

Rose is a rose is a rose...

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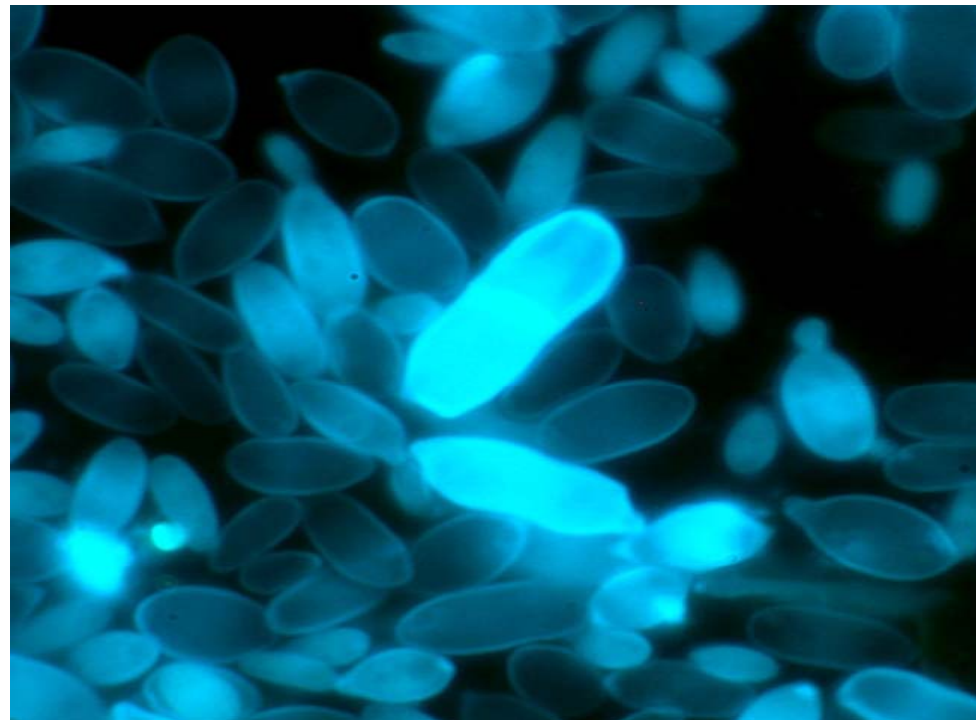
bio-ferm is part of the Austrian family-owned Erber Group with more than 50 branches, active in almost 100 countries worldwide, has more than 1.600 employees and a turnover of 250 mio EUR.

Science cluster Tulln:



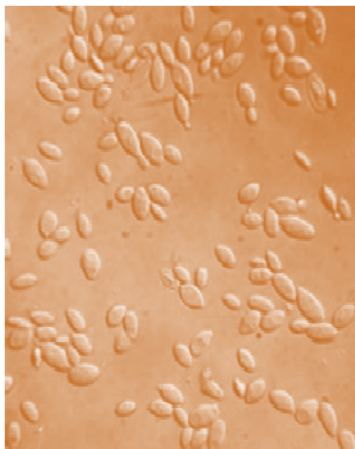
The main players are...

***Aureobasidium pullulans*, DSM 14940 and DSM 14941**



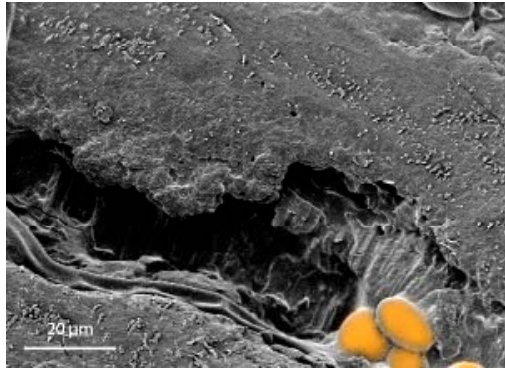
Aureobasidium pullulans

- Ascomycete with asexual, yeast-like reproducing cells (blastospores)
- Natural occurrence in the environment (soil, plant surface)
- Well adapted, resistant to drought and UV radiation
- Shelf life from date of manufacture:
 - at room temperature ($\leq 20^{\circ}\text{C}$) 18 months
 - at cold storage ($\leq 8^{\circ}\text{C}$) 30 months

