

# Newsletter

Volume 6, No. 2: May 2006

MESSAGE FROM THE PRESIDENT

"The chemical industry expects better business developments in Europe in 2006. Chemical production will grow by 2.6%." This is the very encouraging perspective the European Chemical Industry Council (CEFIC) offers in its outlook for 2006.

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CEFIC's very positive message stands in contrary to our and our clients' experiences with the European regulatory authorities in relation to 91/414/EEC registrations. From our day-to-day work we notice that interpretation of clauses get more and more anti-business and NGOs' interests are disproportionally reflected in many European chemical measures. This tendency is topped by the decision-making process as such during which expert advice loses impact. More and more votes are purely based on politics which leads to entirely unforeseeable outcomes with negative impacts to the planning in the chemical industry. Please see section 'Agrochemicals' for more details.

For our clients who are in the process of registering Biocides: the most recent version of the European Commission's "Manual of Decisions" is available. The manual as such and additional information on this crucial tool for product classification you will find under "Biocides" section.

An introduction on our new service tool "Consortia Management" is provided in our Chemicals section.

A number of things have occurred recently on the international level:

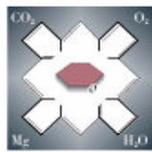
- The Codex Committee on Pesticide Residues approved more than 200 MRLs (maximum residue levels) of pesticides for various food compounds. In addition, a shortened procedure to approve codex MRLs was approved.
- Early this year OECD published harmonized templates that standardise the country submissions to support risk assessments. One single publication is needed to serve the needs of all OECD member states.

With my newsletter I hope to provide you with a brief overview on what has happened in the chemicals sector during the last months both on European and international levels. Certainly my dedicated staff and I will carefully monitor the developments with regards to chemicals legislation and will keep you informed about more or less dark clouds or even sunshine showing up on the horizon.

Please feel free to contact me if you have any further questions. If you wish to meet my team, SCC will be attending ChemCon 2006 in Budapest from 09 – 12 May 2006 and IUPAC Congress in Kobe from 06 – 11 August 2006 – see Calendar on page 9.

Yours sincerely,

Dr Friedbert Pistel  
President



## “No opinion” vote for inclusion of substances to Annex I of Directive 91/414/EEC: Proposals submitted to European Council

The Standing Committee on the Food Chain and Animal Health (the Committee) received proposals for eight substances to be included to Annex I of 91/414/EEC. During its last meeting the Committee was unable to come to a decision. Due to that the decision for inclusion or non-inclusion is still pending.

### The process

For approval or rejection of substances, 91/414/EEC (the Directive) offers specific provisions. All participants in the decision-making process must be in accordance and agree on the basis of a qualified majority. Qualified majority means the number of votes for each Member State are allocated depending on their number of inhabitants.

Participants are the European Commission (the Commission) and the Standing Committee: they need 232 votes and 13 Member States in favour of a specific opinion to come to a qualified majority. The Commission proposes inclusion **OR** non-inclusion to the Committee. If the Committee votes in favour of the Commission's proposal, the substance will be included or non-included.

If for whatever reason the Committee cannot find a qualified majority for the Commission proposal, the Directive offers a “no-opinion” solution. In this case, the Commission forwards its proposal to the European Council (Council) where during three months time a decision will be made once more based on qualified majority. If the Council has not acted by then, the Commission will adopt the proposal.

### A recent example

In March 2006 the Committee received eight Commission proposals for inclusion to Annex I. Some of the substances are under suspicion to be endocrine disruptors or are classified in CMR Cat. 2 etc. For all of them the Committee was unable to find any qualified majority for inclusion, i.e. a no-opinion or an unfavourable opinion case. This means as “... no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken” (Art. 19, Directive 91/414/EEC). At present Member States who voted against the inclusion at the Committee level, work hard to create a qualified majority for their opinion in the Council. If after three months no decision is taken, the Commission will most likely adopt its original proposal.

