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### **Changes and Challenges in 2007**

It has now been decided that REACH will enter into force in the middle of this year. This will impact European manufactures as well as importers and suppliers of chemicals and preparations to the EU territory.

Our SCC expert on REACH, Dr. Werner Köhl has been invited by companies and industry associations from all over the world to provide information on the subject. The events were very well received. Dr. presentation covered aspects of the subject such as the preregistration and the registration process as well as human health hazard assessment and exposure estimation requirements. Dr. Köhl stresses the point that along the lines with "The Globally REACH, Harmonized System of Classification and Labelling of Chemicals" (GHS) will be implemented. For further information on this important issue please see section "Chemicals".

It is well known that our "regulatory world" has become more and more complicated. The preparation of a dossier has developed into an extremely demanding task in terms of scientific and administrative requirements. In addition to the scientific knowledge, SCC can offer systems that facilitate the handling of dossiers including the necessary studies. The SCC systems have been developed over our 18 years of experience, simplifying the retrieval and precise archiving of all necessary regulatory documents.

Among its other functions, our Electronic Dossier and Data Management System (EDDMS) simplifies the compilation of electronic dossiers such as CADDY and IUCLID. We will present more details on our data management system in a special edition of SCC's newsletter to be published soon. For a general overview, please see section "Data Management".

Also in this issue, you will find information on regulatory developments for agrochemicals, biocides and pharmaceutical products.

If you have additional questions please don't hesitate to contact me.

With best regards



Dr. Friedbert Pistel President

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### **Revision in Regulatory Authorities in Europe**

October 2006, Belgian and French registration authorities presented new administrative structures and registration procedures. The authorities organized information events which were attended by SCC.

#### France

Starting in September 2006, AFSSA (Agence Francaise de Sécurité Sanitaire des Aliments) has assumed responsibility for all tasks relating to the registration of plant protection products, fertilizers and adjuvants in France. This includes all tasks on national and EU levels. The full address is:

AFSSA DIVE – UGAmm 10 Rue Pierre Curie 94704 Maisons Alfort Cedex

Tel: 0033 – (0)1 49 77 46 73 Email: <u>dive.ugamm@afssa.fr</u>

Opening hours: 9:30 – 11:45 14:00 – 17:00

AFSSA will consist of various units: UGAmm (Unite Gestion des Amm) is the exit path for all dossiers for which the unit carries out the completeness check. Dossiers are then forwarded to UCEAE (Unite de Coordination de l'évaluation et des Affaires Europeennes) which is responsible for the evaluation of the various sections in the dossier. The results are discussed in a specific expert forum which meets once a month. UGAmm writes the report and proposes a decision. For finalization, the report and the decision are then presented to the agricultural ministry, where they are signed.

The Agency and the ministry have a limited amount of time for final registration of plant protection products: 12 months for a new product or major use extension; 6 months for a

minor use extension or a modification. These time limits will be applicable from December 2008 onwards.

#### **Belgium**

On October 23, 2006, the Belgian "Service Pesticides & Fertilizers" presented its new system for fast track procedures. As a general approach, dossiers that are submitted to the Belgian authority under the fast track procedure will always be treated with the highest priority as opposed to dossiers that are submitted without fast track. This principle also applies to dossiers that have been submitted before October 2006 without fast track.

"The fast track procedure is possible for both new and already submitted [but not yet evaluated] applications, and for any type of application (authorization, prolongation, change of composition, ...). The procedure starts as soon as the Service receives the Product File Note, the Registration Report or the application for Mutual Recognition." In order to accelerate the work, the applicant will be permitted to prepare the reports necessary to the experts: the Product File Note is a short report in simple format which is required if the respective active is not yet on Annex I and if a Draft Assessment Report (DAR) is not available. As soon as the Belgian authority has access to a draft version of the DAR, the more complex Registration Report in a more sophisticated format is required for active substances which are included to Annex I.

For new or existing active substances which will soon be listed under Annex I, a provisional Registration Report can be drafted and finalized once the substance is in Annex I.

Mutual recognition is the fastest way to obtain registration in Belgium. The registration committee that decides about the application via mutual recognition, meets on a monthly basis and makes decisions immediately. For mutual



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recognition, a simple letter as well as a complete Annex III dossier are required. In addition, the Good Agricultural Practice (GAP) from the country holding the original authorization must be compared to Belgian conditions and, if necessary, adapted. To avoid language and translation problems for the experts, the evaluation report from the country with the original authorization should be made available in English, French or Dutch. If the set of information is complete, approvals will be granted within a couple of weeks. According to Belgian regulators, this is only possible if the respective substance is included to Annex I.

