NEWSLETTER

SCC Newsletter Vol. 16, No. 1, March 2016

TIMES ARE CHANGING – REGULATORY NEWS

Dear Subscribers,

Spring is coming… how time flies! This issue of the SCC Newsletter comprises a report on the conference "Crops and Chemicals" held last month in Berlin. Furthermore, very important news on the regulation of Chemicals and Biocides is presented: I would like to draw your attention to the **implementation of IUCLID 6**; submission of REACH or Biocide dossiers by REACH-IT or R4BP 3 must be done using the new format starting at the end of May 2016 (see page 2 for more details, please).
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 for agrochemicals and biopesticides, biocides, chemicals, consumer products, feed and food additives, archiving solutions or Task Force/consortia management, SCC can provide you with high quality service and consulting.
Please also have a look at the calendar to find out where you can meet with SCC experts to personally express your needs or clarify your questions on scientific and regulatory issues.
Finally, please note the interview about PPP (see info box).
We appreciate your feedback and comments regarding the SCC Newsletter.
Please drop us an
E-mail at newsletter@scc-gmbh.de.

Dr Friedbert Pistel

IN THIS ISSUE:

Hot topics in plant protection

Interview with
Dr Bernd Brielbeck, Senior Manager
Regulatory Affairs, at C&C Europe
(http://www.informa-ls.com/event/cropsandchemicals2016)
in February 2016

Link to the interview

BIOCIDES

CHEMICALS/REACH

IUCLID 6 is approaching

The new IUCLID 6 database will be provided by ECHA by end of April 2016. Submission of REACH or Biocide dossiers by REACH-IT or R4BP 3 must be done using the new format starting at the end of May 2016. Currently an IUCLID 6 beta version is available via the IUCLID homepage (https://iuclid6.echa.europa.eu/).

IUCLID 6 has to be set up using one of two different databases. SCC encourages companies to check the IUCLID 6 IT requirements and to get familiar with the new IT sub-structure. Significant efforts might be required to set up/install the program within your company.

SCC is currently preparing for the change to the new system and will establish the new system as soon as available in May.

Migration of the current IUCLID 5 datasets to IUCLID 6 may take some time (up to a few days depending on the number of datasets).

A new validation assistant is already available in the IUCLID 6 beta version. Based on our information and experience with the new database, significant effort is required to generate an IUCLID 6 dataset from an IUCLID 5 dataset.

New templates have to be filled in and new technical completeness check rules have to be passed. Thus a significant number of faults and warnings will appear when using the validation assistant with an IUCLID 6 dataset created from a previous fault-free IUCLID 5 dataset. This occurs due to the migration and the more demanding/different structure of IUCLID 6.

Please contact SCC if you need assistance with an update of your IUCLID 5 datasets to IUCLID 6.

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AGROCHEMICALS

Crops and Chemicals Europe, Berlin 10 – 11 February 2016

From 10 to 11 February 2016 there has again been the Crops and Chemicals Europe Conference in Berlin, Germany. The event covered three individual conferences Chemical Formulation, Registration of Agrochemicals and Biostimulants and Plant Growth. We have been able to meet many of you at our stand during this occasion. For those who have not been able to participate in the event we are summarising the most important points of the Registration of Agrochemicals and Biostimulants and Plant Growth part of the conference.

The keynote plenary session was given by Freija von Duijne, president of the Dutch future society, on the issue of "The future of agriculture: Where will we be in 10 years' time?" She clearly emphasised that the future is playing field of power. But, at the same time, that no one can predict the future. What we all can do, instead of prediction, is to strive for better preparedness and for creating the future. This preparedness rests on a more explicit, contestable and flexible sense of the future. It is based on scenario planning, using megatrends, to reframe our thinking of the future. Those scenarios are not strategic options or "heaven versus hell" decisions, but are alternative frames to address the future.

With respect to agriculture, she devised two archetype scenarios in the timeframe leading up to 2040. One was termed "global efficiency" and is based on sustainable intensification of large-scale productions systems, while the "urban connected" scenario is based on resilient food and farming systems and has its strengths not in large-scale production, but in diversity. She identified then the strategic leadership question for those two different scenarios: How can your business anticipate both of those futures?

She concluded that no one has a crystal ball to look into the future and predictions tend to go wrong or are being used wrongly. More important is that companies develop strategic foresight, as a disciplined approach to address the impact of systemic change.

Miriam Cavaco from the Portuguese Authorities gave a feedback on the zonal authorisation procedure from the perspective of the southern Member States. Portugal will start chairing the southern Steering Committee as of October 2016.

