

Newsletter

Volume 11, No. 1, April 2011



SCC is now in its new home

Over the Christmas/New Year holidays, a relocation of considerable proportion took place as SCC moved into its new headquarters in Bad Kreuznach. One can only imagine what kind of logistics are necessary to relocate 90 employees, project records and archives, our EDDMS and GLP archives and our computer services, all within just a few short days. Special thanks go to all those involved in making the relocation go as smoothly as possible.

With 5000 m² of office, archiving and meeting space, we are now even better prepared to handle existing as well as new business and your special meeting needs.

Task Force management, whether it is general or technical in nature, is one of the main areas of emphasis at SCC. We can accommodate meetings both small and large within our new facilities, with meeting rooms having a seating capacity of up to 150 people. In addition, our event manager can provide assistance with travel, accommodations, and general support in planning and executing Task Force meetings, general meetings and events. Our location is central to the Frankfurt Rhein-Main and Frankfurt-Hahn airports, the main train stations in Bad Kreuznach, Mainz and Frankfurt, as well as the main highways leading to all major cities in Germany and in Europe. One could say that SCC is not only the central point for scientific and regulatory assistance, but also the central point for handling meetings and events of all sorts.

Regardless of whether your needs are in scientific and regulatory support for agrochemicals and biopesticides, biocides, chemicals, feed and food additives, veterinary medicine, archiving solutions

or Task Force management, SCC can provide you with high quality service and consulting. We take care!

An important change has taken place at our office in Japan: Mr. Norio Ohta retired on 31 March 2011 from his position as Director, SCC Liaison Office Japan. Mr. Ohta was instrumental in the establishment of the Liaison Office Japan, and responsible for increasing the recognition of SCC's services and capabilities in Japan. His efforts are very much appreciated and we wish him all the best in his retirement.

This edition of the SCC Newsletter once again provides you with the latest scientific and regulatory information available. For questions, feedback or inquiries regarding special needs and services, please contact us at our offices in Bad Kreuznach or at our SCC Liaison Office Japan. Contact information can be found at the end of this newsletter.

Dr. Friedbert Pistel
President

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AGROCHEMICALS

Transition, update, authorization and renewals: Status of regulatory affairs in light of the new Regulation 1107/2009

The 18th International Conference on the Registration of Agrochemicals in Europe was held in Brussels in April of this year. Regulatory experts from all over Europe came together to hear about the newest developments and updates regarding agrochemical registration. A few highlights are presented here:

Wolfgang Reinert, DG Health and Consumer, European Commission discussed the changes that will occur in 2011 as a result of the New Regulation 1107/2009. The "big standards" that will change on 14 June 2011 are:

- criteria for approval
- zonal system
- data protection and data sharing
- deadlines
- diversification of approval types
- comparative assessment
- safeners, synergists and co-formulants added to the scope.

In addition, integrated pest management (IPM), parallel trade, minor uses, extended approval criteria, national provisional approvals (NPAs), advertising, record-keeping, information duty for users, monitoring and control and fees and charges will also undergo changes.

Transitional provisions will be in place. For active substances, Directive 91/414 will continue to apply with respect to procedure and conditions of approval to substances under AIR 1 (Regulation 737/2007), substances resubmitted under Regulation 33/2008, and new active substances for which completeness of the dossier is established prior to 14 June 2011 (Regulation 188/2011). For products, applications for authorizations pending on June 14 and authorizations to be amended or withdrawn following inclusion/approval on 14 June will be decided on the basis of national law in place prior to

that date. NPAs will be evaluated on a case-by-case basis with no explicit reference under the transitional measures. It appears that Art. 8(1) of Directive 91/414 can be applied after 14 June to active substances to which the completeness of the dossier was established prior to that date.

Of importance with regard to the implementation of tasks is the list of candidates for substitution from currently approved substances (deadline: 14 December 2013) and specific scientific criteria for the determination of endocrine disruptor properties, along with detailed rules for the implementation of the provisions for co-formulants (here no date has been set).

Reinert also listed the guidance documents that are currently being drafted. These include zonal assessment and mutual recognition, renewal of authorizations and risk envelope, among others.

The harmonization and new procedures in regard to product chemistry of actives and plant protection products was also the subject of a workshop held in Braunschweig in March 2011. An additional workshop regarding harmonized classification and labeling of active substances in plant protection products was also held in Berlin in April of this year. One of the major topics was to streamline and coordinate assessment methods under Regulations 1272/2008 and 1107/2009, the discussion process internally and in between the European Commission, Member States competent authorities, EFSA, ECHA and CARACAL (Competent Authorities for REACH and CLP), data submission and the interpretation of results.

