THE REGULATORY WORLD – EVERYTHING CHANGES AND REMAINS THE SAME

Dear Subscribers,

Please have a look at the current issue of the SCC Newsletter which comprises relevant topics of the regulatory field.

This issue of the SCC Newsletter contains an article about new guidance documents for the regulation of agrochemicals, a report on the Article 95 of the biocidal product regulation, and several news concerning Chemicals/REACH.

Furthermore, this edition of the SCC Newsletter presents some guidance documents or scientific opinions of EFSA recently published or currently under preparation dealing with ecotoxicological aspects or environmental fate.

Moreover, the SCC Office Berlin is a topic in this edition; details can be found on page 8.

Please also have a look at the calendar to find out where you can meet with SCC experts to personally address 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 biocides, biocides, chemicals, cosmetics, feed and food additives, archiving solutions or Task Force management, SCC is willing to support you and would be happy to inform you on further subjects, if needed.

On behalf of the staff at SCC, I would like to express our wish to continue our service in all fields, scientific and regulatory, for you to satisfy your needs.

We look forward to working with you in the upcoming period and hope our business relationship continues for many years to come.

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

Dr. Friedbert Pistel

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New guidance documents available

New guidance documents were noted during the meeting of the Standing Committee on Plants, Animals Food and Feed on 13-14 July 2015, concerning the parallel trade of plant protection products (SANCO/10524/2012 rev.5.2), about the renewal of authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANTE/2010/13170 rev. 13) as well as a Draft List of Obsolete Guidance Documents (SANTE/11073/2015). These documents can be found or will be published on the Commission website in the coming weeks.

Further draft guidance / working documents are available at Commission for which discussions are still on-going. These documents relate to the low risk criteria, semiochemicals, the definition of negligible exposure and an update on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 rev. 5.1). In the following a short summary of selected documents is given:

Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANTE/2010/13170 rev. 13)

The Guidance Document indicates the timelines in which the assessment is to be completed. Article 43 of the Regulation (EC) 1107/2009 provides that an application for the renewal of authorisation shall be made within 3 months from the date of entry into force of the decision on the renewal of the approval of an active substance. For products containing more than one active substance this step is to be done after the renewal of each active substance contained in the product. The assessment of the application by the Member State is to be done within 12 months after the renewal of approval of the active substance (Art. 43.5).

The application should include any new product data which are required due to new endpoints or criteria. The published Renewal Assessment Report is to be used to be aware of tests and studies. The EFSA conclusion shows where critical endpoints have been changed in the active substance renewal procedure. Changes concerning authorised uses (e.g. amendment of the GAP) are only acceptable where it is necessary to comply with changes in the assessment of the active substance (e.g. new endpoints or restrictions). One exception is a non-significant formulation change according to SANCO/12638/2011.

Before the application, the so called “pre-notification-form” (as summarised in SANCO/12544/2014) is to be provided by the authorisation holder to the concerned Member State(s). A new outcome of this Guidance Document is that the “pre-notification-form” should be submitted by the deadline for the submission of the supplementary dossier for the renewal of the active substance. An updated version should be submitted within 2 months following the publication of the EFSA-conclusion.

For the application to renew the authorisation, the EU PPP Application Management System is to be used. After every step in the procedure, it should be updated by the applicant or the concerned Member State.

Draft working document on negligible exposure

In Annex II of the Regulation (EC) 1107/2009, points 3.6.3 to 3.6.5, it is stated that an active substance, safener or synergist shall only be approved, if it is not or has not been classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, or it is not considered to have endocrine disrupting effects that may cause adverse effects in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible.

Furthermore, an active substance, safener or synergist shall be approved only if it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms (point 3.8.2., Annex II, Regulation (EC) 1107/2009), unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

As negligible is not equal to zero, definitions need to be set for consistency in decision making.

For negligible exposure to humans the dietary and non-dietary exposure should be considered. A negligible dietary exposure is given where the default value set in accordance with Regulation (EC) 396/2005, Art. 18.1(b) is not exceeded, but it might be changed to the LOQ.

