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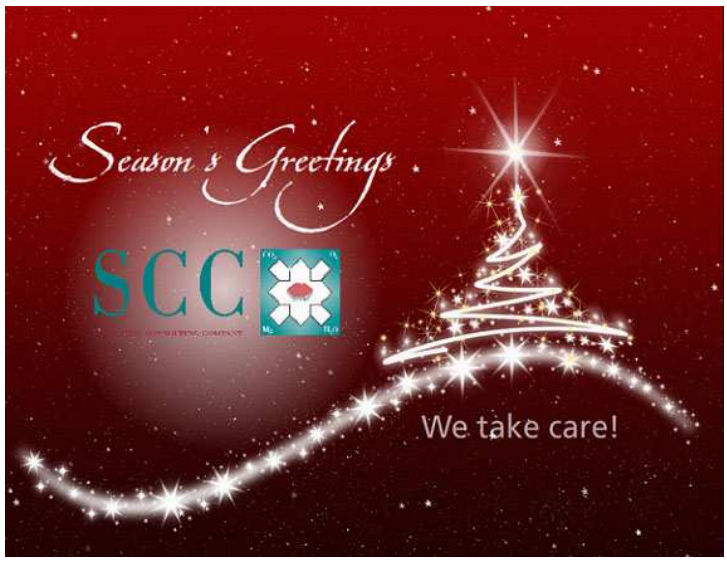

SCC GmbH wishes happy holidays and all the best in 2012

It's once again the holiday season. How quickly a year passes. The beginning of the year was rather busy for SCC, with our relocation and settling in to our new routines in our new building.

At the same time, we had a significant amount of work for our clients and a number of deadlines for submissions to the authorities. We were able to complete our clients' projects in 2011 to their satisfaction, which we had planned and hoped for. SCC looks positively into the future, helping our clients further with their projects.

My heartfelt thanks go to our clients, colleagues and, above all, to our employees. Our business would not be possible without this continued support.

On behalf of the staff at SCC, I would like to take this moment to say thank you and to send our best wishes to you and your families. May your holiday season be filled with much joy and happiness. We also wish you a successful New Year in 2012. We look forward to working with you in the coming year and hope our business relationship continues for many years to come.

This last edition of the SCC Newsletter for the year 2011 will focus on the newest information from the biocides, chemicals, and feed and food additives areas, as well as provide you with new information regarding **SCC EDDMS** and **SCC GMS** archiving solutions. You can also check out our calendar of events to find out where you can meet with SCC experts.

Finally, I would like to remind you that we would be pleased to have your feedback regarding the SCC Newsletter. Drop us an e-mail at newsletter@scc-gmbh.de.

Dr. Friedbert Pistel
President

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BIOCIDES

Draft Biocidal Products Regulation in final stage

On 17 November 2011, the Council and the European Parliament reached a provisional agreement on the draft text of the future Biocidal Products Regulation (BPR). The agreed text was negotiated in "trilogue" meetings between the three institutions Commission, Parliament and Council. This text is not publically available.

The following highlights a few "late changes" introduced by the trilogue agreement:

- The definition of "**biocidal product**" was once again modified: treated articles with a primary biocidal function will be considered as biocidal products.
- A definition of "**nanomaterial**" has now been introduced in the draft BPR legal text.
- Special **labelling provisions for treated articles** are only required if a biocidal claim is made, or if the conditions for approval of the active substance contained in the treated article require a special labelling.
- The **sustainable use of biocides** is more explicitly addressed: by 1 September 2016, the Commission is to prepare a report that will be the basis for deciding whether a specific legal act regulating the sustainable use of biocidal products is needed.
- The scope of **Union Authorization** has again been modified: Union Authorizations cannot be applied for biocidal products in product types 14, 15, 17, 20, 21 and for biocidal products containing active substances that meet the exclusion criteria. From 1 September 2013, products containing new active substances and products in product types 1, 3, 4, 5, 18 and 19 are eligible for Union Authorization. From 1 January 2017, Union Authorization may be applied for biocidal products in product types 2, 6 and 13, and finally for all remaining product categories from 1 January 2020.
- A very important change agreed in the trilogue meetings concerns the possibility for **derived authorizations** or marketing authorizations.
- Finally, the new **data sharing provisions** will include a general mandatory data sharing provision for vertebrate studies. Specifically for existing active substances, a wider mandatory data sharing provision will be introduced for all toxicological and ecotoxicological data including studies where no vertebrate animals are involved.

