



**ČESKÁ REPUBLIKA**  
**STÁTNÍ ROSTLINOLÉKAŘSKÁ SPRÁVA**  
**STATE PHYTOSANITARY ADMINISTRATION**



# **Regulation 1107/2009 – How to get to higher liberalisation?**

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**Pavel Minář**

# Content

- **Aims declared**
- **State of play**
- **Biological efficacy**
- **Czech approach**



# What is declared?

- ...high level of protection of human and animal health and the environment (to safeguard the competitiveness of Community agriculture)...
- ...to increase the free movement of products and availability of products in the Member States...
- ...to avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products...



# State of play

- Interpretation of many key provisions under discussion
- Some interpretations are contradictory with aims declared
- Problems with capacity and deadlines in some MS's
- Support to national regulatory structures and testing organisations by a part of national requirements
- Lack of trust in some areas



# Biological Efficacy

- **Minimum effective dose**
- **Minimum number of trials and their location**
- **Definition of „conditions prevailing in zone“**
- **Comparable x Relevant**
- **National requirements x specific conditions**
- **Registration Report – level of details**



# Biological Efficacy

- **Dossier should cover national conditions**
- **Relevance of data shall be taken into account during assessment or commenting**
- **Possible impact on the label or authorisation**



# Czech Approach

- **Reduction of duplications in the expert area by reduction of national requirements**
- **No divergence between mutual recognition and authorisation**
- **Voluntary initiative in mutual recognition will increase (reduction of emergency authorisations)**



# Czech Approach

- **Focusing on minor uses**
- **Better definition of cases of public interest**
- **Procedures in favour of plant protection and safety; not in favour of regulatory structures**







**Thank you for your  
attention!**

**Name: Pavel Minář**  
**e-mail: [pavel.minar@srs.cz](mailto:pavel.minar@srs.cz)**  
**State phytosanitary Administration**  
**Adress: Zemědělská 1a, Brno,613 00**  
**[www.srs.cz](http://www.srs.cz)**