For further information regarding this subject, contact Dr. Albrecht Heidemann at albrecht.heidemann@scc.gmbh.de.

### Regulation 396/2005 on maximum levels of pesticides

Dr Hohgardt (BVL, Germany) and Hermine Reich (EFSA, Parma) presented the latest news concerning the MRL regulation 396/2005 at the 5<sup>th</sup> Fresenius conference "Food safety and dietary risk assessment".

The MRL Regulation 396/2005 on maximum levels of pesticides (MRLs) in or on food and feed of plant and animal origin will apply 6 months after adoption by the European Commission of Annex I, II, III and IV. It is foreseen that it will go into effect at the beginning of 2008 at the earliest, with Annex V, VI and VII developed later. Until then, the existing MRL directives and national legislation of the Member States will apply.

#### Status:

**Annex I:** list of commodities: published in March 2005 (Regulation 178/2006)

- Total: 380 entries
- Existing commodities from the 4 MRL Directives (230 entries)
- Fish and animal feed plants mentioned, but for the time being exempted from MRL setting (not enough information)

Commodities for which Member States have set national MRLs (150 entries); mainly very minor crops (loquat, spices, lupines), but also cocoa, coffee, sugar plants**Annex II:** EU MRLs proposal not yet avail-able

- MRLs from the MRL Directives will be copied (in progress)
- MRLs for new commodities collected from the Member States (done)
- Database to be developed (in progress)
- Adoption and publication simultaneous with Annex III and IV
- EFSA opinion on risk: within one year after Regulation is applicable

**Annex III:** temporary MRLs proposal not expected before autumn 2007

- Step 1: Database developed to collect national MRLs and assess the highest MRLs (December 2004)
- *Step 2:* MS submitted information on national MRLs (31 March 2005)
- *Step 3:* COM elaborated draft temporary MRLs (June 2005)
- Step 4: COM requested EFSA for opinion on draft temporay MRLs (4 July 2005)
- Step 5: COM collected ADIs and ARfDs used by the Member States when setting national MRLs (December 2005); procedure foreseen: lowest ADI/ARfD will be used, independent of evaluation status on EUlevel

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- Step 6: COM will update the temporary MRL database (September 2006). EFSA will develop EU exposure assessment models (June 2006)

#### Status:

Flexible calculation tool for all Member diets available State developed (procedure/assumptions: food contains residues temporary MRL; no refinement with processing factors; LOQs for all commodities; residue definition = parent; if no ARfD is available, use of ADI instead). Results of this Risk Assessment are planned to be published in March 2007.

- *Step 7*: EFSA to give opinion on temporary MRLs and identify MRLs which are not safe (Expected: March 2007)
- Step 8: COM proposal for discussion with Member States
- *Step 9:* COM adopts temporary MRL Regulation, Regulation 396 will be applicable 6 months later

**Annex IV:** list of substances for which no MRL required: proposal available, linked to discussion on 91/414/EEC --

Member States have sent proposals to COM; list contains pesticides with low toxicity and pesticides that are not expected to be present. The latter do not need to be in Annex IV because the 0.01 mg/kg would apply – discussions ongoing: to be published together with Annex II and III

**Annex V**: substances for which default MRLs applies

**Annex VI:** processing factors

Annex VII: fumigants

Currently MRLs will be requested by the applicants according to 91/414/EEC and the Member States in context of harmonised MRLs. As soon as the MRL regulation will be taken into force beside the applicants, all parties demonstrating a legitimate interest in health, including NGOs, commercially interested parties such as manufacturers, growers, importers could request MRLs. Such a request could be based either on an application dossier, or on literature data or data submitted in the context of 91/414/EEC regulation.

According to the MRL regulation, authorisations of a plant protection product will not be granted without an established MRL.