Steffen Beerbaum, Responsible Expert for active substances and plant protection product authorization at the German Federal Ministry of Food, Agriculture and Consumer Protection discussed Member State feedback on the transition from Directive 91/414/EEC and the new Regulation 1107/2009. Mutual recognition is the most important topic here, as Germany is of the opinion that mutual recognition does not apply to authorizations granted under Directive 91/414/EEC after 14 June 2011. ECPA, on the other hand, expected that authorizations that have been granted according to the Uniform Principles are in accordance with Article 29 of the new Regulation 1107/2009 (Euros Jones, ECPA).

Herman Fontier, Head of EFSA's PRAPeR Unit, discussed the future structure of EFSA. In the future, there will be three scientific directorates:

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- Scientific strategy and coordination
- Scientific evaluation of regulated products
 - application desk
 - feed
 - nutrition
 - food ingredients and packaging
 - GMO
 - pesticides
- Risk assessment and scientific assistance.

These changes reflect the increasing workload on applications and improve service to applicants. It will consolidate resources for public health priorities (chemical and biological contaminants) and animal/plant health. In addition, it will prepare EFSA for future evolutions (financing of activities, evolving role of panels, etc.). The changes will be made in a step-by-step approach with a graduation migration from 1 May 2011 to 1 January 2012.

The new Pesticides Unit will be in place on 1 May 2011. This will replace the PRAPeR Unit and the PPR Unit, which will allow more input from the practice in the development of guidance documents and more flexibility in resource management.

Jeroen Meeussen, DG SANCO, European Commission spoke about the Annex I Renewal programs AIR-1, AIR-2 and AIR-3. The renewal decisions for the seven actives under AIR-1 are expected to be completed by mid-2011. For these substances, the Step 1 procedure must be completed by 31 January 2012; the Step 2 procedure is to be finished by 31 July 2015.

AIR-2 covers 31 substances that would expire in 2011 and 2012, but which have had their expiration dates amended to 31 December 2015 (Directive 2010/77/EU). For these actives, dossiers will be submitted in three groups in 2012: February, May and August. Fifteen RMS and 20 C-RMS are involved in this evaluation process.

The AIR-2 substances fall in the transition phase of Regulation 1107/2009 (14 June 2011). Consequently, procedural rules under 91/414/EEC will apply while the decision phase will fall under Regulation 1107/2009. In addition, AIR-2 substance evaluations are planned to take a total of 29 months, based on time from dossier submission to decision, compared to 21 months for the AIR-1 substances.

AIR-3 substances involve a total of 146 active substances that will expire in the period of 2013 to 2018. All decisions have to be made before the end of 2018. The submissions will be made in "waves" over a three-year period. The substances are not categorized into any particular group, but rather the submissions are based on the dates of expiry of the Annex I inclusion. It is planned to keep the same timelines as for AIR-2. It is also the intention that all MSs are involved, with the RMS/Co-RMS system maintained.

In a presentation authored by William Graham of Monsanto and presented by Mike Carroll of Dow AgroScience, it was stated that the EU peer review for agrochemicals is an "outlier" compared to other systems such as the USA, Australia, Canada and Japan. Graham's proposal was that there should be one agency that totally controls pesticides approvals in the EU, as without it, timelines and transparency of the regulatory process are meaningless and bureaucracy can overtake good decision-making. He also appealed for data call-ins and a legal basis for Task Forces and that only scientifically peer reviewed data should be considered by regulatory authorities, and not other unsubstantiated sources.

Feedback from the three zones was presented by Gunilla Ericsson of Sweden's National Chemicals Inspectorate (Northern Zone), Thierry Mercier from the French Agency for Food, Environmental and Occupation Health (Southern Zone), and Darren Flynn of CRD (Central Zone). Presentations from all three zones reported experience up to now with the dRRs and voluntary work sharing. Gunilla Ericsson reported about the development of respective guidance documents, the establishment of a central steering committee, distribution of work to the zonal rapporteur and the intention for the entire Northern Zone to have a harmonized risk assessment. It was clearly presented that the core dossier should contain all national requirements for the Northern Zone.

Thierry Mercier reported on the experience with more than 30 registration reports in a voluntary work-sharing process, which included the re-registration of existing plant protection products as well as new products. There is already a guidance document in existence for the Southern Zone that describes the special requirements for this zone. Most of the comments regarded formal aspects of the dossiers, although in some sections, such as in the toxicology section, specific items including OPEX, GAPs and risk assessments were discussed.



Workshop on product chemistry in Braunschweig, Germany

The German Federal Office of Consumer Protection and Food Safety (BVL) organized a workshop in Braunschweig on 9 March 2011 on the changes coming with Regulation (EC) 1107/2009 with a view to evaluation of equivalence, formulation changes of plant protection products and other fields of product chemistry. A national monitoring program of the plant protection products market was also discussed at the workshop.

