NEWSLETTER

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CHALLENGING FUTURE – REGULATION OF PLANT PROTECTION PRODUCTS

Dear Subscribers,

It's once again the spring season. How quickly time flies! This issue of the SCC Newsletter comprises a report on the conference "Crops and Chemicals" from 10 - 11 February 2015 in Berlin.
With regard to the regulatory affairs of plant protection products, it becomes clear that a significant time effort will be needed for these activities, for applicants and authorities. For instance, in the central zone approximately 350 plant protection products containing AIR 2 active substances, resulting in more than 2000 applications for re-authorisation, are expected. For more details on this issue, please refer to page 2ff.

Furthermore, this edition of the SCC Newsletter will also focus on recent information about biocides (data sharing) and chemicals (REACH and more) as usual, as well as providing you with some insight on scientific issues.

Well, SCC intends to adhere to its long-term strategy in the future. The previous period was rather busy for SCC due to expanding the Office Berlin, which is also focused on regulatory services.
The coordinates of the Office Berlin are mentioned in the edition notice.

SCC looks positively into the future, helping our clients further with their projects to move on in the field of agrobusiness, chemistry, biocides, food and feed additives, and veterinary medicine.

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

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

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.
Regardless of whether your needs are in scientific and regulatory support for agrochemicals and biopesticides, biocides, chemicals, feed and food additives, veterinary medicine, archiving solutions or Task Force management, SCC is willing to support you and would be happy to inform you on further subjects, if needed.

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

Dr. Friedbert Pistel

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AGROCHEMICALS

Registration of Agrochemicals, Berlin 10 – 11 February 2015

Various issues on the registration of agrochemicals were presented in the two day conference “Crops and Chemicals” from 10 - 11 February 2015 in Berlin. Presentations were made by the Commission, Member States, and industry speakers. Highlights are presented in this article.

In the initial presentation of the conference Jeroen Meeussen of the EU Commission was giving feedback from the EU Commission by running through the Regulation 1107/2009 "article by article". The scope of Regulation 1107/2009 covers not only plant protection products, but also biostimulants and fertilisers. The Commission is currently considering legally consistent definitions, based on clearly identified functions or claims, to minimise unclear borderline cases between the three areas. He then elaborated on article 4, which covers, among other issues, endocrine disrupting properties as approval criteria. The Commission has meanwhile launched a public consultation on endocrine disrupting properties within the framework of its roadmap, for which 25.000 contributions were returned. A workshop is intended in mid-2015 to deal with these contributions. Furthermore, an impact assessment is planned, and the Commission will take this impact assessment into account, when proposing criteria for the endocrine disrupting properties. He emphasised that the endocrine disrupting properties in Regulation 1107/2009 are not purely hazard based, but active substances having such properties “can be authorized, if under realistic conditions of use, the exposure is negligible". A definition of negligible exposure could be based on Regulation 396/2005, where the default MRL is set to the general LOQ of 0.01 mg per kilogram. Currently, a guidance document on this issue is under preparation by the Commission.

There are still on-going discussions on the implementation schedule for the bee guidance document. Details were briefly addressed and it was acknowledged that bee health is certainly a multi factorial issue.

Within the AIR2 programme of the re-assessment of 29 substances, are emerging some concerns about delays. One option, under consideration, is to further extend the currently valid Annex I inclusion. Nevertheless, it was emphasised that within the AIR3 programme very strict and tight timelines (29.5 months from dossier submission until decision) are set and must be kept.

With respect to the applicability of the new data requirements, the Commission is currently preparing an amendment to the legislation to deal with applications for re- authorisations of plant protection products containing an AIR 2 active substance which will be submitted after 01.01.2016.

The Commission is aware that renewals of authorisations, as described in article 43 of Regulation 1107/2009, are very difficult to accommodate, due to the workload for the Member States. Although a revision of that particular article was intended, the legal services of the Commission refused to review or change individual articles, before the due date prescribed in the article 82 of the Regulation itself.

Clear incentives are placed on low risk substances as described in article 22 of Regulation 1107/2009. The approval period can be up to 15 and data protection up to 13 years. Also, the Member States have to decide on the authorisation of a low risk plant protection product within 120 days. The criteria for these special active substances are currently being reviewed by an expert group of EU Member States, Commission, Growers Organisations, NGOs and industry. The aim is to obtain proposals by mid-2015.

Basics substances, such as for example beer which is well-known to act against slugs, were also briefly discussed. It is important that they are not predominantly used for plant protection purposes and are not placed on the market as plant protection products. A working document (SANCO/10363/2012 –rev. 9) is available. Currently there are three substances approved and approximately 20 more under review.

