

# NEWSLETTER

SCC Newsletter Vol. 17, No. 2, August 2017

## REGULATORY DEVELOPMENTS IN EUROPE

### Dear Subscribers,

We are delighted to announce that Mr. **Thomas Roth** has been appointed as the new Head of our Chemicals business unit since July 2017. Mr. Roth is an experienced toxicologist who has spent many years working in the chemical industry. You can find out more on this in the Chemicals/REACH section.

We are also very pleased to present a guest contribution about the European Union Minor Uses Coordination Facility (MUCF) written by Mr. **Jeroen Meeussen** (co-ordinator). The Facility is hosted by the European and Mediterranean Plant Protection Organisation (EPPO) in Paris.

Important progress has also been made regarding the future evaluation of plant protection products (PPP). At the beginning of July, EU Member States voted in favour of the recent proposal regarding criteria for identifying endocrine disruptors (ED) among PPPs. These ED criteria will apply after a short transitional period of six months and a joint guidance document will be prepared by ECHA and EFSA during this time. EFSA also adopted a new guidance document on dermal absorption for PPPs. The document contains important changes compared with the previous version.

This issue of the SCC Newsletter also features a report on the latest BVL Applicants Conference in Braunschweig as well as other important news about agrochemicals/biostimulants, chemicals/REACH and regulatory science.

I would also like to return to the topic of Brexit. After the election in June 2017, Theresa May made a deal with the Democratic Unionist Party to shore up her position as the UK's Prime Minister. On 22<sup>nd</sup> June, 2017, she submitted an offer to grant permanent residence to the three million EU citizens who came to Britain before the Brexit process was triggered. This was criticized by members of the European Parliament (MEPs) who have now threatened to veto her offer on EU citizens' rights. In a joint letter issued in July 2017, MEPs stated that the offer gives Europeans in the UK fewer rights than Britons in the EU. The European Parliament will have a vote on the

final deal but will not be involved in the negotiating stage of the UK's withdrawal.

In the fast-moving world of regulation, SCC is committed to keeping its customers on course for success. We provide high-quality support and consulting for your scientific and regulatory needs. Our expertise here includes exposure modelling and risk assessment and extends over a broad range of areas, including agrochemicals and biopesticides, biocides, chemicals, consumer products, feed and food additives, GLP archiving solutions and task force management.

Take a look at our calendar to find out where you can meet with SCC experts to discuss your needs and find answers to your questions on scientific and regulatory issues.

We appreciate your feedback and comments regarding the SCC Newsletter. Please send us an e-mail at [newsletter@scg-gmbh.de](mailto:newsletter@scg-gmbh.de).



Dr Friedbert Pistel

### IN THIS ISSUE:

GUEST CONTRIBUTION ( <i>Jeroen Meeussen</i> , MUCF)	p. 2
Agrochemicals	p. 3
Chemicals/REACH - <u>new Head of Chemicals business unit</u>	p. 7
Regulatory science	p. 10
Calendar	p. 12
Contact details	p. 13

**GUEST CONTRIBUTION - Jeroen Meeussen, MUCF**

**European Union Minor Uses Coordination Facility**

Because of the extensive data packages required for authorization to market plant protection products, growers face increasing difficulties in gaining authorization for 'minor uses'. Minor use is the need for, and use of, a conventional chemical pesticide or bio-pesticide crop protection product in situations where the use is relatively small scale. Typically, these situations involve high value speciality crops ('minor crops') but can also involve the need for pesticides in areas of restricted pesticide use, the need for pesticides to control emerging pests or diseases or outbreaks of minor pests and diseases in major crops. These speciality crops have a high economic value for growers, but are usually of low economic interest for the agro-pesticide industry. This leads to a lack of authorized products on the market for growers to use on these crops which in turn can lead to illegal uses or to loss of crop production. These crops include most vegetables, fruit, nursery crops, flowers, forest trees and some arable crops. It is estimated that overall they represent more than EUR 70 billion per year, which equates to 22% of the total EU plant production value.

To address this problem in a more coherent way the European Commission has established the EU Minor Uses Coordination Facility (MUCF). Jointly funded, initially, by the EU and the governments of France, Germany and the Netherlands, the Coordination Facility is hosted by the European and Mediterranean Plant Protection Organization (EPPO) in Paris.

The Minor Uses Coordination Facility comprises a technical secretariat, information systems and expert groups to coordinate the programme of work carried out across the EU by Member States in support of minor uses. The work of the MUCF is overseen by a Steering Group. The mission of the Coordination Facility is 'to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an integrated pest management (IPM) framework'.

The coordinator started work on 1 September 2015. As from 1 November 2016 the Coordination Facility is fully staffed with the coordinator, an administrator, an IT-officer and a technical expert.