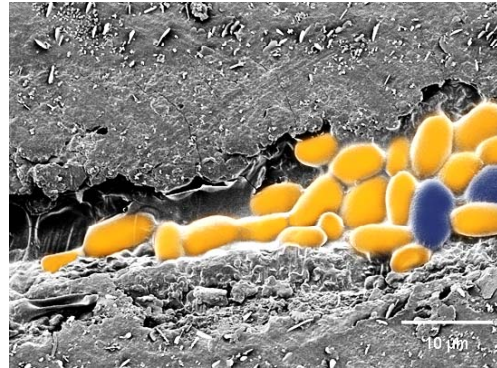


Aureobasidium pullulans, under the microscope, on an agar plate and dried to granules

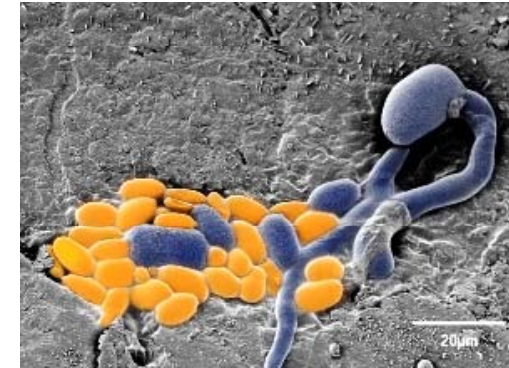
Mode of Action: Antagonism – competition for space and nutrients



1. Micro scratches on the fruit surface represent natural entrances for the pathogen. The scratches are colonized by *Aureobasidium pullulans* immediately after application of Botector® .
(Picture: Mendgen).



2. Due to the high proliferation rate of *Aureobasidium pullulans* the pathogen cannot infect the plant .
(Picture: Mendgen).



3. The micro scratch is completely colonized with *Aureobasidium pullulans*. Botector® acts as a natural shield which protects grape bunches from infection with *Botrytis cinerea* (Picture: Mendgen).

- *Aureobasidium pullulans*
- pathogen

Scale up the production:



Marketing:

Botector® HIGHWINDKAM RESISTENZEST (100% Bio-Produkt)

03.01.2010

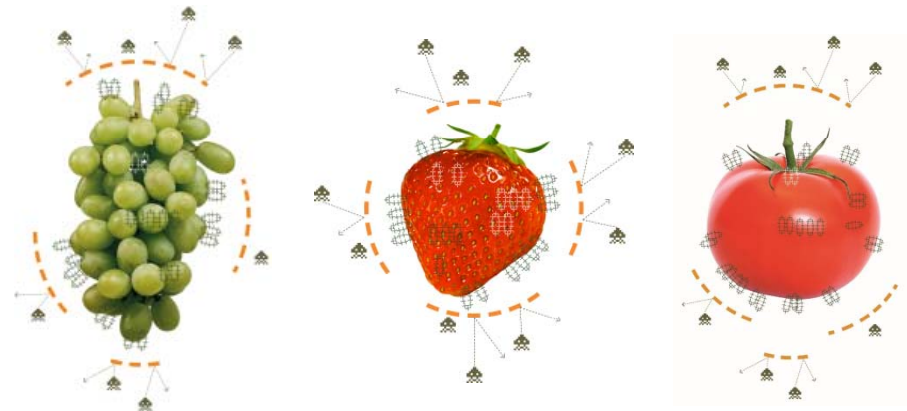
www.bio-ferm.com



Blossom Protect™™



Botector®



- 1989 University Konstanz, Chair of Phytopathologie: about 500 microbial isolates: Schiewe und Mendgen 1992; Falconi und Mendgen 1994, ...
- 1996: End of the research projects at Uni-Konstanz
- 2001: Bio-Protect GmbH founded, Konstanz
- 2005: bio-ferm GmbH founded, Start with the dossier for Annex I
Emergency use permits in several EU countries
Tox, Ecotox, Fate, Field trials
- 2007: EU submission of the dossier for *Aureobasidium pullulans* / Blossom Protect™
- 2009: Provisional registration of Blossom Protect™ in some EU countries
- 2010: Submission U.S.
- 2012: Registration and entry into the U.S. market
- 2014: EU Annex I inclusion, USA: Blossom Protect™ on 6.000 ha in use

