Newsletter

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Positive Changes and Accomplishments

It's spring again. How quickly time flies! The beginning of this year was rather busy for SCC. We had a significant workload and managed a lot of regulatory duties for our clients with special emphasis on REACH and the growing field of registrations of chemicals. Other ongoing tasks included several submissions regarding plant protection products to European authorities on behalf of clients.

Furthermore, we were able to complete our clients' projects in 2012 to their satisfaction, which we had planned and hoped for. SCC looks positively into the future, helping our clients further with their projects to move on in the field of agrobusiness, chemistry, biocides and food and feed additives.

At the beginning of the year a new working group, responsible for Integrated Pest Management, biopesticide and biostimulant related issues, was established in the Agrochemicals and Biopesticides Department of SCC. Establishment of this group accounts for new scientific and regulatory developments and interactions of European regulatory frameworks such as the sustainable use of plant protection products, the use of biostimulants pursuant to fertilizer law or the implementation of organic farming principles. More information about this group will follow in the next SCC Newsletter.

On behalf of the staff at SCC, I would like to express our wish to continue our service in the regulatory field for you to satisfy your needs whenever it is possible. We look forward to working with you in the upcoming period and hope our business relationship continues for many years to come.

You might also have a look at the calendar of events to find out where you can meet with SCC experts to express your needs or clarify your questions on scientific and regulatory issues.

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!

Finally, we appreciate your feedback and comments regarding the SCC Newsletter. Drop us an e-mail at newsletter@scc-gmbh.de.

Dr. Friedbert Pistel
President

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AGROCHEMICALS

Applicability of the new data requirements

[Please refer to the following Commission Regulations:

- *COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.*
- *COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.]*

The applicability of the new data requirements is laid down in Article 5 of Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013. The new data requirements for active substance data and plant protection product data will be applicable to submissions for (re-)approvals of active substances and (re-)authorizations of plant protection products starting 1 January 2014.

Derogations from the applicability date above are stipulated in Article 3 (active substance (re-) approval) and Article 4 (plant protection product (re-) authorization).

With respect to active substance procedures, Article 3a sets forth that approvals or amendments to the approval of an active substance shall be governed by the existing data requirements if the application is submitted by 31 December 2013. Article 3b stipulates the continuation of the applicability of the existing data requirements to AIR 2 active substance re-approvals (by referring to Commission Regulation (EU) No 1141/2010), as long as the dossier is submitted prior to 31 December 2013.

Article 4(1), stipulating procedures regarding the authorization of plant protection products, makes reference to Article 3 and to the submission of dossiers and supplementary dossiers for approval or renewal of approval of active substances in compliance with that Article 3. This reference allows the interpretation that the new data requirements for the authorization of plant protection products apply only after a dossier or supplementary dossier for the active substance has been submitted, disregarding the group the active substance belongs to, but by 31 December 2015 at the latest. For AIR 1 and AIR 2 active substances, the dossiers for approval as well as the dossiers for renewal of approval have to have been submitted prior to 31 December 2013; thus, applications for authorization of these plant protection products fall under the transitional measures laid out in Article 4(1). In the case of AIR 3 active substances, dossiers for approval (!) are to have been submitted well before 31 December 2013, thus Article 3a applies. Moreover, it will continue to apply until dossiers for renewal of approval are submitted according to the agreed timelines, but not after 31 December 2015.

One important issue of the applicability of the new data requirements is the interpretation of Annex II data, which would have to be submitted with a product authorization. As this data would normally be subject to the RMS assessment with a peer review organized by EFSA, it is unclear how such an extended evaluation could be included into the zonal authorization process.

This interpretation of Article 4 is currently under discussion and will be subject to further clarification in the upcoming Post-Annex I committee meeting.

In detail, the respective articles read as follows (highlights (in **bold print**) and amendments (*in italics*) by the author):

Article 3

Transitional measures as regards procedures concerning **active substances**

With respect to active substances, Regulation (EU) No **544/2011 shall continue to apply** (in Reg.

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284/2013: 545/2011 shall continue to apply) as regards the following:

(a) procedures concerning the **approval of an active substance or an amendment to the approval** of such a substance pursuant to Article 13 of Regulation (EC) No 1107/2009 for which the dossiers provided for in Article 8(1) and (2) thereof **have been submitted by 31 December 2013**.

