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NEWSLETTER

SCC Newsletter Vol. 14, No. 4, November 2014

OF COWS, CROPS, AND MAN – INSIGHTS INTO VETERINARY MEDICINE, (AGRO-)CHEMICALS AND MORE

Dear Subscribers,

We are pleased to introduce the new edition of the SCC-Newsletter with news about veterinary medicine, agrochemicals, and other important regulatory areas, e.g. the regulation of pure chemical substances and the finalized EFSA OPEX Guidance.

During the last years SCC has handled various topics related to veterinary medicine. It has often been the case that tasks deal with so-called 'borderline' products those that fall between feed material, feed additives, biocides and veterinary medicinal products. SCC's detailed knowledge of the key guideline for distinction between these materials, namely the European Commission recommendation 2011/25/EU was of benefit for our clients.

To meet future challenges, SCC established additional capacity and hired a senior expert with long lasting experience in the registration of veterinary medicinal products.

With his reputation and SCC's already established expertise, SCC is now also able to support clients from the veterinary pharmaceutical industry with a unique portfolio of scientific and regulatory services.

The timing for the strengthening of this business unit at SCC could not be better: it coincides with the launch of the proposed new legislative framework for veterinary medicines in the EU. You will learn more about the new colleague and the services provided in the field of veterinary medicine on page 2. You will also find a summary of the proposals made by the European Commission for a new regulation on veterinary medicinal products on page 3.

Satisfying our customers is our biggest motivation.

Dr. Friedbert Pistel

IN THIS ISSUE:

SCC´s new Global Office Berlin

To extend our services for our customers, the new "Global Office Berlin" was established in September 2014.

SCC is now able to support clients from the agrochemical sectors with a unique portfolio of scientific and regulatory services combined with short distances to relevant authorities located in/around the main capital of Germany.

You will be able to read more about the Global Office Berlin and the services provided by SCC in some of next issue of the SCC newsletter.

VETERINARY MEDICINE

Introduction of a new colleague responsible for a new business unit at SCC

Herewith I would like to introduce myself. My name is Emmanuel Metz. I am a French Veterinarian graduated from the Veterinary School of Lyon, France. I spent one year of my studies, as well as the research part of my doctoral thesis at the Hannover Veterinary School in Germany. In 1998, I started working for the veterinary pharmaceutical industry. During 3 years, I was responsible for the registration and maintenance of pharmaceutical products at a national level (Germany). During that time, I developed excellent relationships with the German Competent Authorities (BVL), which I maintained over the years.
During the 10th amendment of the German law for medicinal products (10 AMG-Novelle), I submitted updated safety, residue and efficacy parts, including corresponding expert reports for approx. 40 veterinary pharmaceutical products in less than one year.

In 2001, with another veterinary pharmaceutical company, I took over multiple functions and activities of increasing responsibility within Regulatory Affairs, including project management. During that time, I represented Regulatory Affairs in more than 10 R&D project teams and drove 5 projects to complete the licensing process in Europe.
I compiled registration dossiers, also electronically, improved internal procedures for dealing with international packaging material, established and optimized internal procedures for the handling of extended lists of questions for existing products, including requests for new studies.
I was the first contact for CROs (Contract Research Organizations), negotiated prices and established contracts. During that time, I monitored more than 35 residue depletion studies for the defense of veterinary pharmaceutical products.

In 2009, I managed a team of RA professionals located at two different sites (EU&USA), serving as designated points of contact for the registration and regulatory maintenance of pharmaceutical products in about 80 countries outside EU and USA.

When these responsibilities were transferred to another R&D site in late 2011, I accepted new responsibilities in R&D pharma project teams focusing on product registration outside EU/US. In that function, I defined quality, safety and efficacy regulatory requirements and actively participated in Six Sigma projects.

Beginning of this year, I decided to foster new possibilities outside the company and discovered SCC as a reliable and sustainable employer. I accepted the challenge offered to me, i.e. to further develop a business unit within SCC dedicated to veterinary medicine.

We can assist you with full support for the authorization process as a whole or with respect to certain parts of it.