After the European Parliament adopts its position on second reading (indicative date for the plenary sitting is 18 January 2012), the regulation will be officially adopted by the Council in the first half of 2012. Publication of the regulation in the Official Journal of the European Union is expected in May/June 2012. The Biocidal Products Regulation will apply from 1 September 2013 with transitional periods for certain provisions.

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

CHEMICALS, REACH, CONSUMER PRODUCTS

SCC at VCI/TEGEWA conference

On 24 October, SCC attended a REACH conference organized by the VCI (German Chemicals Industry Association) and TEGEWA (association of producers of textile, paper, leather and fur auxiliaries and colorants, surfactants, complexing agents, antimicrobial agents, polymeric flocculants, cosmetic raw materials, pharmaceutical excipients and allied products) in Frankfurt, Germany. The conference focused on co-operation between the chemicals industry and REACH consultants, reviewed the lessons learned from the 2010 deadline, and gave advice for registrations falling under the next deadline in 2013. SCC and three other consulting companies were invited to present case studies from substances registered in 2010. SCC presented its services with a stand and was able to meet with many interested companies.

SCC in Japan

SCC was invited by the Ministry of Environment, Japan (MOEJ) to give a presentation on REACH and CLP, and the latest developments of the EU chemical policy. Approximately 300 representatives of Japanese

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companies from various branches and of different sizes (global players to SME), NGOs, journalists, Ministry representatives, and many more, participated in the seminar.

In addition, a workshop took place to exchange expert opinions with well-known Japanese REACH and CLP experts coming from the different Japanese ministries and well-established Japanese companies, and industry associations. REACH and GHS experts as well as supply chain communication experts used the opportunity to learn more about the recent developments in the EU chemical sector and the implementation (best practice) of REACH and CLP.

Draft Community Rolling Action Plan (CoRAP) published 21 October 2011

For the first time the Community Rolling Action Plan was published which proposes 91 substances to be evaluated by the Member States in the years 2012, 2013, and 2014 (see the ECHA website – http://echa.europa.eu/web/guest/regulations/reach/evaluation – section on Substance Evaluations). In the future, the CoRAP will be updated annually, referring always for evaluation activities for three subsequent years.

The criteria for substance selection in the CoRAP list are as follows:

Hazard related selection criteria:

- Suspected Persistent, Bioaccumulative and Toxic substances (PBTs), very Persistent and very Bioaccumulative substances (vPvBs) and PBT-like substances (e.g. close to meet REACH Annex XIII-criteria and/or based on structural similarities)
- Known PBTs/vPvBs
- Suspected endocrine disruptors (e.g. based on reproductive effects and/or on structural similarities)
- Suspected Carcinogenic, Mutagenic and Reprotoxic substances (CMRs) (e.g. based on structural similarities)
- Known CMRs (Category 1A , 1B and 2 according to CLP)
- Suspected sensitizers (e.g. based on structural similarities)
- Known sensitizers (skin and especially respiratory sensitizers)

Exposure related selection criteria:

- Wide dispersive use
- The number of sites of use
- Pattern and amount of releases/exposure
- The number and type of reported uses and exposure scenarios from different registrants
- The substance is incorporated into mixtures or articles used by the public (e.g. consumers)
- The potential size of the exposed population
- Number of using sites if emission due to industrial use
- Consumer use and exposure of sensitive subpopulations such as children
- Aggregated tonnage

Risk related selection criteria:

- The risk assessment in the chemical safety report shows that risk characterization ratio is not well below 1 (for human and/or environmental exposure)
- Cumulative exposure from structurally related substances with critical hazardous properties (e.g. similar endocrine disrupting property like antiandrogenic or estrogen-like effect)

The final CoRAP is scheduled for end of February 2012. From the publication of the final CoRAP, the respective Member States have one year to evaluate the 2012 specified substances and to prepare a draft decision – if required – for requesting further information to clarify suspected risks.