Comment: The new data requirements for active substance data and plant protection product data will be applicable to submissions for approvals or amendments to the approval of active substances starting 1 January 2014.

(b) procedures concerning the **renewal of approval of an active substance** pursuant to Article 20 of Regulation (EC) No 1107/2009 for which the supplementary dossiers referred to in Article 9 of Commission Regulation (EU) No **1141/2010** (1) **have been submitted by 31 December 2013**.

Comment: By referring to Commission Regulation (EU) No 1141/2010, this article stipulates that submissions for renewal of approvals within the AIR 2 project are exempt from the new data requirements (if dossiers were submitted prior to 31 December 2013, which they were).

Article 4

Transitional measures as regards procedures concerning **plant protection products**

1. Regulation (EU) No **544/2011 shall continue to apply** (in Reg. 284/2013: 545/2011 shall continue to apply) as regards procedures concerning the a**uthorization of a plant protection product**, as referred to in Article 28 of Regulation (EC) No 1107/2009, provided that the respective application **has been submitted by 31 December 2015** and that the plant protection product **contains at least one active substance for which the dossiers or supplementary dossiers have been submitted in compliance with Article 3**.

Comment: Applications for authorizations are exempt from the new data requirements until 31 December 2015, if the product contains an active substance for which Article 3 applies.

2. By way of derogation from paragraph 1, from 1 January 2014 applicants may choose to apply the data requirements, as set out in the Annex to this Regulation. This choice shall be made in writing when submitting the application and shall be irrevocable.

Comment: As of 1 January 2014, the applicant can ask to submit a dossier adhering to the new data requirement. Once applied for this way, it cannot be revoked during the evaluation.

Article 5

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. For **procedures concerning the renewal of approval of active substances whose approval expires on 1 January 2016 or later, this Regulation shall apply as of entry into force**.

As regards all other procedures, it shall apply from 1 January 2014.

Comment: The new data requirements will apply to all AIR 3 active substances.

New Act on Plant Protection Products in Poland

According to the new Polish law implementing Regulation (EC) No 1107/2009, all documents submitted with the application of registration, which includes the dossier and all study reports, must be submitted in Polish and English languages.

The new Act on plant protection products entered into force on 27 April 2013. It is expected to cause further delays in the registration procedure due to the requirement for all applicants to submit active substance and plant protection product dossiers in Polish and English.

It appears that the draft law was not communicated to the Commission for review. Poland should have notified the draft legislation under Directive 98/43 and, according to ECPA, it might be possible to challenge the fact that this does not appear to have been done. Nevertheless, rework of the new Act on plant protection products is expected to take nine months to several years.

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This issue was communicated and discussed in the context of the TSGE Eastern Europe Regulatory Conference on plant protection and biocides (9-10 April 2013, Budapest, Hungary).

Informa Conference: Registration of Agrochemicals in Europe

This year's Informa Conference "Registration of Agrochemicals in Europe", held in April in Brussels, placed special emphasis on the practical implementation of Regulation No. (EU) 1107/2009, the zonal authorizations, endocrine disruptors and the new data requirements.

The new data requirements were published on 3 April 2013 (Regulation No. 283/2013 (EU) for active substances and Regulation No. (EU) 284/2013 for plant protection products. The two regulations are complemented by two communications on test methods and guidelines (2013/C95/01 – Regulation No. (EU) 283/2013) and 2013/C95/02 – Regulation No. (EU) 284/2013).

The new data requirements apply as of 1 January 2014 for the active substance, and by 1 January 2016 for products. Transitional measures are provided and detailed elsewhere in this newsletter.

Francesca Arena, DG Health and Consumers, European Commission mentioned that parts of the Reg. 1107/2009 have increasingly been completed/detailed by the Commission, e.g. rules for renewal with Regulation No. (EU) 844/2012, which describes the general procedures and the RMS and Co-RMS responsibilities with Regulation No. (EU) 686/2012. Meanwhile, approval extension has been published and it is expected that for AIR-3 substances further extensions will be made. A respective guidance document is also available (SANCO 2012/11251). Discussions are still continuing on renewals of authorizations and how to cope with deadlines. Several guidance documents have been adopted (see DG SANCO web page; e.g. parallel trade, Art. 53, DAR, data protection), while some others are still under discussion, e.g. seed treatment, efficacy. Further work in progress comprises basic substances for which a pilot project with five substances (chitosan, equisetum, talc, quassia, CaOH) is ongoing. First decisions are expected in July 2013.

