



ČESKÁ REPUBLIKA
STÁTNÍ ROSTLINOLÉKAŘSKÁ SPRÁVA
STATE PHYTOSANITARY ADMINISTRATION



New PPP Regulation Czech Strategy

CEUREG FORUM XIV
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Content

- **Legal changes**
- **Changes in organisation**
- **Further concepts**



New legal situation

- **PPP Regulation – basic text; not implemented, repeated or interpreted in national laws – **direct application!****
- **Commission Regulations – **direct application!****
- **CZ Act and its Regulations – legal texts of 3rd level establishing**
 - Competences of individual authorities
 - National level processes (those not defined by PPP Regulations)
 - Optional points („MS may“)
 - Further national provisions (not data requirements!)



Legal interpretation

Present state:

- CZ Regulatory authority
- CZ Ministry
- CZ National courts
- Commission (interpretation of Directive)
- ECJ (interpretation of Directive)

From 2011:

- CZ + 26 Regulatory authorities
- CZ Ministry
- CZ + 26 National courts
- Commission
- ECJ court



State of play

- **Draft amendment at the stage of inter-ministerial consultations**
- **Adoption by the Parliament – May 2011**
- **Presidential signature before 14 June 2011**



Main new points in Act

Efficiency of PPP inspections

- **Repackaging**
 - Notifications to SPA in advance
 - Documentation and traceability
 - Transfer of the batch number and expiry date; approved package
- **Distribution**
 - Good distribution practice
 - Documentation and traceability



Main new points in Act

PPP Authorisations

- Better definition of minor uses
- Definition of cases of public interest
- Possibility of SPA initiative in cases of public interest + authorisation via SPA notice

Reduction of administrative upload for farmers



Changes in Organisation and Capacity

- **Still under discussion**
- **Reduction of number of branches within PPP Section**
- **Strengthening of post-registration area**
- **Specialisation of PPP inspectors**
- **National Food Safety Authority before 2013**
- **Seminars for applicants**
- **Better information of public**



Further concepts – biological efficacy

- **Dossier should cover the Czech conditions**
- **Comparability will be taken into account during assessment or commenting**
- **Possible impact on the label or authorisation**
- **Minimum effective dose?**
- **Number of tests?**
- **Expert Group desirable**





**Thank you for your
attention!**

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