

Newsletter

Volume 8, No. 3, October 2008



MESSAGE FROM THE PRESIDENT

The latest information on regulatory issues!

Out of the vast amount of information available on regulatory issues, we have picked out topics that we think you need to know about for this edition of the SCC Newsletter.

The "Regulatory Science" section provides an update from the environmental fate sector as presented during the AgChem Forum in Berlin. A summary on the highlights presented in the field of toxicology will follow in the next edition. Also in this section, you will find a summary of major developments with regard to EU MRL regulation 396/2005, which entered into force with all amendments on 1 September 2008. In addition, a new guidance document on risk assessments for birds and mammals will be published in 2009 by EFSA, which will reflect major changes to risk assessment process.

In "Agrochemicals", you can read about the postponed deadline for the finalization of the review of active substances used in plant protection products under Directive 91/414/EEC, and an explanation of how Member States (in this case Belgium) implement Regulation 33/2008/EEC on re-submission of actives to be used in plant protection products. In addition, you will find a summary on the discussion about the revision of Directive 91/414/EEC held during the AgChem Forum.

Under "Biocides" you will find a summary on how biocidal products are authorized and why a new group called the PA&MRFG (Product Authorisation & Mutual Recognition Facilitation Group) has been established.

The deadline for pre-registration under REACH will close on 1 December 2008. Section "Chemicals/REACH/Consumer products" explains how registrants can postpone this deadline. This section also includes an update regarding SCC's experience with ECHA, based on its day-to-day dealings, as well as detailed information regarding SIEFs, re-imports and substances to be authorized under REACH. This section is rounded out with a report about the implementation of GHS together with REACH, followed by the information that the European "Directive on Dangerous Substances" has been amended through the 30th Adaptation to Technical Progress, regulating the classification, packaging and labelling of dangerous substances. Finally, read about SCC's presentation at the Chemical Daily Workshop in Japan.

The "Data Management" section lists the advantages of SCC's EDDMS archiving system and how it can facilitate the generation of CADDY dossiers at SCC.

In May 2008 new guidelines on rules for the application and the authorization of feed additives were published. Find out more about Regulation (EC) No 429/2008 in section "Food & Feed Additives, Veterinary Medicine".

The new legal frame for the rules implementing the Rotterdam Convention on EU level, which entered into force during this summer, and the European Commission's proposal to add the two pesticides Endosulfan and Trifluralin to the Persistent Organic Pollutants (POPs) Protocol to the United Nation Convention on Long-Range Transboundary Air Pollution are the subjects of the "Global Affairs" section.

Also in this issue you will find under "Calendar" an overview on where to meet our specialists.

SCC is always personally available for any of our clients' individual needs. For questions, please contact SCC in Wendelsheim, or our SCC Liaison Office Japan.

With best regards,

Dr. Friedbert Pistel
President

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Update on MRL issues in light of Regulation 396/2005

On 1 September 2008, the maximum residue level (MRL) regulation went into force with all its amendments.

Regulation (EC) No 396/2005 and amendments:

- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
- Regulation (EC) No 299/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission.

Annex I

- Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply.

Annexes II, III and IV

- Commission Regulation (EC) No 839/2008 of 30 August 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products.
- Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto.
 - [Corrigendum to Commission Regulation \(EC\) No 149/2008](#)

Annex VII

- Commission Regulation (EC) No 260/2008 of 18 March 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annex VII listing active substance/product combinations covered by a derogation as regards post harvest treatments with a fumigant.

Taking into account articles 12(1) and 12(2) of 396/2005, it is EFSA's task to evaluate the MRL as set in Regulation (EC) 396/2005. To do so, EFSA and MSs are working on the database EFSA PROFile comprising all data related to residues and MRLs. In this context some MSs are requesting support from the Notifiers. The evaluation of the substances already listed in Annex I, began on 1 September 2008 and will be done within one year. Within one year, EFSA will prepare a written opinion on the outcome of the evaluation.

A new EU MRL database is now available on the EU website for the purpose of information (http://ec.europa.eu/sanco_pesticides/public/index.cfm). This has been produced to coincide with the introduction of the new EC harmonized MRL regime under EC Regulation 396/2005. The MRLs mentioned in this database have no legal value. The official MRLs are those published in the Official Journal of the European Union.