Concerning endocrine disruptors (EDs), draft criteria on identification have been circulated by DG Environment (DG ENV), with the EFSA opinion available in March and JRC (Joint Research Centre) report in April 2013. Two categories are proposed by DG ENV:

- Cat 1 - Endocrine disruptors
- Cat 2 – Suspected endocrine disruptors

Francesca Arena reported that next steps include Commission inter-service discussion scheduled in April/May and a Commission recommendation with criteria is expected in summer. A proposal to amend Regulation (EU) No. 1107/2009 is foreseen in December 2013 and an adoption to amend Regulation (EU) No. 528/2012 (Biocides) for also planned for December this year. There are still some open issues, e.g. technical guidance to be developed and question of effects on MRLs.

Dave French (ECPA) noted that the ED Expert Advisory Group (ED EAG) reported the group's acceptance of the IPCS/WHO definition of ED as a working definition. This involves demonstration of an adverse effect from which there was convincing evidence of a biologically plausible link to an ED mode of action, and not a secondary consequence of other non-endocrine-mediated systemic toxicity. He further explained that a) ECPA has significant concerns with the DG ENV proposal, as the legislation requires criteria and not weakly defined categories; b) the "suspected ED" category provides potential for blacklisting and subsequent trade impact, and; c) scientifically ED is not analogous to CMR (substance classified as carcinogenic, mutagenic and toxic to reproduction). In addition, industry supports risk-based rather than hazard-based decision making and stressed that it is important to identify and characterize the hazard. Failure to properly characterize the hazard will lead to unnecessarily severe decisions and provide no additional protection to human and environmental health.

Hans Mattaar (ECCA) regretted the missing consistency of regulating the endocrine disruptor issue in different legislation frameworks, i.e. under REACH, biocides, pesticides and cosmetics regulations EDs are solved either by cut-off criteria,

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by comparative assessments and substitution principle or by risk assessment and authorization. If EDs are withdrawn, this could impact 37 active substances in plant protection, resulting in a possible loss of 35 % - 45 % formulated products with 10 % - 20 % yield impact (even more than 50% yield loss in a bad year).

Francesca Arena reported on further Commission work in progress concerning candidates for substitution, for which first discussion with Member States (MSs) on a draft proposal will take place in July 2013. The deadline is 14 December 2013. She further mentioned that the Uniform Principles must be revised due to the new data requirements. This work has not been started and no deadlines were given. Rules for safeners, synergists and co-formulants are scheduled for the end of next year and for the first two are likely to be postponed. For co-formulants a list is to be drawn up. Derogation for MSs is possible until June 2016, but this is not a priority for the moment. Future work for the Commission in 2014 is AIR 2 approvals, continuation of approval on new active substances, and on confirmatory data.

Christian Prohaska, Austria Agency for Health and Food Safety (AGES), mentioned the challenges from Article 43.2 of Regulation (EU) No. 1107/2009 for product renewals. There are tight timelines and workload issues for the MSs and industry, requiring pragmatic solutions. One of the problems for submission is due to the new data requirements, for which a consistent approach has to be established between MSs. He proposed conducting the full review after renewal of the last active substance (for products with more than one a.s.), following the procedure according to Directive 91/414/EEC, and to avoid duplication and triplication of work. However, further discussion is necessary between the Commission, EFSA, MS and industry.

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

BIOCIDES

The BPR replaces the BPD: which are the most important changes?

Overview

On 22 May 2012, the long debated Regulation (EU) No. 528/2012 (Biocidal Products Regulation or BPR) was adopted. Published in the Official Journal of the EU on 27 June 2012, it will repeal and replace the Biocidal Products Directive 98/8/EC (BPD) starting 1 September 2013. It is interesting to note that several errors in the text of the BPR have been identified. These errors have been discussed extensively in the CA Meetings and respective documents have been published on CIRCABC.

Information on how to access CIRCABC can be found on the SCC homepage under Links – Biocides http://www.scc-gmbh.de/SCC/Links/Biocides/.

As a result of these discussions, a new regulation is in preparation: “Regulation of the European parliament and of the council amending Regulation (EU) No 528/2012 [….]” which is likely to be adopted only after 1 September 2013, when the BPR applies.