Projects to close minor use gaps are carried out within 'Commodity Expert Groups' (CEGs). CEGs consist of national minor use experts and representatives of the respective growers' associations or grower groups. Currently there are seven CEGs covering the following commodities: Fruit and Vegetables, Hops, Mushrooms, Ornamentals, Rice, Seeds and Tobacco. The more general issues related to minor uses are discussed in the 'Horizontal Expert Group' (HEG).

The European Minor Use Database (EUMUDA) is an important tool to support the activities of the Commodity Expert Groups and to manage all projects. The Coordination Facility is in the process of developing a new EUMUDA. The benefits of this new database are that it will be a new tool for CEGs, providing a detailed follow up of each project, with information available to growers on minor uses needs, projects overview and crop acreages. The launch of the 'new' EUMUDA took place on 28 June 2017 at a meeting of the Minor Uses Steering Group.

The Coordination Facility will continue to reach out to relevant stakeholders. Involvement of growers in the minor use work is a key aspect in finding adequate solutions to close minor uses gaps.

The first Minor Uses Stakeholder Advisory Forum took place on 25 January 2017 in Brussels. The stakeholders welcomed the establishment of the MUCF and were satisfied with the progress made to date. The MUCF has significant ambition to solve minor uses issues, such as aiming to support a 'level playing field' for growers, focusing on non-chemical solutions, deconstructing regulatory hurdles, and guaranteeing continuity of the MUCF through a long-term funding.

Internationally the Coordination Facility cooperates with existing networks on Minor Uses, such as IR-4 in the USA, the Canadian Minor Use Pesticides Program and the minor use work in Brazil.

More information can be found on the MUCF website ([www.minoruses.eu](http://www.minoruses.eu)), where you can also subscribe to our newsletter to receive regular updates on the work of the MUCF.

**A Short Note on the Author**

Before joining MUCF, from October 2010 until July 2015 Jeroen Meeussen worked in Brussels for the European Commission (DG SANTE) on pesticide issues, including minor uses and biopesticides. Before that he worked as the EU coordinator for plant protection products for the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb). Since 2005 Jeroen has chaired the Expert Group on Biopesticides (EGBP) as part of the Pesticide Programme of the Organisation for Economic Cooperation and Development (OECD).

**GUEST CONTRIBUTION - Jeroen Meeussen, MUCF**

## AGROCHEMICALS



### BVL Applicants Conference in Braunschweig 2017

The annual applicant's conference of the German BVL provided a good overview of all issues currently of interest within the German Regulatory Authorities. The main topic was, of course, the significant delays applicants are experiencing in Germany since many years. BVL observed an exceptionally high number of applications in 2015, which were significantly reduced during 2016. Nevertheless, they expect an increase again, as now Article 43 applications are starting to pour in. BVL has also significantly increased the number of decisions, from 8 in 2012 to 83 in 2016. Still the number of applications exceeds the number of decisions.

Currently, they are working on 709 applications for the authorisation of Plant Protection Products; of these 173 are ZV1, 303 are ZV3, 65 ZVU, 32 Article 43 and 134 DE only applications. Of this total number 253 were delayed: 97 ZV3, 109 ZV3, 47 ZVU.

The German Authorities observe that Germany is selected less as zRMS, but, at the same time, a significant increase in applications for mutual recognitions, where Germany is not included in the evaluation, but asked to accept the evaluations of other Member States (except as stipulated in Article 36, 3). Germany, that is the Ministry (BMEL), as well as the BVL, regret this development and will try to reverse it. The representative of the Ministry emphasised in his presentation that the BMEL expects from all Authorities involved lawful actions, including to deliver decisions within the timeframe stipulated in the law. The Ministry identified harmonisation as one of the main means to speed up the processes in Germany. The permanent secretary of the Ministry gave the clear instruction that this has utmost priority and that compromise is necessary to achieve this goal.

The representative of the Ministry repeated that, where Germany is cMS or an application for mutual recognition is received, the decisions of other Member States should be followed. He also addressed the REFIT procedure of Regulation 1107/2009, which is currently ongoing. It is his opinion and that at the BVL as well, that the experiences of the Member States with tight timelines should be taken into account. In the whole presentation of the Ministry representative the German Environmental Agency UBA, was not addressed, as this Agency belongs to a different Ministry. Nevertheless, Dr Wogram of the UBA (head of the plant protection approvals section of the UBA), was in the audience and confirmed most of the positions that Dr Schneider (BMEL) addressed in his presentation. He specifically named the harmonization. But the concept of compromise seemed to be reserved for all other parties involved in the discussion. He claimed that also UBA does only evaluate issues related to Article 36, 3, when doing the evaluation for mutual recognition. The UBA is irritated about the reduction of applications following the formally correct way (zRMS or cMS) and the significant increase in mutual recognition applications, where, according to Dr Wogram, Germany cannot properly assess the applications received in a depth that UBA would like to.