For the non-dietary exposure all groups, based on the EFSA Guidance Document on Assessment of Exposure
(EFSA, 2014), as well as the aspects of risk mitigation measures and risk calculation need to be considered. In the Annex to this working document a list on the risk mitigation measures are given which contribute to reduce exposure of humans to plant protection products (e.g. closed transfer system, automatic application system). For negligible exposure to non-target organisms in the environment further details are to be expected at later versions of the guidance document. The decision making for substances with mutagenic or carcinogenic properties, endocrine disrupting properties or which are toxic for reproduction is foreseen in a stepwise approach:

1) No approval is foreseen for substances which are mutagen, POP, PBT or vPvB
2) An approval based on negligible exposure, as defined in the Annex of the working document, can be granted. The respective active substance will be identified as candidate for substitution.
3) As a derogation, an approval is possible for cases where a serious danger to plant health cannot be contained by other available means.

Parallel trade of plant protection products (SANCO/10524/2012 rev.5.2)
The requirements for parallel trade are given in Article 52 of Regulation (EC) 1107/2009. The Guidance Document should facilitate the implementation of this Article in a harmonised and consistent way by Member State authorities. The criteria, the procedure for the examination of applications for granting parallel trade permits (e.g. submission, assessment, decision) as well as post-permit issues (e.g. withdrawal or amendment) are explained in the document. One main point of the criteria is the term „the same or equivalent“ which is used in Article 52.3(c) of the Regulation (EC) 1107/2009 in relation to co-formulants which are contained in the parallel traded plant protection product. According to the guidance document, plant protection products should be considered as not equivalent if the product under examination contains either co-formulants which have never been assessed, co-formulants which lead to a worse classification or quantitative variations in all co-formulants that account for more than 10 % of the formulation. The qualitative and quantitative deviations amongst co-formulants as well as the categories (significant or non-significant) are well defined in the document.

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BIOCIDES

Article 95 now full in force – is that the end of freeriding?

Since 1 September 2015, the transitional period according to paragraph 2 of Article 95 of the BPR is over: a biocidal product may henceforth be placed on the market only if the substance supplier or the product supplier is included in the “List of Active Substances and Suppliers” (“Article 95 list”). As was discussed in the document CA-May15-Doc.4.13-rev2 – “Compliance with and enforcement of Article 95”, several stakeholders, Member States and the Commission expect a large ‘dark figure’ of non-compliant products which are still placed on the market. Possible reasons given for this are that the respective companies are still in the process of becoming listed or switching their source of supply to another one on the list, or that they are simply unaware of their obligations.

Please be aware that compliance alone may not be sufficient – several Member States, e.g., Belgium, Cyprus, Hungary or United Kingdom (here: only for products registered under COPR) demand that a proof of compliance for each product on the respective national market is proactively sent to their attention. In doubt, it is advisable to contact the national helpdesks, and to have appropriate proof ready, to be able to produce it upon request.

It may be expected that the authorities which are responsible for market surveillance in the individual Member States will soon begin to identify non-compliant products; CA-May15- Doc.4.13 suggests that Member States should not issue penalties in the first months after 1 September 2015, but to issue warnings and to allow the respective companies a last opportunity to prove their compliance before being penalised (a 6-month time period is suggested). However, it is up to the individual Member States if they will follow this suggestion.
CHEMICALS/REACH

Harmonization of C+L notifications for potential CMR substances

ECHA set up a pilot project to initiate harmonization of C+L notifications for potential CMR substances. Basis for this project is the CMR report published in January 2015. ECHA identified about 100 substances, where CMR classifications are not harmonized within the different notifiers or even are different to the official Annex VI classifications. ECHA wants industry to discuss and agree on a harmonized classification using their C+L platform.

In the event that the substance of concern is already registered, SCC recommends that at least a short notice on the agreed joint classification in the registration dossier is posted by the lead registrant. This should also be considered for substances currently not in focus by ECHA, to at least show good will to harmonize the classifications. Consequences for not agreeing on a joint classification for CMRs substance might even lead to prioritization as SVHC by ECHA.