The list of candidates for substitution has been reviewed and 77 active substances (approximately 20% of the total number of approved active substances) remain on that list, which has been positively voted upon by the standing committee. The list will not affect current approval periods nor on-going applications and (re-)authorisations. On comparatives assessment, resulting from an active substance being a candidate for substitution, a guidance document describing a stepwise approach (SANCO/11507/2013-rev. 12) is available

In a presentation by Nicola Mitchell of Life Scientific, a closer look on article 34 of Regulation 1107/2009, which details the possibility of waving data required for an authorization, was taken. The speaker strongly proposed that the currently existing practice should be revised to follow more closely procedures implemented in the pharmaceutical area, where data protection is clearly linked to the active substance and not the respective product. With respect to the comparability of formulations, it was suggested that the law of equivalence, as defined in the patents legislation, where similar products fall under the same patent, should be implemented also for the comparability assessment of plant protection products.

Darren Flynn from the Commission working group on post approval issues, reported on the new dRR format. As before there will be Parts A, B and C. Part A is to contain also the comparative assessment. A Part B0 is intended to contain all the relevant background information, such as GAP etc. to avoid duplication of this general information in other sections.
The numbering will be according to the DAR. Currently, comments on the format are being collected. The revised template is to be introduced to the standing committee in March and is expected to be applicable as of 01.01.2016. A guidance document on the new format is intended. This information was also presented by Birgit Schreiber from the German BVL in her presentation.
Darren Flynn then addressed the applicability of guidance documents in the authorisation of plant protection products. Although article 36 of Regulation 1107/2009 stipulates that an assessment of an application should be made in the light of current scientific and technical knowledge, this should not be interpreted as the latest guidance document available at the time of assessment. Further to information laid down in the guidance document, additional scientific and regulatory parameters, such as for example other generic products which have been in the market, should also be taken into account. It would be ideal, if for all product evaluations the same guidance documents which were relevant at the time of the active substance approval could be used. In this case new guidance document should only be employed, where new risk assessments are necessary.

Birgit Schreiber from the German BVL and Ricardo Gomes of the Portuguese DGAV reviewed the zonal system of the central and southern zone from the perspective of their respective Member State. In both zones there are regular face to face or telephone meetings between the authorities of the different Member States. In the central zone communication of these meetings is provided to industry through a bullet point list which is published on CIRCA. To further promote harmonisation of the evaluation between the different Member States, the central zone has now initiated regular meetings between their experts of various scientific areas.
In the central zone approximately 350 plant protection products containing AIR 2 active substances, resulting in more than 2000 applications for re-authorisation are expected. Germany estimates to be zonal Rapporteur Member State in 40 cases and in 100 cases concerned Member State, resulting in 140 applications from AIR 2 related products. The average numbers of applications in Germany are 100 to 150 during the whole year.
The southern European zone has the highest amount of pesticides applied for in the whole EU. It is estimated that due to the new guidance document and the new procedure the workload will increase by 20%. The speaker emphasised that mutual recognition is a very good alternative to a normal application. Portugal cannot accept any further applications for 2015, but for 2016 pre-notifications can be placed with Portugal until June of this year. A decision on the acceptance will then be taken by July.

In the following panel discussion it was indicated that for article 43 submissions there is an agreement within the central European zone that no biological assessment dossier has to be submitted. Only a detailed resistance management argumentation is necessary. Nevertheless, it was proposed that in individual cases this general understanding should be re-confirmed with the respective national authorities.

Emma Jenkins from Dow AgroSciences presented the industry view of the implementation of the different articles of Regulation 1107/2009. Industry appreciated the very clear timelines and the resulting predictability given in that Regulation. Then, she presented some statistics from March 2014 (which will be updated in the March 2015 ECPA conference) as to the actual timelines needed for evaluations. The average time for a zonal rapporteur Member State to conclude its assessment is 15.8 month.

28% of the assessments by the zonal Rapporteur take more than 18 months and 33% are finished within the prescribed timeline. Mutual recognition on average takes an assessment time of 10 months and for 30% even more than one year. It is the assessment of ECPA that in 2016 to 2018 more than 10,000 additional assessments will need to be done by the Member States with respect to article 43 re-authorisations of products containing AIR 2 and AIR 3 active substances. As the currently existing zonal system cannot be changed in due course, it must be carefully amended to accommodate this workload, preferably, by harmonizing not only the risk assessment, but also the risk mitigation measures. Also, it is suggested, that most of the national documents, such as application forms, reference lists and procedures, differently interpreted stops of the clock, should be harmonized.