The Commission Audit, which was completed in March 2016 and is published in SANTE 2016-8780, led to an action plan for the German authorities, which included the BVL, JKI, BfR, UBA and the respective Ministries. Also the farmers' Association and the IVA have been included in the discussion. There were many individual issues addressed in the Audit, but BVL complains that the quality of an authorisation was not in the focus of the Audit, only formal points such as delays.

A court decision from December 2016 on proceedings for failure to act, stipulated that Plant Protection Product authorisations are comparable to pharmacological assessments. Based on this, the court stipulated that formal reasons, such as poor registration reports, cannot be a cause for rejecting a mutual recognition. Furthermore, the risk assessments of the country of origin must be accepted as well as data protection stipulations. The only reason for non-acceptance of the mutual recognition can be derived from Article 36, 3. The BVL emphasised that legal courts in other Member States have decided differently on the same question.

In the future there will be much more intensive pre-assessments by the BVL and also a more stringent rejection regime for Plant Protection Product applications. As already done by the UK, BVL in the future, will also start the clock only after a decision on the completeness of an application was taken. They will allow only one post-submission in total and will intensify their cooperation with other Member States in harmonising as many individual areas as possible. In addition, there will be a closer cooperation with neighboring Member States Austria, The Netherlands, France and Sweden.

For DE only applications the BVL asked for a special procedure. To avoid duplication of work, a DE only application will not be processed, but is used to prolong the existing application until a proper Article 43 application is received by the BVL. The original DE only application should then be withdrawn. The BVL will extend the use of DE only applications to ongoing evaluations which are already in a higher state of decision-making. The respective applicants will be addressed by the BVL in the following weeks.

When there is an Article 43 application with more than one Active Substance and the Active Substance Approval dates are within one year, the BVL also asks for a special procedure. Of course, an application is mandatory, after the first Active Substance has been renewed. After the renewal of the second Active Substance, BVL asks not to send in a second application, but to treat all actions related to the second Active Substance, i.e. delivery of dossier or Category 4 studies, as a supplement to the first application. The dRR to be submitted should be complete and the changes compared to a previous dRR should be highlighted. The efficacy should only be compiled in the dRR (according to the EPPO standards). Focus should be on the resistance management. A BAD is not required by Germany. The BVL emphasises that post submissions are not foreseen in Article 43 applications. Instead, in case of data gaps a rejection is foreseen. BVL expects to publish information on Article 43 in the second half of 2017 on their homepage.

In a presentation by the BfR the cumulative risk assessment has been elucidated. As of 1 March 2017 it is conducted by the BfR. As of 1 January 2018 the applicant is obliged to submit such an assessment. There is a publication in the German Bundesanzeiger of 21 February 2017.

In addition the BfR has devised a new concept of protection for the worker which, for the first time, includes a limitation in time beyond the 24 to 48 hours currently already in place. In the future, after

additional clarification with the BVL, there will be the possibility for the following periods: 2, 7, 14, 28 days as well as "until immediately before harvest" and "until including harvest". Also, there is the possibility to limit the daily working time to less than eight hours.

Non-standard applications, such as gassing or aerial applications, should be included in the zonal GAP and in the core dossier of the dRR. BfR conceded that there are different opinions on this in the central zone and the actual way of presentation should be clarified in a pre-submission meeting. Further details can be found on the BVL homepage.

From 23rd to 24th of November 2017, there will be a workshop at the BfR in Berlin on the issue "*What does the future hold for harmonised human health risk assessment*".

In the comparative assessment (Article 50) the applicant in Germany should address the issue, but not provide alternative lists or any reasoning as to why the Plant Protection Product is indispensable. Both will be done by the JKI and the applicant will be given the possibility to comment. No such assessment will be done, if the product is already registered for ecological agriculture, minor uses or emergency uses. Another or the same candidate for substitution can be an alternative in Germany, if it's application mode is different from the one under consideration and assessment.

The BVL has exhausted its product numbers and is issuing, since mid-May, a new version of the number. Instead of a four digit identification number, the first number will be replaced by a letter, i.e. 00 A000-00/00. All other features will remain untouched, i.e. the first two numbers still represent the generation of the authorisation, the two digits following the hyphen the distribution extensions and the two numbers behind the slash are for use extensions.

The BVL will also revise its applicant's portal, which is expected to go online mid-2018. A special applicant's conference will be held before the start.

