Newsletter

Volume 14, No. 1, April 2014 / Globalization & Regulation

SCC and the wind of (global) change

It's once again the spring season. How quickly time flies! Nevertheless, SCC intends to adhere to its long-term strategy in the future: To consistently globalize business and to manage regulatory duties for our clients world-wide and venture into new growth sectors like biopesticides and veterinary medicine.

Thus, the beginning of this year was rather busy for SCC due to establish a new department focused on global account management. We are happy that with Mr. Willem van den Dool, we have acquired an experienced manager who is very familiar with global markets and commerce in Asia and U.S.A. and who will, in his position as Senior Director Global Account Management, in particular push further ahead and shape the ongoing internationalization process of SCC with emphasis on the global target market of agriculture and biocides. More information about global account management, especially on Mr. Willem van den Dool itself, is presented in the related article in this newsletter.

Besides this activity, highly skilled and experienced staff has been appointed to fill the specific needs of SCC's Liaison Office in Japan, e.g. handling queries of regulatory types from several industrial sectors. We are pleased that Mr. Kozo Inoue (Senior Consultant, Kanagawa-ken location) and Mr. Toshiaki Fukushima (Consultant, Shizuoka location) have joined SCC as representatives. Both colleagues have many years of practical experience in the manufacturing industry and good relationships especially to the decision-makers of important branches of the long-established processing/chemical industry of Japan.

Furthermore, this first edition of the SCC Newsletter for 2014 will focus on recent information about chemicals, agrochemicals, and biocides, as well as provide you with some insights on EFSA's intentions concerning cumulative human health risk assessments and serves the recent developments in regulatory apiology linked to the EFSA guidance document for bees, bumble bees, and solitary bees.

In general, SCC looks positively into the future, helping our clients further with their projects to move on in the field of agribusiness, chemistry, biocides and food and feed additives. 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 practical. We look forward to working with you in the upcoming period and hope our business relationship continues for many years to come.

Please have also 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

25 years
and beyond…
watch out…
June 13

In this issue:

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

GLOBAL ACCOUNT MANAGEMENT

SCC takes care of your success, with a new function: Global Account Management

Hereby I would like to introduce myself and the new interesting functional area that has been created within SCC per November last year.

My name is Willem van den Dool. My educational background has two focal points and so has my career development. I studied pharmacy in the Netherlands and started working as a pharmacist/manager, before joining the pharmaceutical industry, where I headed up the national regulatory affairs units for prescription medicines, over the counter products and veterinary medicines. Following half a year in Canada, I moved to headquarters of a world-wide active player in Pharma and was first involved in several pre-marketing projects, thereafter in sales force, local product management, global opinion leader management and strategic brand management for a large blood pressure portfolio. During that period, I got the option to complete an executive MBA in the UK and was trusted with a variety of international projects from US to Japan, as well as with regional sales responsibility for Europe. I learned a lot from international business, from different cultures and from many friendly people that I have met over time.

The new functional area at SCC – Global Account Management – is therefore especially attractive to me, because through my regulatory experience I can understand the core of our business and with my marketing and customer relationship background I firmly believe I can help to fulfill your expectations towards SCC.

Global Account Management at SCC: What is behind that term? SCC was during the last 25 years very successful to convince customers that “we take care”; with more dedication and often with greater success. Or as customers regularly tell us: “When it gets really difficult you go to SCC”. This is an extremely important factor for us: we are dedicated to the success of our customers. However, with a growing amount of customers and projects, it is imminent that we as an organization keep the overview on what our customers exactly want and that we keep picking up signals early whenever there is wish.

So, an important part of my work is to ‘keep eyes and ears’ open and be available for you in case you have a request, a need or an issue on the projects or beyond the projects that we perform for you.

Furthermore, I have been requested to establish SCC as an even more global partner, so that we can address with in-depth expertise any regulatory need you might have, in any market where you are strategically heading to.

I am very much looking forward to interact with you and hope we will have a chance to meet each other live, here in Bad Kreuznach, somewhere in Germany, in Europe, Japan, Asia or in the US.

PLEASE DO CONTACT me,
willemvandendool@scc-gmbh.de , per mail or by tel. +49 671298462

Willem van den Dool
Global Account Management

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

AGROCHEMICALS

Crop protection European Regulatory conference:

A review of some presentations

The Crop Protection European conference was hold on 12 and 13 March 2014 in Brussels and was the first conference being organised by the European Crop Protection Association (ECPA) and the European Crop Care Association (ECCA). The purpose of this conference was the discussion about the zonal product evaluation system and the possibilities of challenges and harmonisation according to Regulation (EC) 1107/2009.

