Opportunities or Challenges?

- Changes in EU Registration Regulation in 2019

SCC – Scientific Consulting Company – was founded in 1989 by Dr. Friedbert Pistel. Since then, it has become one of Europe's largest privately owned and independent regulatory consulting companies, supporting its global customers with all their registration needs for agrochemicals and biorationals, including biostimulants and fertilisers and other industries.

What kind of company is SCC? What has happened to the EU's registration policy for biopesticides and biostimulants in 2019? What are the points to note when registering biopesticides or biostimulants in the EU? Taking this opportunity, AgroPages interviewed Dr Lars Huber, Head of Biorationals, Fertilisers and IPM of SCC.

In the field of Agrochemicals and Biorationals, after more than 30 years of development, SCC has become a leading consulting company in this field. What do you think is the distinctive service of SCC compared with other companies? Why do many companies choose to cooperate with SCC?

Lars: According to the feedback from our clients as well as cooperation partners, CROs and authorities, one of the most distinctive features of SCC is our independence. As we have no own labs for example we are able always to choose the lab or CRO most suited to conduct a specific study in regards to its scientific experience as well as in regards to economic suitability or timing of studies. This feature also emphasises the quality and neutrality of data monitored or provided by SCC in dossiers in the eyes of evaluators and authorities. Furthermore, this independence ensures high flexibility and enables us to offer all different types of projects according to the needs of the client.

Another important fact, especially in case of the quite new and constantly changing field of the registration of biorationals is the long-term experience of SCC with all different types of natural substances under plant protection as well as fertiliser/biostimulant regulatory frameworks. This includes not only the work in regards to registration projects but also in R&D as well as academia research projects. These different activities provide for in-depth knowledge, scientifically and regulatory, and synergies allow for the development of innovative and future-oriented testing and registration strategies for all types of biorationals and regulatory frameworks.

At present, SCC has operations in overseas countries such as Japan and China. Please summarize the global development of SCC, especially in the core market?

Lars: In the case of plant protection products and especially biorationals requests from clients from Asian countries for registrations in Europe increased in recent years. This is partly due to the changes brought on by the new plant protection and sustainability goals, regulations and guidelines in EU. SCC responded to these increasing demands from Asian customers by intensifying or establishing a SCC presence in certain Asian countries to be able to attend Asian customers as best as possible. On the other hand this enables us to offer our other clients services in Asian countries and at least partially use synergies, knowledge and data produced for registrations in Europe or US for example for registrations in Asia.

Could you describe the status and some trends of the agrochemical consulting industry? What do you think is the biggest challenge in the consulting industry?

Lars: Status and challenges differ according to the countries in which registrations are envisaged e.g. EU and US. Differences in regards to rules, regulatory frameworks and procedures as well as data requirements between countries are one of the biggest challenges. Simultaneously, this results in a quite different, country-specific status quo in regards to active substance and product registrations. One of the most recent examples is the establishment of a new legal and regulatory framework for biostimulants in EU, clearly differentiating between biostimulants and biopesticides. In other countries, such a strict differentiation or definitions are missing or only under development.

General topics and trends are given by the technical progress in regards to agrochemical practices such as Integrated Pest Management (IPM), Sustainability or Precision Farming as well as testing methods to be used for study conduct. Overall, requirements for the registration of plant protection products become more and more complex but also more individualised, specifically considering the characteristics of the individual active substance and/or product. This allows for very specific, substance-orientated approaches in regards to requirements, studies and scientific justifications for study waivers for biorationals. Thus, dossiers in general get more complex and scientifically demanding but, on the other hand, increased acceptance of scientific argumentation and use of public literature offers possibilities to reduce study requirements and thus registration costs at least for biorationals.

What does a typical SCC global customer look like? Who are your target customers? What are your plans for future development and expansion into new markets / regions?

Lars: Due to SCCs mode of operation, especially the already mentioned independent character, there is no typical global customer. SCC cooperates, and is able to cooperate, with the full scale of customers interested in or in need of regulatory and scientific services for plant protection products, biostimulants, fertilisers and other related products. Of course, in cooperation with our other departments, biocides or REACH projects for example can also be handled. Some of our clients conduct much of the relevant work themselves. Other clients work with cooperation or distribution partners or even split forces between active substances and products. Still, other clients require the full SCC service from R&D issues, study monitoring, dossier writing, applications, defence and follow-up. Thus, there is no typical SCC customer or even a target customer.

The fact that SCC has not established offices in additional countries does not mean that we are not actively working in registration projects also outside EU such as in US, Australia or Southern American or Asian countries. Although, normally we cover all this work via our global network of cooperation partners, all of them having in-depth knowledge of the national requirements and authorities. Thus, we are already acting on a global scale with international registration projects but of course we will expand further if our clients require respective services.

Regarding the registration of biopesticides, is there any change in the EU's biopesticide registration policy in 2019? How do you think the EU's biopesticide registration policy should be changed to drive the rapid development of biopesticides?

Lars: This is a very complex issue and involves many different areas of the registration process. On the one hand, there are the data requirements itself which clearly are not or only partially suitable for biopesticides, i.e. natural substances and especially microorganisms. These have to be revised and adapted. Respective scientific work dates already back more than two decades but has not been included in the regulatory process. This implementation is currently ongoing on authority level and, after a delay of many years, hopefully will lead to significant improvements in the near future. On the other hand, the specifics of biopesticides have to be considered more detailed in the regulatory process. For one, the Modes of Action of many biopesticides require not a curative but a preventive use. Others do not act directly on target organisms but have an indirect Mode of Action acting via the defence systems of plants. This requires not only their IPM use in the agricultural practise but also the incorporation and acceptance of IPM in the regulatory process. In spite of the fact that IPM is mandatory in EU since 2014 for all professional users, the regulatory process and the requirements do not reflect this. This applies especially to active substances and products with a very narrow range of applications and niche products. Sale revenues for such products often do not justify the investments necessary for a registration. There are some support schemes in place in certain countries but they are still too few and they have to be expanded. But it's not always the financial investment itself that detain companies from the registration. Often, the reasons are the uncertainties and the lack of harmonisation in regards to data requirements, requests for post-submissions during the registration procedure or the timelines. Thus, a regulatory harmonisation and a fast track procedure, at least in regards to the admissibility of an application, would be required. Participation of EFSA in pre-submission meeting is a necessary first step to be welcomed but additional improvements in the regulatory registration process are also be necessary.

Regarding biostimulant registration, is there any change in EU biostimulant registration policy in 2019? In the biostimulant registration section, what services can SCC provide to help customers obtain registration quickly?

Lars: In 2019 the new EU regulation on fertilisers entered into force. This regulation also includes biostimulants and plant aids for example. This of course changed registration possibilities significantly as the regulation introduces EU-harmonised rules. Regrettably, applicability of the regulation will be in 2022 only as the respective guidelines and guidance have to be developed in the meantime. Until then, respective products still have to be registered on a national level if applicable. National registrations can be a good basis for a subsequent registration as an EU-fertilising product. Thus, SCC can assist clients to achieve national registrations in important target markets and evaluate the possible registrability of individual products or product portfolios according to the upcoming EU rules. Thus, SCC can support clients in attaining national registrations and allow for an early entry into core markets and for core products and prepare for the subsequent EU-wide registration of the products after applicability of the EU harmonised rules.