

Newsletter

Volume 11, No. 1S, August 2011



SPECIAL EDITION

SCC GmbH SPONSOR OF CIR 2011 CONFERENCE IN BARCELONA



SCC GmbH is a sponsor of the CIR 2011 Conference to be held in Barcelona from 6 – 8 September 2011. Dr. Bernd Brielbeck and Dr. Norbert Weissmann of SCC's Agrochemicals and Biopesticides Department will make presentations and host a pre-conference workshop respectively. In addition, SCC is present during the exhibition – visit us at Stand 24 in the Fira Palace Hotel. There you can meet with Dr. Brielbeck, Dr. Weissmann, Dr. Volker Harder or Mr. Gunnar Schmidt, the latter two part of the Regulatory Science Department, to discuss your specific regulatory needs in the areas of agrochemicals and biopesticides, biocides or chemicals including REACH.

For more information regarding SCC's sponsorship at the CIR Conference, please refer to SCC's website: www.scc-gmbh.de.

In this special issue of the SCC Newsletter, you will find information concerning new legislation pertaining to agrochemicals and biopesticides, information regarding endocrine disruptors, the status of the new Biocidal Products Regulation (BPR), and the latest news regarding REACH.

Comprehensive information regarding the AgChem Forum will be handled in a special edition Newsletter, which will be released in September 2011.

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AGROCHEMICALS

Commission Implementing Regulations augment Regulation (EC) No 1107/2009

In order to properly implement Regulation (EC) No 1107/2009, a number of Regulations were adopted by the Commission. They include:

Commission Implementing Regulation (EU) No 540/2011: The Regulation transfers the existing list of active substances that were listed on Annex I of Directive 91/414/EEC. This was necessary because, with the implementation of Regulation 1107/2009, Annex I of Directive 9/414/EEC was made obsolete. Almost immediately thereafter, two amending Regulations were approved by the Commission. **Regulation 541/2011** divided the Annex into two parts: Part A is the current list of included actives that are considered to be approved under the new Regulation; Part B sets out a separate list for future approvals under the system. **Regulation 542/2011** adjusted the entry for Carbendazim to reflect its re-renewal.

Commission Implementing Regulation (EU) No 544/2011: This Regulation is concerned with data requirements, including the information needed in the dossier application and the tests needed to be performed. It introduces the cut-off criteria, a critical and controversial criteria (see SCC Newsletters, e.g. Vol. 8, No. 3, October 2008; Special Edition 1S, February 2009). However, the upcoming, agreed-upon requirements are not yet available.

Commission Implementing Regulation (EU) No 545/2011: Data requirements for product approvals including information required for national approvals of formulated products is handled in this Regulation. It also introduces the zonal system for product approvals (see SCC Newsletters in 2010 and 2011). Again, the upcoming, agreed-upon requirements are not yet available

Commission Implementing Regulation (EU) No 546/2011: Specifies uniform principles, providing guidance and templates for the regulatory authorities. Separate sections deal with chemical and microbial products (also in Regulation 545/2011).

Commission Implementing Regulation (EU) No 547/2011: This Regulation deals with product labeling requirements in the EU.

SCC at CIR Conference

During the AgChem Forum in Barcelona from 07-08 September 2011, Dr. Bernd Brielbeck, Senior Regulatory Manager, Agrochemicals and Biopesticides, will make a presentation dealing with the practical experiences gleaned in the preparation of zonal dossiers using the dRR format, including national particularities in dossier preparation and submission, particular national study requirements and considerations in selecting (or trying to select) a zRMS.

In addition, Dr. Norbert Weissmann, Senior Regulatory Manager – Efficacy, Agrochemicals and Biopesticides, will chair the pre-conference Workshop on 06 September 2011. Entitled "Consequences of New Efficacy Data Requirements for Dossier Generation", a panel of experts, which include Mr. Laurent Thibault, Head of Efficacy Evaluation at ANSES, Dr. Patrice Duvert, Bayer SAS, and Mr. David Richardson, former Head of the Efficacy Evaluation Section at CRD, will discuss such topics as dose justification, comparative risk assessment and the development of appropriate resistance management strategies. Insights into the legal basis, an overview of the history and expected future structure of the Biological Assessment Dossier and Section 7 (Efficacy) of the dRR, and a discussion of the consequences for trial programs, dossier planning and generation round out the workshop.

