



⇒ **SCC opens liaison office in Japan**

⇒ **REACH goes into effect**

⇒ **EDDMS now available**

⇒ Over the last 18 years SCC has had several locations in the Rhein-Main region of Germany, and is currently in Wendelsheim. In accordance with the strong desire of our Japanese clients for permanent SCC representation in Japan, we opened our new office near Tokyo on 1 July 2007. This is our first overseas office, which will serve as a contact point for our clients. Our two new colleagues, Mr. Norio Ohta (Director), and Mr. Kenji Makita (Senior Consultant) will be pleased to provide assistance with any inquiry you may have. Both our representatives have strong backgrounds in the agricultural and chemical business, and look forward to using their experience and knowledge for you, our client.

Contact details for the Japan office are:

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⇒ REACH legislation entered into force on 1 June 2007. Registrations under REACH are the full responsibility of producers and importers, resulting in significantly increased industry awareness. At our offices in both Wendelsheim and Japan, we have already begun providing customer support on this issue. It is also evident that the need for this support is rapidly increasing. Please see the Chemicals section for further details.

⇒ SCC has also developed its new Electronic Dossier and Data Management System (EDDMS). EDDMS archives all documents related to the registration of our clients' substances on global, European or Member State level. A brochure on EDDMS was recently published and can be obtained via SCC. For further details please see section "Data Management".

Although SCC has a very full work schedule now and in the future, we are and will always be personally available for any of our clients' individual needs. Please contact SCC in Wendelsheim, or at our SCC Liaison Office Japan if you have any questions.

With best regards,

Dr. Friedbert Pistel
President

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Update on review of Directive 91/414/EEC

The European institutions are currently in the process of reviewing Directive 91/414/EEC which deals with the placement of plant protection products on the market. As one step in the process of generating a revised 91/414/EEC, the European Commission (EC) published a proposal for a revised draft regulation (the Regulation) on 12 July 2006. In the Regulation, the EC lists exclusively its opinions on how plant protection products are supposed to be authorized in the European Union (EU) in the future. Currently, the Council of the EU (the Council) is preparing the next step in the legislative procedure to revise the existing 91/414/EEC. Therefore, the Council discusses and comments the EC's initial draft Regulation. The final decision (vote) in the process was postponed because the Council needs more time to discuss received comments.

Louis Smeets (European Commission, Health and Consumer Protection Directorate-General) presented the major comments in the ongoing discussion during the 14th International Conference on "Registration of Agrochemicals in Europe" which took place in Brussels in May 2007.

In the Regulation, the EC proposes an evaluation and approval period of 24 months for active substances. Of this period, one year is given to the Rapporteur Member State (RMS) to assess the dossier, six months to EFSA, and six months to the EC. The Council agrees in principle, but states that the deadlines to fulfill are rather unrealistic.

Due to strict deadlines for approval of new active substances and authorizations of plant protection products on the Member State (MS) level, national provisional approval is no longer necessary, says the Commission. Contrary to the EC, the Council proposes maintaining national provisional approval as one means for plant protection products based on new actives to enter the market place.

Both the Council and the EC support comparative risk assessment of plant protection products containing candidates for substitution. However, the initially proposed criteria in the Regulation with which candidates for substitution will be identified, are still under discussion within the Council.

Compulsory mutual recognition of authorisations of plant protection products by MSs belonging to the same zone caused considerable discussion between the Council and the EC. While the EC supports the three-zone model including obligatory mutual recognition, the Council insists on the four-zone model with no obligatory recognition of authorizations from another MS.

Both the Council and the EC support the implementation of integrated pesticide management (IPM) procedures into the Regulation from 2019 onwards (the Council) or from 2014 onwards (the EC), respectively. This IPM procedure links the Regulation to the proposed thematic strategy on sustainable use of pesticides. In addition, the Council would like to include specific rules to the IPM procedure provided by the MSs.

Data protection is a major point of discussion in the review process. Both the EC and the Council support the simplification of the currently very complicated data protection procedure in the existing Directive 91/414/EEC. In this respect, the EC proposes a general data protection period of 10 years and 12 years for low risk substances in the Regulation. The Council proposes to add 5 additional years if products are re-evaluated/re-authorized.

