Data protection in the pesticide authorisation process in EU

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Overview

- Protection of Regulatory Data in EU
- Avoiding repeat vertebrate studies
- Special focus on Minor uses
- Public access to documentation

Protection of Regulatory Data in EU

PRD under Directive 91/414: Article 13

- Data for new active substances protected for 10 years at EU level
- Data for existing active substances protected for 5 years at EU level, this includes:
  -Substances from Lists 1,2, 3, 4
  -The 7 substances under the Pilot Project of Annex I Renewal
  -Substances withdrawn and resubmitted (based on regulation 1095/2007)
- New formulation data protected for 10 years in each MS

What has changed from 91/414?

- No data protection linked to AS approval
  - Protection linked to PPP authorisation in each MS
  - **Periods of exclusive use will be different in each MS**
- 10 year period of exclusive use for 1st PPP authorisation is unchanged
  - All 'new and necessary' data now protected (Annex II & III), if they are certified to GLP or GEP
- 30 months period of exclusive use for 'review and renewal'
- Additional data protection linked to minor uses
- Compulsory data sharing for vertebrate data

Protection of Regulatory data – Key elements

- The specific data protection provisions are covered in Articles 59 – 63 of the Regulation
- But other articles also have a major influence on the workings of the “data protection” provisions.
  - In particular Article 43 which deals with renewal of PPP authorisations

What can be protected? - Article 59(1)

The protection shall apply to test and study reports provided they were:

(a) necessary for the authorisation
(b) certified as compliant with the principles of good laboratory practice or good experimental practice

- **To be noted:** Not all Member States have GEP certification for efficacy studies (ROM, HUN, BGR)

Period of protection - Article 59(1)

The period of data protection is ten years starting at the date of first product authorisation in each Member State

- Period is 13 years for low risk PPPs

Review & renewal - Article 59(1)

30 months data protection is given where a study is required for the renewal or review of an authorisation.

- **To be noted:** This provision should ensure protection of all new data
- **Confirmatory data**: 30 months protection

Avoiding repeat vertebrate studies

Sharing of vertebrate studies

- Basically means compulsory sharing of vertebrate studies at Entry into Force (EU approval of substance), if **reasonable steps** to share data through compensation have failed
- Clear wish that all vertebrate studies will be shared between companies, otherwise authorities may allow access in cases of dispute to ensure no repeat testing depending on previous communication (Article 62 paragraph 4)
- Possibilities for arbitration to reach a settlement, and a number of countries already have national provisions (eg UK, Germany, Italy)
- Arbitration is only at national level, there is no EU arbitration body

Sharing of vertebrate studies

- Duplicate vertebrate testing must be avoided, so companies must proactively work together to achieve this goal
- In **Holland**, this is already law since October 2007
  -Companies should contact CTgB before starting any new vertebrate study
- For Annex I Renewal (AIR): if a new vertebrate study is required then the RMS should take a lead to ensure 1 study per data requirement

Comment:

- For an efficient process, it will be important to designate the RMS early for Annex I Renewal

Special focus on Minor Uses

Minor uses - Article 59(1)

10 year period of exclusive use shall be extended by 3 months for each minor use, up to 13 years total:

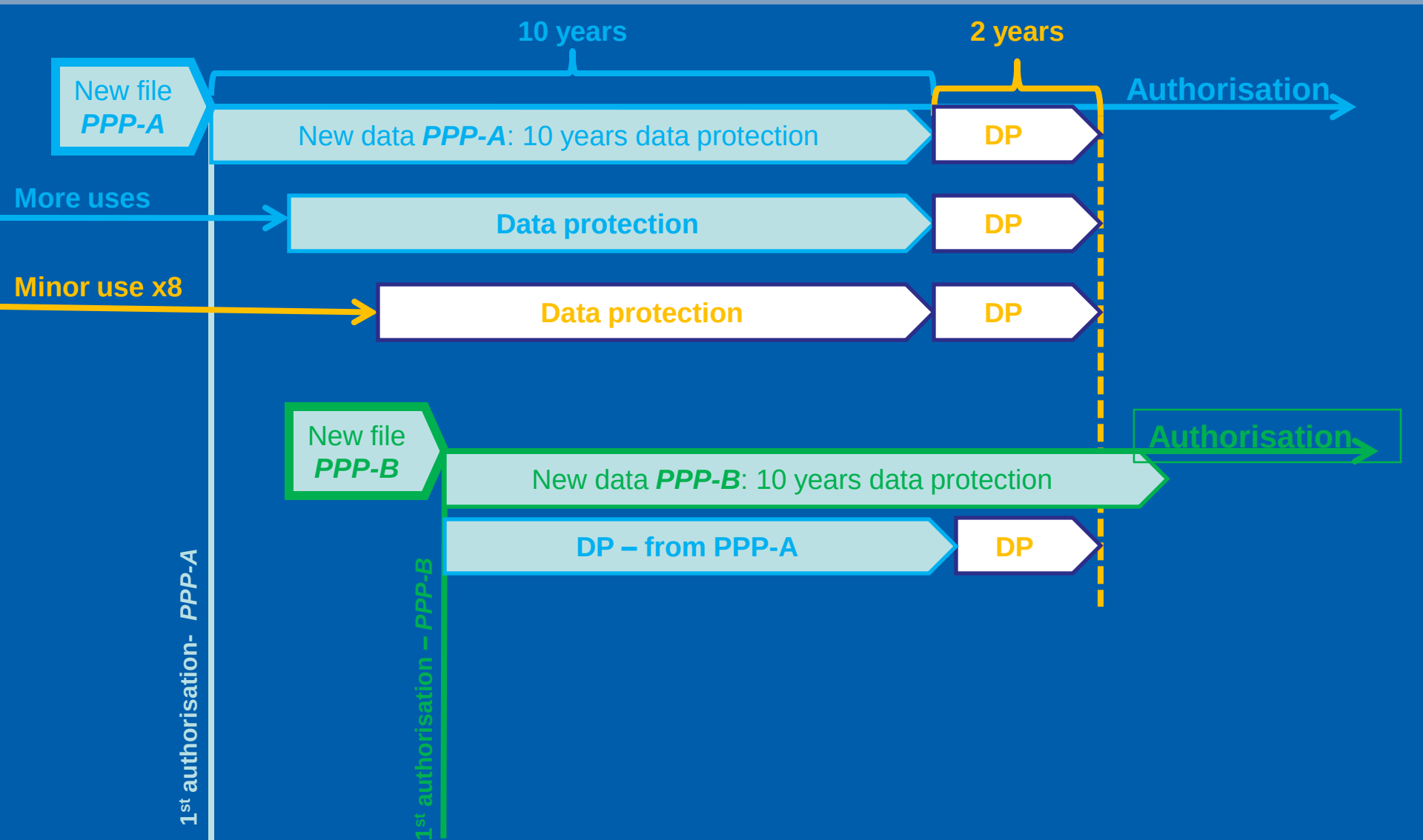
- except where based on extrapolation,
- if the applications are made at the latest five years after the first authorisation in that MS.

Comment:

- What will be considered as a minor use?
  - Article 51(8) states that MSs should establish and regularly update the list
  - Definition in Article 3.26 is rather vague

