

Low Risk Substances

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Overview:

- Regulatory and political framework
- Guidance related to low risk
- Handling of low risk criteria
- Experience and way ahead

- **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
- **REGULATION 652/2014** of 15 May 2014 laying down provisions for the management of **expenditure** relating to the food chain, animal health and animal welfare, and relating to **plant health** and plant reproductive material
- **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
 - DIRECTIVE 2015/1513 of 9 September 2015 amending Directive 98/70/EC relating to the quality of **petrol and diesel fuels** and amending Directive 2009/28/EC on the promotion of the use of energy from renewable sources
 - REPORT of 10 May 2016 on technological solutions for **sustainable agriculture** in the EU (2015/2225(INI)) of the Committee on Agriculture and Rural Development and the MOTION FOR A **EUROPEAN PARLIAMENT RESOLUTION**

Regulatory and political framework (cont.) 2015/2225(INI) – Plenary sitting (10.05.2016)

The European Parliament:

“Calls on DG Health and Food Safety (SANTE) to **establish clear criteria** for defining **low-risk active substances** for the **development and use of low-risk pesticides, ...**”

- **Provisional approval** for use and **priority for evaluation**
- Farmers need to have a **bigger toolbox**
- **More cost-effective alternatives** by supporting field research
- Faster **approvals** process
- Increase Integrated Pest Management (IPM)

Regulatory and political framework (cont.) SANTE-2016-10616–rev 4 of October 2016

“Indicative submission dates for supplementary dossiers for the renewal of substances expiring between 1 January 2019 and 31 December 2021.”

➤ 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

SANCO/11470/2012- rev. 8 of 20 March 2014: Guidance document on **botanical** active substances used in plant protection products

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**

SANTE/12815/2014- rev. 5.2 of May 2016: Guidance document on **semiochemical** active substances and plant protection products

SANTE/12376/2015- 2016 draft: Guidance document on **the amendment of Regulation (EC) No 1107/2009** on criteria for the approval of low risk active substances

- “The plant or animal origin of a substance does **not** confer the low risk status **automatically**”

EPPO Workshop on Efficacy Requirements and Evaluation of Plant Protection Products based on Low-Risk Active Substances, Ede, The Netherlands 2016-04-06/07 - CONCLUSIONS and RECOMMENDATIONS

- ... The **number of (field) trials may be reduced** if data from other sources is available (literature, preliminary data, etc.)...
- **Lower and more variable effectiveness of PPPs** based on low risk a.s. compared to the effectiveness of conventional PPPs is acceptable. Any benefit of the product compared to the untreated control should be shown;
- There is a strong **need for harmonisation** of requirements ...
- **Extrapolation** possibilities related to e.g. mode of action and the use of **data from other EU or EPPO zones** should be further explored and where relevant guidance should be developed...
- **Guidance on efficacy requirements** and evaluation of PPPs based on low-risk a.s. for Competent Authorities/NPPOs and applicants **should be developed** by EPPO;
- A 'pre-pre- submission' **meeting of applicants** with authorities where e.g. **data requirements can be discussed** in an early stage of product development is necessary and should be available in all Member States. Member States should be in close contact to achieve harmonisation on data requirements;
- A good description of the mode of action should be available and **applicants** should be critical (**realistic**) about their own data

Handling of low risk criteria Additional restrictions and requirements

➤ SANTE/11953/2015

- Persistence and leaching

“Persistence' and 'leaching' may **not be appropriate criteria for naturally occurring substances** such as botanical active substances, minerals, and gasses in the compartment where the amount of the substance added to upper soil layers and water consequent from the representative uses will be limited compared to its natural presence”

- Semiochemicals

“A **semiochemical** is expected to be of low risk where the **exposure (by the same route)** caused by the use of the plant protection product is **similar (within one order of magnitude)** to or lower than **natural exposure levels** of the semiochemical (or a group of related semiochemicals when justified)”

Handling of low risk criteria Micro-organisms

➤ SANTE/11953/2015

A **micro-organism** is expected to be of low risk unless it meets any of the **following exclusion criteria** relevant to use in plant protection:

- **Documented** adverse effects on human health,
- **Documented** adverse effects on environment or non-target organisms or
- The **strain** has demonstrated multiple resistance to antibiotics used in human medicine

The sentence "Micro-organisms may have the **potential to provoke sensitising reactions**" is not considered a specific risk mitigation measure which is the result of a risk assessment, but a **precautionary measure**. Therefore, this sentence does not preclude micro-organisms being considered as 'low-risk' substances"

Handling of low risk criteria Additional restrictions and requirements

- SANTE/12376/2015
 - Semiochemical / Natural occurring substances “[...] Chemicals emitted and used by plants, animals and other organisms for communication should be considered as low risk substances.” independent of natural exposure levels and “even if it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100”
 - Micro-organisms should be identified and characterised at strain level also when assessed for compliance with the criteria concerning low risk substances

- 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 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

- GLP labs for micro-organism characterization not sufficient

- 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 ...)

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

- Several incentives regarding approval/authorisation of low risk substances and low risk products are **already available**
- A lot of actions regarding low risk active substances and products are **currently ongoing (SANTE/12376/2015)**
- A significant legal framework on low risk substances and products is **already in place**
- Demand for low risk substances and products **is evident** due to agricultural, environmental and socioeconomic conditions

2015/2225(INI):

- “Establish **clear criteria** for defining low-risk active substances, ...;
- **Provisional approval** for use and **priority for evaluation**
- *Farmers need to have a **bigger toolbox** ...” and **incentives** to use low risk products*
- “**Faster approvals process**”
- **Efficacy and efficacy levels adapted** to low risk and biological products
- Further **Guidance and guidelines** e.g. for micro-organisms
 - Special considerations for low risk substances in case of „dual use products“ according to upcoming **fertiliser** Regulation?



Thank you for your attention

Handling of low risk criteria Chemical active substances

Regulation 1107/2009, Annex II	SANTE/11953/2015
Shall not be classified 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
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
Endocrine disruptor	Endocrine disruptor
Neurotoxic	Neurotoxic
Immunotoxic	Immunotoxic

Handling of low risk criteria Chemical active substances

Regulation 1107/2009, Annex II	SANTE/11953/2015
Can be considered if	
Not persistent (half-life in soil < 60 days)	Not persistent in soil: DT50 lab or field < 60 d
	Not leaching to groundwater through soil: concentration groundwater < 0.1 ug/L For parent compound and <u>metabolites</u>
	Not persistent in water-sediment: DT50 < 30 d or < 10 d if derived separately for the compartment
Biconcentration factor < 100	Bioconcentration factor < 100 for readily biodegradable substances = 100 for not readily biodegradable substances
	No specific mitigation methods for Product Risk Assessment required concerning ecotoxicological acute and long-term toxicity
	Not persistent in air: DT50 < 2 d