BPR Review: An update

Chemical Watch - Key Regulatory Updates: Europe, Asia and the Americas
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Steptoe

Darren Abrahams

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"exceptional expertise on EU regulations on chemicals…and a great ability to understand the complexity of businesses."
"When it comes to things like REACH and chemical law, he is the best"
Chambers & Partners Europe, 2019 and 2020

- **English barrister, *Avocat* at the Brussels Bar**, Partner.
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market**.
- He focuses on **defence of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.
- Chambers & Partners **Europe-wide** Regulatory (2020): **Agro/Food and Environment** Legal Rankings: **top tier practitioner in both, and Steptoe listed as a band 1 firm.**

Hannah Widemann

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- ***Advocaat* at the Brussels Bar** and Associate.
- She advises clients on **EU regulatory compliance** questions in the areas of **chemical** and **product regulations**, including **REACH**, **CLP**, **biocides**, **plant protection products**, and **fertilizers**.
- Her work includes **product defense** and **litigation strategies** before the European Court of Justice and the Board of Appeal of the European Chemicals Agency (ECHA), as well as supporting clients with (data sharing**) negotiations**, **contracts**, and **potential disputes**

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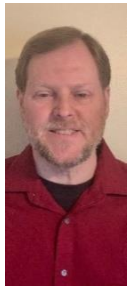

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Outline

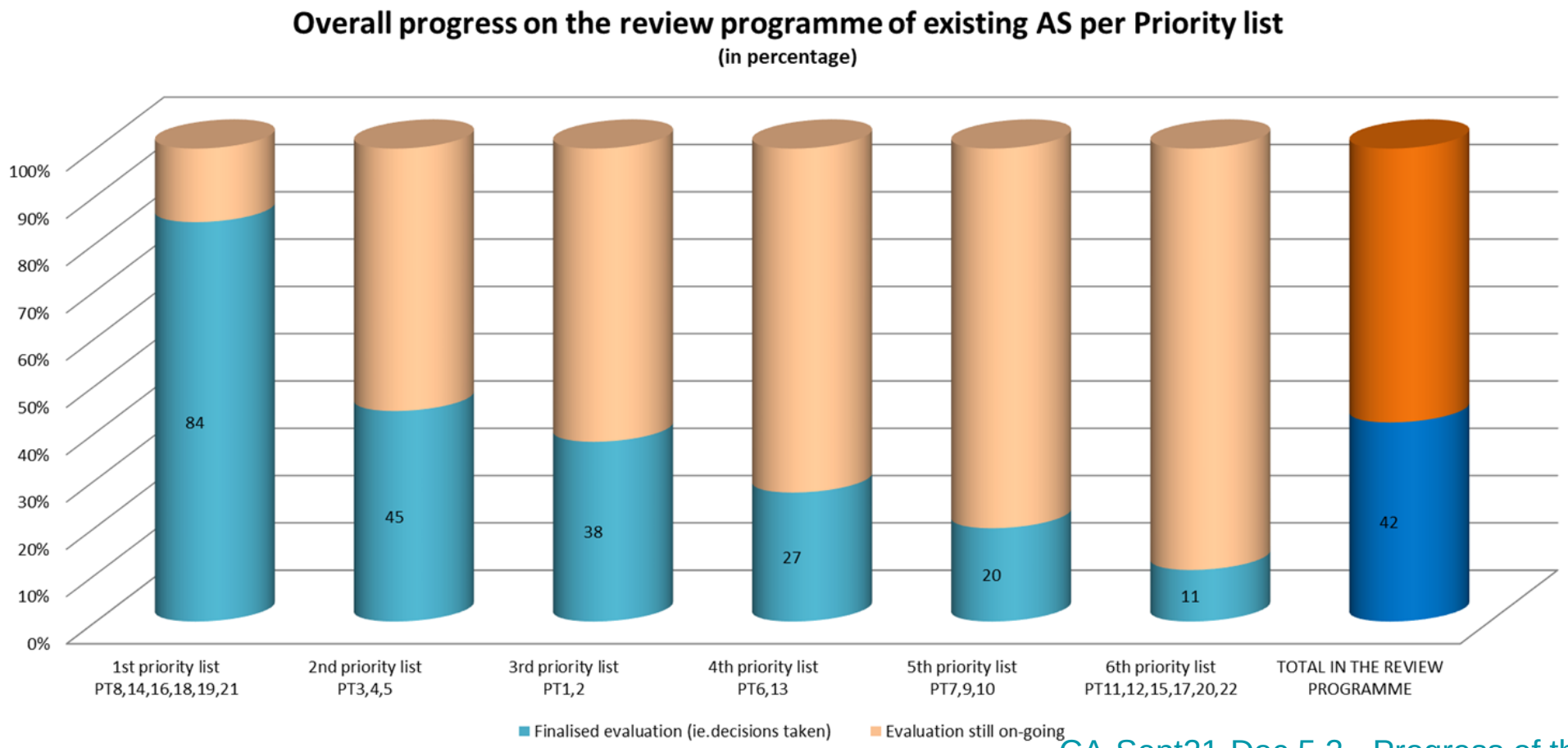
- Introduction
- Review Programme
  - Current Status
  - Impacts on Review Programme
    - Recent legal development
    - Data protection issues
    - Data Requirements
- Treated Articles
- Confidentiality claims, Disclosure, Access to Documents (ATD) under the BPR
- Take away messages

