



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit



Processes for the registration and authorisation of plant protection products

Overview

- **General principles**
- **Zonal concept**
- **Authorisations of plant protection products**
- **Mutual recognition of authorisations**
- **Renewal of authorisations**
- **Risk management**

Principles concerning the placing of plant protection products on the market

- **Active substances contained in plant protection products are assessed on community level**
 - List of approved active substances
- **In future community level assessment also for**
 - safeners and synergists (positive list)
 - co-formulants (negative list)
- **Plant protection products are subject to national authorisation procedures**

Authorisation procedures for plant protection products according Regulation (EC) 1107/2009

- **Authorisations (Art. 33 bis 39)**
- **Mutual recognition of authorisations (Art. 40 bis 42)**
- **Renewal of authorisations (Art. 43)**

Use of plant protection products

- **In principle, plant protection products are allowed to be sold and used only if authorised by a Member State (MS) for its territory**
- **Authorisations are limited in time; renewal after expiry is possible on request**
- **If an authorisation is withdrawn or not renewed the authority may grant a grace period of**
 - **6 months for sale of existing stocks**
 - **additional 12 months for disposal, storage and use**
- **No period of grace is granted where withdrawal or non-renewal due to health or environmental concerns**

Implementation of a zonal system for authorisations under Regulation 1107/2009

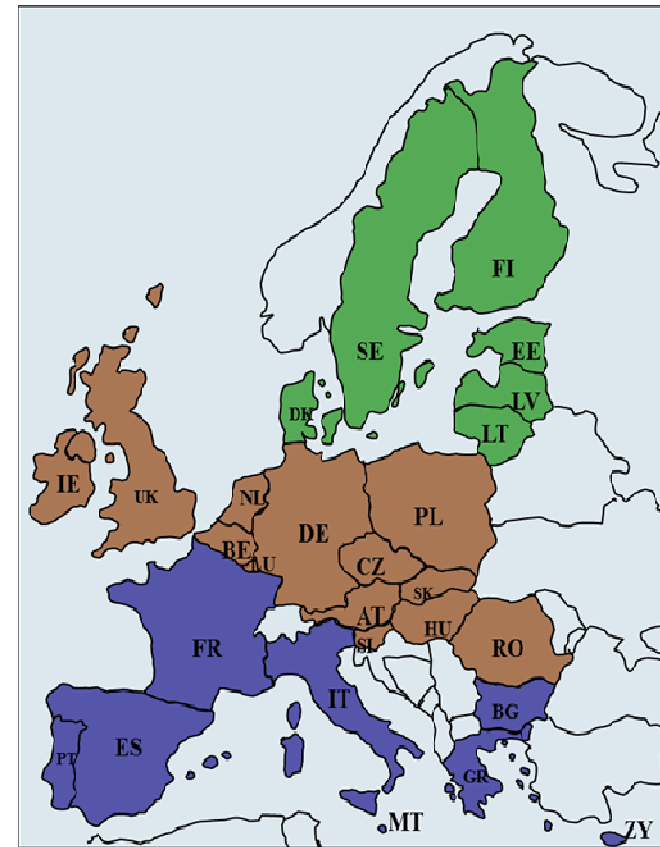
- **Rules and requirements for the new zonal system are laid down in Regulation (EC) Nr 1107/2009**

Accompanied by:

- **Guidance document on zonal evaluation and mutual recognition under Regulation (EC) Nr. 11007/2009 (SANCO/13169/2010)**
- **Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration report (SANCO/6895/2009)**

Zonal concept of Regulation (EC) 1107/2009

- **Zonal assessment**
 - 3 Zones: North, Central, South
 - Greenhouse, seed treatment, post harvest and empty rooms/containers for storage uses are interzonal
 - Separate application in each Member States
 - Work-sharing between Member States – one acting as rapporteur
- **Mutual recognition compulsory within zone, voluntary between zones**



