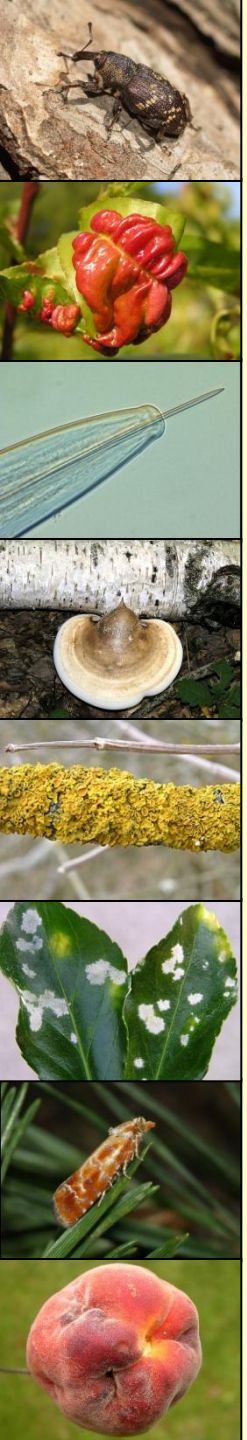


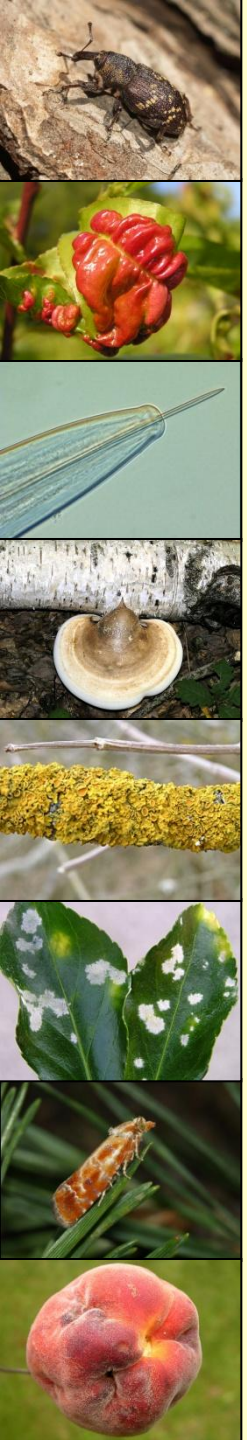
ČESKÁ REPUBLIKA
STÁTNÍ ROSTLINOLÉKAŘSKÁ SPRÁVA
STATE PHYTOSANITARY ADMINISTRATION

Regulation 1107/2009

State of progress

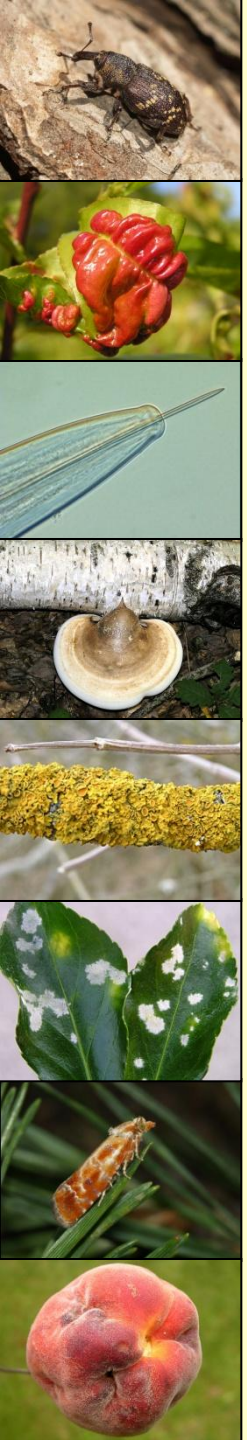
CEUREG Forum XVII, Budapest

Pavel Minář, State Phytosanitary Administration, Czech Republic



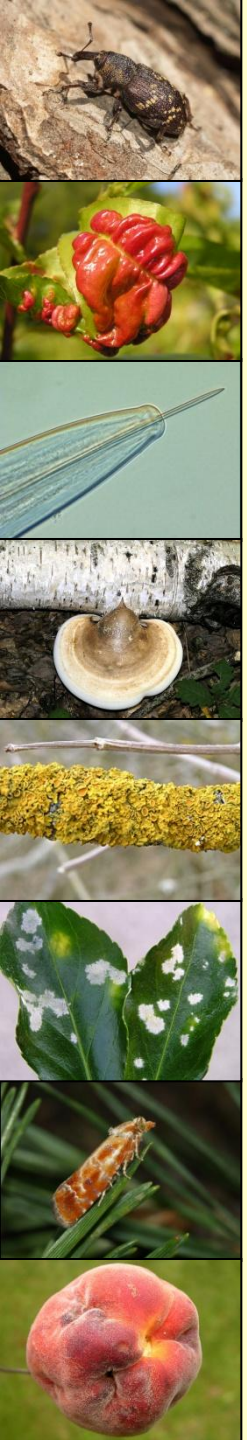
Zonal system - expectations

- **Higher level of safety**
- **Harmonisation, reduction of national requirements**
- **Saving capacity of experts and other staff and costs**
- **Speeding up procedures**
- **Similar PPP availability for farmers**