Dr. Ralf Hänel gave an overview of the changes concerning “product chemistry” coming with Regulation (EC) 1107/2009. The most important changes are: safeners and synergists will be evaluated like an active substance; there will be a list of undesirable formulants; plant protection products will only be granted authorization if the active substances, safeners and synergists contained therein are approved.

The evaluation of equivalence was presented by Dr. Dirk Goebel. In the new regulation, a procedure with fixed timeframes is stipulated for the evaluation of the equivalence of a technical active substance. The RMS will publish the equivalence report at the latest 60 days after submission of the necessary data. The Commission, the Member States and the applicant can then send their comments within 30 days. Should there be open issues to be discussed, the RMS and the applicant have to come to an agreement within another 45 days. If there is no agreement within this timeframe, the Commission will make a decision. A guideline for the evaluation of equivalence is already available (SANCO/10597/2003); an updated version will be published in May 2011.

Dr. Axel Steer presented the actual procedures for changes in the chemical composition of plant protection products in comparison to the new procedures coming with Regulation (EC) 1107/2009. A new guidance document is under preparation by BVL, CRD and others for discussion at EU level. It is suggested that the notification should be done within four weeks and the procedure of change should be completed within four months. The new guidance is intended to be a “living document” also including positive and negative examples. Since safeners and synergists will be handled like active substances, a simple notification process will

no longer be possible when it comes to a change in their concentration or an exchange with similar substances. If the formulation change is greater than 10 % of the total formulation, new toxicology-studies (sensitization, skin and eye irritation, etc.) have to be submitted.

Dr. Dirk Goebel held a presentation on the list of undesirable formulants coming with the new regulation. Based on the legal definition of undesirable formulants (Art. 27) a list is under preparation by the German and Spanish authorities. After its finalization, it will be integral part of the new regulation as its Annex III. The inclusion criteria for listing substances as undesirable formulants on Annex III are based on the requirements of the EU chemicals legislation and on the cut-off criteria for the active substances.

Dr. Claudia Vinke presented a monitoring program of plant protection products placed on the German market conducted by BVL. In Germany, every year two active substances will be in the focus of the program. BVL will randomly collect samples from plant protection products containing the active substances in focus. These plant protection products are analyzed for their physical and chemical properties and for their active substance content. The results are compared to the registered composition.

Dr. Nils Kurlermann explained that such monitoring will protect the users of plant protection products, the consumers of the crops and also the industry. BVL noticed many inconsistencies during inspections in the past, resulting in the need for more inspections. Furthermore a change in the law including more severe penalties is needed to stop the illegal placing on the market of plant protection products.

Finally, Dr. Roos (Bayer CropScience) demonstrated how companies try to take action against illegal trading. He explained that it is not easy to find efficient solutions with the existing legal instruments. In fact, it is possible to make the packaging unique by using for instance special seals, but as long as it is allowed to decant the product this will not really help to fight trafficking.

Another way to check if a product is genuine, is by means of markers, i.e. by adding a special marker substance or by C¹³ enrichment.

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



BIOCIDES

New EU biocides legislation well on its way

In June 2009, the European Commission published their initial proposal of a draft Biocidal Products Regulation (BPR). In the first reading in the European Parliament on 22 September 2010, more than 400 amendments to the Commission proposal were made. The Member States reached a political agreement in the Environment Council meeting on 20 December 2010 based on a text proposed by the Belgian presidency.

The common position of the Council and the Commission is expected for June 2011 and the second reading in the European Parliament is scheduled to be completed by the end of this year. If there are no unforeseen delays, the final adopted text of the BPR is scheduled to be published in the Official Journal of the EU around January/February 2012. As it was originally proposed by the Commission, the BPR could then enter into force sometime next year and apply from 1 January 2013 on.

Council political agreement

The text of the political agreement, including the recitals agreed within the Working Party on the Environment in January this year, was published on the Internet (document 5604/1/11 available under <http://register.consilium.europa.eu>).

Government officials who take part in the Council working group negotiations on the BPR say that this text is very close to the final adopted text. Therefore, it makes sense to take a closer look at the Council political agreement, also with a view to what is different in comparison to the original proposal by the Commission and the amendments by the Parliament. Some of the most obvious new elements introduced by the Council are the following:

- In its article 3, the Council text contains new and modified definitions, often using a different terminology compared to the Commission proposal. For instance, the definition of placing on

the market is more differentiated in the Council text: the new general term “*making available on the market*” is introduced whereas “*placing on the market*” is restricted to the first making available on the market. Furthermore, the term “*Community authorization*” was changed by the Council to “*Union authorization*” to reflect the general legal changes brought by the Lisbon Treaty (Treaty on the Functioning of the European Union). The simplification concept widely known as “*frame formulation*” is now called “*product family*”. Compared to the Commission proposal, new definitions are introduced by the Council and the Parliament: *authorization holder*, *product-type*, *single biocidal product* (instead of “*unique product formulation*”), *advertisement*, *administrative/minor/major change*, *vulnerable groups*. The following definitions were added in the Council text by making reference to existing or future EU legislation: *food and feed*, *Agency*, *nanomaterial*, *small and medium-sized enterprises*.

