Dear Readers,

For our customers we have compiled news and information on events and activities in our regulatory world.

Please read section “Regulatory Science” to get an overview about recent developments in MRL legislation in Europe. Also in this section you will find an article about the project plan for the revision of the current EU Guidance Document on Persistence in Soil. Risk managers and stakeholders were invited to comment the document by March 2008. In addition, you will find an overview on PSD’s new models and guidance documents for the evaluation of operator, bystander and worker/re-entry exposure which can now be used for occupational risk assessments in relation to pesticide registration in the UK.

The revision process for Directive 91/414/EEC has progressed. On 11 March 2008, the European Commission published a revised proposal. The goals of the original proposal were mostly kept, while the amendments incorporated generally clarified the existing text. Moreover, a new ruling on parallel import of plant protection products was published by the European Court of Justice. Please read section “Agrochemicals” for further details. The current status of Annex I inclusions can be found on SCC’s website (www.scc-gmbh.de – Status of Annex I, 91/414/EEC).

SCC attended a two-day workshop on the Revision of the Biocidal Products Directive, which was held on 7-8 April 2008 in Bonn. Further on in section “Biocides”, you will find information on a list reflecting the regulatory status of existing biocidal active substances now available on SCC’s website (www.scc-gmbh.de), which is continuously updated by SCC.

“Chemicals / REACH / Consumer Products” provides you with information on a number of hot topics on REACH, such as pre-registration of substances and the role of the Only Representative.

SCC will soon offer the possibility for downloading free of charge software having significant importance to the regulatory world. Please check section “Data Management” for further details.

SCC has added veterinary medicine to its regulatory department dealing with feed and food additives. Please read section “Feed & Food Additives, Veterinary Medicine” for further information.

News on the regulatory developments in the Rotterdam Convention on Prior Informed Consent (PIC) can be found in “Global Affairs”. Two pesticides – aldicarb and alachlor – are recommended for inclusion to the PIC process.

Also in this issue you will find information on human and veterinarian pharmaceuticals and in “Calendar” an overview on where to meet our specialists.

As in the past, SCC will always be 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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EFSA Project Plan for revision of the current Guidance Document on Persistence in Soil (9188/VI/97 rev. 8)

In January 2008, EFSA introduced a project plan for developing guidance on exposure assessment for terrestrial effect assessment at the EU level in order to revise the current Guidance Document on Persistence in Soil (9188/VI/97 rev. 8). A tiered approach for soil exposure assessments is foreseen, with a simple model based on conservative assumptions serving as Tier 1. For Tier 2, a range of scenarios will be developed representing realistic worst-case conditions for climatic zones (similar to the FOCUS groundwater scenarios) as well as ecological soil properties. Tier 3 is mentioned as an option to use more tailored scenarios (e.g. including crop rotation) but will not be developed in detail.

A Core Persistence in Soil working group has been formed by EFSA that consists of two subgroups (on environmental fate aspects and on ecotoxicological aspects). Besides defining ecozones for EU-27 (i.e. regions with shared ecological properties) and representative species of soil organism guilds, the ecotox experts will determine the ecotoxicologically relevant types of concentrations (ERCs, e.g. soil pore concentrations) that need to be included in the risk assessment. The environmental fate subgroup will develop guidance for the exposure assessment for the selected types of concentrations, and define the role of results of field studies in the tiered assessment. However, the project plan explicitly states that the notifier will have the burden of proof that DegT50 values from field studies are valid for use in risk assessments. As it may be difficult to provide such proof, the use of field data for risk assessment will presumably be limited in the future.

Risk managers and stakeholders were invited to comment on the project plan by March 2008. Once the workgroup has finalised a preliminary draft, one to two workshops will be organised for stakeholder experts before the finalization of the guidance document. At the end of the project, another web consultation is intended. The ecotox subgroup anticipates finishing its activities not later than June 2008. No deadline for the environmental fate subgroup is indicated.

