

Newsletter

MESSAGE FROM THE PRESIDENT

The 11th IUPAC International Congress of Pesticide Chemistry will be held from 6 – 11 August 2006 in Kobe, Japan, focusing largely on the evolution of crop protection and public health and environmental safety issues. Leaders from industry and science will be there to exchange information and technology on chemistry, biology, toxicology, biotechnology, and environmental science in agrochemicals as well as its related novel technology. Luncheons, seminars, workshops and evening seminars along with an exhibition round out this event.

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SCC will once again be a part of this congress. Having participated at the IUPAC International Congresses of Pesticide Chemistry in London (1998) and Basel (2002), it is only fitting that SCC be a part of the Kobe Congress. This year, however, we have planned an additional event to encourage the networking and exchange of information so important in this industry today.

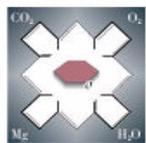
“An Evening of Wine with SCC” will be held on Tuesday, 8 August between 6:00 and 9:00 PM in the MATSU Meeting Room of the Portopia Hotel Kobe. Take some time to stop by and taste a selection of red and white wines produced in the Rheinhessen region of Germany, home to SCC. Mr. Horst D. Neufurth, Senior Manager, Consultation and Liaison, and myself will be present to meet with the delegates and guests of the IUPAC Congress, and to discuss SCC’s services with them.

If you are interested in taking part in the informal get-together, or would like to arrange an appointment with one of us during the Congress, please contact Ms. Lisa Lawrenz at lisa.lawrenz@scc-gmbh.de.

Yours sincerely,



Dr. Friedbert Pistel
President SCC



Still no decision on zonal authorization and mutual recognition

The IBC Life Science conference regarding the "Registration of Agrochemicals in Europe" took place on 23 and 24 May 2006 in Brussels.

Representatives from the agrochemical industry, European authorities and member states presented the most recent experiences they have gained with the implementation, execution and revision of European Union's (EU) Directive 91/414/EEC (the Directive). Among others, the program concentrated on the issues of evolution of zonal authorization strategies, mutual recognition and re-registration, registration of plant protection products from the country perspective, maximum residue levels and new data requirements in light of revision of the Directive.

With the revision of the Directive, the plan is to split up the EU into three zones for the authorization of plant protection products: North (Zone A), Center (Zone B) and South (Zone C). One product registration through a rapporteur member state (RMS) will be sufficient for one entire zone (mutual recognition). This system could be implemented on an optional or compulsory basis.

Currently there is an ongoing EU test project regarding zonal approvals. Representatives for each zone reported on the developments. Because Zone B is the largest (12 countries), any new rules will have a more severe impact here than in the other zones. Overall zonal authorization is supported in the Center zone due to its quick, simple and inexpensive approach using a science-based, harmonized and transparent system. At present in the Center zone, work sharing activities are limited to Ireland, the UK and The Netherlands.

In Zone C the authorities (Greece, Italy, Spain, Portugal) have carried out a pilot project on test substances. Specifically, during the risk assessment, they experienced major problems in the presentation of efficacy trials and the preparation of one dossier covering all uses in Zone C. They also had difficulties with the various ways of expressing application rates and spray volumes. Furthermore, there are no evaluation scenarios available that suit the conditions in southern Europe because most of them were developed in the north.

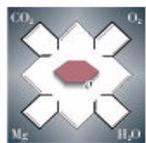
Based on the problems experienced, the countries seek more simplification and harmonization. For example, mitigation measures can be suggested in the zonal registration report but it should be up to the national level to make the final decision.

Pilot projects for risk assessments are also currently underway in Zone A. The Project "North" (Denmark, Sweden, Finland, Estonia, Latvia, Lithuania, Norway) started in May 2005. Five products were selected, and an RMS and a co-rapporteur member state (CoRMS) were chosen for each product. During this project, proposed agreements on operator exposure, groundwater scenarios, residues, ecotoxicology and efficacy were discussed. One year later, decisions on one product in Lithuania and Sweden have been achieved. The new round will start in late 2006. It was suggested that industry applications for authorization be better coordinated, e.g. harmonizing Good Agricultural Practice (GAP) if possible, or accepting a common Annex III dossier.

