

NEWSLETTER

SCC Newsletter Vol. 17, No. 3, November 2017

CHEMICAL INDUSTRY REGULATIONS - CIR 2017 IN NICE - REVIEW -

SPECIAL EDITION

Dear Subscribers,

This special edition of the Newsletter comprises some reports on the last CIR Conference in Nice, focused on the AgChem Forum.

A review of selected presentations on regulatory frameworks is given for your information.

As you know, in the fast-moving world of regulation SCC is ready to keep its customers on a successful course. Regardless of whether your needs are in scientific and regulatory support (like exposure modelling and risk assessment) for agrochemicals and biopesticides, biocides, chemicals, consumer products, feed and food additives, GLP archiving solutions or Task Force management, SCC can provide you with high-quality services and consulting.

Furthermore, we appreciate your feedback and comments regarding the SCC Newsletter.

Please drop us an E-mail at
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Dr. Friedbert Pistel

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SCC Homepage news

Re-launch of the listing

"Approval status of agrochemical & biopesticidal active substances"

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AGROCHEMICALS



Chemical Industry Regulations 6 - 7 September 2017

This year's AgChem forum was held again in Nice in the south of France. The "Regulatory" and "Biopesticides" Streams, of which summaries of some of the presentations are given here, covered a broad range of issues. It started off with a panel discussion on the politicisation of the regulatory decision making process. Paul Leonard of BASF, Julie Girling of the European Parliament and Alastair Leak of the Game & Wildlife Conservation Trust commented and discussed on the increasing politicisation, recently most notable in the handling of the Glyphosate re-approval. With growing influence of social media and the public opinion gaining influence on the decision making process, it becomes crucial for the industry to emphasise the positive aspects of plant protection in contrary to the perception of "dangerous and toxic chemicals being applied to food". An open discussion must be initiated which allows an honest assessment of the benefits versus the risks.

"Regulatory Stream":

Alastair Leak of the Game & Wildlife Conservation Trust presented possibilities to combine intensive agriculture with environmental protection. As the demand on farmland increases steadily, this integrated management of food production and environmental protection becomes more and more important. On a pilot farm he found that making the least productive fields a hotspot for biodiversity could be one approach to deal with this issue.

As in the previous year, Dimitra Kardassi from EFSA reported on the progress and the work of that organisation. Among many other issues, currently a review of neonicotinoids as regards the risk to bees is ongoing. For glyphosate, EFSA is currently assessing the residues in feed and issues of animal health as well as the potential endocrine activity of this Active Substance. EFSA issued a technical Guidance on the assessment of negligible exposure (SANCO/2014/12096), and Guidance on OPEX studies (EFSA Journal 2014; 12 (10): 3874). Also many activities to arrive at a combined DAR-CLH report template, have been finalised recently. It is envisioned that this combined report is to be submitted in parallel to both EFSA and ECHA.

As both agencies then have the same level of information, consistency in the data set for the two processes should be ensured. This procedure is not mandatory, but the Member States are strongly encouraged to use the combined format for all chemical substances used in Plant Protection Products. To improve the EU peer-review the following considerations have been provided. The RMS should address EFSA already in the pre-submission meeting, if complex issues arise. With respect to the expert meetings there is the possibility for the applicant to participate through telephone conferences.

EFSA is planning to implement a database called MATRIX, expecting that electronic submissions of dossiers will be made for all regulated products in the future. A pilot project is expected in September 2017.

The development of criteria for the identification of endocrine disrupting compounds (EDCs) was presented by BfR specialist Glenn Lurman. The heterogeneous legislation in different regulatory areas (plant protection, biocides, REACH, food and feed) is one of the major points which has to be worked on in the future. At the moment, there is a massive uncertainty how to address endocrine disruption (ED) in general. For example, the new guidance document for biocides and Plant Protection Products on ED focuses on hazard identification and is limited to the EATS (estrogen, androgen, thyroid, and steroidogenesis) - pathways. BfR is currently conducting a Literature search (1997-2017, rats and dogs) and a lab survey (how ED studies are actually conducted). For mid October an expert hearing on the results is planned.