The re-authorisations (Regulation 1107/2009 Article 43) for the AIR2 substances amount to 348 applications in the Southern Zone. Around 123 of those come from glyphosate containing products. The re-authorisation of the first AIR3 active substance containing products are currently being coordinated by Portugal and applicants were asked to fill in an excel file slightly different to the original AIR2 request.

What Portugal has learnt under the zonal procedure already, is that a pre-submission meeting is highly recommendable and is proposed for all applicants. It is the speakers' assessment that since June 2011 not a single dossier was considered complete by the Portuguese Authorities. The timeframe of the evaluation only starts after a successful completeness check.

The speaker emphasised that mutual recognition is an important way of obtaining authorisations. The procedure is designed to avoid duplicate work and in Portugal the evaluations of the reference Member State are not repeated. Portugal will not grant any mutual recognition for provisional authorisations. With respect to mutual recognitions originating in an authorisation granted under Directive 91/414, Portugal tries to obtain the registration report, but if no such report is available, the mutual recognition is granted without the report.

The comparative assessments must be done at national level. The Portuguese Authorities want to involve the applicant in the comparative assessment and have formed a working group consisting of the Authorities themselves and the industry association. If Portugal concludes that a substitution, for any of

the uses is appropriate, withdrawal or amendment shall take effect three years after that decision or at the end of the approval period of the candidate for substitution whatever period ends early.
The same issue of comparative assessment was also presented by Martin Prokop of the Czech Authorities. He indicated the EPPO guidance, as well as the EU Guidance document SANCO/11507/2013, for the comparative assessment. He, too, foresees that industry is to be involved in the comparative assessment, which is a step-by-step approach and he urges all involved, to try to reach a conclusion at the earliest possible step. It should be kept as simple as possible and no optional comparative assessment should be made.
His concern is that the comparative assessments is time and money consuming (3 to 5 hours for each use assessment for the Authorities) without any clear advantage, particularly, it does not necessarily lead to a risk reduction. He worries that in this new playing field industry might start a competitive fight involving the Authorities.
He calculated that the workload for the Czech Republic might increase by 6%, if they act as concerned Member State and by additional 13% due to the frequency of the evaluation, i.e. every seven years instead of 10 years. To minimise the workload, the speaker emphasises that industry should start the assessment were the highest probability is expected to stop it. When any of the criteria is fulfilled, the assessment should be stopped and not be taken through the other, unnecessary steps.
Most important reasons, why a given Plant Protection Product should be present in the markets, are resistance management, integrated pest management and minor uses.

The same speaker also presented the candidate for substitution issues underlying the comparative assessment. A first list is now available (Regulation 2015/408 of 11 March 2015) covering active substances which were evaluated until 31 January 2013. A second list, which is expected to cover the active substance evaluated from that date to early 2015, has not been published yet and the publication date cannot be foreseen at the moment.

Claudio Mereu of Field Fisher has given an overview of data protection and confidentiality. He presented the prerequisites for the eligibility for data protection under Regulation 1107/2009. He then continued to give an overview over the interplay between Regulation 1107/2009 in the MRL Regulation.
He observed that under Regulation 396/2005 there is no notification and no submission process foreseen. Instead, EFSA, with the help of the RMS/MS collects all information available on residues and sets an MRL. Typically, the authorisation holders then review or modified there GAP to show compliance. As there is no data submission, there is also no data protection foreseen for this data.
The speaker then asked what should happen, if a Member State actually does require new data under Regulation 396/2005, as was done by Italy. He concluded that there is no legal basis for such a request and therefore also no data protection can be granted.

The speaker explored the request for confidentiality versus access to documents. Regulation 1049/2001 stipulates that access to all documents which contain information on emissions to the environment held by institutions cannot be claimed to be confidential. Article 63 of Regulation 1107/2009 states that the confidentiality applies without prejudice to legislation on access to environmental information. He then quoted a number of case laws where in different cases this issue is being legally explored at the moment. Currently, no clear line can yet be seen and it is a case to case decision by the courts.

He summarised that data protection applies at Member State level, when granting product registration. It may nevertheless be relevant for Annex I renewal submissions. The speaker emphasised that the applicant should think about data protection strategies before submitting data. In the conflict between confidentiality rules and access to data, he identified a clear tension between environmental Regulations (Aharus) and Regulation 1107/2009. Also tension between NGOs/generic producers and data owners were identified. At the core of the different interpretations is the definition of “environmental information” versus “emissions to the environment”.