If you need any assistance with regard to this issue, please get in contact with SCC.

Changed requirements for compilation of safety data sheets from 01.06.2015

The European Commission has published the Regulation (EC) No 2015/830 (dated 29.05.2015) which amended the REACH Annex II with effect from 01.06.2015. Through these changes the requirements for the preparation of Safety Data Sheets are adjusted in accordance with the fifth revision of the GHS requirements for safety data sheets.

On 1 June 2015, two conflicting amendments of Annex II to Regulation (EC) No 1907/2006, one made by Article 59(5) of Regulation (EC) No 1272/2008 and one made by Regulation (EU) No 453/2010, were intended to come into force simultaneously. To ensure that no confusion arises which version of Annex II is applicable from 01.06.2015 onwards; the two conflicting amendments of Annex II have been replaced by the new Annex II.

It should be noted that the new Annex II partly requires significantly more information to be provided within the SDS. A transition period for existing SDS was granted. SDS that were provided to any recipient before the update of REACH Annex II may still continue to be used until 31 May 2017. SCC can provide you regulatory support to compile REACH compliant SDS according to the new requirements.

ECHA reassesses toxicity to reproduction section in IUCLID

Due to recent changes in the REACH Regulation Annex IX and X ECHA requires registrants to update their registration dossiers for the endpoint toxicity to reproduction. The two-generation study (OECD 416) was replaced by the extended one-generation study (OECD 443). ECHA recently announced that registrants should update their dossiers (Testing proposals, Waivers etc.) by end of September 2015 with the new OECD 443 study as ECHA will start examining the pending testing proposals by October 2015.

In addition for developmental toxicity the registrants should also update their dossiers addressing the second species for an OECD 414 test either by a waiver or a testing proposal. ECHA clearly announced that the second species should be clearly addressed independently of a possibly running study for the first species.

Please get back to SCC in case you have any questions on this topic. SCC can provide you with intelligent waiving or testing strategies for reproductive toxicity.

Substance evaluation get in contact with competent authorities as early as possible

At the 10th stakeholders day, ECHA recommended to get in contact with the competent Member State as early as possible. Before substances are included in the CoRAP list a draft CoRAP list is published by ECHA around 6 months before the final list (and consequently before the start of the evaluation process). Ideally contact with the Member State should be established before that time point. Any contact should be informal and not legally binding for both parties. Early contact might help to clarify concerns upfront and it also facilitates contacts during evaluation phase.
National Notification of hazardous mixtures and biocide products according to §16e ChemG (Germany)

The transition period granted by §28 (12) 3 Chemicals Act of the Federal Republic of Germany (ChemG) has expired on 1 June 2016. From that date onwards according to §16e ChemG manufacturers, importers, or resellers that use their own product name, who place a hazardous mixture or a biocide product on the market, have the obligation to submit a notification to the German Federal Institute for Risk Assessment (BfR). The notification should contain information about the product name, the composition, the classification, and the uses and recommendations about preventive measures when using the substance and first aid measures (for more details about the procedure and obligation please follow this link). SCC offers to take care of the notification including data gathering as well as preparation and submission to the authorities.

Classification and labelling of skin sensitisation via in chemico/in vitro test data

Classification of skin sensitisation via in chemico/in vitro tests (OECD TGs 442C, 442D and draft h-CLAT test) is now accepted by ECHA. The ECHA highly recommends investigating at least three key events either by QSAR, non-animal test data or animal and human data in a weight-of-evidence approach. In case only non-animal testing approaches are used, information should be generated at least for three out of four key events (OECD, Adverse outcome pathway for skin sensitisation, 2012). The use of in vitro data for REACH purposes is covered by Article 13(1) and introductory paragraph to Annex VII of the REACH Regulation. The ECHA guidance on information requirements and Chemical Safety assessment R.7a will be updated soon to reflect this new approach. SCC can provide scientific support for you when conducting the new test battery to avoid vertebrate animal-testing.