A special edition SCC Newsletter, to be published shortly after the CIR 2011, will report in more detail on these Regulations and the implications they have on active substance and product registrations, as well as further experience with the new Regulation and its implementation.

For more information, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scg-gmbh.de.



BIOCIDES

New EU biocides legislation to be adopted around mid-2012

In the last edition of this newsletter, we informed you in detail on the political agreement that had been reached in the Environment Council with a view to the adoption of the new Biocidal Products Regulation (BPR) in December 2010. On 21 June 2011, the European Council formally adopted its position at first reading. The outcome of the voting was very much in favor of the proposed text, only Austria and Denmark have abstained. The document that was adopted by the Council comprises 339 pages and can be downloaded on the internet (document 5032/2/11 rev 2 under <http://register.consilium.europa.eu>). This Council text is the basis for the further (and final) discussions between the Council, the European Parliament and the European Commission.

Commission position

The European Commission formally communicated the Council position to the European Parliament by means of document COM(2011)498final dated 11 August 2011. In this document, the Commission signals that they are willing to accept most of the changes that were made by the Council to the original Commission proposal from June 2009. The above-mentioned COM document is a good summary of the past discussions including the first reading in the European Parliament. The Commission notes that the extension of the scope of the Union authorization and the additional tasks allocated to the ECHA (e.g. ECHA delivering binding decisions on technical equivalence, ECHA being more involved in data sharing issues) will lead to a significant increase in the workload of both ECHA and the Commission. The Commission therefore requests a higher financial

budget and more time to take preparatory steps such as the adoption of delegated and implementing acts or the preparation of diverse guidance documents.

Finally, the Commission suggests postponing the date of applicability of the BPR from 1 January 2013 to 1 September 2013.

Second reading in Parliament

After its summer break, the European Parliament (EP) has recently restarted the BPR discussions at second reading. There is a document available issued by the Rapporteur Ms. Christa Klass giving draft recommendations for second reading. It is suggested to “refine” the Council text by means of 101 amendments. The amendments can be summarized as follows:

- the EP introduces several technical amendments intended to simplify and clarify the Council text
- the provisions on product families are reworded; for instance all single biocidal products covered by one product family shall have the same authorization number (that one of the family)
- the EP claims that approved active substance should continue to be listed in an Annex to the Regulation, not just in a detached list of approved substances
- the EP further widens the scope of Union authorization
- the EP suggests to remove the provisions regarding food contact materials, as they can be considered as treated articles
- in some places, the EP reinstates its position at first reading, e.g. when it comes to labelling requirements for treated articles or laying down the legal basis for the authorization of private label products

The EP report for adoption in committee is scheduled for 4 October 2011. The EP plenary vote is planned to take place on 16 January 2012 (indicative date).

For further information, please contact Dr. Holger Zitt at holger.zitt@scg-gmbh.de.

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CHEMICALS, REACH, CONSUMER PRODUCTS

Follow-up activities after registration under REACH

After successful registration under REACH or in preparation of new registrations, registrants should be aware of important follow-up activities as reflected in different lists of substances published on the ECHA's webpage. SCC would like to inform you about the most important lists to be checked on a regular basis.

- REACH-IT message box check:

It is crucial to check the REACH-IT message box after a submission to ECHA on a regular basis. The Agency often contacts registrants exclusively using the REACH-IT message box in case of questions or requests concerning submitted substances (e.g. SME status, dossier evaluation, etc). No additional information via email or postal mail can be expected by ECHA. Deadlines for response times are often quite short (4-6 weeks).

SCC strongly recommends using the automatic email reply option in REACH-IT, which informs the registrant, if a new message is available. SCC can assist you in setting up the email reply in REACH-IT.

- Candidate List of Substances of Very High Concern (SVHC) for authorization:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

The Candidate List for SVHC is usually updated twice a year (last update on 20 June 2011). Suppliers have the obligation to inform downstream users if SVHCs are present in mixtures at levels above 0.1 % within six months after inclusion of the substance on

the Candidate List. If present in articles at levels above 0.1 % ECHA also has to be informed provided that the uses were not yet covered by a REACH registration. Proper monitoring and initiation of SVHC communication is vital for legal compliance.