Article 57 of Regulation 1107/2009 stipulates that Member States shall keep information electronically available on plant protection products authorised or withdrawn. The Commission has now launched a new authorisation application management system, to fulfill this requirement, which was presented by Jeroen Meeussen from the EU Commission. The database is accessible in part for the public, the applicant and Member State authorities. The system is containing information on all 28 Member States and is fully in English language. It includes a notification system which allows contacting the applicant by email if action is the need. Unfortunately, this database will not replace current manual processes that are in place in individual Member States and should not be considered as an electronic system to handle applications on behalf of Member States. Nevertheless, the system will become mandatory for applicants and has to be fed in parallel to the normal application which is submitted to a Member States. The commission system allows only for smaller documents, such as labels, MSDS and GAPs to be submitted and will not contain dossiers. Any applicant has to address the Commission prior to submitting anything to the database to request a login and a password. The release of this new system is intended for calendar week 8 on the Commission website. If anything should be unclear questions can be asked under the following email address: santé-pppadmin@ec.europa.eu

Feedback on the process for the approval of new active substances was given by Léa Riffaut of the French ANSES. The procedure is described in articles 4 to 13 of the Regulation. In this process the Rapporteur Member State expects that guidance documents which were noted at the time of submission of the dossier have been used for the assessment. Since 14.07.2011 France has been involved in the evaluation of seven microorganism active substances and 10 other new active substances.
One important point is the necessity to align procedures under Regulation 1107/2009 and Regulation 1272/2008, because the classification of an active substance directly influences its assessment under the cut-off criteria or as candidate for substitution. At ANSES the same evaluation team is dealing with the DAR and the CLH report. The Authorities consider it unfortunate that, for the same or comparable dataset, very different dossier formats are to be prepared and submitted, IUCLID and Caddy.

Another important point for the evaluation of new active substances is the MRL setting, which also has to run parallel to the formal evaluation under the Regulation. With respect to import tolerances the speaker emphasised that the applicant must provide clear proof of registration of these uses in the exporting country.

Under Regulation 1107/2000 the data protection for studies submitted for the approval on active substance starts with the first authorisation in each Member State of a product containing that active substance, was the first point made by Claudio Mereu of Field Fisher in his presentation on data protection and access to documents/confidentiality. Also, data protection must never have been granted before for a study, including the case where this study has been submitted for a different active substance, as might happen for metabolite studies. Data protection is only granted to studies which are actually submitted for a registration process. Studies not submitted cannot be protected, but also not be used by a competitor in an evaluation process.
Under Regulation 396/2005 data will be "collected" by EFSA. Usually no specific data is generated for MRL setting. In one case Italy has asked for residue data to be generated and to be provided under Regulation 396/2005. As there is no legal base to ask for data in this process, no data protection is foreseen. According to the speaker the Commission is currently assessing this novel situation.

As was already addressed in previous presentations the re-authorisation of plant protection products according to article 43 of the Regulation is one of the most challenging issues to come. Christian Prohaska of the Austrian Agency for Health and Food Safety (AGES) was elaborating on these concerns. Precondition for applications according to article 43 are that the GAP remains unchanged and no new uses or new concerned Member States, for which the product may be new, are included.

As to formulation changes, only non-significant changes according to the guidance document SANCO/12638/2011 are allowed.
If these preconditions cannot be fulfilled, a normal application according to article 33 of the Regulation is required. Nevertheless, the speaker wondered how to address GAP changes that became necessary because of new endpoints derived from the Annex I procedure. As the respective application has to be filed with the Member States three months after entry into force of the renewal of the active substance, data gaps or studies required after the approval procedure of the active substance have been separated into five different categories.

1. Category one studies

Formally required studies which do not impact the safety of the product and which are not related to safety issues. Data gaps mentioned in EFSAs conclusion not to be considered at product renewal unless it is specifically mentioned in the approval Regulation that Member States should pay particular attention.

2. Category two studies

Confirmatory information as required in the approval Regulation. The product renewal should be done without this confirmatory information.

3. Category three studies

Confirmatory information for AIR 2 substances, which could be required according to the new data requirements. The renewal of the product should be done without such confirmatory information.

4. Category four studies

Studies in order to comply with new endpoints for which the time to generate is too short (e.g. mesocosm or residue studies). For these studies a delay of the dossier/study submission should be possible.

5. Category five studies

Data gaps related to new data requirements or new guidance documents, such as for example endocrine disruption. The renewal of the product should be done without such confirmatory information.

In general, Member States may grant an extension of the concerned authorisation of up to 2 years for applicants to provide the studies and 1 year for authorities to perform the assessment, if such studies would fall under category four described above. An issue which directly relates to this point is the start of the data protection period for the active substance studies used in the approval procedure!

In any case application holders must provide an application in time, as otherwise the authorisation will be revoked. The speaker considers it possible that with this application a list of studies to be generated can be submitted. The dRR can then be submitted once all studies are available.

The compliance check of these applications is to be performed by the individual Member States holding the respective authorisations! The work of the zonal Rapporteur Member State (coordinated by the steering committees) would be the evaluation of category four studies, when provided by the applicant. An assessment of the efficacy of the plant protection product is not necessary, except for the possible development of resistance and cross-resistance. The dRR Section B7 consequently should address this resistance issue only. There is no need for an updated biological assessment dossier to be provided by the applicant.

If the GAP has to be changed due to new endpoints etc., there are two possibilities:

1. A new application according to article 33 Regulation is necessary
2. The new efficacy trial reflected in the new GAP could be classified as category four data and post submitted

The latter option will be considered in the new version of the guidance document.

