Newsletter

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SCC's New Headquarters:
Relocation to Bad Kreuznach effective 1 January 2011

I am pleased to announce that SCC is relocating to our new headquarters building located in the spa town of Bad Kreuznach, Germany, only a few kilometers away from our site in Wendelsheim.

Within just 8½ months, our new building, consisting of more than 5000 m^2, was erected. Our new location offers an extensive infrastructure nearby, excellent access to major highways leading to Frankfurt Rhein-Main Airport and Frankfurt-Hahn Airport, and national and international rail connection to Mainz, Cologne, Frankfurt and other European cities. In addition, we have the possibility of hosting seminars and conferences in our conference room (seating up to 150), as well as providing our customers with state-of-the-art technology in our regular meeting and conference rooms. Considerable archiving space, allowing for not only regulatory archiving under EDDMS, but also for our officially certified GLP archiving segment, all under controlled environmental conditions, is another feature of our new headquarters. Energy efficiency and observation of ecological standards are also important aspects of our new building.

Most importantly: although our location is changing, the quality and service that you know and have come to expect with SCC will not change. This is my personal promise to you.

Please note that starting from 1 January 2011, SCC will have a new mail address and new telephone numbers, whereas our e-mail and internet addresses will remain the same. For more details, please go to our internet site www.scc-gmbh.de. We will give you more information shortly in a special edition of our Newsletter.

Although we are in the final stages of preparing our relocation, we remain fully at your disposal to provide you with high quality regulatory and scientific consulting.

In this year's last edition of the newsletter, you will find the latest news from agrochemicals, biocides, chemicals, food and feed additives, veterinary medicinal products and regulatory science.

I hope you will find this edition of the newsletter interesting and helpful. For any questions, feedback or needs for specific consulting, please contact us at our offices in Bad Kreuznach or at our SCC Liaison Office Japan.

Dr. Friedbert Pistel
President

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AGROCHEMICALS

AgCHEM Forum 2010

The presentations given at this year's AgCHEM Forum held in Lyon on 8 and 9 September 2010 spanned a wide rage of different topics, starting with the public concern about the safety of plant protection products to the new Regulation (EC) No 1107/2009 and the Sustainable Use Directive (Directive 2009/128/EC), as well as the Water Framework Directive (Directive 2000/60/EC).

In the opening session, today's concerns about the use of pesticides in Europe were addressed. The three speakers emphasized that there is a need for high public confidence into the use of pesticides. They pointed out that pesticides are not only used in the crop sector, but also in non-crop sectors such as roads, runways and railroad tracks, where they are indispensible for maintaining public safety. Concerns were expressed that plant protection products which were considered to be safe under Council Directive 91/414/EEC, might be forbidden under the new Regulation. This might confuse the public perception of plant protection product safety. The speakers agreed that integrated pest management will increase the acceptance of pesticide use in general, although there will be more demand for non-chemical pest management and pesticide use will decrease under the new Regulation (EC) No 1107/2009.

An invited speaker from the Pesticide Action Network (PAN) was unfortunately not able to attend the conference and present PAN's views on the subject.

The speaker from the German Federal Institute for Risk Assessment (BfR) emphasized that the German authority has published arguments as to why the risk-based assessment should be maintained and no switch to a hazard-based assessment should be made. He presented proposals on how to interpret the concept of negligible exposure outlined in the new Regulation (EC) No 1107/2009. To this effect, a threshold to toxicological concern (TTC) could be used. Also, the acceptable limit of exposure could be reduced to 10 % or 1 % of the ADI, the ARfD or the AOEL. A further possibility would be to modify the assessment factors of exposures, such as the NOAEL, as has already been done by US EPA for many years.

In presentations on the zonal approach, it was emphasized that the risk assessments and efficacy data must be considered together. It would not be acceptable to achieve a very low and acceptable risk if only the amount of active substance applied was lowered below the threshold of efficacy.

