Federal Office of
Consumer Protection
and Food Safety

Analysis of the Status Quo for low-risk Products and basic substances

Annual Biocontrol Industry Meeting – ABIM 2020 19-21 October 2020

Contents

An Emphasis on low-risk products

EU vision on what agriculture should look like in future

- Farm to Fork Strategy
- EU Commission REFIT Report

On a national level

- Ackerbaustrategie 2035

Bioprotection

- Is not legally defined within the EU
- Which legal categories can be considered bioprotection agents within the EU?
  - Microorganisms and plant protection products which are allowed in organic farming
  - Basic substances
  - Biostimulants
  - Semiochemicals
  - Beneficial organisms
  - National categories (e.g. for Germany plant strengtheners)

Legal Framework

- **Two-tier system for Plant Protection Products**
  - Approval of active substance, EU
  - Authorisation of plant protection products (PPPs), national

- **Special consideration to low-risk substances and products**
  - What is low-risk?

Low-risk – Legal Framework

Low-risk active substances and low-risk PPP

- According to Regulation (EC) No. 1107/2009 Article 22

„*low-risk active substance and where it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment as provided for in Article 47(1).*"

- According to Regulation (EC) No. 1107/2009 Article 47

„*Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low-risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment*."

Active Substances and PPP

Active substances in the EU

Approved	474
Low-risk a.s.	24
Basic substances	22
Not approved a.s.	897
Pending a.s.	42
Potential low-risk a.s.	72
EU commission proposed a.s. which might be low-risk (2018/C 265/02)	53

PPPs authorised in Germany

- Total of 21 applications with low-risk a.s.
- 17 decisions – only 5 products were considered low-risk

Difficulties encountered

- Data requirements for potential low-risk active substances are not comprehensive (e.g. multiple antibiotic resistance, secondary metabolites)
- Data requirements for MO are often not precise
- Approval of an active substance as low-risk does not necessarily mean that the PPP containing the active substance is low-risk
- Data requirements for efficacy assessment is reduced for low-risk PPPs – What happens if the product is not considered low-risk even though the active substance is low-risk?!

How can market access be improved by the authorities?

- Authorise low-risk PPPs within 120 days
- Revise data requirements for MO (ongoing)
- Define and harmonise specific risk mitigation measures on a national and international level
- Improve communication with applicants and users on low-risk PPPs

What can the industry do to improve market access?

- Submit complete dossiers for the approval of active substances
- Attend Pre-Submission-Meetings before submitting an application

Legal Framework

- According to Regulation (EC) No. 1107/2009 Article 23 „*a basic substances is an active substances which:*

  a) is not a substance of concern; and

  b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

  c) is not predominantly used for plant protection either directly or in a product consisting of the substance and a simple dilute; and

  d) is not placed on the market as a plant protection product“

What can be done to improve use of basic substances

- Placement on the market should be made possible
- Wider communication of information in regard to the function and use of basic substance

BVL's contribution

- Confident that it will be possible to further develop this field
  - Experience
  - Communication

- BVL has a particular interest in supporting alternative products within the legal limitations.

Thank you for your attention!

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