Products renewal- AT experiences

Article 43 of Regulation (EC) No 1107/2009

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Guidance Document

EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain
Pesticides and Biocides

SANTE/2010/13170 rev. 13
14 July 2015

Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009

- noted at the Standing Committee in July 2015

- further amended (small expert group meeting Brussels, 2nd of December 2015) and discussed at PAI meetings

- to be noted at the Standing Committee in October 2016

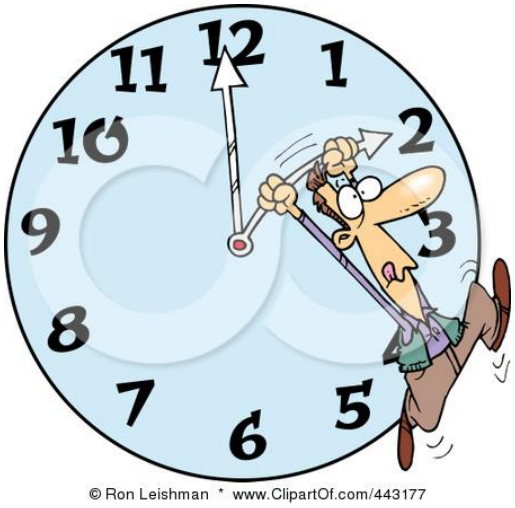
- will every MS follow?

Timelines - Reminder

Renewal of PPP Art. 43, GD SANCO/2010/13170 rev. 13

- **application for renewal of PPP** - **3 months** after Commission´s decision („date of application" DoA) of renewal of the a.s
- **evaluation** [compliance check + assessment] and **decision** on renewal of the PPP by **zRMS** - **6 months** (including Peer review: 3 w.)
- **decision** on renewal of authorisations by **cMS** - **3 months**

!!! Applications by ALL authorisation holders!!!
(notifying and non-notifying companies)
No application for renewal within 3 months or incomplete submissions : expiry of the authorisations or they will be revoked according to Art. 44 (3) and (4)



First Applications (AIR 2 Products)

- **AT zRMS: 11** applications (also for PPP not authorised in AT)
- **AT cMS: 27** applications (Peer Review finalised/ongoing for 5 PPP)

=> concern 38 PSM to be renewed after renewal of 10 a.s

First experiences as cMS:

- **Zonal system!** cMS to await/accept zRMS´s assessment/decisions

- "Cat 4" studies
- await additional data gaps during evaluation

- **Peer review** (3 weeks), cMS must pay attention to:

- new endpoints, uses to be renewed at MS level to be checked!!! [consultation with applicant if needed] …

AT zRMS: 1st experiences

- **Presubmission Meeting**

- when evaluation cannot be finalised on time (>4 months)

  => notification to all Member States so that they can react accordingly

e.g AT: prolongation of the authorisation not necessary:

Date of issue:	2015-11-26
Date of expire:	
Application for reregistration:	2016-06-27

- when applicant provides a list of Cat. 4 studies [including time table for study submission and justification] --**>** to be accepted by the zRMS

  => formal letter to applicant that zRMS accepts

- if 2 as. (renewal <1y); wait until the 2nd a,s renewal !

  => formal application! needed!

zRMS allocation

AIR2 containing products:

- product-based allocation

Problem: different zRMS for comparable products [containing the same active] **=>** different evaluations/conclusions

AIR3 containing products:

- active-based allocation (if possible the RMS/CoRMS for a.s renewal)?
- extended risk envelope approach to be used (e.g. residues, fate)
- avoid different decisions (Cat 4 studies)/evaluations /conclusions for comparable products
- zRMS to accept products evaluation even if products not registered in their countries (not all MS accept)

Problem: some MS disagree with this approach (e.g. SI, DE, PL)

zRMS /AIR3 Products

~ 70 AIR 3 substances (first 6 batches of AIR3 substances)
=>~800 PPP to be renewed in the central Zone

HIGH Priority work: 1st PPP renewals to be applied until **31.01.2017**

- Southern/Northern Zone finalised the planning
  Central: fine tuning still ongoing (Steering commitees level)
- **Central zone:**
  establishment of a list with all PPP to be renewed (AIR3 of the 1st 6 batches)+ zRMS proposals by applicants
- MS to answer if they can act as zRMS until **07/10/2016 (?)**

  + MS to inform whether MS can act as zRMS for any additional applications.
  + inform if free capacity in some assessment areas /willing to workshare

Applicants will be informed by zRMS asap

Non renewal a.s: PPP authorisations?

Consequences for national PPP authorisations:

1/ No application for renewal of approval has been submitted

=> no "official" document, the **a.s "expires"**

=> PPP authorisations expire **1y after expiration of a.s approval** or withdrawn if the PPP expiry date differs from this date *(grace period acc. To Art. 46)*

2/ Decision for non renewal of approval

=> Commission **Implementing Regulation** (EU)

=> grace period for the disposal, storage, placing on the market and use of existing stocks will be given in the Regulation/ to be followed by MS
(Art. 46 or shorter if reasons related to the protection of human and animal health or the environment)

How does it look like?

Compliance check

- **compliance with the conditions and restrictions** of the active renewal/equivalence check if necessary after each substance´s renewal
- **compliance check** to be performed by each MS having authorisations
- **equivalence check(s)** to be performed by the RMS for the active´s renewal

How does it look like?

Data matching check

- for **non-notifying** companies ("generics") and **notifying** companies (missing data/data gaps)
- via e.g. LoA, compensation studies, studies out of protection, reasoned argumentation,…
- data matching check to be included into the application for PPP renewal
- data matching check to be performed **by the RMS** for the a.s renewal on behalf of all zones
- data matching check as for the former "step one" procedure: table (template) will be included into the amended GD

How does it look like?

Data matching check

If "compensation" study not available at the time of application: reasoned statement that the study will be made available (timetable, contract with lab,…) acceptable

Data matching check studies to be made available at the latest by the agreed dossier submission deadline of data compensation studies (this would be a binding date which could not be extended) *[reflected in the latest version of the GD to be noted in Oct. 2016]*

How does it look like?

Mixed products: case "combined toxicity" (opex, birds and mammals, aquatic)

Idea: to await the second a.s renewal

- no agreement within the central zone
- different approaches among MS
- applicant to provide a full combined toxicity assessment (even for cases the second active is not renewed)
- combined toxicity to be dealt by the MS in the national addenda (according to the MS approaches)

Implications for new uses (label amendments), mutual recognitions, Article 33 applications?

- application of Mutual Recognition after Date of Application (DoA) of the Renewal Regulation NOT possible before renewal of the product
- application for label extension after DoA possible if new endpoints are considered (full assessment of the label extension)
- if zRMS issues registration before DoA, cMS should grant the registration within 3 months after DoA at the latest!

Thank you for your attention