Based on the EFSA project plan efforts for soil organisms, risk assessments may be expected to increase due to laborious calculation procedures and requirements for additional effect tests (e.g. soil pore water testing and inclusion of additional representative species).

New Guidance for Occupational Risk Assessments

The Pesticides Safety Directorate (PSD) has recently provided three new models and five guidance documents for evaluation of operator, bystander and worker/re-entry exposure which can now be used for occupational risk assessments in relation to pesticide registration in the UK.

Operator exposure models now include:

- An amended version of UK POEM, which takes account of new values for inhalation exposure and hand contamination during mixing and loading;
- An exposure model for amateur use, which covers a range of pack types, and
- An exposure model for granule applications (professional) based on the Pesticide Handlers Exposure Database (PHED).

In a new guidance document, PSD indicates the development of a new exposure model for bystanders and residents (BREAM) due to be completed in 2010. For assessing the exposure of bystanders and residents, PSD demands to consider three scenarios:

1. Exposure from spray drift
2. Exposure from inhalation of volatilised pesticides to residents
3. Exposure through contact with contaminated surfaces following re-entry of a child.

PSD referred to model calculations as reported in the draft assessment report for triadimenol.
In a new guidance document on the exposure issues for re-entry worker scenarios, PSD adopted the precautionary approach of using the highest of the dermal absorption values for re-entry exposure assessments. Predominantly this is the dermal absorption value for the spray dilution.

Generic models to predict re-entry worker exposure were adopted from the EUROPOEM II re-entry working group. The use of an initial dislodgeable foliar residue value of 3 µg a.s./cm² per kg a.s./ha was considered appropriate. Furthermore, PSD agreed to use the EUROPOEM II transfer coefficients for potential dermal exposure and made allowance for extrapolation to comparable re-entry scenarios. Consideration of PPE for workers is only appropriate if it is worn habitually.

In conclusion, PSD enhanced the database for operator exposure scenarios and provided a basis for the assessment of bystander and re-entry worker exposure to pesticides. Please refer to the PSD website for further information on the changes (http://www.pesticides.gov.uk/approvals.asp?id=2426).

**Update on MRL issues in light of Regulation 396/2005**


Updates to Annexes II, III (part A and B) and IV to Regulation (EC) 149/2008 were published on the European Commission’s (EC) website (http://ec.europa.eu/food/plant/protection/pesticides/index_en.print.htm). These MRLs will become applicable from 1 September 2008.

Regulation 299/2008 dated 11 March 2008 was also published, providing a new role for the European Parliament (EP) in scrutinising proposals for new or modified MRLs under Regulation 396/2005. A period of two months will be allowed for the EP to consider such proposals.

Annex VII of Regulation 396/2005 was established by Regulation 260/2008, which was published on 18 March 2008, entering into force on 8 April 2008.

Taking into account Articles 12(1) and 12(2) of 396/2005, it is EFSA’s task to evaluate the MRLs as set in Regulation 396/2005. To do so, a database will be compiled comprising all data related to residues and MRLs. As EFSA has to submit its assessment within 12 months after entry into force of the Regulation on 1 September 2008, it is possible that the support of the notifier will be needed to hold the timeline. Notifiers should be prepared to provide the necessary data to the authorities.

With respect especially to the German authorities, it has to be noted that they are meanwhile implementing the MRL Regulation 396/2005, i.e. if an EU-MRL should be modified, the notifier should apply immediately for such measures. For this procedure a specific application form has to be used. This form can be found on the Internet at “www.bvl.bund.de - Pflanzenschutzmittel - Für Antragsteller - Höchstmengenverfahren” (plant protection products – for applicants – MRL process). The documents should be filed in duplicate. Submission of a CADDY dossier would be preferred. The same procedures as for MRLs have to be followed for import tolerances. For a currently running registration process, an MRL application needs not to be filed. However, for all new submissions, the MRL application has to be considered. This is relevant for all Member States. Therefore, it should be emphasized that an MRL has to be set before a registration will be granted.