Bernd Brielbeck of SCC presented issues on basic and low risk substances and asked the question, whether this would be Europe’s versatile approach to biopesticides. He concluded that biopesticides as

such are not defined in any way in the EU, which is contrary to legislation in the US. Instead, Regulation 1107/2009 clearly does not exclude any substances from the use in Plant Protection Product, as the relevant article states that this Regulation shall apply to "substances, including microorganisms having general or specific action against harmful organisms".

Instead, the Regulation defines hazard and risk categories which are desirable or undesirable and then evaluates according to those categories. Categories of active substances are: cut off active substances, candidate for substitution active substances, conventional active substances, reduced risk active substances (upon renewal only), low risk substances and basic substances. The speaker then briefly touched upon the criteria that were laid out in Article 23 of Regulation 1107/2009 and of SANCO/11188/2013 for basic substances. With respect to low risk substances the criteria are currently being discussed and a working document is being circulated. The speaker concluded that there is no definition of biopesticides within the EU, but that the bottom-up approach, i.e. defining risk categories and properties which are desirable or not, is the more versatile approach to the issue of biopesticides.

Mike Carroll of Dow AgroSciences was reviewing the registration process of new and existing active substances in the EU. He put himself into the shoes of the regulators. Their assessment is based on regulatory tests and the application of the precautionary principle, which states that, if any action or policy has a suspected risk of causing harm to the public or to the environment and in the absence of scientific consensus that the action or policy is not harmful, the burden of proof falls on those taking an action. Contrary to this, he observed that industry in managing risks, relies on scientific studies to such an extent that he puts the blame of scientism on industry. He defines this as a belief in the universal applicability of the scientific method and approach, to the extent that empirical science constitutes the most authoritative worldview or the most valuable part of human learning - to the exclusion of other viewpoints.

He then analyses the full evaluation process, where industry supplies scientific studies to the regulators, who evaluate the studies. But in between, and interacting in that process through political moves, are NGOs, who successfully claim that these studies are lacking scientific consensus and therefore the precautionary principle has to be applied. The speaker identified the regulators dilemma with Pascal's wager. Where, in the case of the regulators, the option is either to grant or not grant approval; in any case the regulators will either clash with industry or the NGOs. The speaker then described different evaluation processes, clearly favouring the data calling system applicable in the US; which he called a rational system when scientific consensus has been reached on most studies. The European system, where industry is asked to prepare all necessary studies to prove the safety of their products, he considers to be a rational system where many studies lack scientific consensus. He concluded that the possibility of establishing a data calling system in the EU is very minor. He called upon industry to come together with NGOs and the regulators to re-establish a scientific consensus.

In a number of the further presentations and roundtable discussions, Jose V. Tarazona from EFSA was giving a progress report and an outlook of ongoing activities of EFSA. Christian Dobe of Syngenta Crop Protection was linking REACH and PPPR. He addressed the REACH-IN tool of ECPA, which lays out the specific requirements of REACH risk assessments for co-formulants. He also emphasised that the IUCLID dossier should recognise "agrochemical/PPP/pesticide uses". Also, the safety data sheets must identify a use "agrochemical". With respect to Article 27 and Annex III of Regulation 1107/2009, i.e. the negative list of co-formulants, detailed rules are not yet set. Nevertheless, the issue has been addressed in the Standing Committee of December 2015 and a working group is expected to deliver within the next 12 or 18 months. The existing national lists can be maintained for the moment. He called upon all applicants to use REACH studies, to avoid duplicative testing of vertebrates. In separate roundtable discussions AIR3, experiences from a Member States perspective, Article 43, and the authorisation of generic product with reference to Article 34 of Regulation 1107/2009 where addressed. Adolf Heintze of Eurofins presented a new test strategy for algae, for non-specific herbicides using an algae flow-through reactor as a new test design.

Finally, Ainsley Jones of FERA presented incidences related to animal poisoning, which were reported in the UK. From 2009 to 2015, 713 individual incidences with vertebrates have been reported. 48% of these where due to pesticide poisoning of which again 57% resulted from the abuse of these substances. Also the loss of bee populations have been reported to his institution and he could establish that these losses have not necessarily been due to Plant Protection Products, but also Biocides or other active substances which were used incorrectly to control feral bee colonies. He identified that most such poisonings are due to carbamates and pyrethroids, but not neonicotinoide. Thus, his data does not support the current scare on neonicotinodes. An interesting finding was that the level of clothianidin in healthy bees is as high as it is in affected bees. As this last information has not yet been published, the author can be addressed for further details.

