Role of the BPC in Active substance approval and Union authorisation

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Content

- → Introduction to the BPC
- → BPC's role in decision making
- → Status of review programme for active substances
- → Addressing substitution and exclusion criteria at the BPC
- → Recent developments in Union Authorisation
- → Closing messages

Introduction to the BPC

Structure of the BPC

- → Established at ECHA
- → Composed of members from the EU member states (voting rights), Norway and Switzerland.
- → Chair from ECHA
- → Preparatory scientific discussions take place in Working Groups
- → 4 annual meetings
- → Applicants and ASOs can participate in the meetings

Role of the BPC

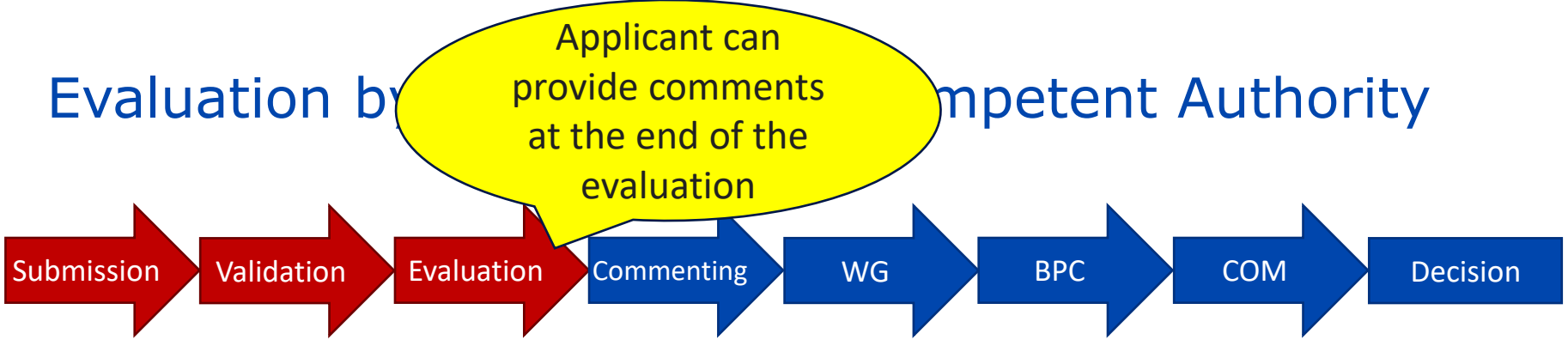
→ Primary role: prepare, discuss and adopt opinions

→ Opinions on:
- Active substances
- Union authorisation
- Art. 15 (review of AS approval) art. 38 (disagreements in mutual recognition) art. 75(1)(g) (any other question)

→ Opinions should be fit-for-purpose to allow the European Commission to take decisions

BPC’s role in decision making

Evaluation by [illegible] mpetent Authority

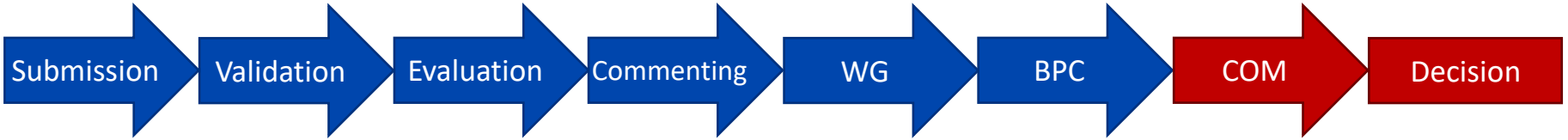


- → Submission of the applicant of a complete dossier, prepared in compliance with the applicable guidance
- → Validation by the eCA of the dossier, considering whether data is present
  - The eCA may request additional data
- → Evaluation by the eCA: preparing an assessment report, draft opinion and, if applicable, a draft SPC
  - The eCA may request additional data

Opinion formin

- → Upon submission of the AR, SPC and opinion, the other member states provide (scientific) comments, which are discussed at the Working Groups (the WG may decide to request additional data)
- → Any open comments and new (regulatory) comments are discussed at the BPC, where the opinion is adopted
- → The opinion is not a decision, it should be seen as an advice to the European Commission for decision making