- The simplification concept formerly known as “*low-risk-products*” was fundamentally revised: the new concept is called “*simplified authorization procedure*” (see new Chapter IVA of the Council text), in which the old terms “*low-risk*” or “*registration*” have completely disappeared. A new BPR Annex I is introduced, in which there are special active substances eligible for the simplified product authorization process. In the current Council text, the following categories of active substances were listed on the new Annex I by political decision: substances authorized as food additives (*lactic acid*, *sodium acetate*, *sodium benzoate*, (+)-*tartaric acid*), substances included in Annex IV to the REACH Regulation (*ascorbic acid*, *linseed oil*), weak acids (*acetic acid*, *propionic acid*), traditionally used substances of natural origin (*lavender oil*, *peppermint oil*), pheromones (*oct-1-en-3-ol*, *webbing clothes moths pheromone*), substances included in Annexes I or IA of the BPD (*carbon dioxide*, *nitrogen*, (*Z,E*)-*tetradec-9,12-dienyl acetate*) and others (*baculovirus*, *bentonite*, *citronellal*, *iron sulphate*). The Annex I of the BPD currently containing ca. 40 biocidal active substances, will not be part of the BPR but become a “*Union list of authorized active substances*”, which will be published and kept up-to-date by the Commission. For applications for simplified authorization, a

relatively small data package is required. Applications for simplified authorization will have to be submitted directly to ECHA. After payment of a fee to ECHA, the application will be forwarded to a Member State Competent Authority, which shall evaluate the application and authorize the product within 90 days of accepting the application as complete. Upon authorization by that authority, the product can be made available on the market in the entire Union without asking for mutual recognition of the authorization.

- The Council has widened the scope of the Union authorization. The current draft BPR version foresees that from 1 January 2013 on, for biocidal products of product-types 6 (*preservatives for products during storage*), 7 (*film preservatives*), 9 (*fiber, leather, rubber and polymerized materials preservatives*), 10 (*construction material preservatives*), 12 (*slimicides*), 13 (*working or cutting fluid preservatives*) and 22 (*embalming and taxidermist fluids*) applications for Union authorization may be submitted to ECHA. From 1 January 2020 on, the scope of Union authorization will be opened to all other biocidal products except those of product-types 14 (*rodenticides*), 15 (*avicides*), 17 (*piscicides*), 20 (*control of other vertebrates, former PT 23*) and 21 (*antifouling products*).

As the new BPR will have a significant impact on all stakeholders in the biocides sector, SCC is closely monitoring the ongoing legislative process on the way to the future EU biocides legislation.

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



CHEMICALS, REACH, CONSUMER PRODUCTS

REACH *in practice*

Authorization under REACH

In February 2011, the first six substances subject to authorization were published in Annex XIV to the REACH Regulation^{1) 2)}. With the publication of these substances also the respective application dates for authorization as well as the last possible date (sunset date) until which placing on the market of Annex XIV substances is allowed without authorization were fixed.

The first six substances subject to authorization are:

1. 5-*tert*-butyl-2,4,6- trinitro-*m*-xylene (musk xylene)
2. 4,4'-diaminodiphenylmethane (MDA)
3. hexabromocyclododecane (HBCDD)
4. bis(2-ethylhexyl) phthalate (DEHP)
5. benzyl butyl phthalate (BBP)
6. dibutyl phthalate (DBP)

The earliest application date is 21 February 2013 for musk xylene and MDA and the earliest sunset date is 21 August 2014 also for these two substances.

With the authorization process under REACH, risks arising from substances of very high concern (SVHC) shall be properly controlled. SVHC will be replaced step-by-step by substances with fewer risks, if economically and technically feasible.

The authorization process already starts with the identification of SVHC substances in articles and publication on the Candidate List, triggering immediate action with regard to communication in the supply chain as well as notification requirements for candidate substances in articles. Once a substance is listed on the Candidate List, it will remain permanently on that list and the respective requirements will permanently apply.



For interested parties it is therefore highly recommended to make use of the commenting phase before a substance is included in the Candidate List.

The ECHA homepage has recently been updated with regard to the authorization section

http://echa.europa.eu/reach/authorisation_under_reach_en.asp

and now provides details on the application for authorization procedure as well as on the notification of substances in articles.