Current status of new regulation for WGK Classification in Germany

On 20 July 2015 the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMU) initiated the notification procedure for the regulation on installations for handling water-polluting substances (AwSV) in the EU. The commission or EU Member States can examine the notified text and if applicable respond appropriately until 21 October 2015. No detailed opinion by COM or Member States are expected as the previous version of 2013 has already been notified. The Ministry explained that the federal government will decide after the notification how to proceed further. It was pointed out that there had been no initiative of the federal states to change the Federal Council Decree of 23 May 2014 to AwSV. Thus, in November 2015 a publication in the German Federal Law Gazette can be expected. The AwSV will replace the individual regulation of the federal states and is expected to enter into force in Q1 2016.

Update of the ECHA Guidance R.12 Use descriptors

The ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12 Use description is currently in the process for consultation for updating existing guidance. In February 2015 a first updated draft was sent to the Partner Expert group (PEG) for consultation. The PEG comments were considered by ECHA and a draft for the committee was issued. During the CARACAL 18 meeting ECHA has announced the publication of the final version of the updated guidance for December 2015. The scope of the guidance was extended from “use descriptor system” to “Use description”. Subsequently explanations of the role of use information in various processes as well as clarification of some terms/concepts/requirement were added. The most considerable changes are the revision of the list of use descriptors (e.g. renaming of PROCs/ERCs, shorter names for PCs and clarification of applicability of ERCs) change and the introduction of a new life cycle stage replacing main user groups SU 3 (industrial uses), 21 (consumer uses), 22 (professional uses), 10 (formulation). Within this guidance document ECHA provided an advice how to manage these changes. The key message is that the update of this guidance as such does not trigger a requirement to update existing registration dossiers.

ECHA identifies four cases how to deal with the requirements of the updated guidance:

- For new registrations being prepared for 2018 deadline after the guidance has been published the updated guidance should be followed.
- Existing registrations which have to be updated because of an external request from authorities are expected to follow the updated guidance when the update takes place after the publication.
Following the Guidance Document on tiered risk assessment for aquatic organisms in edge-field surface waters, which was published in July 2013, this is the second of three deliverables within the mandate to revise the Guidance Document (GD) on Aquatic Ecotoxicology under Council Directive 91/414/EEC (SANCO/3268/2001 rev. 4 (final), 17 October 2002).

Some interesting aspects of the opinion are summarised in the following:
- The sediment risk assessment becomes necessary depending on the occurrence of a substance in sediment and if the chronic toxicity to pelagic organisms is less than 0.1 mg/L. EFSA recommends that the trigger for occurrence of a substance in sediment is met, if more than 10% occurrence after 14 days in the water-sediment study is detected (already used trigger for testing of sediment organisms) or more than 10% of the total annual dose of the active ingredient occurs in sediment at the time of maximum PECsed as assessed by FOCUS modelling.
- According to the proposed decision scheme, two sediment organisms should be tested on chronic level: One aquatic invertebrate species and a second species depending on the toxicity data derived for pelagic organisms. This means (i) if toxicity tests indicate that aquatic invertebrates are the most sensitive species, a second invertebrate species needs to be tested, (ii) if primary producers were most sensitive species, a rooted macrophyte (Myriophyllum sp.) needs to be tested, (iii) if vertebrates are most sensitive, no further vertebrate testing, but surrogates are suggested (e.g. risk assessment with fish compared to PECporewater).  
- For substances with BCF in fish > 2000 and further persistence or adsorption potential, bioaccumulation in food web is to be investigated. Guidance how to incorporate the outcome of invertebrate bioaccumulation studies in an evaluation needs to be elaborated. A guidance for food web modelling is expected to be provided in the future opinion on ecological modelling.

Overall, it can be expected that the sediment risk assessment will get a more distinct position in the aquatic risk assessment. It can be assumed that PEC modelling and the corresponding sediment risk assessment will be more extensive. However, some proposals for modelling and risk assessment made by EFSA need more research and/or are not yet available/validated.

