Review programme

Biocides Stakeholder's Day

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Erik van de Plassche
Chair Biocidal Products Committee
European Chemicals Agency

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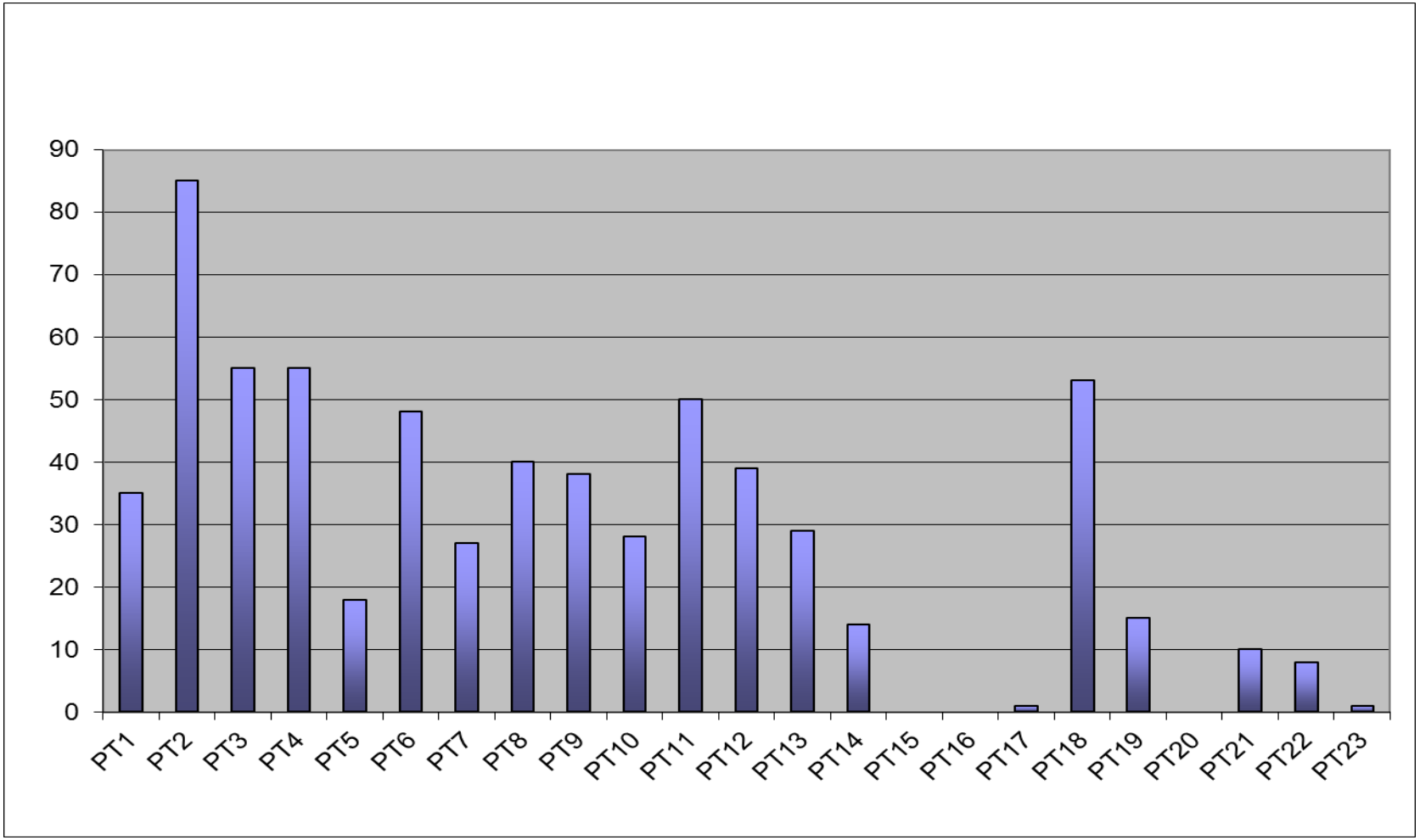
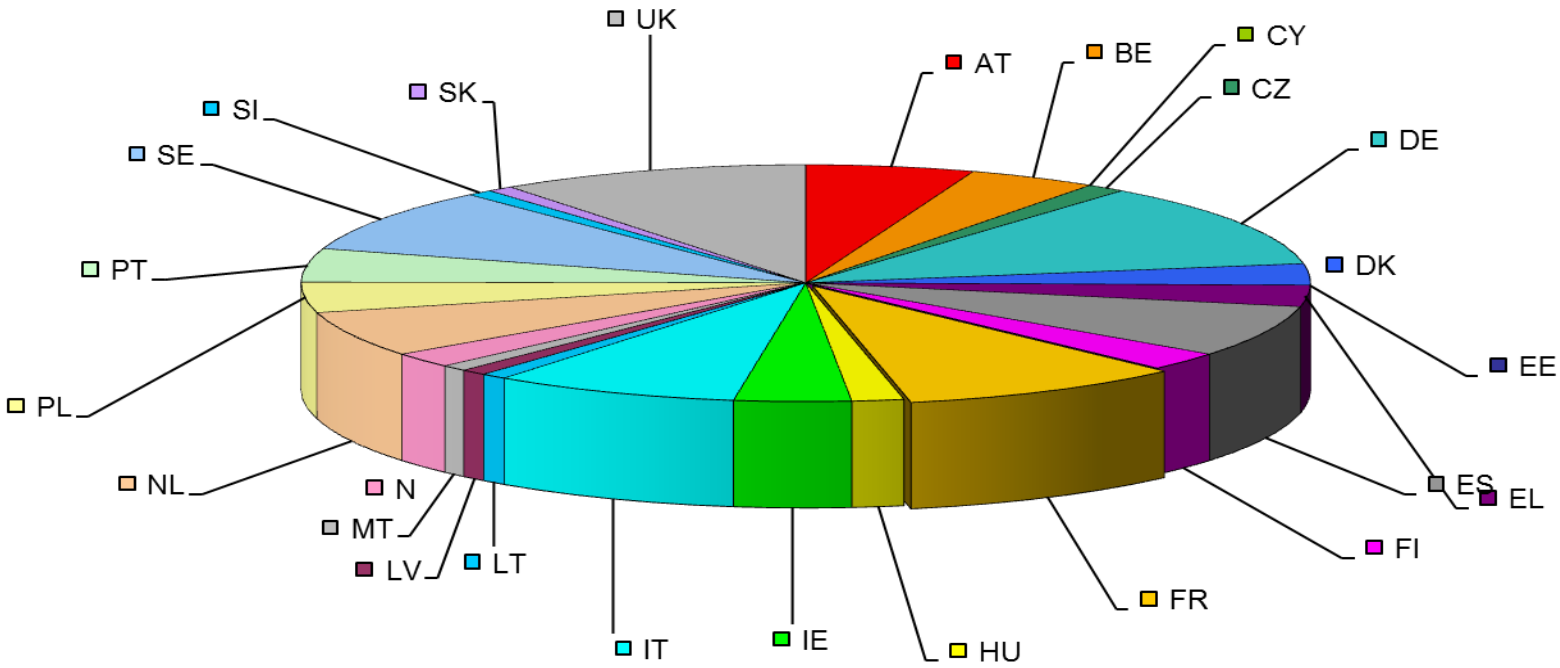
Status review programme

