

NEWSLETTER

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CHEMICAL INDUSTRIES REGULATIONS - CIR 2016 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.

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Dr. Friedbert Pistel

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AGROCHEMICALS

**AgChem Forum, Nice
7 - 8 September 2016**

This year's AgChem forum was held in Nice in the south of France. The "Registration of Agrochemicals" Stream, of which summaries of some of the presentations are given here, covered a broad range of issues. It started off with panel discussions on politics, science, risk and the agricultural industry. Luc Peeters of COPA-COGECA, clearly stated that farmers expect reliable crop protection solutions. This would not necessarily involve more spending, but better spending and focusing of resources. He thinks that the EU has completely overregulated the agrochemical regulatory system and laments that it takes 12 years for products to reach the market. Also, he observed that the trust in science has been decreasing in public opinion and also by decision makers. He also criticized the decision making of Authorities. If there is controversy arising in an evaluation, the way, Peeters observed, is not to take a decision, but to postpone it. He forecasts that in five years' time, European agriculture will be dominated by precision farming and the markets will be split into high-tech, soil and sunless "city farming" versus the eco- and bio-food production. An interesting thought of his is, that we need to develop the agrow business with, what he called, toys such as drones and GPS etc., to keep young people interested in farming.

Keith Pitts of Marrone Bio Innovations, then reported on the difficulties he encountered in the registration of giant knotweed extracts in the EU. While the US EPA accepted a general specification of this extract, the EU asked for marker compounds, which subsequently were reinterpreted to become toxic endpoints and EFSA asking genotox and mammalian tox studies for these marker compounds. It took more than five years to bring this active substance into Annex I.

The next speaker, Roger N. Beachy of Indigo Agriculture, Inc., then emphasised the necessity to pay attention to the whole picture, when assessing plant protection. The various soil organisms built a tightly knit system, which in its entirety allows plants to thrive.

Finally, Massimo Toni of Agronutrition, talked on biostimulants and the new Fertiliser Regulation, indicating that the biostimulant business had a turnover of 578 million Euros last year. He also reported that in the next draft of the upcoming Fertiliser Regulation provisions for data protection will be included.

The representative from EFSA, Dimitra Kardassi, was reporting on the progress and the work of EFSA. One point is the work on negligible exposure assessment. Although there is a draft Guidance of November 2015 available, the Commission wants EFSA to apply the draft version of May 2015 (SANCO/2014/12096). Among many other issues, EFSA is currently trying to establish an electronic submission system for all regulated products. New Guidance documents on birds and mammals, a focus repair action and a Guidance document on isomers are currently under development.

Jean-Pierre Busnardo of DuPont Crop Protection, analysed Regulation (EC) 1107/2009 and its implementation five years after its entry into force. He drew our attention to the recitals of the Regulation, which state the intention of the policy makers, i.e. to protect humans, animals and the environment, harmonisation of rules and criteria and to promote, among others, low risk active substances and Plant Protection Products. He analysed the objectives and visions and drew up a list of positives and negatives, as well as lists of welcome objectives and provisions and unwelcome provisions. Although his list of unwelcome provision is shorter, the issues he raised there, such as hazard based cut-off criteria including endocrine disrupting properties, are much more significant. He observed that there is a lot of talk on safety and very little on agriculture in the discussion of implementation of Regulation (EC) 1107/2009. As the biggest problem of Regulation (EC) 1107/2009 and its interpretation, he identified an unsustainable level of scientific conservatism driven by EFSA. This is currently the main impediment to crop protection in the EU. He emphasised, unrelated to the Regulation, it is his impression that the targeted products seem to be chosen randomly. This makes the EU regulatory system costly and partly unpredictable. As a conclusion he conceded that the EU is an important region for global food supply and crop protection, but the regulatory system is highly protective, excessively complex and somewhat inefficient. One possible solution: re-writing Regulation (EC) 1107/2009 might be required for optimisation but... only when the conditions are right.