Among EU member states, the issues of zonal authorization/mutual recognition are hot topics. Although the revision of the Directive is in a very late draft status it has not yet been decided if the "zonal approach" will be implemented or not. As the member states' reports show, the authorities are still in the test phase.

For more information contact:

Dr. Albrecht Heidemann (albrecht.heidemann@scg-gmbh.de)



Revision of Annexes II and III of Directive 91/414/EEC

SCC attended this year's IBC conference in Brussels from 23 – 24 May 2006. Subject of the conference was the registration of agrochemicals in Europe. Among the topics presented, one issue on the agenda was the changes in data requirements for Annexes II and III in light of the revision of European Union's (EU) Directive 91/414/EEC which is under discussion at the moment.

With the new requirements, the European authorities aim to increase data quality and the resulting relevance of the evaluation. Another major target is to converge EU data and testing methods to OECD requirements/guidelines and the reduction of animal studies.

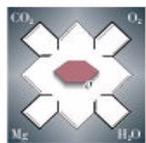
The phys-chem section will codify the current practice in such a way that no significant changes are expected.

On the other hand, a major change is expected for the residue section. Depending on the significance of the crop in diet and trade, the number of residue trials will differ between the absolute minimum of three up to twelve trials for a crop that is significant in trade and diet. The residue trials will also depend upon how widely used the pesticide is in a specific crop all over Europe. Data from one growing season will be sufficient, provided they are generated under comparable conditions.

In the toxicology section, new data requirements are also forthcoming, e.g. ADME study including intravenous administration and in vitro metabolism with different species. Mandatory short-term toxicity studies in dogs will be a 90-day or a 1-year study. The estimation of residential exposure will be requested.

In the fate and ecotoxicology sections, the authorities ask as well for additional tests and calculations such as studies on minor metabolites, PEC_{air} (even though no guidance is available up to now), and aquatic endpoints to be based on mean end concentration instead of mean measured concentration. Based on the already critical situation in the fate/ecotoxicology area today and with the additional data requirements, it is inevitable that higher tier risk assessments will have to be performed.

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REACH activities at SCC

SCC attended ChemCon 2006 in Budapest in May this year. The conference gave an update on the developments in the world of chemicals. Among the many topics presented, the REACH regulation was intensively discussed as it is more or less official that it will enter into force early next year. This regulation will affect practically all manufacturers, producers and importers of chemicals, preparations and articles.

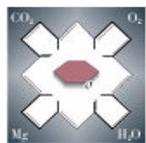
Currently it is rather unclear how this very complex REACH system will be dealt with in small- and medium-sized enterprises (SMEs), as resources to cover REACH requirements are likely to be limited. As soon as REACH is implemented not much time will be left to prepare. The preparatory paperwork consists of portfolio analysis including data analysis for the different chemicals (experimental findings/data), annually handled volumes, and characterization of the potential exposure (exposure categories) to evaluate potential synergisms/exchange with other companies.

During the development process, European authorities inserted a group registration tool. With the so-called *consortia registration*, the Commission offered manufactures, producers or importers dealing with a given substance to register one compound jointly via one single dossier ("one substance one registration" concept). Consortia registration is a very interesting and affordable tool for SMEs to get their compounds registered. However, setting up a consortia and the procedure to get it working efficiently can be a real challenge. In addition to consortia, joint actions via associations might also be an interesting route of cooperation, especially with regard to exposure modeling/assessment. The critical issue in all these activities is the protection of the know-how of the individual companies since potential competitors need to work together. This is often difficult to solve and external support/consultancy might be needed.

With the specific objective to support SMEs, the German Federal Environment Agency (Umweltbundesamt - UBA) organizes conferences on how to make REACH workable for them. SCC attended the last conference on 8 June 2006 in Berlin. Important agenda items were data sharing and protection as well as legal aspects of consortia registration with a special focus on SMEs and how they can potentially manage the additional burden due to REACH. For further information please go to www.reach-info.de.

SCC is involved in research activities for the UBA to investigate bioaccumulation of, e.g. poorly water-soluble substances *in vitro*. This approach is considered to be an interesting alternative to the classical bioconcentration study in fish because it avoids animal tests and potentially supports group approaches, e.g. in the context of REACH. Bearing in mind that very bioaccumulative and very persistent (vBvP) substances, depending on the exposure, are under consideration to undergo an authorization process and to be evaluated within the first period of REACH, SCC is happy to have been one of the initiators of this approach.

