# Products renewal

## - Article 43 of Regulation (EC) No 1107/2009

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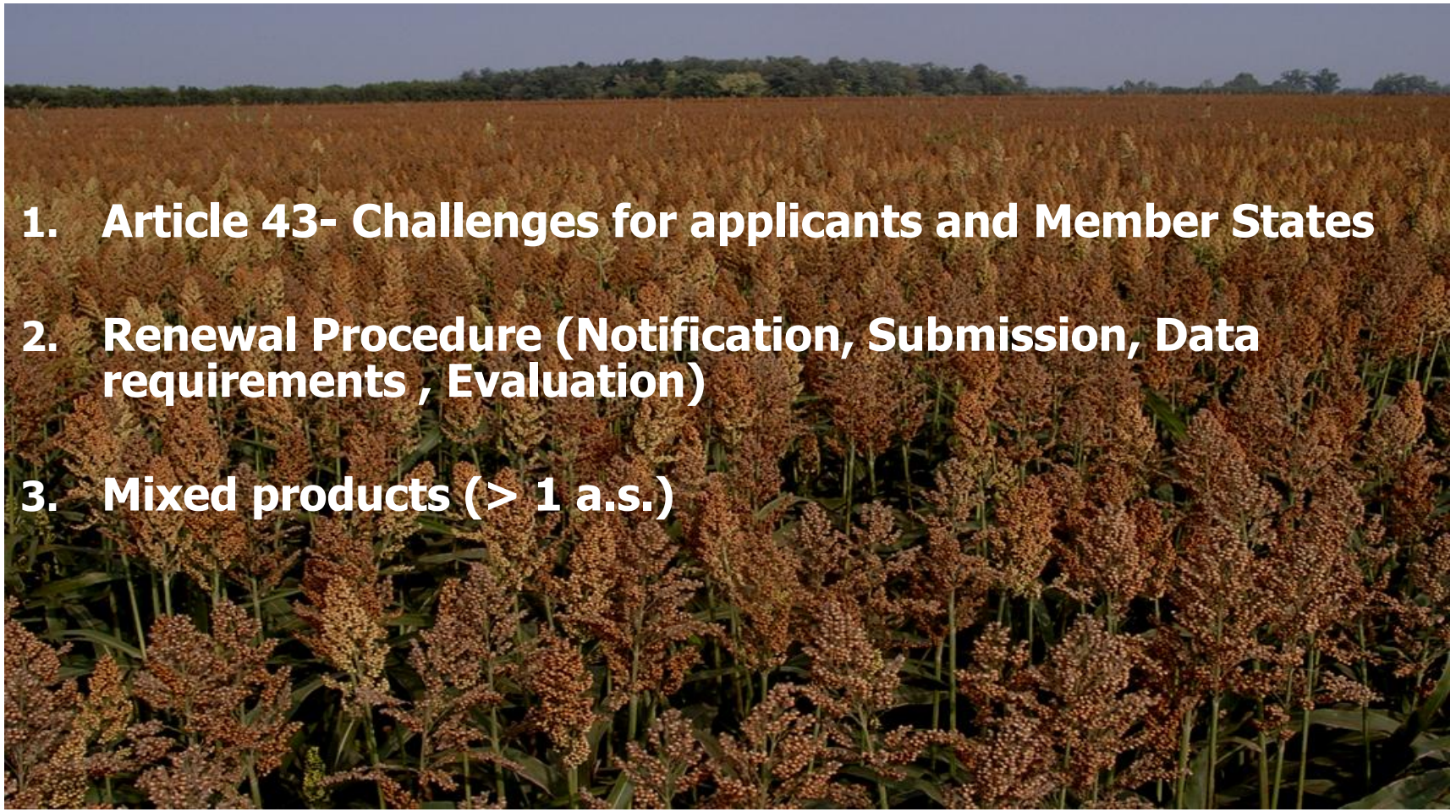
# Outline



1. Article 43- Challenges for applicants and Member States
2. Renewal Procedure (Notification, Submission, Data requirements , Evaluation)
3. Mixed products (> 1 a.s.)

# 1- Article 43- Challenges for applicants and Member States

***General considerations:***

**Renewal of PPP according to Art. 43 and GD SANCO/2010/13170 rev. 8**

- **application for renewal of PPP - 3 months** after Commission´s decision (entry into force) of renewal of the a.s
- **evaluation** [compliance check + assessment ] and decision on renewal of the PPP by zRMS **- 6 months**
- **decision** on renewal of authorisations by cMS **- 3 months**

**No application for renewal within 3 months or incomplete submissions :** authorisations revoked according to Art. 44 (3) and (4)

# 1- Article 43- Challenges for applicants and Member States

***Feasible approach needed:***

- Art. 43 (2): **What should/can be submitted** by the applicant within 3 months
  - any **new information** required as a result of new data requirements or changed criteria
  - any **information** required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the a.s.