If you are looking for someone to:

- Do a gap analysis of your existing dossiers or parts of them
- Maintain or obtain a Marketing Authorization for your veterinary medicinal products in Europe
- Deal with the national or European regulatory authorities
- Source out and monitor your GLP- and GCP(v)-studies
- Compile and submit your registration files
- Follow up the ever changing regulatory framework
- Clarify whether your product is a biocidal product, feed additive or a veterinary medicinal product

PLEASE CONTACT ME AT
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I am very much looking forward to respond to your requests and discuss your needs in registration and maintenance of your veterinary medicinal products.

Dr. Emmanuel Metz
Head of Regulatory Affairs and Product Development
Veterinary Medicine Group

VETERINARY MEDICINE

A summary of the European Commission's new proposals for the revised veterinary legislation

The European Commission adopted a proposal - currently under discussion - for a new regulation on veterinary medicinal products in September 2014. The trigger for the review came for about 5 years ago following discussions between the European Commission (EC) and the European Parliament during the co-decision procedure for the adoption of the revised legislation governing the establishment of residue limits in foodstuffs of animal origin (Regulation (EC) No 470/2009). The outcome of these negotiations was a commitment made by the European Commission in January 2009 in a communication to the European Parliament to review the legislation for veterinary medicinal products.

This proposal was developed with focus on the needs and characteristics of the veterinary sector, with the objectives to:

Increase availability of veterinary medicinal products;

Reduce administrative burden;

Stimulate competitiveness and innovation;

Improve the functioning of the internal market

Address the public health risk of antimicrobial resistance…

…while safeguarding public and animal health and protecting the environment.

Intention of the new proposal is also to convert all the current rules for veterinary medicinal products into one new regulation, which will be called the "basic act". A regulation applying without transposition into national law will allow direct implementation and prevent disharmonized implementation at a country level.

The current Directive 2001/82/EC, as amended by Directive 2004/28/EC, on the Community code relating to veterinary medicinal products, as well as Regulation (EC) No 1234/2008, as amended by Regulation (EC) No 712/2012 related to variations of marketing authorisations, will no longer apply. Provisions regarding marketing authorisations for veterinary medicinal products will be deleted from Regulation (EC) No 726/2004 laying down the Community procedures for authorization and supervision of medicinal products for human and veterinary use and integrated in this new proposal.

The proposal is divided into 11 chapters and 4 annexes. Only the most important proposed changes are summarised below.

Marketing authorisations – general provisions and rules on applications

The veterinary pharmaceutical market in Europe is a multi-species and a pluri-national market. Nowadays, 13% (538 million €) of the veterinary sector's annual turnover is spent into applications for new marketing authorisations and maintenance of existing marketing authorisations (variations, updates of packaging materials and pharmacovigilance). These administrative tasks are representing 6% of the annual turnover in the human medicine sector.

The highest burden concerns packaging and labeling. The current requirements are that the text must be translated in all the official languages of the country where the product is to be placed on the market. Often, the text on the immediate packaging cannot be combined with other languages, and costs associated with country-specific packaging are too high compared to expected sales in smaller markets, such as Malta or some Nordic countries. The new regulation will propose reduced compulsory information on the packaging and labeling, as well as harmonized pictograms and abbreviations, which might allow combination of different languages on the same packaging and labeling. Member States will have some flexibility as to the languages used.

Protection of technical documentation (nowadays called "data protection") should both benefit innovation and increase availability of veterinary medicinal products and might be extended to a maximum of 18 years. The current ten-year period for the initial marketing authorization, as well as the additional 1 year data protection for any extension of the veterinary medicinal products to another species, remain valid. In order to encourage the animal health industry to develop products for minor species, increased protection of technical documentation will apply: 14 years for the initial marketing authorization for a minor species (with the exemption for honeybees, 18 years) and 4 additional years for any extension to a minor species. To secure extension of data protection, any application for an extension must be submitted at least 3 years before expiry of the data protection period. Also new is that the protection applying to environmental data will be identical to the protection applied to safety and efficacy data. The concept of global marketing authorization will continue to be valid for generic applications.

