GEP System in the Czech Republic

CEUREG FORUM XIII
15-16 October 2009, POZNAN

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Legal background

- Council Directive 93/71 amending Annex III to Concil Directive 91/414/EEC:
  - Biological efficacy tests for registration purposes (Annex III, part 6, points 6.2 – 6.7) must be performed by testing organisations
    - Official or
    - Officially recognised

Legal background

- Council Directive 93/71 amending Annex III to Concil Directive 91/414/EEC:
  - Tests under part 6, points 6.2 – 6.7 should be in compliance with:
    - EPPO Guideline 181 + 152
    - Specific EPPO guidelines

Legal background

- EPPO Standard PP 1/181 (3)
  - requires compliance with GEP principles
  - defines GEP principles
  - defines data to be collected and recorded
  - defines trial report, trial series report and biological assessment dossier (BAD)

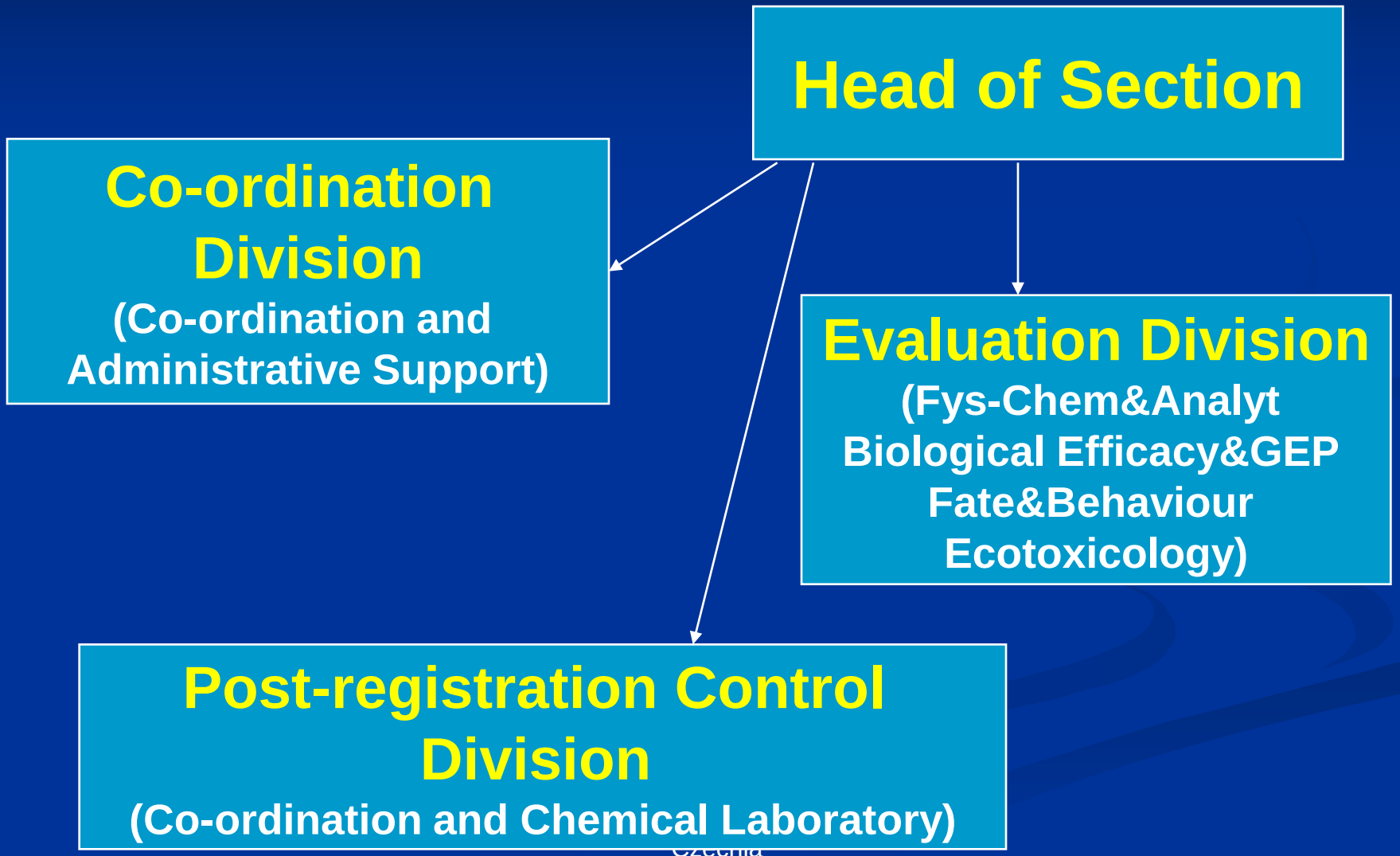
Legal background

- Basic GEP principles are the same for all MS, implementation is specific
- MS‘s apply additional national requirements, e.g.:
  - Waste disposal rules
  - Personal protective measures
  - Handling with harvested crops
  - Buffer zones etc.