For further details, please contact Dr. Monika Hofer at monika.hofer@scc-gmbh.de.
Modified proposal for revision of Directive 91/414/EEC


With regard to the points discussed below, the amendments did not change any major pillars in the COM’s original position. Contradictory parliamentary suggestions which aimed at changing the system were mostly rejected. Amendments incorporated generally clarified the text from the technical or editorial viewpoint, for example clarifications of definitions.

For category 1 and 2 substances in the hazard-based approval system for actives, the COM accepted the modification that “a substance cannot be approved unless exposure is negligible.” Further on, the EP proposed including additional approval criteria. The COM refused to accept the modifications but incorporated the clarification “…that neurotoxic and immunotoxic substances should be approved as candidates for substitution…” allowing substitution of the corresponding products with a safer alternative, if available.

The COM kept the compulsory mutual recognition system in three zones. Any contrary proposal to this key element was rejected. As the text stands, Member State authorities currently only have the right to “impose stricter national measures for worker protection.”

As in the initial proposal, the COM refused to introduce national provisional approval for plant protection products on Member State level because it is incompatible with the zonal authorisation system.

As one of the few new rules, a provision on parallel import was inserted (Article 49a), which defines that the parallel import and the reference product must come from a common origin (Art 49 a (3)).

The next step in the revision process is slated for 19 May 2008, during the next meeting of the Agricultural Ministers on Council level: there, political agreement is expected followed by the common position, which is anticipated in July 2008. If the Council and the European Parliament cannot agree on a compromise during the first reading to be completed with the common position expected in July 2008, the second reading process in the European Parliament is expected to start in September 2008. As pointed out by EU officials, it is the objective of the Council’s Slovenian presidency to complete the new pesticide legislation by the end of this year, including the proposed Framework Directive on the Thematic Strategy on the Sustainable Use of Pesticides. The new law will be applied eighteen months after entry into force of the new Regulation replacing Directive 91/414/EEC.

New ECJ ruling on parallel import of plant protection products: proof of “common origin” required in the future?

Parallel imported plant protection products (PPP) must be identical to a PPP already authorized in the importing Member State (reference product). A Guidance Document from the European Commission (COM) defines which products are identical. The paper takes into account several ECJ (European Court of Justice) cases: for example, C-112/02 “Kohlpharma” clarified that authorizations for parallel imports cannot be refused based exclusively on the fact that the two products don’t come from a common origin.

On 21 February 2008, the ECJ published case C-201/06, COM against France. France required a “common origin” proof for a PPP to be parallel-imported and the reference product already authorized in France. From the COM’s point of view, France acted against current law (case “Kohlpharma”) with this requirement. However, the ECJ ruled in this case that France did not violate its obligations.

For the PPP industry, this means it is acceptable to the ECJ for Member States to request “common origin” for the authorization of a parallel-imported PPP, although the “Kohlpharma” case had a different conclusion. The future (see Art. 49a of the new Regulation replacing Directive 91/414/EEC) will show if proof of common origin will be a pre-condition for further parallel imports of PPP into EU territory, resulting in a possible revision of the existing parallel import rules.

For further details, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de.
Bonn Workshop on the Revision of the Biocidal Products Directive

Dr. Hans-Josef Leusch, Dr. Michael Werner and Dr. Holger Zitt attended the two-day workshop on the Revision of the Biocidal Products Directive (BPD), held on 7-8 April 2008 in Bonn. This event was organised by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in order to provide a forum for discussing key elements of the planned revision of the biocides directive. Amongst the stakeholders invited to the workshop were representatives of the Member States Competent Authorities, the Commission, industry, consultants and NGOs. SCC was partially involved in organising the workshop. The workshop was divided into four sessions.

In the first session, Pierre Choraine (Commission, Directorate General Environment) gave an update of the Commission’s ongoing work regarding the revision of the biocides directive. At the end of 2008, the Commission will present a proposal for a revised biocides legislation, which is likely to come into effect by the end of 2011 / beginning of 2012. As currently discussed in the sector of plant protection, it is most likely that the Commission will propose repealing the Biocidal Products Directive by means of a new regulation. Furthermore, the review program on existing biocidal active substances will be extended for a period of at least two years.