Further on, requirements for requests for clinical trials, which are currently country-specific within Europe, will be harmonized in the future. In addition, a system will be set up to record and report the use of antimicrobials. The Commission will be empowered to establish rules excluding or restricting the use in veterinary medicine of antimicrobials essential for the treatment of human infections.

Procedures for granting marketing authorisations

There will still be 4 different types of registration procedures (national, MRP, DCP and CP). However, the scope of the centralized procedure will be widened: nowadays mandatory for all veterinary medicinal products derived from biotechnology, it will be accessible to any other types of veterinary medicinal products. More interesting is the proposal to "roll out" marketing authorisations of products registered via MRP/DCP into additional member states as an administrative procedure only (without repeated scientific assessment) in order to increase availability of veterinary medicinal products. The proposal also provides unlimited validity of the marketing authorisations, which will also reduce the existing regulatory burden.

Post-marketing authorization measures

It is proposed to have a single product database for all authorized veterinary medicinal products. National competent authorities will have to upload the information re. national marketing authorisations. It will then be easier for veterinarians to identify the products they might need from other Member States.

For variations, a risk-based approach is proposed: only those changes which substantially affect safety and efficacy will need a scientific assessment by the competent authorities before being implemented. The other variations might be implemented already before notification ("do and tell"). Grouping of variations and work-sharing procedures will be kept as such.

As regards to submission of data, electronic submission will be an obligation in the future.

As regards to pharmacovigilance, a database of adverse events will need to be established by the European Medicines Agency, and will link similar groups of veterinary medicinal products (so-called "signal management process"). Also, product characteristics such as dosage, uses and warnings, of similar products that have been authorized at a national level will need to be harmonized. A difference is foreseen between products considered at low risk (will be subject to administrative harmonization), and those which are more likely to present a risk to animal or public health or the environment (will be scientifically re-assessed).

This harmonization will also increase the availability of generic products in Europe. At any time, member states or the Commission can trigger a re-evaluation of veterinary medicinal products on the grounds that they may pose a risk to animal or public health or the environment. The European Medicine Agency will be asked to prepare an opinion and the Commission will publish a decision which will then apply throughout the EU.

Supply and use of veterinary medicinal products

In order to improve access to veterinary medicinal products, retailers will be allowed to sell products via the internet if they are authorized to supply them in the member state in which the buyer is established. However, member states may impose conditions on supplying veterinary medicinal products to the public via the internet, if based on public health reasons.

The provisions - for the veterinarian - on the use of veterinary medicinal products for species or indications outside the terms of the marketing authorisation – the so-called "cascade" - should also be improved with the new regulation.

The regulation should apply two (2) years after its publication, so that those affected have enough time to adapt. Finally, it is worthwhile to mention that the European Commission does not expect any financial impact on the budget of the European Union, with the statement that "all costs for implementing and applying the new rules will be entirely covered by fees charged to the industry".

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AGROCHEMICALS

Feedback from Industry on the Implementation of Regulation (EC) 1107/2009 and the Zonal Authorisation Procedure

Bernd Brielbeck (SCC GmbH) gave a feedback on the implementation of Regulation 1107/2009 and the zonal authorisation procedure from the view of industry.

In an initial assessment, the workload placed upon the different Member States due to their involvement in the EU active substance review was analysed. In the southern zone an average of 11 evaluations as Rapporteur Member State or co-Rapporteur Member State is placed upon the individual authorities. In reality this workload is higher than indicated by this number, because due to their size and capability Bulgaria, Cyprus, Croatia and Malta are not sharing this burden adequately.

Moving on to the authorisation procedure of Plant Protection Products, Bernd Brielbeck indicated that due to the workload there is currently no zonal Rapporteur Member State accepting a dossier before 2016. This means that the new data requirements will apply and have to be addressed.

The harmonisation level within the southern zone is generally good and where no direct application can be placed, in general mutual recognition is accepted or even the preferred choice to obtain an authorisation for Plant Protection Products. In some countries national language is needed or even mandatory to deal with the authorities. The presentation then visited the individual countries of the southern zone, some points were stressed, for example for Portugal that all communication with the authorities is required to take place in the vernacular. Nevertheless, the authorities are very well organised and give straightforward information as to their regulatory process.

