Newsletter

Volume 9, No. 1, February 2009

MESSAGE FROM THE PRESIDENT

The Ever-Changing Regulatory World

The ever-changing regulatory world constantly provides new information and changes. The SCC Newsletter provides our readers with this current information as well as information about the activities at SCC. Here is a summary of what you will read about in this issue:

The new Classification and Labelling rules (CLP Regulation), aligning existing EU legislation with the United Nations "Globally Harmonized System of Classification and Labelling of Chemicals" (GHS) is featured in the Agrochemicals section. The plant protection industry will have to meet important deadlines, which are noted here. Also in Agrochemicals: summaries on regulatory conferences attended by SCC.

An update on the upcoming revision of the EU biocides legislation is provided in the "Biocides" section. A "mini" and "major" revision of the BPD is already in the pipeline.

During the period of 1 June – 1 December 2008 approximately 65,000 companies pre-registered a total of 150,000 substances under REACH. Further information on REACH-related issues can be found in the Chemicals/REACH/Consumer Products section of the Newsletter.

SCC's GLP archive was re-certified in September 2008. Further details can be found in "Data management".

The year 2008 was a very successful first year for the Feed & Food Additives, Veterinary Medicine Department: a number of application dossiers were acquired and there is a prospect for additional re-authorization dossiers in 2009. Besides the evaluation of the current situation, read about the new EU regulation on the marketing and use of feed which is expected to be finalized by spring 2009.

Endosulfan was proposed as POP under the Stockholm Convention on Persistent Organic Pollutants. Further details can be found in the Global Affairs section.

Last but not least, the Calendar gives an overview on where to meet our specialists.

SCC is always personally available for any of our clients' individual needs. For questions, please contact SCC in Wendelsheim, or our SCC Liaison Office Japan.

With best regards,

Dr. Friedbert Pistel
President

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AGROCHEMICALS

Europe Adopts Harmonized Rules for Classification and Labelling

On 16 December 2008, the European Parliament (EP) and the Council adopted the new Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation), which aligns existing EU legislation to the United Nations "Globally Harmonized System of Classification and Labelling of Chemicals" (GHS). GHS is a world-wide system directed at harmonizing all systems for classification of chemical substances and products on a world wide basis. It applies eye-catching easily recognizable symbols and labelling phrases which inform traders and end-users about possible risks of such substances. With entry into force of the CLP Regulation on 20 January 2009, the GHS system was implemented into EU legislation.

The CLP Regulation takes over the provisions on classification and labelling of the REACH Regulation (Title XI: Classification & Labelling Inventory). In addition, it replaces the former EU chemical labelling schemes described in Directive 67/548/EEC and 1999/45/EC. These two directives will be repealed by 1 June 2015.

Under the CLP Regulation, Industry will have to comply with two deadlines:

- All chemicals substances must be classified according to CLP provisions by 30 November 2010
- All mixtures/preparations must be classified according to CLP provisions by 31 May 2015.

For the period of 31 December 2008 until November 2010/May 2015, the Regulation foresees a transitional period during which both the old and the new laws will apply. ECHA, the European Chemicals Agency, must be informed at any time about the classification of all substances and mixtures.

Detailed information on GHS related issues can be found here at the following website: http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.htm.

For further information please contact Dr Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de.

SCC Participation at Two Important Plant Protection Conferences in 2008

3rd Annual Biocontrol Industry Meeting (ABIM)

SCC attended the 3rd Annual Biocontrol Industry Meeting (ABIM) in Lucerne on 20-21 October 2008. The conference was organized by IBMA (International Biocontrol Manufacturers Association) and FiBL (Research Institute of Organic Agriculture).

The steadily increasing number of participants over the last years indicates the great demand for a platform dedicated to the development and distribution of biological plant protection products, especially for small and medium enterprises. In 2008, 330 participants came to Lucerne to talk about the current market situation, political programs and product innovations.

The aim of the meeting was also to discuss issues of common interest, such as regulations and promotion policies, and to provide an opportunity for the presentation of novel products and results from applied research and developmental activities.

Due to the uncertain situation resulting from the pending revision of Council Directive 91/414/EEC, upcoming developments in regulation could not be discussed in detail; instead political programs came to the fore (COST networking, ENDURE, framework program for SME). These programs are concerned with cooperation and coordination of scientific exchange within the European Community. Furthermore the situation and development of the market for biological plant protection products was part of the presentations.

All presentations are available for download: http://www.abim-lucerne.ch/aims.html.