Claudio Mereu from Fieldfisher Belgium gave an overview over data protection and access to documents from a legal perspective. It was highlighted that with respect to Regulation 1367/2006, most data related to fate and ecotoxicity of plant protection substances (actives and products) are subject to disclosure with respect to the public interest in emissions in the environment upon request. One prominent case was Glyphosate; however it was decided in court that only data related to realistic conditions and on the actual use must be disclosed, hypothetical scenarios (e.g. high dose rate studies) do not fall within Regulation 1367/2006.

Bernd Brielbeck of SCC gave a presentation on Low-risk substances. Apart from detailing the new low-risk criteria, which are stipulated in Regulation 2017/1432 of August 2017, he emphasised that the Commission is now putting a focus on the approval of Low-risk substances. SANCO 2016/10616-rev 7, which details the AIR 4 procedure, is grouping the Active Substances called up for renewal also according to their expected low-risk profile. In AIR 4 group 1, 25 of the 51 Active Substances are presumed to be low-risk and group 2 only consists of 38 presumed Low-risk substances. He also observed that the freedom to evaluate on scientific basis is coming back to the regulators with these Active Substances,

which are seen positively from the very beginning of the evaluation. Of course, it is not only naturally occurring Active Substances, which are eligible to be Low-risk substances, but also Chemical or other Active Substances.

Johan Axelman from the Swedish Chemicals Agency (KEMI) proposed improvements to streamline the authorisation process in the future. A holistic approach, which is faster, cheaper and more predictable by an improved dialog between Authorities and applicants is his key idea. Risk managers should be able to feedback to risk assessors, whether latter's management proposals are feasible. Further, a data base on risk levels for easier comparison of different products could help to increase trust in the process.

The first day was closed with a discussion panel on Regulation 1107/2009, where Christian Prohaska from AGES, Johan Axelman from KEMI and Donal Griffin from CRD debated on current issues and further developments. As time lines for evaluation are increasing steadily, the system loses credibility. One of the reasons is the re-evaluation of old studies in accordance to new guidelines. Furthermore, some Authorities do not accept the evaluation of other Authorities. It was agreed that a formal way of evaluation would be desirable. It was also shortly discussed, if a data call-in system for better predictability of data requirements would be feasible, but it cannot be envisioned in the near future. It was also clarified that EFSA could be involved in pre-submission meetings, if the RMS is not sure how to address certain issues. However, this happens between the RMS and EFSA directly, without participation of the applicant.

The second day of the conference was opened by a presentation from Tamara Coja, AGES, on the experiences AGES had with the renewal of Active Substances. It was briefly recapitulated what changed in AIR 3 in comparison to renewals made before. As a survival kit for renewal, the communication (in pre- and post-submission meetings) with the RMS, as well as a full dossier at submission and the availability of the old dossier, was indicated. In case of difficult issues, EFSA (communication via RMS) and the co-RMS should be included in the decision making process before submission of the dRAR to EFSA takes place. In the future, commenting of dRARs for MS could be limited to essential parts to reduce the work load of MS and speed up the evaluation process in general.

Donal Griffin of CRD then followed with an outlook on the potential implications of the Active Substance renewal program. With an algorithm, CRD is currently predicting the possible outcome of the renewal program and, according to his calculations, 20 % of substances will be lost in the current renewal due to e.g. unfavourable classification, ED properties or other safety related issues.

Even for Active Substances with none of the concerns listed before, a 20 % chance of non-reapproval is assumed! Therefore, special attention is paid by CRD to preserve a broad basis of mode of actions, avoiding resistance, in addition to the safety evaluation the renewal process is focusing on. UK has classified 35 a.s. as likely to be lost, but with high importance to food production and is addressing this issue by commenting these a.s. with priority and working with the applicants to ensure the Active Substances are thoroughly supported. However, as the evaluation of the renewal is purely scientific and the algorithm for importance of a.s. of CRD will not apply for other MS, an EU approach remains to be established.