A number of changes now become relevant for the biocides industry. The most important changes are:

- The BPR is a Regulation and does not have to be implemented in national law, which was the case for the BPD.
- The BPR covers *in situ* products and treated articles.
- Under the BPR, product families instead of frame formulations can be authorized. The product families have a wider definition than the frame formulations under the BPD.
- The European Chemicals Agency (ECHA) will play an important role under the BPR, providing both scientific and technical support.
- In addition to the product authorization via Mutual Recognition, starting 1 September 2013 Union authorizations can be granted for products containing new actives and products for PTs 1, 3,

4, 5, 18 and 19, from 1 January 2017 for products in PT 2, 6, and 13, and from 1 January 2020 for all other product types except for PTs 14, 15, 17, 20 and 21.

- A simplified authorization procedure applies to products containing active substances listed in Annex I to the BPR if the respective products fulfill certain conditions.

Transitional regimes for products not covered under the BPD

The scope of the BPR is wider than the scope of the BPD. Not only is the placing on the market but also the use of biocidal products now clearly covered. The use of biocidal active products in treated articles is also covered. For biocidal products not covered by the scope of the BPD but falling in the scope of the BPR, transitional measures apply according to Article 93 of the BPR:

- ***In situ* biocidal products:** the use of *in situ* products, where the active substance is produced without a precursor made available on the market for biocidal purposes, falls under the scope of the BPR. Such use was not under the scope of the BPD and thus, no authorization was needed. In order to allow such products to continue to be used under the BPR, applications for product authorization are to be submitted at the latest by 1 September 2017. Examples are:
  - the generation of hypochlorite through electrolysis from sodium chloride not explicitly made available on the market for this purpose.
  - the generation of ozone from oxygen. In this case, the active substance ozone is not an existing biocidal active substance (not included in the review program). This could mean that it may be necessary to defend this use by submitting an active substance dossier as well.
- **Treated articles:** according to Article 58, there will be labelling requirements for treated articles made available on the market. Labelling requirements are triggered if the manufacturer makes a claim concerning the biocidal properties of the treated article or if the conditions associated with the approved active substance(s) require such labelling.

  If an active substance is used in a treated article which is not in the review program for the respective product type, the treated article can continue to be made available on the market provided an active substance dossier is submitted by 1 September 2016 at the latest (Article 94).

The role of ECHA under the BPR

ECHA is preparing for assuming its responsibilities assigned in the BPR (Regulation (EU) No. 528/2012) on data dissemination (Article 67) and is contacting the applicants for active substance dossiers for which a decision has already been made as well as those where a decision is expected soon. These applicants are asked to review and redact Document IIIA of the CAR, indicating by 1 July 2013 which information should not be published as its publication is potentially harmful for their commercial interests or for the interests of any other party concerned.

Electronic submission of dossiers

IUCLID 5.5 was released on 2 April 2013, allowing for the preparation of biocidal product dossiers in IUCLID format according to BPR requirements.

The R4BP 3.0 system, which will take over from the current R4BP2 system, is currently being analyzed for implementation. After 1 September 2013, the data already entered via the R4BP2 system will be migrated into the R4BP 3.0 system.

Further information will be provided at the ECHA Stakeholders Conference on 25 June. For details please check http://echa.europa.eu.

Status of BPR-related discussions on EU level

Numerous guidance documents and discussion papers concerning the BPR and its requirements have been tabled for the Competent Authority meetings held in the past months. These documents can be accessed on CIRCABC. You can find information on how to access CIRCABC on the SCC homepage under Links – Biocides (http://scc-gmbh.de/SCC/Links/Biocides/). Below we provide you with information on a small selection of the most recent documents available.

Questions on the BPR are answered in two documents (CA-May13-Doc.5.3 and 5.3.a). The questions are grouped per Article of the BPR, with Articles 89, 91 and 92 focused on in the first

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document and *in situ* products in the second document.

A work program to meet the 2024 deadline has been prepared by the Commission in which active substances in the review program are allocated to work schedules for 2013, 2014, 2015 and 2016. This document (CA-May13-Doc.8.3) is available on CIRCABC.

For 2013, a total 30 substance/PT combinations are now scheduled for a vote, which is quite ambitious. For the years 2014-2016, the Commission plans to prepare a minimum of 50 opinions per year and a respective schedule is presented in this document.