Please note that under the terms of Regulation (EC) 396/2005, the new MRLs only apply to produce treated on or after 1 September 2008. Produce treated before 1 September 2008 is subject to those MRLs in place prior to the coming into force of the new EC Regulation.

For more information, please contact Dr. Monika Hofer at monika.hofer@scc-gmbh.de or Dr. Monika Eder at monika.eder@scc-gmbh.de.

Scientific opinion of the PPR Panel on the science behind the Guidance Document on Risk Assessment for birds and mammals

Based on the public consultation on the draft of the revised Guidance Document for the risk assessment for birds and mammals from January this year, an opinion from the EFSA Panel on plant protection products and their residues (PPR) giving the scientific background for the risk assessment for birds and mammals, was adopted on 17 June 2008. A new guidance document based on this opinion will follow in 2009.

In comparison to the current Guidance Document for the risk assessment for birds and mammals (SANCO/4145/2000), the new opinion introduces major changes to the risk assessment scheme:

The risk assessment for short-term exposure is excluded and for long-term exposure, a new approach is presented, the so-called reproductive risk assessment, which focuses on the different phases of the breeding cycles of birds and mammals.

The tiered approach of the risk assessment for sprayed applications for the calculation of the toxicity exposure ratio (TER) is also modified. First, in a so-called "screening step", worst case conditions are assumed to identify those substances which are clearly uncritical. Then in a second step ("first-tier"), more realistic assumptions are made. For further refinements and higher tier assessments, the use of literature data is restricted, meaning that specifically designed field studies will be necessary in many cases.

Concerning the exposure estimate, new default residue values are given and the former avoidance factor is excluded. With regard to the toxicity data, it is now possible to take the geometric mean of available endpoints from different species instead of the lowest endpoint, as was previously the case.

Furthermore, full risk assessment schemes are given for granular formulations and treated seeds, and some approaches are given for substances with endocrine disrupting properties and for the risk from metabolites. Protection goals and the level of protection which is derived by the proposed risk assessment scheme are discussed in detail.

It can be concluded that the opinion further increases the complexity of the birds and mammals

risk assessment and will most likely lead to the need for the generation of more higher tier field data. Therefore, it will increase the efforts which will need to be done by the notifier.

Until the publication of the new guidance document, the current PPR Panel opinion should be the basis for the avian and mammalian risk assessment.

The respective PPR Panel opinion and its appendices are available for download: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902014630.htm

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

Current topics concerning Environmental Fate presented at the AgChem Forum

- The conclusions from the ELINK workshop dealing with linking exposure and effects in the aquatic risk assessment for pesticides were presented. Main issues were the handling of time-varying exposure regimes including the use of time-weighted average concentrations to derive ecotoxicologically relevant concentrations (ERC). A printed guidance document (SETAC publication) is foreseen for the end of 2008/beginning of 2009.
- A proposed Guidance on Assessing Soil Persistence was presented. While the short-term protection goal is addressed by the Annex I assessment, the protection of the structure and functioning of characteristic soil communities (Community Recovery Principle, CRP) in comparison to sustainable agriculture, and this protection in comparison to nature reserves (Ecological Threshold Principle, ETP) are considered in the guideline proposal presented. A trigger (10°C , $\text{pF} = 2$) of $\text{DegT}_{50} > 90$ days is suggested for the CRP, with the exposure concentration 2 years after last application as relevant concentration and a $\text{DegT}_{50} > 180$ days for ETP (7 years after last application).

The validation of the proposed assessment with old substances did not show fundamental shortcomings of the method. However, it was hampered by a fundamental lack of data. This small data basis was criticized and a broader

evaluation before an introduction of the guideline was asked for during the discussion. The proposal of the guideline (Report 601712003) and the evaluation (Report 601712002) can be found on the RIVM website. The finalization of the guideline proposal is foreseen for spring 2009.

- The new Q10 default value based on 99 datasets with 53 compounds ($Q_{10} = 2.58$) and suggested by the PPR Panel was discussed by EFSA. Q10 is used in the Arrhenius equation for temperature correction of DT50 values. The new value leads to longer half-life values for pesticides in soil for the reference temperature of 10°C, while the impact on surface and groundwater PECs is difficult to assess. According to EFSA, the new value should be used for all dossiers submitted after 31 July 2008.