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**BIOCIDES**

Biocidal Products Directive amended

On 30 May 2006, an amendment (2006/50/EC) to the Annexes IVA and IVB to Directive 98/8/EC (Biocidal Products Directive - BPD) concerning the placing of biocidal products on the market was published in the Official Journal of the European Union L 142/6 (May 2006). Annexes IVA and IVB to the BPD list the data requirements for dossiers to be submitted for active substances consisting of micro-organisms including viruses and fungi. According to the published amendment, "... it is necessary to adapt Annexes IVA and IVB to Directive 98/8/EC to technical progress and to developments in related legislation [...], in order to provide a better basis for carrying out risk assessments for micro-organisms and the biocidal products containing them." The structure of the data requirements in the framework of the BPD have been aligned to those of Directive 91/414/EEC concerning the placing of plant protection products on the market.

The objective is to facilitate the work of applicants applying for registration under 91/414/EEC and the BPD as well as the work of the Member State authorities evaluating the dossiers.

Only three active micro-organisms have been notified and are included in the review program (Product Types 2, 3, 5 and 18). As the deadline for the submission of a complete dossier for Product Type 18 has already passed (30 April 2006), the amendment to Annexes IVA and IVB is relevant for applicants planning to submit dossiers for Product Type 2, 3 and 5 in 2007.

The full text is available under

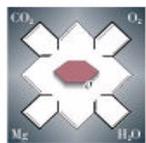
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_142/l_14220060530en00060015.pdf

Withdrawal list now available

On the web site of the Environment Directorate-General of the European Commission, a new list of "Substances, for which all participants have withdrawn or for which no dossier has been submitted within the time period specified in Annexes V and VIII to Commission Regulation (EC) No 2032/2003", was published on 14 June 2006. Refer to <http://ec.europa.eu/environment/biocides/withdrawals.htm> for this list and all withdrawal notices published so far.

For more information contact:

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Regulatory / scientific archiving and new GLP archiving facilities now available at SCC

GLP / ARCHIVES

As you might already have learned from our home page (www.scc-gmbh.de) SCC successfully obtained a Good Laboratory Practice (GLP) certificate for the GLP-compliant archiving of raw data from GLP studies.

SCC is now in the position to offer a complete archiving concept for all regulatory needs to the benefit of all our clients.

SCC can act as your European or world-wide central archive for regulatory/scientific data as well as for GLP-compliant storage. In addition, in-house solutions for the archiving of your regulatory/scientific documents at your premises can be set up by SCC.

SCC can offer you the following archiving tools:

- EDDMS, the Electronic Dossier Data Management System and regulatory archive: this is a unique database system for all regulatory needs, designed and developed by SCC, proven and tested for years as SCC's regulatory in-house dossier management system.
- GMS, the GLP archive Management System: GLP archive for data, electronic media, materials, samples from GLP or similar type studies. The unique archive and database system for all GLP needs, designed and developed by SCC, proven and tested as SCC's regulatory in-house GLP archive management system.

In addition with its GLP expertise, SCC supported an Indian contract research organisation (CRO) in successfully obtaining a full German GLP certificate. Thus, while the Indian GLP compliance monitoring is not yet officially recognized through the OECD system of mutual visits, they can offer fully GLP compliant studies in all OECD areas.

For further information contact:
Dr Bernd Brielbeck (bernd.brielbeck@scc-gmbh.de).

Efficient and soon mandatory method for submitting dossiers: the CADDY dossier

CADDY

CADDY (Computer Aided Dossier and Data Supply) dossiers are an efficient and accepted method for the submission of dossiers in electronic format. Using the approved software for generating a CADDY dossier, reference lists, reports, documentation and dossier updates are easily integrated and can, in conjunction with the CADDY retrieval software (free-of-charge download available on the ECPA website <http://caddy.ecpa.be>) be easily reviewed.

CADDY

A typical CADDY dossier consists of a set of 2-4 CD-ROMs: one or more CDs containing the pages of the "paper dossier", one containing "confidential pages", and one containing index-information. In addition to the viewing and printing features, the CADDY retrieval software provides several features that facilitate the review process: hyperlinks can be set to allow quick navigation within a dossier, and can also be placed in review documents or in electronic communications, allowing direct access to relevant pages in a dossier; annotations can be exported and imported, allowing work sharing between authorities; and Caddy Controlled Files allow integration of different file-types in a dossier (e.g. PDF, Word, XML, etc.).