Total dossiers per product-type



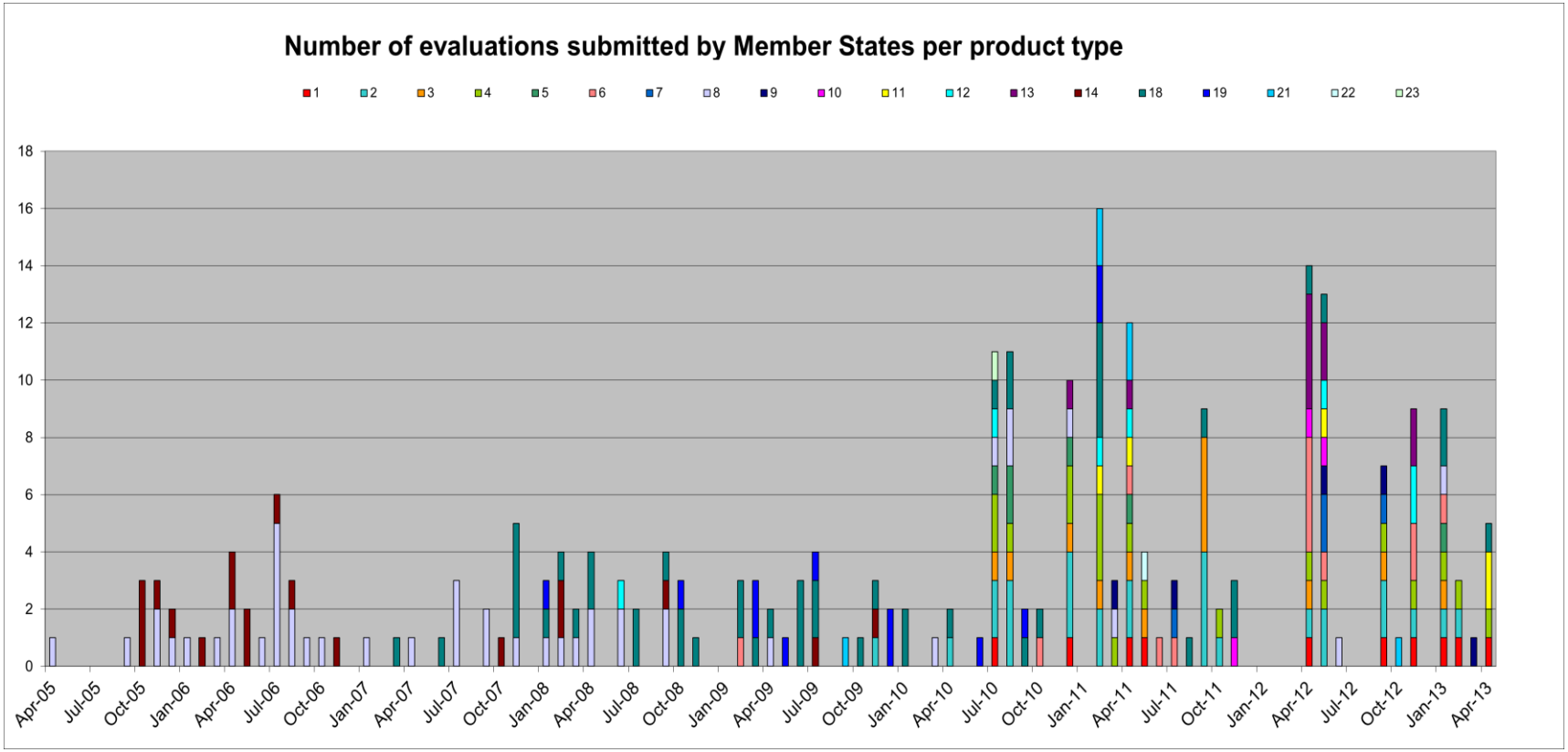
Distribution of dossiers



Regulatory status

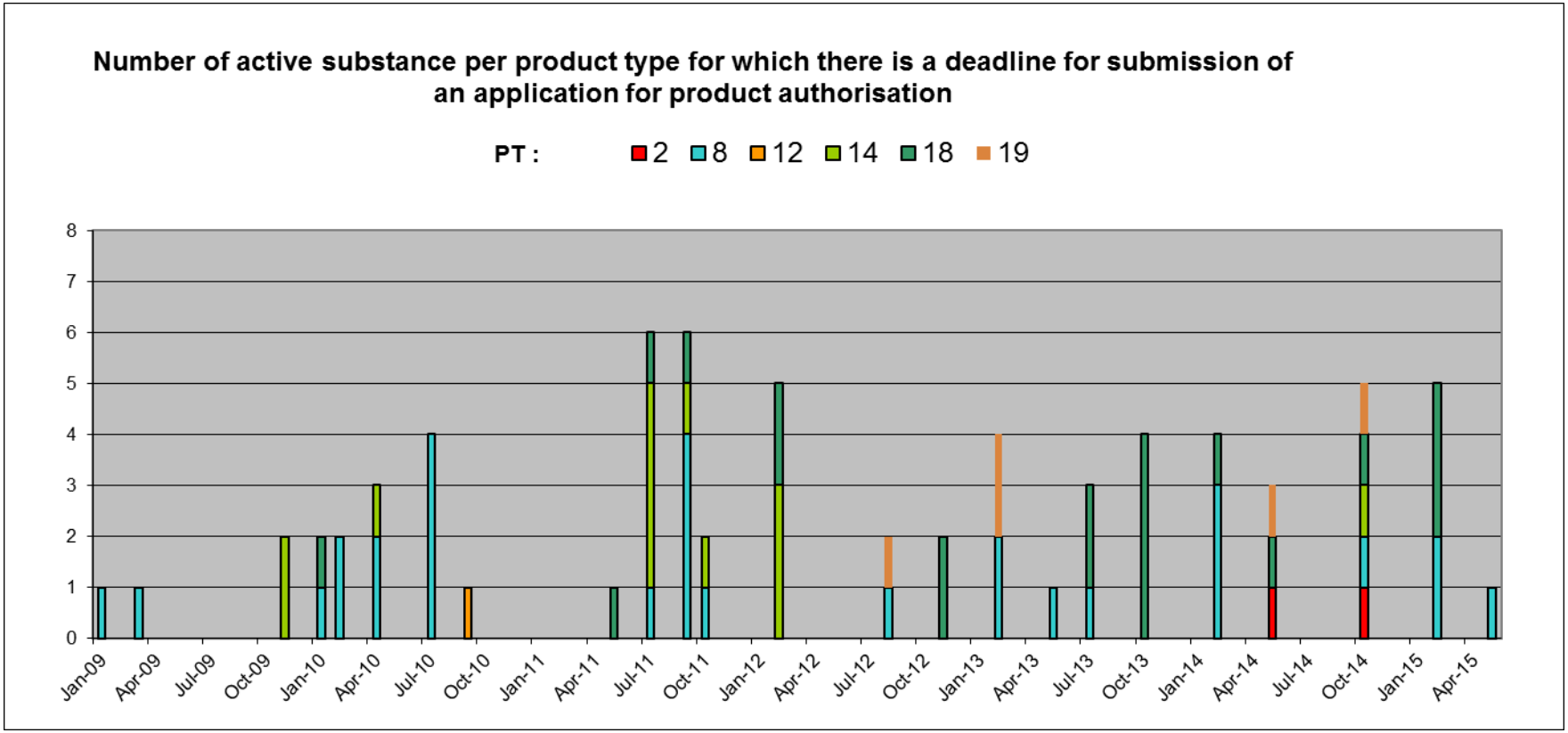
- Article 89(1) states deadline for review programme: 14 May 2014
- Delegated act underway to establish new deadline for finalisation: 31 December 2024
- Review programme governed by Regulation (EC) No 1451/2007
- ECHA will take over coordination from 1 January 2014