For more information, please do not hesitate to contact Dr. Albrecht Heidemann (albrecht.heidemann@scc-gmbh.de)

Please note that the following abbreviations appear in the summaries below:

a.s. *active substance*
Cfs *Candidate for substitution*
cMS *concerned Member State(s)*
COM *Commission*
dRR *draft Registration Report*
ECCA *European Crop Care Association*
ECPA *European Crop Protection Agency*
ED *Endocrine disruptors*
EiF *Entry into force*
EMS *Evaluating MS (for MRL evaluation)*
GD *Guidance document*
MoA *Mode of action*
MR *Mutual Recognition*
MS *Member state(s)*
PPP *Plant protection product(s)*
RMS *Rapporteur Member State(s) (for a.s. approval)*
SCFCAH *Standing Committee on the food chain and animal health*
zRMS *zonal Rapporteur Member State(s) (for zonal authorisation)*

Feedback from Post Approval issue group

Darren Flynn
CRD, UK

There are several harmonisation projects in UK to challenge the national specific requirements in several areas. For environmental fate, now buffer zones up to 20 m are allowed in UK for surface water risk mitigation. In addition drift reduction technology can be used for risk mitigation measures. The harmonisation of surface water risk assessment will be difficult due to drain flow issues.
For the toxicology and the residue section, new EU harmonised models for operator, bystander and consumer should replace the current national models. For operator exposure the GD will be available by end of 2014. For workers a new protection factor is under review to allow gloves as risk mitigation measure.
For birds and mammals risk assessment, it is foreseen that no re-assessment should be necessary for crops grown on < 5000 ha.
For rotational crops, advice is available, how to deal with replant-inclusion on label. Also harmonisation for seed treatment and tank mixes are under construction.

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

Current situation with the application of Article 43

Christian Prohaska
AGES, Austria

In the renewal process according to article 43 of the regulation 1107/2009/EC, very strict timelines (for applicants as well as for the MS) are foreseen. The dRR should be submitted by the applicant within 3 months after EiF of the a.s. For the compliance check (former step I) and the assessment (former step II), zRMS has 6 months. Additional 3 months are foreseen for decision on renewal of authorisation by all cMS in the zone.
Due to new endpoints of a.s. and new data requirements for PPP, the timelines for conducting the studies are sometimes too short. For studies which are needed for the renewal of a PPP due to fulfil new endpoints (e.g. mesocosm studies, residue trials), applicant can request for extension to prepare these studies. Therefore, AGES proposed that according to article 43(6), the applicant should prepare the dRR without these studies and justify the lack of data in the application, with a timeframe when these ongoing studies can be expected. After the extended studies are available, a new updated dRR is to be submitted.
COM is aware of these issues and intends to amend Article 43 accordingly and will issue draft guidance document.

Efficacy and other key challenges in the zonal system

Pavel Minář
SRS, Czech Republic

The Efficacy is not well harmonised in the MS and many national requirements often apply. Hence, difficulties are given in the zonal procedure and especially if a mutual recognition procedure is planned. Discussion points in the Efficacy belong often to the definition of uses and pests, the number and location of trials as well as the minimum effective dose. Hence, a harmonisation of risk mitigation measures is needed and the national systems should be restructured and simplified.

Comparative assessment as part of the zonal system

Maarten Trybou
Belgium

According to (EC) 1107/2009, the comparative assessment shall take authorised minor uses into account. SANCO/11507/2013 rev. 1 point out, that it is not considered relevant to apply substitution in cases that would have adverse consequences on minor use authorisations.
However, a registration will not work only for a minor use. Hence, it is needed to keep a major use to maintain the product on the market. In Belgium 22 % of the a.s. will be candidates for substitution (Cfs). If there is a non-chemical alternative method which is technically feasible, PPP containing Cfs should be substituted. An authorisation is possible if there is no benefit in refusing.
However, especially in the home and garden area, it is questionable if there is a future for herbicides containing Cfs.

Industry overview on key zonal challenges

Kerry Gamble
Syngenta

Kerry Gamble analysed the timelines from application till decision. For this analysis, 12 representative companies responded which submitted 177 applications for new formulations, between June 2011 and December 2012. 58 decisions were made, but 119 applications are still pending. The average time for evaluation was 15.2 months. The problems to reach the timeframes are inter alia the lack of resources, capacity of the authorities and often there is a delay between end of evaluation and official decision.
For MR, 369 applications were submitted between June 2011 and September 2013. 177 decisions were made, but 192 applications are still pending. The average time to decision was 9.6 months. Some problems are different national requirements, and that the reference MS is located in a different zone. Furthermore, MR are often not granted if the original authorisation was given according to 91/414/EEC. In general, it can be stated that harmonisation is needed. Furthermore, ECPA

urgently propose a leadership and governance from the COM.