Advantages/elements of the zonal procedure

- **Work-sharing: one zRMS assesses all uses within the zone**
 - ➡ registration report with core assessment
- **National requirements to be evaluated by the respective concerned MS**
 - ➡ national addendum to registration report
- **Key elements:**
 - Standardisation of the core assessment (EU methodology)
 - Use of risk envelope approach in core assessment
 - Acceptance of core assessment by all MS ↔ harmonisation of risk assessment ↔ reduction of national requirements
 - less/no national addenda

Communication within the zones

- **Zonal committees, e.g. Central Zone Steering Committee (czSC)**
 - All MS of central zone
 - Teleconferences every 2nd month, one face to face every year
 - Chaired by one MS for 1 year on a rotational basis
- **Interzonal Steering Committee (izSC)**
 - 2 MS of each zone (zonal chair and incoming chair) + European Commission)
 - Chaired by Commission
 - Teleconferences every 2nd month, alternate to czSC meetings

Zonal procedure – Application

- **Pre-submission meetings to be held with applicants approx. 6 month prior to submission**
- **Applicants to make proposal for zonal Rapporteur MS (zRMS)**
- **Applicants to define concerned Member States (cMS)**
- **Applicants to submit a „notification sheet“ to zRMS and all cMS**
- **Applicants to submit a zonal application with:**
 - application form [national language(s)/English]
 - dossier (studies with OECD format / EU revised format) [English]
 - draft registration report (dRR) [English]
 - possibly national addenda [English]

Timelines for zonal evaluations

- zRMS has **12 month** from application to decide on authorization
- Clock stop procedure for up to **6 month** where further data is requested
- 8 month after application **6-week** commenting period for MS within relevant zone
- Concerned MS have **120 days** from receipt of zRMS assessment and decision to decide on own national application

Evaluation

- **zRMS evaluates application to uniform principles and using guidance in place at the time of application in the light of current scientific and technical knowledge**
- **Comments from other MS to be taken into account during preparation of assessment**

Decision taking

- **Authorisation period to end one year after the next expiration date of approval of an active substance contained in it**
- **Other MS grant or refuse authorisation based on conclusions of the assessment of zRMS**
- **Derogation allowing**
 - flexibility to apply alternative risk mitigation measures
 - or to refuse authorisations if the use under specific national circumstances poses unacceptable risk to human or animal health or the environment
- **Right of appeal for refusals**