For Spain, knowledge of the local language when making contact with the authorities is highly recommended. At the same time, it is difficult to contact the authorities and get feedback. On many occasions long and significant delays in the evaluation of the dRRs have been observed, even when Spain is acting only as a concerned Member State. Furthermore, Spain is the one country in the southern zone requiring the most translations of dRR parts.
France has shifted its contact and communication in the last few years from accepting French only to a good and competent answering in English. Some delays of evaluations have been experienced, particularly with respect to issuing the certificate of registration by the Ministry after ANSES has finalised their evaluation.

From Italy it was reported that it is difficult to get a meaningful feedback from the authorities with respect to acceptance of the zonal Rapporteur Member State duty.
A reply is often only received without the indication of a possible time frame as to when such a duty can be accepted.
Malta, though not being a significant market, has become a significant, versatile and very communicative zonal Rapporteur Member State. Direct and easy communication in English language is possible. Nevertheless, new applications as zonal Rapporteur Member State are only possible in the second quarter of 2016.
Cyprus also allows direct English communication, but has no possibility at all to act as a zonal Rapporteur Member State.
Greece has had many evaluations ongoing and allows direct communication, also between individual scientists of the authorities and the applicant to solve problems that might arise during the evaluation of a dRR. The Greek authorities are fully booked as zonal RMS until the third quarter of 2016
Bulgaria has shown to be difficult to contact and knowledge of the local language is highly recommendable. A zonal Rapporteur Member State duty might be taken over occasionally, but not on a large scale. The authorities have clearly indicated that their preferred method for registration is mutual recognition.
Finally Croatia, which ascended to the EU on 1 July 2013 also allows very good and direct communication in English, but is not yet up to the zonal procedure and indicates that mutual recognition is clearly the preferred method of obtaining registrations.

A final point, which is not necessarily harmonized, but of great importance is the information that must be given to the concerned Member State when the zonal Rapporteur Member state has completed its evaluation. It depends on the Member State in the individual zones as to how this should be handled. The normal procedure should be that the concerned Member State is informed by the zonal Rapporteur either via email or via CIRCA upload. It has been the experience of Bernd Brielbeck that, in addition, it is helpful and sometimes mandatory that the applicant also addresses the concerned Member State with such information directly.

For more information, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de

BIOCIDES

4th Review Regulation published

On 10 October 2014, Regulation (EU) No 1062/2014 was published in the Official Journal, repealing the 3rd Review Regulation (EU) No 1451/2007. The new Regulation adapts the rules for the continuation of the review programme for the systematic examination of all existing active substances to the provisions of the BPR, by pursuing, *inter alia*, the following goals:

- Simplification of the processes and establishment of stricter deadlines for the evaluating member states.
- To identify the active substance/product-type combinations that may be made available on the market and used under the transitional rules procided by Article 89 of the BPR.
- To enable the inclusion of substances in the review programme where guidance or advice by the Commission or competent authorities had given reason to believe either that the product was not covered by the scope of the BPD or the BPR, or the substance has benefited from the food and feed derogation of the 3rd Review Regulation, or the definition of the respective product types have changed between the BPD and the BPR.
- Further involvement of the Register for Biocidal Products (R4BP) in the review programme and in processes related to the approval of active substances.

Two ECHA decisions on data sharing disputes published

Two decisions on data sharing disputes under BPR have been published on the ECHA website (http://echa.europa.eu/regulations/biocidal-product-regulation/data-sharing/echa-decisions-on-data-sharing-disputes-under-bpr). Both published decisions had a negative outcome for the prospective applicant. However, the decisions may provide valuable insight how both parties, but especially the prospective applicant, should act during data access negotiations. The following key points are emphasized in the decisions:

- Where communication is blocked, both parties should strive “to find alternative solutions and be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that answer, by addressing constructive, clear and precise questions or arguments to the sender;”
- “Each party shall give reasonable time to the other for providing appropriate answers to its questions;”
- […] “When negotiations are substantively progressing and no regulatory deadline is imminent, it is preferable to continue the negotiations;”
- “When negotiations are substantively progressing and no regulatory deadline is imminent, it is preferable to continue the negotiations;”
- "ECHA is never a party in the negotiations. Therefore, all arguments have to be communicated between both parties directly.”