Commission view on the implementation of Reg. 1107/2009

Wolfgang Reinert
DG SANCO

Several guidance documents are under consideration by the COM.
A guidance document for comparative assessment is on the agenda of SCFCAH meeting in March*. Comparative assessment applies from 1 January 2015. Also the list of Cfs is under finalisation and should be completed by that date. The list contains all a.s., which were approved until January 2013.
The new data requirements were published in April 2013 and apply to the PPP dossiers from 1 January 2016, but for renewal of a.s. (AIR3) already from 1st January 2014. Therefore, for AIR2 and new active substances submitted before 1 January 2014, the renewal dossiers were/will be evaluated according to the old data requirements, whereas the PPP dossiers for national authorisations will be evaluated in accordance with the new data requirements. This can lead to some problems in evaluation. According to COM, a possible solution is that old data requirements exceptionally continue to apply for such cases. However, an amended guidance document and a draft regulation will be presented in SCFCAH meeting in March*.
Some other important implementing measures are to expand the existing EPPO codes as well as a public catalogue of EU authorisations.

** Meanwhile, the SCFCAH meeting was held on 19 / 20 March 2014.*

Cut-offs and candidates for substitution: Member State view

Martin Streloke
BVL, Germany

For endocrine disruptors, the assessment scheme was expected for the end of 2013 but impact assessment is still underway. In Germany, for some compounds additional data requirements have been raised. A paper summarising ED activities was prepared by Germany. Substances, with intended endocrine MoA in non-vertebrates, are not regarded as ED, according to German approach. However, the overall situation is not really clear at this time.
In Germany, approximately 80-100 compounds will become Cfs. A national paper will be prepared subsequently to finalisation of EU guidance. For Germany, the role of the applicant is not really clear and a main question is, how many minor uses balance a critical major use.

Development and application of guidance documents – Member States view

Gábor Tökés
NÈBIH, Hungary

In this presentation, the definition and usage of guidance documents was discussed.
Consequences of new or modified guidance documents are a better evaluation and more scientific approach. However, the negative impact is often more costs. E.g. the EFSA new bee guidance states that the magnitude of effects in colonies should not exceed 7% reduction in colony size. But the average coefficient of variation of plant trials, which shows the relative error, is 12%. To catch 7% difference, an extreme higher number of replications is needed.

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

Development and application of guidance documents – industry view

Martin Schäfer
BASF

Regarding the guidance documents, there are some key concerns of industry. Commonly, there is an incorrect use of guidance and draft guidance documents were used before they are finalised. Furthermore, guidance documents are not fit for purpose and the aim should be to provide clarity and harmonisation. Often they are not focused on needs of risk assessors and risk managers.
As an example, the new bee guidance document was mentioned. With this guidance, it is impossible to refine the risk assessment because of unrealistic provisions for higher tier testing. Also testing guidelines for honey bees, bumble bees and solitary bees are not available.

European Commission update on the review of active substances

Jeroen Meeussen
DG SANCO

In this presentation, a detailed overview of the current situation of the AIR programme and the timelines was given.
AIR2 contains 31 substances and for 29 of these a.s., dossiers have been received. The peer-review is ongoing and the expiry date of approval is 31 December 2015.
AIR3 substances are sub-divided into 4 groups. Group 1 contains 40 a.s. and extension of approval is given until begin of 2017.
Group 2 of AIR3 contains 27 substances but only 23 applications were received. For these 23 a.s., extension of expiry date is given until mid of 2017.
Group 3 contains 55 substances, which are extended until mid of 2018 if application is submitted within deadlines. For the 28 a.s. in group 4 currently no extension is foreseen.
Jeroen Meeussen pointed out, that there is a benefit for COM, planning and the timelines if industries submit the applications for renewal as early as possible.
Two new draft overview documents were introduced.
SANCO/10148/2014 rev. 1 contains an overview of the applications submitted for renewal of approval by indicating the date of application, name and address of applicant, RMS and Co-RMS for AIR3 substances.

SANCO/2012/11284 rev. 10 provides an updated overview of indicative submission dates for supplementary dossiers for the renewal of a.s. with an expiry date between 2013 and 2018.

Revision of 1107/2009 – Initial ECPA thinking

Euros Jones
ECPA

Euros Jones presented the ECPA proposals to amend the regulations (EC) 1107/2009 and (EC) 396/2005. The detailed proposal is further pointed out in an ECPA position paper. The suggestion is divided into four phases and contains the implementation of current framework and the amendment of article 43, the review of (EC) 1107/2009 and (EC) 396/2005, the data protection as well as the long-term review.
For the implementation of current framework, the national requirements (inclusive Efficacy data needs) should be removed, an inter-zonal cooperation as well as a zonal helpdesk must be established. For the MRL evaluation one lead EMS and a clear procedure for MRL review after a.s. approval is desired. In article 43 of the (EC) 1107/2009, the need for a full review after the approval of each active substance in a formulation should be withdrawn.
For phase 2, ECPA proposed to replace hazard based cut-off criteria by risk assessment as well as to remove the zonal concept. Furthermore, ECPA demand an unlimited approval period for a.s.
For phase 3, ECPA proposed to modify the data protection review similar to US system. In the last phase (phase 4) a single evaluation of a.s. (with centralised coordination) was proposed. However, ECPA's intention in developing this paper is to start a discussion.

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

BIOCIDES

The BPR amendment has been adopted by the European Parliament: what is likely to change in the near future?

