

Low-risk Substances

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- Regulatory and political framework
 - Handling of low risk substance legislation and guidance
 - Experience and way ahead
 - “Another issue”

REGULATION 1107/2009 of 21 October 2009 concerning the placing of Plant Protection Products on the market

REGULATION 1185/2009 of 25 November 2009 concerning statistics on pesticides

DIRECTIVE 2009/128/EC of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

DIRECTIVE 2009/127/EC of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application

COM(2012) 79 final on the European Innovation Partnership 'Agricultural Productivity and Sustainability'

COM(2012) 60 final Innovating for Sustainable Growth: A Bioeconomy for Europe

EUROPEAN COMMISSION, Directorate-General for Research and Innovation, Directorate E — Biotechnologies, Agriculture, Food, Unit E.1 — Horizontal aspects: Innovating for Sustainable Growth - A Bioeconomy for Europe of 13 February 2012

REGULATION 1305/2013 of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)

REGULATION 1306/2013 of 17 December 2013 on the financing, management and monitoring of the common agricultural policy

REGULATION 1307/2013 of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy

REGULATION 1291/2013 of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)

Directorate-General for Internal Policies, Policy Department B: Structural and Cohesion Policies, Agriculture and Rural Development, Study - Precision Agriculture: an opportunity for EU farmers - potential support with the CAP 2014-2020 of June 2014.

REGULATION 233/2014 of 11 March 2014 establishing a financing instrument for development cooperation for the period 2014-2020

Motion for a European Parliament resolution on technological solutions for sustainable agriculture in the EU (2015/2225(INI))

European Parliament resolution of 15 February 2017 on Low-risk Pesticides of biological origin (2016/2903(RSP))

REGULATION 1107/2009 of 21 October 2009 concerning the placing of Plant Protection Products on the market

REGULATION 1291/2013 of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)

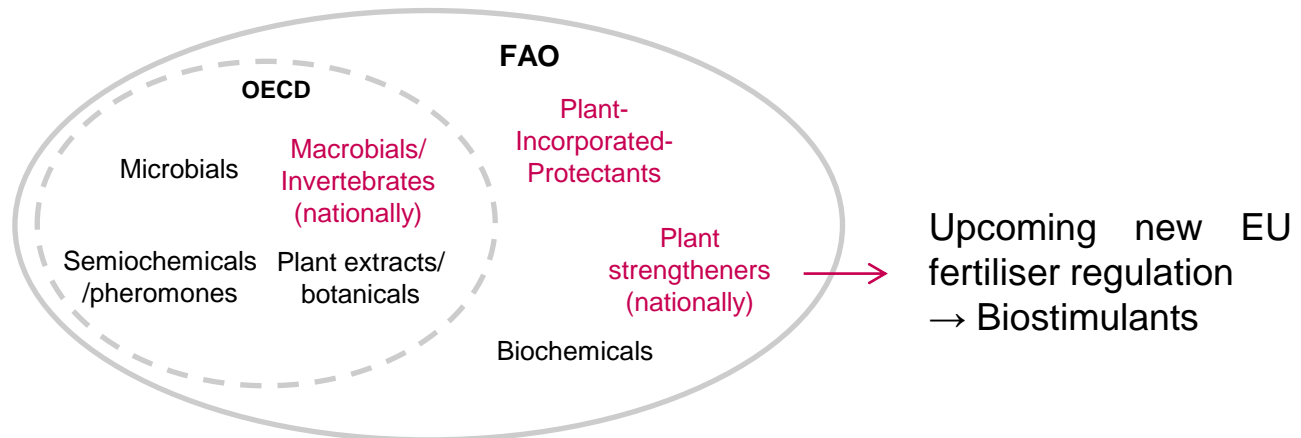
Motion for a European Parliament resolution on technological solutions for sustainable agriculture in the EU (2015/2225(INI))

European Parliament resolution of 15 February 2017 on Low-risk Pesticides of biological origin (2016/2903(RSP))

Motion for a European Parliament resolution on technological solutions for sustainable agriculture in the EU (2015/2225(INI)) + European Parliament resolution of 15 February 2017 on Low-risk Pesticides of biological origin (2016/2903(RSP))

- **Clear criteria** for defining Low-risk Active Substances for the development and use of Low-risk Pesticides
- **Non-chemical alternatives** to Plant Protection Products such as **biological controls**, should be given provisional approval for use and priority for evaluation
- **Faster approvals process** would increase the availability of Low-risk Plant Protection Products on the market and reduce the risk of resistance to Active Substances and the effects on non-target species linked to commonly used Plant Protection Products
- Invite the Member States to include the use of **Low-risk Pesticides of biological origin** in their **national action plans** on the protection of the environment and of human health

EU Regulation 1107/2009: “This Regulation shall apply to **substances, including micro-organisms** having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as ‘active substances’”