Decision making



- → Upon submission of the BPC opinion to the European Commission, a decision is prepared based on this opinion
- → The decision is discussed and voted upon in the Standing Committee

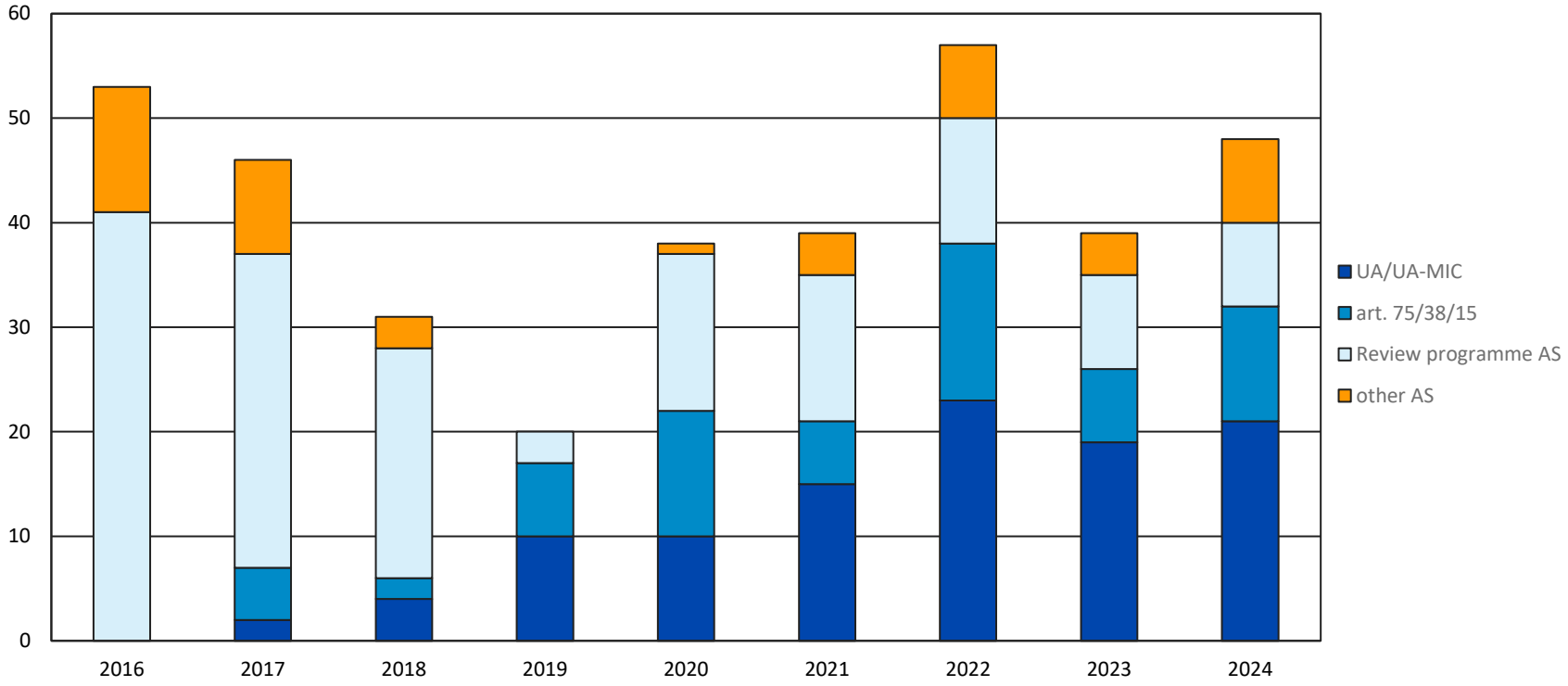
Similar process for most application types

→ Active substances
- Approval
- Renewal (No WG meeting with a limited evaluation)
- Inclusion in Annex I)

→ Union authorisation
- Authorisation
- Renewal
- Major changes (No WG meeting)