Status of Review Programme

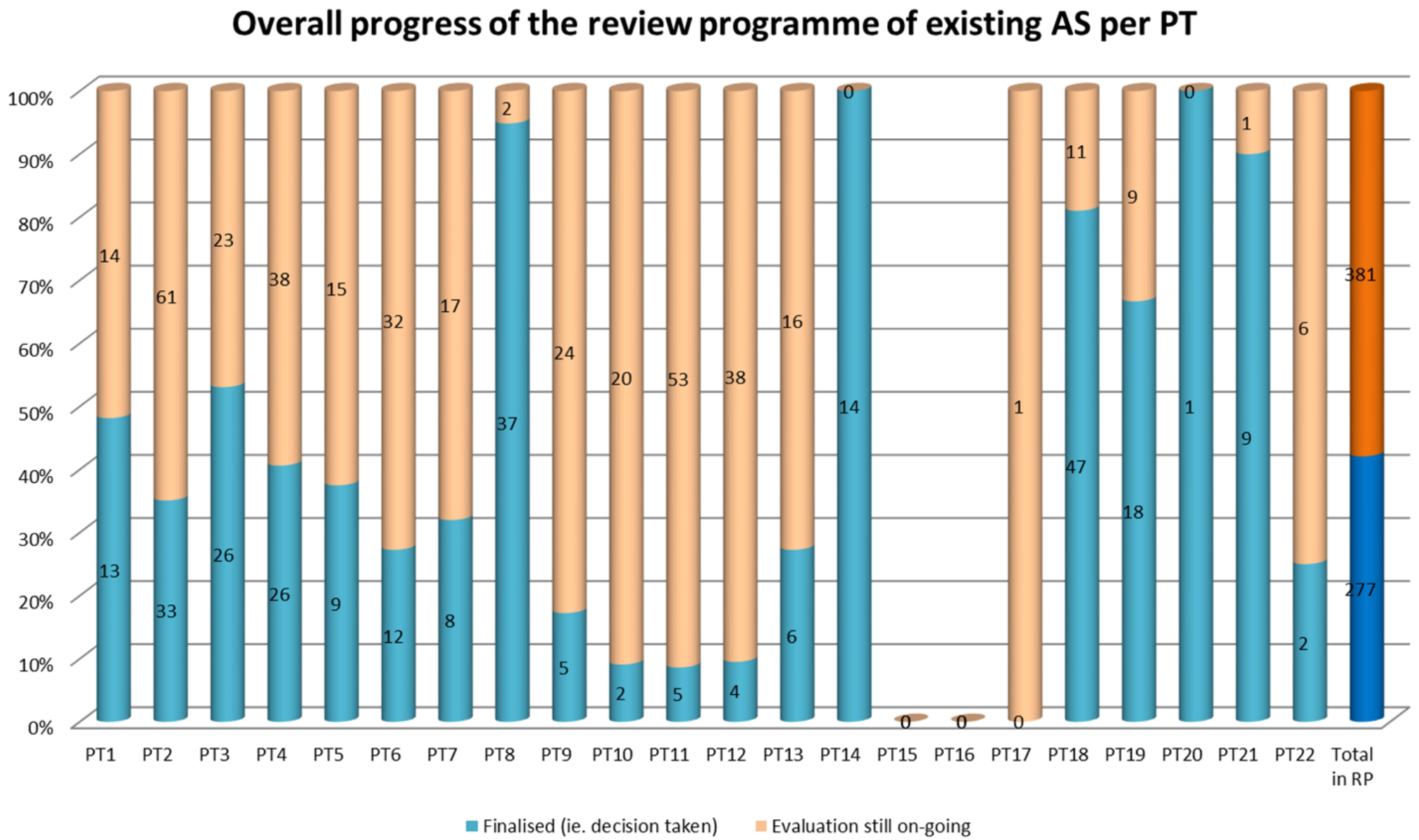
Overall progress on the review programme of existing AS on 1st September 2021