- Testing proposals involving vertebrate animals: request for information from third parties:

http://echa.europa.eu/consultations/test_proposals/test_prop_cons_en.asp

ECHA currently publishes on the website the testing proposals submitted during the last year for public consultation. The consultation period is six weeks. So far only five final decisions have been published, but it is expected that a lot more will be published within the coming months. Companies should be aware of the consultation process of testing proposals for the registered substance(s).

- Harmonizing classification and labelling:

http://echa.europa.eu/consultations/harmonised_cl_en.asp

ECHA publishes dossiers on harmonized classification and labelling (CLH dossiers) submitted by competent Member State Authorities for new inclusion or update of substances on Annex VI of Regulation (EC) No 1272/2008 (CLP). As CLH dossiers focus on potential CMR properties, companies should be aware of changes in official harmonized classification. Most often a more stringent classification and labelling will be the outcome with potential severe market implications. The public consultation phase is six weeks.

- Registry of intentions for Annex XV dossiers:

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_en.asp?substance_state=current

ECHA publishes a registry of intentions for Annex XV dossiers (CLH dossiers) from competent Member State Authorities. These announcements of CLH-dossiers are mainly due to investigation of the substances during the registration processes of other legal acts (e.g. plant protection products, biocidal products), but are also covering other substances of



concern (e.g. registered substances on 2010). Changes may result in a more stringent classification and labelling.

SCC can take care of substances from clients and check the lists regularly. If you are interested in such a service, please contact us.

Global Product Strategy (GPS) Safety Summaries

Cefic has recently published a conversion template to transform REACH dossiers into Global Product Strategy (GPS) Safety Summaries. The aim of GPS is to show the safe use of chemicals in a worldwide, harmonized format. The preparation of such safety summaries is a voluntary initiative and should reduce the differences in evaluation of different uses of chemicals and to safeguard chemicals in a harmonized way between industrial, emerging and developing countries. Cefic and the German VCI encourage companies to prepare GPS safety summaries. Quite some companies have already started preparing GPS summaries from their REACH dossiers. SCC offers to convert GPS Safety Summaries from REACH dossiers on request. Please contact us in case of any questions or if you wish to prepare GPS Safety Summaries.

REACH Enforcement

A new web portal for REACH and CLP inspectors called REACH Information Portal for Enforcement (RIPE) was launched on 27 June 2011. RIPE facilitates enforcement activities in the EU by providing key REACH and CLP information online. RIPE will not be available to the general public.

Online available information is related to the dossier submissions to ECHA and includes details on the submitting legal entity, date of submission, tonnage band, production and uses sites, intended uses, information on C&L, and guidance on safe use. Furthermore, key information on physico-chemical, toxicological and ecotoxicological properties can be accessed by around 2,500 inspectors in the EU Member States, Norway, Iceland and Liechtenstein.

The new online tool is expected to facilitate the work of enforcement authorities significantly and will thus

most likely lead to a better compliance with the REACH and CLP provisions.

Further information on enforcement strategies and minimum criteria for inspections can be downloaded from the following website:

http://echa.europa.eu/about/organisation/forum_en.asp

China – Update on Chemical Control Legislation

In 1994, China's first law to control chemicals was published in the Regulations for Environmental Management on the First Import of Chemicals and the Import/Export of Toxic Chemicals, promulgated by the former State Environmental Protection Administration (SEPA) with General Administration of Customs and Ministry of Foreign Economics and Cooperation (No [1994] 140, March 16th, 1994). In September 2003, SEPA issued the Measures on Environmental Management of New Chemical Substances (SEPA Order No. 17) which were implemented in October 2003.

Since, manufacturers and/or importer of new chemical substances need to apply and obtain registration certificates prior to manufacture and/or import of new substance. Based on volumes, notifications were classified into typical notifications and notification exemption. Typical notifications were basic level (< 10 t/year), level one (10 t ~1000 t/year) and level two (1000 t/year and more). The higher the volume, the more data required. Notably, some eco-toxicology data requires testing in China using Chinese testing organisms.

In January 2010, SEPA Order No. 17 was amended by the Ministry of Environmental Protection to improve the environmental management of new chemical substances and to more effectively control environmental risks posed by new chemical substances. In October 2010, the MEP Order No. 7 was published, repealing SEPA Order No. 17.