According to ECHA's justification of the decisions, important reasons for the rejections were that the negotiations were progressing, and that no relevant regulatory deadline was imminent (in the present cases, reference is made to the deadline according to Article 95 (2) BPR).

For prospective applicants who feel that data sharing negotiations are progressing excessively slowly, ECHA advises to prepare for the proof, "amongst others, that the prospective applicant has not started the negotiations too late, that he has justified to the data owners why the negotiations must be conducted particularly swiftly, and where the data owner cannot or does not explain day delays that he would be responsible for in reaction to the prospective applicant's explanation."

State of discussion on *in situ* generated active substances

For *in situ* generated active substances, there is still a lack of clear guidance. At the moment, the 'main precursor concept' is under discussion (see CA-Sept14-Doc.4.1-rev1). However, the concept seems to be applicable only to in situ systems using only one main precursor (e.g. electrolysis of a single precursor or activation of a single precursor by mineral acids). For *in situ* systems using two precursors of equal importance, there is no agreement yet.

Additionally, there is a need for clear procedures regarding the proof of technical equivalence or the Article 95 listing for precursors or in situ systems.

Proposal on the new concept of biocidal product families to be discussed

The Commission has published a proposal on the new concept of biocidal product families (Subject: Implementing the new concept of biocidal product families (CA-Nov14-Doc.5.8, to be accessed on CIRCABC). The Commission services invite the CA meeting to agree on the proposal outlined in this paper.

The document is structured in 5 sections addressing

a) Understanding of the elements involved in the new BPF concept,

b) Preparation of the application for authorisation of a BPF,

c) Evaluation of the BPF application by CAs,

d) Content of a BPF authorisation and,

e) Post-authorisation notification of new products.

The proposal provides clarity on the authorities' view on the interpretation of the new definition of a biocidal product family, namely that products within a BPF, in addition to having different composition, can be intended for different uses, including different user categories, and also responding to different risk or efficacy levels. It is even foreseen by the proposal that products within a biocidal product family may belong to different product types (or different combinations of PTs)!

To facilitate describing product families in all their variations appropriately, the concept of "meta SPC" is further illustrated, stating that where the assessment of the maximum risk and minimum level of efficacy for the entire BPF is not possible, that assessment may be done at meta SPC level.

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CHEMICALS/REACH

Extension of the effective date for notification of hazardous substances to German authorities according to §28 (12) 3 ChemG

According to the Federal Law Gazette, Germany (BGBl) No 27/2014 the effective date for notifications according to §28 (12) 3 Chemicals Act of the Federal Republic of Germany (ChemG) was extended to 1. June 2016. From that date onwards according to §16e ChemG manufacturer or importer or reseller that use their own product name, who place a hazardous mixture or a biocide product on the market, have the obligation to conduct a notification to the Federal Institute for Risk Assessment. 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. SCC offers to take care of the notification including data gathering as well as preparation and submission to the authorities

Current development with regard to water hazard class (WGK)

At its meeting on 23 May 2014, the Federal Council has adopted the Regulation of "Systems for handling substances hazardous to water" (AwSV). There are amendments that have been introduced by the Federal Council. The current status (November 2014) is that the Regulation is recommitted to the affected ministries (environment, economy, transport and agriculture).
The agricultural department decline the amendments regarding the arrangement of facilities including liquid manure storing systems. If the federal government does not agree, it is suspected that the entire Regulation could be re-opened again in a long lasting process. If the federal government should adopt the Regulation with the changes, the next step will be the EU notification procedure. It is not expected that the AwSV and with it the new rules for WGK classification will enter into force in 2014. Thus a review of the current WGK classification for substances is not expected to be required in the near future.