→ Art. 15 / art. 38 / art. 75(1)(g) (slight changes in the process on a case by case basis)

Number of opinions discussed at the BPC per year



Status of review programme for active substances

Deadline finalisation of the Review Programme

- → Second prolongation ending 31 December 2024
- → Commission discussed with competent authorities in 2023
  - What is needed to conclude the Review Programme?
  - What timeline and how to prioritise substances?
- → Competent authorities agreed in December 2023 on measures to enable the Review Programme finalisation
- → Commission Delegated Regulation (EU) 2024/1398 of 14 March 2024 -> new end date is 31 December 2030

Review Programme measures:

Among others the following measures were agreed

→ Member States to allocate sufficient resources

→ Respect rules and procedures (e.g. withdrawal in accordance with Art. 11 of Com. Del. Reg. (EU) No 1062/2014)

→ All ED data to be provided by 31 December 2026

→ Backlog dossiers to be concluded with BPC opinions by 31 December 2025

→ BPC is competent to conclude on CMR, therefore we will no longer wait for RAC to conclude on a harmonised CLH

CA-Dec23-Doc.5.4 - Final - Extension of RP beyond 2024.docx

Consequences for BPC

→ Successful in getting backlog dossiers to the BPC

→ BPC needs to conclude on CMR properties, for which it previously relied on CLH outcomes (RAC)
- Develop expertise at the WG
- Supported by ECHA staff experienced in classification

→ Delays in the opinion forming of these specific dossiers are observed

→ Overall positive results as after 10+ years there is progress in these dossiers

ECHA support to Member States

ECHA initiated several activities to support the Member States in speeding up finalisation of the review programme

- → Early Working Group discussions to solve issues prior to the opinion forming phase
- → Amending working procedures with the aim to simplify the procedures and to ensure high quality of the output
- → Support on the assessment of ED properties (workshops and one-on-one meetings)
- → Preparations to establish an art. 5(2) ad hoc WG

Addressing both substitution and exclusion criteria at the BPC

Substitution and exclusion criteria

→ Substances meeting exclusion criteria (Art. 5 of the BPR)

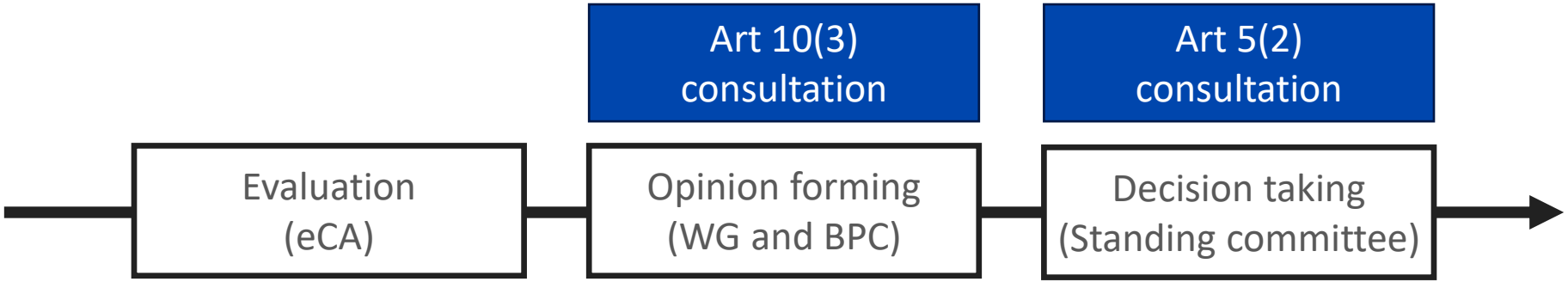
- Substances that are carc., muta., repro. (1A or 1B) or ED
- Not approved unless:
  - risk of exposure is negligible
  - essential to control serious danger
  - disproportionate negative effect on society

→ Substances that are candidate for substitution (Art. 10 of the BPR)

- Substances that e.g .meet exclusion criteria, respiratory sensitiser, meeting 2 PBT criteria
- Comparative assessment for products based on the active substance

Consultation procedure on art 10(3) and 5(2)