Further points raised include:

- In the case where no authorization is granted by the Zonal Rapporteur Member State based on specific national requirements, the other Member States in that zone should be able to continue their evaluation and grant national registrations for their territories. A technical issue of concern in this context is the requirement, set by the new Regulation (EC) No 1107/2009, to submit a copy of the authorization document of the Zonal Rapporteur Member State to the other Member States.
- If registration is only sought in one Member State, the assessment must nevertheless be made available to all Member States in the zone for commenting, as Article 36 of Regulation (EC) No 1107/2009 requires this
- If there are disagreements between the Zonal Rapporteur Member State and other Member States on regulatory issues, they should be solved on a bilateral basis and reported transparently in the reporting tables.

SCC presented the legal background on the setting of risk envelopes. Furthermore, considerations on how to arrive at worst-case estimates in the areas of environmental fate and toxicology were shown. It was concluded that the risk envelope could be counter intuitive.

In a presentation on data protection, it was proposed that the Commission should present a guidance document on the vertebrate data sharing provisions as part of a timely, robust and transparent compliance process.

The comparative risk assessment and the substitution principle will increase the number of new active substances. In particular, more progress is needed in the development of new modes of action. It was the speaker's (Ireland) interpretation of Regulation (EC) No 1107/2009 that the comparative risk assessment is to be done by the Zonal Rapporteur Member State. According to the speaker, it is unclear whether a Member State can mutually recognize a registration from another Member State without again applying the principles of comparative risk assessment and substitution.

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In the presentation on Annex I renewal, it was emphasized that most of the points raised during the AIR-1 project have been incorporated into the AIR-2 Regulation, which is expected to be voted on in September 2010. The evaluations for AIR-2 will take place under the regime of the new Regulation (EC) No 1107/2009. Future submissions for the Annex I renewal shall reflect a representative pattern of use wherever possible, employing a risk envelope approach. Only an overview over the efficacy data is to be included into the re-submission.

After Annex I re-inclusion, the notifier is allowed only three months to apply for renewal of product registrations. It was emphasized that in these product registrations only new Annex III data is to be included.

AIR-3 will cover all the substances that expire between 2013 and 2018 (i.e. 173 active substances).

With respect to legal issues of Council Directive 91/414/EEC and the new Regulation (EC) No 1107/2009, it was emphasized that while data sharing applies to all studies(Articles 61 and 62), forced use of studies is only foreseen for vertebrate studies. Data compensation will remain a Member State issue.

Referring to Article 4 of the new Regulation (EC) No 1107/2009, it was pointed out that endocrine disrupting properties alone are not a sufficient cut-off criterion.

A number of presentations highlighted the latest developments on MRL issues. It was agreed that the setting of private MRLs (i.e. MRLs set by retailers, usually at levels below the official value) is undermining the public trust into the legally set MRLs.

The currently ongoing discussions on methodology for acute consumer risk assessments were presented. For example, the highest residue (HR) could be replaced by the MRL, which would make the calculations more conservative. In addition, a change in the variability factor (VF) is being considered. Finally, new MRL classes are set in SANCO 10634/2010 replacing the currently valid guidance document. As these new MRL classes contain more intermediate values, they will result in setting lower MRLs compared to the current practice.

OECD is currently revising its MRL setting methodology. In general, the OECD methods of setting MRLs lead to higher MRL values compared to the European methods.

The residue behavior of nano-materials is also of concern. The PPR panel cannot at present give a definite statement on whether or not the data requirements as laid out in Annex II and Annex III are sufficient to estimate the risk arising from the use of nano-pesticides.

In harmonizing the residue zones with the zones laid out for the zonal evaluation of the new Regulation (EC) No 1107/2009, Romania and Slovenia will move from the Southern residue zone into the Northern residue zone. France is currently checking whether it will stay in two separate residue zones. The number of residue zones will remain at two.

It is now acceptable that up to 50 % of the residue trials submitted can be conducted outside of Europe, assuming the GAP and the production conditions are comparable.

The following new guidance documents are under preparation:

- Residues in honeys (by France)
- Metabolism in fish (based on OECD 503, which needs to be modified significantly)
- Residues in fish.