No legal definition of “Biopesticide” in the EU. To account for a character of an active substance different “**risk categories**” are used regardless of type or origin of the Active Substance or its chemical or microbial origin

Basic Substance

Low-risk Substance

Any other Active Substance

Basic Substance
Article 23(2)
Including foodstuff

Low-risk Substance *

Reduced risk Active Substance – renewal only

Conventional Active Substance

Candidate for substitution Active Substance

Cut-off Active Substance

* **38** substances AIR 4 renewal programme (05/2017) Group 2 - presumably Low-risk Substances

	Approved	Not Approved	Risk profile
Basic Substance	15	5	
Low-risk Substance *	10	0	
Reduced risk Active Substance – renewal only	395	808	
Conventional Active Substance			
Candidate for substitution Active Substance	73	5	
Cut-off Active Substance		0	
Total	493	818	

Pending 28
Not a PPP 20

SANTE-2016-10616–rev 7 of May 2017

- Group 1 – substances with expiry date before 30 April 2019
51 substances, 32 applications for renewal submitted, 25 substances are **presumed to be Low-risk**
- Group 2 – **Low-risk Substances**
38 substances, **all substances are presumed to be low-risk substances;** all substances will be postponed with one year
- Group 3 – substances that may fail to satisfy approval criteria
13 substances. For all substances there is indication that they may fail to satisfy the criteria listed in points 3.6.2 to 3.6.5 and point 3.7 of Annex II to Regulation 1107/2009
- Group 4 – substances with current expiry dates between 31/07/2019 and 31/12/2021
112 substances. Current expiry dates will be postponed with either 2 or 3 years

SANTE/11953/2015 - rev. 3.1 of 6 November 2015: Low-risk Substances are “in many cases **botanical** Active Substances, **Semiochemicals**, **Micro-organisms** or **Minerals**. **However, neither must the scope of Low-risk Active Substances be limited to this non-exhaustive list of substance groups, nor can all substances belonging to these groups be considered as Low-risk Substances without further assessment”**

SANCO/11188/2013 - rev. 2 of 14 September 2015: Guidance document on criteria for the inclusion of Active Substances into **Annex IV of Regulation 396/2005**

EPPO PP 1/296: Principles of **efficacy** evaluation for **Low-risk Plant Protection Products**

- **Voting September 2017**
- **Publication** scheduled for **October 2017**

- Acceptability of non-GEP trials if **scientifically sound** and in line with other applicable EPPO Standards
- Data to **demonstrate** that product can give a **benefit to the user**
- **Reduction of** number of direct efficacy **trials**, phytotoxicity trials, etc. if applicable
- Possibilities for **extrapolation** from field trials on crops or pests other than those for which registration is proposed
- Use of EPPO **extrapolation tables** for minor uses also to be applied for **major uses**
- **Scientific approach** and justifications e.g. use of MoA to **extrapolate** between different crops and pests,
 - Comparability of target biology
 - Use of worst case circumstances regarding product performance to extrapolate to less critical circumstances
 - Comparability of target biology, growth habit and structure of crop, etc.

Regulation 1107/2009, Annex II		REGULATION 2017/1432 of 7 August 2017	
A.s. other than microorganism shall not be considered as Low-risk			
Explosive		Explosive	
Carcinogenic		Carcinogenic category 1A, 1B or 2	
Mutagenic		Mutagenic category 1A, 1B or 2	
Toxic to reproduction		Toxic to reproduction category 1A, 1B or 2	
Sensitizing chemicals		Skin sensitizer category 1 <i>NEW: Respiratory sensitizer category 1</i>	
Very toxic or toxic		Acute toxicity category 1, 2 or 3 Specific Target Organ Toxicant category 1 or 2 New categories of toxicity: Skin corrosive category 1A, 1B or 1C Serious damage to eyes category 1 <i>NEW: Toxic to aquatic life of acute and chronic category 1</i>	
Endocrine disruptor		Endocrine disruptor	
Neurotoxic		Neurotoxic	
Immunotoxic		Immunotoxic	
Priority substance		Identified as priority substance under Directive 2000/60/EC	
Persistence > 60 days and bio-concentration > 100			

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- REGULATION 2017/1432 of 7 August 2017

Naturally occurring Active Substance

Other than micro-organism and does not correspond to any of the categories above, may be considered as being low-risk, **even if** it is persistent:

- Half-life > 60 days
- Bio-concentration > 100

Active substance for communication

Other than micro-organism, and does not correspond to any of the categories above, Shall be considered as being low-risk, when

- Emitted and used by plants, animals and other organisms for communication

Baculoviruses shall be considered as being of low-risk

- Unless at **strain level** they have demonstrated adverse effects on non-target insects

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- REGULATION 2017/1432 of 7 August 2017

Micro-organisms

An Active Substance which is a **micro-organism** may be considered as being of **Low-risk**

- Unless at **strain level** it has demonstrated **multiple resistance to anti-microbials** used in human or veterinary medicine

BUT e.g.