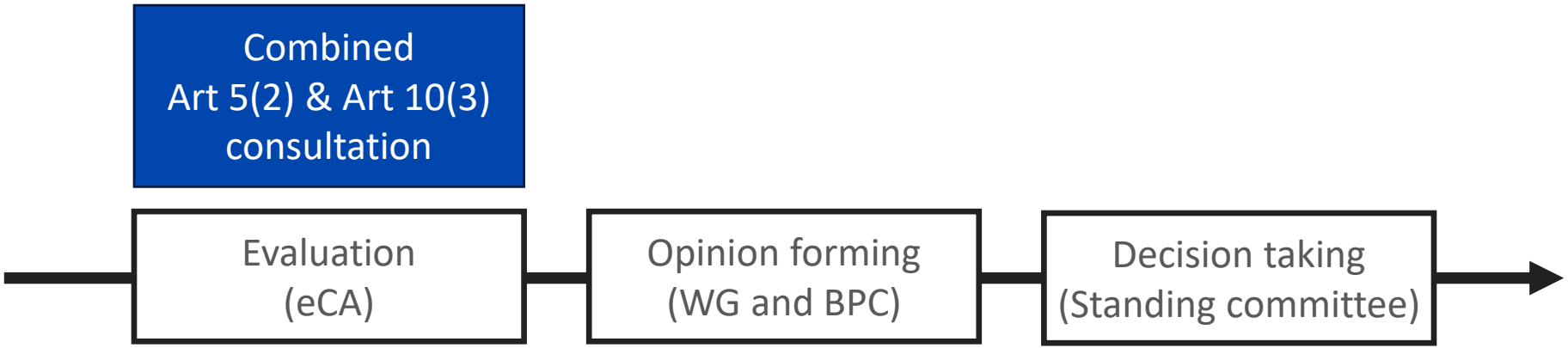
Old situation



The BPC opinion did address alternatives, in line with art 10(3)
The BPC opinion did not address the conditions of art 5(2), which therefore needed to be assessed at the standing committee

Updated consultation procedure

New situation



- eCA to address both 5(2) and 10(3) during evaluation
- Involvement BPC, possibly establishing an ad hoc WG
- Late identification of substances meeting excl./subst. criteria remains issue

Be aware of the consultation procedures

- → Aim: obtaining purposeful information for every use
- → Applicant provides their Analysis of Alternatives, which is published in the consultation
- → Provide detailed descriptions of the use(s) and justifications for derogations - in relation with the availability of chemical and non-chemical alternatives
- → Also consider potential alternative substances meeting exclusion/substitution criteria
- → ECHA communicates the launch of consultations – follow us! (website, newsletter, social media)

Recent developments
Union Authorisation

Current UA developments

→ First opinions on major change issued
- Procedures and timelines available on BPC website
- Applicants should be aware of very short timelines in opinion forming: no WG discussion, therefore no possibility to provide additional data!

→ First applications for renewal expected soon
- Procedures and timelines available on BPC website

https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

Letters of access

- → Practical guide on letters of access has been updated
- → The update includes several clarifications, including on the addressees of letters of access
- → Letters of access for Union authorisation of same biocidal products (UA-BBP/UA-BBS) should be addressed to **ECHA and the European Commission**
- → Letters of access for Union authorisation (UA-APP) should be addressed to **the eCA, ECHA and the European Commission**
- → The letters of access templates were updated accordingly

https://echa.europa.eu/documents/10162/1276600/pg_letters_of_access_en.pdf/16ce6a2c-49a2-494a-b0b8-f1d438709782

Closing messages

Take home messages

→ Prior to submitting an application, Familiarise yourself with:
- the data requirements
- Procedural aspects (possibilities to submit additional data and in general the applicant's involvement in the process)

→ Active substance meeting substitution/exclusion criteria
- Prepare analysis of alternatives
- Prepare for the consultations

→ Union authorisations
- Be aware of the procedural aspects of the various types of applications: timelines and possibilities to provide data
- Quality of the Summary of Product Characteristics (SPC) and quality of the translations

Thank you

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