



EFSA NEW METHODOLOGY ON HISTORICAL CONTROL DATA AND IMPLEMENTATION ACTIVITIES

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NEW METODOLOGY: KEY POINTS

- HCD submission is a **legal requirement**¹ in the context of the peer review of the pesticide risk assessment of an active substance, however compilation, reporting and use of HCD for the assessment of toxicity studies is **not harmonised** leading to possible inconsistencies
- Need of **recommendations** for collation, reporting and use of HCD also captured during stakeholders' workshop in May 2022 (preparatory grant outsourced to AGES & BPI).
- PPR Panel developed a **Scientific Opinion** on the '*Use and reporting of historical control data (HCD) for regulatory studies*':
 - **Stepwise quantitative & reproducible framework** (planning, analysis and use of HCD)
 - **Templates to improve data submission**
 - **Interaction between toxicologists and statisticians**
- Enhances transparency, scientific robustness, and regulatory confidence.
- Requires additional resources (notably statistical expertise), but offers clear methods for planning, evaluation and analysis

¹Commission Regulation (EU) No 283/2013 setting out data requirements for active substances, in accordance to Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

²External Report of the grant available at <https://www.efsa.europa.eu/en/supporting/pub/en-7558>; Workshop Report available at <https://www.bpi.gr/files/workshop/Preparatory%20work%20on%20how%20to%20report.%20use%20and%20interpret%20HCD%20-%20Workshop%20report.pdf>.



CONSIDERATIONS FOR REGULATORY UPTAKE

- Implementation requires a **phased approach**
 - MS assessors need time to be trained
 - A dedicated tool is essential for practical application
- Regulatory implementation should not be immediate
- Possible implementation date (under discussion): 1 January 2028
- This timing would allow sufficient preparation for all stakeholders



ACTIVITIES FOR IMPLEMENTATION

■ 2025–2026

- Publication of the [Scientific Opinion](#)
- **Awareness-raising** and initial dissemination ([webinar](#), SCoPAFF, PSN)

■ 2026

■ **MS training programme** (EFSA/2024/OP/0011-SC1):

- Online pre-trainings + two rounds of hands-on physical training (June & October 2026: call for nominations for the June session sent 4 May)

- Start of **dedicated tool development** (OC/EFSA/MESE/2023/03 - SC27)
- Stakeholders' **feedback** collection (surveys/interviews)

■ 2027

- **Tool testing** (applicants and MS), refinement and documentation
- Analysis of stakeholders' feedback

■ From 1 January 2028

- Possible regulatory application (subject to EC/MS decision)
- **Helpdesk** (toxicology/statistics) & **ad-hoc support mechanisms** during peer review, if needed

■ **Cross-pillar coherence (PPP, REACH/CLP, biocides; OECD/ECHA)**

- Further engagement with ECHA to support alignment across regulatory frameworks
- Contribution to the [VICT3R](#) project and participation in OECD Expert Group activities on Virtual Control Groups (VCGs)



KEY MESSAGES

- EFSA developed an approach that is **scientifically robust, feasible for MS**, and aligned with regulatory needs
- Implementation is being planned in a **progressive and supportive way**
- No immediate mandatory application is envisaged
- **Training, tools and stakeholders' feedback** are central pillars
- 1 January 2028 discussed as a possible implementation date, allowing sufficient preparatory time
- Continued updates will be provided to PSN & SCoPAFF



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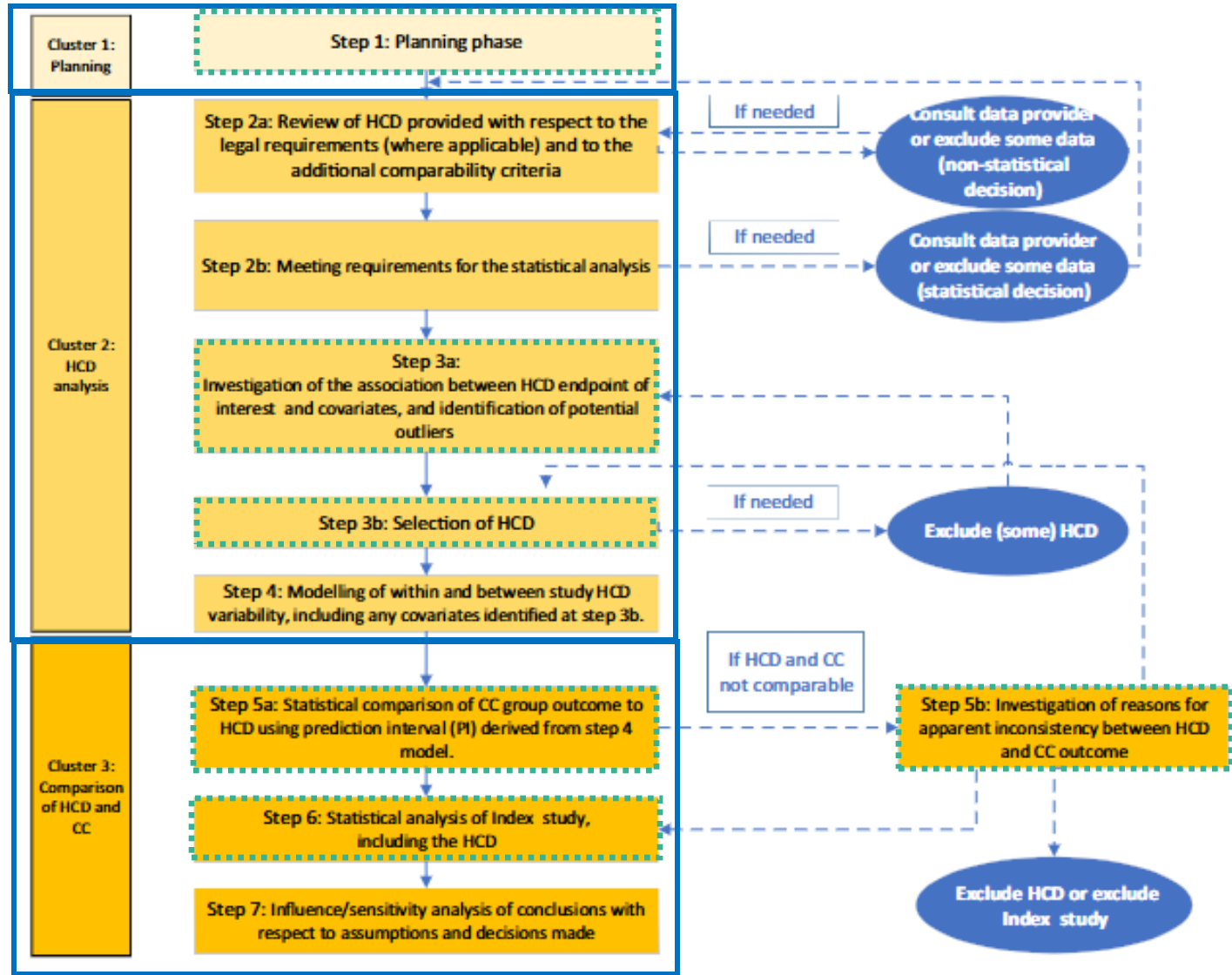