In a product containing more than one active substance an application must be submitted at each active substance renewal. The dRR should be provided once the last active substance has been renewed, if all renewal dates are within a maximum of one year. If the difference is longer, there should not be any need for an assessment of the additional active substances in the product, since no newly agreed endpoints are applicable. In a position not yet harmonised with other Member State, and giving the Austrian authorities opinion only, the speaker proposed that in the latter case, only the following product data should be considered:

1. Storage stability of the products
2. Toxicity, including dermal absorption
3. Product data on ecotoxicology such as bees, arthropod, earthworms, plantings, and aquatic organisms
4. Composition of the product

José Joao Dias Carvalho of Knoell Consulting was speaking on the general aspects of the plant protection regulation. He was calling for a balancing of risks and benefits of the use of plant protection products. As an example, he reverted to work he had previously done on caffeine found in concentrations above the drinking water limit in the environment in Germany. He observed that citizens are too far away from farming and thus not see the benefits of plant protection products. A balance must be struck between the safety concerns, which are legitimate and agricultural productivity. The regulatory system must be predictable to work to the benefit of all.

Also with the wider issues of plant protection regulation was the presentation by George Diriwaechter of Syngenta concerned. He emphasized, by quoting recital six of Regulation 1107/2009, that the purpose of this Regulation is a high level of safety and a competitive community agriculture. He was particularly concerned with the role of EFSA and the decisions taken by the Authority. In an EFSA press release, it was clearly stated that risk assessors provide independent scientific advice on potential threats. Risk managers use this advice as a basis for making decisions to address these issues. EFSA provides independent science-based advice and risk managers decide on the appropriate action using the Authorities expert's conclusions as the foundation for their decisions. The speaker then quoted from an EFSA press release of January 2013 on the Neonicotinoids "only uses on crops not attractive to honeybees were considered acceptable", which is clearly not keeping to the separation invoked before. Also, the selective acceptance of data has been criticized. Proof of harm is easily accepted where as proof of harmlessness not. The speaker is of the opinion that EFSA is striving for an unrealistic level of certainty in their risk assessments, and the precautionary principle is taken much too far.

Don Pendergrast of National Farmers Union was referring to the Andersons report which shows that over the next 5 to 7 years it is probable that of the 250 active substances currently available to growers in the UK, 40 to 87 will be lost. This will have a significant impact on the jobs and incomes available at UK farms. He, too, emphasised that communication to the public is key to the success of the regulatory system and the availability of active substances for the protection of crops.

Tom Heap of the BBC observed a clear disconnection between the opinion of the public and plant protection industry. He asked what does media like. Then, he answered that it must be a piece of information at the same time engaging and new. In addition, the public prefers it to be scary. He sees the media's role to speak truth to those in power, but asked who are the powerful? NGOs, politicians or industry?

There are many fears in Europe, but the dominant fear currently is certainly not hunger within Europe. Even the idea of wildlife genocide causes more fear. He observed that NGOs now are within the society well-established and a very strong power. With respect to their food, people are very suspicions of any change. They do not ask for the advantages that change might bring, but immediately associate it with problems it might cause.

Jose W. Tarazona of EFSA introduced the latest EFSA developments and future plans in the area of pesticides to the audience. EFSA is to publish soon a scientific opinion on the science behind the risk assessment for non-target arthropods which was adopted in December. In the peer-review of plant protection active substances EFSA has published 40 conclusions and 40 technical reports on basic substances in 2014. In reviewing and setting MRLs a total of 86 reasoned opinions were published.

EFSA has been entrusted with setting up a database for the endpoints generated during the review process of plant protection products.

The Authority is planning various activities among which a workshop on soil risk assessment is planned in October 2015, which is also open to industry experts.

Gabriele Kovacs of AGES and Patrice Duvert from Bayer SAS, speaking on behalf of ECPA-EffEG, focused their presentations on efficacy issues. With respect to the data that is to be provided for the assessment, it was made clear that the EPPO standards are regarded as the minimum necessary.

In the generation of the zonal biological assessment dossiers (BAD), a well-structured and readable dossier, including all necessary appendices, is required. It must contain all GEP certificates, for which, if the original is not in English language, a translation must be provided. ECPA is currently keeping available a database containing 1185 certificates of 675 organisations and 427 registered users across the EU. A table containing a list of certificates with the respective hyperlinks to the certificates can be downloaded and copied into dossiers (www.gepcertibase.eu). In the zonal BAD the data available should be grouped by EPPO zones or cropping regions or any other relevant fact. The grouping selected must be justified. When

calculating mean values, the basis of the calculation must be made clear and it must be traceable.
Trials with a low pest pressure, below 5%, should be excluded from those calculations.

Based on the BAD the dRR section 7 should contain only a concise summary of the whole BAD. The dRR will be available to the public, while the BAD not. It must be kept in mind that the dRR must be a stand-alone document. It should include summary tables and provide conclusions.