The following summarizes the way an application in Germany is foreseen:

#### **General procedure:**

- Application will be sent to Member State
- Member State will forward copies to EFSA and COM
- Member State will evaluate application without undue delay (consideration of Codex MRLs foreseen)
- Member State will send evaluation report to COM

### **Example for Germany:**

**BVL**: registration, completeness,

documentation 11 weeks

**BfR**: evaluation.

risk assessment 18 – 29 weeks

**BVL:** risk management,

submission to COM 7 - 10 weeks

#### **Procedure COM:**

- Inform MS about application/evaluation report
- Forward application, evaluation report, supporting dossier to EFSA 2 weeks



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#### **Procedure EFSA:**

- Acknowledge receipt
- Drafting risk assessment
- Dietary risk assessment will be forwarded to applicant, COM and MS
- Publication of reasoned opinion 13 weeks
- Drafting a regulation
- Further expected timelines:
- Proposing regulation by COM 13 weeks
- Discussion of proposal with MS (5 meetings per year) 8 weeks
- WTO notification 8 weeks
- Notification to EP
  (2. meetings per year!!!)
  - (2 meetings per year!!!) 4 or 13 weeks
- Hearing at SCFCAH
   (5 meetings per year)

meetings per year) 8 weeks

- Publication 8 weeks

The overall timeline for application and authorisation of a plant protection product will be ca. 2 years. Thus the link of the MRL regulation 396/2005 and the authorisation process will have a dramatic impact on the time period to authorise a plant protection product.

For more information regarding this subject, contact Dr. Monika Hofer at monika.hofer@scc-gmbh.de.

#### **REACH and GHS**

The Globally Harmonized System Classification and Labelling of Chemicals (GHS) provides a worldwide basis classification and hazard communication for the transport, supply and use of chemicals. It is not legally binding, but was agreed to the World Summit implemented at Sustainable Development (WSSD) in 2002. It has now been decided that REACH will enter into force in Europe in the middle of 2007. This decision will impact industry to a very great extent. Further details in this respect will follow in the next newsletter, as some of the late minor changes (e.g. regarding articles) will have a significant impact for some companies.

GHS is a living document (updated every two years) with the objective of increasing harmonization and improvement in the future. It offers the so called "building block approach": countries are presented a "GHS-toolbox" out of which they choose and implement the parts of the system they need in order to satisfy their individual needs.

The current EU classification and labelling system consists of many pieces of legislation that have been developed over the last 40 years, such as the Dangerous Substance Directive (67/548/EEC) for example. As already stated in 2003, it is the European Commission's (the Commission) clear objective to include GHS into Community law. Their plan is the adoption along the lines with the entry into force of REACH.

In a Commission Draft Proposal on GHS the following items are proposed for implementation:

- Application of general principles of the GHS but keeping the scope as close as possible to the existing EU system.
- Use of GHS building block approach and a few other options to adapt the system to the European Union's needs
- Staying as close as possible to the GHS format and terminology, e.g. "mixture" instead of "preparation" or "hazardous" instead of "dangerous"
- ➤ Maintaining the current level of protection by including EU "left-overs" that are not yet covered by the GHS
- ➤ Definition of classes and categories which should be exempted from the scope of REACH and EU "downstream" legislation, i.e.



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- Gases under pressure (Annex I, 2.5)
- Corrosive to metals (Annex I, 2.16)

The Commission proposes a legal "body text" on general rules and principles as well as a number of Annexes on technical details, e. g.:

**Annex I:** Classification and labelling requirements for hazardous substances and mixtures

**Annex II:** Special rules for labelling and packaging

**Annex III:** List of hazard statements

Annex IV: List of precautionary statements

(TBA)

**Annex V:** Pictograms

Annex VI: Harmonized list of hazardous

substances

Annex VII: Conversion table for

reclassification

**Annex VIII:** Reference table and adaptation of references

For implementation, a transitional period is proposed: in the first phase, substances will be classified, with mixtures classified in the second phase. The EU authorities count three years for substances in line with the notification requirements to the classification and labelling inventory established under REACH, and an additional four to five years for mixtures. The objective is the development of a dual system consisting of existing EU classification and labelling requirements as well as the GHS regulation. Thus, material safety data sheets (MSDS) will become more complex since both systems have to be covered. The 31st ATP (Adoption to Technical Progress) will be the last amendment to Annex I of the Dangerous Products Directive (67/548/EEC). With the implementation of GHS, the list will be transferred into the new legislation. From that point onwards, all newly agreed upon classification and labelling requirements (by European Chemicals Bureau) will address both

systems, the current EU and GHS, for several years.

REACH as such does not include criteria for classification and labelling. However, the system offers connecting links through registration and information in the supply chain, as well as classification and labelling.