Neither in the existing 91/414/EEC nor in the Regulation are provisions on parallel trade of plant protection products foreseen. Thus far, the issue is regulated by the EU treaties and the related case law. With the revision, the Council suggests adding a process on parallel import to the Regulation and to clarify the term "identity" of plant protection products.

The EC proposes information of neighbours before plant protection products are applied. Records must be kept available upon request. The Council did not comment on this so far because there are still open questions.

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

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AGROCHEMICALS

Fast Track Procedure for List 3 and 4 substances

The European Commission (EC) is in the legal process of adopting the draft text SANCO/757/2007 Rev. 15 (SANCO text), which amends the legal rules for the review process under Directive 91/414/EEC for List 3 (regulation 1490/2002) and List 4 substances (regulation 2229/2004). Publication in the Official Journal of the European Union is expected in September/October 2007. The Regulation will enter into force seven days after the publication date.

With the "Fast Track Procedure", the European Commission aims to speed up the review process under Directive 91/414/EEC, which must be completed by end of 2008.

Substances with clear indications that they do not have harmful effects on humans, animal health or the environment will be included to Annex I without instant review. EFSA's view will be delivered at a later time point. On the other hand, where there are clear indications that a substance has harmful effects, the Commission will have the possibility to decide on non-inclusion without consulting the EFSA.

The SANCO text provides criteria that define which substances pose either risks or no risks, and therefore will be included or not included in Annex I.

The European Food Safety Authority (EFSA) will concentrate their review activities on substances where it is not clear whether they pose risks to humans and/or the environment, or not.

In order to make sure that the above given "review deadline" can be fulfilled, notifiers will no longer have the right to submit additional studies to the RMS after the Draft Assessment Report (DAR) has been sent to EFSA. However, the notifier may withdraw his support of the inclusion of the active substance in Annex I to Directive 91/414/EEC within two months after receipt of the draft assessment report. In this case, substances can re-enter the marketplace if the notifier manages to prove through additional studies that the substance meets the uniform principles criteria (Annex VI).

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

REGULATORY SCIENCE

News about the MRL regulation 396/2005

As already described in SCC Newsletter Vol. 7, No. 3 (April 2007), EFSA issued an opinion on 15 March 2007 regarding the possible consumer risks from MRLs in food and feed. Further details can be found at

http://www.efsa.europa.eu/en/science/praper/maximum_residue_levels/mrl_opinion.html.

The outcome of the first screening shows that further refinements are absolutely necessary, e.g. to examine whether the adequate toxicological reference values (ADI, ARfD) are used. Furthermore, it has to be determined whether the risk assessments could be refined using residue data from supervised residue trials (STMR, HR) as well as processing data (e.g. for citrus pulp), and by restricting the risk assessment on registered uses.

After re-evaluation of substances with consumer intake concerns and refined dietary risk assessments, the EU published the draft temporary MRL on 25 July 2007, which is to be the basis for establishing Annex III to MRL regulation 396/2005. See http://ec.europa.eu/food/plant/protection/resources/draft_list_highestmrls.xls for details.

The voting on the temporary MRL proposals will take place in the forthcoming EU residue group meeting on 22-23 October 2007.

In case of adoption of the temporary MRLs, the MRL regulation will enter into force six months after adoption of its Annexes I – IV.

Up to now, MRLs for the new commodities listed in Annex I of the MRL regulation have not been covered. However, after the above mentioned transition period of 6 months, EFSA will start doing dietary risk assessments for the Annex II MRLs (definitive MRLs). They intend to perform a refined dietary risk assessment, i.e. using highest and median residues as well as appropriate processing factors.

For further information contact Dr. Monika Eder (monika.eder@scc-gmbh.de) or Dr. Monika Hofer (monika.hofer@scc-gmbh.de).