Stefan Gartiser (Hydrotox) then summarised the results of the BPD impact study and presented an overview on the tasks and objectives on the impacts of the revision of the BPD.

In the second session an introduction to the five key issues discussed in different working groups by means of short presentations was presented; Working Group 1 “Do we need to streamline the scope of the BPD?”, introduction by Matti Sander (BAuA); Working Group 2 “Adequate use and protection of data”, introduction by Jürgen Gutknecht (Bactria/VCI); Working Group 3 “Product authorisation”, introduction by Frank van Herwijnen (VROM, the Netherlands); Working Group 4 “Appropriate data requirements”, introduction by Holger Zitt (SCC); Working Group 5 “Do we need a higher level of protection?”, introduction by Esther Pozo (Milieu).

In the third session, the five key issues listed above were discussed in parallel working groups. The working groups were chaired exclusively by representatives of national authorities. As a guideline for the discussion, the Ministry of the Environment had distributed background papers one week prior to the conference.

Details on the outcome of the discussion in the working groups are available upon request.

The next conference on the agenda of the revision of the Biocidal Products Directive is a stakeholder workshop, organised by the Commission, to be held on 23 May 2008 in Brussels.

New service available on the SCC internet site

A list reflecting the regulatory status of existing biocidal active substances is now available on SCC’s internet site and is being continuously updated. Just click on the link “Status of Annex I, 98/8/EC” on the SCC homepage. A biocidal active substance can pass through three different states: the status "in" indicates that a substance-product type combination is included in Annex I or IA of Directive 98/8/EC. If a substance-product type combination is "out”, it indicates the existence of a legally binding decision not to include that combination in Annex I or IA of Directive 98/8/EC. Finally, "pending" means that a substance-product type combination is either currently being evaluated (Part A-C) or has not yet been evaluated (substances in Part D for which dossiers have to be submitted by 31 October 2008 at the latest). By using the filters, the list can be searched either for the name of the active substance, the different parts of the review program, or selected product types. Links to the relevant legal documents are also available in the list and can be retrieved by a simple click. To view the list and search for substances, go to www.scc-gmbh.de and follow the link “Status of Annex I, 98/8/EC”.

For more information, please contact Dr. Holger Zitt at holger.zitt@scc-gmbh.de or Dr. Hans-Josef Leusch at hans-josef.leusch@scc-gmbh.de.
Pre-Registration: the pre-registration phase starts 1 June 2008. Potential benefits of pre-registration include making use of extended registration periods and information on other potential registrants. Only through pre-registration is the preparation and submission of registration dossiers without interruption of manufacturing or importing legally possible.

Pre-registration is possible for all EINECS substances, no-longer polymers (NLP) and substances manufactured but not placed on the market (15 year period), as such, in preparations or in articles (with intended release) in volumes of 1 ton per annum or more. Depending on the volume range and risk profile (critical are CMR and N classification and labelling), registration deadlines can be extended to 2010, 2013 or even 2018. Pre-registration is free and provides valuable time for preparing registration dossiers.

However, only legal entities established in the EU can pre-register. For each substance and each legal entity, a separate pre-registration needs to be filed. Note that registration following pre-registration is not mandatory and bear in mind that only through Third Party pre-registration and registration is your identity kept confidential!

The pre-registration period starts on 1 June 2008 and lasts until 1 December 2008. Please do not hesitate to contact SCC for your REACH pre-registration, registration and Third Party needs.

Only Representative: the Only Representative is a great option for non-EU manufacturers to continue to market chemical products in the EU, while keeping full control over the REACH process. Pre-registrations and registrations can be filed without passing confidential business or product information to customers and/or competitors. Exports to the EU via formulators and distributors in non-EU countries are possible for transparent volume transfers.

