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MESSAGE FROM THE PRESIDENT

Notwithstanding the holiday period, Summer 2006 has been a very exciting time. The 11th IUPAC International Congress of Pesticide Chemistry was held in Kobe, Japan, and the European Commission published its proposal for a new plant protection law.

In this issue:

At IUPAC, SCC organized an evening of wine from the Rheinhessen region. The event was frequented by IUPAC delegates consisting of industry and governmental representatives. The IUPAC week gave us once again the chance to present SCC and our services to the regulatory and international scientific community.

I used my stay in Japan to update an interested audience from the plant protection industry about the current situation with regard to the registration of chemical substances in light of the "old" 91/414/EEC directive and the new proposed plant protection regulation for the European Union, published on 12 July 2006. The major changes expected due to the proposed new law are discussed under section "Agrochemicals" in this edition. Besides the regulatory framework directly applicable to the plant protection sector, further legal provisions such as the Rotterdam Convention on Prior Informed Consent (PIC) controlling the overall trade with chemicals, were presented. Although chemicals included in the Rotterdam Convention process or any other convention in the field are not supposed to be blacklisted, we as an industry often get the impression that this is, in reality, the case. So my recommendation: always monitor your substance! If it is mentioned once on any "list", it is very unlikely that you will be able to get off it.

If you need help with the registration or defense of your chemical under 91/414/EEC or PIC procedures, please don't hesitate to contact me in my office.

Yours sincerely,

Dr. Friedbert Pistel
President SCC

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AGROCHEMICALS

Proposal for new plant protection legislation published

On 12 July 2006 the European Commission presented its "Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market".

As already expected and discussed during the development phase, a number of important issues changed or were introduced as follows:

- Assessment of substances no longer risk but hazard based

The proposed regulation adds additional criteria for the approval of substances in the field of human health, fate and behavior as well as ecotoxicology. Substances which fall under CMR (carcinogenicity, mutagenicity, reproductive toxicity category 1 or 2), POP (persistent organic pollutant), PBT (persistent, bioaccumulating and toxic), vPvB (very persistent, very bioaccumulating), or which have endocrine disruption potential, constitute the cut off. The assessment criteria switch from realistic to potential exposure scenarios which deliver very inaccurate results and therefore cannot be supported by industry.

- Market access for new substances delayed

In the recent proposal, national provisional approval for new substances was abolished. Due to more stringent and shortened processing time, there is no longer a need for provisional approvals, according to the European Commission (EC). Based on the proposed system, EC calculates two years before the new active ingredient is approved and additional 9 months for the product approval. In contrast, industry calculates 30 months for the approval of a new active ingredient and additional 18 months for the product approval, as stated by ECPA.

- Categories of substances

Approved substances are categorized as follows: normal substances, with first approval not exceeding 10 years; low risk substances, approval for 15 years; and basic substances, with unlimited approval period. Candidates for substitution receive approval not exceeding 7 years. Based on the substitution principle, these substances can indefinitely be reviewed until complete phase out.

Also, for substances approved under any other category, a new review can be initiated at any time.

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- Mutual recognition of authorization and zonal approval:

With the zonal authorization/approval procedure, the European Union is divided into three areas: North, Central and South. If the authorization holder of a plant protection product can prove that a product is authorized in one member state, it will be registered for use in all member states belonging to the same zone.

- Data protection

For the first applicant, member states must protect test and study reports for a period of 10 years. Only data which is necessary for the authorization or its amendment are protected under the condition that they are certified as GLP/ GEP. Studies that are "...only necessary for the renewal or review of an authorization..." shall not be protected as stated in the proposed regulation.

Member States must make available test and study reports for second applicants upon request. As written in the proposed regulation, the holder of the authorization and the prospective applicant "...shall take all reasonable steps to reach agreement..." on the sharing of test and study reports which are necessary for the authorization. The new law foresees compulsory data sharing for studies carried out on vertebrates.

Overall, industry views the new proposed regulation negatively. The number of active ingredients available will be further reduced, meaning that fewer products for common and minor use crops will be available for the end-user.

With the increasing demands for the assessment of substances, the costs escalate, leading to a further reduction of the number of companies who can afford developing new substances. Since any product can be substituted or taken off the market after a "negative review", the risk to investment increases.

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REGULATORY SCIENCE

Consumer Risk Assessment Training at PSD

SCC participated on a one day training event on Consumer Risk Assessment, held by PSD in York, UK on 3 May 2006. The aim of the day was to raise awareness, provide guidance in the appropriate use of residue values in risk assessment models, and highlight commonly encountered problems in the area of animal burden calculations, variability factors, processing factors, cumulative and aggregate deterministic risk assessment, and probabilistic risk assessment.

Some issues are summarized in the following:

- With reference to the UK consumption data, it was mentioned that currently survey data from 2001 are used; meanwhile, however, new data are available and are foreseen for the inclusion in the model. Furthermore, it is planned to include more processed consumption data in the next model update.

- Regarding the use of data from EU or national monitoring programs in the dietary risk assessment, PSD stated that they might be used in a refined chronic dietary risk assessment; however, due to large uncertainties, monitoring data would not be appropriate for the use in acute dietary risk assessments.