Residue setting was explained from the residue side as well as the toxicological side. It was pointed out that in the dietary risk assessment, mixtures of pesticides should be taken into account, especially when such mixtures have synergistic effects. Nevertheless, the very high safety margin in setting MRLs was emphasized.

One speaker pointed to the fact that the requirements of providing residue data over two climatic seasons was historically a national requirement and should be reconsidered where zonal trials are widely dispersed.

Article 55 of the new Regulation (EC) No 1107/2009 makes explicit reference to the Sustainable Use Directive 2009/128/EC. Consequently, presentations were made regarding the impact of this Directive on the registration of plant protection products. France has introduced a national action plan deriving from the Sustainable Use Directive with the expressed aim of reducing the pesticide use by 50 % over the next ten years. The reduction will focus especially on pesticides where there is toxicological or ecotoxicological concern.

It was emphasized that the Sustainable Use Directive must be carefully implemented at national and European levels to complement, and not to undermine, the placing of plant protection products on the market as expressed in Regulation (EC) No 1107/2009.

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Finally, the impact of the Water Framework Directive, also being explicitly mentioned in the new Regulation (EC) No 1107/2009, was presented. This Directive calls for river basin management plans, which were due in 2009, but which have not yet been delivered by a large number of countries. The speaker pointed out that the limits of pesticides in groundwater are set to 0.1 µg/L as a single pesticide and to 0.5 µg /L for all pesticides present. Findings where drinking water in the UK was of poor quality, was only due to pesticides in 11 % of the samples assessed.

Alert and Watch Lists of Dangerous Pests - Update 2010 – Adaption of Uses and GAPs

As every year, and again in 2010, there were various changes in the alert and watch lists for plant pests and invasive plant species worldwide.

Because of their high potential for spreading and economic damage, two of the most notable plant pests in 2010 are the Spotted Wing Drosophila (*Drosophila suzukii*) and the 'Tomato Leafminer' (*Tuta absoluta*). Unlike most other Drosophila species, *D. suzukii* is able to feed on healthy ripening fruits still attached to the plant. The Spotted Wing Drosophila, a pest of fruit crops native in Asia, was introduced into Europe and North America in 2008 and 2009. In 2010, the insect was found in France (Alpes-Maritimes) and in Italy (Toscana) for the first time. It was added to the EPPO Alert List in 2010 and a Pest Risk Analysis (PRA) is planned.

In North America, the Spotted Wing Drosophila was described in California in 2008 for the first time and spread to five other US east and west coast states (NAPIS) as well as to Canada by 2010. Methods for field and post-harvest control of the Spotted Wing Drosophila are mostly lacking at the present time. On the other hand, various control strategies for the Tomato Leafminer (*Tuta absoluta*) are currently being investigated.

Tuta absoluta originates from Latin America and was introduced e.g. into Europe (first recorded in Spain in 2006), Northern Africa (Algeria, Libya, etc.) and the Middle East (Iraq) over the last few years. In 2010, first reports from Bulgaria, Cyprus, Germany and Iraq were published. In the Mediterranean Basin alone, 15 million tons of industrial tomato are endangered. Various export restrictions for countries with *Tuta absoluta* outbreaks are already in force. Special problems exist because, in its native countries, high-level field resistance of this moth against a variety of old and new classes of insecticides such as organophosphates or pyrethroids is widespread.

Continuous changes in distribution, damage potential or resistance of plant pests require a sustained adaption of uses and GAPs of plant protection products. If you wish to receive an update to the watch and alert lists specifically for your active or product, or if you wish your product to be tested against new pests, let SCC take care. For information on pest updates, planning of study programs, study monitoring, data analysis and dossier generation, all the way to the registration of your product, please do not hesitate to contact us.

CRD conference on Regulation (EC) No 1107/2009

On 19 October 2010, the British authority CRD invited interested parties to come to York (UK) for another conference on the new Plant Protection Products Regulation.

The new regulation, which was published on 24 November 2009, entered into force on 14 December 2009 and will apply starting 14 June 2011. It will have an impact on the approval of active substances, safeners and synergists on the one hand, and on the authorization of plant protection products on the other hand.