(Data might be subject to minor corrections)

Chart 1

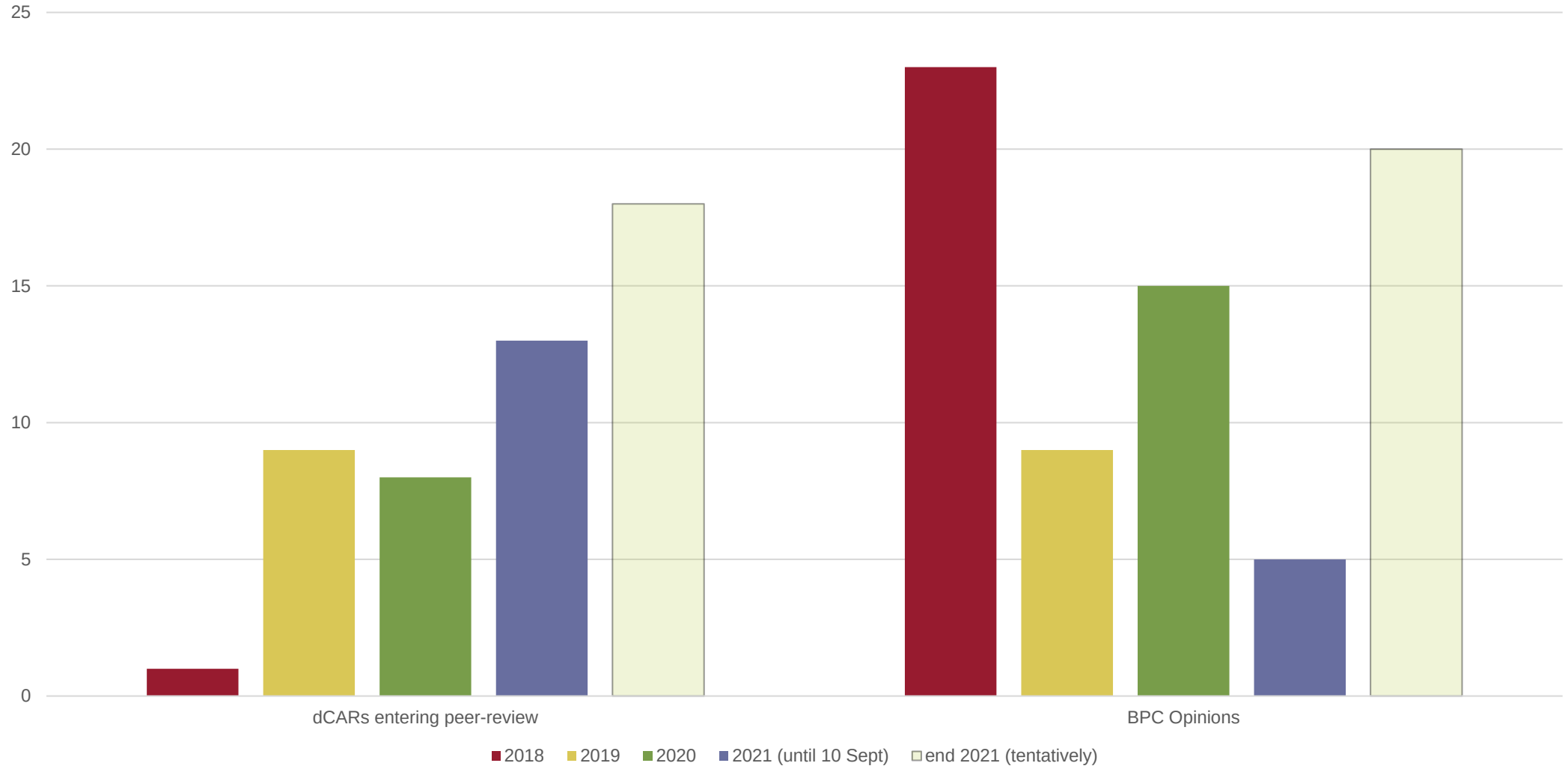


Status of Review Programme



Status of Review Programme

- ECHA's Active Substance Action Plan (ASAP) – September progress report



Impacts on Review Programme – Recent Developments

Judgment of the General Court in Joined Cases T-337/18 and T-347/18, *Laboratoire Pareva*, concerning the active substance PHMB

- Long evaluation process (as always)
  - 10 years between submission of dossier and communication of assessment report to ECHA
- Action for annulment (accompanied by application for interim relief) against both
  - (i) the non-approval of the active substance (PHMB) for certain PTs and
  - (ii) approval (with conditions) of the active substance for other PTs.

- Cases joined for the purpose of the oral part of the procedure

Impacts on Review Programme – Recent Developments

- OJ Notice in Case T-337/18

  1. Substantive procedural errors
     - Commission "*failed to follow procedural steps that were required of it prior to adopting the Contested Decision (…) which, if they had been respected, could have led to a different outcome.*"

  2. Manifest errors of assessment:
     - Commission "*committed a manifest error of assessment by taking into account irrelevant factors in its assessment of PHMB and by failing to give sufficient and due weight to factors which are specific and relevant to the applicant's PHMB.*"

  3. breach of fundamental principles of EU law and of the rights of defence:
     - Commission "*did not guarantee that the applicant was given a full, proper and effective opportunity to submit comments during the procedure.*"

- OJ Notice in Case T-347/18
  - "*three pleas in law which are in essence identical or similar to those relied on in Case T-337/18*"

Impacts on Review Programme – Recent Developments

In its judgment the Court finds, amongst others, that:

- eCA and ECHA not <u>required</u> to accept new studies/additional data after validation of AS dossier ("may" not "must"). Hence only possible in limited situations, subject to four conditions derived from ECHA guidance:

  - BPR and Review Programme Regulation *"make no provision for the applicant to supplement his or her dossier on his or her own initiative after his or her application has been validated, whatever the grounds may be. Nor do those regulations provide for the possibility for the applicant to submit new information after the evaluating competent authority has sent him or her its draft assessment report for comment." (para. 173)*
  - *"in practice, it is **sometimes necessary** for that committee to gather additional information for the purposes of that examination. The submission of new information at that stage of the evaluation procedure is, however, subject to **four conditions** being satisfied. First, the **period of 270 days** within which the ECHA must deliver its opinion can be adhered to, second, it appears during the process that **the outcome of the evaluation** by the evaluating competent authority **can be significantly changed**, third, **the new information is already available and can be submitted immediately** after the meeting of the working group concerned and, fourth, that **working group decided that new information was necessary** and defined it." (para. 174)*

Impacts on Review Programme – Recent Developments

In its judgment the Court finds that:

- Burden of proof is on the applicant
  - *"the **mere claim that scientific and technical knowledge has evolved since the notification does not enable** those who have notified an active substance (…) , to benefit from the opportunity to submit new studies and data (…)" (para. 176)*
  - *"it is for the applicant to prove that the conditions of approval are met (…). In view of that allocation of the burden of proof, where an applicant considers that new data or studies, submitted after his or her dossier has been validated, should have been taken into account for the evaluation of the substance at issue, it is for that applicant to **demonstrate that such data or studies could not be submitted before** his or her dossier was validated, that they are **necessary and that they <u>manifestly</u> call into question the outcome of the evaluation procedure**." (para. 178)*

Impacts on Review Programme – Recent Developments

- Potential Rationale - To avoid abuse of process?

