Central Institute for Supervising and Testing in Agriculture

Experience with the Zonal Process

ISO 9001: 2008 certified

Pavel Minar
Czech Republic
www.ukzuz.cz




Content

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- Possible accelerators
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„Bureaucracy means concentration on details and on procedures while original aims of the activity lay aside“
(G. Pompidou)

Aims of 1107/2009:

- **Saving capacity of regulators and cost of applicants, speeding up processes**

- **More harmonisation, reduction of duplication of the expert essessment**

- **Higher level of safety for humans and environment**

- **Similar conditions for farmers within the EU**

Cooperation

- Communication of experts, expert groups, workshops

- Zonal Steering Committees
- Interzonal Steering Committee

- Post Approval Issues Group (PAI)
- Standing Committee

- Directors Consultation Group (in Central Zone)

Cooperation

CZ DCG meetings 2x/year

- Harmonisation blockers
- Arbitration board
- Zonal secretariat
- Rules of procedure
- List of CZ agreements

- Directors are guarantors of agreements

Positive steps

- dRR, core part of the assessment
- More areas covered by guidelines
- Commenting other‘s evaluation
- Everyday expert communication
- Harmonisation of GAPs, formulations




Czech Republic – situation 2012 - 15

- Number of applications reduced (cca 20 %)

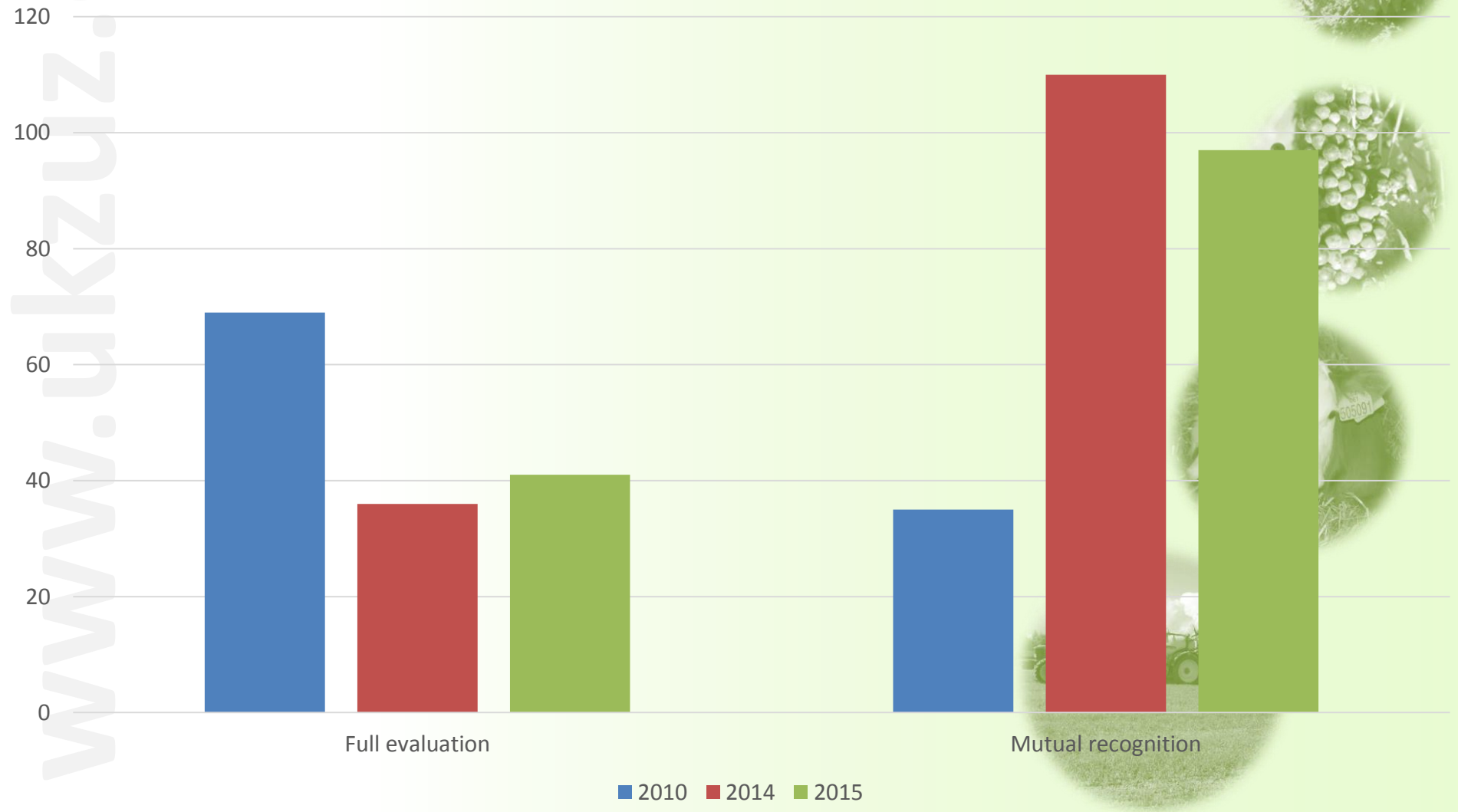
- Increase of mutual recognition – 50 % of new products