For further details please contact Verena Peharz at verena.peharz@scc-gmbh.de.

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AGROCHEMICALS

Crop Protection Conference: Post Patent Products, IPR and Parallel Trade

SCC attended the conference in Amsterdam in November 2008. In summary, it can be said that no special procedure is foreseen for generics in most of the Member States (FR, NL, BE, SLO, PT, DE), i.e. access to AII data or own AII data if data protection applies, and complete AIII dossier.

In the UK, two main types of generic applications exist: "full me-too" approach, where each relevant data requirement is met individually, and the "streamlined" approach, where only a minimum of information is submitted, and all the data requirements are met by reference to unprotected data.

Common origin is required in nearly all Member States (UK, FR, NL, BE, SLO, PT) for parallel trade after February 2008 [ECJ Case C-201/06, EU COM vs. French Republic]. Germany requires identical products but does not insist on common origin.

More information can be obtained from Dr. Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de.

BIOCIDES

Update on the Approaching Revision of the EU Biocides Legislation

In SCC newsletter Vol. 8, No. 1, January 2008, we informed you for the first time about the process of revising the Biocidal Products Directive 98/8/EC (the BPD). In the meantime, the Commission has made some significant progress in the work on the revision. The two-step revision of the BPD is now referred to as a "mini revision" in the first step, followed by a "major revision".

The mini revision

On 7 October 2008, the Commission published the mini revision proposal (document COM(2008) 618 final). The amendments to the BPD basically concern the extension of the 10-year work program referred to in Article 16(2) by three more years. The Commission bases this proposal on a report to the Council and the European Parliament (document COM(2008) 620 final).The Commission suggests that the review program should end on 14 May 2013, with the provision that any remaining "problematic" active substance dossiers may be prolonged by a comitology procedure after 2013.

BIOCIDES

On 18 December 2008, the European Parliament brought forward a new proposal that is currently under discussion in the respective working groups of the Council and the Parliament. The review program should be extended for four more years. For "problematic" substances, the review may be extended for a maximum of two further years. This would mean that the review program on existing biocidal active substances, as a whole, must be completed by 14 May 2016.

Some Member States and industry are trying to push the discussion in a direction that the mini revision should not only prolong the review program, but also include urgent issues around free-riding and data protection.

The outcome of these discussions is open. Parliament, Council and the Commission intend to resolve the mini revision in the first reading.

The major revision

The Commission intends to publish the proposal for the major revision of the BPD in April 2009. The Commission also submitted a request for an analysis by the European Chemicals Agency (ECHA) regarding the Agency's possible role under a revised biocides legislation.

As it stands, the major revision will most likely bring the following fundamental changes: the proposal will be a regulation (no longer a directive); ECHA will take over responsibility for some newly-established central procedures for biocides; treated articles will come under the scope of the new biocides regulation; to apply for authorization of a biocidal product, use of the Register for Biocidal Products (R4BP) will be compulsory; in addition to the existing authorization procedure for biocidal products, two more options will be established: a decentralized authorization procedure (called mutual recognition in parallel) and a centralized procedure (called community authorization); a new centralized procedure "screening for low risk biocidal products" will be established; compulsory data sharing for vertebrate data will be introduced; technical equivalence and parallel trade will be addressed in the legal text.

For more detailed information, contact Dr. Holger Zitt at holger.zitt@scc-gmbh.de.

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REACH News

Pre-Registration

In the period between 1 June and 1 December 2008, some 65.000 companies generated approximately 2.75 million pre-registrations, corresponding to 150,000 substances (105,000 EINECS and others). After the end of the pre-registration phase, ECHA started screening/checking the pre-registrations and removed, for example, those not meeting the substance criteria, or pre-registrations made by non-EU/EEA companies. A preliminary list of pre-registered substances can be downloaded: http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx. The assessment is still going on, especially for non-EINECS substances, e.g. no-longer polymers, etc.

REACH IT functions and stability

After REACH IT shutdown (17 December 2008 through 5 January 2009), an updated version was launched to allow:

- submission of registration
- inquiries
- PPORD notifications
- C&L notifications
- late pre-registrations

However, REACH IT users still experienced heavy traffic and were not able to access the system. ECHA is working on improvement solutions.

The latest REACH IT update on 26 January 2009 offers improvements within the search and message modules, and should create a more stable system for SIEF formation. All users would appreciate such an important change.

Independent of these improvements, based on practical experience, the system is still struggling to provide a practicable and workable tool for the complex issue of REACH, especially when considering the demanding time lines and number of registrations soon needing to be filed. For example, numerous attempts to submit files fail due to the fact that a given and possible procedure is not foreseen in the IT structure.