In the Biostimulants and Plant Growth Stream most presentations focused on scientific issues as well as detailed information on specific product performances. In addition, and that will be the focus of this brief summary, were presentations related to the regulatory situation and regulatory issues of such active substances and products. Luc Peeters, Chairman of Copa-Cogeca Working Party on Phytosanitary Questions, asked with respect to Biostimulants, what we have learned from Pesticide Legislation.
The organisations represented by Mr Peeters are representing European farmers and agricultural cooperatives. In analysing the legislative framework currently dealing with Plant Protection Products and Fertilisers, he observed that some products fall under Pesticide, Fertiliser and, if the Biocides Regulation is included, under three Regulations.
The speaker then looked upon Directive 2009/128 Sustainable Use of Pesticides. With respect to the stipulations he emphasised that the integrated pest management (IPM) should be based on practical interpretation in the field, taking into account economics as well as risks. An effective IPM must provide enough alternatives at the cultural, mechanical, biological and chemical level of pest management. It must take into account economics, risk and labour costs as well as alternatives available in all Member State at affordable prices.

He observed that IPM is the basis of sustainable farming systems, as long as both are based on economic viability, social acceptance and environmental friendliness. He calls for a clear EU framework on registration and more willingness to approve substances. Especially for low risks substances he demanded a fast-track approval procedure.
He observed that farmers are willing to include new tools, as far as these tools contribute to a better end user result.

Subsequently, Eric Liegeois of DG GROW gave feedback on the revised Fertiliser Regulation, which proposes an inclusion of Plant Biostimulants. The revision of that Regulation is part of the EU circular economy action plan from 2.12.2015. This circularity of Fertilising Products includes different stages, such as resource/energy efficiency, critical raw materials, recycled bio-wastes, sustainable sourcing and nutrient use efficiency. Of these, the main question he posed was, whether we can improve the nutrients use efficiency by plants.

The objectives of the revised Fertilisers Regulation proposal are: to create an internal market for such products, levelling the playing field for all Fertiliser Products, address safety concerns, stimulate innovation, reduce the administrative burden and, finally, facilitate controls. The scope is to include “Products, including substances, mixtures, microorganisms or any other materials, which are intended to be applied either on their own or in mixtures, on plants or their rhizosphere for the purpose of providing plants with nutrient or improving their nutrition efficiency, and made available, or intended to be made available, on the market bearing the CE marking”. The new legislative framework will be including all fertilizing products with a CE-Mark. CE-Mark products are compliant with safety, quality and labelling requirements. The certification is either awarded by the manufacturer or by a “notified certification body”. National fertilising products may remain on the market and mutual recognition between Member States continues apply. The new Regulation proposal specifies two categories, one depending on a composition of the CE fertiliser, CMC (component material category), such as CMC 7 for microorganisms. The second category is a product function category (PFC), to which a CE fertiliser belongs. Plant Biostimulants could be either

microbial or non-microbial and thus belonging to PFC6/A or PFC6/B, respectively.

The speaker clearly stated that Plant Biostimulants are a border case, falling into the gap between Plant Protection Products and Fertilisers. To remedy these borderline cases, new definitions are proposed, "A Plant Biostimulants shall be a fertilising product aimed at stimulating plant nutrition processes independently of the products nutrient content, with the sole aim of improving one or more of the following characteristics of the plant: the plants nutrient use efficiency, the plant tolerance to abiotic stress, or the plants crop quality traits to include Plant Biostimulants into the Fertiliser Regulation". To exclude them from the Plant Protection Product Regulation definition it is proposed to replace Article 2 (1) of that Regulation by the following "influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a Plant Biostimulant".

With respect to labelling, the revised Fertiliser Regulation proposes that the following information elements shall be present on the label: physical form, manufacturing expiry date, storage conditions, application methods, dose, timing and frequency of application, effect claimed for each target plant and any relevant instructions related to the efficacy of the product. It was then discussed that such efficacy should also be shown by pertinent studies.

As there are still negotiations with the Council and the EU Parliament ongoing, it is currently unclear whether there will be amendments to the Commission proposal or what would be the timeframe of adoption and entry into force of that new Regulation.