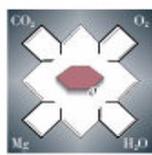
### Representative Use Patterns

Here the so-called representative use patterns have a high potential to impact the marketing and uses of respective crop protection products due to possible restrictions.

Generally, only the chosen representative uses for the active substances are assessed at the EU level. If the use of products exceeds the representative pattern, Member States have the right to authorise the application for their own territory.

For the substances in this recent example, national approvals should be restricted to uses which are proposed by the Commission. This means, uses that are not listed cannot be authorised without again going through the EU review process. If the proposal is agreed as it stands, industry will be forced to go through another cost and time intensive EU procedure if they want to market products outside the specific provisions in the Annex.

For industry this implies further on that products which have been successfully used for years, are in danger of being taken off the market for at least a certain period. Companies expect a delay of 10 years. During this period, manufacturers fear losing the uses, with the gap filled in by other substances from different registration owners. A decision is expected by June or July of this year, corresponding to the end of the three-month period.



### Political decisions

In 91/414/EEC, no rule exists that forbids the inclusion of active substances suspected of being endocrine disrupters or that are classified in CMR Cat. 2. Companies started to invest fortunes for the registration of substances. Within the ongoing registration process, this has changed. Now the inclusion of these substances is blocked or seriously restricted by the EU authorities.

In many cases Member States vote for non-inclusion because they just don't need the specific substance in their countries or they don't want it on Annex I.

The list of arguments shows the very unsatisfying nature of this discussion: Member States clearly make political decisions based on their individual needs without taking sound science or expert advice into account. From the industry point of view this is a questionable way of decision-making.

We will continue to monitor the activities of the involved EU institutions, and will keep you informed about any further developments impacting the plant science industry.

### Status of Annex I Inclusions

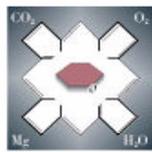
Some movement has been made in the plant protection products evaluations. A summary appears below:

Phase	No. of substances	Being examined	To be examined / notified	Not Supported or withdrawn	In Annex I
First	90	8	0	29	53
Second	148	38	0	98	12
Third	387	147	0	240*	0
Fourth	342	0	254	88	0
<b>TOTAL</b>	<b>967</b>	<b>193</b>	<b>254</b>	<b>455</b>	<b>65</b>

\* Detailed list of withdrawn substances available under Regulation 2076/2002 and 2004/129 (out of which 150 Substances were notified). Please check <http://europa.eu.int/eur-lex/lex/en/index.htm>

With 65 existing and 71 new active substances listed in Annex I, it can be difficult to keep track of what has and has not been evaluated. Please refer to the SCC Website ([www.scc-gmbh.de](http://www.scc-gmbh.de) – Plant Protection Products, Background and News) for a listing of the current status of inclusions and non-inclusions.

For further information please contact: Dr. Albrecht Heidemann, [albrecht.heidemann@scc-gmbh.de](mailto:albrecht.heidemann@scc-gmbh.de)



## 38<sup>th</sup> Meeting of Codex Committee on Pesticide Residues

The Codex Committee on Pesticide Residues (CCPR) held its 38<sup>th</sup> session in Fortaleza, Brazil from 3 to 8 April 2006.

### General outcomes of the meeting

- More than 200 new maximum residue levels (MRLs) have been advanced through the regular Codex process. This is an 8-step-procedure during which proposed MRLs are approved as Codex MRLs. It can take many years.
- In the calculation of short term intake, the Joint Meeting on Pesticide Residues (JMPR) agreed to use the default variability factor of 3 for acute intake estimation. Some delegates proposed to go back to a higher variability factor which would be crop specific.
- The pilot project for estimating national MRLs as interim Codex MRLs was discontinued.
- It was concluded that for JMPR purposes, probabilistic modelling of acute dietary exposure (probabilistic methodology) was unnecessary. The deterministic intake calculation was judged as being sufficient to determine if the acute reference dose might be exceeded.
- The details of the 13<sup>th</sup> GEMS/Food Consumption Cluster Diets are available on the WHO website ([www.who.int/en/](http://www.who.int/en/)).