Overview

Since the Regulation (EU) No 528/2012 became applicable on 1 September 2013, several errors, or unclarities, have been discussed extensively in the CA (Competent Authority)-Meetings and respective documents have been published 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/.
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 [….], with regard to certain conditions for access to the market". The text for the new regulation has been adopted by the European Parliament on 25 February 2014 and shall now be forwarded to the Council.
While the text for the new regulation has not been finally adopted by the Council yet, its current version maps out several changes to the text of the BPR. The following summary gives only a brief, non-exhaustive account of those changes which, from our point of view, bear the most potential to have an impact on the practice of biocides authorisations:

Re-definition of the "biocidal product families" (Art. 3(1)(s) and 19(6)):

- A major change to the concept of biocidal product families (BPFs), which describe a group of biocidal products with similar uses, the same active substances and similar compositions will clarify that the "levels of risk and efficacy" need further on to be "similar" for all members of the BPF.
  The current wording (to be replaced) highlights that the specified variations in the composition for a BPF must not "adversely affect the level of risk or significantly reduce the efficacy" and that "the classification, hazard and precautionary statements for each product within the biocidal product family shall be the same". The proposed amendment should therefore allow for a more flexible definition of biocidal product families in the future, e.g. because the products within a BPF do not need to have strictly identical classification and labelling any more.
- It is clarified that the assessment of a biocidal product family "shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range" of its members.
  The current wording (to be replaced) focuses rather on the allowed types of changes ("reduction […] of […] active substances […,] variation […] of […] non-active substances, and/or the replacement of one or more non-active substances by other specified substances presenting the same or lower risk.") and on the identical C&L (see above).
  This change appears to clarify that any variations within the BPF cannot be judged a priori but will always be subject to the assessment.

To facilitate the practical implementation of these changes, discussions are ongoing in the CA-meetings (see below).

Extended marketing period for biocidal products containing existing active substances and added use period in case of non-approval (Art. 89):

- The transitional period, for which a member state may allow the placing on the market and use of a biocidal product containing existing active substances before authorisation, is extended to up to "three years after the date of approval for the relating active substance" (currently: two years).

This change is meant to allow for a more realistic timeline for the member states to finish the processing of applications, e.g. when the national authorisation is accompanied by mutual recognitions in parallel.

- If a decision is taken not to approve such an existing active substance, the concerned member state may still allow phase-out periods of up to 12 months for the placement on the market and, as added by the amendment, periods of up to 18 months for the use of related biocidal products.

New deadline for active substances generated "in situ" and for active substances in treated articles (Art. 93 and 94):

- Biocidal products containing existing active substances that have been on the market before 1 September 2013, which fall under the scope of the BPR, but which have not been within the scope of the BPD before, such as biocidal products produced in situ, may continuously be placed on the market under the appropriate provisions of Art. 89 if an application for approval of the relating active substances is submitted at the latest by 1 September 2016. Otherwise the market placement and the use of such biocidal products will have to end on 1 September 2017.
- The placement on the market of treated articles is dependent on their use. As a consequence, the use must be covered by an active substance application, at the latest by 1 September 2016. Otherwise the treated article will have to be removed from the market on 1 September 2017.
- If you are the producer of such a treated article and/or such an active substance, please make sure that an application for approval of your active substance for the appropriate product type and use (including, if applicable, the system generating or releasing it) is submitted before 1 September 2016.

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

Ongoing discussions in the CA-meetings

Further concerning the scope of the BPR, numerous discussions are still ongoing in the CA-Meetings. The results of these debates have been published and the documents can be accessed on CIRCABC. Some important and interesting documents which deal with topics including "Transitional Period", "Biocodal Product Family", "Mutual Recognition" as well as "Approval of Active Substances under the BPR" are summarised below.

Transition between national schemes and BPR-authorizations following active substance approvals (CA-March14-Doc.5.1).

The paper addresses an issue in the transition from a "pre-approval" authorization according to national provisions to an authorization under the regime of the BPR: "existing" products may be placed on the national markets, before the relating active substance is approved, under the provisions of Article 89. However, once the active substance has been approved for the relevant product type and, therefore, applications for authorization under the BPR have to be placed, applicants may wish to apply for authorization of a product with a slightly different formulation (sometimes termed as "re-formulated" or "improved" product), which replaces the "existing" product. Therefore, the authorization of existing biocidal products and the transition from national schemes to EU rules as well as a replacement of existing biocidal products by reformulated products should be made possible by clear, simple, harmonized and timesaving principles.

One question in this context is if both the "existing" and the "improved" product will each have to be supported by dossiers to ensure their continuous marketability.

The way forward proposed by this paper suggests that if both the "existing" and the "improved" product contain the same active substance in "similar concentrations", the "existing" product may be granted a phased-out period according to the deadlines provided in the amended version of Article 89 (4), while the authorization of the

improved product shall be covered by the provisions of amended Article 89(3) (see below).
The Commission asks for the views of member states and stakeholders on this proposal.

