

SCC is prepared to meet coming regulatory challenges

In the fast-moving world of regulation SCC is ready to keeping its customers on a successful course. In order to underscore this engagement, two new working groups were previously established, coping with cosmetics and biopesticides:

Firstly, SCC has established additional capacity to meet the challenges of the **new Cosmetic Regulation** (EC) No. 1223/2009. A further expert, Dr. Karsten Schilling has joined the SCC Team. With his reputation and SCC's already established expertise, SCC is able to support clients from the cosmetics industry with a unique portfolio of scientific and regulatory services.

Secondly, SCC has established the new working group '**Integrated Pest Management**' to comply with these new scientific and regulatory needs. Members of the working group have a strong interdisciplinary background in scientific and regulatory aspects of Integrated Pest Management, biopesticides and fertilisers as well as detailed knowledge on all relevant European regulations. Dr. Lars Huber, an expert in viticulture, is the person in-charge for any relevant questions and is part of a wide-reaching network in the international regulatory and scientific IPM world.

You are invited to have a closer look at the new working groups in this issue of the SCC Newsletter.

Furthermore, I would like to express again our wish to continue our service in the regulatory field for you to satisfy your needs whenever it is possible.

Don't forget to have a look at the calendar of events to find out where you can meet with SCC experts to express your needs or clarify your questions on scientific and regulatory issues. One main area of focus is South-East Asia.

Regardless of whether your needs are in scientific and regulatory support for agrochemicals and biopesticides, biocides, chemicals, feed and food additives, veterinary medicine, archiving solutions or Task Force management, SCC can provide you with high quality service and consulting. We take care!

Furthermore, all of us here at SCC would like to wish you a great holiday season, wherever you are.

Finally, we appreciate your feedback and comments regarding the SCC Newsletter. Drop us an e-mail at newsletter@scc-gmbh.de.

Dr. Friedbert Pistel
President

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AGROCHEMICALS

Biopesticides and Fertilisers - new working group of SCC!

SCC has again expanded its scientific knowledge into a new regulatory direction: Biopesticides and Fertilisers. Although SCC has been involved with biological plant protection products as well as fertilisers on several occasions in the past, the time has now come to make it one of SCC's four regulatory working groups of the Agrochemical and Biopesticide Department. Here is a short introduction into the world of the Biopesticides, Biostimulants and Fertilisers.

The World of Biopesticides, Biostimulants and Fertilisers

In recent years, several new regulations and directives have entered into force in the European Union to establish a basis for the safe and sustainable future use of plant protection products with regard to new scientific, economic, ecologic, environmental as well as socio-economic requirements.

With coming into force of the new European legislation plant protection now is strongly linked to other areas of common interest, as specified for example in the Common Agricultural Policy of the EU. With regard to plant protection and plant protection products, the new legal background is primarily based on Regulation 1107/2009 concerning the placing of plant protection products on the market, Directive 2009/127 as regards machinery for pesticide application, the Pesticides Statistics Regulation 1185/2009 and the Sustainable Use Directive 2009/128 (SUS).

The novel character of the new European plant protection legislation is more or less due to of the Sustainable Use Directive 2009/128 the implementation and acts of law linked to this directive, as well as its national implementations. Priorities of the legal framework become obvious from the contents of the Sustainable Use Directive which includes for example the definition of Good Agricultural Practice and the obligatory implementation of Integrated Pest Management (IPM) as well as the establishment and implementation of National Action Plans (NAP).

Following the general rules for authorisation and registration of plant protection products and their active substances, there are various scientific and regulatory based special provisions for biopesticides for example for products containing microorganisms or plant extracts. In addition to this, many biopesticides qualify for authorisation for example as so called basic substance or low risk substance for which often reduced data requirements apply.

Background for the sustainable use of plant protection products is to minimize the risks and impacts of pesticides on human health and the environment. Similar processes are currently ongoing for other agricultural resources such as fertilisers, biostimulants or plant strengtheners. Beside plant protection products, there are various substances and products - often traditionally used - in agriculture such as growth regulators, soil conditioners, biostimulants, plant strengtheners or various organic fertilisers. Such products are liable to various EU and national regulations since the European Fertiliser Regulation 2003/2003 only regulates inorganic substances used as fertilisers. Thus, currently these products mainly have to be registered according to national laws. As this process is often expensive and time-consuming, there are several efforts from industry and authorities to incorporate some of these substances or products into the European fertiliser regulation.

Multiple new regulations and developments are to be expected in future regarding the use and registration of plant protection products, fertilisers, bio-pesticides, plant strengtheners or biostimulants in Europe and worldwide which have to be implemented in the scientific and regulatory day-to-day business of product registration.

SCC's strategy with Biopesticides and Fertilisers

SCC has established the new working group 'Integrated Pest Management' to comply with these new scientific and regulatory needs. Members of the working group have a strong interdisciplinary background in scientific and regulatory aspects of Integrated Pest Management, biopesticides and fertilisers as well as detailed knowledge on all relevant European regulations. In addition to that, members of the working group have established a wide-reaching network in the international regulatory and scientific IPM world.

