

# Biofungicide Polyversum

## Zonal Authorization and Mutual Recognition in Central Zone



Biopreparáty, spol. s r.o.  
Unětice 150,  
252 62 Czech Republic

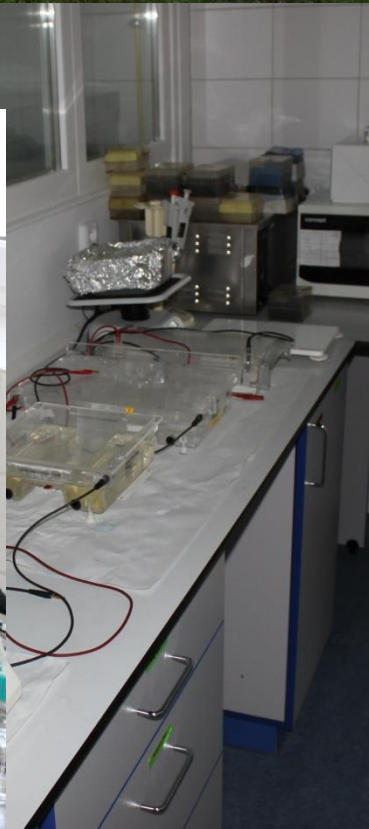
Office: Úherce 1,  
440 01 Úherce,  
Czech Republic

## Our strategy, policy, approach and contribution

### Biopreparáty

- Safe microbial production and formulated products
- Modern production facilities
- Sufficient production capacities
- Social responsibility
  - new production units located in high unemployment region
- Environmental responsibility
  - new production units built up on brownfields





# Biopreparáty, spol. s r.o.

Opening Door for Sustainable Agriculture



## POLYVERSUM – formulated product

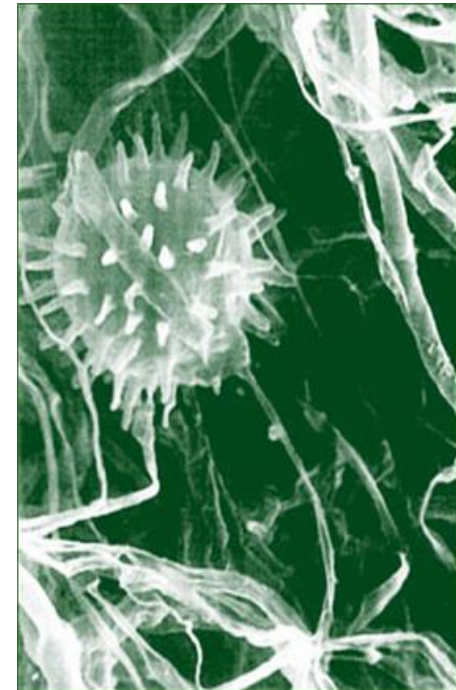
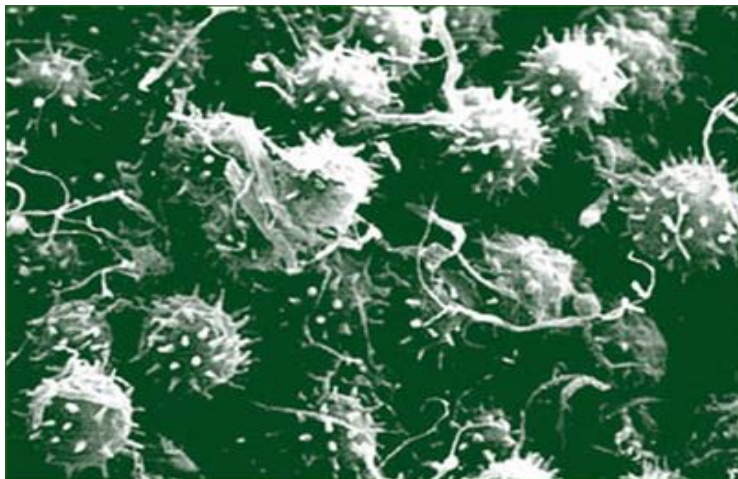
- Formulation: Wettable powder
- Active substance: *Pythium oligandrum* M1
- Oospores per gram - quality assessment factor
- Inert carrier: Silicon Dioxide
- Storability: 2 years



### Active Substance

### *Pythium oligandrum* M1

- Fungi-like microorganism
- Ubiquitous in soils, isolated from free soil in CZ
- Hyperparasite of fungal microorganisms
- Trigger of the induced resistance



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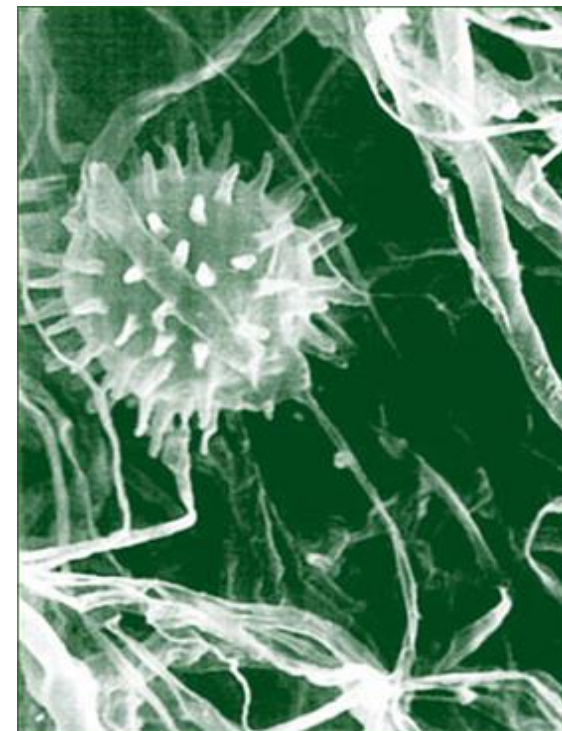
## Opening Door for Sustainable Agriculture