**Canada**

- ✓ Blossom Protect™ since 2012
- ✓ Botector® since 2014

United States

- ✓ Blossom Protect™ since 2012
- ✓ Botector® since 2012

Morocco

- ✓ Botector® since 2009

Tunisia

- ✓ Blossom Protect™ since 2016
- Botector® *pending* since 2016

Turkey

- ✓ Blossom Protect™ since 2012

Israel

- ✓ Blossom Protect™ since 2017

Australia

Botector® expected 2017

New Zealand

Blossom Protect™ expected 2017

Europe



< 2014 **Provisional Registrations**
(Art. 8(1) | Dir. 91/414) and
Emergency Use Permits
(Art. 53 | Reg. 1107/2009)
Final registrations (not EU)

2014-01 **EU Approval of *A. pullulans***

2014-07 **Final Registrations**
(zonal procedure, pending in
C-EU and S-EU)

Transition period:
Provisional Registrations
remain valid until final registration
(e.g. Austria, Belgium, Netherlands,
Poland, Portugal...)

Emergency Use Permits

2007 EU submission of the dossier

2014-02 EU Approval of *A. pullulans*

2014-02 Submission of the renewal as a voluntary zonal work sharing project:

Central zone: zRMS: Austria, cMS: Belgium, Netherlands, Hungary, Slovakia, Poland

Southern zone: zRMS France, cMS: Italy, Spain , Greece, Portugal

dRR issued by FR 2016-10

Commenting 2016-12

No RR till now, cMS not started up to now,

2017:

-> 2 final registrations, AT and HU

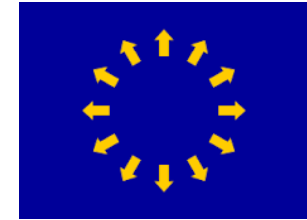
-> no final registrations

WHY?

HOT TOPICS

- **Classification:**

GHS 07 + H317



agreed on EU level (outcome of the PRAPeR meeting in 2009):