Thus, further improvements are urgently needed: a tool to check the completeness of a dossier prior to submission to ECHA is especially needed well before the submission deadline Spring/Summer 2010!!

Authorization list

Of the 15 substances on the candidate list published 28 October 2008, seven substances have been prioritized by ECHA, based on assessment of available information. ECHA's draft recommendation is open to the public until 14 April 2009 http://echa.euraopa.eu/consultations/authorisation/draft_recommendations_en.asp and comprises the following substances:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
- Alkanes,C10-13,chloro (short chain chlorinated paraffins; SCCPs)
- Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified
- 4,4'-Diamino diphenyl methane (MDA)
- Bis (2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)

On the basis of the comments received during the consultation and taking into account the opinion of the Member States Committee, ECHA may modify the draft recommendation. ECHA will submit the recommendation to the European Commission for final decision and inclusion in Annex XIV (List of substances subject to authorization).

ELINCS list

The complete ELINCS and new chemicals dossier number list was published on the website of the "Consumer Products Safety & Quality (CPS&Q) Unit" (formerly known as "European Chemicals Bureau (ECB)"). It can be downloaded here: http://ecb.jrc.ec.europa.eu/documents/New-Chemicals/Dossier_number-ELINCS_number.xls. ELINCS and new chemicals dossier number are needed to claim the REACH registration number via REACH-IT. Unfortunately, this procedure causes some practical problems which hopefully will be solved in the near future.

Deadlines

The first registration deadline (> 1.000 t/a and substances of high concern, e.g. CMR, R50/53 if > 100 t/a) is officially 30 November 2010. However, lead dossiers will have to be completed earlier: based on our experience at least 3 to 6 months prior to this deadline to allow other registrants to refer to the lead dossier and to generate their own dossiers (e.g. covering specific uses).

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FOOD & FEED ADDITIVES, VETERINARY MEDICINE

Evaluation of 2008

2008 was a very successful first year for the Feed & Food Additives, Veterinary Medicine Department. Agreements for several application dossiers were established and there are prospects for many more dossiers for feed additives regarding the re-authorisation process that has to be finalized by 7 November 2010. Furthermore, important contacts have been made with numerous companies to guarantee the flow of work after this deadline.

In a very short time, the name SCC has become very familiar in the area of animal nutrition. In addition, companies that SCC has worked for many years in other regulatory departments now turn to SCC for questions and assistance for their products in the animal nutrition area.

SCC was one of the first companies to join the European Federation of Food Safety Consultants (EFFSACO), a federation of consultants providing regulatory advice and services to the EU feed industry and its suppliers. SCC now has stronger input on behalf of the industry to the European Commission on important issues that we as consultants face in our daily work and that could be dealt with in a more efficient way (read: less expensive). Last but not least SCC has very strong personal contacts to the European Commission, EFSA and CRL.

2009 will bring much more work on dossiers and consultancy for the feed industry. Staff will be increased to build a stronger regulatory department to help the industry in an even more efficient way.

Feed additives vs. feed material

One important new aspect is a new European regulation concerning the marketing and use of feed which will be finalized (most probably) by spring 2009. This new regulation will also solve the current 'grey zone' between feed additives and feed material. Basically, the product's claim will decide which label it will get. Products that belong to the feed additive functional groups no longer can be labelled as feed material. This means that a number of products that are currently marketed as feed material but are used as feed additives can no longer be marketed as such starting in spring 2010. These products can only be marketed if they are registered as a feed additive. This means that an application dossiers has to be generated for these products. SCC is in direct contact with the European Commission on this matter, and is in the position to take care of these dossiers for you!

In you have any questions relating to these or any other subjects, please do not hesitate to contact Ruud Huibers at ruud.huibers@scc-gmbh.de.

GLOBAL AFFAIRS

Endosulfan Proposed as POP

The Stockholm Convention on Persistent Organic Pollutants (POPs) (the Convention), http://chm.pops.int/, is run under the umbrella of the United Nations Environmental Program (UNEP). POPs are chemical substances with a rather long degradation time in the environment and can accumulate in human bodies, causing adverse effects to human health and the environment. These substances are transported through the air in such a way that they can be detected in areas where they have never been used or produced before. The Stockholm Convention targeted the initial 12 POPs. The major aim of the Convention is to reduce or eliminate their release into the environment, to support the transition to safer alternatives, and to target additional POPs (see SCC Newsletter Vol. 7, No. 4, September 2007 for further details).