According to Document "CA-Feb13-Doc.12.1-Drinking water disinfectants", available on CIRCABC, "preservatives which protect water for liquid feed/for feed production or stabilize/sustain/ maintain the quality of water for drinking against deterioration caused by micro-organisms or their metabolites" are covered by Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

New guidance documents in preparation

The **draft evaluation manual for the authorization of biocidal products** (CA-May13-Doc.6.2.d) is available on CIRCABC. In this manual, the data requirements for biocidal products are provided and guidance is given as to how information for the risk assessments is to be used. The manual is intended to be a living document and does not duplicate guidance already presented on the site of the European Commission. Guidance on **efficacy** data will be provided in product type-specific guidance documents. The most recent guidance available is for PT2 (CA-May13-Doc6.2.d).

Guidance on how to deal with **treated articles** is also now available on CIRCABC (CA-May13-Doc5.1.d). This document answers the most frequently asked questions in a question and answer format.

The latest status of the discussion regarding how to perform a **comparative assessment** can be found in document CA-May13- Doc.5.1.h. In this document, a proposal is made how comparative assessments could be conducted efficiently, meaning the avoidance work duplication by authorities and ideally enhancement of synergies. A tiered approach using a decision tree is proposed for defining alternative products or non-chemical alternatives available for a comparative assessment. Whereas the first part of the comparative assessments is risk-based, an assessment of the economic and practical advantages/disadvantages of the alternatives is made in the second part.

These are only a few topics that are at present being discussed. In many cases, the discussions are still on-going. The list should therefore not be viewed as exhaustive.

Recent Annex I inclusions of existing biocidal active substances

In 2012 and 2013, inclusion directives were published in the Official Journal of the EU for the following existing biocidal active substances:

Active substance	Product Type	Inclusion Directive	Date of inclusion
Copper (II) oxide	8	2012/2/EU	1 February 2014
Copper (II) hydroxide	8	2012/2/EU	1 February 2014
Basic copper carbonate	8	2012/2/EU	1 February 2014
Bendiocarb	18	2012/3/EU	1 February 2014
Methylnonyl ketone	19	2012/14/EU	1 May 2014
Margosa extract	18	2012/15/EU	1 May 2014
Flufenoxuron	8	2012/20/EU	1 February 2014
DDA Carbonate	8	2012/22/EU	1 February 2013
Cis-Tricos-9-ene	19	2012/38/EU	1 October 2014
Nonanoic acid	2	2012/41/EU	1 October 2014
Thiamethoxam	18	2013/3/EU	1 February 2015
DDAC	8	2013/4/EU	1 February 2015
Pyriproxyfen	18	2013/5/EU	1 February 2015
Diflubenzuron	18	2013/6/EU	1 February 2015
ADBAC	8	2013/7/EU	1 February 2015

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Annex I Inclusions / Approvals Pending Decision

Based on a review of the documents made publicly available for the CA Meetings, a vote in the Standing Committee has either already been taken or a decision will soon be made for the following substances.

Active Substance	PT
Chlorfenapyr	8
ADBAC	8
Diflubenzuron	18
Corn cob	14
D-Phenothrin	18
Cypermethrin	8
Propiconazole	9
IPBC	6
Tebuconazole	7 19
Benzoic acid	3 4
AIP	20
Etofenprox	18
Nonanoic acid	2 (old PT10)
Bromoacetic acid	4
Copper sulphate	2

For further information please contact Dr. Hans-Josef Leusch at hans-josef.leusch@scc-gmbh.de.

CHEMICALS, REACH, CONSUMER PRODUCTS

Dissemination of IUCLID sections on ECHA website

ECHA will publish both lead and member sections of IUCLID sections 2.3 (PBT assessment) and 11 (Guidance on safe use). Thus, in one disseminated dossier more than one section 2.3 or 11 will appear, depending on the number of registrants. SCC strongly recommends harmonizing these sections within a consortium or SIEF. Not harmonizing these section will lead to confusions especially for downstream users reading the dossier on ECHA website.