Stefano Turati of Dow AgroSciences, analysed the registration of new active substances under Regulation (EC) 1107/2009. He observed that companies investing into plant protection are earning their money by selling Plant Protection Products and thus an effective system to approve active substances has to be complimented by an effective system to authorise the products. He called

on Authorities to recognise that it is most important for industry to have reliable timelines for the whole process. As selling products is also directly linked to the availability of MRLs, it is in his view necessary to more closely align the two systems that lead to registration of products and establishment of MRLs. To make the best of the existing system, he emphasised that very close and continued contact with all participants is of utmost importance. Such contact is very good during the first part of the active substance approval, i.e. with the RMS. Contact to EFSA during peer-review or Commission after EFSA's conclusion is virtually impossible.

A similar lack of alignment between two interdependent processes was observed by Phil Todd, Global Distribution Safety and Hazard Communication Manager, Syngenta, classification and labelling, which is carried out by ECHA, and the registration of agrochemicals involving EFSA. This alignment is becoming more important, as the cut-off criteria and endocrine disrupting properties are directly linked to classification and labelling issues. It is his observation that only a legislative change can actually resolve the current issues in this area.

With a more scientific aspect, the assessment of the new EFSA model, Wolfgang Pfau, Head of Toxicology, GAB Consulting, gave the next presentation. He suggested that in cases where the EFSA model is not leading to a meaningful result, the old models or at least part of the old model data can be used. Not all Authorities will accept such a procedure, however.

Pavel Minar of the Czech State Phytosanitary Administration, was giving feedback on the zonal authorisation process. In his introductory statement he also observed that Regulation (EC) 1107/2009 has clearly reached the aim of giving higher safety, but all other issues raised have been forgotten. There are different Co-operations currently ongoing in the Central Zone, including a director's consultation group, which are trying to address harmonisation blockers. He sees as positive development the establishment of the dRR format, the availability of more Guidelines, the commenting period, the increased experts communication and, finally, the harmonisation of GAPs and formulations across the zone. The Czech Republic observed a decrease in applications for new Plant Protection Products of 20 % between 2012 and 2015. In the same time the applications for mutual recognition have risen 50%. The mutual recognitions speed up the process significantly and in the case of the Czech Republic, no such application has been refused yet. In their strive for procedural simplification, the Czech Republic will switch their administrative applications to notifications in the future. He called upon the EU to revise the data requirements and the Guideline EPPO PP1/226(2) to clearly state what is needed for a successful efficacy evaluation. According to him the procedure has already been initiated, but the timing of

the revision is unclear. He also sees the need for amending Regulation (EC) 1107/2009, but clearly states that he sees this as a dream only and no such procedures are envisioned currently. In particular, the following issues need to be revised: Article 43 procedures, e.g. by providing active substances approvals for an unlimited time period and include revision programmes, he sees Article 36 (1) as critical because in its correct form it might lead to the application of different Guidance documents to authorisations of Plant Protection Products over the time of approval of an active substance, lastly, he called for a better and clearer formulation of the mutual recognition procedures in the EU.

As always in his presentation, Mike Carroll, Global Regulatory Manager, Arysta LifeSciences UK, finds the right pictures for the processes he describes. The implementation of Regulation (EC) 1107/2009 reminds him of the building of the Tower of "Babel"; he informs us, means "confusion" in English! He observed that perception is reality and that instead of managing risks, the risk managers and evaluators are more and more managing uncertainties. He addresses the scientism of industry and the lack of believe in science by the public and the administrators, which is exploited by the NGOs. A correlation he calls 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. He sees regulators as the referees in the game and, if the respect for the referee, i.e. regulator, breaks down, confusion and anarchy is let lose. He closed his presentation with a quote by Shimon Peres: "If a problem has no solution, it may not be a problem, but a fact - not to be solved, but to be coped with over time".

On the second day of the proceedings Dr. Andy Adams of Bayer, speaking on behalf of the European Crop Protection Association, took a closer look at the Commission proposal for scientific criteria for endocrine disrupters. He emphasised the importance of this work, as the identification of an endocrine disrupter is equivalent to the non-approval of the active substance in the same way as the cut-off criteria are. The current draft Commission proposal includes the derogation for negligible risk to human health and the environment, which, unlike its predecessor, negligible exposure, is more scientific and consistent with the Biocides and REACH legislation. With the concept of negligible risk it is also possible to set MRLs at a level above the default, which is in accordance with WTO requirements. He observed that EFSA is still using the interim criteria; which are included in the

screening study as option 1. Under this option 1, the screening study identified 42 active substances as potential endocrine disruptors! The concept now favoured by the Commission, option 2 and option 3 category 1, only identifies 26 endocrine disruptors from the same pool of active substances. And option 4, which includes the potency assessment, i.e. a risk assessment, identifies only 11. He concludes that EFSA identifies many false positives. Quoting from the impact assessment, he concluded that options 2, 3 and 4 offer the same level of protection for human health and the environment, asking, why option 2 plus option 3 category 1 has been selected by the Commission, which is disproportionate. His observation is that this procedure will open the session for more blacklists.

