SCC
WE CARE FOR YOUR SUCCESS

NEWSLETTER

SCC Newsletter Vol. 19, No. 4, November 2019

REGULATORY NEWS

Dear Subscribers,

We are delighted to inform you that **Dr Bernd Brielbeck** succeeded **Dr Albrecht Heidemann** as the Head of the Agrochemicals & Biorationals business unit on 1 October 2019. Dr Brielbeck has been with the company since 2001: During this time, he was entrusted with various important tasks, including his recent position as Regulatory Group Leader and Senior Manager GLP Archives. Dr Brielbeck is well versed in the particularities of regulatory affairs related to plant protection products. *We thank Dr Heidemann for his services and wish him all the best for his future endeavors during his retirement*.

We would also like to inform you that **Dr Karin Lauber** was appointed as new Head of GLP and Regulatory Archives and new Regulatory Group Leader at Agrochemicals and Biorationals in October 2019. As such, Dr Lauber has taken on all of Dr Brielbeck's former responsibilities. Dr Lauber joined the company in 2009, originally starting in the residue group in the Regulatory Science business unit before moving to the regulatory group in the Agrochemicals and Biorationals business unit in 2011.

In this issue you will also find relevant information on agrochemicals, medical devices, and regulatory science.

With regard to Brexit, the date of UK's exit is still not clear although several possible dates for Brexit are currently being discussed. These include 30 November, 31 December and 31 January. Please also refer to the Brexit section of our website for further information on this.

In the fast-moving world of regulation, SCC is committed to keep its customers on course for success. We provide high-quality consulting services for your scientific and regulatory needs. Our expertise extends to exposure modelling and risk assessment and covers a broad range of areas, such as agrochemicals and bio pesticides, biocides, chemicals, cosmetics, consumer products, feed and food additives, food contact materials, medical devices, GLP archiving solutions, and task force management.

We would love to hear what you think about the SCC newsletter, so please do not hesitate to share your feedback and comments with us. Simply send an email to newsletter@scc-gmbh.de.

Dr Friedbert Pistel

CONTENT

AGROCHEMICALS

New Head of Agrochemicals and Biorationals at SCC since 1 October 2019

We are glad to inform you that Dr Bernd Brielbeck succeeded Dr Albrecht Heidemann as the Head of the "Agrochemicals & Biorationals" Business Unit on 1 October 2019.
Dr Heidemann had filled this responsible position since joining the SCC in 1994. He retired on 1 October 2019, after which Dr Brielbeck followed him as Head of Business Unit to ensure the continuity and continued competence you expect from SCC.
Dr Brielbeck has been in the company since 2001 and has been working in the Business Unit of
Dr Heidemann ever since he started, filling the responsible position of Group Leader for the Regulatory Group. Dr Brielbeck is well versed in the particularities of regulatory affairs of plant protection products. To many of you, he is personally known through meetings or presentations on the various aspects of plant protection regulatory affairs.

We are certain that Dr Brielbeck has accumulated all the necessary and detailed experience to fill his new responsible position. We are very happy that we were able to fill this position with an experienced SCC staff member, who has the necessary intimate knowing of the needs of our clients and the regulatory field that Dr Brielbeck has worked on for so many years already.

We thank Dr Heidemann for his services and wish him all the best for his future endeavors in his retirement.

For more information, please contact
Dr Bernd Brielbeck at
bernd.brielbeck@scc-gmbh.de

German UBA´s biodiversity use Restrictions (Biodiversitätsflächenauflagen) claimed to be without legal basis

In November 2018 German UBA started to give consent to some herbicide and insecticide applications under the precondition that the farmer using that pesticide runs at least 10% of his arable land as so called biodiversity area: fallow land, flower strips or sparse seed, areas on which no pesticide applications may be made. The biodiversity use restrictions are based on a legal assessment that had been issued on behalf of UBA in 2017 (UBA Texte101/2017)
https://www.umweltbundesamt.de/publikationen/rechtsgutachten-schutz-von-terrestrischen

At present several law cases against the biodiversity use restrictions are pending at the Administrative court in Braunschweig. Depending on the outcome of these law cases the provisions of UBA may have to be followed after 1 January 2020.