New IUCLID 5.4 section 3.7

The new section 3.7 (Exposure Scenarios, exposure and risk assessment) asks for very detailed information with regard to risk assessment, such as tonnages, risk management measures and exposure values. So far, this information was only given in the CSR. For the tier II deadline in Mai 2013, it is not mandatory to fill in this and it is not TCC (technical completeness check) relevant. Later on, this section may be mandatory for all dossiers submitted after May 2013. So far, this section will not be disseminated on the ECHA website, but it is not clear that this will not happen in the future. Thus, SCC recommends not filling in this section by hand for the 2013 deadline, as this will cause a lot of additional work. When using an exposure assessment tool such as CHESAR or Easy TRA, this section can be filled in automatically. The registrant should carefully check this automatically filled-in section and consider deleting confidential business information.

ECHA publishes dossier evaluation decisions on their website

In accordance with Article 15 of the Treaty on the Functioning of the European Union (TFEU), ECHA will publish dossier evaluation decisions on compliance checks and examination of testing

proposals on their website. Registrants will be informed beforehand about the dissemination via the REACH-IT message box. Some confidential parts of the decisions, such as substance name and name of the registrant, will not be published. Registrants may request to make additional parts of the document confidential. Such requests have to be submitted to ECHA within 5 working days and have to be justified.

New REACH Fee Regulation

In March a new REACH fee Regulation (EU) No. 254/2013 came into force, amending Regulation (EC) No. 340/2008. Registration fees for SMEs were reduced, whereas the fees for non-SMEs were significantly raised. Be aware that the fees for dossier updates have also changed, which might influence dossier submission strategies.

Downstream user obligations

Downstream users also have different obligations under REACH. Uses missing in eSDS received have to be reported to ECHA. In addition, classification differences have to be reported when the downstream user does not follow the classification of their suppliers. In a recent ECHA webinar, an excellent overview was given about when downstream users need to report to ECHA, including when to report classification differences. The two options for reporting were outlined, namely using the web form or submitting a IUCLID dossier via REACH-IT. The presentations can be downloaded via the following link: http://echa.europa.eu/web/guest/view-article/-/journal_content/title/how-and-when-downstream-users-need-to-report-to-echa.

Dossier Quality Assistant

In order to improve dossier quality, a Dossier Quality Assistant was made available in February 2013 as an additional tool incorporated in the new version (5.4.3) of the Technical Completeness Check (TCC) plug-in for IUCLID 5. It does not introduce any changes to the current TCC rules or affect the outcome of the TCC, but rather helps registrants to identify potential shortcomings.

BAUA survey

The German Federal Institute for Occupational Safety and Health (BAuA) was looking for possibilities to improve the whole REACH process by an on-line survey. The outcome will have an impact on the revision process by the German government at EU debates.

IUCLID 5.5

IUCLID 5.5 was published in April 2013. It includes new dossier types to fully support the preparation of applications under the Biocidal Products Regulation that will enter into operation on 1 September 2013 and new templates for nanomaterials. Due to the compatibility between the new and previous versions, companies re already preparing their REACH dossier for the upcoming registration deadline can continue working with IUCLID 5.4 and only update to the new version when it is most convenient for them.

IUCLID 6 Survey

Further developments and improvements will result into IUCLID 6 and might lead to “architectural changes” (e.g. transition from PostgreSQL to JavaDB and from Tomcat to Glassfish). For communication on this, IUCLID users were asked to participate in a respective survey on IUCLID 6.

News on Cosmetic Regulations

The European Commission has confirmed that the full ban on animal testing for cosmetics entered into force on 11 March 2013. This was accompanied by a communication on the animal testing and marketing ban, and on the state-of-play in relation to alternative methods and an impact assessment on the animal testing provisions in Regulation (EC) No. 1223/2009 on Cosmetics (refer to the EU website: http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/index_en.htm#2013).

The **SCCS's Notes of Guidance (NOG) for the Testing of Cosmetic Ingredients and their Safety Evaluation**, 8th Revision, was adopted on 11 December 2012. The NOG contains relevant information on the different aspects of testing and safety evaluation of cosmetic substances in Europe. An important development is the 2009 legislative recast, which transforms the cosmetic Directive 76/768/EEC into a Regulation and from 11 July 2013

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onwards, this Regulation (2009/1223/EC) is fully applicable (refer to the EU website: http://ec.europa.eu/health/scientific_committees/consumer_safety/sccs_09-13/opinions_en.htm).

ECHA-REACH 2013 registration statistics

On 12 April 2013, ECHA updated the statistic on substances registered and of registration dossiers received to date for the 2013 deadline. Overall, ECHA expects 1676 substances that will have been registered for the 2013 deadline.