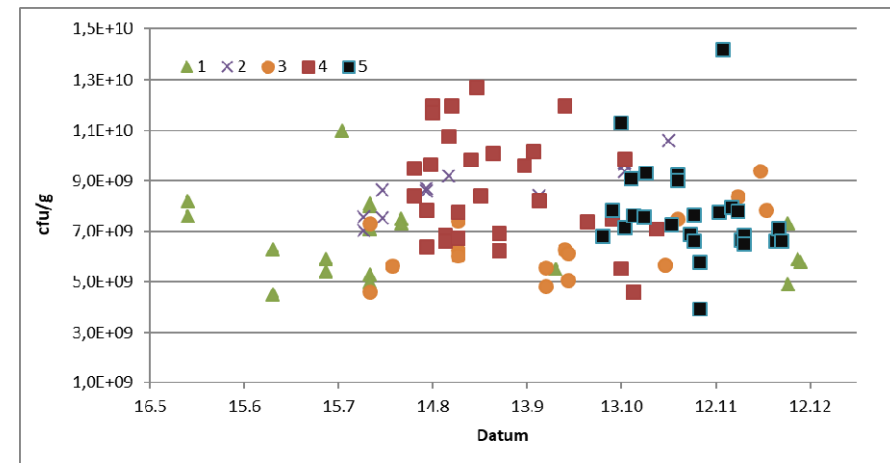
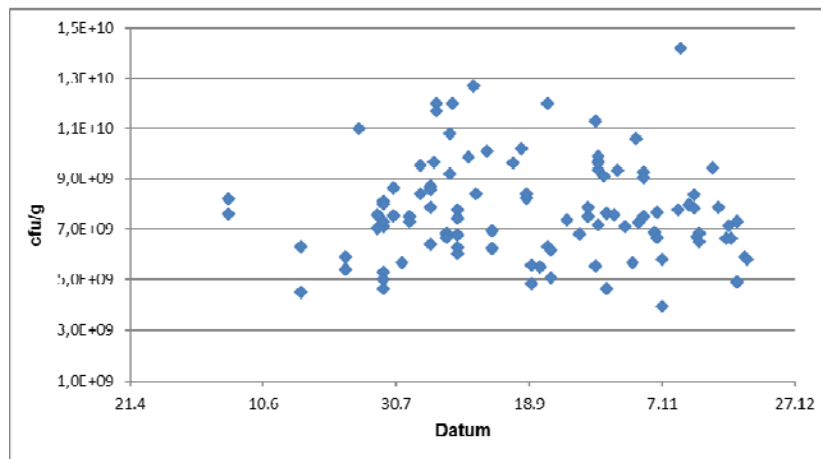
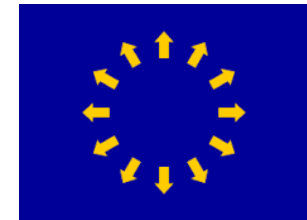
- the Regulation 1272/2008 is not applicable to microorganisms.
- no classification and labelling is required for the environment and mammalian toxicology for a microorganism, like *Aureobasidium pullulans*.
- because microorganisms have a sensitizing potential, a hazard phrase (but not a classification) will be proposed for the microorganisms in each EFSA conclusion in relation to sensitisation.
- the agreed warning phrase for microbials is:
'Microorganisms may have the potential to provoke sensitising reactions.'
EUH 208 – Contains (name of sensitising substance). May produce an allergic reaction.

HOT TOPICS

- **Identity: Storage Stability**

Nominal value in CFU/g, exponential growth possible

Interlaboratory study according to ISO 5725-2



HOT TOPICS

- **Environmental Fate and ecotoxicity of microbial plant protection products**

Calculations, Models?

FOCUS et.al?

Dose response in Ecotoxtests?

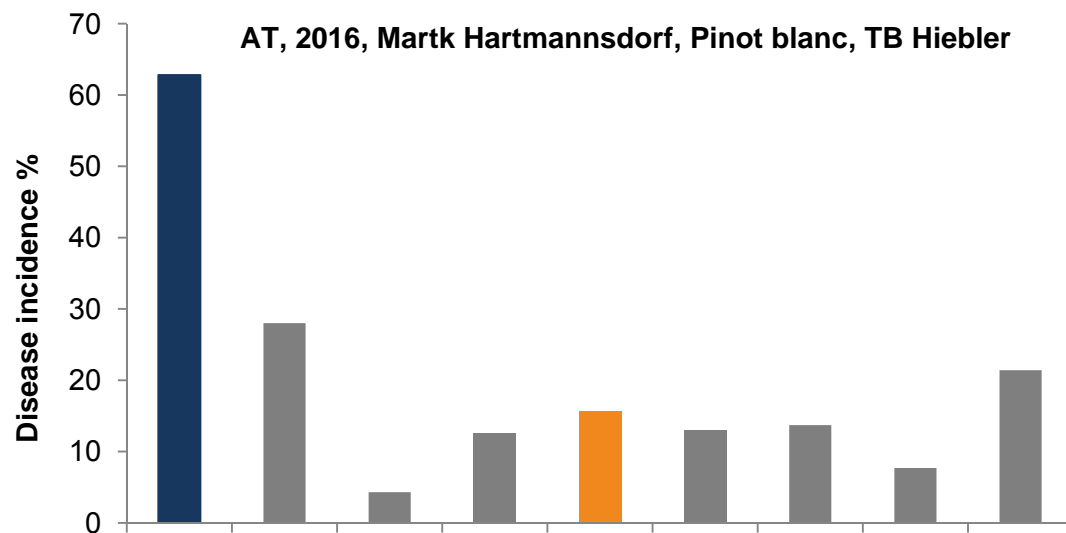
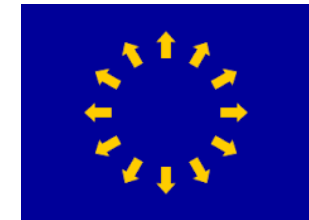
Buffer zones?

