3.2**

**+case types & workflows/improved usability**

**++case types & workflows/improved usability/enhanced productivity/ SPC**

Testing

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## Communication, guidance and support

- >100 specific web pages
- Guidance documents
- Practical guide: NEW
- Webinars
- Participation in conferences and workshops
- Helpdesk support + national support + HelpNet



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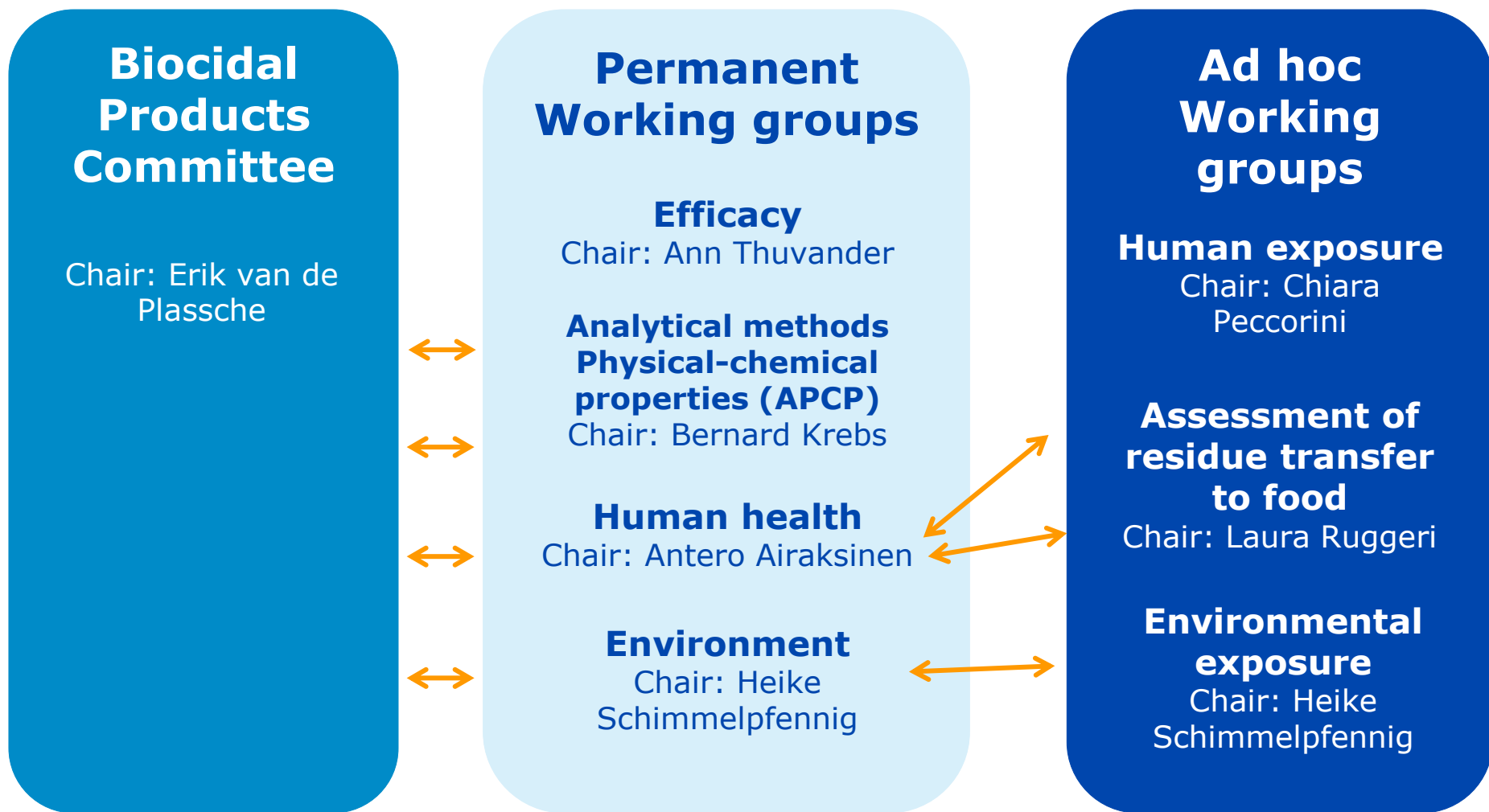
## Cooperation with stakeholders

- Support to applicants  
(before and after submission)
- Participation to BPC and WG meetings
- Involvement of accredited stakeholder organisations
  - feedback and suggestions
  - coordination role
  - specific meetings
  - dissemination of information

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# Structure of the BPC and its Working Groups





# Biocidal Products Committee and its Working Groups

- Biocidal Products Committee (BPC):
  - 3 preparatory meetings (2013)
  - 5 meetings in 2014
  - 18 opinions already adopted
- BPC Working groups:
  - >20 meetings in 2014

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## Coordination Group

- Settlement of mutual recognition disputes
  - 3 formal disagreements (2 solved)
  - informal discussions
  - 2 meetings in 2013
  - 6 meetings in 2014
- Forum for discussions on product authorisations:
  - Requirement for renewal applications
  - Format of Summary of Product Characteristics (SPC)
  - Feedback on IT tools

## Conclusions

- Thanks to a collective effort with MSCAs and Commission, much has already been achieved
- Still work in progress (new legislation, implementation, improvement)
- ECHA is here to help

# Thank you

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