For more information regarding these or other topics concerning Regulatory Science, please contact Dr. Monika Hofer at monika.hofer@scc-gmbh.de.

Deadline for completion of review under Directive 91/414/EEC postponed for Lists 3 and 4

On 28 August 2008, Regulation (EC) 848/2008 (the Regulation) was published in the Official Journal. With the new law, the deadline for the termination of the review process for existing substances in lists 3 and 4 is set for 31 December 2009. As stated in the Regulation, a Draft Assessment Report (DAR) has been prepared for most of these substances and a decision for (non)-inclusion will be made by the end of 2008. For those substances where no decision has been made, the deadline has been postponed to 31 December 2009.

The Belgian approach to implementing Regulation 33/2008

On 27 August 2008 the Belgian registration authority published a press release in which they informed the public on how the national authority will implement the provisions set out in European Regulation 33/2008 (the Regulation) in Belgium. The Regulation describes the re-submission procedure for active substances which were either non-included to Annex I of Directive 91/414/EEC or were voluntarily withdrawn.

As stated in the Belgian press release, the

publication of the non-inclusion decisions for voluntarily withdrawn substances was expected in September 2008. Within six months after publication of the non-inclusion decision (3rd and 4th stage substances), and within 6 months after entry into force of Regulation 33/2008 for stage 2 substances, a dossier with additional or new data on the substance must be re-submitted. The EU authorities and the RMS will evaluate the new data and will prepare an additional draft review report resulting in a proposal for inclusion or non-inclusion to Annex I of Directive 91/414/EEC. To date there are 49 substances that were voluntarily withdrawn based on the provisions in the Regulation.

According to the press release, 33 substances of the 49 mentioned above are currently marketed in Belgium. For these 33 existing active substances, the Belgian authority developed specific provisions. It was decided to withdraw all authorizations for products based on these substances by 31 December 2010. At the same time, no new authorizations, re-authorizations or prolongation of authorizations for these substances will be possible during this time period. Only existing authorizations can be maintained.

With regard to the 33 substances, the Belgian national authority will only deal with specific issues such as, for example, change of registration holder, authorization of parallel import, and the change of product uses due to new MRL setting as determined by regulation 396/2005/EC. If authorizations for these products expire prior to 31 December 2010, registration holders are asked to apply for re-authorization by 15 November 2008 at the latest. In the cover letter accompanying the application, it must be mentioned that the substance was voluntarily withdrawn. In addition, all other claims with regard to the substance concerned must be listed in the letter.

If a dossier for a voluntarily withdrawn substance is resubmitted in the European process and the following evaluation results in a non-inclusion decision to Annex I of Directive 91/414/EEC, the registration for the substance will be withdrawn on 31 December 2010 as well. Storage and disposal of products based on these substances will no longer be permitted. Stocks already sold may be used during one additional year.



Revision of Directive 91/414/EEC: Differing opinions presented at AgChem Forum

The highlight of the AgChem Forum (30 September to 01 October 2008 in Berlin) was the very lively discussion between the participants and the Members of the European Parliament, Mrs. Hiltrud Breyer (Group of the Greens/European Free Alliance), and Mrs. Erna Hennicot-Schoepges (Group of the European People's Party (Christian Democrats) and European Democrats) on the revision of Directive 91/414/EEC.

For Mrs. Breyer and Mrs. Hennicot-Schoepges, the crisis of the financial system clearly indicates that the free market cannot regulate itself; therefore, according to Mrs. Breyer, the new regulation is absolutely necessary, and, while a collapse of the financial system might take some years to recover, a collapse of the ecological system will take many hundreds of years to fix. It can surely not be in anybody's interest to have toxic pesticides on the market, which is what the cut-off criteria for approval of actives under the revised Directive 91/414/EEC will prevent. She criticized that the PSD, in their recent position paper "Assessment of the impact on crop protection in the UK of the 'cut-off criteria' and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products in the market" (Pesticides Safety Directorate, May 2008), combines cut-off candidates and candidates for substitution. She insisted they must not be mixed and therefore an 85 % reduction of the registered pesticides, as indicated in this paper, is incorrect and unfair to the public. She emphasized that this is not the right moment to create panic by publishing such figures! Mrs. Hennicot-Schoepges, stressing that she spoke in the name of 450 million European voters, insisted that the revision of 91/414/EEC must be seen by the chemical industry as an incentive to develop safer products and, if this would already have been done under the current Directive, there would be no need for the revision.