Besides discussing the main provisions of the regulation, as for example cut-off criteria, comparative risk assessment and candidates for substitution and zonal product authorizations, the focus of the conference was also on managing the transition from the "old" Directive 91/414/EEC to the "new" Regulation (EC) No 1107/2009. In other words: what will happen on 14 June 2011? In this context the transitional arrangements (timelines, procedures) are an important issue that will be decided on further under national law (Art. 80 of regulation). In order to avoid different "national interpretations" of the transition process, and thus to achieve a harmonized procedure, the Member States intend to discuss this topic more in detail during Standing Committee meetings, internal workshops, etc. within the next six months.

In their concluding statements, representatives of the CRD pointed out that the new regulation is not to be seen as a stand-alone instrument, but rather interpreted in the context of other existing systems related to plant protection products, such as the Sustainable Use Directive, the Machinery Directive, the Statistics Regulation or the EU Water Framework Directive.

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If you are interested in more details on the proceedings and the outcome of the conference, please feel free to contact us.

Future opportunities and risks for the biocontrol industry

The impression of the Annual Biocontrol Industry Meeting (ABIM) in Lucerne (25 and 26 October 2010) was the general sanguinity of the participants. This is especially true for conference sessions destined for the presentation of new products. However, the importance and the future opportunities of biocontrol were highlighted in sessions dedicated to regulatory issues and R&D.

The main points of several presentations were the implications of Directive 2009/128/EC and Regulation (EC) No 1107/2009 regarding the sustainable use of pesticides and the implementation of IPM standards, as IPM is giving priority to non-chemical methods in general. Mr. Heilig (IBMA) focused his presentation on the provisions of Directive 2009/128/EC for National Action Plans (NAPs). Central issues are the definition of the objectives, targets and measures to achieve a sustainable use of pesticides and the implementation of Integrated Pest Management (IPM). According to the speaker, only some Member States (MSs) currently already have a draft or a finalized version of NAPs. For most MSs the release of an NAP is expected in 2010, and five MSs have still not indicated a date for the release of a NAP. Deadline for the submission of NAPs to the Commission and other MSs is 26 November 2012. The revision of NAPs must be finished in 2017 at the latest. Legislative proposals *mutatis mutandis* are to be expected after the report of the Commission to the European Parliament and the Council in 2018. Different approaches of NAPs were presented using the two exemplary NAPs from France and Germany. Whereas the main objective of the French NAP is the quantitative reduction of pesticide use by 50 % within the next 10 years, the German NAP is focused on risk reduction. This reduction is fixed at 25 % by 2020. In the same context, MSs have to report to the Commission on measures for low pesticide input by 30 June 2013 because IPM must be implemented by all professional users by 1 January 2014. Regarding the new legislative acts, Mr. Heilig highlighted the huge opportunity for the biocontrol industry and organic farming. His view was supported by the presentation of Ms. Pitton (DG Health & Consumers). Ms. Pitton emphasized the need for integrating the efforts of all parties involved to be able to achieve the ambitious objectives stipulated by the new acts of legislation. This is also due to the fact that the legislative process is not completed yet.

Mr. Bolckmans (Koppert Biological Systems) even went further, recalling that one of the driving forces of reduced pesticide use and food safety was food retailing, implementing extra-legal requirements such as black-listed pesticides or safety margins for MRLs. The speaker concluded that food retailers will bring sustainability into the discussion in addition to food safety aspects, thus enhancing future requirements for food producers as well as increasing the opportunities for the biocontrol industry.

Regarding future requirements, the procedure of Access and Benefit Sharing (ABS) and the possible implications of the CBD COP10 conference in Nagoya were discussed by Mr. van Lenteren (Wageningen University, IOBC) and Ms. Maric Fasel (Swiss federal Office for Agriculture). Mr. van Lenteren advanced the opinion that ABS can become a serious problem for biological control if (future) ABS regulations do not recognize the specific features of biological control (compared e.g. to the pharmaceutical or seed industry). The commission on biological control, access and benefit sharing of IOBC Global wrote a report to comment on these issues (FAO background paper no. 47). The main objectives are that organisms in biological control are not patented and the information about biological control agents used is publicly shared. Additionally, there are societal benefits for using biological control. On the other hand, he emphasized the need for the biological control community to attend more closely to ABS in future.