This issue has been intensively discussed at the application´s conference of the German BVL in Braunschweig on 2nd July 2019 (see report on page 3 of this newsletter).

Now the summary of an extensive legal assessment, originally written on behalf of a pesticide producer: „Biodiversitätsflächenauflagen im pflanzenschutzrechtlichen Zulassungsverfahren – Eine initiative ohne Rechtsgrundlage" (Biodiversity use restrictions in pesticide registration procedures – An initiative without legal basis) was published by Hans-Georg Kamann in Zeitschrift für Stoffrecht (StoffR 2/2019). The author notes that the biodiversity use restrictions are not direct risk mitigation measures related to the use of the particular pesticide but classical compensation measures, aiming to balance the unavoidable indirect effects which take place after use of a pesticide. The requested measures are qualified as an unauthorized encroachment on rights of the farmers, conflicting with several articles of the Charter of Fundamental Rights of the European Union (Charter). Therefore, before setting any implementation order, a legal general EU standard has to be issued that follows the principles of sufficient precision, clarity, predictability and freedom from arbitrariness. German administrative jurisdiction generally requires that the rules for far-reaching compensation measures have to be set by parliamentary legislation and not by administrative bodies. At present specific authorization rules concerning biodiversity are neither fixed in EU nor in national law. The author questions if such rules could be set by German law, *e.g.* by amending the Pflanzenschutzmittelanwendungsverordnung and refers to the harmonizing character of the requirements of Art. 34 of regulation (EC) 1107/2009.

Finally the question arises if the BVL as leading (federführende) registration authority could or even must ignore UBA (non)consents that are in key parts without legal basis. Article 36(2) of regulation (EC) 1107/2009 clearly states that "The Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32." The European Court of Justice stated in precedent case Fratelli Costanzo that union right has to be respected on national level. The author concludes that BVL would even be obliged, particularly in case of obviously unlawfully denials of consent, to follow the evaluation of the zonal rapporteur member state and to grant the respective registrations.

The complete article of Hans-Georg Kamann (in German) can be ordered following this link: https://stoffr.lexxion.eu/article/STOFFR/2019/2/0

Application's conference of the German BVL on 2 July 2019 in Braunschweig

The yearly applicant's conference of the BVL was held on 2nd July 2019.
Dr Sawinsky of BVL announced a new applicant's portal that should be available by the end of 2019 simplifying the use of the portal. With the availability of the new applicant's portal, more than one representative can be named, the submission and the download of documents is possible without using a VPS-client, the so-called "Pseudonym"-number is not required anymore and notifications will be send out by email to all authorised users when new documents are available in the applicant's portal.
BVL asks applicants or representatives to use the following email address for reporting problems when using the current applicant's portal: *uhd-e-psm@bvl.bund.de*. This email-address should also be used when the authorised users of the portal are not able to download documents provided by BVL.

Compared to 2018, the number of new applications for product authorisations remained stable. Dr Savinsky emphasized that the number of concluded evaluations increased and therefore the number of delayed evaluations decreased. In 2018, 100 applications have been received with Germany as zonal Rapporteur (zRMS), concerned Member State (cMS) or for Mutual Recognition (MR). In addition, 58 applications concerning Article 43 have been received. In the first quarter of 2019, no applications have been received with Germany as zRMS, 10 applications with Germany as cMS and 23 applications for MR. The trend for disregarding Germany as a zonal Rapporteur continues, while the number of MR applications continues to increase.

With respect to the delays in evaluation, Dr Savinsky emphasised that the co-evaluating authorities JKI and BfR finalise their reports in time now.