Richard Davis (Head of Approvals, PSD, UK) indicated the essential shift in the evaluation from Directive 91/414/EEC to the revised regulation, is from risk- to hazard-based assessment. And, while the UK supports many points of the new regulation, the UK is very much concerned with the hazard criteria and the proposals for substitution. The biggest problem seen in this context is

endocrine disruption, as currently no international available and agreed-upon test guidelines for the assessment of substances with endocrine disrupting potential are available. The speaker then presented the data assessed in the PSD paper criticized by Mrs. Breyer. It was shown that in this paper, the non-inclusion and the substitution are clearly separated. Nevertheless, it is PSD's interpretation of the parliament's proposal that candidates for substitution cannot be re-authorized after the first five year period. Therefore, after this period, these active substances will be lost for use in agriculture and it is justified to group them together with those not included under Annex I.

The ensuing debate was very lively and no compromise or mutual understanding could be seen.

The European Parliament's proposal for the article of the revised regulation under discussion in this forum is quoted below (bold print as given on the website to indicate amendments by the European Parliament on Council's common position):

Article 24 – paragraph 1

1. ***By way of derogation from Article 5 and Article 14(2)***, an active substance complying with the criteria provided for in Article 4 shall be approved ***once*** for a period not exceeding ***five years, where other already approved active substances or alternative agricultural methods or practices are significantly less toxic for consumers or operators or present significantly fewer risks for the environment. The assessment shall take account of the criteria laid down in point 4 of Annex II.***

(<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-412.104+01+DOC+PDF+V0//EN&language=EN>;

DRAFT RECOMMENDATION FOR SECOND READING on the Council common position for adopting a regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, 2006/0136 (18.9.2008)).

For more information regarding these or any other topics concerning Agrochemicals, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scg-gmbh.de.

Authorization of biocidal products

Directive 98/8/EC concerning the placing of biocidal products on the market not only anticipates the evaluation and approval of biocidal active substances before they can be placed on the market; but also stipulates that biocidal products containing such approved active substances have to be authorized or registered in a second phase prior to being placed on the market.

For products based on so-called existing biocidal active substances, a derogation was granted allowing them to remain on the market without authorization, provided that the existing active substances will be part of the 10-year review program. According to an estimate by the EU Commission, there is an impressive number of approximately 50,000 such existing biocidal products¹ in the European Union.

The more actives that enter Annex I/IA, the more biocidal products based on those actives will have to be authorized/registered. Eventually, a huge workload of product authorization procedures will have to be handled by applicants and national competent authorities.

At the present stage of the review program, 13 active substances have made it into Annex I/IA. With each additional active listed, it becomes even more important to develop a workable regulatory system for the authorization/registration of existing biocidal products.

Directive 98/8/EC lays down a national system of product authorizations/registrations, i.e. the application for authorization/registration of a biocidal product has to be filed with the national competent authority in the member state where the product will be marketed. After evaluation of this application, the national competent authority may grant the authorization, which by definition is limited to its national territory only.

If a biocidal product is to be marketed in more than one Member State (MS), Directive 98/8/EC, Article 4, provides for a special procedure called mutual recognition of authorizations. When applying for mutual recognition, a biocidal product which has

already been authorized in one member state may be authorized in other member states in a simplified procedure. In fact, the general provisions of mutual recognition as laid down in Directive 98/8/EC have a great potential of reducing the huge workload for the upcoming authorizations of existing biocidal products down to a manageable dimension.

Keeping in mind the factual failure of the mutual recognition system in the framework of Directive 91/414/EEC on plant protection products (which served as a “role model” for the biocides legislation), and considering the slow progress made in the biocides review program, the competent authorities are well aware that a smoothly functioning mutual recognition procedure for biocides, which is applied throughout the EU in a harmonized manner, is not just a central task but will also be of key importance to the overall credibility of the EU biocides legislation in the future.

Therefore, a new group called the PA&MRFG has been established. The group’s complex name (Product Authorisation & Mutual Recognition Facilitation Group) indicates where its emphasis will be placed.