Biocidal Product Families (CA-March14-Doc.5.12)

One further important paper concerning refers to the new definition for biocidal product families (BPFs) and a new approach for their authorization requirements, which will be addressed in the amendment of the BPR as discussed above.
The discussed amendments should provide new opportunities, e.g. facilitating "the placement on the market of new products belonging to the biocidal product family but not explicitly identified in the original authorization." The background to this is that, similarly to an authorization of a single biocidal product, for the authorization of BPFs, the variations of the individual biocidal products, i.e. different composition, different uses, category of users, etc. have to be summarized in "Summaries of Product Composition (SPCs)". Once if one of the aforementioned "new" products is to be placed on the national market, the concerned CA is obliged to handle this process within 30 days.
To structure the complex information that has to be entered into the SPC of the BPF, and to clarify what is exactly authorized, the Commission proposes that "three levels of information in authorisations of BPFs" should be provided:

- 1st level would describe the composition and permitted variation of the authorized biocidal family;
- 2nd level would provide the different meta SPC, each describing a group of products of the family having similar compositions, the same uses and the same levels of risk and efficacy;
- 3rd level would provide the composition of the different products of the family

For a better illustration of this proposal please refer to the chart in the annex to the document CA-March14-Doc.5.12. Due to the fact that the expression **"similar"** leaves room for interpretation and discussion, it remains to be seen how the CA will decide in the individual biocidal product family authorizations.

Complementary guidance on the handling of applications for MR (Mutual Recognition) under Article 91 of the BPR (CA-March14-Doc.5.3)

This document represents an amendment to the agreement reached at the 53rd CA meeting, on document CA-Sept13-Doc.5.1.g-Final. This complementary guidance calls attention to difficulties which were revealed by two member states during MRP (mutual recognition in parallel) as well as during MRS (mutual recognition in sequence) for product authorisations submitted under the BPD regime and on which a decision has not been taken by 1 September 2013.
To facilitate mutual recognition in these cases, the commission agrees that an additional step and, possibly, the introduction of an acceptance phase for the payment of the fee as well as for the submission of documents (e.g. summary dossier, translation of the first authorization, letters of access, labels or safety data sheets) to be submitted under "step 2" of the MR (according to the MR procedures under the BPD) may be necessary.
Considering this paper, the updated version (CA-March14-Doc5.3.a) of document CA-Sept13-Doc.5.1g-Final can be accessed on CIRCABC.

Principles for taking decisions on the approval of AS under the BPR (CA-March14-Doc.4.1-Final)

One amendment in this document, of which the final version is now available, is that active substances fulfilling the exclusion criteria shall be approved for a maximum period of 5 years, and the active substances fulfilling the substitution criteria will be approved for a maximum period of 10 years.
In case of the potential of active substances for being endocrine disruptors (Article 5(1) (d) and 5 (3) of the BPR), there are still ongoing discussions concerning the definition criteria of a substance as an endocrine disruptor (ED). At this time, substances classified as C2 (Carcinogen Cat. 2) and R2 (Reproductive toxicant Cat. 2) as well as

substances that are identified in accordance with Article 57(f) and 59(1) of REACH as having ED properties shall be considered as EDs, whereby substances classified as C2 and having toxic effects on endocrine organs may be considered as EDs. The results of further discussions as well as the decisions remain to be seen.
Concerning treated articles, substance approvals will only contain specific restrictions when a major concern has been identified during the evaluation. This decision will be made on a case-by-case approach.

The summaries given above represent only a small outline of the present discussions still ongoing in the CA Meetings.

CHEMICALS, REACH, CONSUMER PRODUCTS

News from the Chemicals & Consumer Products Department

Several issues with relevance for REACH are presented below. For more information, please contact Dr. Werner Köhl at werner.koehl@scc-gmbh.de

Sediment risk assessment

By the end of 2013 ECHA has published the proceedings of the workshop "Setting scientific principles for sediment risk assessment" (http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-on-risk-assessment-for-the-sediment-compartme-1). The impact of the workshop outcome is quite extensive, since the workshop intended to set scientific principles for assessing risks to the sediment compartment in all regulatory contexts. There, recommendations on when to trigger the risk assessment for the sediment compartment, what should be the basic principles and how to use the equilibrium partitioning method for screening purposes were discussed. The proceedings will serve as a basis for reviewing and potentially updating the guidance for REACH and biocides. Furthermore, other regulatory systems (like European Food Safety Authority (EFSA), the European Commission and the US Environmental Protection Agency) might use the workshop outcome for updating their guidance on sediment assessment under the Plant Protection Products Regulation, the Water Framework Directive, and the US sediment assessment framework.