### Accelerated procedure for proposed MRLs with no intake concerns

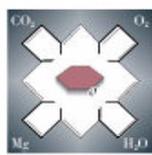
It was agreed that proposed MRLs can be advanced to step 8 with the omission of steps 6 and 7 when they have been evaluated by JMPR and no intake concern was noted. The proposed MRL would be adopted by the Codex Alimentarius Commission (CAC) at step 8 of the procedure.

CCPR agreed to the accelerated procedure under the provision that the respective JMPR report is available by early February every year and a proposed MRL is circulated for comments as prescribed by step 3 of the procedure. The accelerated procedure applies to new compounds as well as to substances that are under periodic review.

If all conditions are fulfilled (i. e. JMPR evaluates and has no intake concerns, JMPR report available in February, and circulation and commenting on proposed MRLs), the compound immediately enters step 8 of the Codex step procedure and the proposed MRL is set as Codex standard during the next meeting of CAC.

If CCPR delegates have doubts about advancing the MRL, they can fill out a concern sheet. CCPR/JMPR will address the concern at one meeting and decide if the MRL will be advanced or not.

The full report is available under [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp).



## OECD adopts “Harmonized Templates” for reporting test study summaries

In March 2006 the Organisation for Economic Co-operation and Development (OECD) adopted 86 harmonized templates for reporting summary information of the results from chemical testing. The harmonized templates are aimed at database developers and serve for the exchange of information among OECD countries and other involved parties. Governments of OECD member states are encouraged to incorporate the harmonized templates into their national programs.

The templates which are available on the OECD website prescribe the format with which the results should be entered into the database with the objective to make the data electronically accessible and transferable. On the templates the data resulting from tests with chemicals will be listed such as chemical properties, toxicological and ecotoxicological endpoints for each substance. The templates can be used for any type of chemical, e.g. pesticides, biocides and industrial chemicals.

The full set of templates can be downloaded under the OECD website: [http://www.oecd.org/departement/0,2688,en\\_2649\\_34383\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/departement/0,2688,en_2649_34383_1_1_1_1_1,00.html).

For further details on Regulatory Science please contact: Dr. Monika Hofer, [monika.hofer@scg-gmbh.de](mailto:monika.hofer@scg-gmbh.de)

## REACH data requirements: Chemical industry and downstream users are highly impacted

**REACH**, the Registration, Evaluation and Authorisation of Chemicals, is the new EU regulatory framework for the registration of chemical substances that will go into effect in 2007. This wide-ranging regulatory legislation will affect all producers, importers and users of chemicals. For registration of products an extensive set of data is required.

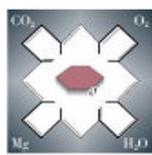
REACH bundles the current regulations concerning the registration and testing of chemicals following the principle “One Substance, One Registration”. Manufacturers and importers of substances must pre-register their substances 12 to 18 months before REACH enters into force if the produced amount is above 1 ton per year. For pre-registration, significant work into portfolio analysis/chemical inventory and substance characterisation, etc is needed.

The approval of REACH is expected early 2007 with pre-registration starting in April 2008. Depending on the production amount per year, all substances will be reviewed in three Tiers during 2011 and 2019.

A certain amount of core data must be provided for the registration. Importers or manufacturers of chemicals must prepare technical dossiers or a basic set of data for all chemicals above 1 ton per annum (tpa). For products with volumes above 10 tpa, chemical safety reports (CSA) must be prepared assessing the risks for humans and the environment. If producers plan to add new fields of use, a supplementary CSA must be provided.

### 1 tpa and more...

Our clients who deal with substances above the “1 tpa level” are strongly impacted by REACH – regardless if they are producers, importers or downstream users. For all registrations, various sets of data, such as basic information, phys-chem data as well as toxicological, ecotoxicological, and environmental fate data are needed.

**CHEMICALS**

SCC has had years of experience with the registration of more than 100 new chemicals as well as defending high volume chemicals. We are quite familiar with the testing methods required by REACH and can help you establish contact with GLP-certified and SCC-audited labs who can carry out especially labor-intensive tests (e.g. chronic toxicity) at very competitive prices. We have also established a network with university experts for QSAR-modelling to support waiving/group approaches.