From 1 June 2008 only chemical substances registered under REACH can be marketed in the EU in volumes of one ton or more. However, non-EU manufacturers are not legally authorized to register. For non-EU manufacturers, registration is only possible through a subsidiary established in the EU, the importer, or alternatively, an Only Representative. The first two options possibly require confidential business or product information to be made public. In contrast, the Only Representative allows for full control of the registration process and complete confidentiality through Third Party status.

Please do not hesitate to contact SCC for Only Representative services and keep full control over your REACH registration process.

New Substance Registrations under REACH: without REACH registration, no chemical substance as such, in preparations or in articles (with intended release) in volumes of one ton per annum or more may be manufactured, imported or marketed in the EU. Once accepted by the European Chemicals Agency, a registration is valid throughout the entire EU, and registered substances can be marketed in all Member States. However, registrations are valid only for a specific substance and are assigned to only one registrant.

Substances registered with ELINCS are automatically assigned a REACH registration number. This includes new substance notifications for substances in volumes of less than one ton per year. The status of the notifier of the new chemical substance automatically changes into that of a REACH registrant. Only when reaching the next tonnage threshold is further action required.

Please do not hesitate to contact SCC for your REACH registration needs.

Registration Fees: on 16 April 2008 EU Directive 340/2008 was finalised. The Directive lays down fees for the registration of chemical substances under REACH. Note that pre-registration for REACH is free. Further, to alleviate the burden on small and medium sized companies, fees are reduced according to company size and business volume.

However, costs for claiming confidentiality for business information or study data are considerable! The Agency levies a fee per item for which a request is made. This includes requests concerning study summaries or robust study summaries, in which case a fee is levied for each study summary or robust study summary for which the request is made.

For more information, please contact Dr. Werner Köhl at werner.koehl@scc-gmbh.de.
SCC offers new service tools for clients

On our website (www.scc-gmbh.de) we will soon offer our clients and interested public the chance to download free-of-charge software for programs with high importance to our regulatory world.

In order to register plant protection products, many national authorities require CADDY dossiers. Specific software is necessary to make data generated in this format readable. Our in-house specialists are developing a new CADDY retrieval software which will simplify your life. SCC's “CADDY Viewer” will enable users to display CADDY dossiers in a modern and user-friendly way. We will inform you as soon as the free-of-charge “CADDY Viewer” download is available.

In addition to this service, our website will offer free-of-charge access to a demo version of SCC's universal regulatory database “Electronic Document and Dossier Management System” (EDDMS). The demo version provides an overview of how EDDMS supports our clients in managing the necessary documents needed to register chemicals all over the world. It can be used for all regulatory submissions: for chemicals, plant protection products, biocides, pharmaceuticals, consumer products, feed and food additives or any other type of product. Our customers who are already using EDDMS will soon be offered the possibility to obtain updates via SCC's website directly.

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

Inclusion of Veterinary Medicine

After the introduction of the new Regulatory Department Feed & Food Additives at SCC, we have now also included Veterinary Medicine into this regulatory area. The requirements for the registration of veterinary medicines is of course quite different, but SCC has already done specific work in this area in the past (mainly environmental risk assessments). A great advantage is that SCC (with Ruud Huibers) now has many contacts into the veterinarian world, both in the industry as well as in the governmental area. In addition, SCC regularly attends training workshops all over the world to further develop our knowledge.

The presentation and content of a dossier for veterinary medicine is well described in a 190-page document published in 2004 by the European Commission. In 2007, some additional documents were published, giving a full perspective of the information requirements for a dossier. The content of a Veterinary Medicine dossier basically includes administrative, technical, quality, safety and residue, and efficacy documentation. These aspects are within the realm of SCC's almost 20 years of experience. Independent expert reports are a vital aspect of the dossier and exactly this is one of SCC's core competencies.

