



**Bruxelles, DG SANTE Advisory group on the food chain, animal and plant health
27 April 2018**

Low risk active substances in plant protection

state of play

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European Commission**

Low Risk active substances main provisions in Regulation (EC) No 1107/2009

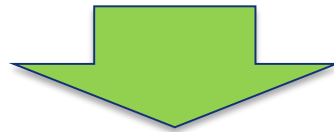
- *Approval of low risk active substances up to **15** years*
- *Definition of low risk plant protection product: all actives low risk no need of risk mitigation measures*
- *Member States to decide in **120** days*
- *Data protection up to **13** years*
- *Allowed to be mentioned in advertising*

Annex II

- *Low risk criteria*

Basic substances main provisions in Regulation (EC) No 1107/2009

- *not a substance of concern;*
 - *not inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;*
 - *not predominantly used for plant protection purposes but useful in plant protection directly or in a product consisting of the substance and a simple diluent and*
 - *not placed on the market as Plant Protection Product.*
- Food in accordance with definition of Reg.178/2002*

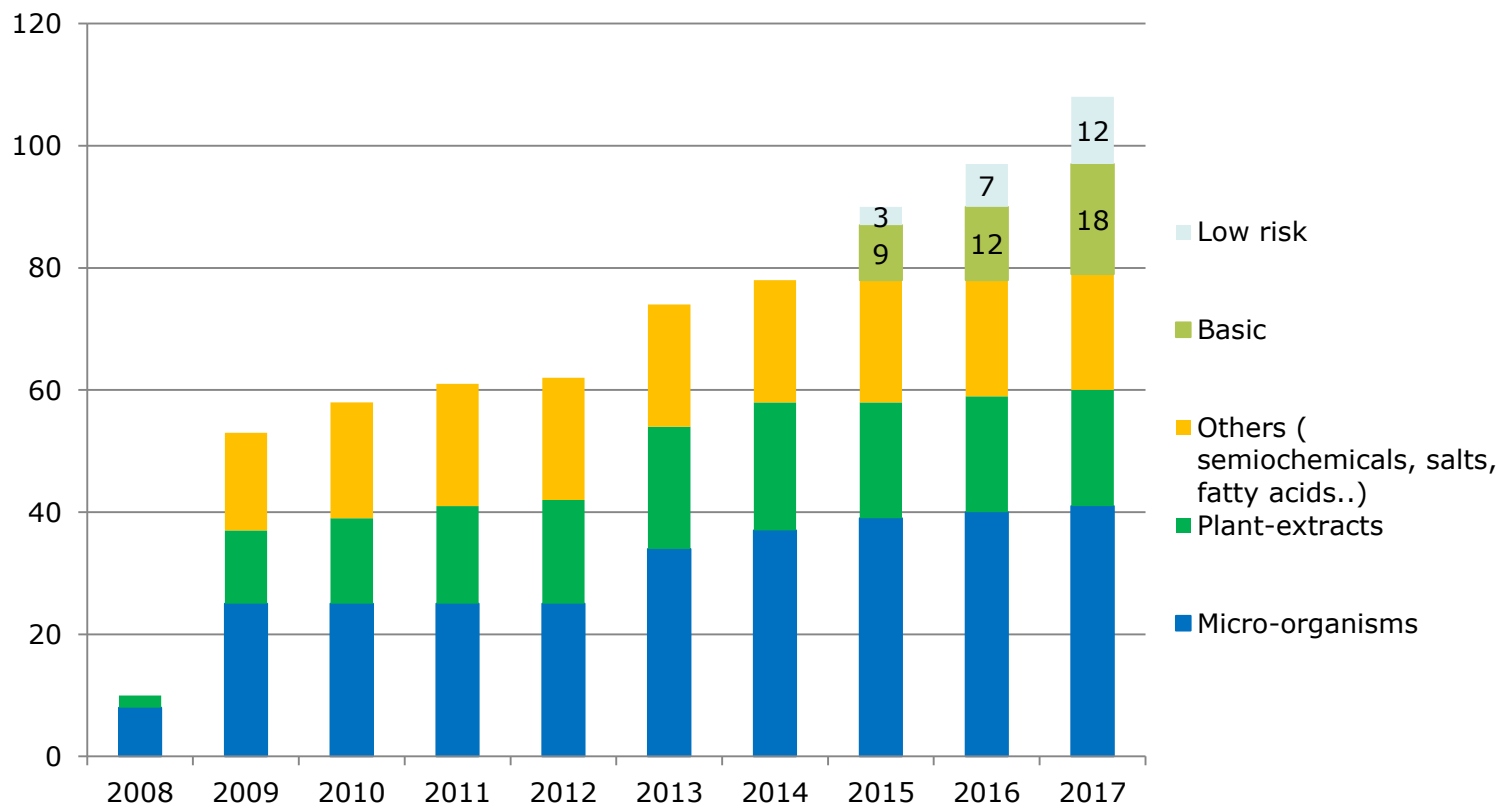


- *Approved where any relevant evaluation carried out under other Community legislation shows that the substance has no harmful effect on human or animal health nor an unacceptable effect on the environment.*



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Naturally occurring, low risk and basic substances already approved

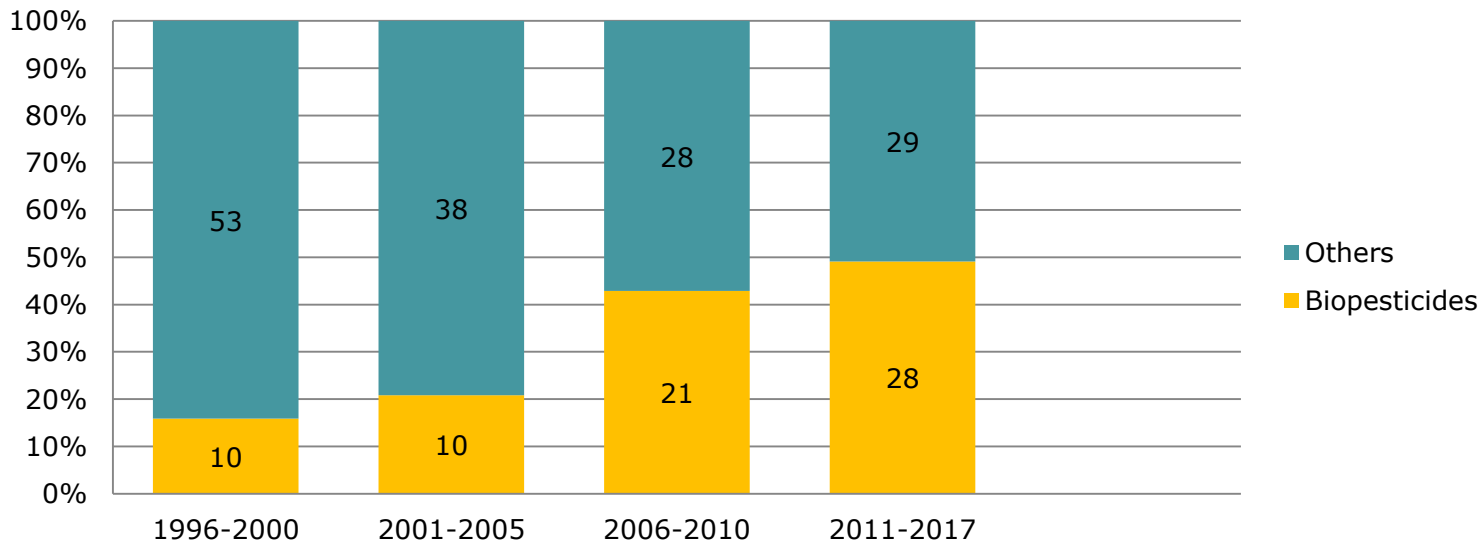




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More and more new applications "biopesticides"