Metabolites in Groundwater

There are several opinions among authorities as to when metabolites in groundwater derived from de-graded plant protection products (ppp) become relevant. According to the guidance document SANCO/221/2000, metabolites detected at concentrations up to 10 µg/l in groundwater may be treated as non-relevant depending upon their (eco-)toxicological profile. SANCO/757/2007 is the draft Commission regulation amending the detailed rules for the review of list 3 and list 4 substances under Directive 91/414/EEC. The draft text says that parent substances and their metabolites detected at a level above or equal to 0.1 µg/l in all modelled scenarios may lead to harmful effects for example on groundwater and therefore cannot be included to Annex I of Directive 91/414/EEC.

In November 2006 the metabolite Dimethylsulfamide was detected in drinking water in Germany. The metabolite is derived from ppps containing the authorized substance Tolyfluanid. The German authorities informed the European Commission about the detection of the metabolite. Dimethylsulfamide in drinking water is problematic because it is converted during the ozonization process for drinking water into a nitrosamine (NDMA) which is harmful for human health. Nitrosamines are proven or under suspicion to be genotoxic and carcinogenic. We reported on occurrence of Dimethylsulfamide in drinking water in SCC Newsletter Vol. 7, No. 2 (March 2007).

During the 9th AGRO conference "Behaviour of Pesticides in Air, Soil and Water" from 27 to 28 June 2007 hold by Akademie Fresenius the German "Bundesamt für Verbraucherschutz und Lebensmittelsicherheit" (BVL) presented the recent discussion status.

As a follow up to the detection of the metabolite in groundwater the European (EU) authorities published their decision 2007/322/EEC (dated 4th May, 2007) with which Member States (MS) that use ozone for the treatment of drinking water have to implement security measures to protect drinking water towards contaminations through Tolyfluanid or the metabolite.

To fulfill this objective MS using ozone for drinking water processing must withdraw or adapt authorizations for ppps containing Tolyfluanid if their application can contaminate groundwater and/ or surface water. RMSs are asked to investigate all substances currently under review if their use can possibly lead to similar problems.

As a follow up on national level German authorities withdrew the use authorization for ppps containing Tolyfluanid for outdoor use. Currently they discuss limited re-authorization under the pre-condition that Tolyfluanid is only applied outside water catchment areas. Beside the Tolyfluanid problem BVL presented open questions on how to deal in general with toxic degradation products that possibly could be formed during the drinking water preparation processing, for example: are all metabolites identified which may form dangerous products? Which drinking water disinfection methods must be taken into account beside ozonization (e.g. chlorination, UV-light)?

A further question in this situation is how to deal with non-relevant metabolites in drinking water defined according to SANCO/221/2000. BVL explained the situation using the example of an unspecified metabolite which derived from ppps based on the active substance Chloridazon. The unspecified metabolite was detected in concentrations up to 10 µg/l in groundwater and drinking water. According to SANCO/221/2000 the metabolite was classified as non-relevant and consequently the authorization was not modified. But the authorization holders and the German authorities agreed on adapted use instructions and a limited maximum application rate in order to reduce the detected level.

As mentioned above there are several views on how to deal with metabolites in groundwater and drinking water (SANCO/221/2000 and SANCO/757/2007). Currently authorities responsible for water quality and/ or the registration of ppps as well as drinking water suppliers are in the process of setting up a mutually agreed framework on European level.

Contact Dr. Monika Hofer (monika.hofer@scc-gmbh.de) for more information.

Registration, Evaluation and Authorisation of Chemicals (REACH)

REACH legislation on Registration, Evaluation and Authorisation of Chemicals was implemented on European level through Regulation no. 1907/2006 and entered into force on 1 June 2007. The European Chemicals Agency (ECHA: <http://ec.europa.eu/echa/>) is the European institution responsible for the implementation of REACH. Currently the ECHA only operates a limited number of services, scheduled to be fully operational on 1 June 2008. In a nutshell: REACH requires the registration of all existing and future new substances, substances in preparations and substances in articles. For the first time the burden of proof for guaranteeing chemical safety is transferred from Member States' authorities to producing and importing companies. The regulation further introduces responsibility for downstream users to provide information on uses and associated risk management measures.

REACH will affect all European chemical manufacturers and importers, producing and importing > 1 t/anno. Exemptions from REACH need to be carefully reviewed. For phase-in substances, including e.g. EINECS listed substances or no-longer polymers, pre-registration will take place from 1 June 2008 through 1 December 2008. Pre-registration allows making use of the transitional periods offered for registration. Without pre-registration no transitional periods will be granted.