Status Feed Additives

Within the area of Feed Additives, SCC is fully involved in the major process of re-authorization of all substances before the deadline of November 2010 (dossier for a few thousand substances have to be made). The final guidelines from the European Commission are expected to be published in May/June of 2008. SCC has a template with the specific needs of the dossier, based on the category of feed additive we are dealing with and some other basic questions that will decide the final content of a certain dossier (a full dossier is rarely needed, many exemptions of information are possible).

If you have any questions relating to these subjects, please contact Ruud Huibers at ruud.huibers@scc-gmbh.de.
Two new chemicals are recommended to be added to the PIC process

The Rotterdam Convention on the Prior Informed Consent (PIC) (www.pic.int) is a multilateral agreement which controls and monitors the trade with certain hazardous chemicals on an international basis. It is run under the umbrella of the United Nations Environmental Program (UNEP).

The prior informed consent system was set up in order to “empower countries to take informed decisions on the import of hazardous chemicals in order to minimize the risks posed to human health and the environment.” Currently there are 28 pesticides and 11 industrial substances listed in the PIC procedure.

On 13 March 2008, an international expert group within the Rotterdam Convention proposed to include two additional pesticides to the PIC procedure: aldicarb (insecticide) and alachlor (herbicide). Both substances are used in important crops on a worldwide basis.

Via an administrative process, substances can be added to the PIC procedure through the official bodies of the convention. If two countries from two different world regions ban or severely restrict the same substance, they independently inform the convention’s secretariat. In correlation with the secretariat, an international group of experts verifies these notifications and proposes a draft decision to the Conference of the Parties (COP), where all members are represented. Through voting, COP delegates decide if a chemical will be added to the convention or not.

If after the COP vote the substances are included to the PIC procedure, the importing countries must decide if they want the substances to be imported into the country or not. The national authorities must take this decision before the import can go ahead.

For further questions on environmental risk assessment and study programs for veterinary medicinal products please contact Dr. Achim Schmitz at achim.schmitz@scc-gmbh.de.

For further information please contact Ruud Huibers (ruud.huibers@scc-gmbh.de) or check the section Feed & Food Additives, Veterinary Medicine in this newsletter.
Stakeholder Workshop on the Revision of the Biocidal Products Directive
23 May 2008, Brussels, Belgium
The Stakeholder Workshop on the Revision of the Biocidal Products Directive, sponsored by the EU Commission, will be held on 23 May 2008 in Brussels. Four sessions dealing with issues that have arisen during the implementation of 98/8/EC (the Biocidal Products Directive) are included in the agenda, highlighting simplified procedures and data requirements, data sharing and protection, product authorization and fees, and scope issues - treated objects and relationship between biocides and other legislation. Dr. Holger Zitt, Senior Manager Regulatory Affairs, Biocides, will attend this workshop.

PSD MRL Seminar/Workshop: From Risk Assessment to Risk Management
21 May 2008, York United Kingdom
Dr. Monika Eder and Stefanie Schumacher of the Regulatory Science Department will be on hand at this training dealing with Maximum Residue Levels.

SETAC Europe 18th Annual Meeting
25-29 May 2008, Warsaw, Poland
The 18th Annual Meeting of SETAC Europe is Europe's leading environmental toxicology and chemistry conference and will focus on scientific and applied issues of different stressors in the present world. Sandra Seimer, Dr. Ingo Loeb and Heike Schimmelpfennig will take part in this meeting.

European Pesticide Residue Workshop
1-5 June 2008, Berlin, Germany
The objective of the workshop, the premier European meeting for the presentation and discussion of the latest concepts and developments in the field of pesticide residues in food and drink, is to exchange information and experience, and bring together analytical chemists, quality managers, pesticide regulators and other scientists. Dr. Jutta Goerg and Dr. Alexander Koehl will attend this workshop.

PSD Technical Training Day - Technical Equivalence & Analytical Methods
17 June 2008, York, United Kingdom
The UK's PSD is sponsoring a one-day workshop dealing with technical equivalence and analytical methods. Dr. Jutta Goerg and Cordula Nieslony will be at this workshop.

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.