Application for new active substances since 1996



Sustainable plant protection working group in 2016-2017

- **Objectives: identify actions on increasing low-risk plant protection product availability and accelerating integrated pest management implementation**

Focus on:

- **expedite** approval and authorisation procedures (within limits of Regulation 1107/2009)
- **identify measures** to support stakeholders to apply for low-risk approval and authorisation
- **clarify** regulatory requirements
- **cooperate** and share experience between MS
- input for **REFIT** of 1107/2009 to increase regulatory incentives for low-risk products

Implementation plan

- *Endorsed by AGRIFISH Council in June 2016 under NL Presidency Plan available @ [Council website](#)*
- *Identified 40 actions to increase low risk product availability and accelerate the implementation of Integrated Pest Management in Member States*
- *Actions for COM, MS, EFSA, stakeholders*
- *Four lines of action:*
 - *Low-risk substances and products*
 - *Integrated Pest Management*
 - *Research*
 - *Input for REFIT pesticide legislation*
- ***Progress report January 2018 : 22 MS + Norway responded to questionnaire, stakeholders interviewed***



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Progress report: which main actions for low risk products? (1)

Member States

- *Zonal system delays (30% addressed)*
- *Expedite low risk potentials (30% addressed)*
- *Refrain from additional national requirements (30% addressed)*
- *Efficacy EPPO guidance for low risk ppps (published 2017)*
- *Reduced fees or Pre-submission meetings free (80%)*
- *Dedicated experts for assessment (35%)*
- *Assistance for basic substances applications (40%)*

Progress report: which main actions for low risk products? (2)

Applicants :

- *Submit high quality and complete dossiers*
- *Consider the use of the so-called "risk-envelope approach"*
- *Make use of pre-submission meetings provided by Member States*

Stakeholder's views on progress by applicants:

- *Industry associations advise new members about preparing dossiers for applications (e.g. training sessions)*
- *Communication on risk envelope and importance of good dialogue between authority and applicant.*



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Progress report: which main actions for low risk products? (3)

COM :

- **Prioritisation of potential low risk active substances under the renewal** process AIR4 through Commission Implementing Decision issued in September 2016 (2016/C 357/05)
- **Progress in developing procedural and technical Guidance** to facilitate assessment process
- **2017 focused workshop** with MS to discuss /identify low risk options for REFIT
- **Low risk criteria adoption of COM Reg.2017/1432**
- COM work on a **non binding list identifying** potential low risk active substances which were approved prior of full applicability of Regulation (EC)No 1107/2009

Progress report: which main actions for IPM?(1)

Member States:

Results from COM SUD reports

- *Focused applied research on IPM – 22 out of 28 MS invest in IPM research projects, 7 for more than 1 mio euro. In 8 MS cofinanced by private parties.*
- *Demonstration farms – 12 MS have demofarms networks, 9 are considering setting up demofarms or expand scope to include IPM.*
- *Share info on implementation of IPM – within MS: 23 have IPM guidelines, various other methods reported.*
- *Ensure qualified advisory bodies on IPM – all MS have advisory services. 3 MS: from competent authority; 8 MS: private sector; 17: combination.*

Progress report: which main actions for IPM?(2)

COM :

- *On 10 October COM published two reports on state of play of implementation of the Sustainable Use Directive*
- *COM webportal linking to IPM info – available*
- *Develop BTSF course on IPM implementation – 12 courses on application equipment in 2017-2020; IPM course from 2018 onwards, 14 courses planned*
- *Move forward on harmonised risk indicators – proposal under discussion*
- *Develop methodology for assessment of IPM*

**Coordination
Sustainable
use Directive
working group**



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European Commission / Food, Health and Food Safety and Analysis

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Overview Reports



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- Use the middle part of the form to search by country, by date range, and/or by text search.
- Use the lower part of the form to search by report publication date

Note: all audit numbers are now listed in the standardised format: *YEAR-NUMBER*.