Illustrating his observations by examples, he chose Iodine. It is included on the endocrine disrupting list of option 2, while at the same time, it is in the low risk assessment stream of the Biocides evaluation. If potency would be included in the ED assessment, as is done for option 4, this contradictory evaluation will be avoided. As a second example he quoted KEMI's proposal on Cholecalciferol (Vitamin D3), that there is no risk to human health identified and that the combined exposures from rodenticide use, supplements and food is expected to be well within the tolerable daily upper intake level. Nevertheless, the substance under the Commission proposal is clearly identified as endocrine disrupting substance with all the subsequent regulatory consequences. According to the Commission provisions, this substance should be banned.

Dr. Tamara Coja of the Austrian Agency for Health and Food Safety (AGES), spoke about the experiences of her Agency as an AIR3 coordinator. She identified some legal facts that the Member States were aware of before starting on the AIR3 programme. Other facts were unexpected and surprising:

- Re-opening of studies from the DAR for sections other than fate and behaviour to align with current scientific and technical knowledge
- Partially complete re-evaluation ending in an "new" substance during the peer review
- Questioning of validity of old studies and comparison of old and new OECD Guidelines
- Data gathering of analytical methods and the discrepancy between data requirements of EFSA and PAI
- Acceptance or non-acceptance of legally allowed waivers where no OECD Guidance Document is available
- The use of draft Guidance Documents to conduct risk assessments

One of the main challenges was the unpredictability of approaches and requirements and the frequent changes in everything that could change during the 1.5 years of the evaluation together with the very short time period

given to address any unexpected issue. For the comparative in vitro metabolism study in pivotal species, she observed for example, that officially this study can be waived, but practically such waivers led to data GAPS. The most important point she found during her assessments is the need for direct communication and permanent dialogue between the RMS' and the Notifier's experts. The Notifier, she recommended should insist on communication. Finally, she urged Notifiers to submit joint dossiers, because "rubbish" that a possible competitor submits, is also directly affecting the evaluation process of any other entity involved.

The Member State requirements for product authorisations were presented by Christian Prohaska, also of AGES. He explained that the zonal Rapporteur allocation for AIR2 active substance containing products was product based, while for AIR3 active substance containing products the allocation will be active based. He conceded, that not all Member States agree to this approach, examples being Slovenia, Germany and Poland. If possible, the zonal Rapporteur should be the RMS/co-RMS of the active substance re-approval to avoid different conclusions for comparable products and to extent the risk envelope approach as much as possible. The data matching check is to be performed by the RMS, not by the zRMS, and should be valid for all zones. The exception being Germany, which will perform data matching only if products containing that active are registered in nationally. The data matching check is reminiscent of the former "step one" procedure and an appropriate template will be included into the amended Guidance Document. For non-notifying companies there is consent within the Central Zone that no new applications (Article 33), should be accepted until the 2.5 year period of data protection has elapsed, as otherwise the company would still be relying unprotected data. Studies that need to be conducted to comply with new endpoints, new data requirements or new Guidance Documents and the time is too short to conduct such studies (Cat. 4 studies) the Member State may grant an extension of the concerned authorisation up to 2 years (and even longer if more time is needed to contact the study/follow-up studies). For combination products, containing two or more active substances, the dRR is to be provided when the second active substance has been renewed, if the renewal dates of both active substances are not farther apart than one year (the original expiry dates apply). The comparative assessment (if needed) is to be provided at the same time as the dRR. He emphasised that for each product at the time of each active substance re-approval an application must be filed! For products containing AIR2 substances, the old format of the dRR and the old product data requirements apply. For AIR3 substances new dRR format and new product data requirements are mandatory. For products containing both AIR2 and AIR3 active substances, the old format and old product requirements

apply, if only one assessment is needed. If two assessments are needed the old format and old data requirements apply for the first assessment and new format and new data requirements for the second assessment. To fulfil the necessities of mutual recognition, a full dRR is to be provided for a re-authorisation application and changes are to be highlighted. In the case of efficacy only resistance is needed, if no GAP change was made; with the exception of the Northern Zone, which needs a full efficacy package including a biological assessment dossier. To assess the combined toxicity in mixed products the second active's renewal should be awaited irrespective when the second re-approval is granted. There is no agreement on this subject within the Central Zone and different Member States have different approaches. The applicant is to provide a full combined toxicity assessment in the core dossier, even for cases where the second active is not renewed.