A brief review of the Annex I renewal process was presented by Jane West of Syngenta. She observed that 95% of the AIR 2 substances have the stipulation that Member States should pay special attention to some particular issue. For more than 50% of the approved AIR 3 Active Substances confirmatory data were requested. In the AIR 2 programme cut-off issues were not relevant or not primarily the reason for non-renewal, an unfavourable conclusion was mainly reached based on a proper risk assessment. In the case of the AIR 3 substance Linuron, which falls under the cut-off criteria, there is a debate on MRLs and import tolerances ongoing. In general, she observed that the RMS tends to recommend the renewal, but EFSA in its conclusion identifies critical areas of concern. Syngenta usually starts 6 to 7 years before the expiry date of the Active Substance to consider on how to proceed. She acknowledges that the delay due to Commission is certainly a big problem especially as in the meantime Guidance Documents might change. She calls upon the Authorities to name the RMS early in order for the applicant to start discussions. In particular AIR 5 decisions would be needed now. She observed that in many cases Guidance Documents are applied retrospectively (e.g. endocrine disrupting issues) and calls upon the Authorities not to continue with this practice. In general, the current renewal process is extremely difficult and unpredictable. The ongoing REFIT should consider this and maybe include the idea of a data call-in.

The next presentation was given by Lindy Meschendorp of Ctgb, reflecting on the current status and recommendations for Article 43 in the Netherlands. Article 43 will lead to a high work load for Authorities and is hardly projectable due to delays in the active substance renewal. The time lines for Article 43 evaluation are not considered feasible by Ctgb, instead 2.5 years can be expected. It was pointed out that Article 43 excludes major formulation and GAP changes (except where EU endpoints demand the latter). For a smooth handling of Article 43, endpoints of the active substance renewal should be used, and problems discussed with the zRMS. In addition, category 4 studies are assessed case by case

by Ctgb and the applicant should discuss with the RMS and zRMS to come to a mutual understanding. The use of QSAR to support regulatory decisions in Plant Protection Products under Regulation 1107/2009 in context with other regulatory frameworks was presented by Antje Gerlof-Elias of Dr. Knoell Consult GmbH. She reported that the use of QSAR is increasing to support weight of evidence arguments and avoid animal testing and is used in various legislative frameworks. For metabolites QSAR can be challenging, but automated pre-screening of chemical families can speed up the process.

Mia Gao of REACH24H spoke about the new Chinese pesticide regulation system and new compliance strategies. Mid 2017 the regulation on pesticide administration came into force and regulates the approval of Plant Protection Products and Biocides in China. The Ministry of Agriculture is involved, among others, in the registration process. A registration can be gained for 5 years either as an experimental permit or as full registration. Application and evaluation takes 2-3 years and a legal person in China is needed to be eligible for application. An important change to the previous regulation is that GLP studies are no longer acceptable. Studies must be conducted in China or by laboratories accredited by the Chinese Authorities. A list of accredited laboratories will be published by the Authorities.

As always in an entertaining and lively presentation Christian Prohaska of the Austrian Authorities turned his attention to comparative assessment and candidate for substitution, giving experience of his Member State. The legal requirements and Guidance Documents for this issue are laid down in Article 50 of Regulation 1107/2009 and Guidance Document SANCO11507/2013 rev.12. The comparative assessment is only mandatory, when the Plant Protection Product contains a candidate for substitution. For new products or new uses the comparative assessment must be made five years after the first authorisation at the latest. The speaker then defined "new" as a product containing a candidate for substitution plus an additional Active Substance or different ratios of the candidate for substitution. In case of use extensions, only the new use is assessed with respect to the comparative assessment. Were a product has no alternatives in minor uses, also the major uses will remain without comparative assessment.

The speaker then described the tiered comparative assessment. Step 2 stipulates that the product, containing a candidate for substitution, is to be compared with chemical and nonchemical alternatives, for the resistance situation, for economic effects and the impact on minor uses. Austria has so far received 48 applications were a comparative assessment had to be done. Only 14 of those proceeded into Step 2 and all of those assessments were stopped there.