In many fields the current EU system is similar to GHS: one system for hazard classification and labelling and the coverage of more or less the same hazards including hazard communication and equal classification criteria. In addition to the current system, the EU will need to consider the adoption of criteria for the transport, supply and use of chemicals, the definition of further hazard classes and categories, and changes in labelling elements as well as a different approach to tank mixtures.

All in all GHS will classify more substances as dangerous or of higher danger class.

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

### New withdrawal list available

On the web site of the Environment Directorate-General of the European Commission, a new "List of active substances of the 2nd phase of the review programme, for which a notice has been published that all participants have withdrawn or that no dossier was submitted or that none of the dossiers submitted could be considered as complete", was published on 22 September 2006. Please refer to

http://ec.europa.eu/environment/biocides/pdf/substances\_2ndlist\_out.pdf for this list and http://ec.europa.eu/environment/biocides/withdrawals.htm for other withdrawal notices published so far.



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### New guidance documents agreed upon in the 22<sup>nd</sup> Competent Authority Meeting

Two additional guidance documents relevant for the preparation of complete BPD dossier were adopted at the 22nd Competent Authority Meeting.

The first document gives guidance on the level of detail for data that has to be submitted addressing exposure during manufacture of biocidal active substances, as "(...) with the assessment of the first dossiers submitted for the inclusion of existing active substances in Annex I or IA to BPD, it has become clear that Member States have indeed different requirements regarding the need for information relating to manufacture. The purpose of this document is to outline the problem and to suggest a practical proach to this issue."

For the complete document, refer to the following link:

http://ecb.jrc.it/Documents/Biocides/TECHNIC AL NOTES FOR GUIDANCE/Additional Guidance for Exposure during manufacture.pdf

The second document gives guidance for the preparation of product dossiers. It is stated that "This paper aims at providing guidance for the Member States and the applicants on what the requirements for the product dossier are at the Annex I inclusion stage." One of the main statements in this guidance document is that "(...) During (...) previous discussions, the TM has agreed that the product dossier for Annex I inclusion does not need to be complete, and that it is possible to submit model data for the biocidal product at the Annex I inclusion stage (dummy product). This is in line with the earlier recommendations (...)." For the complete document, refer to the following link:

http://ecb.jrc.it/Documents/Biocides/TECHNIC

AL\_NOTES\_FOR\_GUIDANCE/Additional\_guidance\_for\_Product\_information\_for\_annex\_I in clusion.pdf

Addendum to the Technical Notes for Guidance (TNsG) on data requirements for active substances (Endorsed at the 23rd CA meeting, Nov. 2006) - New guidance document on how to deal with extracts and oils of plant or animal origin

A new guidance document was published on the web site of the ECB, describing the compositions that have to be tested for active substances of biological origin. The main conclusion of this guidance document is, that extracts and oils of plant or animal origin should be regarded as the active substance as such, as "(...) it is not possible to distinguish between individual modes of action assigned to each single constituent" and "(...) studies conducted with single active constituents can be used for supporting the evaluation to predict how an extract / oil might behave but they can normally not replace studies which were conducted on the full extract / oil. Some testing should be done on the extract / oil to ensure synergistic effects are not overlooked, and scientific reasons have to be given that readacross is possible." For the complete document, refer to the link below:

http://ecb.jrc.it/DOCUMENTS/Biocides/TEC HNICAL NOTES FOR GUIDANCE/TNsG DATA REQUIREMENTS/Addendum-TNsG-Data Requirements Oils and extracts.pdf

### New Draft Competent Authority Reports for Active Substances published online

New Draft Competent Authority Reports on rodenticides and wood preservatives were published online and can be downloaded from:

http://ec.europa.eu/environment/biocides/evaluation\_reports.htm

For more information, contact Dr. Hans-Josef Leusch at <a href="mailto:hans-josef.leusch@scc-gmbh.de">hans-josef.leusch@scc-gmbh.de</a>.



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### Medicinal products for Human Use: Guideline on Environmental Risk Assessment became effective December, 2006

Since 1 December 2006, the guideline on the environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/4447/00) has been in effect.

#### Legal background

"In accordance with Article 8(3) of Directive 2001/83/EC, as amended, the evaluation of the potential environmental risk posed by medicinal products should be submitted, their environmental impact should be assessed and, on a case-by-case basis, specific arrangements to limit the impact should be considered."