Notification dossier

The notification of SVHC in articles is required above a concentration of 0.1 % w/w and above 1 ton per year. The new IUCLID5.3 software (Substances in Articles notification dossier) is to be used. The corresponding REACH-IT update 2.2 was completed on 13 April 2011 and should now allow for electronic notification accordingly.

The first notification deadline is 1 June 2011 for substances included in the Candidate List prior to 1 December 2010. For all other substances, a deadline of 6 months after the inclusion in the Candidate List applies. There is no fee charged for the notification.

However, some exemptions with regard to the notification requirement are possible if substances

- do not come in contact to humans or the environment;
- have already been registered for that use.

A justification for the exemption reason (especially with regard to the exposure exemption) should be prepared so that it can be presented to enforcement authorities upon request.

Application dossier

After prioritization of Candidate List substances and their inclusion into Annex XIV to the REACH Regulation, substances cannot be placed on the market or used after the sunset date. Unless specific exceptions apply, Annex XIV substances may only be placed on the market if an authorization has been granted for a specific use. An application for authorization of an Annex XIV substance is required and must be submitted to ECHA using IUCLID5.3.

The base fee³⁾ for an application for authorization covering one applicant and one use is 50,000 EUR. Additional fees per substance, use and applicant may apply.

The European Commission will decide if authorizations are granted. ECHA's Committees on Risk Assessment and Socio-economic Analysis provide the Commission with opinions on the applications for authorization.

References for this article:

- 1) Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- 2) Corrigendum to Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- 3) Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

REACH Extended Safety Data Sheets – Obligations for Manufacturers, Importers, Suppliers and Downstream Users

REACH safety data sheet (SDS) requirements became legally binding on 1 June 2007. Annex II of the REACH Regulation, as amended in May 2010, provides detailed guidance on how to compile an SDS. There are several changes to previous formats and additional information also needs to be included. In addition, the CLP Regulation requires classification and labeling according to the GHS starting from 1 December 2010 (for substances) and from 15 June 2012 (for mixtures), respectively.

Each SDS needs to display a version number, a revision number and a supersession date on the first page. The SDS cannot contain any blank subsections. Substances that are bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in concentrations of equal or more than 1 % (w/w) need to be listed as well as those substances listed on the SVHC Candidate List with a concentration of equal or more than 0.1 % (w/w). For dangerous substances, the defined exposure scenarios need to be listed in a separate annex (extended SDS, eSDS). The information in the annex outlines the conditions for safe use and



needs to be consistent with the conditions included in the chemical safety assessment.

Downstream users have the obligation to identify, apply and recommend risk reduction measures and, if necessary, to communicate conditions of safe use by means of their own safety data sheets (REACH Article 37). The first obligation is to identify their own uses and to communicate these uses upstream in the supply chain. After that, their uses need to be compared to already existing exposure scenarios. If the own uses are included in those scenarios, exposure may need to be scaled down and on-site risk management measures installed or optimized. In the case where own uses are not included in existing exposure scenarios or if it is advised against the uses, downstream users have to contact ECHA and perform their own chemical risk assessment.

It has to be noted here that the deadlines for downstream user obligations are indeed critical. Downstream users need to comply with their obligations at the latest twelve months after receiving a registration number. Communication of own uses to ECHA is required at the latest six months after receiving a registration number.

Safety Data Sheet Required?

Suppliers need to provide safety data sheets for a substance or mixture, if a substance

- or a mixture is classified as dangerous
- is considered PBT or vPvB in accordance to criteria set out in Annex XIII to the REACH Regulation
- is included in the SVHC Candidate List for other reasons

Upon customer request, SDSs need to be supplied for mixtures that are not classified as dangerous according to Directive 1999/45/EC, but contain

- a substance hazardous to human health or the environment at a concentration of equal or more than 1 % (w/w) or 0.2 % volume for gaseous mixtures
- a PBT or vPvB substance at a concentration of equal or more than 0.1 % (w/w)
- a substance listed on the Candidate List at a concentration of equal or more than 0.1 % (w/w)
- a substance for which there are EU-wide workplace limits (country specific SDS may be required if national limits exist).

Finally, suppliers need to provide an SDS if special cases according to Annex I (1.3) of the CLP Regulation apply, e.g. gas containers intended for propane, etc.

An SDS does not need to be provided for substances (and mixtures) which are not classified as dangerous and which are not PBT, vPvB or of equivalent concern. Furthermore, SDSs do not need to be provided for certain products intended for the end-user (e.g. medicinal products or cosmetics), and if dangerous substances or mixtures are sold to the general public with safe usage communicated effectively (e.g. a corrosive cleaner where the danger is clearly displayed on the product label).

2nd Adaptation to Technical Progress to the CLP Regulation

The 2nd ATP to the CLP Regulation (Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008) entered into force on 19 April 2011.