In this context, international experts assessed the organochlorine insecticide Endosulfan. During their last meeting in October 2008, they came to the conclusion that this substance fulfils all of the criteria for classification as a POP under the Stockholm Convention. In the next step, a draft risk profile will be developed based on technical information provided by participating parties. The experts will then develop a risk management evaluation and decide under which control measure the substance will be listed in the Stockholm Convention.

For further details, please contact Dr Friedbert Pistel at friedbert.pistel@scc-gmbh.de.

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DATA MANAGEMENT

SCC's GLP Certificate Re-Issued

In September 2008 SCC was reviewed by the State Office of the Environment, Water and Trade Control (Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany), regarding conformity with GLP (Good Laboratory Practice) standards for its GLP-compliant archiving facilities. SCC's successfully received re-certification: **the GLP certificate was re-issued.**

SCC continues to archive raw data on behalf of its European and worldwide clients with help of its unique GMS (**G**LP Archive **M**anagement **S**ystem), developed by SCC. Data, electronic media, materials, samples from GLP or similar type studies are stored at ambient temperature within a guaranteed temperature and humidity range as well as at refrigerated or deep frozen conditions.

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

CALENDAR

International Symposium Pool Water Chemistry and Health

02 – 03 March 2009 Dessau, Germany

The international symposium on pool water chemistry and health, sponsored by the Germany Environmental Protection Office (UBA) in co-operation with the Technical University in Karlsruhe, the Engler-Bunte-Institut (EBI), Wasserchemie, and the German Federal Ministry for Education and Research, will discuss results of recent research made regarding the health risks posed by swimming pools, as well as well as current developments in the area of swimming pool water hygiene. Dr. Dorothe Pfeifer, Manager Regulatory Affairs Biocides, will be at this symposium, which will be held in Dessau, 2-3 March 2009. For more information regarding the symposium, contact UBA at www.umweltbundesamt.de.

CALENDAR

9th International Fresenius Conference - The Biocidal Products Directive

23 – 24 March 2009 Düsseldorf, Germany

The 9th International Fresenius Conference, The Biocidal Products Directive, will be held on 23 and 24 March 2009 in Düsseldorf. Representatives of the European Commission will inform about the latest status of the Directive's revision and give an update on guidance documents and guidelines. Moreover, they will share their experience gained during the product registration process. Guest speakers from the industry will talk about market difficulties and explain what they expect from a revised Directive. EU Member State activities to promote harmonization will also be on the agenda of the two-day Fresenius Conference as well as several approaches for risk and exposure assessments delivered by biocide experts. Dr. Holger Zitt, Senior Manager Regulatory Affairs Biocides, will also make a presentation about environmental risk assessment. In addition, Sabine Goosens and Michael Schweitzer from the SCC Biocides Department will be in attendance. For more information, contact the Akademie-Fresenius at www.akademie-fresenius.de.

National Registration of Plant Protection Products in Germany – Information Day for Applicants

29 April 2009 Braunschweig, Germany

The German BVL will be sponsoring another Information Day for applicants regarding the national registration of plant protection products in Germany on 29 April 2009. Topics will include the status of plant protection registrations, the implementation of the revisions to Directive 91/414/EEC, mutual recognition, re-submission and renewals, and the submission of efficacy documentation. SCC will be present at this information seminar and will provide details of its content in a Special Edition Newsletter that will come out after the meeting.

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CALENDAR

16th International Conference on the Registration of Agrochemicals in Europe
19 – 20 May 2009 Brussels, Belgium

Key issues to be discussed at the 16th International Conference on the Registration of Agrochemicals in Europe, which will take place on 19-20 May 2009 in Brussels, Belgium, include:

- The New Regulation: Main issues, provisions and advice to applicants
- Latest initiative for product authorizations
- Developments with ongoing reviews
- EU MRLs

Dr. Monika Hofer, Dr. Albrecht Heidemann and Dr. Thomas Roth will be at this informative event. More information can be found at www.informa-ls.com/agrochemicals.

informa's CIR 2009 (including REACH, AgChem Forum, BPD, PIE and GHS)
23-24 September 2009 Barcelona, Spain

SCC will once again be present at **informa's** industry conference. Dr. Bernd Brielbeck will also be a speaker at the AgChem Forum. More information will follow as soon as it becomes available.

To make an appointment during one of these events, please contact Ms. Lisa Hubrich at +49-(0)6734-919115 (tel.) or at lisa.hubrich@scc-gmbh.de.

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