Finally, the BVL asked to supply the full dossier, which was also submitted in the original country, to the BVL. Such applications should be placed to the BVL at the latest four months before the renewal of the Active Substance.



## Co-formulants in plant protection products under REACH

In an urgent letter the European Crop Protection Association (ECPA) alerts all manufacturers and importers to the fact that co-formulants in plant protection products need to include this as an Identified Use in their corresponding REACH registration dossier and ultimately in the Safety Data Sheets. Where relevant, exposure scenarios which explicitly take into account plant protection product applications should be used. To support such activities, REACH-IN was developed collectively at ECPA. The existing exposure modelling tools do not properly consider specific use conditions for plant protection products, while the EFSA REACH-IN tool delivers more realistic exposure scenarios for both workers and the environment.

The tools, a short introductory webinar, and full documentation are available on the ECPA REACH-IN page:  
<http://www.ecpa.eu/industry-resources/reach-registration-evaluation-authorisation-and-restriction-chemicals>

## New guidance document on work sharing for the Northern zone

Version 6.0 of the guidance document for registration of plant protection products in the Northern zone is now available. The revised version includes various updates on information accepted in the Northern zone for risk assessments in toxicity, environmental fate and ecotoxicity sections.

For example, risk mitigation measures accepted in the different Northern zone countries for toxicity exposure assessments according to EFSA model are listed. Here, only six out of fourteen mitigation measures are accepted in all counties of the Northern zone: Tiered approach, respiratory protective equipment (RPE) and head cover for operator, workwear and tiered approach for workers in greenhouses and workwear for workers in field. Other mitigation methods such as closed cab for operator (not accepted by Norway and Finland) or re-entry periods for workers (case by case decision in Finland) are not harmonised.

The guidance document further provides a good overview over national requirements and particularities apart from risk mitigation. For example, Sweden does not accept minor formulation changes as defined in the EU guidance document for Minor Changes (Swedish chemicals Agency should be contacted for guidance) and Denmark considers all groundwater metabolites as relevant, but in some cases, and after

evaluation by DEPA (see the Danish national guidance), some metabolites may be accepted at concentrations up to 0.75 µg/L.

These examples show that the guidance document is an essential and indispensable tool when preparing plant protection product evaluation documents for authorisation in the Northern zone. Another important point stated in the guidance document concerns existing authorisations of plant protection products, for which the expiry date of the active substance on EU-level was prolonged due to delays in the renewal process. Only Norway and Denmark extend the authorisations of concerned products automatically and free of charge. All other Northern zone member states must be notified with a letter by the authorisation holder, otherwise the product authorisation will expire.

## Biocontrol products for crop protection in France - Recommendations by the CGAAER

The French General Council for Food, Agriculture and Rural Areas (CGAAER) was mandated to review the development of biocontrol products and make recommendations for their deployment in the French agricultural sector. The CGAAER was responsible for reviewing advances in product research and development, identifying barriers and levers, and specifying actions to be taken to broaden product offerings and increase their use by farmers.

The CGAAER carried out non-directive interviews with all stakeholders in the sector. These exchanges revealed sensitive issues such as the transfer of laboratory results to field conditions, evaluation phases and experimental conditions favouring the provision of effective solutions to farmers.

From the outset, the mission identified obstacles to the innovation for biocontrol products and limiting their access to users. Innovative companies in this field, often small and with limited resources, face difficulties in finding financing and pooling their skills needed to develop and commercialize a biocontrol product. Products derived from living organisms have characteristics, which make their development and use different and more complex. The whole system for granting marketing authorization and user distribution has been designed for synthetic products. Therefore, provisions specific to biocontrol products must be adopted for each stage, from research to use.

The CGAAER identified 5 major obstacles and published 5 recommendations in the report.

1. The CGAAER found that the word “biocontrol” is used as a heterogenic and vague term and proposed a regulatory definition for “biocontrol” products: *“A product is considered to be a biocontrol product when it uses natural mechanisms to protect plants or strengthen their natural defenses against harmful organisms by means of macroorganisms or plant protection products including chemical mediators, natural substances of plant, animal or mineral origin, or identical to them, and basic substances, while presenting a high level of safety for public health and the environment.”*
2. The CGAAER found that the delays in the evaluation of marketing authorization dossiers are a major obstacle to the availability of biocontrol products. It recommends that ANSES submit to the supervisory authorities an action plan, in order to comply with the processing deadlines provided for by the regulations for these products from 1 January 2018.
3. The CGAAER noted the lack of structure in the field of biocontrol research. It recommends the drafting of a ministerial roadmap defining research priorities for the sector biocontrol, which could be implemented by the Biocontrol Consortium.
4. After official authorization, the deployment of biocontrol products is hampered by the lack of references on the good conditions of use of the products and the training of technicians and users. The CGAAER recommends systematic use of biocontrol and characterization and valorisation of these products, for example within Ecophyto 2 program.
5. The CGAAER noted that biocontrol cannot provide all the solutions necessary for the protection of plants in the short term, but considers it necessary to promote biocontrol products in all public policies through e.g. improving the French vision of biocontrol.