The aim of the new group is “to facilitate the dialogue between MSs on questions linked to procedures for granting product authorizations/registrations and mutual recognition of these”, to develop and keep updated guidance for member states and applicants; to discuss procedural, regulatory and scientific issues; to provide for the overall management of mutual recognition in the future, and to act as a central forum for discussing points of disagreement.

The group, consisting mainly of representatives of the member states, is chaired by the member state which provides the presidency in the Council. Furthermore, Industry participates as an observer and the Commission provides support to the group e.g. by drafting the summary notes after each meeting. The group meets regularly before the Competent Authority meetings.

In our newsletter, we will keep you up to date on the most important developments and proceedings of the PA&MRFG.

For more detailed information about this or other topics concerning Biocides, please contact Dr. Holger Zitt at holger.zitt@scc-gmbh.de.

¹ An existing biocidal product contains one or more existing biocidal active substances listed on Annex I/IA of Directive 98/8/EC and has been placed on the market before the latest date of inclusion in Annex I/IA of its active substances.



Technical aspects from daily work with ECHA

In the last few months, SCC has gained significant practical experience through filing documents to the European Chemicals Agency (ECHA). Based on this, we would like to share some **general aspects** with you **in preparing inquiries and technical dossiers (IUCLID 5)**, especially with regard to general data required by the authorities for substance identification. ECHA takes ANNEX VI very seriously. Although some missing data might not cause a problem with regard to the completeness check, the following data certainly will be required by ECHA:

- CAS number and CAS name if available in the CAS database – ECHA requires this information not only for the main constituent(s), but also for impurities and additives. This data can be obtained from the Chemical Abstract Service (CAS). SCC can support you in getting this information.
- According to Annex VI of Regulation (EC) No 1907/2006, spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) and chromatograms (HPLC, GC) have to be provided (including parameters and interpretation of the results). If some of these analytics are not technically feasible, or if they do not appear scientifically necessary, a convincing rationale has to be presented.
- According to Annex VI of Regulation (EC) No 1907/2006, a description of the analytical methods or the appropriate bibliographical references is necessary for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information must be sufficient to allow the methods to be reproduced. If this requirement is not already covered by spectral data and chromatographical information, the respective method has to be provided.
- Moreover, referring to section 1.4 of the dossier, ECHA asks for a description of methods for quantification of main constituent(s), as well as of relevant elements of the main constituent(s), if applicable, and for the quantification of impurities and additives. The determination of the

substance's purity and the concentration of the impurities/additives have to be confirmed using the methods described here.

Specific technical aspects of dossier preparation and other technical aspects involving REACH will be dealt with in future newsletters.

Pre-registration: Deadline approaching

Generally under the new chemicals regulation, REACH, each potential registrant of phase-in substances manufactured or imported in quantities of at least one ton per year has the possibility to benefit from extended registration deadlines (2010, 2013 or 2018) depending on the substance and the tonnage. Pre-registration is not obligatory; however, those who miss the deadline of 30 November 2008 will have to submit a full registration dossier without delay or must stop production/import. The same applies to all non phase-in substances that are manufactured or imported in quantities of one ton or more.

Pre-registration requires just a few pieces of information about the substance to be submitted to ECHA in Helsinki using the REACH-IT portal on the ECHA website. All pre-registered substances and substances for which available information is relevant for QSAR, will be listed and published, using a grouping of substances as well as the read-across approach (identified by EINECS, CAS and/or other identity codes) by 1 January 2009 on the ECHA website, outlining a first anticipated registration deadline.

Prior to any data submission to ECHA, each user has to sign-up in REACH-IT and create a user account (a detailed description is provided on the website, guiding the applicant through the different steps). Only a European legal entity can act as a registrant.

In general, there are two options to pre-register substances using the REACH-IT portal: either each substance is pre-registered separately, recording all data required directly into the system, or a pre-registration for several substances is submitted in a single XML-file using the bulk registration functional. Alternatively, a IUCLID 5 plug-in can be used.

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Usually for each phase-in substance, one **Substance Information Exchange Forum (SIEF)** should be established at the beginning of January 2009. Prior to this date, pre-registrants of the same substance will be sorted and pre-SIEFs formed. By the end of 2008, each participant will have to check if the pre-registered substance is indeed the same for the purpose of SIEF formation and registration.

