

Ongoing business in Austria

Rebecca Reboul

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Institute for Plant Protection Products

OVERVIEW

- **What is going on in Austria?**
- **Generic authorisations (Art. 33 in combination with Art. 34)**
- **Comparative assessments and substitutions in AT (Art. 50)**
- **Experiences with PPP renewals (Art. 43)**
- **Re-allocation of work - Brexit**

What is going on in Austria?

Ongoing evaluations...

Presently ongoing/Oct. 2017

Austria is	Art. 33	Art. 43
zRMS	21 new PPP 13 amendments	18 applications
cMS	78 applications	29 applications

- zonal assessments →
 - AT zRMS: Art. 33, Art. 51, Art. 43
 - AT cMS: peer review and national evaluations

- re-registrations (voluntary worksharing or national) → Presently ongoing/Oct 2017: ~90

- mutual recognitions → Presently ongoing/Oct 2017

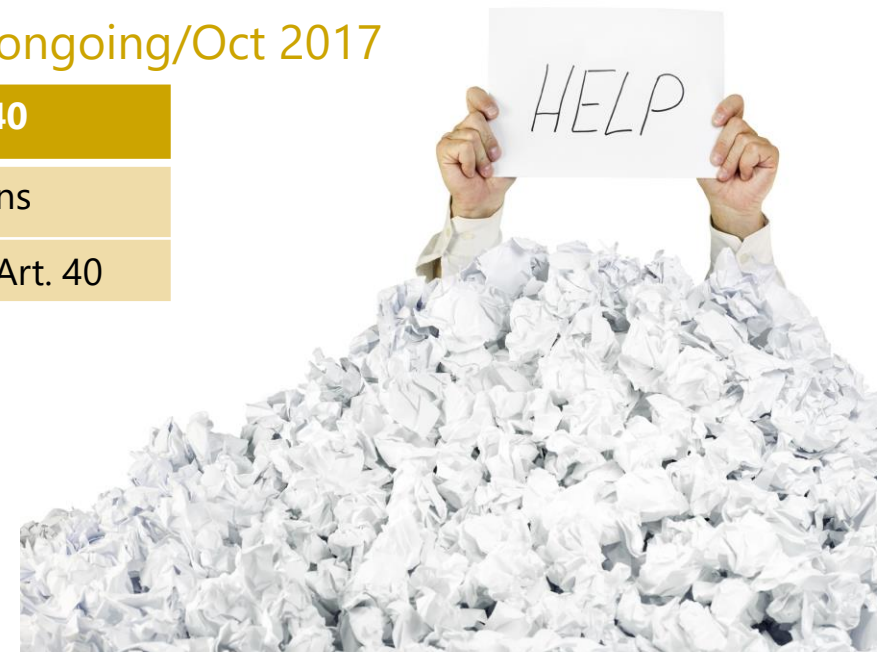
- active substances (AIR3, AIR4 and new a.s.)

- evaluation for MRL-settings/ equivalence checks/ confirmatory information

- ...

Presently ongoing/Oct 2017

Art. 40
29 applications
+ 8 Art. 51 / Art. 40



What is going on in Austria?

Daily business... is rising slowly but surely

- ↪ administrative changes acc. to Art. 45 (extension of use, prolongation of expiry date...)
 - 100 applications yearly
- ↪ meetings (internal, presubmission...)
- ↪ telefonconferences
- ↪ preparation of Guidance Documents (Peer review, drafting...)
- ↪ working groups (COM, EPPO...)
- ↪ ...



Deadlines ???

**numbers
applications**

brexit

work pressure

deadlines

What is going on in Austria?

Internal prioritisation mandatory

- ☞ numbers of applications increasing yearly, coming later as expected
- ☞ work not predictable (*Art. 40, Art. 45, ...*)
- ☞ Art. 53: 47 in 2017 (*expected to be more /PPP „frozen“ at renewal*)
 - difficulty to plan/ foresee the workload (*number of experts not growing so fast*)

Solutions/where to start ?