It was emphasized that communication between authorities and applicants is most important; also specific pre-submission meetings, focusing on efficacy are helpful and welcome. The authority recommends meeting 1 to 2 years before the application will be submitted.

The new dRR is considered to be a big a step in the right direction of a more versatile format for presenting efficacy details. In the new dRR efficacy will be contained in section 3 and will have a new and more organised table of content, which will improve clarity of the different chapters in the dossier. Benefits are presented followed by the potential risks of the plant protection products to crops. A chapter 3.0, which is located at the beginning of the section, will contain a summary on the conclusions from the zonal Rapporteur Member State associated to a GAP table with recommendations.
A balance must be found between the information provided in the core dRR and in the national addenda. A guidance document to this respect is available from CRD and published on the EPPO homepage: http://archives.eppo.int/MEETINGS/2013_conferences/zonal_evaluation/03_Mattock/index.html

Gabriele Kovacs, as the speakers before her, also addressed the article 43 renewals of authorisation. Provided that the GAP stays unchanged, no new crop or use was added, the product or a particular use is not new for a Member State authorisation and there are no significant formulation changes, the efficacy dossier and assessment can be limited to an update of the resistance risk assessment.

With respect to mutual recognition the speaker identified a mismatch in different articles of Regulation 1107/2009. While article 41 refers to article 36 (3), which is concerned with human, animal health and the environment as possibilities to refuse a mutual recognition, article 29 refers to article 4 (3), stipulating that the products shall be sufficiently effective. Thus, strictly speaking, a mutual recognition must not be refused on the basis of efficacy concerns. It is the Commission's opinion that authorisation in this case must be granted.

Pavel Minár of the Czech Authority (UKZUZ) presented the developments with low risk and basic substances. Low risk substances currently still adhere to criteria as laid down in Regulation 1107/2009. Mainly, these criteria are hazard based and related to the classification as stipulated in Regulation 1272/2008. The Regulation 1107/2009 clearly sets incentives for the registration of low risk substances. An approval up to 15 years, data protection of 13 years and an application for authorisation assessment within 120 days.
Currently, an expert group is revising the procedures, incentives and criteria. Output is expected in the middle of 2015.

Basic substances are not predominantly used as plant protection products. Again there are criteria as to when a substance can be considered to be a basic substance laid out in Regulation 1107/2009. If the active substance is considered and approved as basic substance, but the formulation does contain a co-formulant to administer the active substance, an approval as plant protection active substance is required. It was indicated that plant extracts with different specifications may be approved differently, i.e. as active substance and as basic substance. The basic substances must not be advertised as a plant protection product and it is up to the Commission and the Member States to put measures into place to inform the public of the respective registrations. A working document on basic substances is available: SANCO/10363/2012.

Linda Sibbes of the Dutch Authority (Ctgb) approached a similar issue from a different angle by talking about the registration procedure of biopesticides. In her presentation microorganisms, botanicals (plant extracts) and pheromones were considered to be biopesticides. Currently regulation 1107/2009 applies to these active substances the same regulatory procedure is as for normal active substances. Data requirements are only different for microorganisms (including viruses), as laid down in Regulation 283/2013 (part B).
The Ctgb has a lot of experience with biopesticides, especially with microorganisms, and most of the new active substances which are under evaluation are now biopesticides. Ctgb has integrated all aspects on biopesticides in a special expert group. Ctgb advises applicants to seek a pre-submission meeting in any case, even if he thinks it is not necessary.

Also, the speaker considers it pertinent for applicants to seek support from a consultant with experience in the preparation of biopesticide dossiers. In any case, a thorough and proper literature search is mandatory, even when the dossier is built on literature. One of the reasons for inadmissibility of dossiers so far, has been a faulty literature search.
Microorganism formulations often contain additional substances in their formulations and the key question to be addressed in an application for authorisation is whether these additional substances are active or not.
With respect to efficacy both, number of tests required are lower and an efficacy below 80 % compared to the reference product are acceptable.

A Dutch initiative has the objective to simplify the authorisation procedure of "green" plant protection products with their low risk to humans, animals and the environment. Currently 10 green plant protection products and two microorganisms are assessed.

The presentation of Cordula Nieslony from BASF was concerned with the registration of seed treatment products. The procedure for approval of the active substance and the seed treatment product is the same as for other active substances and products.
It is important to know that for seed treatment product authorisation, Europe is considered to be one single zone. Unfortunately, in real life dossiers sections differ significantly, for example in the setting of focal species and in different leaching and operator exposure input parameters. In Regulation 1107/2009 article 49, it is stipulated that treated seeds should not be considered as plant protection products. But the treatment of seeds is the application of a plant protection product.
In the new draft seed treatment guidance document are specific risk assessments for e.g. dust drift deposition. The speaker criticised that the standard drift values, which are employed in this specific risk assessment, are based on three studies only, although many more are available. In this new risk assessment the three worst cases are combined leading, in the impact assessment of the ECPA, to the fact that none of the products currently on the market passes the tier 1 of this risk assessment!