Pre-registration period lasts from **1 June up through 1 December 2008**, meaning that almost two thirds of the time has already elapsed: less than two months remain to pre-register! As the deadline approaches, all potential registrants who have not yet pre-registered should take the opportunity to gain time and postpone their registration deadlines.

It is important to note that due to increasing activities over the last few weeks, access and exchange with the respective IT tool has slowed down significantly and requires much more time even for simple tasks.

SCC offers support for pre-registration, either directly or as a third party, to allow companies to benefit from the extended deadlines.

ECHA adds new section to its website

In order to publish public information and document from REACH processes as they become available, ECHA has added a new section to its website. The following information will be available:

- Registry of intentions (e.g. Annex XV dossiers)
- List of pre-registered substances
- Candidate list of substances of very high concern (SVHC) for authorization
- Substance information of registration dossiers

The new section can be accessed by the following link: http://echa.europa.eu/chem_data_en.asp.

Re-imports

According to article 2(7)c of the REACH Regulation 1907/2006/EC, substances re-imported into the EU are only exempt from registration if they have been previously registered. Pre-registration by EU manufacturers does not fulfill the exemption's requirements. The exemption only applies after substance registration by the manufacturer in the supply chain. This position on re-imports has been confirmed by several national help desks.

For this reason, re-importers are advised to pre-register all re-imported substances. Industry organizations issued complaints to ECHA about the re-imports issue, stating that it causes unnecessary burdens to industry and to increases the number of pre-registrations and SIEF participants unnecessarily.

The agency then approached the European Commission to assess options for avoiding pre-registration of re-imported substances, since the only option would be to amend the REACH Regulation. Even though feasible, such a change is unlikely to be made before the pre-registration period ends on 30 November 2008. Therefore, SCC recommends pre-registering re-imported substances. Re-importers should not count on potential changes to the legal text.

REACH HOT TOPICS

Authorization

After its meeting in October, the ECHA Member State Committee will publish the first candidate list of SVHC that will potentially be subject to authorization. The candidate substances will be taken from a list of 16 substances which were subject to public consultation in July and August. The list of 16 substances and their respective substance dossiers can be downloaded from the ECHA website (http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp).

The first candidate list to be published this autumn will be evaluated according to defined criteria (PBT (persistent, bioaccumulative and toxic), vPvB (very Persistent, very Bioaccumulative), wide dispersive use, high volume) in order to priorities candidate substances for the criterion of Annex XIV, which is planned to be published at the latest by 1 June 2009. A "sunset date" will be individually set for each substance until the manufacturing/importing of the substance is allowed.

An application for authorization to continue the use of authorized substances has to be sent to ECHA at least 18 months prior to the sunset date. Producers have to unsolicitedly inform recipients if an article contains a substance listed on the candidate list and if the substance is present at levels > 0.1% to allow safe use. This information must include, as a

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minimum, the name of the substance in question. This information must also be provided to consumers if they request it. The relevant information is to be provided free of charge and within 45 days of the request.

SCC participates in REACH workshop in Japan

SCC was invited to give a presentation on a one-day REACH workshop on 8 September organized by "The Chemical Daily" in Tokyo, with approximately 200 participants. Dr. Charlotte Krone, Manager Regulatory Affairs, made a presentation at this workshop. Mr. Kenji Makita and Mr. Norio Ohta of SCC's Liaison Office Japan were also in attendance.

Dr. Krone's presentation dealt with "Principles, Strategies, Lessons Learned, and Consequences for the SIEF". The four European and seven Japanese speakers updated representatives of some of Japan's most well-known companies about the latest developments in REACH and pre-registration, respectively. The expert audience appreciated the sophisticated level of knowledge presented at this workshop with respect to REACH. SCC was very pleased for the opportunity to share its REACH knowledge with interested parties in Japan.

New labelling and classification rules for chemicals in Europe

GHS is the United Nation's (UN) globally harmonized system of classification and labelling of chemicals. The European Parliament (EP) agreed to the European Commission's (EC) proposal on the implementation of GHS in the European Union (EU) on 5 September 2008. Through GHS, the industry is forced to adapt material safety data sheets (MSDS) and labelling to the harmonized international rules.