German Authorisation procedure – Institutions involved

Federal Office of Consumer Protection and Food Safety



- Designated authority
- Assessment: Chemistry, Analytics
- Risk management

Julius Kühn-Institute



- Assessment: Efficacy and use

Federal Institute for Risk Assessment



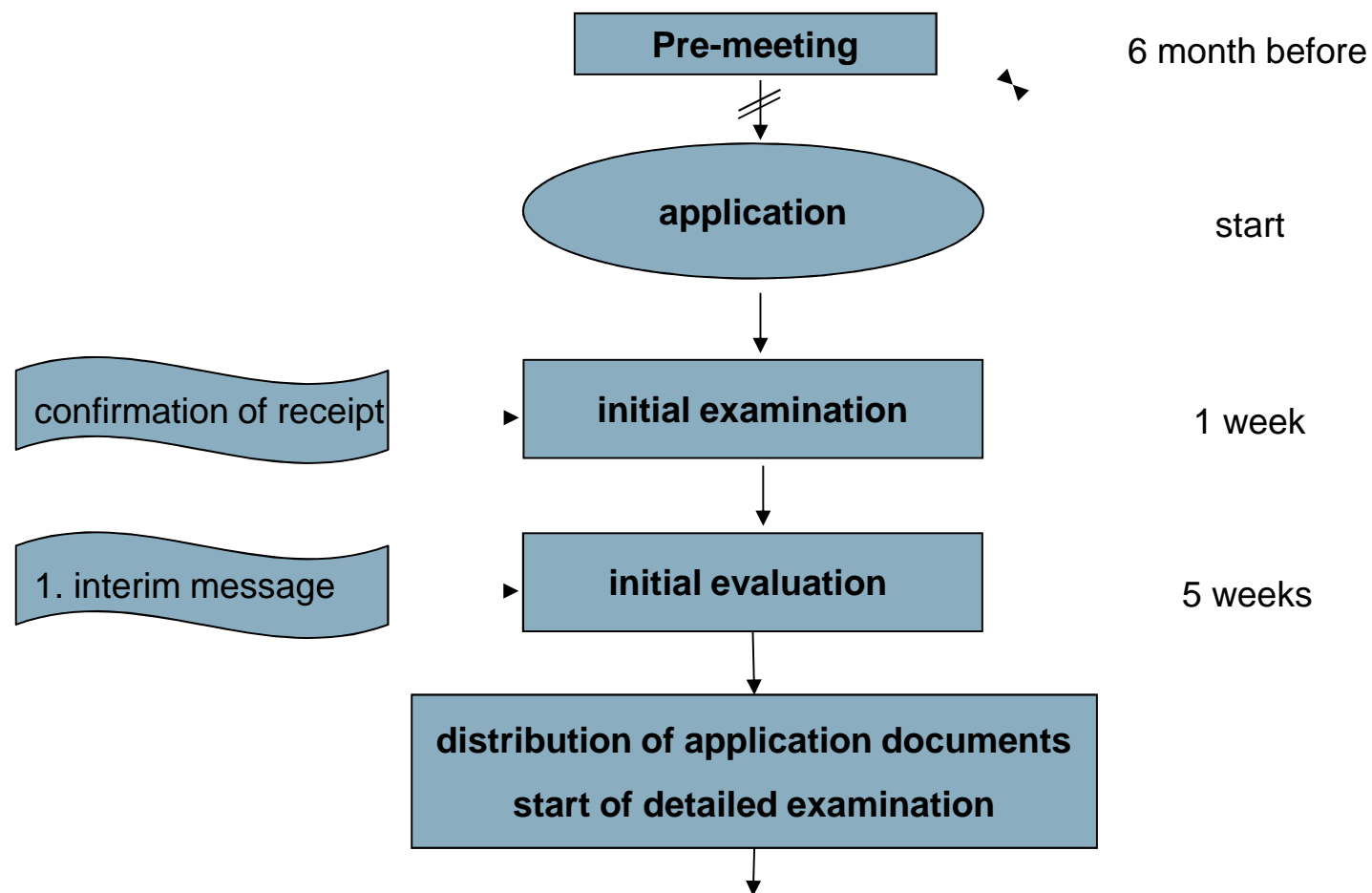
- Assessment: Toxicology, Health

Federal Environmental Agency

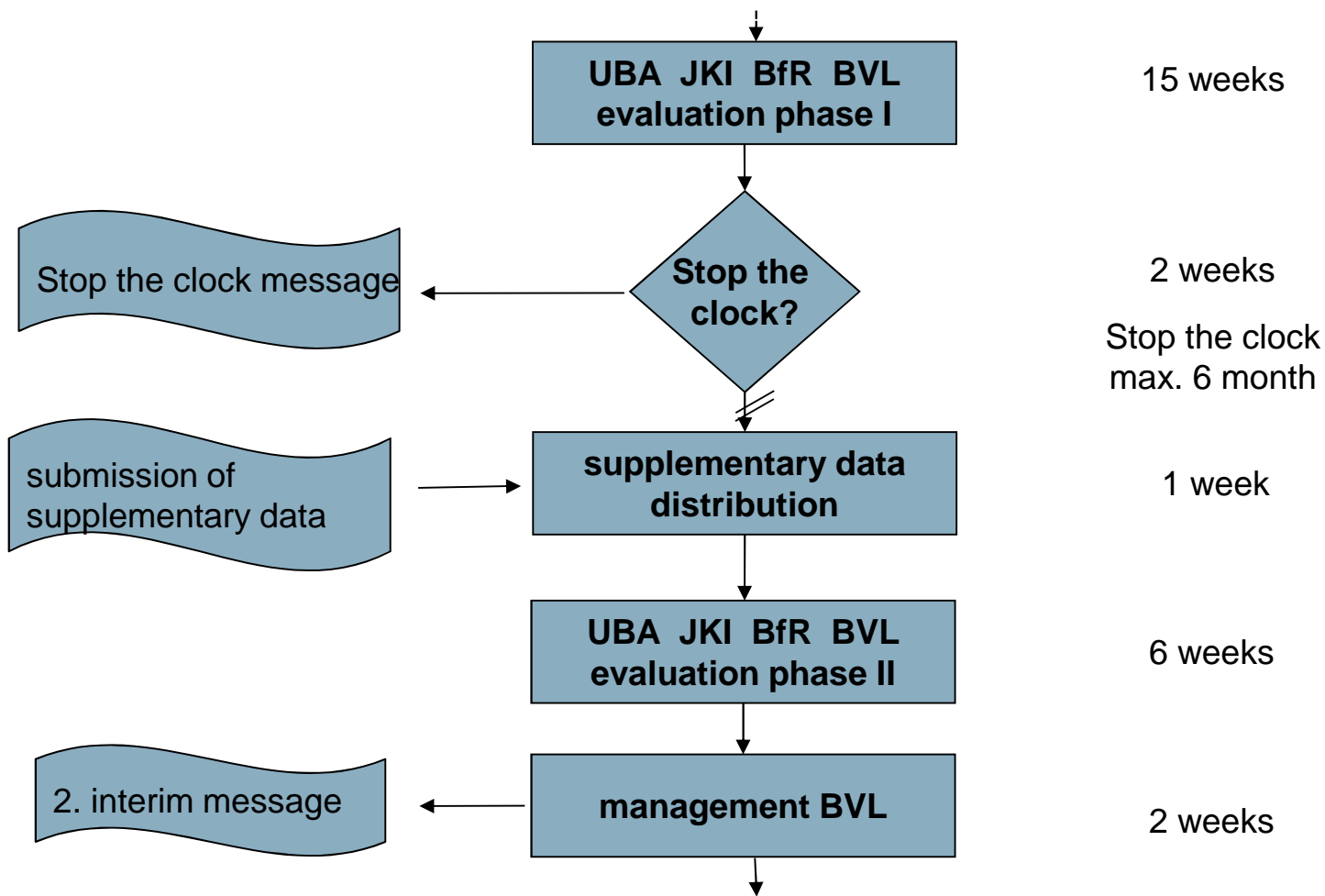