Regulatory guidance

Regulatory guidance for REACH is provided in form of REACH Implementation Projects (RIPs). All final RIP documents can be downloaded from the ECHA website. In addition to the final documents, draft RIP documents are available through the European Chemicals Bureau (URL: <http://ecb.jrc.it/reach/>). In addition to the RIP documents, guidance to REACH is provided by a number of European and national help

desks, allowing specific questions to be posed. Notably, neither RIP guidance documents nor help desk information are legally binding.

Several RIPs and guidance documents are already available, for example "Guidance on registration" (former RIP 3.1), RIP 3.4 on pre-registration and data-sharing, and "Guidance for identification and naming of substances under REACH" (former RIP 3.10).

Monomers and Polymers

REACH offers a number of exemptions from the registration requirement, e.g. for polymers. In contrast monomers or other substances (additives such as pigments, lubricants, flame retardants, etc.) have to be registered if the (monomer) substance is present in the polymer in amounts > 2 %. Consequently, producers/importers of substances have to thoroughly analyze their product portfolio to assess the need for registration and to prepare a well-directed registration strategy prior to the pre-registration deadline.

Difficulties may arise in regard to the registration process of, e.g. monomers produced outside the European Union as non-EU manufacturers do not have to register but can register through an "Only Representative" located in the EU. Therefore, it is recommended to pre-register all monomers imported to European territory in order to avoid any possible restrictions/delays on the import.

SIEFs and Consortia

Substance *I*nformation *E*xchange *F*ora (SIEFs) are initiated by the Agency. They serve as fora for the exchange of information among potential REACH registrants during the pre-registration phase and are mandatory. Their aim is to facilitate data sharing for the purposes of registration, thereby avoiding the duplication of studies, and to agree on the classification and labelling of the substances in question.

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The legislation offers applicants the chance to prepare joint submissions and, to a certain extent, this includes the sharing of data to avoid new testing especially on vertebrate animals. Co-operation among applicants is of crucial importance because the first registration deadline will expire in December 2010, just two years after the pre-registration deadline. By that date selected dossiers including a complete set of data must be submitted to the Agency.

A consortium is defined as an industry-initiated group which may evolve (but not required by REACH) from a SIEF, with the purpose of reviewing the existing data base and developing strategies on how to close possible registration data gaps for one specific substance in question. Experience shows that manufacturers and importers often cannot provide a complete set of registration data for their substances. This is especially true for toxicological data. In this respect, it is important to note that besides the “regular” data generation through new testing, there are other means to close data gaps. With intelligent testing strategies, time and money can be saved because less data must be generated, for example through (Q)SARS, the read-across approach, and data waiving.

Companies have constraints on the relation between REACH and European competition law. To address this topic, RIP 3.4 on pre-registration and data sharing was recently published. In the guidance document, the European authorities discuss and provide practical and specific support in regard to sensitive data related to SIEFs, joint submission, cost sharing, confidential business information, and co-operation between companies (e.g. consortia).

For further details please contact Dr. Werner Köhl at werner.koehl@scc-gmbh.de.

BIOCIDES

News from the biocidal actives review program

Prior to the submission deadline for existing biocidal active substances in the third priority list, a new withdrawal notice was published by the Commission on 22 June 2007. The list of withdrawn substances can be downloaded from http://ec.europa.eu/environment/biocides/pdf/070622_withdrawal_notice.pdf. Producers, formulators, associations or other persons wishing to take over a withdrawn substance/product type combination should inform the Commission accordingly by 22 September 2007.

Most likely a further withdrawal notice will soon be published this year. The Commission estimated that overall only 50% of all originally notified substances in the third priority list will actually be supported by a dossier. Still, this would mean that a vast number of dossiers will have been sent to the European Competent Authorities (CAs) by the end of July (about 300 combinations active/product type). We will keep you up to date on the status of active substances supported in the review program.