- Mutual recognition process sped up
- Most of deadlines met

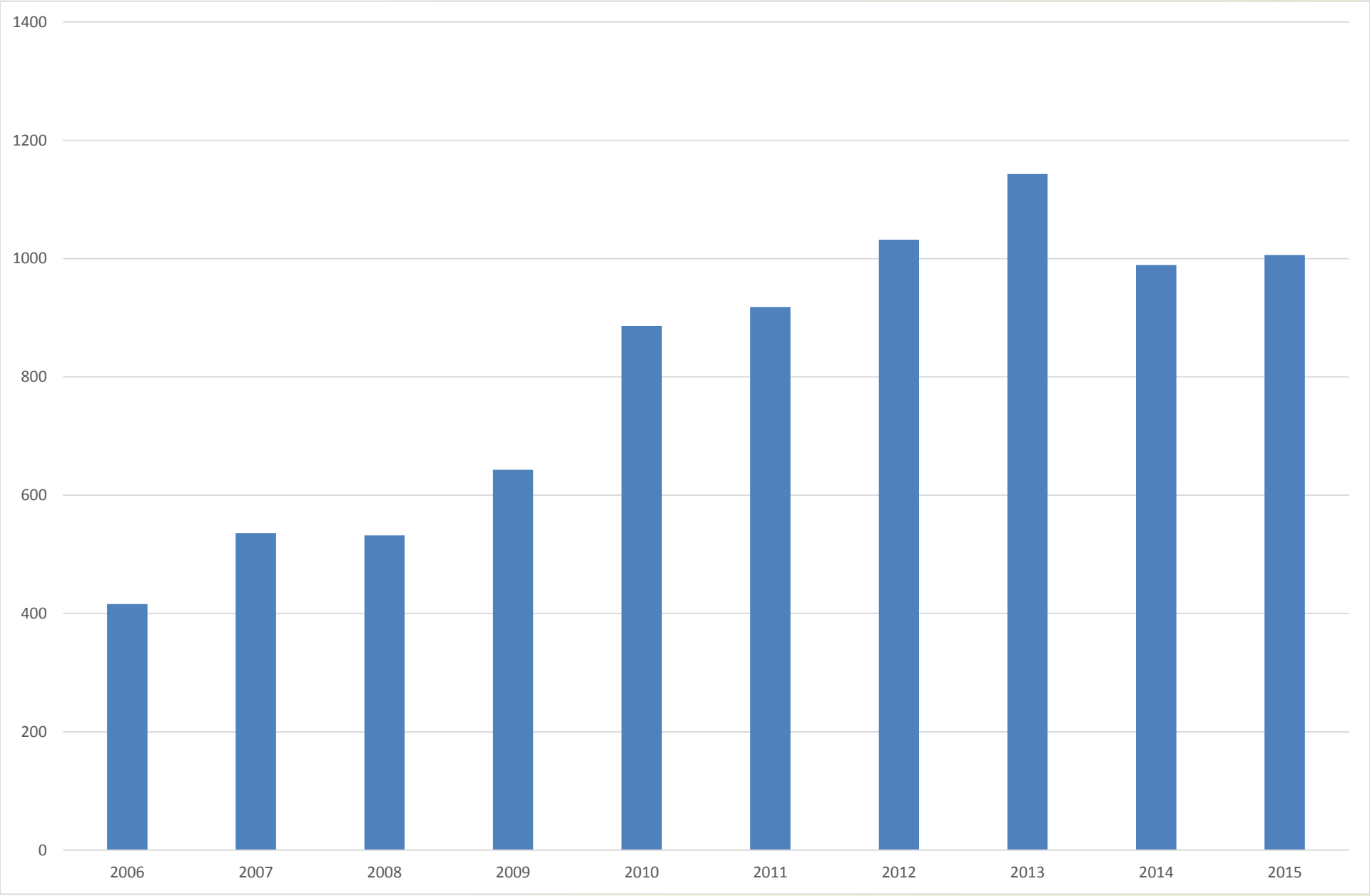
- Analysis of possible procedural simplifications

Zonal system – submission changes

Type of submission - CZ



Number of submissions in CZ 2006 - 15



Expectations

- More personal capacity
- More mutual trust
- Mutual recognition should be improved
- More certainty as to EU data requirements
- Reduction of national data requirements




Possible accelerators

Capacity + trust + mutual recognition

- Willingness to profit from mutual recognition
- Avoid double-check of details of the risk assessment, concentrate on risk management
- Reasons for MR refusal:
  - Data protection issues
  - Impossible to mitigate the risk
  - GAP or composition not relevant
  - Expiry date of the original authorisation (renewal process)
  - Confirmatory data
- Role of directors to establish clear rules

Possible accelerators

More certainty as to EU data requirements

- Biological efficacy often mentioned
- EPPO Standard PP 1/226(2)Number of efficacy trials to be amended and clarified:

„As a general guide, a total of 10 trials with results that are fully supportive….“
„ in a range of diverse conditions, such as across an authorization zone …number of trials may need to increase.“
„In some situations, there may be the opportunity to reduce the number of trials…“

Possible accelerators

Other EU and national data requirements

- Arbitration board if different approach identified
- Bilateral or zonal agreements - role of directors
- Leadership and governance from the Commission




Amendment of 1107/2009

- No timeframe so far

- Article 43 amendment
- Ideally approvals for unlimited time period + revision programmes

- Critical also Article 36 par. 1

- Better formulation of articles on mutual recognition

Conclusions

- Zonal system has good preconditions to work

- Restructuring and simplification of national systems desirable

- Role of directors is to set up clear frame for experts

- Emphasis on risk priorities
- Harmonisation of risk-management

Thank you for your attention!

UKZUZ, PPP Division
pavel.minar@ukzuz.cz