Authorization process and Community Rolling Action Plan

Under REACH there are several processes where substances are under special focus by ECHA and Member State Competent Authorities with regard to risk assessment and control.

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

The evaluation as part of the **Community Rolling Action Plan** aims to clarify the initial concern that the manufacture and/or use of these substances could pose a risk to human health or the environment.

Update of Authorization List

The amendment of Annex XIV of REACH ("Authorisation List") was published on 18 April 2013 in the Official Journal. Eight new substances are now subject to authorization for being used after the sunset date. With this third update of the Authorization List by the Commission, there are now in total 22 substances included in Annex XIV.

The authorization process already starts with the identification of SVHC substances in articles and publication on the Candidate List, which triggers 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 on the Candidate List.

In December 2012, the first substances with respiratory sensitizing properties were added to the Candidate List, which, according to the Member State Committee, gives rise to an equivalent level (Article 57 (f)) of concern according to CMR substances.

ECHA will prioritize the Candidate substances step-by-step and prepare a draft recommendation for inclusion in Annex XIV.

The Authorization List can be found on the ECHA webpage: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list.

The Candidate List is also on the ECHA webpage: http://echa.europa.eu/web/guest/candidate-list-table.

Community rolling action plan (CoRAP)

In March 2013 the second Community Rolling Action Plan was adopted by ECHA, now including 151 substances.

In the CoRAP list, the grounds for the initial concerns are briefly described for each substance. In many cases, the concerns are related to potential persistency, bioaccumulation and toxicity, endocrine disruption, or carcinogenicity, mutagenicity and toxicity to reproduction, in combination with wide dispersive or consumer use(s). The CoRAP also indicates the Member State responsible for the evaluation of each substance. From the publication of the final CoRAP update, the designated Member States have one year to evaluate substances specified for the first year of the CoRAP update and, where deemed necessary, to prepare a draft decision for requesting further information to clarify the suspected risks.

In 2013, there are 46 substances subject to evaluation, and for those cases the deadline for submitting any draft decisions to ECHA is 19 March 2014.

Please visit the CoRAP list on the ECHA webpage: http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan.

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

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REGULATORY SCIENCE

New data Requirements and the Development of New Guidance Documents

At the Informa Conference "Registration of Agrochemicals in Europe" held in Brussels in April, focus was made on the new data requirements and on the development of new guidance documents.

The new data requirements for active substances (Regulation (EU) No. 283/2013) and for plant protection products (Regulation (EU) No. 284/2013) were voted in the Standing Committee in July 2012 and published on 3 April 2013. They are accompanied by Commission Communications (2013/C95/01 and 2013/C95/02 for active substance and plant protection product, respectively), which detail the test methods and guidance documents to be considered for each data point. These communications will be updated regularly as new test guidelines and guidance documents become available. In the Annexes to Regulations 283/2013 and 284/2013, the data requirements for active substances and plant protection products, respectively, are listed. There is a new structure with new locations for information and data previously required and with new data points for the new requirements.

There are several questions and challenges to cope with in light of the new data requirements: where no test methodology is available, where guidance is required, and where there is insufficient time to perform "long-term" studies.

At the Standing Committee on 15 March 2013, a guidance document on preparing dossiers (SANCO/10181/2013) was noted. This guidance document applies to dossiers for new active substances as of 1 January 2014 and for the renewal of approval of active substances under Regulation (EU) No. 844/2012 ("AIR 3"). However, the guidance document is not applicable to national product (re)authorization dossiers (dRRs).

A new format for dRRs is currently being developed by the dRR Member State Working Group and it is not clear whether the work will be finished by the end of 2013. There will be a transitional period for the new format that probably will be mandatory from 1 January 2016 onwards.

Furthermore, several risk assessment guidance documents are under development:

- Combined exposure – non-dietary
- Combined exposure – dietary
- ADI and AOEL – update of existing guidance
- Aquatic ecotoxicology – update (first element: tiered risk assessment – edge of field surface waters (adoption in June 2013))
- Terrestrial ecotoxicology – update (2015-2017?)
- EFSA guidance on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents (adoption in 2013?)
- Risk assessment of PPP on bees (including *Apis mellifera*, *Bombus spp.* and solitary bees) (adoption in May 2013)
- Evaluating laboratory and field dissipation studies to obtain DegT50 in soil (2014?)
- Estimating PEC in soil (2014?)
- Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment
- Emissions from protected crops (2014?).