IUCLID and REACH-IT Updates in 2012

The next IUCLID update has been announced by ECHA for summer 2012. This new version IUCLID 5.4 and Chesar will have substantial changes in some of the sections.

The REACH-IT tool for submitting the new IUCLID version is announced for the end of 2012.

Changes in the IT tools will impact the overall registration strategy of the registrants (timeline, software version, etc.).

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

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FEED & FOOD ADDITIVES, VETERINARY MEDICINE

New lists for Food Additives!

With the publication of Commission Regulations (EU) No 1129/2011 and No 1130/2011, both on 11 November 2011, the new Annexes II and III of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on Food Additives have been established. This means that the old annexes from various Directives are now being replaced. Formally, these new lists of registered food additives will apply from 1 June 2013. Foods that have been lawfully placed on the market before 1 June 2013, but do not comply with this regulation, may continue to be marketed until their date of minimal durability or use-by date.

SCC is working on several registration processes of new additives and the extension of current food additives. Also in this area, a personal contact exists with the responsible unit of the European Commission. In a very recent communication with this unit, it was mentioned that the European Commission would not in all cases ask EFSA for an opinion. This all depends on the quality of the application dossier plus the content of the food additives. Thus, it is most important to have a good dossier ready for a fast registration process! Let our knowledge be of your advantage!

Also, the Food Ingredient Europe 2011 (Fi Europe 2011) took place in Paris from 29 November till 1 December. Ruud Huibers was present there and had several interesting meetings with current and possible new clients. This also includes questions in the area of Food Contact Material.

In the **feed additive** area we now see that after the various questions from EFSA have been answered (or are being answered), new application dossiers are emerging. Some very interesting products in completely new areas are among them! Especially the highly scientific knowledge of the various PhDs working at SCC (about 65) is a welcome help in these tasks. Lots of questions also keep coming to us regarding labelling and claims (referring to Regulation 767/2009).

Finally, we are currently also involved in some projects concerning the establishment and maintenance of quality systems (either obligatory or voluntary).

For more information regarding these topics, contact Ruud Huibers at ruud.huibers@scc-gmbh.de.

REGULATORY SCIENCE

AgChem Forum 2011 – STREAM 3: Environmental safety: Ecotox and Fate

In the environmental stream of this year's AgChem Forum, 17 presentations on different topics were given by speakers from EFSA, national authorities, industry, research institutes and academia.

A main focus on day 1 was put on the implications of the new Regulation (EC) No 1107/2009 for regulatory ecotoxicology, especially the new hazard based cut-off criteria.

Martin Streloke (Federal Office of Consumer Protection and Food Safety, BVL, Germany) presented some critical issues for the regulatory work at member state level. He pointed out that the cut-off criteria for active substances need to be specified, e.g. endocrine disruptors. Furthermore, possible conflicts between the new zonal approach and member state assessments (e.g. with regard to risk mitigation measures) were elucidated.

Endocrine disruption as a cut-off criterion was discussed in further presentations. Amy Brooks (CRD, UK) focused on the UK regulatory approach to identify endocrine disruptors. However, some definitions of different terms are unclear, e.g. what is an "adverse effect", or what is "negligible exposure". There is also a lack of internationally agreed test guidelines. James Wheeler (Syngenta, UK) gave an industry perspective on these issues and also pointed out problems related to the lacking definitions and test guidelines.

Some possible testing strategies and methods used to test for endocrine disruption were presented by Werner Kloas (Humboldt University, Germany) and Hans Rufli (ecotoxsolutions, Switzerland). A main focus was put on possible testing strategies in fish, e.g. from the tier 1

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fish screening assay (OECD 230) or fish short-term reproduction assay (OECD 229) to higher tier full life cycle testing.

