Low-risk Substances

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October 2017
Overview

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

- 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 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
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
Regulatory and political framework (cont.)

- 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
  - 15
  - 10
  - 395
  - 73
- Not Approved
  - 5
  - 0
  - 808
  - 5
  - 818
  - 20

Risk profile
- High risk profile Pending 28
- Not a PPP 20
Handling of Low-risk Legislation and Guidance

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”

Handling of Low-risk Legislation and Guidance (cont.)

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.
### Handling of Low-risk Legislation and Guidance (cont.)

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<tbody>
<tr>
<td><strong>A.s. other than microorganism shall not be considered as Low-risk</strong></td>
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<tr>
<td>Explosive</td>
<td>Explosive</td>
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<tr>
<td>Carcinogenic</td>
<td>Carcinogenic category 1A, 1B or 2</td>
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<td>Mutagenic</td>
<td>Mutagenic category 1A, 1B or 2</td>
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<tr>
<td>Toxic to reproduction</td>
<td>Toxic to reproduction category 1A, 1B or 2</td>
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<tr>
<td>Sensitizing chemicals</td>
<td>Skin sensitizer category 1</td>
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<td></td>
<td><strong>NEW:</strong> Respiratory sensitizer category 1</td>
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<td><strong>Very toxic or toxic</strong></td>
<td><strong>Acute toxicity category 1, 2 or 3</strong></td>
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<td><strong>Specific Target Organ Toxicant category 1 or 2</strong></td>
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<td><strong>New categories of toxicity:</strong></td>
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<td>Skin corrosive category 1A, 1B or 1C</td>
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<td>Serious damage to eyes category 1</td>
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<td><strong>NEW:</strong> Toxic to aquatic life of acute and chronic category 1</td>
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<td>Endocrine disruptor</td>
<td>Endocrine disruptor</td>
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<td>Neurotoxic</td>
<td>Neurotoxic</td>
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<td>Immunotoxic</td>
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<tr>
<td>Priority substance</td>
<td>Identified as priority substance under Directive 2000/60/EC</td>
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**Persistance > 60 days and bio-concentration > 100**
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
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
Experience and way ahead

- **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 …)
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
**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)
Attractant (AT)
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Plant Growth Regulator (PG)
Pruning
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Synergist
Virus Inoculation (VI)

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