With MEP Order No. 7, there are three significant changes:

- 1) New Substance Notification. The volumes of new chemical substances have to be notified. Notifications are classified according to volumes of one t/year and more. Simplified notifications

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are possible for low volumes under specific conditions. Simplified notifications include volumes < 1 t/year (basic), process and production development, scientific research and polymers of low concern. Guidance documentation on notifications is now available.

- 2) Chemical risk assessment. Typical notifications now require filing a risk assessment report. Guidance on chemical risk assessment is not yet available.
- 3) Improvement of supervision. The holder of a registration certificate needs to submit an initial activity report followed by an annual report. Notably, local environmental protection authorities were issued with increased responsibility on supervision.

With MEP Order No. 7 China has significantly increased the regulatory requirements for new chemicals. With the legislation on management of import and export of toxic chemicals as well as the 12th Five-Year Plan on Prevention and Control of Environmental Risks of Chemical in progress, China aims to improve the integrated environmental management of chemicals.

USA – Update on Chemical Control Legislation

Currently, US activities on chemicals focus on:

- 1) Implementation of the Global Harmonized System (GHS)
- 2) Toxic Substances Control Act (TSCA) Reform

Several US agencies are engaged in the GHS implementation process:

- Department of Transport (DOT): Classification and labelling for all transport routes;
- Occupational Safety and Health Administration (OSHA): Safe handling at the workplace;
- U.S. Environmental Protection Agency (EPA): Safety in the environment;
- Consumer Product Safety Commission (CPSC): Safety of the general public.

The focus is to implement and to adapt the Purple Book – i.e. the UN basic document of the GHS – into the national US legislation and rules, especially in view of the influence of GHS rules on MSDS and labels. The alignment of the Hazard Community Standards (HCS) with the GHS rules is also a major working field. A final rule is expected in August 2011.

EPA has announced plans for the reform of TSCA in September 2009. Enhancement of chemical management programs are based on several challenges, for which a number of basic principles have been established. In view of the Safe Chemicals Act of April 2011, the principles aim to enhance safety standards for handling and use of chemicals. However, US politics seem to slow the reform procedures down and no further updates are expected until 2012 or later.

Canada – Update on Chemical Control Legislation

The following legislative activities are currently of special interest in Canada:

- Canada's Chemicals Management Plan (CMP),
- CMP's Industry Challenge,
- Update of the Canadian Domestic Substances List (DSL).

Ongoing activities are:

- Canadian New Substances Notification Regulations (NSNR) and the NSN Requirements,
- Environmental Assessment Regulations and the revision of the In-Commerce List of substances regulated under the Food and Drugs Act,
- Canadian chemicals legislation on nanomaterials.

The objective of the Chemicals Management Plan is to assess existing chemicals in a stepwise approach: CSDSL – a systematic, science-based process for the Categorization, and prioritized Screening (CS), of the ca. 23,000 grandfathered substances that formed the Initial Domestic Substances List (DSL). The CSDSL program was established by Environment Canada and Health Canada to systematically categorize and prioritize the screening assessment of medium- and high-interest substances grandfathered onto the DSL,



without prior risk assessment through the nomination process back in the early 1990's.

Notably, government and industry alike recognize this risk based program as a workable and favorable alternative to other similar programs, e.g. EU REACH.

The main frame of the CSDSL is the Categorization of the DSL Inventory into classes of screening assessment priorities, using computer-modelling programs, existing hazard classifications from international organizations, and assessment of readily accessible test data. Substance categorization and assessment aims at identification of hazardous substances ('CEPA Toxic' substances). This classification will then involve further assessment, with risk management of known and possible uses as driver.

Requirements for New Substances Notifications have increased. Generally, there is a higher demand for controls and restrictions accompanying NSN approvals. Additional information may be requested from notifiers, due to the government's greater interest in exposure from potential uses beyond intended markets.

Products regulated under the Food and Drugs Act will no longer be exempted from the NSNR rules. These new Environmental Assessment Regulations (EAR) will address unique properties of these substances and, accordingly, are anticipated to have lower notification trigger levels than chemical substances which are currently notified under the New Substances Notification Regulations (NSNR).

Nanomaterials that are manufactured in or imported into Canada are subject to the same regulatory requirements as chemicals and polymers. Notifiers must submit a New Substances Notification package prior to the manufacture in or import into Canada under the requirements of the Canadian Environmental Protection Act. Further activities on nanomaterials are expected to be initiated by Environment Canada, which proposed a two-phased regulatory framework in 2007.