CADDY also plays an important role in the European review program where, in addition to new submissions, a large number of dossiers for existing substances have been submitted in the CADDY format. Early in 2001, the Standing Committee on Plant Health decided that submission of electronic dossiers (CADDY only) should be encouraged for the review program. This is evident during the distribution to Member States (MS) process, in which a total of more than 60 sets of dossiers are required. Given a dossier consisting of 60-80 volumes, this would mean exorbitant amounts of paper, time and money being expended in copying the dossier, not to mention the additional transport and storage costs involved. The generation, copying and distribution of a CADDY dossier costs only a fraction of the above-mentioned expenditures.

Recently, the German Federal Office of Consumer Protection and Food Safety (BVL) introduced the pilot phase of electronic submissions for the registration of plant protection products. The BVL's goal is to eliminate completely paper dossiers and to accept only electronic submissions. This will allow for the completely electronic processing of the application while assuring increased transparency and quality during the evaluation process. The first step to this goal is the submission of reference lists in CADDY format. This of course means that at least the documentation submitted for a dossier must be stored in CADDY format to allow the generation of this reference list. Discounts in fees for the registration of plant protection products will also be granted for CADDY dossier submissions.

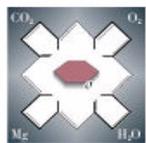
It makes sense to generate a dossier in the CADDY electronic format, especially since it can be used for plant protection products and for biocidal products. Because the software is extremely expensive with annual licensing fees required, it is often a costly expenditure for small- and mid-sized companies. That's where SCC can help.

SCC has generated over 25 CADDY dossiers since 2003 for plant protection and biocidal products. The experience gleaned through working closely with the software is seen in the quality and completeness of the dossier. Compliance is assured through the use of the conformity check software. SCC is capable of generating dossiers for new and existing actives, Annex III dossiers for plant protection products, upgrade dossiers for MS distribution, and supplements to existing dossiers, all in CADDY format.

SCC is your expert for the generation of CADDY dossiers.

For further information contact:

Dr. Albrecht Heidemann (albrecht.heidemann@scc-gmbh.de)



Want to meet with SCC staff? Here is a listing of upcoming events that will be attended by SCC.

11th IUPAC International Congress of Pesticide Chemistry **Kobe, Japan**
06 August 2006 – 11 August 2006

The situation surrounding agrochemicals has dramatically changed during the last decade. The focus of this IUPAC Congress will be the evolution for crop protection, public health and environmental safety. The Congress will provide many opportunities to exchange information and technology on chemistry, biology, biotechnology, toxicology, and environmental science on agrochemicals as well as its related novel technology among scientists from industries, governments, and academic fields. Dr. Friedbert Pistel and Mr. Horst Neufurth will attend on behalf of SCC, and will have a meeting room at the Portopia Hotel.

Risk Assessment Industry Exhibition **Amsterdam, The Netherlands**
26 September – 27 September 2006

The Risk Assessment Industry Exhibition combines the AgChem Forum, IBC's 13th Annual Conference on the Biocidal Products Directive, and the REACH Conference into one comprehensive industry exhibition focussing on risk assessments. SCC will be a part of the exhibition. Participants will have the opportunity to meet with Dr. Friedbert Pistel, Dr. Albrecht Heidemann, Dr. Monika Hofer, Dr. Hans-Josef Leusch and Dr. Werner Köhl during this two-day event.

BCPC Conference **Glasgow, United Kingdom**
23 October 2006 – 25 October 2006

Once again, SCC will be attending the BCPC Conference and exhibition in Glasgow. We will be at the Pentagon Centre, 36 Washington Street, just across from the Menzies Hotel. Make an appointment to discuss your specific needs for Annex III plant protection dossiers, biocide dossiers, notifications of chemicals or SCC archiving systems (including GLP-certified archiving!).

To make an appointment during one of these events, please contact Ms. Lisa Lawrenz at +49-6734-919115 (tel.) or at lisa.lawrenz@scc-gmbh.de.

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