Finally, Mariusz Godala of the Bureau for Chemical Substances, Poland, detailed the content of Regulation 1272/2008. The speaker emphasised that plant protection products are not exempted from those CLP requirements. The transition from the original classification under DPD to the reclassification of CLP under the regiment of translation tables was detailed in the slides.

In an example, mixture studies were available with the same parameters that have previously been translated via the tables. It became obvious that there might be discrepancies, mostly overestimating the hazards, if it is derived via the translation table.

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BIOCIDES

A series of interesting documents has been issued in the context of the 59th CA meeting, which can be found on CircaBC (https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp).

We would like to draw your attention to the following:

Practical guides on data sharing

On 23 February 2015, the Commission issued a letter announcing the release of a series of practical guides on "data sharing", "letters of access" and "consortia", which are now available on CIRCA BC as working documents.
These guides are expected to turn out particularly helpful for Small and Medium Enterprises (SMEs). So far, data sharing guidance has only been available for REACH. For biocides, only an explanatory note bridging to the REACH guidance existed.

Extensions in the concept of 'same biocidal products' authorisation

Regulation (EU) No 414/2013 ('the SBP Regulation') provides for an authorisation procedure for a so-called "same biocidal product" (SBP) which is identical to a "reference product" which is already authorised or for which an application has already been submitted.

In the Note for Discussion (CA-March15-Doc.4.7), the Commission supports the interpretation by industry that 'where a same product authorisation is sought for a single biocidal product, the related reference product can be either a single biocidal product or an individual biocidal product belonging to a biocidal product family (BPF) authorisation.'

Where the SBP is linked to an application for a BPF authorisation, a detailed description of the individual product needs to be submitted with such application: e.g. meta SPC to which the product belongs + proposed trade names(s) and specific composition within the ranges of the meat SPC. Data access is only required to data supporting the meta SPC to which the reference product belongs.

The Note for Discussion also clarifies that, as by now, the SBP Regulation is adamant about the areas of authorisation: where the reference BP or BPF has been authorised via Union Authorisation, same biocidal products can only be applied for at Union level, too. In a footnote, however, it announces upcoming discussions at CA meetings with a view to amend the SBP Regulation in that point. A related Note for Discussion was only shortly available on CircaBC. If such an amendment would become real, it could be expected to largely promote ways of cooperation like sublicensing of authorisations from active substance suppliers, or the creation of consortia by SMEs at the product authorisation stage.

Report on fees

The Commission has issued a report (CA-March15-Doc.7.2) on the implementation of Article 80(2) of the BPR, i.e. the setting of fees by the Member States of the EU, Switzerland and the EEA countries Norway and Iceland (hereinafter referred to as the MSs). One important aspect of this document is to determine, to what extent the MSs have followed the recommendations provided in the 'Guidance Concerning a Harmonised Structure of Fees' (see CA-Dec12-Doc.5.1.b - Final).

To that end, the national fees for several standard cases (evaluation of a chemical active substance, for one or more product types; authorization and mutual recognitions of biocidal products and families), also considering annual fees and existing measures supporting SMEs, are compared and discussed.

Besides providing an analysis of the actual levels of fees, the report highlights several interesting conclusions, some of which are:

- Seven MSs are still (18 months after the applicability of the BPR) in the process of adopting their fees legislation, which is stated to be a matter of concern for the proper functioning and delivery of relevant procedures under the BPR.
- A majority of MSs (23) have fees structures in place where 'flat' fees, which are equal for a given type of application, are collected. Depending on the complexity of the application, most of these countries will add top-up fees e.g. for additional product types, comparative assessment etc.
- Nine countries raise annual fees for the registration of authorized BPs, most of them fixed in the range of 100-1200 EURO, while in Sweden the annual fee is calculated based on the previous year's sales and may range from 300-30.000 EURO. However, it is not yet clear, if these Member States' annual fees also apply for products authorized by the Union, for which ECHA will demand annual fees as well.

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CHEMICALS/REACH

Dossier Evaluation: ECHA tightens its practice on dossier updates

In order to increase efficiency and transparency in dossier evaluation, ECHA has published a list of likely cases for compliance checks, focusing on substances dangerous for health and environment. The list will be updated a few times per year; it is only indicative – not exhaustive, i.e. checks of additional dossiers possible. Registrants are advised to check regularly.
The compliance check mainly focuses on eight endpoints:

- Genotoxicity
- Repeated-dose toxicity
- Pre-natal developmental toxicity
- Reproduction toxicity
- Carcinogenicity
- Long-term aquatic toxicity
- Biodegradation
- Bioaccumulation

Important:
Dossier updates submitted after the draft decision has been sent to the registrant for comments will no longer be considered by ECHA. The 30-day period given to registrants to submit comments on the draft decision is not affected. A more flexible approach may on request be taken (e.g. in case of testing proposals for animal studies, read-across resp. categories approach, etc.). The applicable deadlines will be stated in ECHA's draft decision and the notification letter.
Possible outcomes of the compliance check:

1) No action towards the registrant

Dossier actually considered compliant under REACH – additional compliant checks possible.

