



# **State of play of the work of DG SANTE on biocontrol solutions for agriculture**

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Agrifood 11 déc. 2019

## Kyriakides: Curbing pesticide dependency to set a world sustainable standard

Currently renowned for producing safe, nutritious and high-quality foodstuffs, the European farming sector should also become a world standard for sustainability, according to the new Food Safety Commissioner Kyriakides.

Source : Euractiv

EU's new agriculture Commissioner vows to promote organic farming  
The EU Commissioner for Agriculture, Janusz Wojciechowski, highlighted the promotion of organic farming as a key aim for the new European Commission in his inaugural speech yesterday (10 December).

***“The European Green Deal is our new growth strategy – for a growth that gives back more than it takes away. It shows how to transform our way of living and working, of producing and consuming so that we live healthier and make our businesses innovative”***

*Excerpt of President Von De Leyen's mission letter to Commissioner Kriakides*

## Farm to Fork strategy for sustainable food

“The Strategy will increase the level of ambition to reduce significantly the use and risk of **chemical pesticides**, as well as the use of fertilisers and antibiotics. The Commission will identify the measures needed to bring about these reductions based on a stakeholder dialogue.”

In spring 2020, the Commission will present a **Farm to Fork Strategy** to:



make sure  
Europeans get  
affordable and  
sustainable food



tackle climate  
change



protect the  
environment



preserve  
biodiversity



increase  
organic  
farming

**BIODIVERSITY STRATEGY**  
**Achieve more sustainable**  
**agriculture and forestry - Target 3**  
By 2020, the conservation of species  
and habitats depending on or affected  
by agriculture and forestry, and the  
provision of their ecosystem services  
show measurable improvements

Farm to Fork  
strategy for  
sustainable  
food

Zero pollution ambition

Targets?

Indicators?

Timelines?

Actions?

Farm to Fork  
strategy for  
sustainable  
food

**BIODIVERSITY STRATEGY**  
**Achieve more sustainable**  
**agriculture and forestry - Target 3**

By 2020, the conservation of species and habitats depending on or affected by agriculture and forestry, and the provision of their ecosystem services show measurable improvements

Zero pollution ambition

A must !  
A reality?



**Alternatives to chemical/synthetic/highly hazardous  
PPPs !!!**

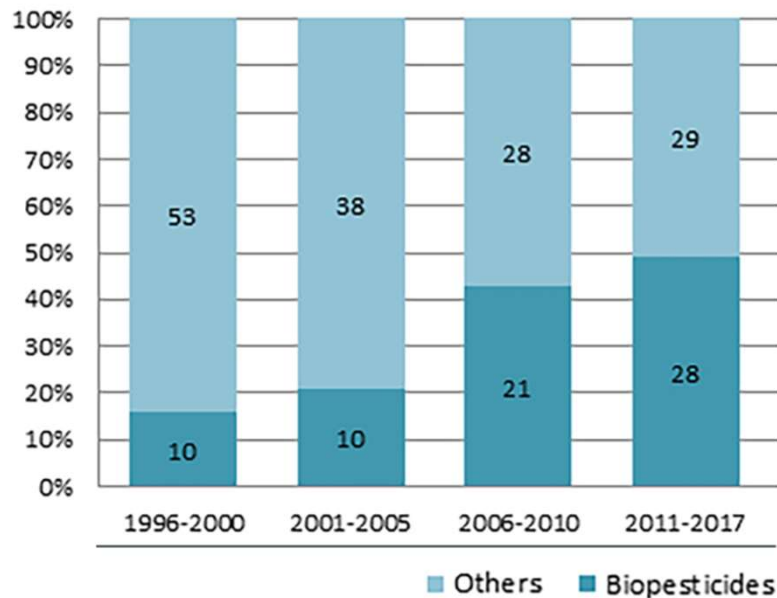


**LOW-RISK : Microbials, Semiochemicals, Botanicals,  
Macrobials, Mechanical,...**

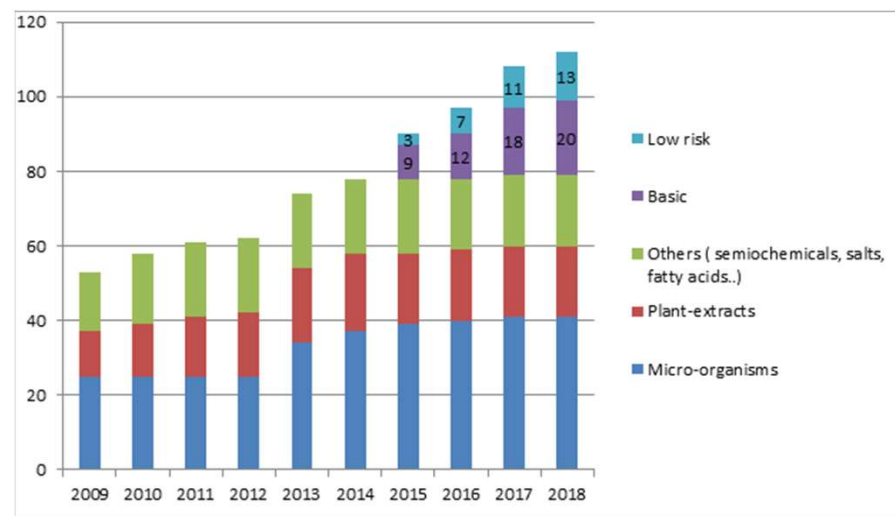
## Need of more specific and flexible approach:

- *New challenges/ new PPP*
- *The evolution of science supporting risk assessment*
- *Increased number of applications for microbial PPP*

APPLICATION FOR NEW ACTIVE SUBSTANCES SINCE 1996



Availability of Low Risk Substances



## More innovations to come (H2020) – Expanding the toolbox



Viroplant project:  
viruses to protect  
plants



Novel biocontrol  
agents for insect  
pests from  
neuroendocrinology



**IWMPRAISE**  
Integrated Weed  
Management: PRActical  
Implementation and Solutions  
for Europe



SuperPests - Innovative tools  
for rational control of the most  
difficult-to-manage pests  
("super pests") and the  
diseases they transmit





## ***Our ongoing works on the regulatory framework for microbials***

### ***1. New guidance documents***

***Anti-microbial resistance GD***

***Metabolites of potential concern***

### ***2. Revision of data requirements***

***Regulation 283/2013 – Active substance***

***Regulation 284/2013 – PPPs***

***Regulation 546/2011 – Uniform Principles***

## 1- Guidance documents



### **Guidance on Antimicrobial Resistance**

*"Acquired and transferrable" AMR leads to negligible acceptance*

### **Guidance on Secondary Metabolites of Concern**

*Tiered-based approach:*

1. Determination of assessment type
2. Collection of basic info (Identification of "metabolites of potential concern")
3. Identification of "metabolites of concern"
4. Risk assessment

## 2- Updated data requirement



## Current DR

Need

Subject

Process

## Current data requirements

- *Reg. 283/2013 active substances, part B*
- *Reg. 284/2013 plant protection products, part B*

*Minor review conducted in 2013, but a major review is needed (e.g. avoid mimicking part A and developed legal text tailored for microorganisms)*

- *Reg. 546/2011 uniform principle, part B*



## **Subject of priority data requirements revision:**

*Art 3(15) Reg.1107/2009 defines **microorganisms** as "any microbiological entity, including lower fungi and viruses, cellular or non cellular, capable of replication or of transferring genetic material"*

### Definition of substances:

- *Art 3(2) Reg.1107/2009*

## **OTHER LOW-RISK SUBSTANCES?**

*Semiochemicals, botanicals = part A adaptation, for later.*



## **Process – activities conducted (1)**

- **Q4 2018:** *identification of issues of the 3 Regulations*
- **Q1 2019:** *categorization of issues of current DR*
  - Data requirement cannot be technically met
  - Meaningfulness of data requirement
  - Technical inconsistency between Reg. and UP
  - Appropriateness of txt (in light of technical evolution)
  - Clarification/ interpretation issue
  - Lack of guidance
  - Inconsistency with guidance

**2- Updated data  
requirement**



**Current DR  
Need  
Subject  
Process**

## **Process – activities conducted (2)**

- **Q2 2019:** *review of issues and proposal on way forward*
- **Q3 2019:** *identification of “Biological Properties” of Reg. 283/2013 as the “cornerstone chapter”*
- **Q4 2019 and Q1 2020:** *initial drafting of revision of Reg. 283/2013*



## **Process – agreed principles (1)**

- *No need to start from scratch! Source of inspiration:*
  - Existing text
  - Other legislations involving MO
  - Experience on current applications
- *Be good at the first time!*
  - “Need-to-know” approach (i.e. which questions are we trying to answer?)
  - More details and explanatory points for applicants
  - More emphasis on request to justify missing data

**2- Updated data  
requirement**



**Current DR  
Need  
Subject  
Process**

## **Process – agreed principles (2)**

- *New scientific approaches:*
  - Evolution of science and technology reflected in the legal txt
  - More importance to literature review
  - Experience with current applications
- *Tiered-based approach (mandatory and conditional requirements)*
- *Stable and flexible data requirement*



**2- Updated data  
requirement**



**Current DR  
Need  
Subject  
Process**

## **Process – next steps**

- *SCoPAFF*
- *Consultations (not necessarily in this order):*
  - ❖ EFSA panel
  - ❖ Stakeholders
- *Formal adoption process*



***1. New guidance documents***

***2. Update data requirements for microorganisms***

***3. Improved risk assessment process and quality of dossiers***

### 3- Improve RA process and dossiers quality



## Actions supporting increased awareness towards biocontrol agents:

*Risk assessors/ manager: expertise in microbiology to avoid misuse of chemical approach in risk assessment of microbial PPP*

*Better Training for Safer Food: from 2020, BTSF for risk assessors dedicated to microorganisms.*

*Applicant: understanding of risk assessment process to better comply with data requirements (pre-submission meetings, guidance documents,...)*