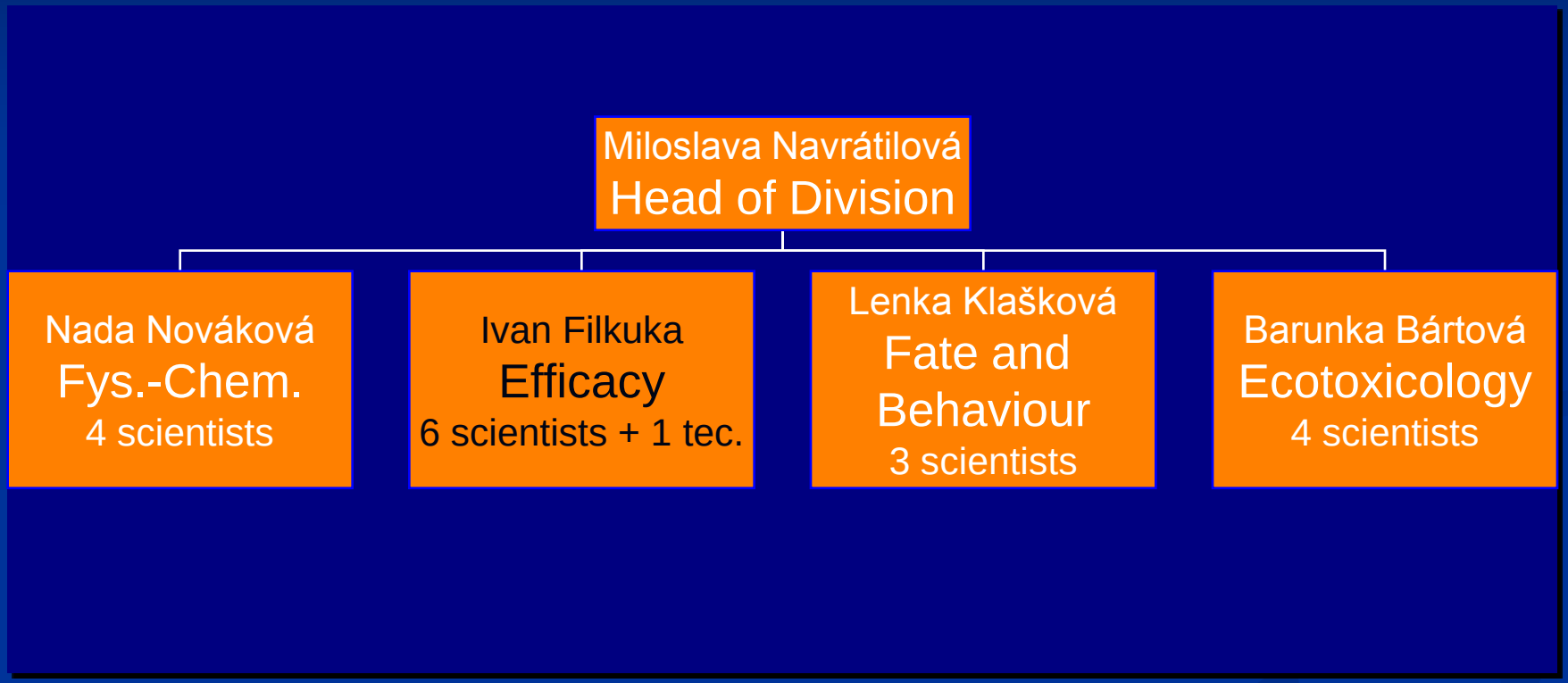
Background

- CZ system established in 1996 based especially on French model and GLP
- Later amended following UK, DK and DE system and own experience
- 1997 – 32 testing organisations
- 2003 – 23 - " -
- 2007 – 28 - " - = 39 testing stations
- No official organisations (same rules for everybody)

Structure – PPP Section of SPA



Evaluation Division



Application for GEP certificate

- 2 inspectors (biological efficacy experts; 30 % of working capacity)
- 1 technician (logistics + inspections)
- further experts as co-inspectors
- co-operation with department of chemistry and department of application machinery
- GEP Certificate signed by PPP section
- Validity up to 5 years

Application for GEP certificate

Submission of the application form

Submission of a dossier

- Quality Manual
- SOP set
- Metrological Rules

Application for GEP certificate

- Deadline – 60 days
- Evaluation of dossier (cca 3 weeks)
- Audit (1 day or repeatedly)
- Audit report (3 days)
- Stop the clock in case of problems
- Decision and Certificate (10 days)

GEP Inspections

- 2009 – 24 inspections (each TS at least once per 2 years)
- 5 – 7 hours
- Check-lists
  - Changes
  - Trials (2 – 4 per visit)
  - Knowledge of procedures
  - Deviations
- Control visit report (structure like the audit report)

GEP organisations

- 12 research institutes (3 state and 9 private)
- 2 universities
- 13 private testing organisations
- 1 chemical company (BASF)

Information to be notified

- Each GEP test to be notified 7 days before 1st treatment incl. locality (at the latest)
- Important changes to be notified immediately (esp. changes in staff, status etc.)

Recent developments

- 2007 - SW for communication between TS, sponsors and SPA
  - GEP applications
  - Experimental use permits
  - GEP trials requests and notification
  - Trial lists and summaries
  - Related documents sharing

Basic information

WWW.SRS.CZ

- SPA contacts
- Procedure and fees
- Guidance documents
- List of GEP organisations