Speeding up the review program

On the first day of the 24th CA meeting held on 13-17 March 2007 in Brussels, the Commission organized a workshop on the “mid term review of the biocides review program”. Representatives from different directorates of the Commission, the ECB, OECD, industry and from almost all of the 27 EU member states, as well as Norway and Iceland, took part in the workshop and discussed improving the review program. Representatives from Switzerland, Croatia and Turkey also participated as observers.

Mr. Ladislav Miko (European Commission, Head of Directorate General Environment B.3) opened the workshop by presenting an in-depth analysis of the present state of the review program and by discussing the issue of major delays and their consequences. Because the review program is progressing much too slowly, one goal is to increase the speed of the peer-review procedure in order to be able to process up to 40-50 Competent Authority Reports (CARs) per year starting in 2008. In noting the consequences of the delay, the Commission

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also mentioned ongoing free-riding and “impaired innovation due to the fact that the existing substances are allowed to stay on the market while review is ongoing whereas the new substances have first to get an approval at Community level”. The overall credibility of the system is therefore seriously questioned. Conclusion: The deadline must be extended, but the delay must be kept to an absolute minimum.

Leena Yla-Mononen and Pierre Choraine from DG Environment presented possible reasons for the delay and concrete proposals for improvement, such as better document management (e.g. publication of the assessment report only instead of the whole competent authority report on DG Environment’s website) and simplification of the peer-review. Two concepts on accelerating the peer-review process were presented:

1. The traffic light approach, categorizing substance into three classes:

- “red” substances (i.e. candidates for non-inclusion, cut-off criteria might be the same as for authorization under REACH: PBT-substances, CMR cat. 1 or cat. 2 substances, for example),
- “yellow” substances (regular route of peer-review) and
- “green” substances (low concern, very clear cases for inclusion, fast-track peer-review).

2. The “80/20 approach” meaning that peer-review should focus only on the “worst 20%” of active substances.

Steven Eisenreich, head of the European Chemicals Bureau (ECB), pointed out that the ECB would like to play a more central and a more scientific role in the future of the review program. In joining resources with the member states, ECB could either provide the staff for dossier quality checks or for issuing scientific opinions on risk-assessments. He concluded by asking the Member States, whether they would welcome such an expanded role of the ECB in the future.

Sweden and the UK, being the Rapporteur Member States for the first two substances included in Annex I to Directive 98/8/EC (Sulfurylfluoride and Dichlofluanid), presented their views. They recommended not changing the rules in the course of the review program, and that the Member States, the Commission and industry would have to improve equally.

Industry was also given the opportunity to present their perception.

CEFIC stated that speeding up the process was in their interest; there was some concern, however, that this should not lead to unacceptable short-cuts. Resources within the Rapporteur Member States and the Commission have to be increased. A central committee could relieve RMS from critical decisions, increase consistency, drive harmonization and speed up decision making.

UEAPME representing the small and medium sized enterprises in Europe, proposed to set May 2014 as a new deadline of the review program and appealed to the Commission to solve the free riders issue by establishing compulsory data sharing (as in REACH) under fair compensation.

Next on the agenda was a “tour de table”, where all other Member States and observers were given the opportunity to contribute their ideas. ECB’s offer to play a more important part in the review program was accepted almost unanimously.

All in all, there was a general consensus to streamline the review-program but without loss of quality. Early contacts between authorities and industry are very important. Co-rapporteurship was positively mentioned. It was decided to review the traffic-light approach to determine whether it will bring any advantages to the review process. Some Member States asked the Commission to use their influence on slower Member States. It was agreed that joint resources are a key for improving the system.

Even if the review program could be significantly accelerated, it is highly unlikely that the official deadline of 14 May 2010 will be met. The Commission avoided engaging in a discussion whether an alternative deadline should be set. This will however be an important issue when it comes to reviewing Directive 98/8/EC next year.

The preliminary conclusions were summarized by the Commission in a separate paper. Comments from several Member States have been received since March 2007 and the entire issue was once again discussed at the 25th CA-Meeting (19-21 June 2007). Although there is agreement on speeding up the process, it seems difficult to initiate the streamlined procedures.

For more information, contact Dr. Holger Zitt at holger.zitt@scc-gmbh.de or Dr. Hans-Josef Leusch at hans-josef.leusch@scc-gmbh.de.