CTGB: *“In general all micro-organisms which fit the approval criteria and do not show multiple resistance to anti-microbials used in human or veterinary medicine will be considered as Low-risk substances. Some exceptions however are made. For example, the recently approved *Beauveria bassiana* 147 was not granted low-risk status **due to a relevant metabolite**”*

COM: *“...we are still working on a focused technical document with respect to implementation of Low-risk criteria...”*

- Will the **exception to the rule become the rule?**

➤ REGULATION 1107/2009

Article 47 - Placing on the market of Low-risk **Plant Protection Products**

*3. The Member State shall decide within **120 days** whether to approve an application for authorisation of a low-risk plant protection product*

Does not apply to:

Article 43 - Renewal of authorisation

*5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest **12 months** after the renewal of the approval of the Active Substance, safener or synergist contained therein*

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- **Scientific** approach often not sufficient – **regulatory “execution”** of data requirements requested
 - Actual handling of Low-risk Substances often contrary to intentions as stated e.g. in Parliament motion 2015/2225(INI)
 - **A.s. batch analysis**: Peak clarification < 0.1% to additionally prove Low-risk status
 - **Additional toxicity testing** to prove Low-risk status (incl. vertebrate testing)
 - **FOCUS calculations** for micro-organisms

 - Availability **GLP labs** for micro-organism characterization

 - **Copyright issues** for publications to be cited in dossiers

 - Lack of **transfer of knowledge to farmers** – “use”, relevance and incorporation in IPM unclear
 - Market acceptance for Low-risk a.s. and products impaired

 - Existing/upcoming Guidance **e.g. endocrine** (loss of **nat. substances** such as Vitamin D3, caffeine, Genistein ...)

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- Besides development of new Legislation and the Guidance there are several **positive new developments** regarding Low-risk, also at MS level, e.g.
 - **DGAL/SDQPV/2016-279** du 01/04/2016: Liste des produits de biocontrôle mentionnée à l'article 1er de l'arrêté du 9 mars 2016 fixant le taux de la taxe sur la vente de produits phytopharmaceutiques
 - **CTGB (2017)**: Evaluation Manual for the Authorisation of Biopesticides according to Regulation (EC) No 1107/2009 - Microorganisms, Botanicals, Semiochemicals version 1.0; July 2017

 - **Maintain risk assessment at a high level** (2016/2903(RSP))
 - Keep “snake oil products” out of the market
 - **Verify reliability** of Low-risk Products (and Biopesticides) to foster IPM and Precision Farming Systems and safeguard EUs future agricultural needs

“Another issue”

Revision of Regulation 1107/2009 and Definition

Current Art. 2 of Reg. 1107/2009

“(b) influencing the life processes of plants, such as substances influencing their growth, **other than as a nutrient**”

Upcoming Art. 2 of Reg. 1107/2009

“(b) influencing the life processes of plants, such as substances influencing their growth, **other than as nutrients or other than as plant biostimulants**”

Upcoming Addition to Art. 3 of Reg. 1107/2009

34. "**plant biostimulant**" means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of **improving** one or more of the following **characteristics of the plant**:

- (a) Nutrient use efficiency
- (b) Tolerance to abiotic stress
- (c) Crop quality traits

“Another issue”

Existing categories and approvals Regulation 1107/2009

Pesticide Categories

Acaricide (AC)
Algicide (AL)
Attractant (AT)
Bactericide (BA)
Desiccant (DE)
Elicitor(EL)
Fungicide (FU)
Herbicide (HB)
Insecticide (IN)
Molloscicide (MO)
Nematicide (NE)
Other Treatment (OT)
Plant Activator (PA)

Plant Growth Regulator (PG)

Pruning
Repellant (RE)
Rodenticide (RO)
Safener
Soil Treatment (ST)
Synergist
Virus Inoculation (VI)

Sea-algae extract (formerly sea-algae extract and seaweeds)

“Acts as a growth regulator in many horticultural crops. In particular it:

- Promotes root development increasing plant’s ability to take up nutrients
- Promotes growth of young tissues
- Improves crop yields through improved blooming and fruit set
- Improves quality of fruits
- Improves plant resistance to **stress**, frost, adverse weather conditions, **pests and diseases**” (DAR)

No application for renewal of the a.s. submitted

“Another issue”

Existing categories and approvals Regulation 1107/2009 (cont.)

Pesticide Categories

Acaricide (AC)
Algicide (AL)
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Elicitor(EL)
Fungicide (FU)
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Prospects of regulatory differentiation of abiotic and biotic stresses:

- **Loss** of useful Substances/Products required in plant protection especially regarding IPM and resistance management
- (Illegal) **use** of PPP uses (biotic stress) under fertiliser regulation?

Alternative

- **Registration of “biostimulants” under PPP legislation with strongly reduced data requirements**