

# Biopesticide and Biostimulant Growth Prompts Need for Registration



**Dr Lars Huber**  
Head of Biostimulants,  
Fertiliser, IPM of SCC.

*Scientific Consulting Company (SCC) is a dynamic regulatory consulting company with currently more than 130 employees in the global. Till now, SCC has become the leading independent regulatory expert in Europe, supporting its global clients with all their registration needs in agrochemicals, biopesticides, biocides, chemicals/REACH, consumer products, cosmetics, feed and food additives, pharma pre-clinical and archiving. Recently, AgroPages had the opportunity to chat with Dr Lars Huber, Head of Biostimulants, Fertiliser, IPM of SCC.*

**As an independent regulatory consulting company, what kind of services can SCC provide in the field of biopesticides and biostimulant? Compared with other competitors, where do you think are the advantages of SCC?**

SCC of course offers all services relevant for the registration of biopesticide a.s. and products as well as biostimulants including study monitoring, dossier preparation, submission and follow up. In addition to this registration work, SCC experts are involved in various R&D projects for biopesticides, biostimulants, IPM and precision farming including technical and scientific steering of research projects and academic co-operations, also in regards to guideline development. Therefore, SCC experts have in-depth knowledge exceeding the normal requirements for a.s. and product registrations. SCC's clients benefit from this additional knowledge e.g. for development of suitable registration strategies for their biopesticides and biostimulants including precise and intensive use of literature data, study waivers and scientific rationales.

**How is the SCC's performance in the past few years? What do you think is the main driving force behind the growth of the company? And could you share what are the goals of the SCC in the next five years?**

In the last years SCC has steadily grown, both in regards to the scope of our services and the number of clients we service as well as the number and fields of knowledge of SCC's employees. The growth is partly due to permanent requests from our clients for SCC's services also in non-European countries. Thus, in

March 2018 Dr Hans-Josef Leusch (former head of the biocide department) has been appointed as head of SCC's new functional area 'Corporate Development'. In close cooperation with SCC's various business units, he is exploring SCC's opportunities in key markets outside the EU. The focus is on services related to the registration of plant protection products, chemicals, and biocides to offer SCC's clients constant regulatory support in key markets such as Asia, Australia and the Americas.

**Biopesticides and biostimulants have been in full swing in recent years. What do we need to pay attention to when registering these products compared with traditional chemical pesticides?**

The political will and consumer demands have become quite clear in the last few years, fostering sustainability and low risk plant production methods. Thus, it's not necessary for manufacturers anymore to consider if it is economic to register biopesticides or biostimulants in EU from the sales side of view, the demand for such products is high and constantly increasing.

Today it is more important to pay attention to the registration strategy, especially considering the currently still ambiguous regulatory status of biostimulants and products on the borderline between biostimulants and biopesticides. In addition, the experience with the registration of low risk plant protection products, including authority evaluations is still very limited. Thus, it is for the applicant to develop a registration strategy employing all of the possible benefits the regulations and guidelines set out

for low risk biopesticides. Such a registration strategy, on the one hand, has to consider the regulatory relevant aspects including national incentives for biopesticides such as authority fees or any type of green deals. On the other hand, studies have to be conducted and respective dossiers have to be prepared in a way providing the relevant scientific evidence for scientific justifications and study waivers to authorities. This includes for example the use of public literature. The benefits which can be gained by a suitable scientific-based registration strategy and the savings in costs and time are the biggest difference compared to chemical pesticide applications.

**Can you tell us about the current large-scale biopesticides and biostimulant companies that have chosen SCC's services? What do you think are the main reasons that they choose SCC but not others?**

I'm sorry, but regrettably this is not possible as, of course, SCC handles all customer-related information strictly confidential. To answer your question I would like to refer to your second question and politely ask the reader to read between the lines of this interview and perhaps have a look at SCC's homepage at which he will find certain evidence of SCC's expertise e.g. by the publications in the "News" section. This should answer these questions, at least to a certain part. According to the feedback from our biopesticides and biostimulant clients they have chosen SCC mainly for SCC's competence and experience in successfully registering and defending also very complex substances, strictly keeping the agreed time lines or regulatory deadlines. The special scientific expertise which our experts have, not only from regulatory projects but also from several R&D projects in which they participate, e.g. in the field of IPM or precision farming, is of huge interest for our clients. These are some points why these clients have chosen SCC.