The text incorporates the changes introduced by the 3rd revision of the United Nations Globally Harmonised System (GHS) into the CLP Regulation. Apart from amendments of the legal classification of four substances in Annex VI of the CLP Regulation, there are important changes to existing hazard classes and a new class was included. These are the most important changes:

- **Skin and respiratory sensitization:** The new sub-classes 1A and 1B were added. The generic concentration limits for the classification of mixtures containing skin sensitizers were revised, leading for example to a rather low limit of 0.1 % for the classification of a mixture in skin sensitization Cat. 1A.
- **Chronic toxicity to the aquatic environment:** If chronic aquatic toxicity studies are available, the classification will now be based on the results of these studies. There are two new tables indicating the NOECs and the resulting classification for degradable and non-degradable substances. The degradability of classified substances has an impact on the cut-off limits for the classification of mixtures with respect to chronic aquatic toxicity. So far, unclassified substances have to be classified for potential chronic aquatic toxicity applying the new rules.

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- **Hazardous to the ozone layer:** This is the new hazard class that has been added. The criteria for classification with respect to an ozone depleting potential are based on the properties and the predicted or observed environmental fate and behavior of a substance.

The new rules will apply to substances from 1 December 2012 on and to mixtures from 1 June 2015 on, but can be applied on a voluntary basis even before those dates. Transitional provisions are foreseen for substances / mixtures already placed on the market (1 December 2014 for substances and 1 June 2017 for mixtures).

Nevertheless, SCC recently obtained feedback from ECHA on a specific Annex VI report (CLH dossier on the harmonized classification and labeling) showing that authorities may request the consideration of the provisions of the 2nd ATP earlier than 1 December 2012.

SCC has gained experience in preparing CLH dossiers over the last months and has submitted dossiers to ECHA. Please feel free to contact us if you need assistance for the preparation of such dossiers.

Update of ECHA's IT-tools: REACH-IT 2.2. and IUCLID 5.3

As already announced in mid-February 2011 (ECHA NEWS Alert, 17 February 2011), ECHA performed for an update of - its IT tools in support of the REACH and CLP Regulations in order to adapt to the latest changes in legislation. This also includes additional dossier types such as Downstream User Reports (Art. 38, REACH) and Notifications of Substances in Articles (Art. 7(2), REACH).

For detailed support regarding the practical application of these updates, please also refer to the new Data Submission Manuals Part 20, 21 and 22 - all available on the ECHA homepage since mid-April 2011.

To allow time for the transition, IUCLID 5.3 was released at the end of February 2011; related plug-ins for the Chemical Safety Report, the Technical Completeness Check and the Dissemination and Fee Calculation were subsequently launched at the beginning of April and can be accessed via the IUCLID website. The update of REACH-IT then followed in mid-April 2011 in order to synchronize both IT systems. The new version 2.2 includes features such as adaptation of all C&L notification tools (online,

IUCLID 5.3 and bulk) to the 2nd ATP of the CLP Regulation.

Due to these modifications, all dossiers that have been prepared with the previous version of IUCLID 5 are no longer accepted by REACH-IT 2.2., meaning that an update to the latest 5.3 version has to be made. From the technical point of view, once the new IUCLID 5.3 application has been downloaded, the migration of data (e.g. existing datasets on substances) to the new format will take place automatically.

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



FEED & FOOD ADDITIVES, VETERINARY MEDICINE

The first dossier that SCC prepared has been formally re-authorized in the Community Register!

After the storm of the European deadline for the re-authorization of **feed additives**, we see that many companies are now taking some time to take a deep breath. But this calm period is not for long because the first questions from EFSA have already been received and partly been answered as well.

As mentioned in the last newsletter, SCC was involved in the preparation of 36 dossiers for re-authorization. The first feed additive has now been formally re-authorized in the Community Register! Some others are in the scientific risks assessment phase or in the completeness check by EFSA. Since the European Commission (EC) is managing the flow of dossiers to EFSA (using their priority list), some dossiers that we filed have not yet been formally forwarded to EFSA. It could take quite some time before the last dossiers are forwarded to EFSA.

For this year (and a few to follow), application dossiers for completely new substances are underway. We are fortunate to have some very interesting products among

them. Close contact with the EC and EFSA will be very useful and fruitful in this process.

Talking about the EC, an important change this year is that Willem Penning is leaving the Department of Feed of the European Commission. The new head of the Feed Department of the European Commission will be James Moynagh from Ireland, who has already worked within the EC for many years.

As always, **Japan** is a very strong partner country for SCC. This works in both ways: with Japanese companies who want to register their products in the EU but also with European companies wanting to register and sell their products on the Japanese market. In both cases, our liaison office is a very important connection. Our new Director, **Mr. Toshiyasu Takada**, has very promising connections and an extensive network in Japan, also in the animal nutrition area.