- Assessment: Environmental issues

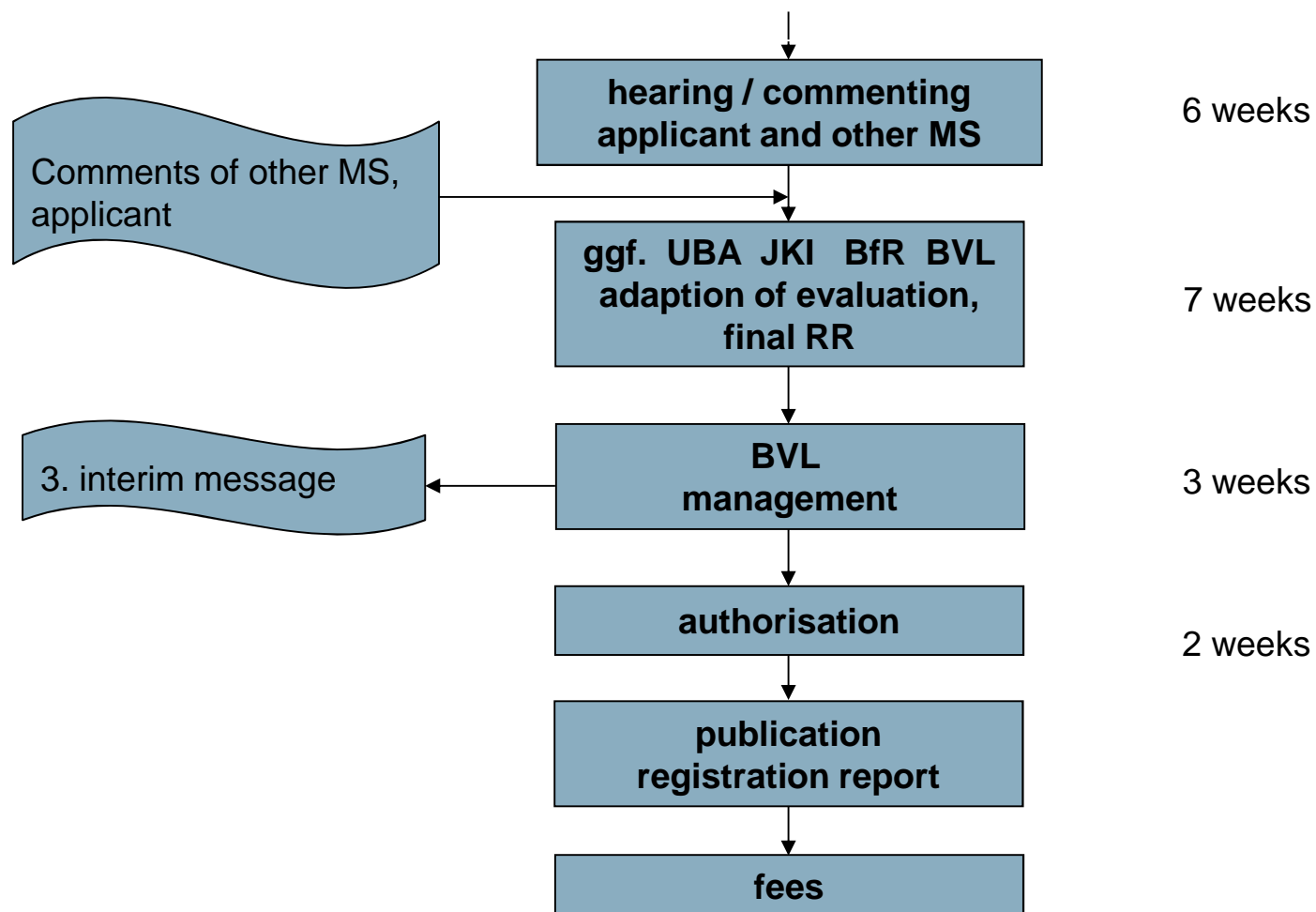
Evaluation process in Germany (DE = zRMS)



Evaluation process in Germany (DE = zRMS, cont.)



Evaluation process in Germany (DE = zRMS, cont.)



Mutual recognition of authorisations

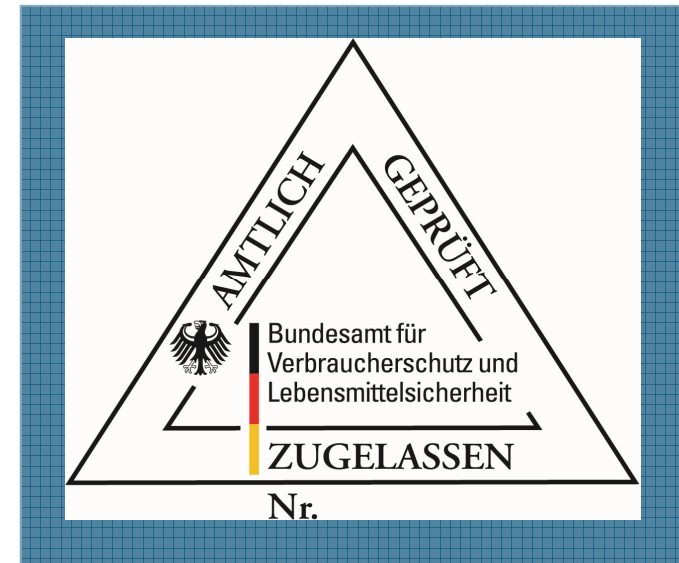
- **Mutual recognition only for same product, the same use(s) and under the same environmental practices**
- **Authorisation holders as well as official or scientific bodies involved in agricultural activities or professional agricultural organizations can apply for mutual recognition with and without consent of the authorisation holder**
- **In case of no consent authorisations may be granted on grounds of public interest**
- **Mutual recognition obligatory within the zone, voluntary between zones**