2) Quality observation letter

Prepared by ECHA e.g. in case questionable information has been submitted and clarification by the registrant needed. ECHA informs MSCAs about these letters.

3) Decision to request additional information

Request on additional testing or other information. This might be accompanied by quality observation letter (2).

In case of non-compliance for more than one information requirement, registrants may receive multiple compliance check decisions to request additional information on the same dossier at different times.
Further details see:
http://echa.europa.eu/en/view-article/-/journal_content/title/echa-tightens-its-practice-on-dossier-updates

New IUPAC Rules - Name your substance correctly

In December 2013 the new *Nomenclature of Organic Chemistry IUPAC Recommendations and Preferred Names* also referred to as Blue Book was published. The most important change is the concept of "Preferred IUPAC Name" (PIN). Further important changes are chain length prior to unsaturation and multiplication over substitution. Now, Al, Ga, In and Tl are regarded as "organic elements" (naming as organic compounds instead of organometallic) and also less trivial names are allowed. Many other more specific changes are also included. These changes have a major impact on the naming of substances. It should be kept in mind that PINs are intended to be used in regulatory documents and legal texts. The increased number of valid IUPAC names for one substance will certainly complicate the communication along the supply chain. SCC can assist you on clarification about substance sameness with regard to IUPAC names.

Public Access to the Meeting documents of CARACAL (Competent Authorities for REACH and CLP)

In the regulatory business it is of key importance to be aware of the current progress and developments regarding REACH and CLP. In the past it has been shown that one may influence the strategic discussions and regulatory progress of the EU Bodies and Member State Competent Authorities at an early stage of the process. Thus, an access to the information ahead of time is crucial. It is not widely known that the access to the CARACAL documents is possible via the CIRCABC (Communication and Information Resource Centre for Administrations, Businesses, and Citizens) platform.

Using the link
https://circabc.europa.eu/w/browse/84998de9-01ff-4434-b566-85367d2fae5b one can gain access to the CARACAL documents published after the respective meetings. SCC regularly monitors the CARACAL dis-

cussions to be aware of upcoming issues as early as possible and to provide you with up-to-date regulatory consultation.

Requirements for the physical - chemical test for classification purpose

Currently MSCA (member State Competent Authorities) ECHA and the industry are discussing about the interpretation of Article 8 point 5 of Regulation (EC) No 1272/2008. There it is stated that: "Where new tests for physical hazards are carried out[…],they shall be carried out, […], in compliance with a relevant recognised quality system[…]". At the 15th CARACAL meeting this issue was controversially discussed. The majority of the MSCA as well as ECHA shared the position that a recognised quality system has to be understood as GLP compliance or at least an accreditation according to DIN/EN/ISO 17025. In contrast, in the view of the industry associations GLP compliance is not necessary to fulfil the obligation of the CLP regulation. The industry argues that GLP compliance for phys-chem hazard tests (e.g. in-house flashpoint test for mixtures) will significantly increase the cost for the industry. No final conclusion was reached at 15th CARACAL meeting. This issue will be discussed again at a future meeting. We will keep you updated.

ECHA is prioritising CMR substances for risk management

On 19 January 2015, the European Chemicals Agency (ECHA) released its "2014 carcinogenic, mutagenic, reprotoxic (CMR) report". This report reveals how notifiers and registrants currently adhere to the harmonised classification of CMR substances and furthermore focuses on identifying potential CMR candidates.
For this report, the authority evaluated the existing registrations and C&L Inventory notifications and concluded that companies are adhering well to the harmonised classification of substances with potential CMR properties. Only about 3 % of notifications for CMR properties are not in line with Annex VI of CLP (Regulation (EC) No 1272/2008) and the responsible companies will soon be contacted by ECHA for further revision of the classifications.
Additionally, while evaluating the C&L Inventory, the authority identified over a thousand CMR substances that potentially merit further regulatory action such as harmonised classification and, where relevant, identification as Substance of Very High Concern (SVHC). ECHA, together with Member State competent authorities, is now prioritising such substances for appropriate risk management actions. The overall aim is to include all relevant substances of very high concern in the Candidate List by 2020.
(The full "2014 CMR report" can be accessed via the following link: http://echa.europa.eu/view-article/-/journal_content/title/echa-is-prioritising-cmr-substances-for-risk-management)

Korea REACH - Existing Chemicals Subjective to Registration

In Korea, the Act on Registration and Evaluation of Chemicals of Korea (also known as "Korea REACH") came into force on 1 January 2015 and will from now on regulate the registration of chemicals. The scope of Korea REACH includes new and existing chemical substances and products by implementing tonnage band depending requirements for registration, hazard evaluation and risk assessment. On 31 October the Korean Ministry of Environment has published a draft priority list of existing chemicals that have been selected for registration under Korea REACH. This list includes 518 chemicals which have been selected based on a number of criteria, including severe hazards as carcinogenic, mutagenic or repro-toxic (CMR) properties or severe effects towards the environment. The final version of this list is expected to be published by June 2015. Once the final list is officially published, the existing substances on that list will have to be registered within the following three years. The Korean authorities are intending to update the list of existing chemicals that will require registration in 2018 and 2021.