Austria so far has not substituted products. Nevertheless, the applicant must address all 4 Steps of the comparative assessment in his application. For the discussion of the availability of nonchemical uses he referred to a DEFRA study. Austria stipulates that, if only 4 modes of action or less are available, substitution will not be made. He identified one of the future challenges as what to do if an Active Substance is identified as a candidate for substitution and this hazard identification is later revised by the Authorities, but substitution has already occurred. He concluded that in this case a new application for the product must be filed.

The talk on Member State experience with the Zonal Authorisation System in the Southern Zone by Panos Theodoris from the Directorate of Plant Product Protection in Greece was replaced by a round table, where the experiences of industry with the Southern Zone registration process were discussed. Evaluations from Authorities often being a black box and delays and unwillingness of Member States accepting evaluation are main concerns.

The Nordic Zone is of particular interest to Anna Olevik from Nordisk Alkali AB. In that zone 4% of the agricultural land of the EU is located. Norway has implemented last year Regulation 1107/2009 and can now act as Rapporteur Member State as well as zonal Rapporteur Member State for evaluations. Also Iceland is part of the Northern Zone. The main crop grown in the zone is cereals. The Northern Zone has an ongoing dialogue with a once yearly meeting between Authorities and Industry. The speaker observed that the Northern Zone is taking a different approach for Article 43 re-authorisation. She referred to the available Northern zone guidance document on this issue. They accept the harmonisation of the GAP, although without any new uses. They also accept additional Member States. The remaining hurdles for the Northern Zone are the timelines still being challenging, and whether the harmonisation within the Northern Zone is leading away from the rest of the EU. The main problem she observed is that it is a small market especially for minor crops.

On behalf of the ECPA efficacy expert group, Beth Hall focused her talk on the efficacy experiences in the zonal authorisation system. As with all industry representatives she emphasised that a predictable system is most important. Predictability extends to timelines, requirements and evaluation criteria. If there is a change in a Guidance Document she proposes to observe a transitional period before its application. For the Southern Zone she confirmed that they mostly adhere to their Guidance Document with respect to Article 43.

Also some adjustments of the GAP are acceptable, such as harmonisation of the GAP, if the new value had already been included in the original GAP range, or the reduction of the number of applications. Also the BBCH range can be decreased. Expression or change of water volume is a case-by-case decision. But in all these cases above the Southern Member States usually do not request new data. Also the Central Zone has its own Guidance Document on Article 43.

But in this zone any minor GAP change is a case-by-case decision and the applicant must extensively justify it. The ECPA has not yet initiated a dialogue with the Northern Zone. She announced that the EPPO plans a workshop on comparative assessment within the next 12 months.

The Irish citizen Mike Carroll of Arysta LifeScience UK (having lived a lifetime in the UK), observed in his talk a debasing of the regulatory currency, which are scientific studies. He emphasised that we are technical bureaucrats and not scientists and that the re-registration process is all about safety. This process is informed by science, but ends eventually in a purely political decision. His observation is that restoring confidence in the regulatory system is paramount! As before he observed the NGO trap: The precautionary principle feeds scientism, by posing endless regulatory uncertainties, resulting in ever more complex and expensive studies from industry; which in turn enhances scientism feeding the precautionary principle by volunteering to answer any regulatory uncertainty with scientific studies which results in an endless list of regulatory uncertainties. The result is an overwhelming and very expensive uncertainty due to lack of scientific consensus - which cannot be overcome by science. With respect to debasing the currency he presented a slide showing the Deutsch Mark as opposed to the East German Mark. He observed that in that case the highly valuable West German Mark replaced the less valued East German Mark. His fears are that in the realm of regulatory affairs the opposite might happen. He highly values the GLP system, because those studies are fully validated and giving traceable results. He objects to the reliance on open scientific literature, because academic science is not equivalent to GLP standards and is putting the regulatory process at risk. It makes regulatory decision making virtually impossible resulting in chaos. The only kind of remedy he can foresee for academic science would be a similar externally validated system as under GLP. Nevertheless, he observes that politics can always overwrite sciences, as can be seen in the recent discussions on Glyphosate, endocrine disrupting properties and genetically modified crops.