## France: National measures and a revision of the National strategy on endocrine disruptors

EU Member States adopted on Tuesday, the 4<sup>th</sup> of July 2017, the criteria for defining endocrine disruptors used in pesticides.

At French level, in a joint press release issued by the Ministries of Ecological and Solidarity Transition, Solidarity and Health, and Agriculture and Food, the French Government announced additional National measures and a revision of the National strategy adopted in April 2014 on endocrine disruptors.

Among the measures announced, Ministers of the Ecological and Solidarity Transition, Solidarity and Health, and Agriculture and Food, will seize ANSES to conduct a risk assessment of the most widely used products containing these substances. With regard to the substances covered, where concerns are expressed, the Government undertakes to use the procedure provided for by European law, on the basis of scientific and technical analyses carried out at national level, **to prohibit the placing on the French market of products containing these substances.**

A list of plant protection products authorized in France that may contain endocrine disruptor substances has been published. The products listed are products containing one or more of the 26 active substances included in the impact assessment of the European Commission as falling within the definition as proposed by the European Commission. The definition adopted is broader, including also substances for which endocrine disrupting action is “plausible”.

Please note that the products contained on the list have not yet been scientifically evaluated to verify their endocrine character based on the definition adopted by the Member States. Substances can therefore be withdrawn or added to this list.

The 13 page list could be downloaded from:  
[http://agriculture.gouv.fr/sites/minagri/files/liste\\_ppp.pdf](http://agriculture.gouv.fr/sites/minagri/files/liste_ppp.pdf)

The impact assessment containing the 26 active substances (page 112) could be downloaded from:  
[http://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/2016\\_impact\\_assessment\\_en.pdf](http://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf)

Please refer also to the article  
“Short notice: Endocrine disruption –  
EU Member States adopt criteria for PPP”  
on page 10 for further information.

## Agreement on new rules for organic farming

On 28 June 2017 the negotiators of the Council and the European Parliament reached a preliminary agreement to update the EU rules on organic production and labelling of organic products.

The new rules focus on harmonisation and simplification of production rules, strengthening of the control system, guaranteeing fair competition for farmers and operators, introducing a new system of group certification for small farmers and providing a more uniform approach on pesticides.

In a next step the agreement needs to be approved by the Council's Special Committee on Agriculture (SCA). After a thorough legal and technical revision of the text and formal endorsement by the Council, the new legislation will be submitted to the European Parliament for a vote and to the Council for final adoption.

The new regulation will apply from 1 July 2020.



For more information, please contact  
Dr Albrecht Heidemann at  
[albrecht.heidemann@scg-gmbh.de](mailto:albrecht.heidemann@scg-gmbh.de)

## CHEMICALS/REACH



### New Head of Chemicals business unit

Herewith I would like to introduce myself. My name is Thomas Roth. I have a Ph.D. in food chemistry and I am a certified and European registered toxicologist. I have been with SCC for more than 8 years already as Head of the Toxicology Group within the Regulatory Science business unit. Before my career within SCC, I worked for 10 years in the chemical industry as a toxicologist. Since July 1 I am the Head of business unit "Chemicals/REACH, Consumer Product, Cosmetics, Food and Feed".

I am very much looking forward to respond to your requests, discuss your needs and give you my support related to your chemicals.



For more information, please contact  
Dr Thomas Roth at  
[thomas.roth@scg-gmbh.de](mailto:thomas.roth@scg-gmbh.de)

## ECHA provides more clarification about the enhanced technical completeness check after dossier submission

The European chemical agency (ECHA) has updated the frequently asked Questions section (Q&A) on the ECHA webpage. The Q&A with the ID 1326 is in particular worth mentioning.

ECHA provided more clarification with regard to the consequences of a technical completeness check and a failure of such close to the May 2018 deadline.

One can expect that close to the deadline numerous dossiers are going to be submitted. One has to keep in mind that a member dossier for a substance which is not already registered can only be submitted after the lead dossier has been submitted.

In this context the ECHA clarifies that a dossier is considered to be submitted if it has been uploaded in REACH-IT and passed the business rules step.

In addition, ECHA states that: *“Member registrants cannot receive their registration numbers before the lead dossier is found to be complete. This means that submitted member dossiers are ‘parked’ in the submission pipeline until a decision is taken on the completeness of the lead dossier.”*

In case the lead registrant dossier will be rejected due to incompleteness, a registration number is also not issued for any member registrant of that joint submission.