### What does this requirement concern? What does it not concern?

Directive 2001/83/EC, as amended, relates to environmental risks of medicinal products arising from use, storage and disposal, and not to environmental risks arising from synthesis or manufacture of medicinal products for human use. Thus, the EMEA guideline describes the assessment of environmental risk due to the use of medicinal products.

An environmental risk assessment (ERA) is required for all new marketing authorisation applications for medicinal products (centralised, mutual recognition, decentralised or national procedure).

For Type II variations and extension applications, an ERA is required if there is a (potential) increase in the environmental exposure.

No ERA is required for Type IA/IB variations and for renewals.

Other exceptions are vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates and lipids as they are seen unlikely to pose significant risk to the environment. Vaccines and herbal medicinal products are also exempted.

In all cases, except for Type I variations and renewal applications, an ERA or a justification for the absence of it should be provided in Module 1.6 of the MAA (Marketing Authorisation Application).

### Tiered approach of environmental risk assessment

The risk assessment according to the EMEA guideline consists of two phases:

#### Phase I:

- Calculation of the Predicted Environmental Concentration in surface waters (PEC<sub>sw</sub>) based on default values for a market penetration factor, intake mainly via sewage treatment plants, an even distribution etc. (biodegradation in sewage treatment plants or metabolism in patients are not considered at this first step)
- Estimation of PBT-properties (persistent, bioaccumulative, toxic)

#### Phase II Tier A:

If the Phase I - calculation results in a  $PEC_{sw} > 0.01 \mu g/L$  (which is the case according to the standard formula if the daily dose per patient is higher than 2 mg),

- data on the physical-chemical properties of the substance as well as on
- fate, behaviour and
- long-term effects on aquatic organisms have to be provided.

The data on microbial inhibition and on long-term effects to algae, daphnia and fish are the basis to derive Predicted No Effect Concentrations (PNEC) which are then compared with the  $PEC_{sw}$ -values.

#### Phase II Tier B:

In case of further concern after Tier A risk assessment, refined risk assessments for the aquatic and, if triggered, for the terrestrial environment have to be provided in Tier B.

**PHARMACEUTICALS** 

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### SCC offers services on environmental risk assessments for pharmaceuticals

Based on its extensive experience with environmental risk assessments (fate, exposure, effects, risks), SCC can offer full scientific and regulatory service to fulfill the requirements of the new EMEA guideline. SCC can evaluate the available data and, if necessary, can assist by planning and monitoring such studies as:

- studies on the environmental fate and behavior
- studies on effects to aquatic and terrestrial organisms

SCC can prepare expert statements regarding questions on ecotoxicology, environmental fate and behavior. The performance of environmental risk assessments, comparing potential exposure with potential effects, is an integral part of our services and can be provided as required by the new EMEA guideline including Phase I and Phase II Tier A and B, including PEC modeling and reporting ready for inclusion in Module 1.6 of the dossier.

For more information, contact Dr. Achim Schmitz at <a href="mailto:achim.schmitz@scc-gmbh.de">achim.schmitz@scc-gmbh.de</a>.

### **Implementation of the Rotterdam Convention on the EU Level**

The Rotterdam Convention on the Prior Informed Consent (PIC) 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 (UN). The work of the convention is co-ordinated and facilitated by the Food and Agriculture Organization (FAO) as well as the United Nations Environment Program (UNEP).

The objective of the agreement is to promote shared responsibility in the international trade on chemicals through facilitating information exchange among parties, as the convention text states. The information exchange is guaranteed through the PIC procedure which makes sure that no shipment of certain listed chemicals can take place without a positive response of the importing party.

The Rotterdam Convention is implemented on national or regional level through Parties: "Parties can be States or Regional Economic Organizations" such as the European Union (EU). Out of 25 Member States (MSs) 22 ratified the Convention. The MSs have in total 28 designated national authorities (DNAs) carrying out administrative tasks for the Rotterdam Convention. The Commission is appointed to act as common DNA for the EU.

Before the Rotterdam Convention entered into force on the international level in 2004 the EU ratified and implemented the PIC procedure in January 2003 through regulation 304/2003. The regulation goes further than the provisions of the Convention. It covers additional substances and establishes the general principle of "explicit consent": a positive response must be received from the DNA of the importing country BEFOER export can proceed. Prior Informed Consent (PIC) is not sufficient. It also provides detailed requirements for exports of chemicals out of the EU and less specified obligations for imports.