Another general topic of discussion was the need to find new ways for screening, registration and commercialization of biopesticides to be able to develop tailor-made BCAs in a market-driven, quick and cost effective way. Mr. Köhl (Plant Research International) additionally presented results of a thorough investigation on the current procedures in developing commercial products. He concluded that it is necessary to modify the developmental process and use a step-wise approach to avoid expensive field testing with unsuitable organisms, for example. For that commercial questions have to be considered early during evaluation of potential BCAs. A similar view was advanced by Mr. Miille (AgraQuest) who also proposed a new model for the rapid lead evaluation. Ms. Marrone (Marrone Bio Innovations) picked up these topics and presented

examples in which some innovations in the developmental process are already applied by industry. All speakers stressed the need for a closer collaboration between industry and scientific research. In her presentation Ms. Gwynn (Rationale Biopesticide Strategists) expanded this view even further. In order to be able to develop the next generation of biocontrol technology, research is needed regarding various topics such as systemic activity (e.g. endophytic activity), plant interactions and many more. As Mr. Avé (Valent BioSciences Corporation) additionally discussed in his presentation, this is also true for the development of quality standards. To point out the need for the development of quality standards, the speaker pointed out a study conducted with various BT-products. In this study, huge differences in the content of actives as well as amelioration of BT-products with chemical pesticides were proven. To prevent those cases which negatively affect the whole biocontrol industry, all parties have to work together to ensure a certain level of product quality.

As already mentioned, there was a general consensus that there are huge opportunities for biological control in the future. Mr. Devanur (Bio-Agri Inputs Producers Association) centralized this issue in his presentation. The need for new biological plant protection products outside the EU was additionally highlighted for Brazil and Africa in the presentations made by Mr. Bueno (Federal University of Lavras) and Ms. Helbig (COLEACP).

AIR-2 Regulation published

The procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC (COM Regulation (EU) No 1141/2010) was published on 8 December and will enter into force on 28 December 2010 (see the SCC website "News" to read the Regulation. This "AIR-2" evaluation process (Annex I Renewal – 2nd group of active substances) involves a number of tasks including data analysis, acceptability review of mandatory studies, completeness check, evaluation of cut-off criteria, application including the updating statement, establishment of work programs. And, because application has to be submitted to RMS and Co-RMS by no later than 28 March 2011, it is important to start data analysis and the preparation of the application now!

Let SCC help you with your AIR-2 submission program!

SCC's experience with 91/414/EEC dossier submission and defense is second to none. The numbers speak for themselves:

- 39 substances defended under 91/414/EEC – 36 existing, 3 new
- 25 inclusions in Annex I
- 10 pendings / re-submissions after withdrawal of List 3 substances
- 4 non-inclusions (based on political or commercial considerations)

Take advantage of SCC's expertise and assistance with your AIR-2 substances. We offer you:

- Completeness check, data analysis, acceptability review of mandatory studies and the establishment of work programs
- Preparation and submission of application including updating statement
- Pre-submission contact with the RMS and co-RMS
- Dossier preparation for the renewal
- Submission of the dossier

If you have actives covered in the AIR-2 Regulation, contact us for more information regarding our services for AIR-2 submissions.

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

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BIOCIDES

News from biocidal products authorization

The EU authorization system for biocidal products is emerging with more and more active substance being included in Annex I of the Biocidal Products Directive 98/8/EC. In 2010, a total of nine biocidal active substances were included in Annex I. This does not sound like much, but if you have a look at the applications for authorization of biocidal products, the numbers become more impressive: in September this year, the Register for Biocidal Product (R4BP) – the Commission's electronic database which is recommended to be used in order to generate applications for biocidal products authorizations – contained roughly 3,000 entries. Currently, the Commission plans a re-launch of the R4BP to be ready in June 2011. The new version of the database will not only have a greater capacity to cope with the next wave of applications in 2011, it will also have new features.