  - *"(…), it would be tantamount to granting to the notifier of the active substance – who has a better knowledge of the substance at issue –* ***a right of veto over the possible adoption of a non-approval decision of that substance*** *(…)." (para. 176)*

  - *"(…) Where an applicant submits studies which are not reliable or are incomplete to the evaluating competent authority, he or she cannot be recognised as having the right, after his or her dossier has been validated, to provide new studies without any restriction regarding timing, otherwise he or she* ***would, de facto, be entitled to extend that evaluation procedure indefinitely****, without it being possible to adopt a decision on the risks of the substance evaluated, even though that substance is on the EU market pending the adoption of that decision. (para. 209)*

Impacts on Review Programme – Data Protection Periods

- All data protection periods start from when data under BPD or BPR is submitted for the first time. No cumulative protection periods once they have expired. (Arts. 60 and 95). Longstop of 31 December 2025.

ACTIVE SUBSTANCE (AS)	BIOCIDAL PRODUCT (BP)
Approval of a NEW AS **15 years** from the first day of the month following the date of adoption of AS approval decision (i.e. adoption of Implementing Regulation) of each AS/product-type combination	**BP with a NEW AS** **15 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
Approval of an EXISTING AS **10 years** from the first day of the month following the date of adoption of AS approval of each AS/product-type combination If AS (product-type combination) is not already approved before Sept. 1, 2013, all data protection periods for AS (product-type combination) still under review remain until a (longstop of) **December 31, 2025.**	**BP with ONLY EXISTING AS** **10 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
RENEWAL/REVIEW of an AS approval **5 years** from the first day of the month following the decision on renewal/review of a the approval of an AS	**RENEWAL/AMENDEMENT OF BP AUTHORIZATION** **5 years** from the first day of the month following the decision on the renewal/amendment of a BP authorization

- If /when 31 December 2024 deadline for Review Programme (Article 89(1) BPR) is extended, what happens to the data protection longstop?

Impacts on Review Programme – Data Protection Periods

Moving data targets during Review Programme *whilst* data protection eroded:

- Constant guidance, CA Notes, &/or practice changes, & change of scope of BPR (*in-situ*).

- Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the **determination of endocrine-disrupting properties** pursuant to BPR. Applies since 7 June 2018

- Commission Delegated Regulation (EU) 2021/525 of 19 October **2020 amending Annexes II and III** to BPR. Will apply from 15 April 2022 to allow applicants to "make the necessary arrangements to meet those requirements" (+ application now, on a "voluntary basis") .

Impacts on Review Programme – Data Requirements

- Commission Delegated Regulation (EU) 2021/525 of 19 October **2020 amending Annexes II and III** to BPR. Will apply from 15 April 2022:
  - Prior to any data submission, requires *mandatory* pre-submission meetings between the applicant and the prospective evaluating body for both active substance approvals and applications for authorization of biocidal products.
  - Pre-submission consultations have to be documented by the applicant and their outcomes included in the respective applications.
  - Applicant *may* decide to consult with the eCA on the testing on vertebrates that the applicant proposes to carry out. (subject to the inquiry obligation set out in Article 62(2) of the BPR to avoid duplication of vertebrate animal studies).
  - The revised annexes generally foresee tiered testing, to reduce testing on vertebrate animals.
  - The tiered-testing strategy may require certain studies (e.g., EOGRTS or PNDT) which may be standard information requirements under the REACH Regulation – but no mandatory data sharing across regimes.

Impacts on Review Programme – ED Risk Assessments

- Once an active substance is identified as an ED, the question becomes, how to incorporate this fact into a determination of risk:
    - Mandates issued to ECHA by the European Commission, in the context of active substances DBNPA and Cyanamide.
    - Quantitative assessment or qualitative assessment more appropriate?
- Complex questions on how to determine a methodology for ED risk assessments should be available - in a BPC Opinion - for use by the end of 2021. Extremely ambitious.