Annex I of regulation 304/2003 lists the substances that fall under the EU's legal regime. It is separated into parts 1,2 and 3. Part 1 covers all chemicals that have been banned or severely restricted in the European Community. This means all or virtually all uses are prohibited by regulatory action in at least one MS. Part 2 lists all chemicals that qualify as "PIC candidates". These are the chemicals that are in the administrative process of becoming a "PIC substance". Meaning two different



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countries from two different world regions notify independently the PIC secretariat (administrative head of the Rotterdam Convention) about the ban or the severe restriction of the same chemical. Part 3 refers to chemicals which are confirmed PIC substances.

For the export of Annex I substances out of the EU the regulation stipulates the following:

Export of part 1 substances must be notified to the importing country before the export takes place (export notification). The importing country must provide a acknowledgement of receipt.

For the export of "PIC candidates" (part 2) the importing country must be informed before the export takes place and agree to go ahead (export notification and explicit consent). At the very end of the process for a chemical becoming a "PIC substance" (part 3) parties to the convention decide whether they permit the import of the substance or not. With the party's prior positive decision the import can go ahead without any further contacting of DNAs. In case of a negative import decision trading of the substance is anyhow prohibited.

Importing a chemical into the EU that is banned or severely restricted in the exporting country requires an export notification to EU as DNA to the Rotterdam Convention and its acknowledgement of receipt. Importing chemicals that are listed in regulation 304/2003 requires the following:

- Part 1: export notification including acknowledgement of receipt
- Part 2: export notification with explicit consent
- Part 3: depending on decision of importing party during administrative process.

Import and export of chemicals in and out of the EU are controlled by the "European Database of Export and Import of certain Dangerous Chemicals" (EDEXIM). The database run by the European Chemicals Bureau lists among others all export and import notifications.

For further details please check http://ecb.jrc.it/import-export/.

From an industry point of view, the listing of chemicals under the Rotterdam Convention leads to more administrative burdens, such as additional contacts with authorities that permit imports to countries. Although not meant as a consequence, PIC can lead to blacklisting of substances, leading to a negative reputation for the producing companies and resulting decrease of sales. This may be the equivalent to essentially banning products in many cases.

On top of this, the EU implemented the provisions of the Rotterdam Convention by adding additional rules and chemicals to the respective law, regulation 304/2003 with Annex 1 (parts 1, 2 and 3). This adds supplementary administrative burdens onto the companies trading with chemicals on EU territory. For producers and retailers it is often very unclear which law applies: international or EU law. Responsibilities are not clearly defined. It is very difficult to find ones way through the "administrative jungle" in order to obtain proper information on PIC issues. It is an open question if DNAs will be sufficiently staffed, trained and informed in future.

And the system works: Annex I of regulation 304/2003 was last amended on 23 May 2006. For further details on PIC please check http://www.pic.int/.

For further information, contact Dr. Friedbert Pistel at <a href="mailto:friedbert.pistel@scc-gmbh.de">friedbert.pistel@scc-gmbh.de</a>.

#### **SCC to launch new EDDMS**

DATA IANAGEMENT

SCC is currently in the final stages of development for the new Electronic Dossier and Data Management System (EDDMS). Comprehensive information regarding the new program and its benefits will be showcased in a special SCC Newsletter, appearing soon.

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## CALENDAR

### Newsletter



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

### **Conference on the Registration of Products York, United Kindom**

8 March 2007

The Pesticide Safety Director will host a conference on the Registration of Products Post Inclusion on Annex 1. The event is targets at those involved in the preparation of applications for both re-registration and mutual recognition. A series of presentations will be given by experienced PSD staff. Cordula Nieslony, Manager Regulatory Affairs Agrochemicals, will be at this informative event.

### 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 your specific needs for Annex III plant protection dossiers, biocide dossiers, notifications of chemicals or our EDDMS archiving systems (including GLP-certified archiving!). And, an additional treat: on Tuesday, 16 October, SCC will sponsor a wine-tasting for participants of the BCPC Conference. Contact SCC for more details!

To make an appointment during one of these events, please contact Ms. Lisa Hubrich at +49-6734-919115 (tel.) or at <a href="mailto:lisa.hubrich@scc-gmbh.de">lisa.hubrich@scc-gmbh.de</a>.

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