The exigency to revaluate the WGK classification of substances and mixtures

The legal basis for deriving the WGK classification for substances and mixtures is currently under revision by the German authorities. During this process the criteria for classification according to Regulation (EC) No 1272/2008 (CLP) will be implemented into the new regulation on installations for handling of substances hazardous to waters (AwSV). Specifically that means that the data for long-term environmental hazard will have a stronger impact on the WGK classification as they are currently not covered by DSD legislation. Furthermore the draft regulation obligates the operators of facilities to inform the Federal Environmental Agency (UBA) in writing and without delay when (long-term) data leading to a WGK classification which differs from the official WGK classification published by the authority so far. The new regulation will be published probably in Q1 or Q2 2014. Thus, we recommend checking the WGK classification.

International Notifications/Registrations

The regulatory programs are in many Asian countries under development and thus requirements are changing a lot lately. Even though in Korea and Taiwan the legislation is still draft only, some important details/changes are already known.

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

Latest developments in South Korea

In Korea, the Act on Registration and Evaluation of Chemicals of Korea (also known as "K-REACH") will come into force on 1 January 2015 and will from then on regulate the registration of chemicals. The scope of K-REACH will include new and existing chemical substances and products by implementing tonnage band depending requirements for registration, hazard evaluation and risk assessment. Although K-REACH has some similarities to EU-REACH, such as tonnage based registration deadlines/requirements and the "Only Representative" concept, other aspects such as polymer notifications and annual reporting obligations on uses and tonnages are additionally required under K-REACH. It is noteworthy that K-REACH foresees a certain grace period for the registration of existing chemicals (as listed on the Korea Existing Chemicals Inventory) and for notifiers of a substance which has successfully been notified under the TCCA regulation but yet not published on the existing inventory.

Latest developments in Taiwan

In Taiwan, there is actually no registration program for chemical substances in place. End of 2013 the revision of the current piece of legislation, the Toxic Chemical Substances Control Act (TCSCA), was approved by the national legislative body. The scope of the revision includes not only the control of hazardous substances but also the establishment of a chemical registration program for new chemical substances and designated existing substances. The provisions related to the chemical registration scheme are scheduled to enter into force in December 2014.

The registration scheme for new chemical substances includes a standard, a simplified and a small quantity registration. Different exemptions (e.g. Polymer of Low Concern, Scientific Research) exist also.

Taiwan's existing chemical substance inventory includes approximately 79,000 substances amended in different nomination phases. Another supplementary nomination was recently announced for May or June this year to ensure that all existing substances are included in the inventory.

Substances eligible for this supplementary nomination are those which have been manufactured, handled, used or sold in Taiwan as well as imported to Taiwan during 1 January 1993 and 31 December 2011. The nomination procedure will most likely be similar to the previous one in 2012. All substances not included in the inventory (http://csnn.cla.gov.tw/content/Substance_Query_Q.aspx) are considered new chemical substances.

News on Cosmetics Regulations

Since 11 July 2013 cosmetics in Europe are regulated by Regulation (EC) No. 1223/2009 to ensure a high level of protection of human health. As this regulation is a dynamic feature, it is constantly updated. The most recent update came into force on 25 November 2013 by Commission Regulation (EU) No. 1197/2013. This regulation amended Annex III listing in order to ensure furthermore the safety of hair dye products for human health by limiting maximum concentrations of 21 hair dye substances. This measure took into account final opinions of the Scientific Committee on Consumer Safety (SCCS).

In addition, on the same date the Commission implemented decisions on guidelines for Annex I (Decision 2013/674 (EU) to assist responsible persons in complying with their regulatory obligations especially in respect to the preparation of product information files. However, these guidelines were not introduced to replace the knowledge and expertise of a qualified safety assessor as required by Regulation (EC) No 1223/2009 (http://ec.europa.eu/consumers/sectors/cosmetics/regulatory-framework/index_en.htm).

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

REGULATORY SCIENCE

Technical Meeting with Stakeholders on Cumulative Risk Assessment / Parma, February 2014

On 11 February 2014 EFSA organized a technical meeting with stakeholders on cumulative risk assessment. Veerle Vanheusden from DG Health and Consumers presented the legal framework and the perspective of DG SANCO.

The assessment of the active substances' cumulative risk, as laid down in Regulation (EC) No 1107/2009 and Regulation (EC) 396/2005, is considered as one of the biggest challenges for the future by DG SANCO. The initial aim to use the cumulative risk assessment for the review of all existing MRLs under Art 12 of Regulation 396/2005 cannot be met. However, it is foreseen that EFSA will collaborate with RIVM, who has conducted the ACROPOLIS project, which is a probabilistic dietary exposure model. In December 2013 an electronic Working group with MS experts has been set up by DG SANCO. As one of the long term means for SANCO an impact assessment of using cumulative risk assessment in MRL setting and authorization procedures, including impact on international trade should be conducted. One of the main challenges will be to define the level of protection (percentile of the population that will have an exposure below the toxicological threshold values). Veerle Vanheusden mentioned that all cumulative assessment groups (CAGs) should be established and further open questions need to be resolved before cumulative risk assessment can be implemented in practice

Prof Kortenkamp from the Brunel University in London presented the concepts of mixture effects: dose (concentration) addition should be applied for similarly acting chemicals whereas independent action should be assumed for chemicals with different mode of actions. It was stressed that reference cases for dissimilarly acting mixtures are rare in mammalian toxicology.