Latest developments in Taiwan

The chemical regulation in Taiwan was significantly changed recently.
The "Regulation of New Chemical Substances and Existing Chemical Substances Registration" which is in accordance to 7-1 of the Toxic Chemical Substance Control Act (TCSCA) became effective on 11 December 2014.

Additionally, the "Regulation of New Chemical Substances Registration and Management" which is based on Article 13 of the Occupational Safety and Health Act (Osha) entered into force on 1 January 2015.

The TCSCA based regulation applies to new and existing chemical substances, while the Osha based regulation applies to new chemical substances only.

The requirements for hazard and exposure assessments differ for each regulation, and existing chemical substances, as listed in the Taiwan's Chemical Substance Inventory (TCSI), can benefit from extended registration deadlines after a successful pre-registration.

The registration scheme for new chemical substances includes a standard, a simplified, and a small quantity registration.

For more information, please contact
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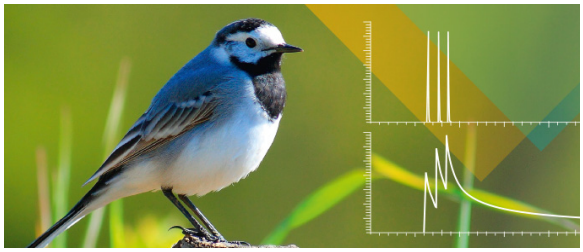
REGULATORY SCIENCE



13th International Fresenius Conference "Pesticides: Food Safety and Dietary Risk Assessment"

The 13th International Fresenius Conference "Pesticides: Food Safety and Dietary Risk held on 18/19 February in Mainz, Germany, brought up some new information and developments in the residue sector for the registration of plant protection products.

The development of an OECD guidance document on rotational crops has been presented. This new guidance document details the tiered approach for assessing residues in rotational crops. On the one hand, the guidance document aims at resolving some unclear points in the new data requirements, namely the definition of persistence in the context of rotational crops triggering confined rotational crop studies (tier 1), the crops to be investigated in limited field studies (tier 2; triggered in case residues of concern > 0.01 mg/kg occur in tier 1) and guidance for extensive field studies (tier 3, triggered by residues >0.01 mg/kg in tier 2). Especially when it comes to extensive field studies, a large study program which could encompass a significant number of trials (up to 40) across 4 geographical regions is under discussion. It was emphasized that although a label restriction would in principle be possible to avoid extensive field trials (tier 3) and possible post-registration monitoring data generation (tier 4); the preferred option should be to perform tier 3 studies to be able to set MRLs for rotational crops. The guidance document is still under development.

Another issue is the new data requirement for metabolism studies in fish. In the guideline (SANCO/11187/2013), two triggers are defined for such studies, i.e. only substances with a log Pow ≥3 are concerned and where the dietary burden for fish is >0.1 mg/kg dry feed. Up to now, no agreed methodology for calculating fish dietary burden was available. In the conference, a dietary burden calculator was presented. This calculator is in development stage and gives a range of different scenarios for a given input value. As the range of scenarios covers often a large span of dietary burden (from clear trigger exceedance to no concern), there is no conclusion on the use of the fish dietary burden calculator yet.

An issue that is constantly and increasingly in the focus is how to deal with metabolites. An authority database (METAPATH) was presented in which all metabolism studies (rat, plant, livestock and soil) will be entered in a defined format. The database will allow generation of standardized tier 2 summaries but also allows searching across all active substances easily identifying common metabolites. Currently, the database is filled with data for rat metabolism but the next priority will be the soil, plant, and livestock metabolism data.

For more information, please contact
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CALENDAR

Biocides Symposium 2015
11-13 May, Ljubljana, Slovenia

The focus of this annual symposium will be on the various processes of product authorisation that are foreseen under the BPR, including Union authorisations and biocidal product families, but also other currently 'hot' topics of, for instance, Article 95, in-situ systems, treated articles and data sharing will be discussed. A broad array of expert speakers from both industry and authorities has been invited, including a keynote presentation from the European Commission.
Dr. Martina Galler, Senior Manager Regulatory Affairs Biocides, and Dr. Stefan Nave, Manager Regulatory Affairs Biocides, will attend this conference and will be available to talk to you about your regulatory needs regarding biocidal active substances and biocidal products. If you intend to set up an appointment, contact us at scc@scc-gmbh.de, please.

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