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**Risk assessment on sediment organisms in edge-of-field surface waters**


In conclusion, one should be prepared for the changes in life cycle description. These new requirements may be applicable earlier than expected (due to request by authorities, request by downstream users). In order to minimise attention during ECHA screening proactive action may be necessary. SCC can assist you to update your use descriptors (and issuing a CSR update).

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**REGULATORY SCIENCE**

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Risk assessment of plant protection products for non-target arthropods


At present the Non-Target Arthropods (NTA) risk assessment is performed in accordance with the "Guidance Document on terrestrial Ecotoxicology (SANCO/10329/2002 rev.2 (final), 17 October 2002)", the ESCORT 2 Guidance Document and the recommendations given in the proceedings of the ESCORT 3 workshop.

In the new Opinion on NTA, EFSA reviews the existing risk assessment scheme for plant protection products and makes proposals how the NTA risk assessment could be performed in the future.

In the current Tier 1 risk assessment, testing of two species is required (Typhlodromus pyri and Aphidius rhapsalosiphon). In the new Opinion on NTA, EFSA suggests mortality and reproduction testing of four species at minimum in order to represent different taxonomic groups and lifestyles. To address herbivorous NTA species in the tier 1 risk assessment, one of the four species should be a lepidopteran larvae. However, a validated test guideline for lepidopteran larvae does not yet exist.

Furthermore, EFSA provides proposals for specific protection goals aiming to protect important ecosystem services, i.e. food web support, pest control, pollination, cultural services (aesthetic value) as well as biodiversity and genetic resources. Within this context, the "classical" separation into in-field and off-field area as well as separate risk assessments for both compartments is questioned by EFSA.

EFSA is of the opinion that risk assessments on a local-scale are not sufficient to demonstrate an overall acceptable risk to the whole NTA community. Therefore, EFSA suggests conducting both a local-scale and a landscape-scale risk assessment already in the Tier 1 risk assessment. For the landscape level Tier 1 risk assessment EFSA suggests to provide "look-up" tables with pre-modelled trigger values. For the Higher Tier local-scale and landscape-scale risk assessment, the implementation and the use of specific risk management options and modelling in combination with the results of NTA field studies will be of major importance.

Based on the information given in this opinion, it can be assumed that the risk assessments will be more extensive and sophisticated in the future as the existing NTA risk assessment is not deemed sufficient. However, at present the new risk assessments and modelling approaches, cannot be defined, especially for the higher Tier, as the data required to generate and calibrate the risk assessments and models do not yet exist. This opinion could be regarded as a research request to start to generate the data base for the forthcoming Guidance Document.

With regard to the further timeline of the NTA Guidance document, EFSA plans to have a public consultation for the 2nd quarter 2018 and to issue the Guidance Document in the 4th quarter 2018.

EFSA – environmental fate and behaviour

With respect to the development of a new procedure for determination of PEC
target under the direction of EFSA, implementation of respective guidance documents may be expected in 2017. Regarding annual field crops under conventional and reduced tillage, the final guidance document (EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2015;13(4):4093, 102 pp., doi:10.2903/j.efsa.2015.4093) has already been issued together with the corresponding modelling tools. A corresponding guidance document and modelling tools for PEC in soil for permanent crops and crops grown on ridges are currently under preparation and are not expected to be available before 2017. As different procedures for the separate crop groups should be avoided, both guidance documents are intended to be implemented at the same time.

Regarding the guidance document on PEC calculations for protected crops (EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615), the Committee agreed to postpone the date of application from 1 May to 1 December 2015 in view of the final comments raised by Member States.

Joint EFSA/FAO/WHO Stakeholder Meeting in Geneve, September 2015

On 7 September 2015 the Joint EFSA/FAO/WHO Stakeholder Meeting took place in Geneve in order to discuss the modification of the equation used within
the deterministic acute dietary risk assessment for calculating the International Estimate of Short-Term Intake (IESTI).