He also stated that the delay of UBA's evaluations is reduced nearly completely and expects that new applications will be evaluated in the time frame given by the Regulations (EU) 1107/2009.

Dr Savinsky reported an increasing number of lawsuits and confirmed a total of 56 lawsuits out of which three are related to compensation of damage.

Dr Savinsky clearly stated that applications for mutual recognition for Plant Protection Products containing active substances regarded as candidates for substitution are rarely successful. Only 3 out of 25 applications being essential for German agriculture were concluded successfully.
Germany has revised its position regarding applications for Mutual Recognition from UK: all applications submitted before BREXIT will be evaluated (Administrative Court of Braunschweig, decision of 3 April 2019, Az. 9 B 23/19, unpublished).

Dr Streloke addressed product authorisations that are limited until 31 December 2019 due to the biodiversity use restriction of UBA.
With the Commission Implementing Regulation (EU) 2017/2324 for the renewal of glyphosate specific provisions had been announced that"… Member States shall pay particular attention to … the risk to terrestrial vertebrates and non-target terrestrial plants, the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions …". Based on this implementing Regulation and as of autumn 2018, UBA is linking its consent for the authorisation of Plant Protection Products, especially herbicides and insecticides, to new use restrictions referring to biodiversity that should be implemented by January 2020.

As pointed out by Dr Streloke, BVL rejected UBA's interpretation, but no agreement between UBA and BVL was achieved and the controversy even reached the chancellor of Germany. Meanwhile, BVL had issued 31 authorisations limited until 31 December 2019. BVL is expecting first decisions on the pending law suits in September 2019. However, up to now, it is not clear how these legal decisions will be implemented until January 2020.
Dr Schneider as a representative of BMEL (Federal Ministry of Food and Agriculture), stated that a first instance decision on the pending lawsuits will be accepted by all parties involved. He carefully indicated a preference for refugial habitats instead of small sized refuges on individual fields.
As to practical consequences on the prolongation of the limited authorisations, Dr Savinsky and Dr Schneider (BMEL), pointed out that product authorisations can be prolonged with or without new use restrictions referring to biodiversity (depending on the decision of Court).
Dr. Wogram (UBA) pointed out that UBA, when setting the use restrictions, does not discriminate between Plant Protection Product authorisations for organic or conventional farming. He also pointed out that these use restrictions are mainly set for products used in field crops, minor uses are exempted.

With respect to Central Zone, Dr. Roth stated that Agreements of the Central Zone Steering Committee (CZSC) are published on CIRCABC and, once published, are applicable.

In the last meeting of CZSC the harmonization of the evaluation of uses in protected crops (*i.e.* walk-in tunnels, foil tunnels, glass houses, etc.) between all three European Zones was addressed. Also, the harmonization of the evaluation for non-professional uses was discussed. Dr Schreiber informed the audience that authorisations for Plant Protection Products are currently granted without taking into consideration residues in honey. The new guidance (SANTE/11956/2016 rev. 9) is applicable from 1 January 2020 and then residue data must be submitted. CZSC also addressed allocation of zRMSes for product re-authorisations (AIR 4, group 1-3) and sending out the questionnaire for product re-authorisations (AIR 4, group 4) to industry in spring 2020.

A joint meeting between CZSC, ECPA, ECCA and IBMA discussed the leaf-wall-area-concept (LWA concept) for high growing crops. This concept will not be used for applications according Article 43. The subsequent discussion revealed a controversy between BVL and JKI, in which JKI pointed out that a conversion to leaf wall area is necessary. The use of conversion factors still remains under discussion.

It was clearly stated that in spite of BREXIT, UK is still a member of the maritime EPPO zone; therefore, efficacy trials conducted in UK under GEP and in line with the current EPPO guidelines are accepted.