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



REGULATORY SCIENCE

Impacts of guidance document SANCO 7525/VI/95 – rev. 9 March 2011

The guidance document 7525/VI/95 “Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs” has been revised. According to the new revision 9 the climatic zones have been re-arranged:

Northern and central zone: Sweden, Norway, Iceland, Finland, Denmark, United Kingdom, Ireland, Northern France, Belgium, The Netherlands, Luxembourg, Germany, Poland, Czech Republic, Slovakia, Austria, Hungary, Switzerland, Estonia, Latvia, Lithuania, Romania and Slovenia.

Southern zone: Spain, Portugal, Southern France, Italy, Greece, Malta, Croatia, Serbia, Bosnia and

Herzegovina, FYROM (Former Yugoslav Republic of Macedonia), Turkey, Bulgaria, Cyprus.

Furthermore, the distribution of France between the two regions and the corresponding crop distribution is added to the revision 9.

The criteria for classifying a crop as “major crop” have been changed. Based on the new categories, the following crops are additionally categorized as “major crops”:

- Northern and central zone: cherries, beetroot, pepper, watermelon, sunflower seed, soya bean.
- Southern zone: plums, kiwi, courgettes, watermelon, cauliflowers, peas without pods, rape seed.
- World (for import tolerances): kiwi, pineapple, beetroot, courgettes, watermelon
- Some crops are now classified as minor crops:
Northern zone: Brussels sprouts and hops
- Southern zone: table olives and cucumber
- World (for import tolerances): table olives and hops.

A minimum of eight residue trials are required for extrapolation, except when otherwise stated in the revised extrapolation tables of the new guidance document.

The revision 9 of this guidance document is applicable as from 1 April 2011, with the exception of the “new major crops”. The “new major crops” will apply from 1 April 2013 in order to allow applicants to generate further residue trials, i.e. in the framework of Art. 6 to 11 of MRL regulation 396/2005 further residue trials are needed. In the framework of Art. 12 of the MRL regulation for substances included/non included in Annex I after 1 April 2013 the “new major crops” should be considered. Whereas, for substances included/non included before 1 April 2013, EFSA should identify if additional residue trials are necessary to comply with the new classification of “major crops”. In this case the applicant should submit the trials to the Rapporteur Member State within 2 years from the publication of the Commission Regulation of Annex I inclusion following the relevant EFSA opinion on Art. 12 of MRL regulation 396/2005.

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



Data requirements under Regulation (EC) No 1107/2009

At the conference “Registration of Agrochemicals in Europe” in Brussels, 6-9 April 2011, Ms Arena presented the status of the discussion regarding data requirements under Regulation (EC) No 1107/2009.

The revision of the data requirements was started in 2002 and is now close to finalization, but as it is not final, a transfer of the current data requirements will be done by 14 June 2011, when Regulation 1107/2009 will apply. The publication of the transfer of the “old” data requirements is envisaged in April 2011. The “new” data requirements are expected to be voted at the SCFAH in June or July 2011 and published in December 2011 or January 2012. There will be a two-year transitional period before the new data requirements will apply, i.e. the “old” data requirements are applicable until December 2013 / January 2014.

In the following, the main changes in data requirements are summarized:

Toxicology:

No need for a 1-year dog study; optional carcinogenicity study in mouse (unless it is scientifically justified that it is not necessary); more toxicokinetic data (e.g. information on interspecies differences, blood/tissue concentrations in short- and long-term studies of relevant species); address neurotoxic, immunotoxic and hormonal effects; cumulative and synergistic effects.

Residues:

Fish metabolism and feeding studies; residues in honey and pollen; two residue zones for MRLs; residue trials from one growing season sufficient; 3 step approach for rotational crops.

Fate and behavior:

Stronger link to Water Framework Directive; address aerobic mineralization of surface water; and potential

for ozone depletion / formation, global warming and acidification. In addition, a need for guidance to interpret POP, PBT, vPvB criteria is seen.

Ecotoxicology:

In long-term studies additional to NOEC approach endpoints EC10 and EC20 to be derived; the risk to amphibians and reptiles to be addressed even though no specific study data requirements are set; address chronic risk to bees, honey bee brood test and risk for bees from drift or dust. Some vertebrate studies dropped (e.g. short-term birds, acute oral one bird species); new aquatic vertebrate data required (FELS); change from functional to structural assessment in soil compartment (litterbag dropped, collembolan and soil mite mandatory, earthworm reproduction instead of acute); soil microflora only N-formation. Endocrine disrupting potential should be evaluated by considering existing data and OECD guidance document.