The speaker also addressed the uncertainty, whether UK will continue to act as zonal Rapporteur after the BREXIT. But nothing is concluded on this subject, as was clear from various discussions, until the "divorce" procedures are well underway and the status of the UK can be foreseen.

As the previous speaker, Claudio Mereu of Fieldfisher (Belgium) LLP also emphasised that applications must be made for every product containing a renewed active substance. The application must be made to all Member States in which the product is being supported, i.e. the zonal Rapporteur Member State and all concerned Member States. Products not supported at the three month deadline will expire one year after the expiry of the previous approval of the active substance. A subsequent 18 month grace period will normally apply. In the "Questions and Answers" document, published by the Commission on 8 March 2016, clarification is given on the data matching and equivalence check, the application processes by the authorisation holder and the assessment by the Member States. The request for matching data can be fulfilled by providing argumentation from published literature, through a letter of access or by repeating the study (possibly as category 4 study). The speaker observed that category 4 data may be identified during the data matching step, if the specifications of the reference source were modified during renewal. If such category 4 data are identified, no dRR will be submitted and no product evaluation will be done on these points until such data is available.

Whether an equivalence check of the active substance is necessary or not lies within the responsibility of the authorisation holder. The speaker proposes a stepwise approach, first to determine whether the existing agreed technical specifications complies with the renewal requirements, in which case no further consideration is

required by the zonal Rapporteur Member State. If the specifications, however does not comply with the requirements set out in the specific renewal Regulation, such specification may not be used until the revised specification is agreed. The applicant also has to provide evidence that the product complies with the stipulations and restrictions in the relevant active substance approval Regulation. All applications should include a separate statement specifying the fact that the existing uses of the product complies with any restrictions set out in the relevant renewal Regulation. An important legal issue related to Article 43 evaluations is the pending authorisation applications under the previous criteria (still legally applicable) versus new renewal criteria (not yet legally binding). The speaker asks why the zonal Rapporteur Member States should apply new endpoints to pending applications since Article 36 clearly states that Member States must apply criteria applicable at the time of dossier submission, not evaluation. He concludes, that the zonal Rapporteur Member State should stick with strict legal requirements and apply the old criteria or the legal services of the European Commission must define a "phase in" process and timeframe for all pending applications.

Taking up the afternoon's subjects of low risk substances Maristella Rubiani of the Istituto Superiore Di Sanita of Italy, focused on the use of Plant Protection Products in restricted and sensitive areas by giving an update of the Sustainable Use Directive (2009/128/EC). Such areas include water abstraction sources, ground water vulnerable landscape features, areas used by the general public vulnerable groups and equivalent areas, where that Directive stipulates that users shall wherever possible use low risk or biological Plant Protection Products. She clearly stated that the use of Plant Protection Products helps to keep these public spaces safe, beautiful, and functional. One concern addressed in detail was the cumulative risk assessment. It takes into account all possible routes of exposure, e.g. use of cosmetics, insect repellents, flea collars for dogs, drugs, disinfectants, varnishes, wood preservatives and even individual habits such as smoking. In addition, exposure to lifestyle substances is taken into account which also includes, for example, Ethanol.

Different countries have implemented different procedures for the reduction of pesticides in such public areas. Denmark, Belgium, Switzerland, Poland, and France, have completely or to a large extent banned pesticide use. Germany and Italy have allowed only specific products to be used in such public areas. The speaker finally introduced the Italian green list of herbicides. This list contains, interestingly, many Glyphosate formulations, leading the speaker to elaborate on the possible future of Glyphosate registrations.