Qualitativ vs. quantitative risk assessment?



HOT TOPICS

- Efficacy Evaluation

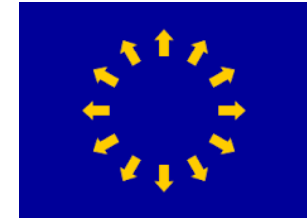


-
- active substance
-
- STD1 Cyprodinil/Fludioxonil
 - STD2 Fenhexamid
 - STD3 KHCO₃
 - BOT *A. pullulans*
 - STD4 Boscalid
 - STD5 Pyrimethanil
 - STD6 Fenpyrazamine
 - STD7 Folpet
-

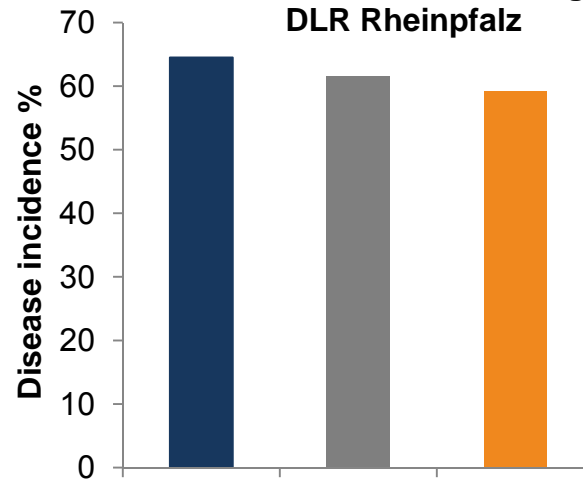
Efficacy	-	55	93	80	75	79	78	88	66
Significance	a	b	e	cde	cd	cde	cde	de	bc
BBCH 68	-	STD1	STD2	STD3	BOT	STD4	STD5	STD6	STD7
BBCH 77	-	STD1	STD2	STD3	BOT	STD4	STD5	STD6	STD7
BBCH 83	-	STD1	STD2	STD3	BOT	STD4	STD5	STD6	STD7
BBCH 85-89	-	-	-	-	-	-	-	-	-