**Europe and North America are the mature markets for biopesticides and biostimulants. However, in recent years, biopesticides and biostimulants have developed rapidly in emerging markets such as China and Brazil. Is there any business related to SCC in these regions? What do you think is the biggest challenge for biopesticides and biostimulants in these places compared to Europe and North America?**

Of course we are also involved in projects in countries outside EU such as China and Brazil. In our experience, we see the biggest challenge in the acceptance of such products by authorities, especially in regards to biopesticides in Brazil. There are several problems in biostimulant and biopesticide registrations in countries outside Europe and North America which are often linked to missing definitions as well as handling and implementation of existing regulations. But, as grower demand

for such products constantly grows, the pressure on authorities to approve such products has also increased. Some changes can already be observed as evident by increasing numbers of such products in these markets. In addition, national regulations in certain countries, such as the new Chinese Regulation on the Management of Pesticides of 2017, more and more include provisions explicitly giving preference to low risk products or biopesticides, similar to the provisions in EU. The new Chinese Regulation for example states that the State shall gradually reduce the use of pesticides by promoting biological controls, physical controls, advanced spraying devices and other measures (Article 32) as well as that extremely toxic and highly toxic pesticides shall not be used to prevent sanitary pests on vegetables, fruit, tea, fungi and Chinese herbal medicines for the control of aquatic plant pests (Article 34).

In regards to SCC's own business in these regions, SCC is currently exploring the additional opportunities in these key markets. In regards to China for example, in 2018 SCC will have at least two new cooperation managers in China, managing biopesticide and biostimulant registrations in China as well as supporting Chinese clients with the registrations of their products



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in EU. This will be handled in very close cooperation with the Chinese plant protection registration consultancy BIOREG.

**Recently, U.S. Farm Bill Draft defines plant biostimulants for first time. What impact do you think this will have on the biostimulant industry?**

To have clear and detailed definitions and separation of related topics, as in the case of biostimulants and certain biopesticides, is always helpful, at least for regulators. Thus, increase in clarity in the frameworks regulating this market should provide industry with a good basis for decision making and placing of investments. As a scientist and regulator, I have certain reservations in regards to the definition chosen. Similar as in Europe there is a clear separation of abiotic stress, ascribed to biostimulants, and biotic stress, ascribed to biopesticides.

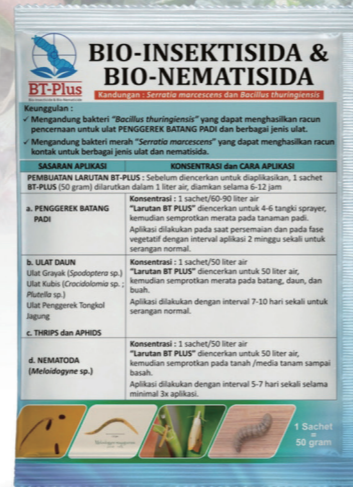
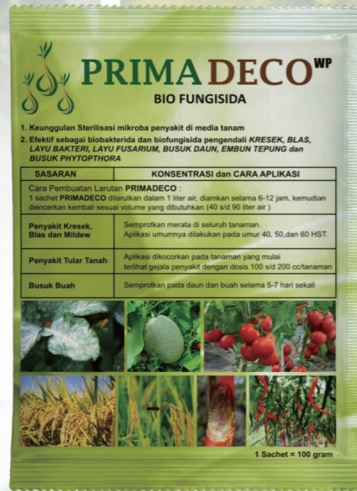
But several of these biorational active substances act against both, biotic and abiotic stress. Thus, this may cause certain uncertainties and problems in registering a substance or product under the most suitable framework. In addition, this regulatory separation may lead to the loss of substances and products for plant protection purposes.

**Can you share with us the latest developments in European legislation in the field of biostimulant? What impact these developments have on SCC's business?**

End of last year, draft EU fertiliser regulation which will also regulate biostimulants was debated in the European Parliament whereat 404 amendments to the upcoming EU fertiliser regulation were discussed which already gives an idea on the status of this draft. Several amendments were adopted by the

plenary, others not and the draft proposal was referred back to the Committee on Internal Market and Consumer Protection, opening up the interinstitutional negotiations with the Council again after the original publication of the regulation was scheduled for 2015... Thus, central themes as well as the entry into force of the regulation are still unclear and the framework for business decisions and registration strategies are still unclear.

This still unclear regulatory situation of course also impacts SCC's business and instead of helping our clients to register products we have a lot of requests explaining the draft and possible implications. At the moment, the major interest of our clients is how to bring products on the market using national registrations, using also mutual recognition for fertilisers and biostimulants, and preparing their portfolios for eventual entry into force of the new regulation.



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