

Efficacy and risks of „Biorationals“ in organic and integrated pest management – acceptable??

Comments of IBMA on the results of 8th International Symposium 13./14.12.2017 in Braunschweig

During the Symposium some issues were concluded (bullet points). From referents and participants (incl. IBMA-members) perspective the following recommendations could derive (green arrows):

- **Definition**
There is no generally accepted definition of Biorationals yet. As a working definition the term was used for Biocontrol, Biostimulants and Biofertilizer agents, including microorganisms, natural occurring substances (botanical extracts, minerals, chitosan etc) and semichemicals. Macrobiotics were not in focus also they are part of the biocontrol concept.
 - The word ‘biorational’ is not commonly used, and is not part of any regulations; therefore IBMA does not support the use of that term. For the conference however it created an interesting approach, showing regulative shortcomings due to dual functions of different products (see below). Thus the approach could lead to constructive solutions and serve sustainable plant protection strategies (see below).
- **Efficacy trails under natural conditions**
The experienced efficacy of Biorationals in lab and greenhouse is not always reproducible under natural conditions, since it depends on environmental conditions (e.g. under nitrate application microbial consortia increase phosphorous availability inefficiently, while under ammonia application they deliver P reliably).
 - Define flexible models for efficacy trails under field conditions. They should refer to the latest EPPO Guideline on efficacy for low risk PPPs, which has been accepted by EPPO and the EU MSs, including Germany. PP 1/296 (1) Principles of efficacy evaluation for low-risk plant protection products Bulletin OEPP/EPPO Bulletin (2017)0(0), 1–8
- **Efficacy in IPM**
Biorationals are part of IPM and organic farming. Therefore they have to be considered as part of a management concept but not as a tool box for conventional farming. Low efficacy is tolerable under these circumstances, since the general principle of IPM is prevention, not intervention. Also in conventional programmes Biocontrol Agents and Biostimulants are valuable alternatives and often crucial for resistance management.
 - Promote “revitalised” IPM strategies within the national NAP and SUD strategies to achieve sustainable plant protection. E.g. foster suppression of harmful organisms and resilience of crops through promotion of cultural methods and non-chemical alternatives. .
 - Hence communicate the recommendations of the Symposium to competent authorities on EU and member states.
 - Elaborate and promote local extension services, since the success of IPM depend on farmer skills.
- **Legislation, registration and innovation**
Biorationals work with complex but effective mechanisms. In reality there is an overlap of stimulating and biocontrol effects. – The molecular response pattern to biotic and abiotic stress can be characterized as overlapping gene responses, where in total 417 genes are

involved. In consequence the flowing transition between Biostimulants and Biocontrol lead to a Dual Function. In registration this Dual Function is causing conflicts since Biocontrol falls under legislation ((EG)2009/1107 while Biostimulants falls under (EG)2013/2013).

- Manufacturers suffer from long and expensive registration procedures under ((EG)2009/1107. The development costs of PPP are estimated to amount up 5 to 10 Mill Euro, including registration costs of 2-3 Mill. Euro. The biggest hurdle is the very long registration process like about 5 years. In consequences the companies are hesitant and many innovative substances and products don't enter markets. In several cases legislative conditions (e.g. cut off criteria and low efficacy) even hamper innovative solutions and holistic approaches (e.g. chitosan). In consequence a fast track system is needed.
- Policies, consumer's preference as well as the regulation 2009/128/EG foster specific plant protection solutions. This has economic implications especially for minor crops, where the return of investment of PPP is low.
- Uniform rules in the EU do not mean that PPP are uniformly available.
- The interaction of registration and innovation is critical for the resistance management, if less than 3 PPP per crop and indication are available. –
- Generally the principles of the (EG)2009/1107 (e.g. efficacy approach and risk assessment) were supported and efforts of authorities (EU and National) to smoothen the process were perceived. Still ...
 - Push for a faster, reliable and cheaper registration process.
 - Realize a fast track for minor uses, with minimum data requirements and thus costs.
 - Create – for a minority of products (e.g. naturally occurring substances like copper, botanical extracts and microorganisms with dual function) flexible and pragmatic solutions (e.g. guidelines, specialised personal in the CA, accepted Data gaps, if requests are not applicable under explained conditions , QPS for Bacolo viruses, registration of strains).
 - A reasonable solution could even be an alternative regulation in addition to (EG)2009/1107, including a consistent risk assessment for naturally occurring biologicals (including microbials) applied in agriculture with real expert evaluators at EFSA and MS level (e.g. USA EPA biopesticides stream). In respect the term “Biorational” act as a valuable forerunner model as mentioned under the first bulled point.
 - Provide “low risk” label at the beginning and not at the end of registration procedure, to avoid that the ‘non-approval’ criteria ‘low efficacy’ will act as an innovation killer for low risk products.
- The approach of the fertilizer legislations (EG)2013/2013 seems promising but many questions are still unsolved (e.g. Complementation of Positive List, CE Label). A transparent and well reflected approach is recommended based on the expert consultations. It was stated that the communication between authorities and experts is insufficient so far.
 - Establish an expert network to foster exchange, information flow and consultation.
- **Strain level requirement**
For microbial products there is the requirement of providing information on the identity of the microorganism. Usually this is provided on strain level and is well accepted; as specific features are strain specific. However, it was raised that for some technology like Mycorrhiza it might not be possible, but since Mycorrhiza is already on the Positive List it is exempted from strain specific notifications.

- Include in the fertilizer legislations (EG)2013/2013 an amendment to the strain specific requirement by adding “, where possible.” This amendment would allow providing technology relevant information on the identity different from information on the strain.
- Encourage applicants and governmental evaluation bodies to be pragmatic and flexible to provide/accept alternative data. The data should serve the purpose of the data requirement, like overall safety and prove of label claims. Governmental evaluation bodies should not insist on the formal availability of specific data that cannot be provided due to the nature of the technology. This would suppress innovation.