HOT TOPICS

- Efficacy Evaluation



DE, 2011, Neustadt, Pinot gris,
DLR Rheinpfalz

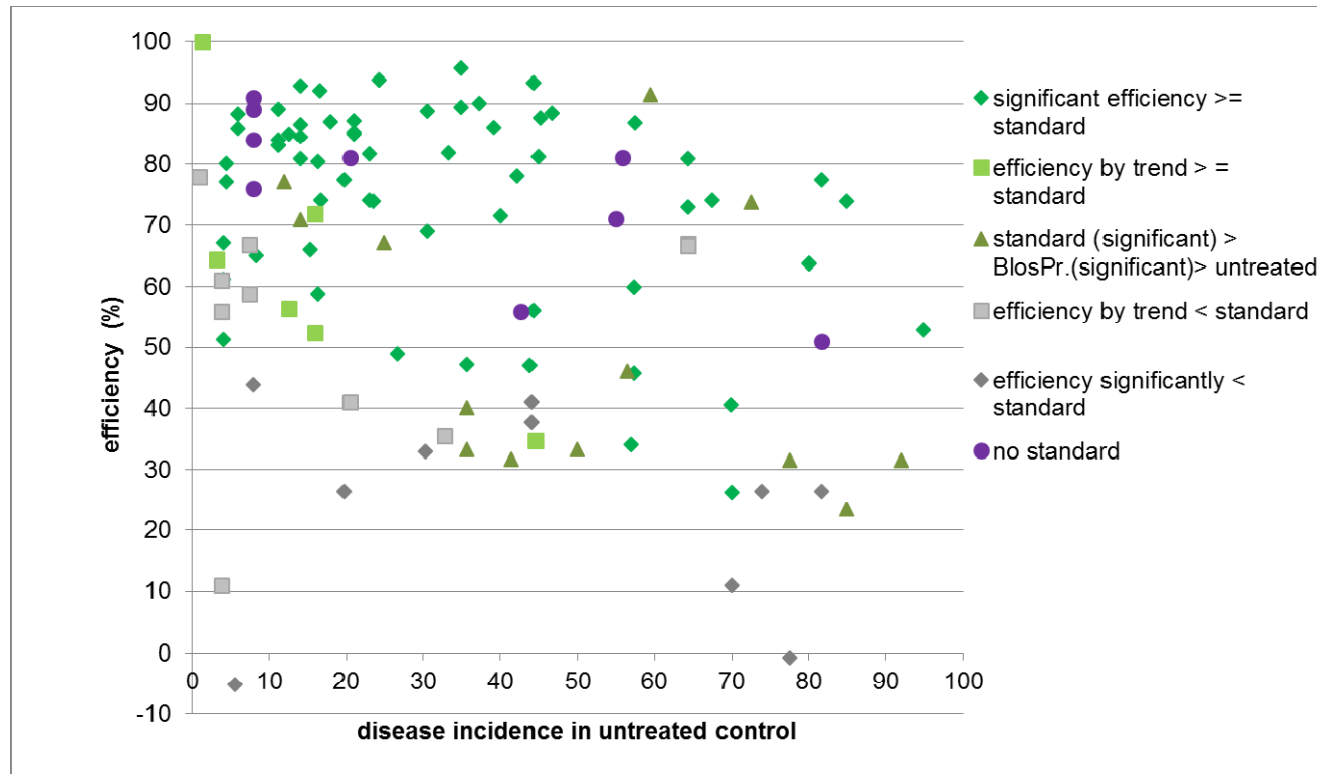
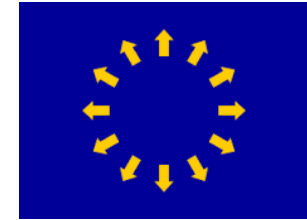


Efficacy	-	5	8
Significance	x	x	x
BBCH 68	-	-	-
BBCH 77	-	CH1	BOT
BBCH 85	-	CH2	BOT
BBCH 85-89	-	-	BOT

	application rate	active substance
CH1	0,96 kg/ha	Cyprodinil/Fludioxonil
CH2	1,6 kg/ha	Fenhexamid
BOT	0,8 kg/ha	<i>A. pullulans</i>

HOT TOPICS

- Efficacy Evaluation



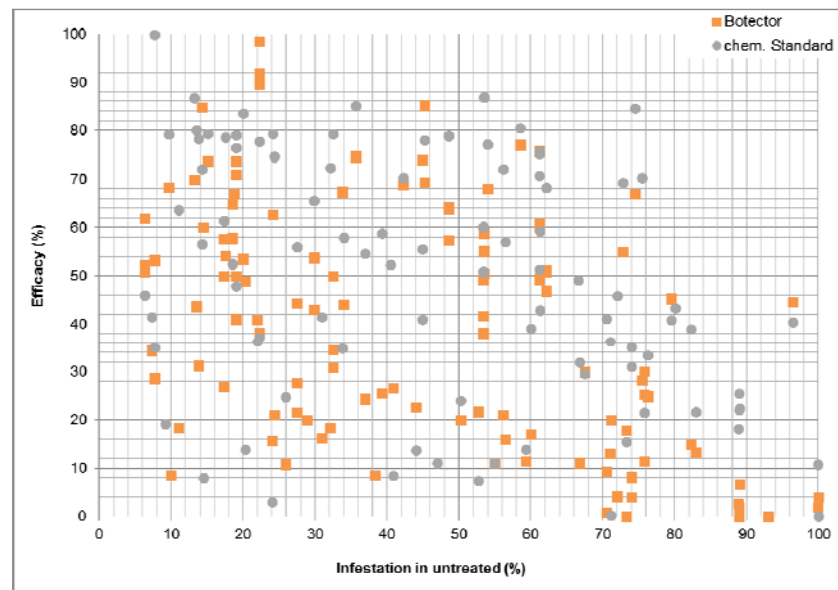
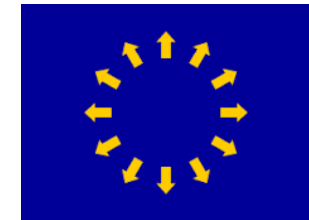
HOT TOPICS

- **Efficacy Evaluation**

Suppression vs control:

Label claims do influence marketing and sales!