- Currently the Member States are thinking about whether the use of MRL values in the acute dietary risk assessment would be adequate. In this context, discussions are on-going to set the MRL as close as possible to the highest residue of the supervised residue trials, in order to prevent cases where the ARfD is exceeded when using the MRL, although the risk assessment based on the highest residues indicates a safe use.

- The development of probabilistic techniques are on-going. Comparable to the discussions of the probabilistic risk assessment on ecotox level, it is under consideration to separate between uncertainty and variability. However, the most crucial point is still the question of where risk managers put the limits of “acceptability”. Generally, the use of probabilistic tools will be a risk management decision. In the case that cumulative and aggregate dietary risk assessments will be done in the future, the probabilistic risk assessment would be an essential tool.

For further information contact:
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CHEMICALS

REACH services available at SCC

REACH is the new EU regulatory framework for the registration of chemical substances that will go into effect first/second quarter of 2007. It will affect all producers, importers and users of chemicals, new or existing substances as well as downstream users, formulators and producers of articles.

"REACH bundles the current regulations regarding the registration of existing chemicals and new chemicals," explains Dr Werner Koehl, Senior Manager at SCC. "Chemicals will undergo broader regulations covering all aspects down the drain from hazard identification and quantification as well as exposure assessment to an overall risk assessment for the different applications of the life cycle of a chemical."

REACH requires each manufacturer or importer of more than 1 ton of a chemical substance or a preparation containing more than 1 ton of a given chemical per year to prepare a technical dossier which will be registered in a central database within a time period of more than 10 years, depending on annual volume and hazard characteristics.

For new substances, a base set of data must be prepared before introduction onto the market.

For all chemicals, new or existing, produced or imported in quantities of 10 tons or more annually, the dossiers will also require a Chemical Safety Report (CSA), which evaluates the potential risks to man and environment.

Importers and producers must prepare the report with regard to the intended uses of the substance, while the downstream user must prepare the CSA if their specific use is not covered in the CSA prepared by the manufacturer.

REACH registration requires a comprehensive data package:

- For all substances with a production or import quantity of 1 ton per annum (tpa), the following information is required:
  - Name of substance
  - Safety data
  - Annual production / import volume
  - CAS No.
  - Intended uses.

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- For all substances with a production or import quantity of 10 ton per annum (tpa), additional endpoints are required: phys-chem data as well as toxicological, eco-toxcological and environmental behavior data.

- For substances with a production volume above 100 tpa, in addition to the information listed above, supplementary data (e.g. mutagenicity, genotoxicity, chronic toxicity) and a description of the intended use are required for the REACH registration.

To achieve the aims set forth in REACH, it is necessary to thoroughly understand the notification requirements and their associated data requirements.

SCC has this knowledge and can provide you with:

- Data review and identification of data gaps
- Establishment of study requirements and monitoring of those studies
- Analysis of potential analogous/family approaches, and development of test strategies
- (Q)SAR e.g., to support group approaches
- Comparison of “intended uses” and “identified uses”
- Exposure modeling
- Human and environmental risk assessments (all relevant models are established and well-understood at SCC)
- Preparation of the Chemical Safety Report
- Submission / defense of dossier at authority level
- Consultation and Consortia Management
- Review of existing safety data sheets

SCC recently launched its new brochure on REACH – Registration, Evaluation and Authorization of Chemicals. Copies of the REACH brochure can be obtained by contacting SCC.

For further information contact:
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BIOCIDES

Testing the new IUCLID5 software

The **I**nternational **U**niform **C**hemica**L** **I**nformation **D**atabase (IUCLID) is the basic tool for the data collection and evaluation in the frame of the European Risk Assessment Program on Existing Substances. The program serves to enter, store and report data on biocidal products under Biocidal Product Directive (BPD) and after entry into force on chemicals under REACH. A new version – IUCLID 5 – will be available from December 2006 onwards.

On 21 June 2006, SCC participated in a testing course for IUCLID5 at the European Chemicals Bureau (ECB) in Ispra, Italy. Representatives from industry and governments had the chance to try out the beta version ("final draft") of the program during an on-site testing event. The aim of this meeting was to identify bugs, get a first impression of the new software, and give suggestions for possible improvements.

Overall, IUCLID5 is ORACLE-independent and based on an SQL-database. It is free of charge and can be downloaded from the ECB´s website (http://ecb.jrc.it). For data on physical chemical properties, fate and (eco-) toxicological studies, IUCLID 5 fully implements the structure of the corresponding OECD harmonized templates, which can be found on the OECD homepage.

In 2007, version 5 may already become the relevant tool for the submission of biocide dossiers under BPD; however, this point still has to be clarified with the respective Rapporteur Member State (RMS) reviewing the notification dossier. Another open point is whether or not IUCLID5 will replace the submission of paper copies to the RMS, which is compulsory for the moment. Files already written in IUCLID4 can be transferred into IUCLID5 with the help of a so-called migration tool, which will be available in the roll-out version.