Australia – Update on Chemical Control Legislation

In Australia, industrial chemicals are regulated under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS is a chemical entity-based notification and risk assessment scheme, i.e. it does not assess products (mixtures of chemicals) or articles, but only substances as such in the context of their use. The scope of the risk assessments includes the full life cycle of chemicals and comprises three elements:

- 1) occupational health and safety,
- 2) public health,
- 3) environmental impact.

NICNAS has undergone major reforms of its regulatory requirements to increase the efficiency of the new chemicals assessment and notification system. These reforms have been introduced under the Low Regulatory Concern Chemicals (LRCC) initiative. The scope of LRCC comprises such chemicals with a low hazard profile, chemicals with highly controlled intended use or chemicals that have been assessed by a reputable national or international authority. Elements of the LRCC include expansion of some permit categories (low hazard or highly controlled intended use), recognition of the hazard from a national or international authority with equivalent standards, provision of assessment report by notifier for a polymer or chemical of low concern (or non hazardous) and additional exemption categories as well as an increase in the low volume threshold of the existing exemptions (10 to 100 kg).

New Zealand – Update on Chemical Control Legislation

In New Zealand, all hazardous substances are controlled under the Hazardous Substances and New Organisms Act (HSNO). HSNO regulates a broad range of hazardous chemicals, including explosives, dangerous goods (flammable, oxidizing or corrosive substances), pesticides and veterinary medicines, toxic substances, cosmetics and other consumer products as well as gases under pressure. The full lifecycle of substances is covered, from import and/or manufacture through to disposal.

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All hazardous substances introduced in New Zealand require upfront approval. The assessment and approval process for new individual substances involves classification, risk assessment and the assigning of controls. The hazard classification scheme closely follows the harmonized GHS system.

Each hazardous property classification triggers a number of controls aimed at managing the adverse effects of a substance. There are two general types of controls, hazard property controls applying to biological and physical hazards, and life cycle controls, relating to packaging and containing as well as identification (information on labels, signs, documentation, advertising and safety information).

Unlike any other regulatory program, HSNO includes "Group Standards", allowing for approval according to groups of substances of similar nature, similar type or similar circumstances of use. All substances in a Group Standard are subject to a single set of controls and conditions. There are group standards for paints, adhesives, flavors and fragrances, lubricants, industrial and domestic cleaners, cosmetics, polymers and many more. The manufacturer or importer is responsible for identification an existing group standard for that substance (if one exists). Assigning a Group Standard to a new chemical can significantly reduce regulatory requirements.

Globally harmonized system (GHS) for classification and labelling of chemicals implementation worldwide

The United Nations Globally Harmonized System GHS is a worldwide initiative to harmonize existing chemical hazard communication systems. It was first adopted by the United Nations in 2002 and since then countries have been encouraged to implement the system without delay. Initially, the worldwide implementation of GHS was planned to be finalized by 2008.

GHS includes a "building block" approach to facilitate its implementation. The single countries have the option to take up standardized hazard classes and/or categories. Thus, even though GHS brings standardization to classification and labelling,

implementation of building blocks will also provide a certain degree of individuality.

GHS is updated every two years. The fourth revised edition of the GHS will be published in 2011. For more information about the GHS please go to:

http://live.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

The European Union implemented the GHS system in 2008 by adopting Commission Regulation (EC) No 1272/2008, the CLP Regulation. In the meantime two adaptations to the technical process were made, including the introduction of the third revision of the UN GHS to European law. Further CLP Regulation updates are expected to follow biannually.

The implementation of the GHS in north America is ongoing. In the USA four regulatory agencies (DOT, OSHA, EPA and CPSC) formed an Interagency Working Group for GHS implementation. A three-year implementing period is expected to begin now in August 2011. Despite Canada's special role in the global GHS development as a leading member of the UN sub-committee, the implementation process is somewhat slow. Canada started working on the implementation, but the proposed changes in the regulations are not expected to be adopted well after the publication of the US final rule.

In Asia some countries introduced the GHS by amending existing laws. Japan (in 2006), Korea and Taiwan (both in 2008) were the first countries to implement the GHS, followed by Vietnam and Indonesia in 2009 and 2010, respectively. China amended their law in March 2011 and it will enter into force in December 2011. Other countries such as Malaysia, Thailand, Philippines, India and Australia have already drafted amended legislation, but they have not yet published the implementation dates.