It is the aim of the European authorities to implement GHS together with REACH. Therefore, the re-classification and labelling of *substances* must be completed by 1 December 2010, which is as well the deadline for registration of substances above 1000 tons and other substances of high concern under the REACH Regulation. *Mixtures* must be classified

according to GHS by 1 June 2015 at the latest. With the entry into force of the GHS system, the current EU classification and labelling system will be replaced on 1 June 2015. During the interim period, both classification and labelling according to both systems will be required for the MSDS.

30th Adaptation to Technical Progress (ATP) was published on 15 September 2008

The 30th Adaptation to Technical Progress (ATP) was published on 15 September 2008 in the Official Journal of the European Union (<http://eur-lex.europa.eu/en/index.htm>) and will enter into force in October 2008.

This document amends 67/548/EEC known as "Directive on Dangerous Substances". This directive regulates the classification, packaging and labeling of dangerous substances in the EU aiming at the protection of human health and the environment. According to the European Commission's website, the 30th ATP amended or incorporated the classification, packaging and labeling requirements for more than 800 substances. With regards to REACH, it is important to note that substances which are categorized (category 1 or 2) as carcinogenic, mutagenic or having reproductive toxic effects under the provision of Directive 67/548/EEC, may need authorization to be used or placed on the market

On the UN level, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) sets the framework for classification criteria and labeling rules on the international level. These provisions are on their way to being implemented on the EU level through the proposed "Regulation on the Classification, Labelling and Packaging of Substances and Mixtures". It is expected that the proposed Regulation will soon replace the current Directive 67/548/EEC.

For more information about these or other topics pertaining to Chemicals, REACH or Consumer Products, please contact Dr. Werner Köhl at werner.koehl@scc-gmbh.de.

EDDMS-system and CADDY-format – how are these terms associated?

What is EDDMS?

SCC's Electronic Dossier and Data Management System (EDDMS) is a data archiving and retrieval system that guarantees fast and reliable access to archived information for a variety of needs. It electronically archives and stores all regulatory and scientific information available from all over the world for our clients' active substances and products. EDDMS can be used to facilitate all regulatory submissions: for chemicals (REACH), plant protection products, biocides, pharmaceuticals or consumer products, or any other type of product. EDDMS has tools for data administration, data presentation, tracking of studies and regulatory submissions, as well as a comprehensive search and archiving function. For a more detailed description of the tools please refer to our EDDMS brochure under www.scc-gmbh.de/brochures. Additional information can be found in previous SCC newsletter editions, for example Vol. 7, No. 4, September 2007, Vol. 8, No. 1, January 2008, and Vol. 8 No. 2, May 2008 which can be retrieved under www.scc-newsletter.de.

What is the CADDY-format?

CADDY (Computer Aided Dossier and Data Supply) is a standardized *electronic format* for the exchange, archiving and evaluation of complex dossiers. It is the only electronic dossier format accepted by the European Commission and the majority of European Member States. The most recent version of the specific retrieval software can be found under <http://caddy.ecpa.eu/>.

How are EDDMS and CADDY associated?

All regulatory information needed to generate a dossier in CADDY format is entered into EDDMS once. This information is then electronically imported from EDDMS into the CADDY format – correctly and efficiently (an exclusive feature at SCC). There is no need for documents to be handled, no chance of typing errors, and all entries are correct. Based on this data pool, as many dossiers in CADDY format as needed can be generated. Through the submission of dossiers in CADDY format, a very limited number of paper copies have to be provided to regulatory authorities. This approach is less time consuming and therefore less cost intensive.

Without the exclusive import feature that transfers information from EDDMS into the CADDY format, the requested information must be re-entered by hand. For each additional dossier that may need to be generated in CADDY format the requested information must be re-entered by hand – again and again. That means taking each document, typing in all the information, paging through the document to find pertinent information, then laying the document aside so that the next one can be entered. This approach involves a high risk of errors and is very time consuming.

Advantages for the client in generating a CADDY dossier at SCC through the use of EDDMS:

- Generation of CADDY dossiers via EDDMS significantly reduces the possibility of errors.
- Generation of CADDY dossiers is considerably easier and faster, saving time and money.

Additional advantages of EDDMS:

- Efficient compilation of dossiers.
- Complete regulatory information at hand everywhere you need it, including electronic documents and submission details.
- Regulatory status of studies can be determined – the question which studies were submitted why, where and when is easily answered!
- Reference lists can be generated in any required format for all authorities world-wide!
- Data storage and retrieval is quick and easy.
- Available data can be searched, sorted and printed depending on needs of the user.
- Submissions can be quickly handled and compiled electronically!
- Inquiries for studies from authorities around the world can be quickly answered!