Withdrawal of submissions

To withdraw a submission to ECHA, the “cease manufacture” functionality in REACH-IT can be used. Therefore, after logging in into REACH-IT, “Registration/notification” needs to be chosen from the menu and then “cease manufacture” has to be selected. In the next step the registration for which cease manufacture is claimed can be chosen. The application wizard then leads through the functionality. Ceasing manufacture results in updating the registered volume to zero and in marking the registration’s status as inactive (according to Article 50(2) of REACH). This functionality is not only applicable for REACH registration dossiers, but also for all other kind of submission and dossiers like downstream user reports. The term “cease manufacture” is misleading in these cases, but is the only possibility to withdraw such submissions.

ePIC

ECHA developed a new submission system (ePIC) for any tasks related to the implementation of the PIC (prior informed consent) Regulation (EU) No 649/2012, concerning the export and import of hazardous chemicals. The export of such chemicals is subject to two types of requirements: export notification and explicit consent. As the former submission system EDEXIM was closed down in August 2014, ePIC is now the only processing system for all PIC tasks. Please also consult the ECHA website (http://echa.europa.eu/home) for further information. Please contact SCC if you need further assistance with regard to ePIC or the PIC regulation.

European Commission clarified interrelationships regarding REACH requirements and Cosmetic regulations

The European Commission (EC) in cooperation with ECHA has published a fact sheet that clarifies the implications of the Cosmetic Regulations regarding its animal testing and marketing ban in the context of REACH. The new Cosmetics Regulation (Regulation (EC) No 1223/2009) stipulates that cosmetic products are prohibited to be placed on the market in cases where the final formulations, ingredients in a final formulation, or a finished product were tested in animals.
However, following the joint EC/ECHA clarification there is no general exemption from the information requirements of REACH concerning the registration of substances used as cosmetic ingredients. In all cases (mixed uses or only cosmetic uses) the registrant is permitted and/or required based on REACH requirements to perform animal testing for all environmental endpoints. Furthermore, the registrant is permitted and/or required based on REACH requirements to perform animal testing as last resort for human health endpoints in order to perform worker risk assessment. There are only two cases in which no animal testing is required, e.g., the final cosmetic product is imported only or used under strictly controlled conditions. For details please refer to: http://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation

ECHA announcement on the need of OECD 414 test with a second species

ECHA currently clarified the need of an OECD 414 test (pre-natal developmental toxicity test) with a second species for the REACH tonnage band over 1000 t/a. ECHA clearly stated that this endpoint has to be addressed in an Annex X dossier either by a test, a testing proposal or a waiver. This has been currently confirmed by a Board of Appeal decision (A-004-2012).
In parallel ECHA announce to improve and change their technical tools to select substances for compliance check in 2015 with special interest on higher tier toxicity endpoint like reproductive toxicity. Thus, ECHA might (is likely to) be able to check dossiers for an IUCLID entry for OECD 414 second species via IT check. Dossiers without this information will then be considered non-compliant and a Statement of non-compliance (SONC) will automatically be issued by ECHA.

To avoid enforcement by the authorities SCC strongly advices registrants to update their Annex X dossiers and to address the OECD 414 second species data gap properly. SCC can assist you with intelligent testing strategies or waiving concepts.

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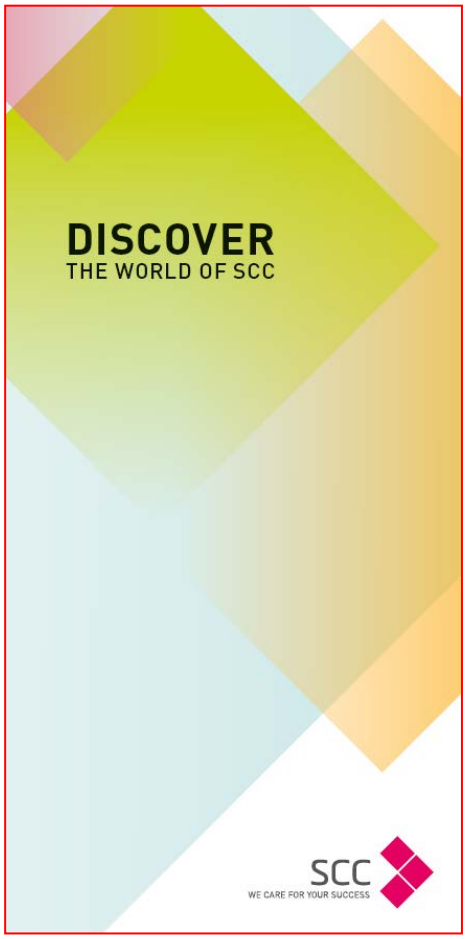
The world of SCC at a glance