We work in close contact with EU institutions and the related industry and scientific organisations, such as CEFIC and European Chemicals Bureau (ECB). Our contacts guarantee you the comprehensive of information on written and unwritten laws.

SCC will make sure that your REACH registration will go as smoothly as possible, so that your compound can enter or stay on the market place.

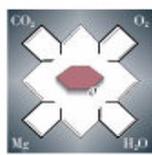
### **Our new Service Tool: Consortium Management**

During the REACH development process, European authorities inserted a group registration tool. With the so-called *consortia registration*, the Commission offered manufactures or producers dealing with substances from the same category the ability to register the compound jointly via one single dossier. This is one solution to comply with the very short time frame for registrations and tremendously reduces the associated financial burden per compound.

We support the creation of consortia by finding the right consortium partner for you. We can manage the consortium by offering scientific and administrative support as well as archiving resources. We can also offer contacts with regard to legal advice and model agreements for the creation of consortia, including data protection agreements.

Over the years SCC has been involved in over 30 Task Forces and is currently active in more than 10. Further information is available on our website under "Task Force Support".

Contact: Dr. Werner Köhl, [werner.koehl@scc-gmbh.de](mailto:werner.koehl@scc-gmbh.de)



## New edition “Manual of Decisions” available

### Information on how to improve the classification of Biocides updated

In December 2005 the Commission published its most recent edition of the “Manual of Decisions” (MOD). This is a compilation of questions which have been raised by industry and Member States dealing with the authorisation of products which fall under the Biocidal Product Directive (98/8/EEC) (BPD).

Products which have a “... controlling effect on harmful organisms by chemical or biological means (Art 2 (1) )” fall under the BPD and, depending on their use, are grouped into product types (PT 1- PT 23): products for human hygiene PT 1, disinfecting products PT 2, etc.

During the registration process for BPD compounds, a number of open issues developed. For these problematic issues, the MOD proposes solutions but it does not provide any legally binding answers. Authorities involved in the registration process (European Commission, Rapporteur Member State or industry) might have a different opinion.

Some discussed issues with impact to the industry are:

which products fall under the BPD? An example: generally speaking rodenticides are judged as biocidal products as long as they are used to protect plants for the purpose of human hygiene (prevention of contamination ). But rodenticides can also be used to protect roots of young trees or in seed beds. If they are used for plant protection purposes, as in forestry, the product falls under the Plant Protection Directive 91/414/EEC.

As shown in the example the same product can be used in various ways and, depending on the use, it may or may not fall under the BPD. If a product can be registered or used in various ways, directives in the fields of plant protection (91/414/EEC), food additives or cosmetics could apply. A substantial portion of the manual is dedicated to questions in these so-called borderline cases, and assists manufactures in properly classifying their product. More detailed documents on borderline cases are available under the EU website: <http://europa.eu.int/comm/environment/biocides/borderline.htm>.

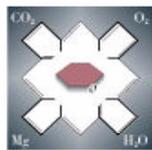
If the substance falls under the scope of the BPD, the next point is registration under the correct product type group. Example: a hygienic paint which reduces insects in rooms using an included additive. What is to be registered, the active substance as a disinfectant (PT 2) or the paint as such under film preservatives (PT 7)? The MOD lists various unclear questions and invites the reader to find a fitting answer for the individual case.

Why is it of such importance to industry under which regulation or product group (PT) the compound falls? Current estimates for bringing a new molecule to the market – including regulatory costs – range between \$180 to \$220 mill., and 9 to 10 years to get the first revenues out of the new product.

A large part of these costs are associated with the various risk assessments that are required to prove that neither human beings nor the environment are harmed and that the product can be used safely. Depending on the regulation (or for BPD, under which product type) under which the new compound falls, a different level of risk assessment is required. Consequently, the classification is of major interest to industry as the risk assessments require abundant resources.