“Biopesticides Stream”

In the “Biopesticides” stream, David Esdaile from Citox-lab gave a talk concerning the issues to address data requirements for Biopesticides through testing.

For many Biopesticides, the currently available test systems are not suitable, and for many tests only US EPA guidelines, but no EU-guidelines, exist. However, many data requirements can often be addressed via literature and no special testing might be needed. Should testing be required, particular attention must be paid to stability, homogeneity and concentration of the Biopesticide to ensure a valid setup of the test.

Jeroen Meeussen gave a clear overview about the feedback from the OECD expert group on Biopesticides in his presentation. He also summarises the establishment of the minor use coordination facility (MUCF) and the importance of minor uses.

Further information on the MUCF can be also found in our last newsletter, where Jeroen Meeussen wrote a guest contribution.

The next talk from the “Biopesticides” stream was held by Rüdiger Hausschild of GAB Consulting GmbH, focusing on the regulatory experiences with Biopesticides worldwide. The different groups of “Biopesticides” (botanicals, semiochemicals and microorganisms) were briefly presented. For microorganisms he pointed out that many metabolites found *in vitro* do not have an influence on the metabolite profile found e.g. in soil and that requests from Authorities regarding these *in vitro* metabolites are often disproportionate to the risk they may pose. Also, the practise of Authorities transferring a general sentence on the possible sensitising properties of microorganism into a hazard statement (H317) – even if no indication on sensitisation for the microorganism is found in literature – was criticised, as this leads to unnecessary restrictions in resale (no home and garden use).

As the focus was on the Regulatory Stream, only some presentations of the Biopesticides Stream could be addressed here, but many more were held as interesting as the selection we could present.



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REGULATORY SCIENCE



AgChem Forum – Nice, 6 – 7 September 2017

Specific focus of the Environmental Safety track was given in particular to the current status of EFSA documents as the basis for the risk assessment of plant protection products. A wide range was covered to address Guidance Documents, draft documents and ongoing efforts to drive this process forward. These included risk assessment used for aquatic organisms, birds and mammals, pollinators, amphibians and reptiles, soil organisms and non-target arthropods, as well as non-target terrestrial plants. Each of these sections are summarized below.

Aquatic Risk Assessment

The EFSA Aquatic Risk Assessment Guidance Document follows a tiered approach and has been seen as one of the more successful guidance documents in this field so far. Nevertheless, it continues to develop and improve to include latest findings and tools. This was presented by Veronique Poulson (ANSES).

Over time it is seen that statistics used in aquatic risk assessment is increasingly questioned, as well as the representativeness of the use of GAPS or expression of – especially chronic – endpoints.

Currently, a revision of algae endpoints is underway. The concern raised was that focusing on growth rate alone instead of also considering biomass, risk assessment would not be protective enough. Further discussion may be expected to be seen on the use of long-term endpoints. In many cases, endpoint was expressed in EC10, yet in other cases it was expressed as NOEC or NOAEC. This topic was a point of discussion on several occasions during the conference, which still did not come to a resolution.

On the front of higher tier assessments, it was recommended to test concentrations to cover all relevant focus scenarios that required refinement. Therefore it was highly recommended to present FOCUS profiles in dossiers. When considering macrophyte sampling in mesocosms, inclusion of intermediate endpoint samplings were suggested. Overall, it was seen that MDD analysis has been requested more often, also including re-submitted studies. An alternative to mesocosms are modeling options, such as GUTS and TK/TD models.

At present, there is no model that is currently agreed on in Europe.

It was suggested that there is a need for greater harmonization between member states and EFSA, which might be achieved by an improved Aquatic Guidance Document.

Birds & Mammals Risk Assessment

In 2009, the first Birds and Mammals Guidance Document (GD) for EFSA was made available, which was then implemented in 2010. As was presented by Juan Pascual (BASF), a revision was to be expected by end of July 2017 as an updated Draft Guidance Document, with the final revision and a corresponding calculator tool to be expected by end of July 2019.