After the technical completeness check of the lead registrant dossier is completed ECHA will grant a registration number and all submitted member dossiers for that joint submission will be released from being ‘parked’ and will be processed for completeness. The registration date will be the date of the first submission.

ECHA announced that in the peak phase in May 2018 the completeness check will take up to 3 months. Thus, a final registration number for lead and member registrants submitting their dossier close to the deadline might be issued by ECHA in August 2018

or even later if ECHA requests additional data during manual completeness check.

*These circumstances should be kept in mind in case downstream users or other companies along the supply chain will request a registration number immediately after the deadline.*

## New form to help describe the manufacturing process of UVCB substances

ECHA has published a new form to describe substances of unknown or variable composition, complex reaction products, or biological materials (UVCB substances). UVCB substances are identified by, among other things, the description of the manufacturing process. Thus, it is essential that the SIEF participants provide the information in a manner that allows a conclusion about substance sameness. With this new form manufacturers and importers now have a format to report or request this information and use this information directly for the substance sameness discussion.

Furthermore, ECHA requests to include the description (as provided in the form) in the IUCLID dossier for PPORD notifications, inquiries, registrations, and CLP notifications.

The form can be found using the following [link](#).

*Please get into contact with SCC in case you need further assistance on REACH substance identification issues.*

## CBI substantiation needed for TSCA submissions

Prior 22 June 2016, Confidential Business Information (CBI) claims simply never expired. With the new revised TSCA, not only detailed substantiation of CBI claims is required but most CBI claims expire after 10 years unless the submitter re-asserts and re-substantiates the CBI claims.



In this context, please beware of following deadlines:

- From 21 March 2017 onwards, all CBI claims must be substantiated at the time of CBI-submission to EPA (except for information pursuant to TSCA Section 14(c)(2)).
- For all TSCA submissions filed between 22 June 2016 and 21 March 2017, CBI claims have to be substantiated until 19 September 2017 (again except for information pursuant to TSCA Section 14(c)(2)). Without timely substantiation of CBI claims, EPA will provide the affected business a 30 days' notice and the last chance to complete all substantiations.

EPA is obliged to review the substantiation and make determinations of the CBI claims within 90 days after receipt of the claim. In addition, EPA is required to create a unique identifier for a chemical when it approves a CBI claim for its chemical identity

## **Turkey: New Chemicals Regulation (KKDIK) is published and will come into effect on 23 December this year**

The final REACH-like regulation (KKDIK) was published in the country's Official Gazette on 23rd June 2017. It was approved by the Prime Minister Yahya Kesimal, head of the chemicals department at the Ministry of Environment and Urbanisation (MoEU), who said that the KKDIK has been effectively transposing "60-70%" of the REACH regulation until now.

The KKDIK-Regulation will come into effect on 23 December this year. KKDIK-Regulation places responsibility on industry to provide safety information on and manage the risk of chemicals. The KKDIK sets a registration deadline of 31 December 2023 – postponed from the previous deadline of 2021. Pre-registrations must be submitted by the end of 2020. KKDIK requires submissions to be made in Turkish which could be a stumbling block.

## **Late-Preregistration Phase closed on 31 May 2017 – “No data no market” applies for newcomers on the market**

Until 31 May 2017 newcomers on the market could benefit from the transitional period lasting until 31 May 2018 for the registration of phase-in substances in the 1-100 tonnage band. This option is no longer available as a late pre-registration can only be submitted until 12 month prior to the relevant registration deadline. Thus, REACH Article (5) – no data no market – fully applies since 1 June 2017.

As a consequence, companies which intend to place substances as such or in mixtures or articles on the EU market have to register these substances upfront. As first step, an inquiry according to REACH article 26 has to be submitted to ECHA including analytical data. The data will be manually checked by ECHA staff in order to evaluate the substance ID and to grant access to the respective SIEF. This process will take some time (depending on the current workload at ECHA, usually between 4-12 weeks). After the inquiry process is completed one can proceed with the registration process. In case of joining an available joint submission, the letter of access has to be organised and a member dossier has to be prepared.

*In conclusion, before a company can place a substance on the EU market it will take significantly more time and efforts to achieve regulatory compliance compared to the procedure during the transitional period.*



For more information, please contact  
Dr Thomas Roth at  
[thomas.roth@scg-gmbh.de](mailto:thomas.roth@scg-gmbh.de)

## REGULATORY SCIENCE



### Short notice: Endocrine disruption – EU Member States adopt criteria for PPP

ED criteria (adopted latest revision of Draft Legal Act under the Plant Protection Products Regulation)<sup>1</sup> were adopted by MS<sup>2</sup> on the occasion of the latest SCoPAFF Pesticides legislation meeting held 4 July 2017 in Brussels<sup>3</sup>.