GLOBAL AFFAIRS

The Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants (POPs) (the Convention) 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 which may cause adverse effects to human health and the environment. These substances are transported through the air in such way that they can be detected in areas where they have never been used or produced before. The Stockholm Convention targets the initial 12 POPs. The major aim of the Convention is to eliminate or to reduce their release into the environment, to support the transition into safer alternatives and to target additional POPs.

In November 2004 the European Community (EC) ratified the Convention, thereby becoming a party to the Convention. Similar to substances listed under the Rotterdam Convention (see SCC Newsletter Vol. 7, No. 3 (April 2007)), the European regulations go further than the Convention requires. The main legal framework implementing the requirements of the Stockholm Convention on European level includes among others Regulation 850/2004 (EC) on persistent organic pollutants, and Regulation 304/2003 (EC) on import and export of dangerous chemicals.

Each party to the Convention is obliged to establish an implementation plan to prove that concrete action is being taken to eliminate all POPs listed in the convention worldwide. The implementation plan for the European Community was adopted on 9 March 2007 completing the national plans of the EU Member States. Further details can be found at http://ec.europa.eu/environment/pops/index_en.htm.

The EC is in the process of identifying further substances with POPs properties as required by the Convention (Art 3). This task will be supported through the new European chemicals legislation. The knowledge about substances will be improved substantially through REACH activities. The impact on POPs related issues remains to be seen.

Contact Dr. Friedbert Pistel (friedbert.pistel@scc-gmbh.de) for further information.

DATA MANAGEMENT

SCC develops universal regulatory database

SCC has developed its new universal regulatory database "Electronic Document and Dossier Management System", EDDMS.

It is well known that our "regulatory world" has become more and more complicated and complex. The preparation of a regulatory dossier has developed into an extremely demanding task in terms of scientific and administrative requirements. Extensive dossiers covering multiple data requirements must be generated by the applicant, requiring reliable documentation and tracking of submissions and corresponding information. With experience obtained over almost two decades of working for the chemical industry and knowledge acquired from hundreds of dossier preparations and international submissions, SCC has developed its new regulatory database system.

Let the advantages of EDDMS work for you:

- universal use, independent of regulatory area
- easy update guaranteed through SCC's update service or client's in-house capacity
- instant data access on individual PCs, computer networks or on a global scale, depending on your organisation
- complete regulatory information at hand everywhere you need it, including electronic documents, submission details and project documentation
- flexibility for your specific in-house needs, including integration of already existing databases, guaranteed by SCC specialists

EDDMS can be used for all regulatory submissions: for chemicals (REACH), plant protection products, biocides, pharmaceuticals or consumer products or any other type of product.

For further details please see SCC's flier "EDDMS" at www.scc-gmbh.de under section "Brochures" or contact Dr Friedbert Pistel at friedbert.pistel@scc-gmbh.de.

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PHARMACEUTICALS

Risk assessments and modelling for the pharmaceutical industry

SCC's scientists perform ecotoxicological risk assessments according to current guidelines (e.g. new "EMA guideline") and regulations, and also take into consideration recent developments in the regulatory framework of the European Union.

SCC is well-versed in study monitoring: pre-clinical studies on mammalian toxicology, studies on the environmental fate and behaviour and studies on effects to aquatic and terrestrial organisms. Environmental risk assessments, comparing potential exposure with potential effects, are an integral part of our services.

For further information please contact Dr. Achim Schmitz at achim.schmitz@scc-gmbh.de.

CALENDAR

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

Informa Industry Conference – Agro-Chem Forum, REACH, Biocidal Products, Environmental Risk Assessments

Berlin, Germany 25-26 September 2007

Agrochemicals, biocidal products, REACH, pharmaceuticals, environmental risk assessments: each of these topics will be handled at the industry conference held at the Palace Hotel, Berlin, Germany. SCC staff is also on hand at the exhibition. Come by to talk to us about your specific regulatory needs.

BCPC Conference

Glasgow, UK 15 – 18 October 2007

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 Annex III dossier preparation, EDDMS, and much more.

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

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