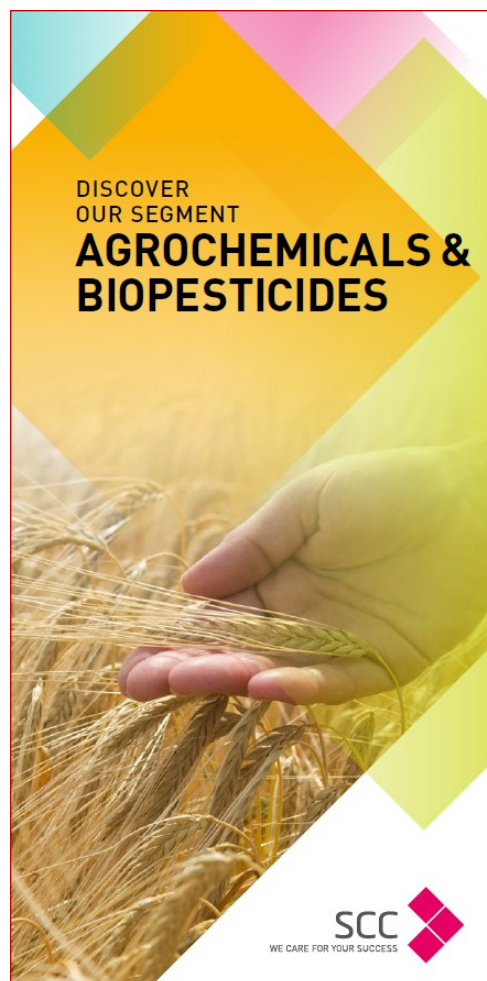
Dr. Bernd Brielbeck of Scientific Consulting GmbH (SCC GmbH) took up the initial comments of Luc Peeters from COPA-COGECA and Keith Pitts from Marrone Bio Innovations in his presentation on the regulatory aspects of low risk substances in Europe. He called upon the audience not only to focus on Regulation (EC) 1107/2009 when thinking about the development of low risk substances, but to also review other pieces of legislation, communications, reports or strategy studies of the European Union. Especially, in the common Agriculture Policy Documents the use of low risk substances is stipulated. Regulation (EU) 1306/2013 for example introduces a greening idea, Regulation (EU) 1307/2013, which sets out the framework of the common agricultural policy, introduces ecological focus areas for which currently the use of Plant Protection Products is highly debated. It might be that a common ground between not using any Plant Protection Products and not restricting the use of them, might be the approval of low risk substances, as has already been indicated in the previous presentation. He stated that the European Union is willing to spend a significant amount of money (€80 billion between 2014 and 2020) in its Horizon 2020 vision laid out in Regulation (EU) 1291/2013 to establish an alternative to classical Plant Protection Products. The European Parliament's initiative called on DG SANTE to establish clear criteria for defining low risk active substances by, for example, considering provisional approvals and prioritisation of their evaluation. At the same time the Parliament acknowledges that the farmer needs to have a big toolbox to counter resistance. The EP initiative explicitly asks for a faster approvals process, i.e. approval of active substances! Also details of SANTE/11953/2015, which is to revise the existing criteria for low risk substances, were given. Furthermore, an EPPO workshop on the efficacy requirements of Plant Protection Product based on low risk substances called for a reduction of the trials needed, as well as for a lower and more variable effectiveness to be acceptable for such products. Extrapolation should be possible across the EU over various EPPO Zones. Such a change of current policy would be an additional incentive allowing companies to actually save money when developing low risk active substances and products.

The practicability of the comparative assessment was questioned by Janet Williams from Bayer. She accumulated all different Guidance Documents that are available on comparative assessment: EU Guidance, ECPA Guidance, EPPO Guidance, as well as Member State Guidance Documents from Belgium, Czech Republic, Spain, France, Portugal, Slovenia, and the UK. Although, mandatory comparative assessment must be conducted as of the 1 August 2015, the Netherlands refuses to act accordingly. Also, she fears that the assessment has to be done multiple times in the case of mixed products. Further uncertainty arises, as the applicant is called upon to submit a comparative assessment himself,

which might be up to 2 years ahead of the actual Member States evaluation. This assessment is to include all products which are currently sold, which is an information not necessarily available to the applicant. Thus, the applicability of the comparative assessment, in the way it is currently envisioned, leads to a very difficult situation.



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BIOCIDES



The CIR 2016 took place in Nizza from 6th to 8th September 2016. Selected key presentations of the Biocides track are summarized in the following.