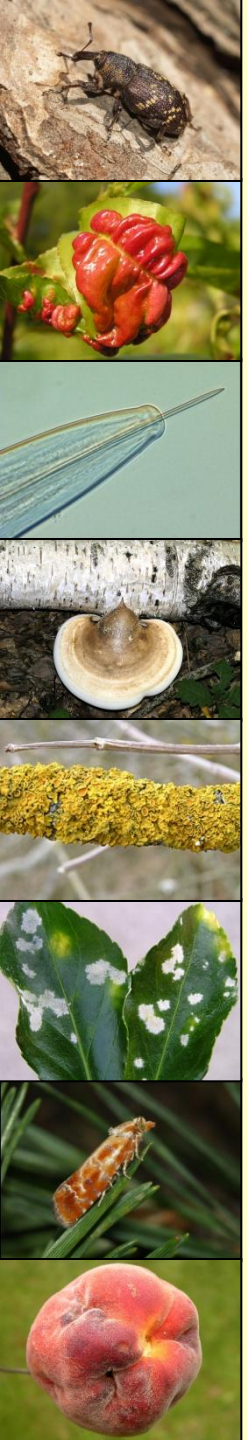
Role of CMS

- Confirm the reciept of the application
- Communication with the applicant possible
- Time to familiarize with the dossier
- Comment the dRR
- Grant or refuse the authorisation on the basis of ZRMS conclusions
- Timely identification of data gaps important



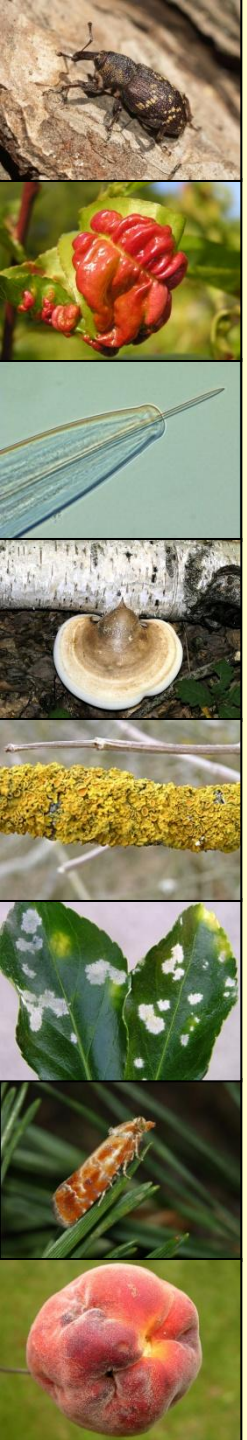
120-days procedure

- **Evaluate national data if submitted**
- **Check the relevance of the risk assessment conclusions**
- **Check the relevance of risk mitigation measures established by zRMS**
- **Grant the authorisation certificate**



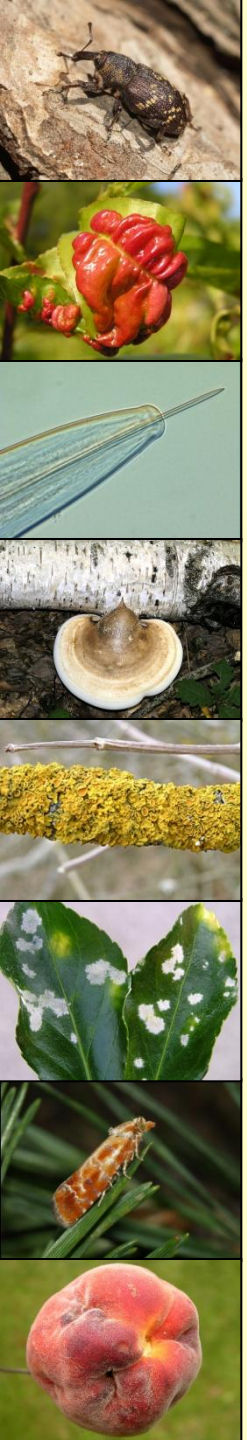
Mutual Recognition procedure

- **Deadline 120 days**
- **Registration report quality**
- **Data availability (no cross references to non-authorised products)**
- **Divergence between mutual recognition and standard authorisation not desirable**
- **Mutual recognition in case of public interest**
- **Reduction of emergency authorisations**