Treated Articles

- CA discussions on risk management measures (RMM) for Treated Articles
  - Q&A on risk mitigation measures (RMMs) for treated articles (CA-Dec20-Doc4.8)
  - Discussions on RMM on Treated Articles (March21 and June21)
  - Note for CA on labelling of treated articles (CA-June21-Doc.4.2.b)

- Sweden‘s position on the regulation of treated articles (CA-Sept21-Doc.4.1.)
  - to list accepted uses in treated articles in the biocidal active substance approval
  - Would *“provide consistency between evaluations at product authorisation as further risk mitigation measures can only be taken within the umbrella of the measures listed at substance approval”*

- OECD Guidance on principles for claim development of treated articles (November 2020)

Guidelines on Confidentiality

- New "Guidelines for assessing the confidentiality of the information contained in the Competent Assessment Report (CAR) and Product Assessment Report (PAR)":
  - application dossiers for approval of an active substance
  - application dossiers for authorisation of a biocidal product
  - evaluation and preparation of the Competent Assessment Report (CAR), active substance renewal (RAR) and Product Assessment Report (PAR).

- Working model is that if MSCAs get their assessments wrong, this will be reflected in what is later disseminated by ECHA (Electronic Public Access, Art. 67 BPR).

- System consists of:
  - Disclosure on Request (ATD Regulation)
  - System of Confidentiality Claims
  - Active Dissemination (ECHA website)

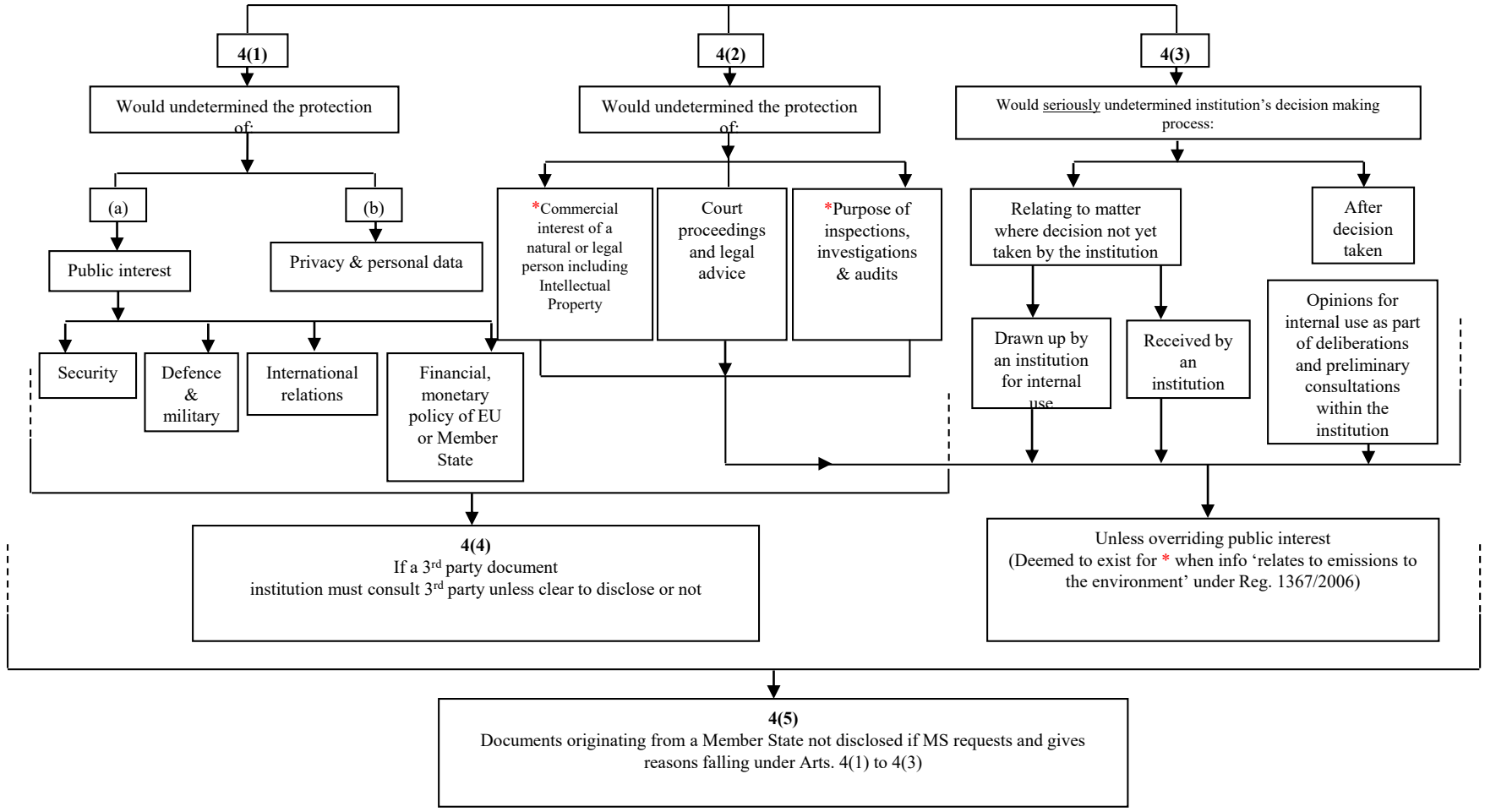
- New guidelines to be reviewed in 1st half of 2024.