- Art. 43 (3): **Nature of the assessment**? Role of the RMS/zRMS?
  - MS "shall check **compliance of all PPPs**" containing the a.s
  - The MS referred to in Art. 35 within each zone shall **coordinate the compliance check and assessment** (i.e. zRMS)

# 1- Article 43- Challenges for applicants and Member States

***Feasible approach needed:***

- Art. 43 (6): In which case(s) does an **extension** of authorisation apply?
  - *MS should extend the authorisation for the period necessary to complete the examination*

- **mixed products** (PPP with >1 a.s.): renewal of PPPs according to Reg (EC) 1107/2009 after each renewal of approval of each a.s

# 1- Article 43- Challenges for applicants and Member States

***Feasible approach needed:***

- **old/new data requirements** (Reg (EC) No. 283/2013) for PPPs to be renewed

  – AIR2 PPP: old data requirements apply, provided that the application is submitted before the 31.12.2015

  – AIR3 PPP: new data requirements apply

# 1- Article 43- Challenges for applicants and Member States

***Feasible approach needed:***

- **old/new data requirements**

**Problem:**

If the renewal of the a.s. (using old data requirements) is not finalised in time, new data requirements for the PPP as well as for the a.s. have to be applied!

**"GD on the interpretation of the transitional measures for the data requirements for chemical active substances " will be amended**

# 1- Article 43- Challenges for applicants and Member States

***Challenges:***

- **short timelines** (for applicant as well as for MS)
- high number of PPPs within a zone
- new data requirements for PPP (Reg (EC) No. 283/2013)

**Meeting MS/ECPA/ECCA/COM/IBMA (16.09.2013)**

# 2- Renewal Procedures

## *Allocation of zRMS –worksharing*

- **notification sheet** for renewal (in preparation) should be provided to the MSs **in advance** to application of PPPs (~2 years). Applicant may/should give its preference for the zRMS

- **steering commitees** plan renewal workload within the zone;
  zRMS will be allocated based on MS capacities, who is the RMS for the a.s., one zRMS for one a.s. in case of multiple applicants for this a.s.

# 2- Renewal Procedures

***Necessary considerations…***

- presubmission meeting
- quality of the dRR to be provided by the applicant
- „new" consideration of the risk envelope approach for some sections like residues, fate (worst case: GAP for one PPP? other PPPs covered?)

***Compliance Check***

- **Approval conditions** to be checked by each MS separately
- **Equivalence check** (if needed) by RMS of a.s. approval

# 2- Renewal Procedures

***Application includes:***

- complete dRR for each PPP?
- information/studies/risk assessment as listed in Art. 43 (2)

Some dossiers will **not be complete** due to lack of time to comply with **new data requirements, new endpoints, to complete long term or seasonal studies, or capacities of laboratories!**

***Which data can be submitted later?***

- small expert meetings (COM,MSs, industry)

  - Application should include a reasoned assessment about data that cannot be submitted on time - **Justification needed** for each data point

  - **submission of the delayed data: Max. 2 years after approval of the a.s. (3 years if Residue definition has changed)**

# 2- Renewal Procedures

## *In case of delayed submission of data:*

- Begin of the evaluation? when **all studies are available (i.e. all sections are complete)**
- MS prolong the authorisations since the cause is considered as „beyond control of the authorisation holder"- Art. 43 (6)
- **data cannot be submitted after 2/3 years: PPPs authorisations will be revoked**

## *Implication for Data protection*

- 30 months data protection from the renewal of the PPP (for a.s. and PPP data) - Art. 59
- if delayed submission => delayed begin of the 30 months data protection: renewal of a.s. + max. 2y+1y evaluation

# 2- Renewal Procedures

***Because of the tight deadlines, applications according to Art. 43 are restricted to:***

- **uses already authorised in the zone**

  => additional use in the zone can only be applied for after the renewal of the PPP, as an amendment according to Art. 33

  => change of the GAP for one already authorised use is only possible if the change does not imply a higher application rate

- **formulations already authorised in the zone**

  =>PPP with significant composition changes (according to SANCO/12638/2011) is considered as a new PPP (application according to Art. 33)

# 3- Mixed products (>1 a.s.)

- for mixed PPPs for which the period between the renewals of both a.s. is less than 2 years, option 2/ will apply.
- for mixed PPPs with 4 a.s , 2 expiring ealier in a short period, and 2 expiring in the same period more far away, the first 2 can be grouped and evaluated together, and the 2 last ones grouped together too.

***Mixed PPPs and old/new data requirements:***

- AIR1 PPP: old data requirements apply
- AIR2 PPP: old data requirements apply, provided that the application is submitted before the 31.12.2015
- AIR3 PPP: new data requirements apply

# Thank you for your attention