



# Efficacy and low risk products

Introduction on the scope

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# Content

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- Some background on the green deal
- Low risk definition
- Scope and objectives of this workshop

## NPPO

- Efficacy approaches
- Lines of thinking



# The “Green Deal”

## Objectives:

- To stimulate sustainable plant protection by collaboration between government and industry
- To resolve obstacles in the authorisation process
- To stimulate the market access of low(er) risk products
- To stimulate farmers toolbox with low(er) risk products

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# Issues for industry and RA

For the industry:

- Development of new active substances and products
- Building a dossier and registration of the products

For the regulatory agencies:

- To assist the SME's
- To innovate along with industry instead of stifling innovation

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# Green Deal

- 8 pilots with products
- 2 pilots with active substances
- Contribution to harmonisation
- Document and share the lessons learned



# Lessons learned 1

- A Pre Submission Meeting (PSM) is important to clarify possibilities and difficulties
- Managing of expectations  
Efficacy important issue in PSMs
- A specialised “greenTEAM” of assessors for intake and assessment
- Tailor made solutions for dossiers

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## Lessons learned 2

- The current, “chemistry based”, requirements are not always helpful
- Sometimes the data requirements are not realistic
- There is a need to harmonise guidances within EU and worldwide

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# Lessons learned 3

## Contribution to harmonisation

- Workshop micro-organisms and human toxicology assessment
  - > PPE
  - > exposure versus risk assessment
  - > secondary metabolites
- Workshop *Efficacy requirements and evaluation of PPP based on low-risk active substances*

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# Low risk

- Definition regulation 1107/2009
- Status new definition
- 5 substances approved low risk:
  - Isaria fumosorosea* strain Apopka 97 (renewal)
  - COS-OGA (new a.s.)
  - Cerevisane (new a.s.)
  - Ferric Phosphate (new a.s.)
  - Pepino mosaic virus strain CH2 (new a.s.)
- Criteria **not** subject of this workshop

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# Efficacy and low risk

- Not dealt with in active substance dossier
- EPPO standards not for LR (micro's)
- Mode of action important story
- Low risk > less harm > less efficacy??
- Justification of the claim
- Need for harmonisation

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# Aim of this workshop

- Start process of harmonisation:
  - requirements
  - efficacy evaluationfor low risk ppp
- Starting point for EPPO standards for assessment of low risk ppp
- Without losing flexibility or complicating matters

# Less hurdles