Claudio Mereu of Field Fisher took up some issues raised with the revision of the Fertiliser Regulation. One point was the difficulties whether to apply other Regulations to Biostimulants such as Regulation 396/2005 on residues. Most importantly, he raised the question and clearly indicated the omission of any data protection mechanism, both at substance and product level, for Biostimulants as currently foreseen in the Fertiliser Regulation. The situation is further complicated by the fact that no authorisation scheme is foreseen by the Authorities, but data could be needed by the applicants to obtain their product certification. He clearly emphasised that data protection issues are still relevant and questions concerning them are justified and necessary!

Finally, Alessandra Trinchera from the Council for Agricultural Research and Analysis of Agrarian Economy in Italy presented the Italian experience and legislation of Biostimulants and Plant strengtheners in conventional and organic farming. In the Italian Decree number 75/2010, under Annex 6 "Products of specific actions", which covers Fertilisers on soil and plans, includes Biostimulants. When evaluating dossiers of Biostimulants for approval, a Technical Advisory Committee is involved. The Committee is made up of the Italian Ministry of Agriculture, Environment, Health, Industry, University researchers, fertiliser manufacturers, farmer associations and others. In a second piece of legislation (DPR of 22 April 2013, number 55 "Plant Strengtheners in organic farming"), detailed requirements for authorisation of Biostimulants are laid down, including label requirements.

Efficacy: Progress in leaf wall area concept for dose expression in 3D crops

The application of plant protection products on three-dimensional crops (e.g. grapes, hops, fruiting trees) has been under intensive discussion for many years. In contrast to the two-dimensional field crops there are several ways to express the applied dose rate, and regulatory authorities used different approaches to address this issue.

Currently, EU member states still prefer different concepts for determining the application rates with partly complicated conversion procedures. Farmers and technicians in the different countries are generally familiar with the national dose rate expression on three-dimensional crops and the imposition of any dose unfamiliar to them is unlikely to be understood, resulting sometimes in incorrect doses rates being applied. Some crops show great differences in size, shape, crop structure and are often recommended to be treated "until run-off". This may be practical information for the experienced end user, but will not satisfy regulatory requirements.

Companies who plan an efficacy trial program for Europe-wide PPP registration, e.g. on grapes, apples or Christmas trees have to deal with similar problems when they prepare a zonal GAP as basis for the study protocol. As recommended in EPPO PP 1/239(2), "to allow better exchange of data between countries, to avoid unnecessary repetition of trials and to prevent residue problems between countries, dose expression should be harmonized in trial reports. This can be achieved if the reports contain all relevant information allowing calculation of the applied dose whatever the model chosen by the registration authority". In other words, trial programs have to be designed to make conversion between different dose expressions like, kg/ha , kg/ha and meter crown height or 10.000 m2 leaf wall area possible.

Of course dose rate adjustment to the actual situation in the field (kg/ha) is a process consequently needed and considered as a separate step by which the dose applied is reduced or increased in accordance with canopy size and density to obtain minimum variation in deposit across a wide range of crop structures.

For example, the UK authorities describe the dose expression for three-dimensional crops as dose/ha ground, comparable to the dose rate expression normally used for agricultural crops.
Another approach is represented by Belgium and, most recently Austria, giving the dose expression as dose/ha leaf wall area. Germany has a different point of view indicating the dose expression as dose/ha ground for every meter canopy height.

Due to these special requirements efficacy trials on three-dimensional crops pose a special challenge for the monitors of the accordant trial programs. The experts at SCC have long-standing experience regarding the planning and monitoring of efficacy trials in viticulture, fruiticulture, hops and other three-dimensional crops and are willing to give any kind of support for development and realization of adapted trial programs to meet these special challenges.

An EPPO workshop will take place in Vienna in October 2016, explicitly dealing with the application of plant protection products on three-dimensional crops, organized by the Austrian Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES).

The aim of this workshop is to harmonise the dose rate expressions across the EU. SCC will be represented at this workshop by members of the efficacy group.

Complaints on efficacy reporting quality

At the ECPA/ECCA joint PPP conference in Brussels on 9 - 10 February 2016, the head of the Belgian FPS, Maarten Trybou complained about the quality of efficacy reports. Many applications for mutual recognition are being refused by Belgium due to the efficacy dossier. The problem is not the lack of efficacy of the products but incomplete dossiers. Often study reports are not fully compliant with EPPO guideline PP 1/181. Belgium requires complete reports, signed and with GEP certificates. Simple ARM printouts are not sufficient. Even though several member states still accept "incomplete or untraceable" study reports, SCC highly recommends to closely monitoring actual programs in order to avoid later problems with incomplete reports. At the conference a "Belgian compromise for efficacy" was presented, mentioning a minimum of 8 efficacy trials per use which should fully comply with EPPO PP 1/181. The hint was given that it is possible to amend incomplete trial reports.