Comprehensive guidance on product authorization –the "draft Evaluation Manual"

On the EU level, there is work currently ongoing that aims at developing a harmonized Evaluation Manual concerning the authorization of biocidal products. This manual is intended to be used in the future by the competent authorities for biocides when evaluating applications for the authorization of biocidal products. The Dutch competent authority for biocides (the Ctgb) has initiated this work because there has been a pre-marketing authorization system for biocidal products in place in the Netherlands for a long time. The Ctgb prepares and regularly updates the regulatory procedures and data requirements in their Dutch Handbook for the Authorization of Pesticides. The most recent update of that handbook was translated into English and made available to the other Member States under the working title "The Evaluation Manual". After first discussions at TM II/2010 (14-18 June 2010), it was decided to streamline the draft guidance documents more to ensure a smoother discussion. In a first step, the efficacy, human toxicological and environmental part will be re-drafted. In a second step, the identity, physchem and analytical methods parts will be re-issued in early 2011. SCC is involved in commenting the draft guidance documents on behalf of Cefic.

Changes to product authorizations – Commission to propose a draft Regulation

After authorization to place a biocidal product on the market, there are different circumstances that will require a modification or a change of that authorization (e.g. a change of the address of the authorization holder or a change in the composition of the product). As the current legislation does not provide any detailed rules on handling such changes, and with a view to authorizations that were granted based on mutual recognition, a common legislative approach for handling such changes is needed. At the December meeting of the PA&MRFG (Product Authorisation and Mutual Recognition Facilitation Group), the Commission presented for the first time a draft "Commission Regulation concerning changes to the terms of authorizations of biocidal products".

A key element of this legislative proposal is that different categories of possible changes are laid down: An administrative change is defined as an amendment of an existing authorization of a purely administrative nature involving no change to the biocidal product's properties or efficacy. A minor change means an amendment of an existing authorization that is not of a purely administrative nature and requires only a limited re-assessment of the biocidal product's properties or efficacy. A major change is an amendment of an existing authorization that is neither an administrative change nor a minor change.

Apart from these three change categories and the different associated procedures, the draft Regulation also defines what an extension of an authorization should encompass and what procedures are to be followed.

The draft Regulation on changes to authorizations is intended to apply simultaneously with the new Biocidal Products Regulation (BPR). The first reading of the draft BPR in the European Parliament was completed on 22 September 2010. It is expected that the Member States will reach a political agreement in the Council meeting on 20 December 2010. As it stands, the BPR is scheduled to apply starting 1 January 2013.

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

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CHEMICALS, REACH, CONSUMER PRODUCTS

New bulk upload tool for CLP notification

A new version (1.2) of the MS Excel bulk upload tool for CLP notifications was put on the ECHA website on 7 October. This new version fixes problems encountered with the German and French versions of the tool. If the classification of a substance is already harmonized, it will now be possible for the C&L information to be automatically filled in by entering the index number. The tool can be downloaded for MS Excel 2003 and 2007. Please refer to tools download on the ECHA website (http://echa.europa.eu) under CLP, notification to the C&L inventory, subheading "how?".

REACH in practice

ECHA homepage – occasional check for news recommended

In general, ECHA's news alert system has improved considerably since its very first set-up. However, still not all updates (new manuals, updated versions, etc.) are automatically communicated (see also CLP inventory). We recommend an occasional check for any updates independent of news alerts provided via e-mail or referred to in the news section of the ECHA Homepage.

Updating ELINCS dossiers without undue delay

The European List of Notified Chemical Substances (ELINCS) contains substances notified according to the Dangerous Substances Directive 67/548/EEC. In the days before REACH, ELINCS substance notification dossiers had to be submitted to the Competent Authorities of the Member States using the Substance Notification Information Format (SNIF). With REACH and the establishment of ECHA, the national Competent Authorities migrated all SNIF dossiers to the IUCLID5 format and transferred the substance information to ECHA. This information now needs to be updated for two reasons:

First, classification and labelling information according to the Global Harmonized System (GHS) needs to be included according to the CLP Regulation (EC) No 1272/2008. Registration dossiers are to be updated without undue delay. Notably, registrants are responsible for the submission of a complete registration dossier. In practical terms, this requires updating SNIF-based ELINCS dossiers to IUCLID5 standard, including a chemical safety assessment and report (CSA/CSR), if required.