Dr Solecki (BfR) identified improvements and refinements of EFSA guidance documents and the collection and integration of new experimental data for improved risk assessment models as key task for his authority. BfR is developing a database for compulsory registration and publication of planned experiments with laboratory animals by the German Center for the Protection of Laboratory Animals at BfR. Also, changes on the templates for dRR/RR and DAR/RAR allowing a clear discrimination between the contribution of authority and the preparatory work of the applicant are discussed.

Dr Wilkening, in a subsequent presentation, pointed out that in Germany only studies required for the evaluation of an application should be listed in the reference lists. Studies that cover more than one point should be listed in the reference list for each individual data point.

Dr Marutzky, in his short presentation on the procedure for setting or amending the maximum residue levels (MRL) stated that pre-harvest interval classes are set in document 7039/VI/95 of the European Commission and deviations from these are not required. BVL asks to stick to the set pre-harvest interval classes and in cases of a deviation detailed and conclusive reasoning is required.
When submitting confirmatory data during the assessment of existing MRLs according to Article 12 of the Regulation (EU) 396/2005 as described in SANTE 10235/2016 Rev. 3, BVL asks to provide a short description in the section “remarks” of point 1.7 part B of the application form and to indicate which data gaps they apply to.

When the submission of confirmatory data is aligned with the application for the renewal of the active substance, BVL asks to submit the confirmatory data together with the application for setting a MRL and the active substance dossier to BVL when Germany is the Rapporteur Member State (RMS) and to inform the Member State responsible for the evaluation according to Article 12 of the Regulation (EU) 396/2005 accordingly.

Maximum residue levels for active substances not approved by the European Commission will be set to the limit of quantification (LOQ). Applications for setting import tolerances can be submitted afterwards and will be evaluated by RMS and EFSA.

With respect to the instruction of use, a concept introduced on 1 May 2018, Dr Röver, BVL, will publish a list of frequently asked questions. BVL is also in communication with farmers, operators, federal and regional authorities, agricultural
Organisations and producers of personal protection equipment (PPE). BVL also intends to improve the availability of PPE for operators by initiating expert discussions and by the creation of a data base on PPEs.

Finally, Dr Gathmann spoke on the avoidance of dust drift during sowing of treated seeds. As currently the risk assessment is only possible up to a maximum wind velocity of 5 m/s the use restriction NH681 is set by BVL, not allowing sowing of treated seeds when this wind velocity is exceeded. High quality seeds and the use restriction NT699-1 and NT715-2 might be alternatives to NH681. NT699-1 refers to seed treatment facilities listed on the homepage of JKI; however, many facilities are not yet certified and listed. NT715-2 refers to seed treatment methods that limit the amount of the active substance to a reference value of 0.2g/180 kg seeds per hectare. However, JKI is currently developing of a consistent evaluation concept.

This year’s applicant’s conference was concluded by a final discussion.
When asked for me-too-registrations, *i.e.* application according to art 34, BVL insists on receiving a full dossier. A statement showing the comparability of the new formulation with the reference formulation and the submission of a study list will not be regarded as sufficient.
A key concern of the BVL and subject of an extensive discussion is the reduced numbers of applications with Germany as zonal Rapporteur Member State or as concerned Member State. BVL clearly stated that they want to reverse this trend through various measures, keeping the legal time frames is one of them.

The audience also asked why the UBA does apply Guidance Documents not valid at the time of application, but in the latest or draft version, with the latter not being available to the applicant.
Dr Wogram (UBA) denied that this is the case.

However, he also stated that where this might have been the case, it was only due to the delays in evaluation stretching over years. He stressed the fact that due to the reduction of delayed decisions, there should be no discrepancy between the guidance applicable at the time of submission of the application and latest version of guidance documents available when conducting the evaluation. The discussion was very lively.

For more information, please contact
Dr Bernd Brielbeck at
bernd.brielbeck@scc-gmbh.de

MEDICAL DEVICES

Call for candidates to enter the EC medical device expert panels

Currently, medical device companies fail short to fully implement the MDR (EU) 2017/745 due to several open decisions, missing common standards and guidance documents. However during September this year, some new information about the expert panels has become available.