Germany: Efficacy dossier requirements for PPP re-authorisations according to Art. 43

After several other member states now also Germany agreed to accept a "light dossier" for efficacy in which only national aspects, like the resistance situation has to be updated, only. The national requirements should be presented in a national addendum. However, this should also cover further aspects like earthworms, NTAs and NTPs. The studies have to be presented in the BAD and Section 3 of the dRR in the same depth like in the ecotox section and also be referenced in the efficacy section as KCP documents.

OUICK NEWS: Draft Fertilizing Products Regulation published by European Commission

On March 17th COM published the draft of the new fertiliser Regulation (COM(2016) 157 final) with new rules on inorganic, organic and waste-based fertilisers, also defining biostimulants and the borderlines between fertilising products and Plant Protection Products.
Details of this Regulation will be provided in a special edition of SCC's newsletter.

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BIOCIDES

Make sure now that imported treated articles continue to be BPR compliant!

If your company is importing articles from third countries into the EU, which have been treated with or which incorporate active substances, giving the so-called 'treated article' a biocidal property or function, you should make sure that the active substance(s) in your treated article(s) are either supported or approved in the EU, for the relevant biocidal product type, before 1st of September 2016. Otherwise, such treated articles may not be imported or placed on the EU market after 1st of March 2017!

Common examples for treated articles might be a paint containing a preservative to protect the paint itself from decay, or an article which has been disinfected (in the form as it is placed on the EU market) to render it sterile, or a T-shirt incorporating antimicrobial substances to suppress the presence of odour-causing bacteria. However, these are only a few examples out of a broad range of known treated articles, and there surely is a dark figure of yet unidentified ones!

Notification deadline for redefined *in situ* generated active substances

Following last year's redefinition of all *in situ* generated active substances in the Review Programme, the deadline for notifications of alternative precursors or systems for *in situ* generation expires on 27th of April 2016.

Notifications have to be done for each individual generation pathway of an active substance, but may also be necessary for the active substance itself if it is placed on the market as a biocide on its own (not generated *in situ*).

As an example, sulphur dioxide is redefined as "sulphur dioxide generated from sulphur by combustion", but if it is supplied and used in pure form as an active substance, a separate notification will be required.

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CHEMICALS/REACH

New Regulation on harmonised information relating to emergency health response

According to Article 45 of Regulation (EC) No 1272/2008 (CLP) importers and downstream user have the obligation to submit information about mixtures classified as hazardous that are placed on the market.

The aim of the regulation is to specify which information needs to be submitted to an appointed body in the respective Member State. The information to be submitted for the respective mixtures by importers and downstream users commonly includes product identification, hazard identification, and toxicological information. Furthermore a harmonised XML format maintained by the European Chemicals Agency (ECHA) has to be used for the submission of the information in order to allow companies operating in different Member States to use the same submission or submission format among Europe. The regulation foresees a transition period for the notifications. A submission provided to appointed bodies before the date of application of this Regulation (1st July 2019) should remain valid for until 1st January 2025.

Approaching of the Effective date for notification of hazardous substances to German authorities according to § 16e ChemG

From 1st June 2016 manufacturers, importers or resellers that use their own product name and place a hazardous mixture or a biocide product on the German market have the obligation to conduct a notification to the 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 immediate life-saving measures.
The BfR was appointed as official body in the meaning of article 45 of Regulation (EC) No 1272/2008 (CLP). Thus, a notification in accordance with §16e ChemG will also fulfil the obligation of importers and downstream uses according to Article 45 of Regulation (EC) No 1272/2008. SCC offers to take care of the notification including data gathering as well as preparation and submission to the authorities.

Turkey

Turkish SEA vs EU (CLP) – UN-GHS: The Turkish SEA Regulation has been implemented for substances since 1 June 2015 and it will be executed obligatory for mixtures from 1 June 2016. The SEA Regulation equivalent to the EU CLP is compared to UN-GHS on the side that both regulations are using the same building blocks. This fact will simplify the work of the EU suppliers and other suppliers who are familiar with EU CLP criteria in order to consider the classification of their products that are exported to Turkey.

In this context all mixture products classified as hazardous that a company places on the Turkish market must be labelled with legitimate Turkish Labels, including hazard pictogram, and correct Turkish signal word, H and P statements in accordance with Turkish SEA before 1 June 2016 at the latest.
Wrong/incomplete Turkish labels are likely to cause serious trouble.