DECISION SCHEME



Need for a trained statistician

Time for the analysis



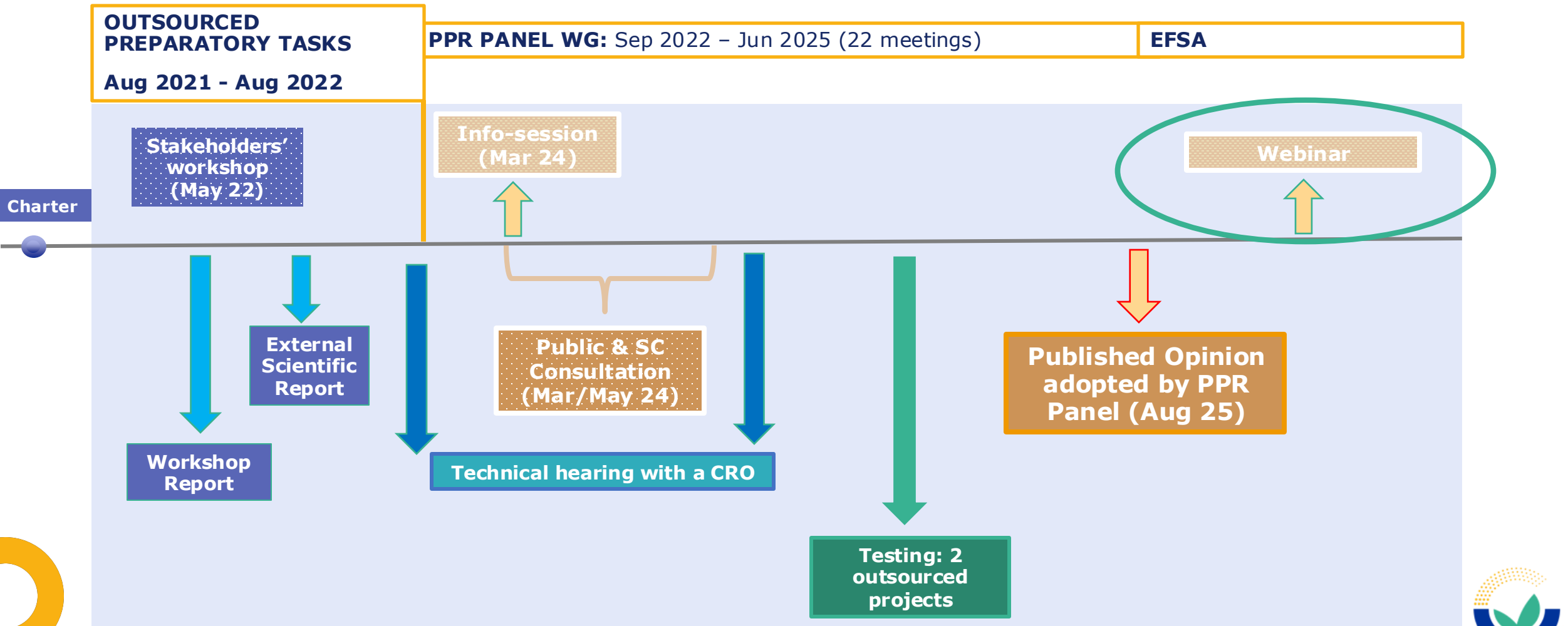
A priori plan - not data driven

Structured and reproducible approach

Enhanced power

Dialogue statisticians/domain experts

PROCESS



Charter