As the current GD stands, Juan Pascual informed that there is good correlation between acute no-risk PPPs compared to the real world. However, chronic risk assessment had never been validated and a high proportion of PPPs fail Tier 1 and trigger refinement. Added difficulty is given in a high variation between regulators in accepting specific refinement options as well as interpretation of refinement options by risk assessors. It is seen that regulators often take a conservative approach by using lab studies and default values obtained from the Guidance Document instead of actual field data. Also, for chronic endpoints, a conservative approach is often taken by using toxicity endpoints from human toxicity in mammals to transfer these to wild animals. With such an approach, refinements are typically needed for 10 to 25% of acute studies and 50 to 75% of chronic studies, considering active substances. A publication by A. Brooks *et al.*, 2017 (published in Environmental Toxicology and Chemistry) demonstrated this point.

The goal of the revised Birds and Mammals Guidance Document will be to define Specific Protection Goals. It is not expected that the updated risk assessment methods are significantly changed. This should include clarification of methods and harmonization of higher Tier risk assessment within the EU zones.

At present, Data collection is ongoing, for which a Consortium was formed by Alterra, AGES and ANSES. The Consortium (EFSA tender) is working with the industry to gather data on ecology (focal species, proportion time and diet), residue levels (initial RUD), and residue decline (DT_{50}).

Risk Assessment for Bees

Information on the status of the Draft Bee Guidance Document was given in a presentation by Axel Dinter (DuPont) as well as during Question & Answer Sessions with Franz Streissl and Dimitra Kardassi (EFSA).

In 2015, EFSA stated to apply the Draft Bee Guidance Document. Due to the lack of a final GD, Belgium had introduced its own in 2017.

In spite of the efforts put forward by EFSA, at present there does not seem a specific date when a decision is made for the implementation of the final EFSA document. Overall, there are still too many gaps and points that require addressing to bring in line appropriate risk assessment and agricultural needs. Although EFSA takes the stand that Guidance Documents which are not implemented cannot be used in risk assessment, it is still seen differently for bees, as the Specific Protection Goals can only be covered by this draft document (Dimitra Kardussi).

At the same time, one of the representatives of a member state pointed out, that they would not require adherence to the Draft GD, as it had not yet been implemented. This discrepancy in opinions marks the current difficulty for applicants.

It can be expected that additional residue data on pollen and nectar may be made available still in 2017.

Amphibians & Reptiles Risk Assessment

Based on the EU Data Requirements provided by EC Regulations 283/2013 and 284/2013, risk assessment for amphibians and reptiles are required. In spite of this, no Guidance Documents are available for these groups of species. This issue was addressed specifically by presenters Franz Streissl (EFSA) and Peter Dohmen (BASF). To cover this gap, an EFSA Panel on PPR (Plant Protection Products and their Residues) is planning on publishing a Scientific Opinion by December 2017. It is expected that a Draft Guidance Document could be available two years after reaching an agreement on Specific Protection Goals.

Due to their differing physiology and life-stages, neither amphibians nor reptiles can be compared to birds and mammals in risk assessment. With the lack of test guidelines (with two exceptions for amphibians) and previous guidance, a broader scope is taken at first, though, to include considerations of birds and mammals, but also aquatic risk assessment. As for focusing on one group over another, i.e. reptiles versus amphibians, there are differing opinions. While Franz Streissl (EFSA) mentioned an indication that PPPs may contribute to decline of both groups (and faster than seen for birds and mammals), Peter Dohmen (BASF) presented that typically there is no effect seen on reptiles and therefore to keep the initial focus on amphibians.

Special considerations for amphibians must be given to their typically migratory nature that includes aquatic as well as terrestrial life stages and metamorphosis. Also, the function of their skin, important for gas and water exchange and contributing to their immune system,

pose added unique characteristics, in addition to hormones being able to override genetics during sex differentiation of gonads. As Peter Dohmen pointed out, the existing Aquatic Guidance Document could provide some information for risk assessment of amphibians, however focusing on aquatic life stages only. When selecting test types especially for amphibians, though, dermal (contact) exposure may be of greater relevance compared to oral exposure. Also, FOCUS scenarios may have to be reconsidered, as the current FOCUS pond scenario may not be protective enough. This was demonstrated by Franz Streissl, who reported that 70 – 90% of ponds used by amphibians are smaller than the FOCUS water bodies, in addition to amphibians occurring also in flow-through water bodies, which may not be covered by FOCUS as well.