According to Article 54, the expert panels must be consulted for assessment of the clinical evaluation reports for certain class III and class IIb devices. In addition, the expert panels are also assigned to contribute to the development and maintenance of the common standards (CS), international standards as well as guidance documents, *e.g.* for clinical evaluations. They will also provide opinions in response to inquiries by manufacturers according to Article 61(2) and offer advice to notified bodies and member states.

With respect to *in vitro* diagnostic medical devices, the expert groups should also be consulted in cases where no CS are available for class D devices and where it is also the first certification for that type of device.

The commission implementing decision (EU) 2019/1396 provides for the following 11 expert groups:

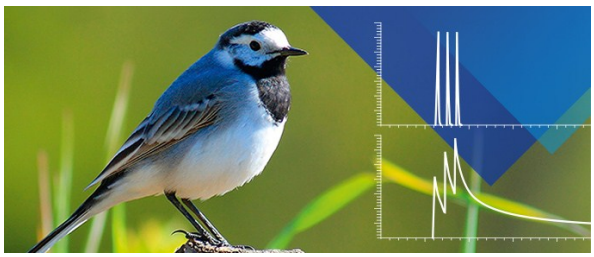
- Orthopedics, traumatology, rehabilitation, rheumatology
- Circulatory system
- Neurology
- Respiratory system, anaesthesiology, intensive care
- Endocrinology and diabetes
- General and plastic surgery and dentistry
- Obstetrics and gynaecology, including reproductive medicine
- Gastroenterology and hepatology
- Nephrology and urology
- Ophthalmology
- In-vitro diagnostic medical devices (IVD)

It is interesting to note that there will be a separate expert panel that will decide whether to provide a scientific opinion on the notified body's clinical evaluation assessment report or not.

On 30 September, the European Commission published a call for expression of interest to appoint experts to scientific panels. The application deadline will end on 10 November 2019.

In case you have any questions or need support, please contact
Dr Alexander Theis
alexander.theis@scc-gmbh.de

REGULATORY SCIENCE



5th International Conference „Endocrine Disruptors“ 23 – 25 September 2019

The 5th International Conference on Endocrine Disruptors took place in Berlin on 23th and 24th September 2019 with a subsequent workshop held on 25th September. Speakers and participants were representatives of national and international authorities, industry representatives as well as academics. The conference was hosted by Chem Academy.

One of the major discussion topics was the meaning of a “sufficient data set”. When following the guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (ECHA and EFSA, 2018), in most cases the data set for an active substance will be considered as not sufficient and further data would need to be generated.

According to the OECD Conceptual Framework (2012) and GD 150 (2018) Level 2 studies must be performed before Level 3 studies, and Level 3 studies must be performed in case that the outcome of Level 2 studies was negative.

In case of PPPs, an assessment strategy was presented as an example where following situation was given with respect to EAS modalities:
Although no adversity was observed, the dataset for an active substance was regarded as not sufficient. In conclusion, further data would need to be generated:

- Level 2 *in vitro* studies (OECD TG 455 (ER transactivation assay), OECD TG 456 (H295R Steroidogenesis Assay), OECD TG 458 (AR STTA assays), and OPPTS 890.1200 (Aromatase assay)
- In case of a negative result of OECD TG 455, further testing is requested (OECD TG 440 (Uterotrophic assay)) [if ToxCast ER Bioactivity model is not available]

If the above tests are negative, the active substance will not meet ED criteria for EAS modalities.

In total, strictly following the ED guidance will lead to generation of a vast amount of new studies as long as authorities hesitate to come to a final conclusion based on a true Weight-of-Evidence (WoE) approach.

Christian Desaintes, PhD, from the European Commission’s Directorate-General for Research and Innovation (DG RTD) presented an overview of the biggest EU Research and Innovation programme, Horizon 2020, and the next EU research and innovation programme, Horizon Europe, which is intended to be an evolution and not a revolution of Horizon 2020.

