

IBMA Position Paper on Incentives for Low-risk Active Substances

IBMA have strong reservations that traditional incentives applied to low-risk conventional chemical pesticides are neither sufficient nor appropriate to the needs of biocontrol companies submitting low-risk biopesticide applications.

Background: Existing incentives and inherent differences with conventional pesticides and their manufacturers.

It has become common practice to give first priority to addressing issues with substances that pose most risk to human health and the environment. This has been seen in some ways as best practice but is not without unintended consequences. Constant relegation through the virtue of presenting substances and products of low risk to human health and the environment has resulted in the biopesticide industry suffering disproportionately through resourcing issues and facing severe delays to registrations and review conclusions. This should not be compounded by merely accepting incentives also designed for conventional chemical solutions.

Policymakers have expressed in parliamentary debate at EU and MS level and through legislation (SUD-Dir. 2009/128/EC and Reg. (EC) No 1107/2009 a desire to increase the availability of low risk substances and products containing them. Administration needs to facilitate that these aspirations are met and amendments and exemptions should be implemented to Reg. (EC) 1107/2009 should they be necessary. The regulation provides for incentives by extending the protection of data generated for low risk substances as well as by extending registrations and reducing evaluation periods for products containing such a.s.'s. Intellectual Property (IP) and data protection based incentives are an established means for conventional chemical pesticides by which an applicant can effectively protect investment into substances developed.

Several differences support the need to re-evaluate the traditional approaches:

- SMEs represent a high percentage of biopesticide a.s. applicants as compared with substantially fewer for conventional chemical a.s. applicants;
- A high percentage of biopesticide applicants have research, development and regulatory costs exceeding 100% of their turnover whilst conventional chemical applicants would budget these costs typically at 5-10 % of turnover;
- Some (SME) biopesticide applicants have yet to establish any turnover whilst awaiting registration of their initial biopesticides;
- With a large percentage of biocontrol applicants being SMEs, an extension of 5 years to the approval of a substance and the authorisation of products shown to be of low risk is insufficient, and re-evaluation could be considered an inefficient use of resources of the EU Commission, EFSA and Member State competent authorities;
- For biopesticide substances IP is mainly irrelevant. With information from open literature contributing substantially to dossiers and active substances originating from nature, the ability to protect intellectual property is severely restricted and may be limited to processes or formulations only.

Proposals: Incentives needed

As there are clear differences between conventional chemistry and biopesticides, separate definitions and incentives need to be developed tailored to the industry and product type.

As a general principle, time and cost are the most critical constraints on applicants of biopesticide active substances and products. Speed of entry into the market is critical for biopesticide producers attempting to deliver farmers and growers the solutions policymakers in Europe are calling on them to use in the green growth of modern sustainable agriculture. Intellectual Property protection and a longer finite registration period of 15 years as incentives are insufficient.

Proposals: Means to deliver appropriate incentives

1. Active substances (a.s.)

- A new procedure should be established where active substances proposed at the pre-submission meeting as satisfying the criteria of low-risk be given an accelerated (Fast-track) a.s. approval process by means of a pre-screening procedure, leading to fast provisional or conditional approval. This is followed by a full assessment, with possibly additional dossier / information requirements and possibly due to a withdrawal of low-risk classification to a normal substance should the substance be re-classified during the approval process.
- Active substances proposed at the pre-submission meeting as satisfying the criteria of low-risk should be given a priority for evaluation by the rapporteur member states and EFSA.
- An adaptation of the a.s. dossier / information requirements tailored to the nature of the various categories of active substances should be used in low-risk products. Where necessary, Guidance Documents shall be developed with all stakeholders involved.
- The active substance approval shall not be time limited and subject to automatic re-evaluation. Re-assessment should only be required if sufficient concern of additional risk to human health or the environment is reported with scientific evidence post the initial evaluation of the active substance.
- A means by which substances that are already approved today are treated needs to be proposed. This could be done through a retrospective low-risk evaluation of those active substances and should result in granting the same status and incentives as applicable to any future, new evaluations and approvals. These tasks for existing recently approved or reviewed active substances should be done immediately and not merely wait for a review or renewal to be conducted. To do otherwise would discriminate against these substances in the marketplace.

As a principle low risk substances should not incur fees for evaluation to encourage the bringing of them to the market. To ensure best practice this could be achieved by implementing the following procedures:

- Pre-submission deposit is paid (where required by a MS rapporteur) prior to a pre-submission meeting and then the balance of 25% of outstanding evaluation fee on submission. Should the evaluation confirm that the active substance satisfies the criteria for low-risk then no further fees would be payable.

- A re-imburement of all fees paid for the active substance dossier administration and evaluation shall be made once the first product authorisation has been granted and all conditions on the active substance approval have been met.

2. Products

- Product applications only containing low-risk substances shall be given an automatic accelerated (Fast-track) approval process for low-risk products. If an a.s. or a.s.'s satisfy low-risk criteria, products shall be marketed after simple notification to a zonal rapporteur or member state provided that the product fits any conditions established for the low-risk listing/s of the substance(s) and conditions for low-risk PPPs established in Reg. (EC) No 1107/2009 Art.47(1). As an absolute minimum requirement, MS shall adhere to the 120 day evaluation period allowed for low-risk PPPs. under Reg. (EC) No 1107/2009 or after that interval the product shall be automatically authorised.
- Priority should be given at member state level to accept dossiers, evaluate and authorise products containing low-risk substances over those that do not meet these criteria.
- No fees should be charged for low-risk product evaluations to encourage a proliferation of these products and facilitate their use in smaller niche markets.
- No authorisation expiration date and hence no time-related re-evaluation should be seen as the standard practice for products approved as meeting low-risk criteria. Re-evaluations are still possible when a specific call is made for a product or for products in general based on a particular active substance.

Outcome:

The system of incentives as proposed delivers low-risk products to the farmer/grower as per the intentions of EU policymakers and reduces burden upon this young developing biopesticide industry. It further encourages investment in the industry to discover and develop new technology as a significant burden is removed as an obstacle for the expansion of the biocontrol industry and its investors. Timely income from investment in R & D allows companies to be profitable, will create new jobs in SMEs, and develop further products.

Funding the financial incentives could come from charging at member state level a premium on fees charged for products that do not meet the low-risk criteria or from an EU fund to promote the innovation of alternative non-chemical tools as a means of encouraging best practice and development of the safest tools available for sustainable crop protection.