Active Substance

*Pythium oligandrum* M1

- European Union – since 2009 Regulation (EU) No. 540/2011 implementing 1107/2009 EC
- USA – registered by EPA since March 2007
- People's Republic of China – registered by Department of Agriculture since August 2009

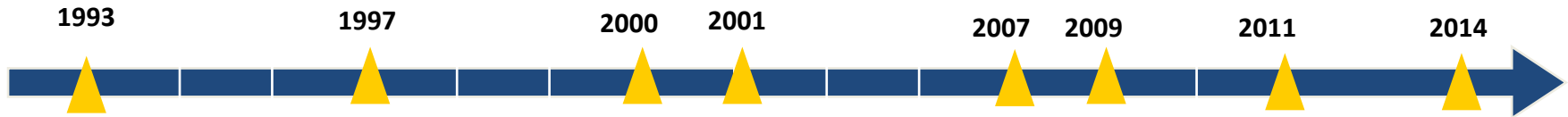


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## Opening Door for Sustainable Agriculture



### Registration – Global overview



- 1993 *Pythium oligandrum* authorized as seed treatment compound
- 1997 set up of BIOPREPARÁTY spol. s r.o.
- 2000 Polyversum registered in Poland
- 2001 Polyversum registered in Slovakia
- 2007 Polyversum and *Pythium oligandrum* registered in the USA
- 2009 *Pythium oligandrum* Annex I inclusion (EU)
- 2009 Plant Protection Product and *Pythium oligandrum* registered in China
- 2011 Polyversum registered in Hungary
- 2011 extension of Polyversum authorization in Czech Republic
- 2014 Slovakia Polyversum re-evaluation 1107/2009
- 2014 Polyversum zonal authorization for Central zone of the EU

### Polyversum Regulatory process – overview

- 1993 first registration Polyversum
  - *Pythium oligandrum* M1 -> old active substance
- 2006 extension for OSR
- 2009 *Pythium oligandrum* M1 – annex I
- 2011 extension for cereals - according to 1107/2009
- 01 - 2011 re-evaluation of product, zonal evaluation Central zone, RMs CZ
  - Changes of required formats
  - Technical discussion (EFSA, RMs)
- 05-2014 zonal authorization Central zone



## Scope of the Zonal Authorization

- Oil seed rape
  - Blackleg (*Leptosphaeria maculans*)
  - Sclerotinia stem rot (*Sclerotinia sclerotiorum*)
- Cereals Wheat and Spring Barley
  - against Ear fusarioses

## Polyversum - National Authorization (EU)

- Czech Republic 1107/2009
- Poland 91/414
- Slovakia 1107/2009
- Hungary 91/414



### Mutual recognition – Central zone

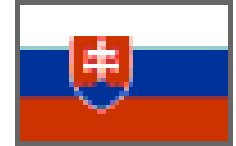
- Strategy
  - Neighboring countries
    - National authorization based on the application for the MR
    - Upgrade + extension of the existing national authorization
- Communication with the authorities
- National specifics/requirements

### Poland



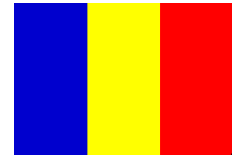
- Regulatory activities - BIOPREPARATY + Importer
- National requirements
  - Translation of the documentation to Polish language  
(Journal of Laws of the Republic of Poland, item 455, Act of 8 March 2013 on plant protect products, Chapter 2, article 4)
  - Change of the law in process
    - Approved by Sejm, received by Senate, final approval President
    - Change expected 01-2015 → translation will not be required
- Submission of application for the MR of Zonal Authorization

## Slovakia



- Regulatory activities - BIOPREPARATY
- Application for the MR of Zonal Authorization – submitted 10/2014
- Existing national authorization 1107/2009
  - Extension for indications in the Zonal Authorization, no change on others
- SK authority
  - Professional and competent, friendly and helpful approach
  - No additional or specific national requirements
- National evaluation **X** Zonal evaluation

## Romania



- Regulatory activities - BIOPREPARATY + Importer
- Preferred communication ROM-ROM
- Submission of application for the MR of Zonal Authorization

### Hungary



- Regulatory activities - BIOPREPARATY
- Local staff needed
- Submission of application for the MR of Zonal Authorization

### Austria



- Regulatory activities – BIOPREPARATY
- Seeking for distributor

## Mutual recognition – Central zone

- Regulatory procedure
  - Formal and procedural actions
  - Time
- What we consider as an issue:
  - List of low risk products
  - List of candidates for substitution
  - IPM rules implementation into operational routine



## Integrated Pest Management

- Regulation 1107/2009
- Directive 128/2009 + following
- National law implementation
  - National action plan,.....
- Candidates for substitution
- Low risk products



## Integrated Pest Management

- Country by country 
  - National action plan
    - Teaching farmers, explanation of the rules and targets
  - Tools / Motivation
    - Subsidies
    - Taxes
    - Sanctions
- EU global approach 
  - Unification of the agri policy and market
  - Unification of the rules and tools for professional users

## THANK YOU FOR YOUR ATTENTION

**Jiří Uher**

Business Development  
Manager

+420 777748415

uher@biopreparaty.eu