Susanne Hougaard Bennekou from the Danish EPA presented the status of the establishment of CAGs. It was highlighted that the pesticides have been grouped into CAGs by identifying specific effects on the basis of data summarized in the DAR (only in some cases study reports were checked). Information on mechanisms or mode of action which represents the most valuable data for grouping is only rarely available for pesticides since the data requirements for the approval of pesticides, as laid down in Commission Regulation (EU) No 283/20136, are not geared towards meeting the requirements of cumulative risk assessment.

So far, the following groups have been established: CAG for effects on thyroid system (containing 103 of 287 active substances); CAG for the nervous system (containing 68 of 287 active substances). Thus, the grouping methodology has yielded CAGs with a large number of pesticides. However, the majority of pesticides might not contribute significantly to a given combination effect, either because exposure is low, and/or because potency in relation to the effect considered is weak. It is assumed that cumulative effects are driven mainly by a few active substances within the group.

Further CAGs will be established (until end of 2015) on effects on the liver, adrenals, eye and developmental and reproductive systems. It is intended to develop a guidance how the CAGs should be included in the renewal process of active substances.

Federica Crivellente from EFSA summarized the outcome of the public stakeholder consultation on the CAG opinion. One of the main comments was that the consideration of exposure and potency is lacking in the current methodology on cumulative risk assessment. The assumption that chemicals with the same phenomenological effect may have a similar mode of action was considered overly conservative and precautionary.

Furthermore, Karen Hirsch-Ernst from BfR (Germany) presented the relevance of the dissimilar mode of action for cumulative risk assessment. As strictly independent actions are difficult to prove in practice, the PPR Panel concludes that dose addition should be used as conservative default approach for the approximation of mixture effects to protect consumer health.
Andy Hart from Fera (UK) presented the concept of the probabilistic methods for assessing dietary exposure to pesticides, which was already summarized in the Scientific Opinion (EFSA Journal 2012: 10(20): 2839. One key-point would be to determine the uncertainty in the knowledge of the exposure. Based on the fact that in Regulation (EU) 1107/2009 it is stated that pesticides shall not have any harmful effects on human health, the outcome of the probabilistic risk assessment, i.e. percentage of population at risk, has to be characterized regarding its frequency and magnitude of upper tail exposures.

The cumulative and aggregate exposure assessment to pesticides was investigated within the ACROPOLIS project. Jacob van Klaveren presented the possibilities to conduct the cumulative and aggregate risk assessments with a web-based tool. Based on the first experiences the application of the optimistic model is considered to be feasible, whereas the pessimistic model which considers the inclusion of MRLs of animal commodities resulted in unrealistic conclusions. In the discussions with the regulators it was pointed out that the proof of principle and the need for realistic scenarios that combine the optimistic and pessimistic models are necessary. One important point to be clarified in the future is the agreement to share dietary data, which are owned by Member States.
At the end of the meeting, Hermine Reich from EFSA showed the challenges for implementation of cumulative assessment in practice. Based on the results of the monitoring data, probabilistic risk assessments might be difficult due to the small number of samples where an MRL is exceeded together with the high number of non-detects and the illegal uses (if any). Furthermore, monitoring data might not reflect the latest changes of the approval of a substance. There are also some first thoughts to include the results of the supervised field trials in the cumulative risk assessment. Beside the parents the cumulative risk assessment should be extended to cover the metabolites as well.
It was concluded that the implementation of cumulative risk assessment should be be an iterative process. The gain of experiences is very important.

From the Notifier perspective, it seems not so easy to implement the system at an early stage as the exposure data for such an approach are not yet accessible, and it is unclear whether the CAGs for the different compounds are correct as they are based on summaries in the DAR, which were not compiled for this task. Overall, it is not possible to forecast the outcome of such a complex risk assessment for Notifiers at this stage.

For other areas like operator, bystander, worker risk assessments EFSA is at the beginning of the discussion to implement the cumulative risk assessment, up to now they do not have a mandate for this work.

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

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

Current status of the new EFSA guidance document on bees, bumble bees, and solitary bees in Europe

The new EFSA guidance document on bees, bumble bees, and solitary bees ('GDBEE') was criticised due to the conservatism in risk assessments and the significant new testing requirements often lacking respective agreed guidelines. Therefore, the Commission organized a workshop and the GDBEE was discussed in the Standing Committee of the Food Chain and Animal Health (SCFCAH) in December 2013.

It is mentioned in the report of the SCFCAH meeting in December 2013 that the main issues concerning the new guidance document on bees, which were discussed at the respective workshop, had been outlined and a summary will be circulated by the Commission when available. It was concluded at the SCFCAH "**that a full and immediate implementation is not possible at this stage"**. The Commission will draft a roadmap for the implementation, which will be discussed in a Working Group with experts from Member States and EFSA. In addition, **"EFSA agreed to restructure the Guidance Document to make it more user-friendly"**.