- ☞ check: priority to PPP for which a.s. will soon be renewed
- ☞ strategy for Art. 40/ keep to timelines (120 days)/ trust the evaluation of the ref. MS
- ☞ re-registrations acc. 91/414 not finalised/if possible to be replaced by Art. 43 (?)
- ☞ communication with applicants (and vice versa) if prioritisation needed

Generic authorisation (Art. 33 in combination with Art. 34)

With/without technical assessment



- Stepwise:**
- 1st step: application for comparability check
 - 2nd step: application: „full“ Art. 34 (only RR Part C+A)
or only some sections (e.g bridging trials)

GD on significant/non significant changes

GD on zonal evaluation and MR under Reg. (EC) No 1107/2009

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- ref. PPP has to be registered
 - advice: no cMS, Art. 40 in a 2nd step (*Data protection national/ cannot be checked by zRMS*)
 - data protection for PPP 91/414: 10 years for new data provided for a change of composition or a change of GAP (*GD on data protection*)

Rising demands for applications Art. 33 in combination with Art. 34 (new PPP or extension of uses...)

Comparative assessments and substitutions in AT

Article 50 of REG VO 1107/2009 and GD GD SANCO/11507/2013 rev.12:



Applications from 1st of August 2015 – 1st of June 2017

- 48 applications out of 195 with a need for comparative assessment (*estimation 2014: 20%*)
- 14 products already assessed (until 31st of December 2016) – 6 fungicides and 8 herbicides
- for all 14 products assessment stopped at step 2
- **no product was substituted**

→ *Extra work...any added value?*



Experiences with PPP Renewals (Art. 43)



- ☞ companies' willingness to harmonise formulations within zone before applying Art 43!!
 - ➔ amendment of formulation acc. to Art. 33
- ☞ mixed PPP (a.s expiry dates falling within a year)
 - ➔ apply for Art. 43 (formal) after the 1st a.s .renewal !!
- ☞ extension of a.s. expiry date: not all MS pro-actively extend the PPP authorisations
 - ➔ Art. 45 „extension of expiry date“ for PPP to be applied !!
- ☞ AT cMS: agreements zRMS/ applicant to be accepted (Cat. 4, mixed PPP..)
- ☞ AT zRMS: if Cat 4 or evaluation delay ➔ info to the cMS !!



Re-allocation of Work -Brexit

How to get prepared?



- ☞ 30.03.2019: UK will become a Third Country
- ☞ working group Commission Services/ MS/ EEA countries to provide clarifications
- ☞ Pesticides - European Commission

QUESTIONS AND ANSWERS RELATED TO THE UNITED KINGDOM'S WITHDRAWAL FROM THE EUROPEAN UNION WITH REGARD TO PLANT PROTECTION PRODUCTS AND PESTICIDES RESIDUES

*"Preparing for the consequences of the UK's withdrawal from the Union is not just a matter for European and national authorities, **but also** for private parties. "*

Re-allocation of Work -Brexit



How to get prepared?

- ☞ **on-going procedures:** UK is RMS, zRMS or evaluating MS for MRL-conf. information-data matching check
 - business as usual
 - BUT where clear indications/ deadline cannot be kept at *UK's withdrawal*
 - Applicant to take action: change of evaluating MS may be required
- ☞ **submissions of new applications:** → Applicant to take into account expected timelines: choose another evaluating MS in order to avoid change of zRMS / MRL evaluating MS at a later stage
- ☞ **Review programme of a.s,** for which the UK was assigned as RMS and co-rRMS by law (Commission Implementing Regulation (EU) 686/2012)
 - Discussions COM/MS for re-allocation a.s. to a new RMS or co-RMS. Reg. (EU) No 686/2012 will be amended accordingly.

Knowing the amount of work performed by UK, not an easy task!!

CONCLUSIONS



- ↪ amount of work has steadily increased
- ↪ “no capacity” is no excuse (Brexit...) especially for Art. 43
- ↪ we have to organise the work in the most efficient way (priorisation within each MS,, communication between MS, need of a harmonisation in the zones, concentrate on the “real” problems)

Thank you for your attention



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