Renewal of authorisations

- Authorisations normally expire one year after the first expiration of the approval of one of the active substances contained in it
- Application for renewal of the authorisation within 3 months after renewal of the approval of that active substance
- Submission and evaluation of new information/data only (due to e.g. new endpoints, new GD, new data requirements)
- Zonal evaluation, but within only **9 month** period
- Procedure without stop the clock

Risk management: Content of the authorisation

- Establishment of the uses (crop - pest)
- Description of the application (technique, dose, timing, etc.)
- Pre-harvest intervals
- Labelling phrases (e.g. safety instructions)
- Use restrictions (e.g. non-spray zones to surface water)
- Classification regarding hazard to bees
- Clearance for amateur gardening (non-professional use)



Further information

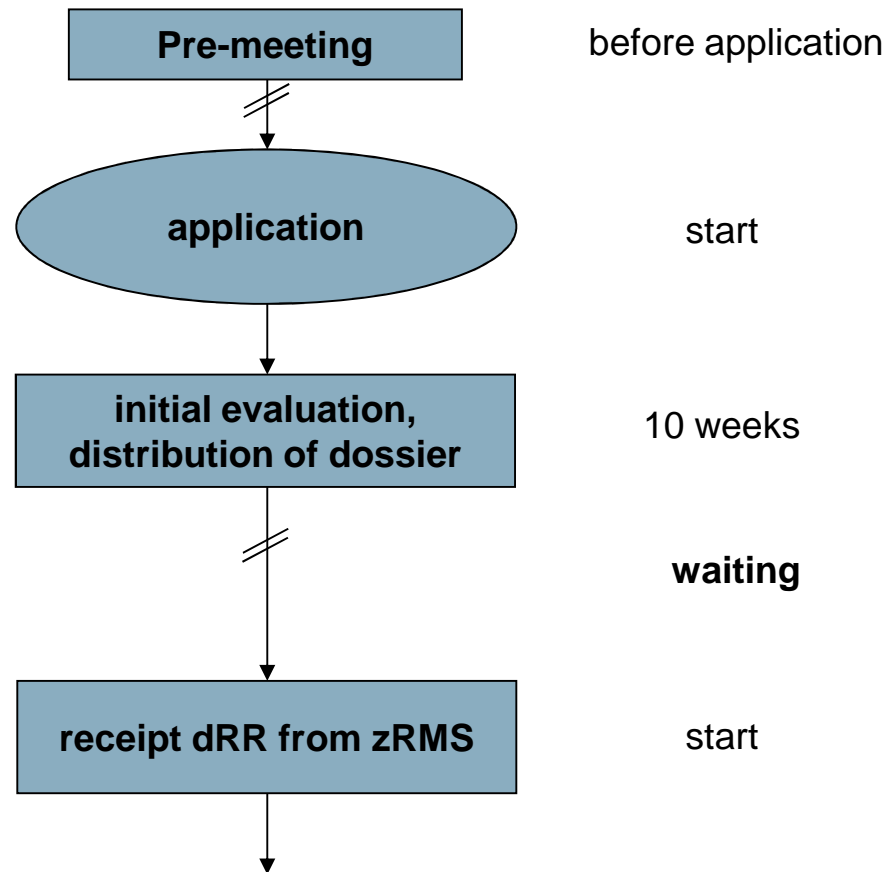
www.bvl.bund.de > Plant Protection Products

Contact:

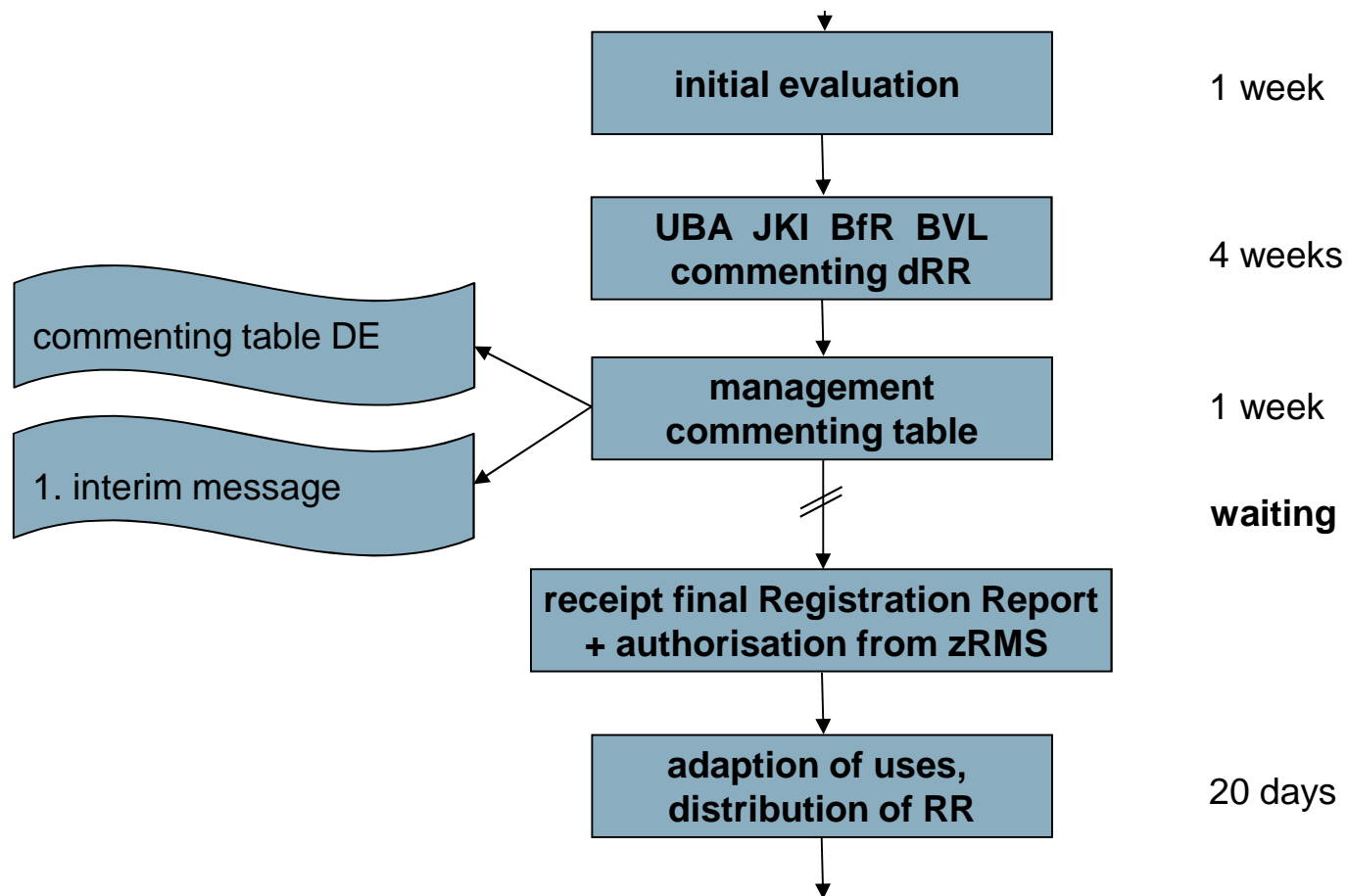
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Evaluation process in Germany (DE = cMS)



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