In the afternoon of day 1, Mark Egsmose (EFSA, Italy) reported on the current activities of EFSA on new guidance documents (GDs) in the environmental field. Time lines for publication were mentioned as follows:

- GD on persistence in soil will be final end 2011 (public consultation currently ongoing)
- GD on emission from protected crops in spring 2012 (public consultation currently ongoing)
- GD on DT50 in soil targeted for spring 2012
- Aquatic GD (modular document): Adoption 2012 - 2014
- Terrestrial GD (modular document): Adoption 2012 - 2017
- Bees: Opinion on exposure through nectar and pollen: April 2012

On day 2, the main focus was put on honeybees and terrestrial ecotoxicology and fate. Anne Alix (Ministry of Agriculture, France) gave a presentation about the regulatory situation regarding honeybees in France. Work is currently ongoing to assess the risk to bees posed by guttation and dust from seed treatments as well as the acceptability of effects in field studies and the design of post-registration monitoring studies. Gabe Weyman (Makteshim-Agan, UK) gave an interesting industry perspective on the public discussions about honeybee declines. He made clear how emotional and conflicting this issue is discussed.

In the following presentations, new approaches regarding the exposure assessment for soil organisms were discussed. Jos Boesten (Alterra, NL) introduced the new approaches for PEC soil calculations according to a draft opinion from EFSA, where public consultation was ongoing this year . Different PEC soil values will have to be calculated in a tiered approach for each regulatory zone in Europe. Furthermore, it is differentiated between the concentration in total soil and in pore water. A model for calculating the tier 1 – 2B will presumably be made available by EFSA in 2012.

Axel Dinter (DuPont Crop Protection, Germany) gave an industry perspective on the new approaches proposed in the draft opinion by EFSA. When the PEC soil is calculated according to the draft opinion for the top 1 cm layer only, this would pose an unrealistic worst case for many soil organisms. Additionally, the current PEC soil model might be considered to be sufficiently protective based on an evaluation of earthworm field study results, where the studies were triggered for substances that failed the current standard risk assessment. Frank Scheer (Bayer CropScience, Germany) gave a talk about exposure aspects of soil risk assessments in relation to protection goals. Exemplary calculations showed that the PEC soil values calculated according to the draft opinion by EFSA can increase up to a factor of 80 in comparison to the current model. This was discussed in the light of potential and effective exposure of soil organisms.

The last presentation on terrestrial ecotoxicology from Steve Norman (Dow AgroSciences, UK) focused on field studies for birds and mammals. A comprehensive program of generic field studies and field effect studies conducted for the insecticide chlorpyrifos was presented. The conference was rounded off with presentations on aquatic policy and fate concerning the Water Framework Directive and its implementation (Dieter Schäfer, Bayer CropScience, Germany) as well as the risk assessment for leaching to groundwater (Bernhard Gottesbüren, BASF SE, Germany).

AgChem Forum 2011 – Human Safety: Toxicology and Exposure

The main topics of the AgChem Forum stream Human Safety: Toxicology and Exposure were (i) the cumulative risk assessment for residues of plant protection products, (ii) the use of a probabilistic risk assessment approach, and (iii) the hazard/risk assessment for endocrine disruptors. The following condensed information on toxicology and exposure is considered noteworthy:

With regard to mixtures, combinations and cumulative risk assessment a status update on the EU ACROPOLIS (**a**ggregate and **c**umulative **r**isk **o**f **p**esticides: an **o**n-**l**ine **i**ntegrated **s**trategy) project was provided, accentuating the advantages of the underlying probabilistic modelling approach (e.g. a higher flexibility) as compared with the currently used deterministic assessment tool PRIMO (**P**esticide **R**esidue **I**ntake **Mo**del). However, since EU member states own the national input data on consumption and residue concentrations, a willingness to share data is required in order to establish this single platform. Based on industry feedback, grouping of substances, e.g. according to their specific effect or by time of exposure, is pivotal in cumulative risk assessment. Examples for the assessment of cumulative dietary exposure to endocrine disrupting pesticides by

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means of a probabilistic and relative potency factor-based approach were presented.

In view of emerging areas in toxicology testing, a qualitative scheme (causal relationship grid) was presented which allows for allocation of a substance according to available toxicological and epidemiological evidence with the aim to establish a causal relationship between agent and effect. Considering plant metabolites, concern was raised that, based on current toxicity testing schemes, humans are exposed to compounds, here plant metabolites of active ingredients, whose toxicity was not tested in experimental animals. Since the OECD test guideline 443 for an extended one-generation study was recently adopted (28 July 2011), a CRO representative presented relevant aspects in the conduct of this study. It was highlighted that the decision point for the assessment of a second generation represents a bottleneck in the new protocol because, as a basis for decision-making, a vast variety of data has to be evaluated in a short period of time.