New Turkish SDS Regulation (O.G. 29204) was published on December 2014. Every professional downstream user is legally obliged to provide a compliant Turkish SDS for each product classified as hazardous and/or contains any substance subject to an occupational exposure limit. Compliant Turkish SDSs must be authored by certified person and the SDSs must be provided in Turkish. SDSs should comply with the new SDS regulation before 1 June 2015 for substances and before 1 June 2016 for mixtures. Submitted and revised SDSs (including the revision to comply with the new SDS regulation), must be re-sent down the supply chain within a month after the revision to which the product has been supplied within the last 12 months.

ECHA announced two year moratorium for guidance updates ahead of the 2018 REACH deadline

ECHA has recently announced to apply a two year moratorium on updates of the majority of its guidance. The moratorium is set to begin on 31 May 2016. ECHA´s intention with this stand-still period is to provide a sufficiently long period of stability for registrants to manage their preparations and negotiations in the substance information exchange forums (SIEFs) undisturbed. Nevertheless, guidance documents will be updated during the moratorium in rare cases, e.g. when REACH legislation has been modified, or IT tools have been updated. The guidance update with the greatest impact are just finished or will be finished in due time (e.g. Guidance on data sharing). We want to point attention to the recently updated guidance on

use descriptor (IR/CSA R.12) which will be applicable to all new registration dossiers or dossier updates requested by ECHA. We highly recommend getting familiar with the new guidance as the naming and the scope of the used descriptors has changed. Please get into contact with SCC if you need support with regard to future dossier updates, updates due to requests from authorities or dossiers which have to be prepared for the 2018 deadline where the updated guidance R.12 has to be taken into account.

ECHA´s Common screening approach – impact to and action by registrants

Since 2013, ECHA is applying a common screening approach, and have now further refined the IT based screening (please refer to http://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf for further information). The outcome of the screening is the basis for ECHA to prepare a list of a pool of potential candidate substances to be manually screened by authorities. This list (so called short list) is annually published on the ECHA website. Furthermore the registrants of a shortlisted substance will be informed via REACH-IT. With this informative letter a timeline for dossier update will be indicated. If your substance is shortlisted it is highly recommended to update the lead dossier with regard to the endpoints of concern before the manual screening work starts. The date until which an update will be taken into account is the 13th of March of the respective year. Alternatively one can submit an update plan for updates requiring longer time. In any case we highly recommend getting into contact with ECHA as the outcome of the manual screening by the Member State competent authority is the basis for further regulatory measurements as Compliance check, substance evaluation or PBT/endocrine disruptor assessment and may finally end in a substance of very high concern (SVHC). Thus, prompt reaction when your substance is shortlisted could avoid or at least reduce further regulatory actions by ECHA at an early stage. Please get into contact with SCC if you need support with regard to dossier updates.

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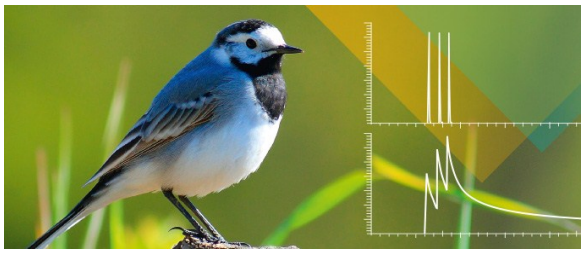
REGULATORY SCIENCE



EFSA Technical Report – Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology

In December 2015 EFSA published a Technical Report reflecting the outcome of the ecotoxicology experts' meeting on general recurring issues noted during the EFSA peer reviews of active substances.
Several aspects in the area of ecotoxicology related to the risk assessment to mammals, aquatic organisms, bees and soil organisms were identified and discussed to enhance the harmonization of the risk assessment of active substances.

Recommendations for the peer review of the active substances in the area of the risk assessment were compiled for Rapporteur Member States and applicants.

In addition, recommendations are given to provide additional clarification regarding the scientific interpretation of the applicable guidance documents when preparing the dossiers or the Draft/Renewal Assessment Reports. In total EFSA identified 12 major issues which are elucidated in the technical report.

In the following the expression of aquatic toxicity endpoints from tier 1 studies and aspects of the new data requirements are exemplarily presented.

Regarding the aquatic risk assessment EFSA identified the following issue: How to express the endpoints from tier 1 studies.