The keynote session was given by Valerio Spinosi (Biocides Assessment Unit at ECHA) on “ECHA’s role and involvement with the BPR: Experience to date”. Regarding the recent Article 93 and Article 94 deadline of 1st of September 2016, ECHA received in total 60 submissions. In 2016, so far, 41 substances were approved and 24 BPC opinions were published out of a total of 50 BPC opinions expected this year. For comparison, in 2015, 39 active substances were approved and 49 BPC opinions (out of the 50 expected) were published.

Regarding Union authorization, ECHA has received 14 applications this year so far (expected are 18). The applications are mainly biocidal product families and cover the product types of disinfectants, insecticides and preservatives. As reported in the Commission report “Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision” (Final report, 15 April 2016), in terms of number of applications, ECHA expects between 98 and 310 applications for Union authorization until the year 2020.

Furthermore, the speaker presented some, by industry highly anticipated, news about the IT systems of ECHA. A new version of R4BP3 and the SPC editor will be available in October 2016 (R4BP 3.8). This update will support the new Commission Implementing Regulation (EU) 2016/1802 of 11th October 2016 amending the same biocidal products regulation. The main advantage offered by the new legislation is that a national authorization can be granted by referring to a “master” Union authorization. In addition, it will be possible to define an individual member of a biocidal product family as a reference product. Similarly also for the simplified authorization: Notification of single products or a reduced family to another market will be possible when the reference product family has already a simplified authorization.

The SPC editor will support in its new version the biocidal product family concept including the meta level.

A presentation about a currently very popular and often discussed subject was given by Koen Van Maldegem (Partner at Fieldfisher) in his talk “Biocidal Product Families and Consortia”. According to Mr. Van Maldegem, the combination of three key concepts of the biocidal products regulation, namely biocidal product families, Union authorization and same biocidal products application, offer clear advantages in the context of consortia formation. Firstly, the family allows that products and companies can be grouped into one authorization. Secondly, if Union authorization is chosen, according to Mr. Van Maldegem, there is less administrative burden and the fees can be shared within the consortium. Thirdly, once the “master” authorization is obtained, the same biocidal products authorization allows the flexibility to have subsequent authorizations for the same or different companies. Nevertheless, he emphasized the importance to define a clear scope and duration of the consortium. Usually also a decision-making structure should be set up, including secretary, treasurer and data submitter. In addition, voting rights and clear and objective conditions for membership including rules for cost sharing should be defined. In any case, it is important to observe competition law compliance, ensuring that membership rules are sufficiently flexible and clear conditions for membership applications are provided. Also sharing of information concerning meta-SPCs and individual products with other members need to be handled with due care by the consortium manager and even competent authorities.

In her talk “Enforcement of Article 58 of biocides regulation, Treated Articles”, Margareta Daho (Swedish Chemicals Inspectorate) spoke about enforcement in the context of the CLEEN project 2014-2015 (Chemical Legislation European Enforcement Network). This project had the aim to make the distributors and producers aware of the obligations under the Biocidal Product Regulation and to develop harmonized enforcement tools. In the course of the project, inspections were performed in different European countries with the focus on the correct labeling according to Article 58. In case where non-compliance was identified, the companies involved received a “yellow card” in the form of an information leaflet (non-severe cases).

For some companies other actions were prescribed and few were obliged to remove the products from the market. In future, further aspects may be subject to inspection, as e.g. is the active substance allowed in the actual PT, analysis of the treated article and assessments of efficacy.



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REGULATORY SCIENCE



AgChem Forum September 2016 – ecotox section

Theo Brock was elaborating on the status quo and the potential of effect modeling approaches for risk assessment. By focusing on aquatic ERA, he presented current and future models for supporting both, the ecological threshold option (ETO) and the ecological recovery option (ERO). For the ETO, lower tier information, e.g. single species tests can be extrapolated to population-level effects and time-variable exposure regimes. On the example of TK/TD models the speaker revealed how the degree of validation of the models minds the confidence that authorities admit to the respective model. Brock summarized the acceptance of effect modeling by authorities as quite variable, from nearly total rejection to large interest. Nevertheless, Brock emphasized that authorities await a potential EFSA Guidance on the use of effect modeling before they will accept the effect modeling for regulatory risk assessment.