Further activities in this context will be the update of the uniform principles (start 2012), the definition of POP, PBT and vPvB criteria (soon) as well as for endocrine disruptors (end 2013), the guidance document on operators, workers, bystanders and residents (May 2011) and the risk assessments for bees (April 2011 a mandate to EFSA expected).

For the AIR-3 project (Annex I Renewal-3 project covering 146 active substances with expiration of Annex I listing in 2013 – 2018) a submission in waves over 3 years is planned. It is under discussion whether the new data requirements will apply to all AIR-3 compounds or whether the “old” data requirements will apply to early batch(es) of AIR-3 compounds, i.e. depending on when submission deadlines will be set and when the new data requirements are applicable.

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

Your feedback is important to us!

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

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

Our e-mail address: newsletter@scc-gmbh.de

THANK YOU!

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DATA MANAGEMENT

Archiving at SCC

As previously announced, SCC has moved to its new headquarters in Bad Kreuznach. After establishing the GLP archives and climatic conditions, the GLP paper archive was successfully moved from Wendelsheim to Bad Kreuznach. The GLP authorities were informed and involved in both the transfer and the storage of the archived material at our new premises. The new archives are fully equipped according to official requirements, with a high-tech security system and a sophisticated climate control system, thus guaranteeing safe archiving of GLP raw data.

SCC offers a central storage site for all your regulatory data, either in secured archive storage rooms or in archives certified under GLP. Furthermore, the central archiving of data and documents in a secured location is managed by the SCC databases GMS (GLP Management System) and EDDMS (Electronic Document and Dossier Management System), providing fast and reliable access at a competitive price.

We appreciate your confidence in us and look forward to working together with you in the future.

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

CALENDAR

SETAC Europe Milan 2011 Annual Meeting – 15-19 May 2011, Milan, IT

The annual SETAC meeting takes place this year in Milan with the theme "Ecosystem protection in a sustainable world: a challenge for science and regulation". This is Europe's biggest meeting on environmental toxicology with more than 1500 presentation in parallel platform and poster sessions. Dr. Gertraud Wirzinger, Manager Regulatory Science, Ecotoxicology and Risk Assessments, will attend.

2nd Symposium on National Schemes for Biocidal Products – 19-20 May 2011, Vienna, AT

This two-day symposium will systematically focus on the details of existing national systems or practices for marketing biocidal products in certain member states. Dr. Martina Galler and Dr. Holger Zitt, Senior Managers Regulatory Affairs, Biocides, will be at this important event.

6th International Fresenius Conference: Pesticide Residues in Food – 24-25 May 2011, Frankfurt, DE

The Akademie Fresenius is sponsoring this informative 2-day conference that will highlight regulatory aspects such as changes in EU pesticides regulation, residue analysis including new approaches, and monitoring. Dr. Thomas Reisinger, Manager Regulatory Affairs Agrochemicals and Biopesticides, will attend this event.

VCI Information Meeting REACH GHS, 27 May 2011, Frankfurt, DE

Dr. Carsten Baehr, Senior Manager Regulatory Affairs, Chemicals and Consumer Products, will be at this meeting, which in previous years has attracted more than 1000 participants involved in REACH.

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2nd International Fresenius Conference: Endocrine Disruptors – 7-8 June 2011, Frankfurt, DE

Another Akademie Fresenius conference focusing here on the mechanisms of endocrine disruptors, assessment approaches, endocrine disruption in chemical legislation and regulatory views, roles and activities. Boris Rosenkranz, Assistant Manager Regulatory Science, Ecotoxicology and Risk Assessments, will attend.

ChemCon Asia, 28 June – 1 July 2011, Hong Kong

ChemCon Asia 2011 is a global platform that brings together more than 200 company experts representing companies, authorities and international organizations from over 25 countries. Dr. Carsten Baehr, Senior Manager Regulatory Affairs, Chemicals and Consumer Products, will attend.

CIR 2011, 7-8 September 2011, Barcelona, ES

Informa's industry conference for agrochemicals (AgChem Forum), biocides, REACH and environmental risk assessment will be held this year in Barcelona. Dr. Bernd Brielbeck, Senior Regulatory Manager Agrochemicals and Biopesticides will be at this event and make a presentation at the AgChem Forum. In addition, Dr. Norbert Weissmann, Senior Regulatory Manager, Agrochemicals and Biopesticides, Efficacy, will conduct a pre-conference workshop on the generation of biological assessment dossiers.

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Due to the retirement of Mr. Norio Ohta, Director, SCC Liaison Office Japan (please see page 1 for more details), correspondence for the Liaison Office should be forwarded to either Mr. Takada or Mr. Makita at the addresses shown above.

Previous Newsletters can be found on our website www.scc-gmbh.de, under **Newsletter Archive**. You can also subscribe to the Newsletter (free-of-charge) at this site.

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