Angeliki Lysimachou from PAN presented the NGO’s view regarding the need for fundamental changes in the calculations of dietary exposure to toxic pesticides to guarantee consumer’s safety. Monika Bross presented the industry view and Volker Wachtler from the European Commission, DG Santé, the considerations of the European Commission. The view of food producing / exporting countries has been presented by Pampilad Saikaew from Thailand.

The aim of the meeting was to gather different points of views of the stakeholders regarding the revision of the IESTI equations which should be considered within the Scientific Workshop (8 – 9 September 2015). The overall aim of the workshop is the preparation of a joint EFSA/FAO/WHO Technical Report on a renewed IESTI equation that will serve as a basis for discussion by JMPR, the European Member States and the European Commission.

The outcome of the Scientific Workshop will be important for the approval / authorisation of pesticides as the modifications under discussion, e.g. use of the MRL instead of the highest residue levels from supervised trials might lead to an exceedance of the acute reference dose, i.e. non-acceptance of uses of pesticides currently authorised.

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

SCC OFFICE BERLIN

Welcome to Berlin

In addition to its Headquarters located in Bad Kreuznach, SCC has opened its second Germany office right in the middle of Berlin. Starting in September 2014 a team of regulatory scientists has been built to work with a present focus on projects in the field of environmental fate and ecotoxicology.

Our colleagues in Berlin have a professional background in chemical industry, contract research organizations, scientific consultancies, and regulatory authorities.

The SCC team in our office in Berlin is part of our HQ’s Regulatory Science Business Unit. In total, this guarantees the same spectrum of expert knowledge together with the service and the quality SCC customers are used to for years. Moreover, our Berlin Office enlarges the possibilities and capacities for our clients.

Beyond that, Berlin has much to offer – once being there, e.g. for a conference, or for a meeting with authorities, our clients have already used the Berlin Office for meetings with SCC to discuss projects or to prepare for meetings with governmental authorities like the Umweltbundesamt (UBA) in Dessau (ca. 1-2 h distance) or the Bundesamt für Risikobewertung (BfR) in Berlin (ca. 30 minutes distance).

If necessary the SCC experts from Bad Kreuznach can easily attend the project meetings in Berlin via video or telephone conference.

Recently the team of the SCC Office Berlin visited the environmental research facilities of the UBA in Berlin Marienfelde, with their higher tier aquatic test systems like pond mesocosms and the flowing, flow-through and stagnant system simulation facility (FSA).

And what to do after a meeting day in Berlin? It’s hard to get bored in Berlin - plenty of shops, restaurants, museums and touristic highlights are within walking distance from the office or can be easily reached via public transport.

Please feel free to contact us:

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CIR Chemical Industries Regulations 2015
22-25 September, Barcelona, Spain
SCC GmbH is a sponsor for this 15th annual AgChem Forum 2015 which will be held in Barcelona.
Dr. Bernd Brielbeck, Senior Manager Regulatory Affairs, Agrochemicals and Biocides, will make a presentation about “Biopesticides - do they exist in EU legislation?”. Dr. Norbert Weißmann, Senior Manager Regulatory Affairs, Agrochemicals and Biocides – Efficacy, Dr. Monika Eder, Senior Manager Residues and Consumer Risk Assessment, and Boris Rosenkranz, Manager Ecotoxicology and Risk Assessment, will also participate in the conference. Meet with them on the exhibition stand no. 15 to discuss your needs in registrations of Agrochemicals and Biopesticides, but also for any other business matters.

Biocides Europe 2015 - 18th Annual Conference, 25-26 November 2015, Vienna, Austria
This Conference highlights legal issues and trade aspects of Biocidal products. A pre-summit workshop (24 November) provides a practical introduction to the Biocidal Product Regulation. Furthermore, some half-day workshops on 27 November offer a more in-depth and hands-on study of several topical issues.
Dr. Martina Galler, Senior Manager Regulatory Affairs Biocides, and Dr. Stefan Nave, Manager Regulatory Affairs Biocides, will attend this conference and will be available to talk to you about your regulatory needs regarding biocidal active substances and biocidal products.
For further information on Biocides Europe 2015, please refer to:
http://www.europeanbiocides.net/

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