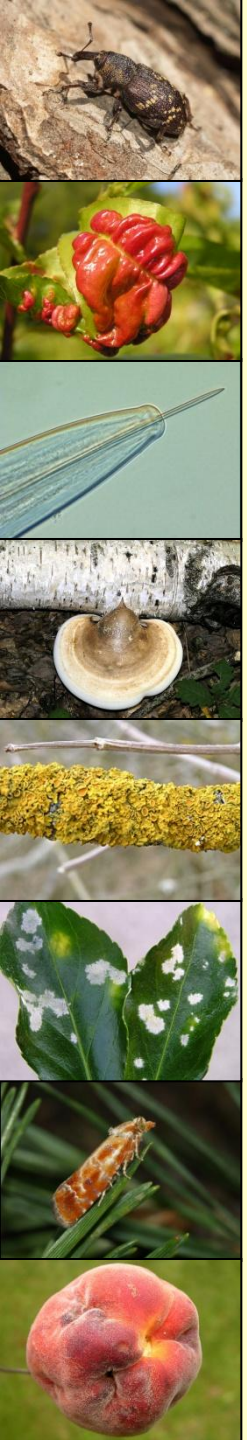
Biological Efficacy

- Dossier to cover the conditions prevailing in the zone
- Minimum effective dose
- Levels of efficacy
- Not all EPPO zones sufficiently covered
- Different application rates
- Some uses not sufficiently supported
- Data gaps affect the label



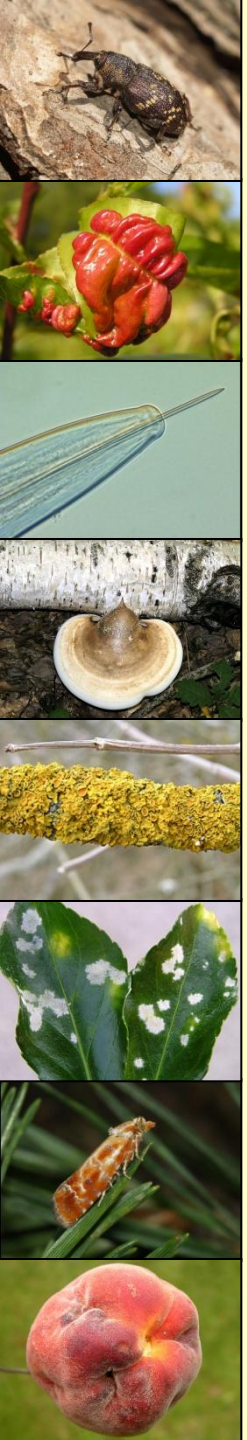
Saving capacity

- **MS‘s low personal capacity**
- **Some MS’s refuse to act as zRMS**
- **Obligatory deadlines often not met**
- **Limited involvement in commenting**



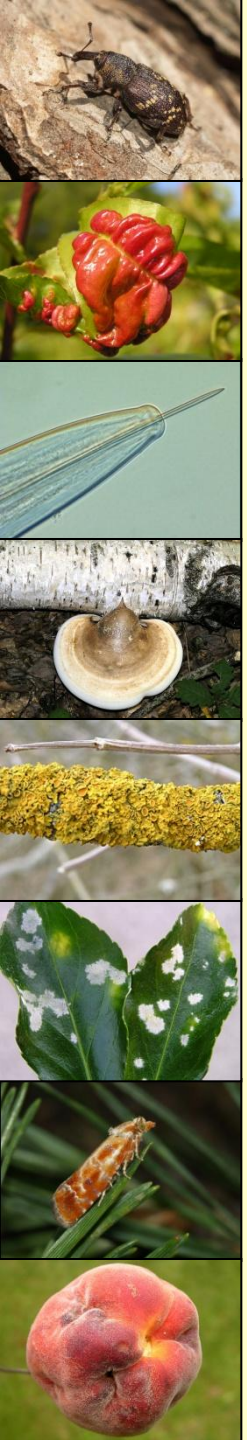
Present CZ situation

- **Estimate 35 applications as ZRMS per year**
- **1 – 3 active ingredients as RMS**
- **Totally about 1300 applications / year, incl, 200 administrative + 400 parallel imports.**



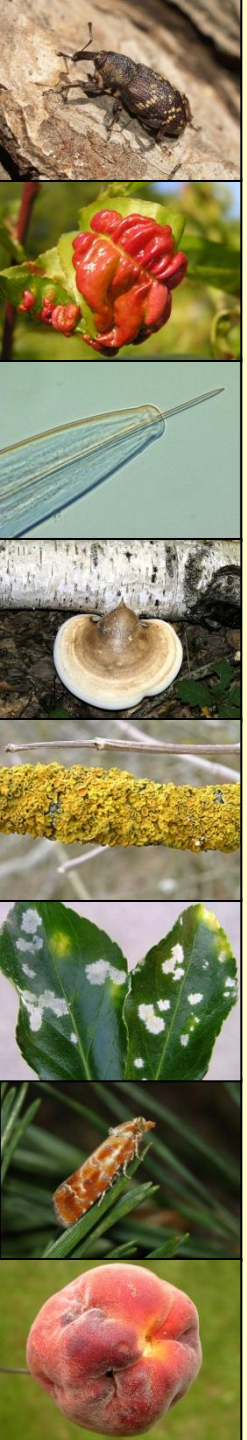
Recommendations

- **Risk management harmonisation**
- **Description in dRR the range of conditions for which risk-assessment was performed**
- **Acceptability of data gaps (risk mitigation measures)**



Recommendations

- **Authorities to focus on effectiveness and priorities**
- **Compare effectiveness of experts and capacity in MSs**
- **Commenting limited to crucial issues**
- **Consistency of experts in each MS and industry**
- **More trust necessary – role of managers**



Thank you for your attention!

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