The EFSA Technical Report gives clear recommendations that the expression of the toxicity endpoint from aquatic tier 1 studies must depend on the actual exposure throughout the whole exposure period and thus, the toxicity endpoint should be deduced as follows:

- Nominal concentration, i.e. test concentrations were maintained ± 20 % of the nominal at all times throughout the test.
- Initial measured concentrations, i.e. initial test concentrations were below 80 % of the nominal and this concentration was maintained throughout the test (within ± 20 % of the initial).
- Mean measured concentrations, i.e. test concentrations were not maintained within the range of ± 20 % of the nominal or initial measured AND the test item was still present at the end of the exposure period.
- When the test concentrations were not maintained and the test concentrations at the end of the test or renewal period were not present, the validity of the study should be questioned. However, the recommendations in the OECD Testing Guideline 23 for difficult substances using LOD or half of the LOQ could be used if intermediate measurements are available.

Based on the EFSA recommendations on the expression of the toxicity endpoints of aquatic studies above one should consider including more sampling points for unstable substances.

Another major topic of the workshop was the new data requirements (Commission Regulations (EU) No 283/2013 and 284/2013). In the ecotoxicology section it is requested to provide EC10 and EC20 values together with the NOEC for all chronic/long term/reproductive toxicity studies.

In the EFSA Technical Report it is clarified that EC10 and EC20 values shall be calculated for all studies designed for ECX derivation. A list of test guidelines is given in the EFSA technical report for which EC10/EC20 values are not routinely derived. In general it is stated that for existing studies and new studies designed for deriving a NOEC (e.g. reproductive studies on birds and mammals), the NOEC should be maintained as the primary endpoint. For new and existing studies carried out with an experimental design which allows the calculation of ECX these values should be reported together with their 95 % confidence interval. Regarding the use of ECX in the risk assessment, the experts agreed that where a reliable median EC10 is calculated it should be considered together with the NOEC and whatever value is lower should be used for the risk assessment.
For more details please click here

For more information, please contact
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GLP & REGULATORY ARCHIVING

SCC´s GLP Certificate Re-Issued!

In October 2015 SCC was reviewed by the State Office of the Environment (Landesamt für Umwelt, Rheinland-Pfalz, Mainz, Germany), regarding the conformity of its GLP-compliant archiving facilities with GLP (Good Laboratory Practice) standards. SCC successfully received re-certification: the GLP certificate was re-issued.

SCC continues to archive raw data on behalf of its European and worldwide clients with the help of SCC´s self-developed, unique GMS (GLP Archive Management System). Data, electronic media, materials and samples from GLP, or similar type studies, are stored within a guaranteed temperature and humidity range, monitored 24 hours per day and 7 days per week.

We continue to offer a complete archiving concept for all regulatory needs (GLP-compliant storage and regulatory/scientific archiving) to benefit our clients as European or worldwide central archive and to provide an adequate and perfectly safe storage for all archive materials.

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CALENDAR

Meet us at Ctgb Workshop on biocides in Ede (NL), 5 April 2016

Please meet **Dr Silvia Wagner** and **Dr Stefan Nave,** Managers Regulatory Affairs Biocides, at the Ctgb Workshop on authorization of biocidal products based on Peracetic acid at the Ctgb's new headquarters in Ede (NL) on April 5, 2016.
Don't miss this chance to discuss your regulatory needs for biocidal products with our experts.

Meet us at EPPO Workshop on Efficacy in Ede (NL), 6 - 7 April 2016

We are pleased to announce that
Anke König-Wingenfeld,
Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides – Efficacy, will join the EPPO Workshop on Efficacy requirements and evaluation of PPP based on low-risk active substances in Ede (NL), this April.
Don't miss a chance to discuss your registration needs for Agrochemicals and Biopesticides with our regulatory and efficacy specialist.

Meet us at Eastern Europe Regulatory Conference, Budapest (HU), 12 - 13 April 2016

Please meet **Michaela Glanz**, Assistant Manager Regulatory Affairs Agrochemicals and Biopesticides – Efficacy, at the Plant Protection Products Conference in Budapest. Our regulatory and efficacy specialist looks forward to discussing your needs in registrations of plant protection products as well as other regulatory or scientific issues you might want to address.

Meet us at Biocides Symposium 2016 in Budapest (HU), 10 - 11 May 2016

Please meet **Dr Martina Galler,** Senior Manager Regulatory Affairs Biocides, and **Dr Rebecca Hamm,** Assistant Manager Regulatory Affairs Biocides at the Biocides Symposium 2016 in Budapest (HU). Our experts will be happy to discuss your regulatory needs with you.

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