The same applies for the registration of Biocides under the correct product group (PT). Some member states such as Germany charge companies fees for the registration on a product group basis (and not per compound). A second registration of the same substance under a different product group is very costly.

The European Chemicals Bureau (ECB) provides scientific and technical support for the approval of biocidal products as laid down in BPD. Detailed information including the MOD is available under <http://ecb.jrc.it/>.



## No change in status of active substances

It's still too early to expect any major changes in the status of biocidal active substances: the authorities are busy with the completeness checks and further evaluations necessary on the dossiers. A list of the current status can be found on the SCC Website ([www.scc-gmbh.de](http://www.scc-gmbh.de) – Biocides, Background and News or Newsletter/ Archive/ Vol. 6 No. 1).

For further information on Biocides, contact Dr. Hans-Josef Leusch, [hans-josef.leusch@scc-gmbh.de](mailto:hans-josef.leusch@scc-gmbh.de)

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

### SETAC Europe 16<sup>th</sup> Annual Meeting

The Hague, The Netherlands  
07 May 2006 – 11 May 2006

The 16<sup>th</sup> Annual Meeting of SETAC, Europe's leading environmental toxicology and chemistry conference, will focus on the controversies and solutions in environmental sciences, in an attempt to bridge the gaps between laboratory and field, as well as between science and policy. Dr. Achim Schmitz and Dr. Christine Klein will be at this meeting and are available to meet with you.

### ChemCon 2006

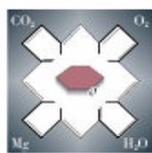
Budapest, Hungary  
09 May 2006 – 12 May 2006

The ChemCon 2006, an international conference on chemical control legislation and trade aspects, will be held in Budapest (Hungary). Dr. Albrecht Heidemann and Dr. Werner Köhl will be attending this conference, and will be able to meet with you to discuss your specific needs, especially with regard to REACH.

### Registration of Agrochemicals in Europe

Brussels, Belgium  
23 May 2006 – 24 May 2006

The 13<sup>th</sup> International Conference on the Registration of Agrochemicals in Europe is the place to obtain essential new information for 2006 including: results and conclusions from the impact assessments on proposed changes to 91/414/EEC; EFSA updates; France and Poland country updates on product registration; and much more. Dr. Albrecht Heidemann and Dr. Monika Hofer will be there to meet with you.

**Behaviour of Pesticides in Air, Soil and Water****Frankfurt-Mörfelden, Germany****21 June 2006 – 22 June 2006**

The 8<sup>th</sup> AGRO Conference on fate, exposure and regulatory issues conducted by the Akademie Fresenius will include such topics as: revision of Council 91/414/EEC, thematic strategy on sustainable use of pesticides; modelling the fate and behaviour of pesticides, and much, much more. Heike Schimmelpennig and Sven Peter of the SCC staff will be at this informative conference.

**11th IUPAC International Congress of Pesticide Chemistry****Kobe, Japan****06 August 2006 – 11 August 2006**

The situation surrounding agrochemicals has dramatically changed during the last decade. The focus of this IUPAC Congress will be the evolution for crop protection, public health and environmental safety. The Congress will provide many opportunities to exchange information and technology on chemistry, biology, biotechnology, toxicology, and environmental science on agrochemicals as well as its related novel technology among scientists from industries, governments, and academic fields. Dr. Friedbert Pistel and Mr. Horst Neufurth will attend on behalf of SCC, and will have a meeting room at the Portopia Hotel. To make an appointment, contact Ms. Lisa Lawrenz at +49-6734-919115 (tel.) or at [lisa.lawrenz@scc-gmbh.de](mailto:lisa.lawrenz@scc-gmbh.de).

**BCPC Conference****Glasgow, United Kingdom****23 October 2006 – 25 October 2006**

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 SCC archiving systems (including GLP-certified archiving!). To make an appointment, contact Ms. Lisa Lawrenz at +49-6734-919115 (tel.) or at [lisa.lawrenz@scc-gmbh.de](mailto:lisa.lawrenz@scc-gmbh.de).

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