Second, existing safety data sheets of dangerous substances are to be developed further to include not only GHS, but also to incorporate relevant exposure scenarios according to the use descriptor system (SU, ERC and PROC). The updated registration dossier, specifically the CSR, is the basis for safe exposure scenarios to be included in the extended safety data sheets (eSDSs).

The eSDS is an important communication tool not only relevant for manufacturers and importers, but also to participants of the supply chain. Importantly, eSDSs are the basis for downstream user REACH compliance. Each downstream user is required to ensure the safety of his own uses.

IUCLID issues

An upgrade for IUCLID 5.2 was made available in October. The change to version 5.2.3 is unproblematic as the exchange of files between version 5.2.3 and all previous 5.2 versions is supported and no data migration is needed. Some minor improvements facilitate the work with this tool (e.g. faster searches).

Furthermore an additional IUCLID plug-in has been available since September that allows the calculation of dossier fees (also accounting for information that are flagged as confidential). This new plug-in works properly.

Dossier submission via REACH IT works smoothly and ECHA's invoices are in turn received only a few hours after submission. ECHA recently informed again that upon submission of a dossier certain information from the registration dossier will be published on the ECHA website without further notice, in accordance with Article 119 of the REACH Regulation. It is therefore strongly recommended to use the dissemination plug-in (which is available from http://iuclid.echa.europa.eu) to preview which information will be published.

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

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FEED & FOOD ADDITIVES, VETERINARY MEDICINE

Together we made it!!!

SCC has timely delivered 36 application dossiers for feed additive re-authorization to the European Commission. This marks the end of a very extensive deadline that was imposed by Regulation (EC) No 1831/2003. All substances involved are now secured in the future for sales. As always, the last few months were quite hectic and stressful but in the end, the last dossiers were shipped to the Commission on Friday 5 November (we wanted to have a few days of spare in case there would be another strike going on in Belgium or Italy). We wish to thank all our clients for helping us with this task by delivering sometimes new or extra data at the very last moment. The next step will involve answering the questions that are coming back from EFSA.

Of course SCC also visited the EuroTier 2010 in Hannover and made some very interesting new contacts. We also had some time to meet our current clients and have some nice relaxing talks about the last year.

The focus now is on new feed additives and on the other areas of this Department. Already quite a bit of consultancy has been done in the area of labelling, specifically after Regulation (EC) No 767/2009 became applicable as of the 1 September 2010.

Other areas that we are currently working on concern the registration of veterinary medicinal products and excipients (technological aids used in pharmaceuticals), and the use of certain chemicals as food contact material.

Coming towards the end of this year, it is clear that 2010 was mainly focusing on the deadline for re-authorization of feed additives. In 2011, SCC will make a fresh start from a completely new building and we are looking forward to working with you again!

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

REGULATORY SCIENCE

AgCHEM Forum 2010 – environmental aspects

One stream of this year's AgCHEM Forum Conference was entitled "Environmental Safety – working with current and new Regulations". The opening plenary session has already been summarized above under the agrochemicals section.

In the ecotox session, 18 presentations on different topics were given by speakers from EFSA, several national authorities, from industry and from research institutes.

Dr. Chris Leake (Bayer CropScience, Germany) gave an overview on the preparation of environmental reports under the new regulation (see guidance document SANCO/6895/2009 rev. 1). The key aims of draft registration reports (dRR) are:

- They contain all the information that was in the historical Annex III
- They already include zonal approach and country addenda
- They use the "risk envelope" approach
- They will be drafted by industry and finalized by the Member States.

This new concept of dRR as one document will improve efficiency and transparency. A team approach to e-fate, modeling and ecotox chapters is essential. The dRR concept will be continually developed further over the next years.