In consequence, the GDBEE was not voted at the SCFCAH meeting in December 2013 and was put on the agenda of the recent SCFCAH meeting in March 2014 to discuss next steps, e.g. the timeline for the implementation of the new guidance document on bees. Details from the discussion and new timelines for the update and implementation of the GDBEE are not available yet. It is unclear if, and if so, to what extent the GDBEE will be modified and when it will be implemented.

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

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

CALENDAR

Zulassung von Desinfektionsmitteln und *in-situ* generierten Bioziden, April 28 2014, Dortmund, DE
Main topic of this symposium is the authorization of disinfectants and *in-situ* generated biocides. The Federal Institute for Occupational Safety and Health (BAuA) as a governmental research institution organizes this event. The language of communication will be German.
Dr. Hans-Josef Leusch, Head of Biocides Department, Dr. Martina Galler, Senior Manager Regulatory Affairs Biocides, and Dr. Michael Werner, Senior Manager Biocides Regulatory Toxicology will participate in this event.
For further information, please refer to:
http://www.baua.de/de/Aktuelles-und-Termine/Veranstaltungen/2014/04.28-REACH.html

~

Environmental Risk Assessment of Biocides, May 7-8 2014, Mainz, DE
This 3rd International Fresenius Conference about environmental risk assessment of Biocides covers all relevant issues like the assessment procedure, relevant exposure scenarios, risk assessment itself, monitoring and risk management and exposure asssessment models.
Dr. Michael Schweizer, Manager Environmental Risk Assessment & Modelling Biocides, will be at this conference and be available to talk with you about your regulatory needs.
For further information, check out following website:
http://www.akademie-fresenius.de/konferenz/output.php?kurs=432

~

Biocides Symposium 2014, May 22-23 2014, Bratislava, SK
This two-day Symposium will focus on Regulation (EU) No 528/2012 and will examine several product authorization processes foreseen within the Regulation. It will also include presentations on applications for first authorization and mutual recognition. The symposium will feature keynote presentations from both the EC and ECHA with regard to product authorization for biocides together with a review of implementation activities relevant to product authorization.
Dr. Martina Galler, Senior Manager Regulatory Affairs Biocides, will attend this conference and would be delighted to answer your questions concerning regulatory topics.
For further information on the symposium, please refer to:
www.europeanbiocides.net/Biocides-Symposium-2014-brochure.pdf

~

Continued on next page

Newsletter
Volume 14, No. 1, April 2014 / Globalization & Regulation

Chemspec Europe 2014, June 18-19 2014, Budapest, HU

Chemspec Europe, the fine & speciality chemicals connection, announced that the regular conference is going to be held in Hungary this year. Chemspec Europe will offering a series of conference events, seminars and workshops held over both days of the main conference for both exhibitors and visitors to attend.

Dr. Werner Köhl, Head of Chemicals, Consumer Products, Cosmetics and Feed & Food Department, will be at this event and will speak about relevant REACH issues in the REACHReady Conference (Regulatory Services Zone); contact him at scc@scc-gmbh.de to set up an appointment during this two-day conference to discuss your specific regulatory needs. Furthermore, Dr. Charlotte Krone, Senior Manager Regulatory Affairs will also participate in this conference and would be delighted to answer questions you may have on the registration of chemicals.

For further information on CSE2014, check out their website:
http://www.chemspecevents.com/europe/conference/overview

Edition notice

SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH
Dr. Friedbert Pistel, President
Am Grenzgraben 11 · D-55545 Bad Kreuznach
Phone +49 (0) 671-29846-0 · Fax +49 (0) 671-29846-100
scc@scc-gmbh.de · www.scc-gmbh.de

Liaison Office Japan
14-24 Tokiwadai,
Kashiwa-shi
Chiba-Ken 277-0087, Japan
Phone/Fax.: +81 (0)4-7162-4262

Mr. Toshiyasu (Ted) Takada, Director
e-mail: toshiyasu.takada@scc-japan.com

Liaison Office Japan
6-2-14 Asagayakita,
Suginami-ku
Tokyo 166-0001, Japan
Phone/Fax.: +81 (0)3-6762-5261

Mr. Kenji Makita, Senior Consultant
e-mail: kenji.makita@scc-japan.com

Liaison Office Japan
1-28-20, Fujimigaoka,
Ninomiya-machi, Naka-gun
Kanagawa-ken, 259-0122, Japan
Phone/Fax.: 81-(0)463-73-0912

Mr. Kozo Inoue, Senior Consultant
e-mail: kozo.inoue@scc-japan.com

Liaison Office Japan
14-8, Midori-cho,
Mishima-shi
Shizuoka 411-0848, Japan
Phone/Fax.: +81-(0)55-976-1686

Mr. Toshiaki Fukushima, Consultant
e-mail: toshiaki.fukushima@scc-japan.com

In order to access links noted in this Newsletter, please copy the address into your browser.
We cannot guarantee that links will function and assume herewith no liability.

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.