Gero Eck from Eurofins elaborated the approaches for mixture toxicity assessment for aquatic organisms. He compared the evaluation done by whole mixture (product data) or component based calculated mixture toxicity. He concluded that product data are of limited significance for field exposure but relevant to indicated potential synergisms. In contrast, the compound based risk assessment for concentration addition is more relevant for the field exposure and practically mostly used in regulatory decisions. In contrast to product data, the compound addition allows integration of higher tier data, the direct use of time resolved mixture toxicity assessment and FOCUS exposure profiles.

Thomas Preuss from Bayer Cropscience AG presented the pesticide model BEEHAVE that allows the extrapolation from standard biotest to protection goals on colony level. BEEHAVE can take all exposure routes and effect endpoints from standard regulatory studies as input. As specific protection goal (SPG), EFSA determined the reduction of colony size for honey bees. The developers of BEEHAVE defined the size of a colony as number of workers and use laboratory and semi field data for modeling effects on colony level and colony dynamics in a worst case scenario. The model validation is done by tunnel tests and field studies. Preuss illustrated that BEEHAVE consists of 3 models, the first to determine the external exposure of the bees, the second to simulate

the fate in the hive and the third to estimate the effects on survival and behavior of the bees. Preuss summarized the further steps as Bayer and Syngenta conducted validation studies parallel to the finalization of model documentation and testing and the planned free accessibility in Netlogo.

Ainsley Jones from Fera Science Ltd. reported on bee monitoring in England and Wales.

Mark Miles from Bayer summarized industries' concerns on bee monitoring as requested according to EC No.1107/2009, which are mainly the lack of reliable, robust, reproducible and practical test methods, especially for solitary bees and bumble bees. As well Miles summed up the critical points on the EFSA bee guidance document (EGD) (routes of exposure, trigger values linked to an unrealistic protection goal). Industries invitation to work on method development and data generation in a workshop was not accepted by Commission, MS and EFSA. However, industry supported the development and ring testing of several tests, e.g. testing on larvae OECD TG 237 (7day acute test) and OECD 239 (22day repeated dose testing) and adult chronic testing. An evaluation of 87 compounds according to EFSA EGD by industry showed that EFSA chronic risk assessment on bees is too conservative and higher tier options are missing. Mainly the EFSA default values are point of criticism due to the fact that the exposure during different stages of bee and the attractiveness of different crops is generalized.

AgChem Forum September 2016 – fate section

Mark Egsmose from EFSA gave an introduction to the new OECD guidance on field dissipation studies, which has been published in March 2016 following an elaborate development and approval process. The final version can be downloaded from OECD webpage. The efforts resulted in a harmonized guidance on how to conduct terrestrial field dissipation (TFD) studies with a basic module to robustly determine dissipation and degradation rates applicable for similar ecoregions in North-America and EU. Furthermore, a tool for the comparison of ecoregions and to assist with study site selection has been identified. Mr. Egsmose emphasized the fact that the harmonized approach includes the definition of a single application rate based on the annual or seasonal maximum as well as the commitment, that the study duration should be sufficient to determine Dist90 for both parent substance and relevant metabolites. The latter point is also considered important for rotational crop studies.

The new EFSA Guidance document for predicting environmental concentrations in soil was presented by Aaldrik Tiktak from PBL Netherlands. In contrast to the document published in 2015 referring only to "standard" annual field crops, the guidance now covers most cropping systems including planting on ridges and in rows as

well as permanent crops. As the cropping system may impact on soil properties (e.g. the amount and distribution of organic matter with depth) a total of 12 scenarios representing annual and permanent crops in three geographical regions and differentiated for total soil and pore water concentrations have been developed for the analytical model PERSAM. The new version of Guidance does also include leaching from the target layer and degradation between applications within a year. The tiered approach further includes PEARL and PELMO models. Finalization of the guidance is scheduled for end of 2017.