BPR and Access to Documents (ATD) Regime

Held byECHA or MSCA

- Disclosure always (Art. 66 (3)):
  - name and address of the authorisation holder;
  - name and address of the biocidal product manufacturer;
  - name and address of the active substance manufacturer;
  - content of the active substance or substances in the biocidal product and the name of the biocidal product;
  - physical and chemical data concerning the biocidal product;
  - methods for rendering the active substance or biocidal product harmless;
  - summary of the results of the tests required for Product Authorisation to establish efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;
  - recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;
  - SDS
  - methods of analysis for Product Authorisation
  - methods of disposal of the product and of its packaging;
  - procedures to be followed and measures to be taken in the case of spillage
  - or leakage;
  - first aid and medical advice to be given in the case of injury to persons.

ATD Regime: Narrow Exceptions



BPR and ATD Regime

Held byECHA or MSCA

- **Presumption of non-disclosure** (save where health, environment or public interest urgency), Art. 66(2) :
  - details of the full **composition** of a biocidal product
  - **precise tonnage** of the active substance or biocidal product manufactured or made available on the market
  - **links between** a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;
  - name and addresses of **persons involved in testing of vertebrate** animals

Electronic Public Access: Actives

Held by ECHA or Comm

- **Disclosure <u>always</u> Post-Approval**, Art. 67(1):
  - where available, the ISO name and the name IUPAC nomenclature; if applicable, the name as given in the EINECS
  - classification and labelling, including whether the active substance meets any of the BPR exclusion criteria
  - physicochemical endpoints and data on pathways and environmental fate and behaviour
  - result of each toxicological and ecotoxicological study
  - acceptable exposure level or predicted no-effect concentration
  - guidance on safe use
  - specified analytical methods

Held by ECHA or MSCA

- **Disclosure always <u>unless</u> valid justification** submitted why disclosure could potentially be harmful to commercial interests, Art 67(3):
  - if essential to classification and labelling, the degree of purity and identity of impurities and/or additives known to be hazardous
  - study summaries / robust study summaries
  - other information in SDS
  - trade name(s) of the substance
  - assessment report

Submit claim in IUCLID

Electronic Public Access: Products

Held by ECHA

- **Disclosure <u>always</u>** of info held by ECHA or Commission **Post-Authorisation**, Art. 67(2):
  - terms and conditions of the authorisation
  - summary of the biocidal product characteristics
  - specified analytical methods

Held by ECHA or MSCA

- **Disclosure always <u>unless</u> valid justification** submitted why disclosure could potentially be harmful to commercial interests, Art. 67(4):
  - study summaries, or robust study summaries
  - assessment report.

Submit justification in IUCLID

Confidentiality Claims

- Applicant:
  - Possibility to update existing confidentiality claims and/or submit additional ones, in cases where new information is requested after the initial submission or is taken into account in the final version of the assessment report prepared by the Competent Authority.
  - Mere statement that the information is confidential is not sufficient. Justification entered by applicant in IUCLID dossier, inside the flag indicating the confidentiality request:
    - "A valid justification demonstrates the existence of a commercial interest worthy of protection which could potentially be harmed if the information concerned is disclosed".
    - No generic statements.
    - Explain how the disclosure would cause the type of harm claimed.
    - In addition to these type-specific justifications, the applicant can refer to a secrecy agreement in its justification – and must provide evidence of the actual existence of such an agreement.
    - Info. cannot be already in the public domain (on all public databases, websites etc). Consider parallel EFSA dissemination.

Take Away Messages Questions