ECHA and EFSA are in charge to prepare a joint guidance document for the implementation of the ED criteria. The draft version of this GD will be available for public commenting in autumn.

According to the Commission press release<sup>3</sup>, *“the criteria will apply after a short transitional period of six months”* during which ECHA and EFSA can finalise the GD. This underlines the importance of ED issue for the COM as can be also seen from the following statement: *“as for pesticides and biocides, the Commission will not delay any action and will already apply the criteria to substances for which assessment or re-evaluation is undergoing or for which confirmatory data concerning endocrine properties have been requested.”*

The criteria are mainly based on WHO definition for ED. The EU Impact Assessment (SWD(2016) 211 final)<sup>4</sup> allocated 26 compounds potentially affected by the definition based on Option 2 (WHO definition).

Since the COM will apply the criteria also to the ongoing procedures of the evaluation of plant protection products as well as biocides, one should closely follow up all developments in the area (especially, the GD currently under preparation by EFSA and ECHA) and consider whether further steps/actions for individual compounds are needed.

<sup>1</sup> Draft Legal Act under the Plant Protection Products legislation, revised version 30 May 2017  
([https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/20170530\\_ppp\\_draft\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/20170530_ppp_draft_en.pdf),  
first version published 15 June 2016,  
[https://ec.europa.eu/health/endocrine\\_disruptors/policy\\_en](https://ec.europa.eu/health/endocrine_disruptors/policy_en))

<sup>2</sup> Minutes of the last meeting with Member States (04 July 2017). From the 28 MS, 21 voted in favour of the proposal, with three voting against it, and four having abstained from the vote.  
([https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/20170704\\_paff\\_sum\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/20170704_paff_sum_en.pdf))

<sup>3</sup> COM (2017). Endocrine disruptors: major step towards protecting citizens and environment (press release), Brussels, 4 July 2017  
([http://europa.eu/rapid/press-release\\_IP-17-1906\\_en.htm](http://europa.eu/rapid/press-release_IP-17-1906_en.htm))

<sup>4</sup> COM (2016). IMPACT ASSESSMENT Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation, SWD(2016) 211 final, Brussels, 15.6.2016  
([https://ec.europa.eu/health/endocrine\\_disruptors/impact\\_assessment\\_en](https://ec.europa.eu/health/endocrine_disruptors/impact_assessment_en))

### Short notice: New EFSA Guidance Document on Dermal Absorption

EFSA published a new Guidance Document on Dermal Absorption on its homepage on 30 June 2017. The document was adopted on 24 May 2017<sup>1</sup>. A Technical Report<sup>2</sup> was also published which includes the statements and answers given by EFSA in the commenting phase.

Relevant differences compared to the previous version are listed in the following:

- Decreased dermal absorption default values of 10% (concentrate) and 50% (dilution) for water based/dispersed and solid formulations (previously 25% and 75%) are presented.
- For organic solvent based formulations default values of 25% (concentrate) and 70% (dilution) are listed.
- The previous ‘25% rule’ for read-across between similar formulations has been changed. The permitted variations now decrease from 100% to 5% depending on the increase of initial concentration range of the constituent.
- Concerning the active substance, formulations are regarded as similar when the active substance concentration is within permitted variations of that in the reference formulation based on the FAO and WHO specifications for pesticides. The permitted variations decrease from 15 - 25% to 2.5% depending on the increase of initial concentration range of the active substance.

- A multiple of the standard deviation should be added to the mean dermal absorption value to address variability between replicates (independently of the relation of mean value and standard deviation).
- Values should be rounded to a maximum of two significant decimal figures.
- A proposal for reporting dermal absorption data for Draft Assessment Reports and Registration Reports is provided (minimum information).

According to EFSA<sup>3</sup>, the new EFSA Guidance on Dermal Absorption *“supersedes the previous output published on 25 April 2012 (EFSA PPR Panel, 2012). The European Commission will decide the implementation time for the mandatory use of this guidance in the regulatory context.”*<sup>1</sup>

<sup>1</sup>EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. <https://doi.org/10.2903/j.efsa.2017.4873>

<sup>2</sup> EFSA, Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G and Chiusolo A, 2017. Outcome of the public consultation on the draft EFSA Guidance on dermal absorption. EFSA supporting publication 2017:EN-1250. 106 pp. doi:10.2903/sp.efsa.2017.EN-1250

<sup>3</sup> Guidance on dermal absorption, <http://www.efsa.europa.eu/de/efsajournal/pub/4873>



For more information, please contact  
Dr. Monika Hofer at  
[monika.hofer@scc-gmbh.de](mailto:monika.hofer@scc-gmbh.de)

## The world of SCC at a glance



Access our website at

<http://www.scc-gmbh.de/downloads-scc/brochures>

## CALENDAR



### CIR Chemical Industries Regulations in Nice, France 5 - 7 September 2017

Meet SCC at the annual AgChem Forum 2017 in Nice. **Dr Bernd Brielbeck** will be happy to welcome you to his **presentation on low risk substances** as a part of the Regulatory Frameworks stream on Day 1 at 14:55 (CEST).

