

Update from the PAI group

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Institute for Plant Protection Products



Content

- ☛ Chapter 1: PAI - Changes?
- ☛ Chapter 2: New actives data post approval
- ☛ Chapter 3: Data protection
- ☛ Chapter 4: Data matching
- ☛ Chapter 5: Any further news



Chapter 1: Changes?



Changes

- ☞ Terms of References (ToR) – on public section of CIRCABC
- ☞ Extended minutes made available to stakeholder
- ☞ Change of chair (UK->AT)
- ☞ Co-Chair (ES)
- ☞ Secretariat (DE)

Chapter 2: New active substances data post approval

Better known as



- ☞ Confirmatory information will be introduced by COM to a less and less extent
- ☞ More and more issues shifted to „MS may pay particular attention to“, which means to be addressed at product level (zRMS)
- ☞ Many of those are to dealt with at EU level rather than on zonal level:
 - Relevance assessment of groundwater metabolites
 - Relevance assessment of metabolites in food of plant and animal origin
 - Residue definition

- ☛ New procedure to be established – which would mean further delay of Article 43 assessments (ca. 10 month)
- ☛ *GD on the evaluation of new a.s. data post (renewal of) approval* to be amended
- ☛ 1 MS assesses the data on behalf of all MS (as a matter of principle the RMS for the active's approval - CoRMS in case UK is the RMS after BREXIT)

Chapter 3: Data protection



?? There is
no data
protection ??

☞ Change of paradigm introduced by ECCA:

- Data protection rules applies to active substance data and product data (representative formulation only)
- All other product data: no data protection?

➡ Most MS and COM: not in the spirit of REG 1107/2009

- Data protection of 10 years after renewal of the active substance for a new product (instead of 30 months)



Not in the spirit of REG 1107/2009?

Chapter 4: Data matching

How do you want
them to be
matched?



- ☛ Draft Guidance prepared by UK/to be finalised by NL (consideration of comments received) – to be finalised in the March meeting (PAI)
 - Template to be used; examples in Appendix 2
 - RMS on behalf of MS
 - Studies necessary for assessment (not studies relied on)
 - Study list to be provided by RMS (on request / to be published on DG SANTE's homepage)

Chapter 5: Any further news

Do you really
want to know
that?



- ☞ GD on non-significant formulation change (to be amended)
- ☞ GD physchem properties (based on CRD guidance)
- ☞ Article 43 GD (amendment? Further amendments?)
- ☞ GD on zonal evaluation and mutual recognition (introduction of low risk products)
 - SCoPAFF
- ☞ ...

Dedicated to Darren Flynn