Gerhard Goerlitz (BCS) summarized refinement options for groundwater assessments. Refined parameters may be based on higher Tier studies, i.e. terrestrial field dissipation studies (EFSA guidance available), time dependent sorption studies (TDS, CRD draft guidance available, which is currently under review by EFSA) and studies on plant uptake (PUF, a proposed method was tested in a collaborative trial). Additionally, refined scenario approaches are available for France (frogs) and The Netherlands (GeoPEARL). In view of many options to design gw monitoring studies, a SETAC advisory group EMAG Pest/GW is developing guidance for monitoring approaches. For the studying of exposure in surface water, Goerlitz also emphasized the limitations of the evaluation of only one year in FOCUSsw. Multiyear runs for all spatial scenarios would overcome these limitations and may also be expected to influence the aquatic exposure patterns. A FOCUSsw "repair" could adequately address representativeness as well as a multiyear approach.

Dale Mason from Syngenta illustrated industries efforts regarding data on spray drift in order to improve representation, management and mitigation of spray drift for PPP. "Armed" with a hand spray gun he demonstrated the complexity of spray drift and the technical uncertainties, but also that spray drift is mainly driven by main significant parameters and thus can be handled. The outcome of a workshop 2016 "SETAC DRAW" was an agreed field protocol for drift studies, targeted efforts to address measurement uncertainties and a database consolidation and review. A second workshop is planned to develop crop specific differentiations and reference scenarios.

The current version of the MAGPIE toolbox was presented by Anne Alix. The toolbox provides an overview of state-of-the-art mitigation measures with technical details and supporting data. It was developed by a SETAC working group and MS, EFSA and US EPA and introduced to risk assessors by a SETAC Europe Special Science Symposium.

AgChem Forum September 2016 – risk assessment issues related to fate and ecotox section

Veronique Poulsen and Arnaud Boivin presented the French view on higher tier aquatic assessment.

The test design of higher tier studies is directly related to the FOCUSsw profiles scenarios. Therefore, both speakers emphasized the need for absolute confidence in and robustness of the FOCUS scenarios. Also in the evaluation of cosms, the representativeness of the PEC values compared to the GAP are more and more questioned by authorities and the representativeness of the exposure profiles related to the ecotox studies becomes relevant. From effect side, questions on different studies may arise during the evaluation process: For outdoor pond tests with macrophytes, Poulsen recommended to add intermediate endpoint measurements (not only at the beginning and at the end of the study) in order to show if recovery occurs. Additionally, the NOEC/NOAEC should be compared to the initial PECs or the exposure in pond should be compared to the FOCUS profiles. For cosm studies, the MDD analysis is systematically requested nowadays for new and also old studies. Concerning the effect modeling, Poulsen also confirmed the highly divergent opinions of the MS, mostly based on the need of additional competence and the difficulties to validate of the models. Her proposal is to organize special training courses for risk assessors and the development and validation of a tool box on EU Level (proposed as task for SETAC and EFSA).

Gregor Ernst from Bayer crop science presented the ECPA working group on terrestrial invertebrates. He summarized the future soil risk assessment of PPP from industries' perspective. He weighed up the Ecosystem services (EsS) of the in-field crop protection against the specific protection goals (SPG) on protection of in-field and off-field biodiversity as proposed by EFSA. He concluded that some SPG are not measurable and potentially heavily impede agricultural production. Therefore, different specific protection goals for in-field and off-field should be considered, e.g. soil fertility – in-field; protection of biodiversity – off-field. He presented the ECPA project on functional soil testing on different levels. As a consequence, ECPA suggests that EFSA should revise the SPG for the nutrient circle, where EFSA proposes unacceptable risk for initial effects of >65% or >35% for longer than 6 month on functional groups. In a second step, Ernst summarized the industry opinion on the calibration of the lower tier risk assessment on earthworms and emphasized the need of adjusting the current lower tier risk assessment.



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CALENDAR


Meet SCC at Biostimulants Europe 2016 in Almeria, Spain, 30 November – 1 December 2016

Please meet

Anke König-Wingefeld, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides - Biostimulants, Fertilizer, IPM

at the **Biostimulants Europe 2016 in Almeria, Spain**. Feel free to discuss with our regulatory and biopesticides specialist your registration needs for Agrochemicals and Biopesticides as well as other regulatory or scientific issues you might want to address.

Meet SCC at Biocides 2016 in Vienna, Austria, 30 November – 1 December 2016

Please meet

Dr. Martina Galler, Senior Manager Regulatory Affairs Biocides, and

Dr. Felix Koziol, Senior Manager Regulatory Affairs Biocides, at the Biocides 2016 in Vienna, Austria.

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