SCC has about 50 regulatory scientists with a wealth of scientific knowledge and experience covering all registration-relevant areas and thus has a very strong team available for the preparation of necessary dossiers and handling of all regulatory tasks for the biopesticide and fertiliser industry.

SCC's philosophy is to replace expensive studies with less expensive expert work whenever scientifically justified! In addition, SCC is independent: it intentionally does not have laboratories of its own (so there is no need to fill them with unnecessary studies) and is therefore free to cooperate with any laboratory which best suits the needs of our clients in case studies are required.

If you have any questions, please do not hesitate to contact Lars Huber at lars.huber@scc-gmbh.de. Also you can find more information on our website (www.scc-gmbh.de) under the heading Agrochemicals and Biopesticides and under the link "Brochures".



CHEMICALS, REACH, CONSUMER PRODUCTS

News on Chemicals & Consumer Products Department to meet the challenges of the new Cosmetic Regulation

Scientific Consulting Company (SCC) has successfully supported the cosmetics industry for more than two decades and prepared safety assessments for numerous raw materials and final cosmetic products. However, new developments in the regulatory environment of cosmetics lead to new challenges. Thus, completely in the spirit of its mission "We take care", SCC has expanded its regulatory and scientific advice by establishing additionally capacity for the cosmetics industry.

News on Cosmetics Regulations

Cosmetics in Europe are regulated by **Directive 76/768/EEC** and its amendments until 11 July 2013. One important development is the legislative recast, which transforms the cosmetic Directive 76/768/EEC into a Regulation. This **Regulation (EC) No. 1223/2009** is fully applicable **from 11 July 2013** onwards. This means that its provisions have to be applied in all Member States, without alterations, when translated into national legislations. In principle, the content of Directive 76/768/EEC was taken over in the Regulation, but certain elements were strengthened to ensure a high level of protection of human health.

In the context of **Regulation (EC) No. 1223/2009**, the European Commission has confirmed the full ban on animal testing for cosmetics from **11 March 2013** onwards. This was accompanied by a communication on the marketing ban as well as on the current situation in relation to alternative methods and an impact assessment.

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However, the majority of cosmetic ingredients are also in use in many other products, such as food/animal feed, pharmaceuticals, house hold & consumer products and products for industrial use. Thus, animal testing may be necessary to ensure compliance with the legal frameworks applicable to these products, generally subjected to the horizontal REACH requirements.

The **Scientific Committee on Consumers Safety (SCCS) Notes of Guidance (NOG) for the Testing of Cosmetic Ingredients and their Safety Evaluation**, 8th Revision, was adopted on **11 December 2012**. The NOG contains relevant information on the different aspects of testing and safety evaluation of cosmetic substances in Europe.

Scientific Consulting Company's (SCC's) strategy with Cosmetics

SCC is prepared to take care on the multiple challenges originating from the new Cosmetics Regulations and has recruited Dr. Karsten Schilling to lead the new group on cosmetics. Karsten Schilling is a Veterinarian and has a broad interdisciplinary background in toxicology. His detailed knowledge about all relevant national and European cosmetics regulations is generally accepted. He has a wide-spread network in both, the cosmetics industry, including its associations, and the governmental world. During the last decade, he prepared numerous safety dossiers for a wide variety of challenging cosmetics ingredients ending up with favorable SCCS opinions. Amongst UV-filters, preservatives and hair dyes also nanomaterials, products of botanical origin and CMR categorized substances were successfully defended.

Thus, with Karsten Schilling's reputation and SCC's already established expertise on different scientific and regulatory disciplines, SCC is able to support clients from the cosmetics with an unique portfolio of scientific and regulatory services. Depending on your demand, SCC is capable to develop appropriate safety strategies, to perform data gap analysis, to prepare dossiers and product information files, to place and monitor scientific and regulatory reasonable studies, as well as a

variety of other measures of assistance. For further information, please do not hesitate to contact Dr. Karsten Schilling at Karsten.schilling@scc-gmbh.de or at +49 671 298 46 0. You can also find more information on our website (www.scc-gmbh.de) under the heading "Consumer Products".

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CALENDAR

CIR 2013, 5-6 September 2013, Barcelona, ES

Informa's industry conference for agrochemicals (AgChem Forum), biocides, REACH and environmental risk assessment will be held this year in Barcelona. Dr. Bernd Brielbeck, Senior Regulatory Manager Agrochemicals and Biopesticides, will be at this event and make a presentation at the AgChem Forum. More information regarding SCC's involvement in this important industry gathering will follow soon.

For further information regard CIR, check out their website: <http://www.informa-ls.com/event/CIR2013>.

ChemCon Asia 2013, 10-13 September 2013, Seoul, South Korea

ChemCon Asia 2013 is a global platform which brings together more than 200 experts representing companies, authorities and international organizations from over 25 countries. Presentations given by more than 35 speakers from governments and industry will focus in the field of international chemical legislation all over the world, like REACH, GHS and country specific information on inventories, labelling requirements, etc. Dr. Werner Köhl, Head of the Chemical and Consumer Products Department, will be at this conference and be available to talk to you about your regulatory needs regarding REACH.

For further information, please refer to: <http://www.chemcon.net/>

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