Access our website at
http://www.scc-gmbh.de/downloads-scc/brochures

COSMETICS

News on Cosmetics Regulations

Since 11 July 2013 cosmetics in Europe are regulated by Regulation (EC) No. 1223/2009 to ensure a high level of protection of human health. As this regulation is a dynamic feature, it is constantly updated. Since our last newsletter, the regulation was updated twice. The most recent update came into force on 08 August 20014 by Commission Regulation (EU) No 866/2014 amending Annexes III, V and VI. Based on opinions of the Scientific Committee on Consumer Safety (SCCS), preservatives (Alkyl (C12-22) trimethyl ammonium bromide and chlorides, alkyl (C16, C18, C22) trimethylammonium chlorides, citric acid, silver citrate) and the UV filter Tris-biphenyl triazine in its nano-form are regulated with new maximum concentrations in ready for use preparations. The UV filter is not permitted to be used in sprays.

Prior to this amendment, Commission Regulation (EU) No 358/2014 was released on 9 April 2014. This regulation amended Annexes II and V especially with regards to parabens and triclosan. For triclosan, the SCCP considered that its use at a maximum concentration of 0.3% in toothpastes, hand soaps, body soaps/shower gels and deodorants, face powders and blemish concealers and special nail products is safe as well as a maximum concentration of 0.2 % in mouthwashes. Amongst the parabens, isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentylparaben are prohibited in cosmetic products and listed in Annex II. No concerns were raised on the safety of 4-Hydroxybenzoic acid and its salts (calcium paraben, sodium paraben, potassium paraben). The respective maximum concentration in ready for use preparation are 0.4% (as acid) for single ester and 0.8% (as acid) for mixtures of esters.

http://ec.europa.eu/consumers/consumers_safety/ cosmetics/legislation/index_en.htm

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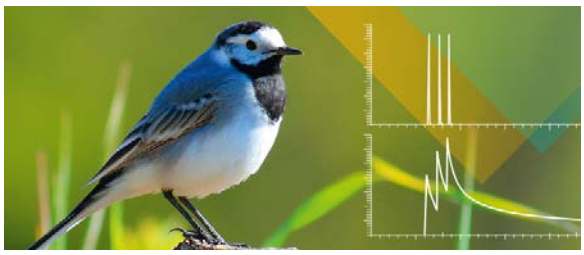
REGULATORY SCIENCE



EFSA has finalised the guidance on human health risk assessment for plant protection products

The “Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products” was accepted 17 October 2014 and published by EFSA on 23 October 2014.

This document is based on a Scientific Opinion on “Preparation of a Guidance Document on Pesticide Exposure Assessment for workers, operators, residents and bystanders” prepared in 2010 and followed by several developments and the revision after public consultation which was held in 2014.

The current EFSA guidance is intended to assist when estimating potential non-dietary, systemic exposures as part of regulatory risk assessment for Plant Protection Products (PPPs). Such risk assessments are needed for all scenarios of exposure for operators, workers, bystanders, and residents that can be expected to occur based on the intended use.

In the guidance document, standardised first tier exposure assessments are available. If a scenario is not covered by these standardized exposure assessments, an *ad hoc*-approach needs to be presented that is judged to be the most appropriate. A higher tier *ad hoc*-approach may also be used for exposure scenarios that are covered by a standardised first tier method. Such a higher tier approach could be justified when a more reliable and realistic estimate of exposures can be provided compared to the standardized exposure assessments.

For PPPs which are acutely toxic, an additional acute risk assessment should be performed for the operator, bystander (covers resident), and worker using normally the 95th percentiles of the data set.