You will [meet](#):

**Dr Bernd Brielbeck**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides,  
**Dr Norbert Weißmann**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides – Efficacy,  
**Dr Karin Lauber**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides, and  
**Ms. Karin Gärtner**, Assistant Manager Regulatory Affairs, Regulatory Science – Ecotoxicology.

To view the programme, please follow [the link](#).

### 13th International Symposium Hazards of Pesticides to Bees in Valencia, Spain 18 - 20 October 2017

This symposium organized by ICPPR is aimed to improving protection of bees and other pollinators from adverse effects due to the use of pesticides.

**Ms. Marion Binder**, Manager Regulatory Science - Ecotoxicology, will join this workshop and will be available to talk to you about your regulatory needs. The bee protection group “aims to develop, improve and harmonize test methods and risk evaluation procedures and to stimulate the scientific debate on the available approaches in the area of bees, other pollinators and pesticides.”

For more information, please follow [the link](#).

### CEUREG Forum XXI meeting in Bratislava, Slovak Republic 24 - 25 October 2017

We would like to inform you that

**Dr Bernd Brielbeck**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides, and  
**Dr Karin Lauber**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides,  
will also speak on *low-risk substances* and the *amendment of Regulation (EC) 1107/2009* during the CEUREG Forum which will take place in Bratislava in October 2017.

More information about the CEUREG FORUM in general are available on the web page [www.ceureg.com](http://www.ceureg.com).

### Plant Protection Products - Current Hot Topics in Ecotoxicology in Vienna, Austria 7 November 2017

This one-day session presented by AGES will address recent developments and updates in the field of ecotoxicology risk assessment to fulfill the requirements of Regulation (EC) 1107/2009.

**Dr Stephanie Reischke**, Assistant Manager Regulatory Science - Ecotoxicology, will attend the workshop and would be glad to discuss regulatory or scientific issues you might want to address.

To view the programme, please follow [the link](#).

### Biocides 2017 - 20th Annual Conference in Vienna, Austria 5 - 6 December 2017

This Conference highlights the application of the EU Biocidal Product Regulation.

**Dr Silvia Wagner**, Senior Manager Regulatory Affairs Biocides, will attend this conference and will speak on “*Human Health Risk Assessment for in-situ products using peracetic acid generated from TAED and sodium percarbonate as an example*”. She will be available to talk to you about your regulatory needs regarding biocidal active substances and biocidal products.

For further information on Biocides 2017, please refer to: <http://www.europeanbiocides.net/>.



## CONTACT DETAILS

### SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH

Dr Friedbert 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](mailto:info@scc-hq.de)  
[www.scc-gmbh.de](http://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](mailto:achim.schmitz@scc-gmbh.de)

Address  
Friedrichstraße 40  
D-10969 Berlin

#### Liaison Office Japan

*Coordinator Agrochemicals & Biopesticides,  
Pharma, Pre-Clinical*  
Mr Toshiyasu Takada  
Director Agrochemicals and Biopesticides  
[toshiyasu.takada@scc-japan.com](mailto:toshiyasu.takada@scc-japan.com)

*Coordinator Chemicals/REACH,  
Biocides and other services*  
Mr Kozo Inoue  
Director Chemicals/REACH,  
Biocides and other services  
[kozo.inoue@scc-japan.com](mailto:kozo.inoue@scc-japan.com)

*Chemicals/REACH and OR Services*  
Mr Kenji Makita  
Senior Consultant  
[kenji.makita@scc-japan.com](mailto:kenji.makita@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 <http://www.scc-gmbh.de> under News. You can also subscribe to the Newsletter (free of charge) at this site.

NOTICE: While we have compiled the enclosed information with the utmost care, SCC GmbH is not liable for the consequences of anyone acting or refraining from acting in reliance on any information. Further, SCC has no control over the websites that the reader is linked with using our Homepage/Newsletter. Users linking to other websites do so at their own risk and use these websites according to the appropriate laws governing their usage.

Do you have any comments, questions or suggestions?  
Drop us an E-mail at [newsletter@scc-gmbh.de](mailto:newsletter@scc-gmbh.de).