Number of evaluations submitted by Member States



- Since 2005 around 250 evaluations submitted
- After submission by Member States: peer review process at EU level

Decisions on dossiers



- Around 70 active substances approved (Annex I under BPD –› Union list active substances under BPR)

Summary status review programme

- Number of dossiers (active substance product-type combinations):
  - Total: 660
  - Approved: 70
  - In peer review process at EU level: 160
  - Still to be submitted by Member States: 430

- Commision intends to decide on 30 dossiers in the second half of 2013

Work programme to meet the 2024 deadline

Based on proposal Commission:

”Review programme of active substances: establishment of a work programme to meet the 2024 deadline” (CA-May13-Doc.8.3)

Submission deadlines by product-types

Priority list	Product-type	Submission evaluation by Member State to ECHA	Submission BPC opinion by ECHA to COM
1	8; 14; 16; 18; 19; 21	31 Dec 2014	30 Sep 2015
2	3; 4; 5	31 Dec 2016	30 Sep 2017
3	1; 2	31 Dec 2018	30 Sep 2019
4	6; 13	31 Dec 2019	30 Sep 2020
5	7; 9; 10	31 Dec 2020	30 Sep 2021
6	11	31 Dec 2022	30 Sep 2023
7	12; 15; 17; 20; 22	31 Dec 2023	30 Sep 2024

Principles

- Deadlines in various procedures applied more strictly: i.e. applicants submission of additional information requested by Member States during evaluation
- From now on for submissions of dossiers by Member States: finalise harmonised classification and labelling under CLP and PBT assessment, where relevant, first
- Once ECHA starts to work on a dossier: the Biocidal Products Committee has 270 days to deliver its opinion

Further steps

- Endorsement of Commission proposal in 10–12 July meeting of competent authorities
- Commission will amend Regulation (EC) No 1451/2007 to establish legally binding deadlines
- ECHA to develop detailed work programme for Biocidal Products Committee for 2014–2016 with the objective of 50 opinions on existing active substances per year

Principles for decision making

Based on proposal Commission:

”Note of the principles for taking decisions on the approval of active substances under the BPR” (CA-May13-Doc.3.0)

Issue

- Evaluations submitted by Member States under the Biocidal Products Directive (BPD)
- However, decisions will be taken under the Biocidal Products Regulation (BPR)
- Conclusions regarding compliance with general requirements of BPD are also valid for establishing compliance with general requirements of BPR

New requirements for approval of active substances in BPR

- Exclusion and substitution criteria
- Nanomaterials: approval shall explicitly mention if it covers the nanoform
- Treated articles:
  - Provision on labelling of treated articles established in approval if a specific concern is identified in an assessment
  - Concerning the limitation on the possibility of active substances used in treated articles: restrictions only where a specific concern is identified versus ”positive listing”
- Potential for inclusion in Annex I of BPR

Procedures for approval

- New provisions of the BPR need to be taken into account and reflected in assessment report
- Exclusion and substitution criteria: limited to those criteria for which there are clear rules, i.e. CMR and PBT –› comparative assessment under product authorisation
- Only possiblity for applicants to provide additional information under Article 90(2) of BPR: to demonstrate that the conditions for derogation to the exclusion criteria according to Article 5(2) are met

Conclusions

Conclusions

- End Review Programme: 31 December 2024
- Total 660 dossiers for which 70 decisions have been taken on approval of an active substance product-type combination
- Commission is considering establishing legal deadlines for seven lists for groups of product-types
- BPR will apply for evaluations submitted by Member States

Thank you

erik.vandeplassche@echa.europa.eu