Besides the European regulatory requirements, participants of the conference had also the chance to hear about the US regulatory framework on endocrine disruptors, the regulatory requirements and challenges in Japan and the regulation of endocrine disruptors in India.

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

GLP & REGULATORY ARCHIVING

New Head of GLP and Regulatory Archives at SCC since 1 October 2019

We are pleased to inform you that Dr Karin Lauber is the new Head of GLP and Regulatory Archives and the new Regulatory Group Leader at Agrochemicals and Biorationals since 1 October 2019.

As Dr Brielbeck follows Dr Heidemann as Head of Agrochemicals and Biorationals, Dr Lauber succeeded Dr Brielbeck in his former positions.

Dr Lauber has been in the company since 2009, starting in the residue group of the Regulatory Science business unit. She moved to the regulatory group of Agrochemicals and Biorationals business unit in 2011. Many of you already know her through meetings, expert discussions and/or presentations at different conferences.

Ensuring the continuity and continued competence you expect from SCC, we are very glad to fill these positions with a qualified SCC staff member.

With strong commitment, hands-on experience in the regulatory field of plant protection products and profound understanding of the needs of our clients, we are certain that Dr Lauber has full qualifications to fill her new responsible positions and further develop a trustworthy relationship with our clients and partners.

For more information, please contact
Dr Karin Lauber at
karin.lauber@scc-gmbh.de

CALENDAR

2019 Annual Conference on International Pesticide Registration in Kunshan, China
7 - 8 November 2019

We are pleased to announce that together with our partner BIOREG we are going to participate at the Annual Conference on International Pesticide Registration in Kunshan, China.

At the event, you will meet Dr Bernd Brielbeck, Head of Agrochemicals and Biorationals, who will be giving a presentation on Regulatory approach for the Registration of an Active Substance and a Plant Protection Product in the EU.

Request a meeting with our senior expert at the event in Kushan to discuss your specific regulatory needs for agrochemicals and biorationals within and outside the EU.

To learn more about the upcoming conference in Kunchan, please visit its official website. Please note that the website is only in Chinese language.

Biocides Europe 2019 in Vienna, Austria
3 - 4 December 2019

Meet our experts at the Biocides Europe 2019, taking place in Vienna in December:
Dr Martina Galler, Head of Biocides, and
Dr Ana Maria Toma, Assistant Manager Regulatory Affairs – Biocides, will be looking forward to talking to you about your regulatory needs for biocides registration within and outside the EU.

The upcoming conference in Vienna will deal with key aspects of Regulation (EU) No. 528/2012 concerning the approval of active substances and authorisation of biocidal products and the latest developments from the European Commission and ECHA. For more information, please visit the official website of Biocides Europe 2019.

CONTACT DETAILS

SCC Scientific Consulting Company
Chemisch-Wissenschaftliche Beratung GmbH

Dr Friedbert Pistel, President
Florian Pistel, President

Headquarters Bad Kreuznach

Am Grenzgraben 11
D-55545 Bad Kreuznach
Tel. +49 671 29846-0
Fax +49 671 29846-100
info@scc-hq.de
www.scc-gmbh.de

Office Berlin

Dr Achim Schmitz
Branch Manager SCC Office Berlin
Senior Expert Ecotoxicology
Tel.: +49 30 2592-2569
achim.schmitz@scc-gmbh.de

Address
Friedrichstraße 40
D-10969 Berlin

SCC Scientific Consulting Company Japan K.K.

Atsushi Ohtaka
Representative Director
Phone: +81 3 6629-3166
Fax: +81 3 6629-3167
atsushi.ohtaka@scc-japan.com

Address
8F Tri-Seven Roppongi,
7-7-7 Roppongi, Minato-ku
Tokyo, 106-0032 Japan

Do you have any comments, questions or suggestions?
Drop us an E-mail at newsletter@scc-gmbh.de.