The main message with respect to endocrine disruptors and human safety was that there is up to now no agreed definition of endocrine disruptors and where adversity of endocrine disrupting effects begins. From the industry perspective, discrimination between endocrine disruptors of low or high concern, the latter requiring regulatory action, is considered crucial since otherwise the list of endocrine disruptors will soon get out of hand.

Regarding non-dietary exposure assessment for plant protection products, the EU BROWSE (**b**ystanders, **r**esidents, **o**perators and **w**orker**s** **e**xposure models) project reviews, improves and extends models currently used in the risk assessment. This single modelling framework includes recent exposure data and more scenarios and will build on new approaches from BREAM (**b**ystander and **r**esident **e**xposure **a**ssessment **m**odel). Workshops with stakeholders are ongoing. Industry feedback showed that current exposure models used in this field are based on high levels of conservatism without adequate consideration of substantial reductions in exposure by, e.g. development of application technology, low drift nozzle technology, operator training and company stewardship programs. It was proposed that estimates of exposure from new models should be compared against exposure resulting from current agricultural practice.

A tiered approach to risk assessment for stereo-isomeric active ingredients of plant protection products was proposed by an ECPA representative. Based on this approach, if there are significant qualitative or quantitative (i.e. potency) differences between the stereo-isomers of an active ingredient for relevant toxicological or ecotoxicological endpoints, then a risk assessment for the individual stereo-isomers may be considered appropriate.

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

DATA MANAGEMENT

SCC Archives - Your solution for data management

SCC offers complete archiving concepts for all regulatory needs (regulatory / scientific archiving and GLP-compliant storage). Clients can designate SCC for its European or worldwide central archive, either in secured archive storage rooms or certified under GLP.

SCC EDDMS = Electronic Document and Dossier Management System, the proven SCC archiving and database system, provides guaranteed fast and reliable access to your data from all over the world, via a password-protected online portal. Submissions can be created quickly and economically using the database.

SCC GMS = GLP Management System, SCC's secure archive storage according to official GLP requirements. This validated GLP management system allows a complete audit trail of all entries and exact, immediate and easy retrieval of archived materials and data.

Our paper and electronic archiving facility provides enough space for all your documents. A dedicated archiving area can be established close to your European markets. Secure and safe storage of valuable data is guaranteed.

The archives are fully equipped according to OECD and legal requirements. All facilities are integrated in a building monitoring system, activated and monitored 24 hours per day, 7 days per week.

In addition, SCC can set up in-house solutions for the archiving of regulatory / scientific documents at your premises.

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Experts take care...we take care.

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

CALENDAR

5th Forum on Product Safety in the Chemicals Industry - 23-25 January 2012, Cologne, DE

The 5th Forum on Product Safety will be held in Cologne from 23-25 January 2012, sponsored by the Chem Academy. The convention will deal with such topics as a discussion on the experience gained from prior control projects, preparations needed for REACH 2013, and the coordination in implementation by ECHA and on the national levels. SCC is a sponsor for this event. Be sure to contact us to arrange a meeting with Dr. Charlotte Krone, Senior Manager Regulatory Affairs, Chemicals and Consumer Products.

3rd International Fresenius Conference "Feed" Efficacy – Claims – Mode of Action – 13-14 February 2012, Cologne, DE

Consumer protection is becoming increasingly important and the legal requirements in regard to quality assurance in the production and use of food have become much more stringent. This important exhibition and conference will deal with such topics as the achievements and further developments in European Community policy, EFSA requirement since the re-evaluation of feed additives, and industrial guidelines for claims on compound feed for food producing animas, among others. Ruud Huibers, Head of the Feed and Food Additives, Veterinary Medicine Department at SCC will be at this important and informative event.

ChemCon Europe 2012 – 5-9 March 2012, Madrid, ES

ChemCon Europe 2012 is a global platform which brings together more than 200 company experts representing companies, authorities and international organizations from over 20 countries. Presentations given by more than 35 speakers from governments and industry will focus in the field of international chemical legislation all over the world. SCC is an exhibitor at this important informative event.

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