« ALL TOPICS

News

New Commission reports focus on how EU countries should use pesticides more sustainably

Released: 10-10-2017
Under: News

Report finds good monitoring systems of antimicrobial resistance in animals and food and some areas of improvement.

Released: 27-07-2017
Under: News

Two reports on authorisation and control of pesticides identify need for improvements

Released: 24-07-2017
Under: News

Last 5 Reports

Title	Report number	EU Member States or non-EU Countries	Audit period
Sustainable Use of Pesticides	2017-6291	EU	Report details
Overview Report - Identification and Response to New Plant Health Risks	2016-8993	EU	Report details
Interim Overview Report - Antimicrobial Resistance Monitoring in Zoonotic and Commensal Bacteria	2016-6239	EU	Report details
Plant Protection Products - Marketing and Use	2016-6004	EU	Report details
Plant Protection Products - Authorisation	2017-6250	EU	Report details

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Progress report: which main actions for research?

COM :

- *Continue considering IPM as important area for EU funding of research: most recent Horizon 2020 calls 27 mio allocated to:*
 - ***Integrated health approaches and alternatives to pesticide use***
 - ***New and emerging risks to plant health***
 - ***Stepping up integrated pest management***

Member States :

- *Identify and translate needs of farmers into research; promote applications for Horizon 2020 projects: 11 MS actively promoted Horizon 2020 applications.*



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Other ongoing actions ...

- **Development of technical guidance for the assessment of substances :**
 - Biopesticides working group :
Guidance document on secondary metabolites produced by micro-organisms in preparation, discussion on multiple antimicrobial resistance
 - Working document on basic substances *a new revision in preparation to reflect experience gained in these last years*
- COM recommendation on the **non binding list identifying potential low risk active substances** which were approved prior of full applicability of Regulation (EC)No 1107/2009
- Specific focus to address low risk and basic substance issues within the ongoing **REFIT evaluation**

Conclusions and way forward

- *Concrete actions were taken by COM, EFSA and MS and others are in progress*
- *All stakeholders involved to continue working on key areas identified*
- *COM continue to work together with MS and EFSA in WG's (Biopesticides, Low risk, Basic substances) and AIR4 assessments*
- *Follow up on implementation of SUD and coordination with other relevant policies*
- *REFIT outcomes ...*



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THANK YOU FOR YOUR ATTENTION!

For up-to-date information DG SANTE website:
https://ec.europa.eu/food/plant/pesticides_en

Select criteria

Category: All

Status: All

Class. (Reg. 1272/2008): -

Authorisations: -

Legislation: -

Type: Low-risk active substance

Candidate for substitution: low ADI / ARFD / AOEL, two PBT criteria, nature of critical effects, non-active isomers, carcinogen 1A / 1B, toxic for reproduction 1A / 1B, endocrine disrupting properties

ADI: All

ARFD: All

AOEL: All

Approval date: All

Expiration date: All

Reset filter

PLANTS
EU Pesticides database

European Commission > Food Safety > Plants > Pesticides > Pesticides Database

HEALTH FOOD ANIMALS PLANTS

Search active substances

Showing 1 to 12 of 12 entries 50 records per page

Name	Status under Reg. (EC) No 1107/2009	Date of approval	Expiration of approval	Legislation
Bacillus amyloliquefaciens strain FZB24	Approved	01/06/2017	01/06/2032	Reg. (EU) 2017/806
Cerevisane	Approved	23/04/2015	23/04/2030	Reg. (EU) 2015/553
Coniothyrium minitans Strain CON/M/91-08 (DSM 9660)	Approved	01/08/2017	31/07/2032	Reg. (EU) 2017/842Reg. (EU) No 540/2011 (03/79/EC,Reg. (EU) 2016/950,Reg. (EU) No 823/2012)
COS-OGA	Approved	22/04/2015	22/04/2030	Reg. (EU) 2015/543
Ferric phosphate	Approved	01/01/2016	31/12/2030	Reg. (EU) 2015/1166Reg.