Muriel Dunier-Thomann (PPR Panel, EFSA) gave feedback from EFSA on ongoing activities concerning new guidance documents (GD). The 2nd revision of the GD on persistence in soil (SANCO/9188VI/1997) was published in October 2010. The GD on aquatic and terrestrial ecotoxicology is scheduled to be published in 2011.

Dr. Juan Pascual from BASF SE, reported on first impressions regarding the implementation of the new GD on birds and mammals (EFSA 2009) from an

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industry point of view. The new GD is a more scientific document, has an increased complexity and requires expert judgment. The tier 1 risk assessments are improved; however, it includes more uncertainty for regulatory decisions especially in the higher tier risk assessments. Thus, the new guidance will increase workload and costs, complexity and uncertainty for zonal dossiers. Finally, it will lead to less predictability on final regulatory decisions by authorities. As a next step, a joint working group was asked to consider the scientific opinion on open issues and to find a way forward to develop the GD by deciding on different risk assessment options. Industry assumes that EFSA would soon review the open questions raised by the joint working group and that this would be implemented into the GD in its revision in 2012.

Peter van Vliet, (ctgb, the Netherlands) and Mike Coulson (Syngenta, UK) summarized the ESCORT III workshop held in the Netherlands in March 2010. The ESCORT (European Standard Characteristics of Non-Target Arthropod Regulatory Testing) workshop was performed to appoint the current and future direction in the field of non-target arthropods testing in the context of the review of the current terrestrial GD by EFSA. The main question asked at the workshop was, if the current tiered risk assessment is sufficiently predictive and protective for NTA communities. A manuscript of the workshop will be published in December 2010.

The key discussion points at the ESCORT III workshop were as follows:

- Level of protection and test design (e.g. impact on biodiversity and the ecosystem)
- The off-crop environment (divided in off-crop in-field margin area and off-field area)
- Recovery (return of populations, communities and functional groups)
- Field studies (performance and interpretation).

A clear reduction of level of protection “in-field” and an increase in protection off-crop is expected from this workshop. This will lead to a need to re-design off-crop assessments and studies. Field studies seem to be of limited value for in-crop assessment but more useful for lower tier data. Further on, it is unlikely to use in-crop field studies to assess risk off-crop but it is still possible to bridge between crops and countries (e.g. North/South) if it is supported by good technical arguments.

Veronique Poulsen (Anses, France) gave an overview of the current work in aquatic macrophyte risk assessment, AMRAP workshop (Aquatic Macrophyte Risk Assessment for Pesticides) held in the Netherlands back in January 2008. According to the current data requirements information on the toxicity of herbicides and plant growth regulators to algae and lemna are required. Due to this current approach the question was raised, if the use of algae and lemna data underestimated the risk to aquatic macrophytes. The recommendations of the workshop are to implement an additional test with a rooted macrophyte species to the risk assessment scheme (a ring test with myriophyllum sp. is ongoing) and to develop an appropriate design for higher tier studies (effects on natural communities). The results of the AMRAP workshop are pertinent to the revision of the GD on aquatic ecotoxicology scheduled by EFSA for 2011.

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

Your feedback is important to us!

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

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

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THANK YOU!

Newsletter

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CALENDAR

4th Forum: Product Safety in the Chemical Industry - REACH and GHS in praxis – Cologne, DE
24 and 25 January 2011

The Chem-Academy presents its 4th forum on product safety in the chemical industry - REACH and GHS in praxis, which will be held in Cologne, Germany, on 24 and 25 January 2011. This forum will cover such topics as:

- Implementation and control of REACH and GHS on the national level
- Content and details required in the safety data sheets
- Information obligations up- and downstream in various roles
- Implications in the implementation of GHS
- Expectations of the authorities after the 2010 deadlines.

Dr. Carsten Baehr, Senior Manager Regulatory Affairs, will speak about "The lessons and experience gained from the first REACH registration deadline - steps towards successful registration in 2013."

For more information regarding this event, check out their website: http://www.chem-academy.com/psc.

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