However, a reliable acute Worker exposure assessment is not possible since insufficient data are currently available. The previous concept of an 'Acute Acceptable Operator Exposure Level' (AAOEL) has been removed in the final version of the guidance document due to the lack of an appropriate methodology to derive such a reference value. At present, it is indicated that the acute risk assessment should be performed using the most appropriate reference values without providing more details which is applicable.

In addition to the current guidance document, an exposure calculation spreadsheet was published to enable the exposure assessment of operators, workers, bystanders, and residents.

Reference

EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.
EFSA Journal 2014;12(10):3874,
55 pp., doi:10.2903/j.efsa.2014.3874

Article and Excel calculator:
http://www.efsa.europa.eu/de/efsajournal/pub/3874.htm

Current status of the new EFSA guidance document on bees, bumble bees, and solitary bees in Europe

The EFSA guidance document on bees was also topic at the AgChem Forum in Barcelona in September 2014. Currently, guidelines for bumble bee (acute and semi-field) and honey bee (chronic adult, chronic larvae) studies are under development. Regarding the guideline for honey bee field studies available in the guidance document, the feasibility was questioned (e.g. requirement of a high number of fields and hives in similar landscapes for both control and treated fields, high level of exposure in treated fields required). After the workshop in December 2013, the bee guidance document was restructured and the updated version was published in July 2014. In addition, in June 2014 EFSA provided a draft calculator tool for the screening step and Tier I (SHVAL). The experience of experts was that the tool has coding errors and flaws in the methodology. Therefore, this tool is currently undergoing a review.

In the Standing Committee of the Food Chain and Animal Health (SCFCAH) meeting of the Commission in July 2014, the bee guidance document and the roadmap for the implementation were not voted. Several Member States were against the adoption of the guidance document and concerns were raised to the Commission and other Member States. Thus, the risk assessment for bees remains to be a political issue and it is still unclear if, and if so, to what extent the bee Guidance Document will be modified and when it will be implemented.

New guidance of EFSA

Information on the work and timelines with regard to the EFSA guidance documents and/or scientific opinions were provided by EFSA representatives at the AgChem Forum in Barcelona in September 2014. In 2014, EFSA scientific opinions on good modelling practice and on the risk assessment for non-target plants have been published.
Guidance on emissions from protected crops and on the evaluation of dissipation studies to obtain degradation half-time values in soil has also been published in 2014. In 2015, the soil exposure guidance as well as the guidance on aged sorption are announced. EFSA opinions on the risk assessment are scheduled for 2015 (non-target arthropods and sediment organisms) and 2016 (soil organisms, amphibians/reptiles and effect modeling for aquatic organisms).

For more information, please contact
Dr. Monika Hofer at
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BRAND NEW BROCHURES ON REGULATORY SERVICES OF SCC

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CALENDAR

THE EUROPEAN REACH CONGRESS,
18-19 November 2014,
Düsseldorf, Germany

Dr. Werner Köhl, Head of Chemicals/REACH, Consumer Products, Cosmetics, Feed & Food Additives Group will be participating in that Congress and be available for you. He would be pleased to respond to your requests and discuss your needs in registration and maintenance of your chemical products. You may also contact him upfront at werner.koehl@scc-gmbh.de to set up an appointment during this two-day conference to discuss your specific regulatory needs.
On 19 November *Dr. W. Köhl* will be also giving a presentation on "Evaluation under REACH – general concepts, strategic issues, practical examples" at 9:30 am.
Meet us at THE EUROPEAN REACH CONGRESS
@ Stand No. 26.
For further information please visit the REACH Congress webpage: http://www.reachcongress.com

Biocides 2014 - 17th Annual Conference,
10-11 December 2014,
Vienna, Austria

The conference focuses on key aspects of EU Regulation No 528/2012 regarding the approval of active substances and authorisation of biocidal products. The latest information and advice on application of the EU Biocidal Products Regulation (BPR) will be discussed. Lectures will include the latest developments from COM and EU authorities on the core procedures.
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.
For further information on Biocides 2014, please refer to:
http://www.europeanbiocides.net/index.php/meetings-a-trainings/conferences-a-trainings

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EDITION NOTICE

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