For chemicals falling under REACH, IUCLID5 will replace the currently used SNIF-files in stages. For more information regarding IUCLID5 and REACH, please refer to the ECB homepage (http://ecb.jrc.it/REACH-IT-INFORMATICS/).

Currently, SCC is in the process of beta-testing IUCLID5 software to be ready for the upcoming registration period for biocidal products and chemicals under REACH. From an overall perspective, the program is much more user-friendly than the previous version. Besides some technical problems which were identified by SCC users and communicated to ECB, the program is a very useful tool and will facilitate the registration of substances in the future.

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GLOBAL AFFAIRS

The Rotterdam Convention on Prior Informed Consent

The Rotterdam Convention on the Prior Informed Consent (PIC) is a multilateral agreement which controls and monitors the trade with certain hazardous chemicals on an international basis. It is run under the umbrella of the United Nations (UN). The work of the convention is co-ordinated and facilitated by the Food and Agriculture Organization (FAO) as well as the United Nations Environment Program (UNEP).

The objective of the agreement is to promote shared responsibility in the international trade on chemicals through facilitating information exchange among parties, as the convention text states. The information exchange is guaranteed through the PIC procedure which makes sure that no shipment of certain listed chemicals can take place without a positive response of the importing party.

On 24 February 2004, after a process lasting for more than 40 years, the Rotterdam Convention entered into force. From that day onwards, it became legally binding to all signatories who ratified the convention.

PIC applies to pesticides and industrial chemicals that are banned or severely restricted. This means regulatory actions took place which prohibit all or virtually all uses of these substances. For severely hazardous pesticide formulations used under developing world conditions, a specific regulatory frame was set up.

Via an administrative process, new substances can be added through the official bodies of the convention. If two countries from two different world regions ban or severely restrict the same substance, they independently inform the convention's secretariat. In correlation with the secretariat, government-designated experts verify the so-called notifications and propose a draft decision to the Conference of the Parties (COP), where all members are represented. Through voting, COP delegates decide if a chemical will be added to the convention or not.

From an industry point of view, the listing of chemicals under the Rotterdam Convention leads to more administrative burdens, such as additional contacts with authorities that permit imports to countries. Although not meant as a consequence, PIC can lead to blacklisting of substances, leading to a negative reputation for the producing companies and resulting decrease of sales. This may be the equivalent to essentially banning products in many cases.

Today there are more than 40 chemicals listed under the Rotterdam Convention, and the system works: the next COP meeting is scheduled for October 2006. Among others, delegates will decide if chrysostile asbestos will be added to the convention or not. Please check www.pic.int for more information.

For more information about PIC contact:
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CADDY

New CADDY-xml Format – The CADDY of the future

Since the development of the CADDY format specification in 1995, document management technologies have progressed considerably. Whereas 10 years ago TIFF standards were at the forefront of technology, today xml-based web technologies have become standard. To accommodate the changes in technology and to make the CADDY standard attractive to other regions besides Europe, the CADDY-xml software was developed.

CADDY-xml is based on the CADDY 2.0 format, while introducing some important differences by providing the general information, a table of contents, confidential and non-confidential documents, report information and hyperlink information in an XML framework.

The TIFF-files are replaced by PDF/A (portable document format for archiving and preserving documents) versions of the documents, which can be either image-based or text-based. Additionally, a CADDY-*xml* based dossier can be instantly viewed with a common web-browser supported by Acrobat Reader. This standard is flexible to accommodate different dossier structures such as OECD, EU or any other standard.

The XML-representation can be thought of as the backbone of the dossier. It references every document that is included within the directory structure.

CADDY 1.1 and 2.0 format compliant dossiers will remain as the European submission standard. The CADDY Retrieval Software will be maintained, but no further developments in its functionality will be made.

Further information regarding CADDY-xml can be found on the CADDY homepage http://caddy.ecpa.be .

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

CALENDAR

Umwelt von Humanpharmaka –
Welche Anforderung stellt die neue EMEA-Richlinie **Dortmund, Germany**
18 September – 19 September 2006

After years of discussion regarding the environmental risk assessment of pharmaceuticals, the EMEA Directive "Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use" will soon go into effect. A number of experts from research, industry and government will be on hand to provide information regarding the correct implementation of this new Directive. Dr. Achim Schmitz will be at this conference, and would be happy to meet with you during this time.

Deutsche Pflanzenschutztagung **Göttingen, Germany**
25 September – 28 September 2006

The German plant protection products conference takes place every two years. More than 1300 participants are expected at this, the largest meeting of experts of its kind for phytomedicine and plant protection products in Europe. Dr. Norbert Weissmann and Anke König-Wingenfeld will be at this meeting, which will also be attended by representatives of research, industry and government.

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!). And, an additional treat: on Tuesday, 24 October, SCC will sponsor a wine-tasting for participants of the BCPC Conference. Contact SCC for more details!

7. Fresenius Conference: The Biocidal Products Directive **Bonn, Germany**
30 November 2006 – 1 Decemebr 2006

The current and future developments from the EU, changes to the BPD, criteria for comparative assessment and what is expected in the post-Annex I procedures are all topics of this conference. Dr. Nikola Bitsch and Isabel Kirbach will be at this two-day event.

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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