Difficulty for developing risk assessment for reptiles lies within the extreme diversity in this group, as Franz Streissl presented, where some are closer to birds than they are to other reptiles. Specific considerations need to be given to their specialty of skin, which rather absorb lipophilic substances (vs. hydrophilic in amphibians) and varying behavior, such as large meal sizes in snakes, or temperature dependence in sex determination in tortoises.

For neither group of animals, mesocosms are recommended, but rather investigation of toxicity on a field and landscape scale.

Risk assessment for soil organisms and non-target arthropods

Presented by Mike Coulson (Exponent), a steering committee was introduced that had been formed to aid in the development of a non-target arthropod Guidance Document. Leading up to the Guidance Document, a Scientific Opinion of 2015, considering the preceding ESCORT workshops, was released. In 2017 an additional Scientific Opinion was released on risk assessment for in-soil organisms.

A SETAC Non-target Arthropod and Soil Organisms Steering Committee has been initiated, combining a total of 9 members of academia, business and government. Currently, previous work is being collected to be brought together and discussed at a NTA/Soil workshop in 2018. The results of the workshop are expected to be available in 2020.

Risk assessment for non-target terrestrial plants

Formulation of Specific Protection Goals are expected for 2019, with a Draft Guidance Document to be available earliest in 2020.

As Joanna Davies (Syngenta) presented, the current Scientific Opinion (2014), would pose some major difficulties not only for risk assessors, but also for agronomist and farmers. The main concern is given with a re-

definition of the term “non-target plants” in an in-field scenario. In this case, the new definition would require the protection of non-crop plants that grow in-crop, i.e. protect also weeds.

In terms of off-field risk assessment, data on crop species is used to predict effects on wild species. In the 2014 Scientific Opinion, an extrapolation factor is used to bridge from vegetative vigor effects in crop species to reproduction effects in wild species. As a result, only 25% of herbicidal products would pass under strict mitigation scenarios (increase in buffer zones and drift reducing nozzles). With such an approach, especially smaller fields could lose up to and over 50% of their area which can no longer be used for food production. Further changes would increase the amount of standard endpoints by adding 5 non-crop species to the 6 to 10 standard crop species.

To address the NTTP risk assessment prior to the Draft Guidance Document, a SETAC Global Plant Interest Group was formed to combine efforts from academia, regulators and government as well as CROs to address these issues. The working group is open to all interested scientists.



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CALENDAR



SECP Conference: The Development and Regulation of Crop Protection Technologies in Southern Europe 2017 in Barcelona, Spain

We are delighted to announce that SCC will be a sponsor of the conference on Development and Regulation of Crop Protection Technologies in Southern Europe, taking place in Barcelona on **30 November - 1 December 2017**.

Dr Marta Álvarez Chamorro, Manager Regulatory Affairs, Agrochemicals and Biopesticides, will join the conference. Please use this chance to talk to Marta about your regulatory needs regarding plant protection products.

The event in Barcelona brings together professionals concerned with the health and protection of crops in Southern Europe. In particular, the programme will focus on the regulation of chemical, biological and agronomic technologies

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

Meet SCC at the Biocides Europe Conference 2017

Dr Silvia Wagner, Senior Manager Regulatory Affairs Biocides, will speak on “**Human Health Risk Assessment for in-situ products using peracetic acid generated from TAED and sodium percarbonate as an example**”.

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

Biostimulants Europe Valencia, Spain, 17 - 18 January 2018

Anke König-Wingenfeld, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides, will join the conference. Please use this chance to talk to Anke about your regulatory needs regarding plant protection products.

The second Biostimulants Europe Conference is an occasion to discuss during two days the challenges and future opportunities in the field of biostimulants. For further information on this event, please refer to: <http://www.rsc.org/events/detail/28079/biostimulants-europe>

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