An updated overview on worldwide GHS implementation (total of 67 countries) can be accessed via the following link:

http://live.unece.org/trans/danger/publi/ghs/implementation_e.html

For more information, contact Dr. Werner Köhl at werner.koehl@scc-gmbh.de.

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REGULATORY SCIENCE

2nd International Fresenius Conference – Endocrine Disruptor

The new plant protection products Regulation (EC) No 1107/2009 includes exclusion criteria for endocrine disruptive substances with impact on human health and environment (cf. Annex II, point 3.6.5 and 3.8.2, respectively). The aim of the 2nd international Fresenius conference (June 2011) was, among other things, to present different assessment schemes and how to deal with endocrine active compounds.

In the EU, endocrine disruptors are dealt within different legislations (PPP, Biocides, REACH) and with different regulatory purposes (e.g. criteria for cut-off or candidate of substitution), despite a harmonized endocrine disruptor definition. At present, under the new Regulation 1107/2009, the Commission is mandated to present a decision scheme with scientific criteria for endocrine disruptors having an impact on human health and the environment by December 2013. Nevertheless, substances identified as endocrine disruptors of very high concern in accordance with Article 57 of the REACH regulation (1907/2006) should be considered by a case-by-case assessment. A review of this procedure is required by June 2013 (cf. Article 138(7)).

For the time being, different (regulatory) activities are ongoing at the EU level to find a solution on how to deal with endocrine disruptors. An OECD Guidance Document is currently under revision including a Conceptual Framework scheme (Version 11, May 2011). Further, several member states have presented proposals in relation to human health and environmental criteria for endocrine disruption

according to REACH and plant protection products, e.g. a position paper by the Danish EPA “Establishment of Criteria for Endocrine Disruptors and Options for Regulation” from May 2011, or a joint position paper authored by Germany and the United Kingdom “Regulatory Definition of an Endocrine Disrupter in Relation to Potential Threat to Human Health”, which was also published in May 2011. In addition, the EFSA has established an internal taskforce on endocrine active substances and published a scientific report on the development of a common approach towards these substances (November 2010).

The suspense continues as to how the different EU bodies, EU member states and international organisations will find a global consensus on testing strategies for both hazard identification as well as for risk assessment. A first indication is expected by the end of the year, when the first results of the Endocrine Disruptor Screening Program (EDSP) developed by US EPA will become available. This program was charged with the task of determining the endocrine-disrupting potential of pesticides and other substances. The experiences of the EDSP assay have shown there are technical and regulatory challenges associated with revising and implementing rules on how to define and handle endocrine disruptors in the regulatory environment of plant protection products, biocides and under REACH. It is hoped that there will soon be a final clear guidance.

For more information, please contact Dr. Monika Hofer at monika.hofer@scc-gmbh.de.

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Your feedback is important to us!

The SCC Newsletter strives to provide its readers with the latest information regarding regulatory affairs in the areas of agrochemicals, biocides, chemicals, REACH, feed and food additives, and regulatory science. However, without your feedback, we can't know if we are providing YOU with the information you need.

Tell us how we're doing. Please take 5 minutes and send us a mail. Tell us what we're doing right (or wrong) and what information you find important or would like to see more of.

Our e-mail address: newsletter@scc-gmbh.de

THANK YOU!

SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH

Dr. Friedbert Pistel, President

Am Grenzgraben 11 · D-55545 Bad Kreuznach

Phone +49 (0) 671-29846-0 · Fax +49 (0) 671-29846-100

scc@scc-gmbh.de · www.scc-gmbh.de

SCC Liaison Office Japan
14-24 Tokiwadai,
Kashiwa-shi
Chiba-Ken 277-0087, Japan
Phone/Fax.: +81 (0)4-7162-4262

Mr. Toshiyasu (Ted) Takada, Director
e-mail: toshiyasu.takada@scc-japan.com

SCC Liaison Office Japan
6-2-14 Asagayakita,
Suginami-ku
Tokyo 166-0001, Japan
Phone/Fax.: +81 (0)3-6762-5261

Mr. Kenji Makita, Senior Consultant
e-mail: kenji.makita@scc-japan.com

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