Competitors showing resistance problems without having claims on the label



Changes in the GAP (2 m crown height -> 3 m crown height), LWA?

Dose Respons?

CONCLUSIONS:

30 years after investigation, 10 years after submission in EU

-> timelines in registration, especially EU

-> market potential:

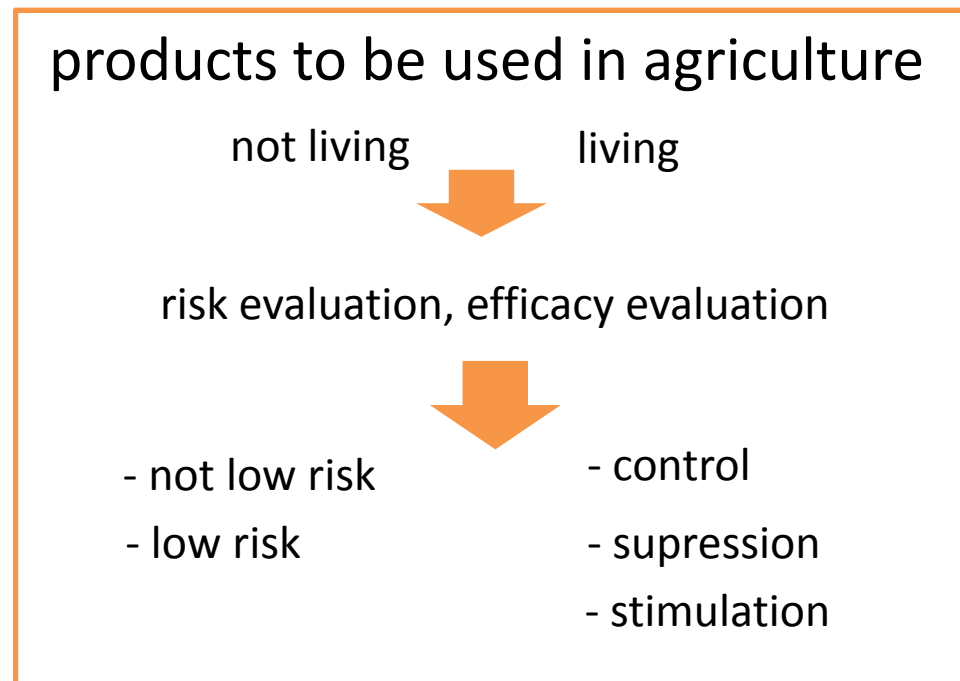
trust of advisers and farmers in new techniques, that the efficacy of a biological product can be equivalent to chemical pesticides.



Rose is a rose is a rose...

... please make no difference!

- In safety evaluation
- In efficacy evaluation



Thank you for your attention!



2014-02 EU Approval of *A. pullulans***2014-02 Submission of the renewal as a voluntary zonal work sharing project:****Central zone:** zRMS: Austria, cMS: Belgium, Netherlands, Hungary, Slovakia, Poland

dRR issued by AT 2015-05

Commenting 2015-11

RR ready 2016-09 (+2,5 years after AI inclusion)

cMS status today (+3,5 years after AI inclusion, +1 year after RR):

- Belgium: postponed several times, now pending,
- Netherlands: pending, expected 2017
- Hungary: clear time schedule, **registration granted 2017-07**
- Slovakia: pending, unclear situation, mixture of old and new procedure
- Poland: pending, expected May 2018

Southern zone: zRMS France, cMS: Italy, Spain , Greece, Portugal

dRR issued by FR 2016-10

Commenting 2016-12

No RR till now, cMS not started up to now, no final registrations