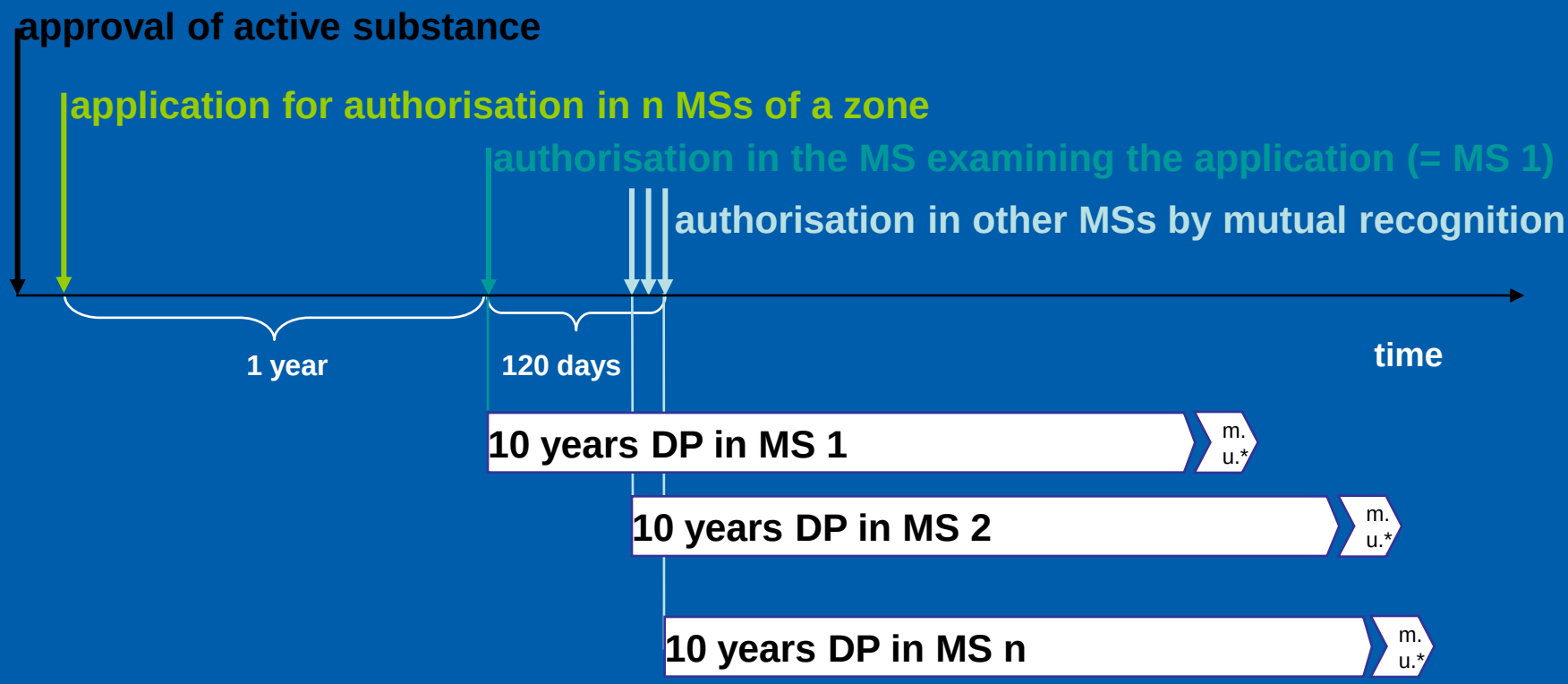
Data protection Scenarios

Scenario 1: Two new PPPs based on same AS



Data protection Scenarios

Scenario 2: A new PPP in the zonal system



*: 3 months per minor use, max 3 years

Public access to documentation

Article 63: Confidentiality

- General tendency at Brussels level (Council, EP, Commission) that more documents/information is made available to the public
- Under directive 91/414, all data was confidential unless otherwise specified
- In Article 63, only CBI and specific documents are per se kept confidential
- However, companies can also claim for confidentiality of documents in their dossier if they believe it would undermine their commercial interests

What can be made public in the future ? (after sanitisation of CBI)

- DAR by EFSA as before (Article 12.1)
- Summary dossier of active substance after admissibility check by EFSA (Article 10)
- Information on new studies for the notification for Annex I renewal for a second EU approval of a substance (Article 16)
- Confidential information, where there is ‘an overriding public interest in its disclosure’ (Articles 10 & 16)
- Upon a request for access to information, the RMS shall decide what information is to be kept confidential (Article 7.3)

New submissions - Article 59.3, Article 63.1

For all future submissions for active substance approval or product authorization, companies must:

- Claim for data protection at the time of submitting the dossier in each MS
- Provide to each Member State the reasons why the information is necessary
- Confirmation that data protection has never been granted or that any period granted has not expired

- Claim which documents should be treated as confidential

Conclusions

- Protection of regulatory data will continue to be an important part in implementing the new regulation
- Incentives for companies, where realistic business wise, to support EU agriculture by developing data for minor uses
- Industry will need to work together to avoid duplicate/repeat vertebrate studies
- Public access to regulatory documentation will need greater attention under the new regulation

Thank you for your attention

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