Overall, the new data requirements and the development of new guidance documents target sound scientific risk assessments. However, it was criticized that recent guidance documents are increasingly complex, disconnected (users and context of use) and conservative. This can be seen for the bee guidance, where 95 % of the compounds would fail at Tier 1 (i.e. Tier 1 is not well defined), or the soil organism guidance (draft under review), where the first top soil without interception should be used in Tier 1. It was underlined that the new developments are proportionate and implemented with clear and realistic timelines that fit into the already complex processes (e.g. "AIR 3" active substance renewal program and post renewal authorizations).

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

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FEED & FOOD ADDITIVES, VETERINARY MEDICINE

Feed Additives

November 2012 was again the date for the bi-annual EuroTier fair in Hannover. It looks like the space needed for the feed additive industry expands every time! Ruud Huibers was present during the entire week and had numerous very interesting meetings with existing and (potentially) new clients. As always, it was a great opportunity to meet each and every one again involved in the animal nutrition industry.

In the meantime, a lot of questions are coming in from EFSA regarding the safety assessment of all dossiers for feed additives. Somehow it seems that the workflow has become somewhat stagnated by all this. Still many questions are being asked about the safety of additives that have been safely used within the EU for many decades. EFSA has even called for a tender for an independence scientific organization to make the first safety assessment for dossiers that still need to be addressed.

Furthermore, the discussion about the use of several products in water for drinking has still not been finalized by the European Commission. EFSA recommended that those additives that have a UL or any other established maximum dose should not be allowed to be used simultaneously in water for drinking. Argumentations against this statement were presented to the European Commission but no final decision has been taken yet (after more than one year).

In all situations, SCC is staying in close contact with all organizations involved to hasten the registration processes of its clients' products as much as possible. Our work only ends when the additives are finally (re-)authorized.

Legal implications???

One very interesting legal case that occurred last month needs to be closely monitored. The case was about the suspension of a feed additive that had been on the European market since the 1980s. Now in the re-authorization process, based on the 'lack of new data', EFSA could not guarantee its safety and with that, this product was banned from the European market until this new data becomes available. The company involved appealed at the General Court of European Union based on the 'long history of safe use' and the Court declared the regulation "to ban the additive" void. The Court considers it necessary to adapt the interim measures until a resolution to the present process is completed.

As to how far this will influence the entire process of re-authorization remains to be seen, but it seems that legal argumentation of a 'long history if safe use' is becoming more accepted.

Other regulatory activities

In the regulatory field of Food Contact Materials, a lot of movement has also been made in the last few weeks. Quite a number of new European Regulations have been published. More and more, an overall European approach will be followed with these substances.

The new Regulation for Veterinary Medicinal Products has been delayed by the European Commission. It is expected, however, that this still will be published sometime this year.

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

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CALENDAR

15th International Fresenius Agro Conference: "Behaviour of Pesticides in Air, Soil and Water, 24-25 June 2013, Mainz, DE

Experience with the evaluation of plant protection products has shown that efforts towards harmonization and risk minimization are of the utmost importance. At this informative conference, participants will have a chance to hear about current progress with regard to harmonization, risk minimization and the newest developments in environmental behavior and exposure. Dr. Christine Klein, Senior Manager Regulatory Science, and Lydia Pape, Assistant Manager Regulatory Science, will attend this interesting and informative conference. More information can be found at www.akademie-fresenius.com/2087.

CIR 2013, 5-6 September 2013, 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. More information regarding SCC's involvement in this important industry gathering will follow soon. For further information regard CIR, check out their website: http://www.informa-ls.com/event/CIR2013.

ChemCon Asia 2013, 10-13 September 2013, Seoul, South Korea

ChemCon Asia 2013 is a global platform which brings together more than 200 experts representing companies, authorities and international organizations from over 25 countries. Presentations given by more than 35 speakers from governments and industry will focus in the field of international chemical legislation all over the world, like REACH, GHS and country specific information on inventories, labelling requirements, etc. Dr. Werner Köhl, Head of the Chemical and Consumer Products Department, will be at this conference and be available to talk to you about your regulatory needs regarding REACH.

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