For further information, please contact Dr Friedbert Pistel at friedbert.pistel@scc-gmbh.de

Update Feed Additives

The long awaited guidelines on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council regarding the preparation and presentation of applications, and the assessment and authorization of feed additives (Commission Regulation (EC) No 429/2008) were finally published at the end of May 2008. In total, many thousands of feed additives (that have partly been used in animal nutrition for over several decades) have to apply for re-authorization before the deadline of 7 November 2010. SCC is in full swing in this process of re-authorizing feed additives. The vast majority of these feed additives are so-called “non-holder specific authorizations” and only a few hundred are “holder specific authorizations”.

SCC has already finished the first application dossier with two active substances according to the new guidelines. This dossier was discussed with the European Food Safety Authority (EFSA) in September and, based on the outcome of that discussion, all other dossiers will follow the same line.

Since this is mainly a re-authorization process, a full dossier is rarely needed. SCC has developed a template with the specific needs for each individual dossier. Based on the category of feed additive and some other basic questions concerning the active substance, the demands for each dossier can be seen in a matrix format. Of course, new additives can be registered at any time.

If you have any questions relating to this Regulatory Department, please do not hesitate to contact Ruud Huibers at ruud.huibers@scc-gmbh.de.

New regulation on export and import of dangerous chemicals

Regulation 304/2003 implemented the Rotterdam Convention on prior informed consent (PIC) on the European level, which entered into force on 24 February 2004. In 2006, the European Court of Justice annulled Regulation 304/2003 because it was based on an insufficient legal frame. At the same time, the Court stated that the effects of 304/2003 were supposed to be maintained until the adoption of a new Regulation which is “founded on appropriate legal bases”. On 31 July 2008 Regulation 689/2008 was published replacing Regulation 304/2003.

The Commission proposes to add two new POPs

The European Commission (COM) has proposed amending the Persistent Organic Pollutants (POPs) Protocol to the UN Convention on Long-Range Transboundary Air Pollution. COM proposed adding the pesticides Endosulfan and Trifluralin. Both substances have been reviewed under Directive 91/414/EEC with the result that both substances “exhibit characteristics of POPs”. In the EU, plant protection products based on Endosulfan were withdrawn by December 2007 and plant protection products based on Trifluralin will be withdrawn by December 2008. This proposal will be discussed during the next meeting of the Executive Body in December 2008.

For further information, please contact Dr. Friedbert Pistel at friedbert.pistel@scc-gmbh.de

Newsletter

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CALENDAR

20 – 21 October 2008: 3rd Annual Biocontrol Industry Meeting, Lucerne, Switzerland

The international Biocontrol Manufacturer Association and the Research Institute of Organic Agriculture are sponsoring the 3rd annual biocontrol industry meeting in Lucerne, Switzerland, from 20 - 21 October. Verena Peharz, Assistant Regulatory Manager Agrochemicals, will be at this informative event.

18 – 19 November 2008: 3rd annual Conference Crop Protection: Post Patent Products, IPR and Parallel Trade, Amsterdam, The Netherlands

Informa Life Sciences 3rd annual Crop Protection: Post Patent Products, IPR and Parallel Trade conference is a unique forum, designed to bring together all parties involved with the further development and registration of off patent crop protection products. This year's agenda will provide key market intelligence and commercial insight plus practical advice on how best to navigate the European regulatory system in order to obtain marketing authorizations for your products. Dr. Albrecht Heidemann will be there and looks forward to meeting you to discuss your regulatory needs.

04 – 05 December 2008: Biocides 2008, Vienna, Austria

Dr. Hans-Josef Leusch, Dr. Martina Galler, Dr. Stefanie Schirmer, and Dr. Jürgen Gutknecht, Senior Advisor Regulatory Affairs, will attend this multinational conference that focuses on the legal issues and trade aspects of biocidal products. The meeting will be held in Vienna on 4 and 5 December 2008. More information can be obtained at the [Feierl-Herzele website](#).

To make an appointment during one of these events, please contact Ms. Lisa Hubrich at +49-(0)6734-919115 (tel.) or at lisa.hubrich@scc-gmbh.de.

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