NEWSLETTER

SCC Newsletter Vol. 19, No. 5, December 2019

LOOKING FORWARD TO 2020 – REGULATORY NEWS

Dear Subscribers,

Welcome to the final edition of the SCC Newsletter for 2019.

This issue features relevant information on agrochemicals (*e.g*. parallel trade), biocides (K-BPR), chemicals (*e.g*. nanoforms and registration dossiers), medical devices (class 1 devices), and regulatory science (non-dietary exposure model).

With regard to the current situation in the UK, Britain's Conservatives won their biggest majority since the 1980s in the December election. As a result, they will have a mandate to take the UK out of the EU. In line with that, PM Boris Johnson announced on 13 December 2019 that "*we will get Brexit done on time by 31 January, no ifs, no buts, no maybes*." We will keep you updated on this on-going process; please refer also to the Brexit section of our website for further information.

In the fast-moving world of regulation, SCC is committed to keeping its customers on course for success. We provide high-quality consulting services for your scientific and regulatory needs. Our expertise extends to exposure modelling and risk assessment and covers a broad range of areas, such as agrochemicals and bio-pesticides, biocides, chemicals, cosmetics, consumer products, feed and food additives, food contact materials, medical devices, GLP archiving solutions, and task force management.

We would love to hear what you think about the SCC newsletter, so please do not hesitate to share your feedback and comments with us. Simply send an email to newsletter@scc-gmbh.de.

Finally, all of us here at SCC would like to wish you a joyful festive period with plenty of opportunity to rest and relax before starting the year ahead.

Dr Friedbert Pistel

Content

AGROCHEMICALS

Annual Conference on International Pesticide Registration in Kunshan, China 7 - 8 November 2019

SCC has participated as speaker in the 2019 Annual Conference on international pesticide registration in Kunshan, China. Dr Brielbeck gave a 40 min presentation on the intricacies of European plant protection registration. He emphasised that the procedure in Europe consists of a stepwise approach, approval of the a.s. being the first and the subsequent authorisation of the end use products in the individual Member States via the zonal approach the second step. His slides elucidated that each step consists again of individual sub-steps. To successfully complete the registration of an a.s. or a plant protection product in Europe, it is important to realise that it is not an administrative procedure, but that each step demands continuous attention. He also listed some special issues, such as cut-off, Candidate for substitution and Low Risk criteria and special cases in the process, such as establishing the equivalence of an a.s. and the Mutual Recognition procedure.

Parallel trade

Judgement of the Court of 14. November

The Administrative Court of Appeal for Trade and Industry, The Netherlands requested for a preliminary ruling before the Court concerning the the interpretation of Article 52 of Regulation (EC) No 1107/2009.

The request has been made in proceedings between Vaselife International BV ('Vaselife') and Chrysal International BV ('Chrysal') and the Netherlands Board for the Authorisation of Plant Protection Products and Biocides ('the competent Netherlands authority'), concerning, primarily, the refusal by that authority to renew the parallel trade permit previously granted to Vaselife.

The reason for this legal dispute is as follows:
The company Vaselife applied for the product Vaselife UB a parallel trade permit.
The product Vaselife UB is imported from Italy to the Netherlands and does not differ fundamentally from the reference product VBC 476. Both products were manufactured by the same producer.
The registration holder of the reference-product applied for re-registration, which was granted until 01.12.2025.

Subsequently, an amendment to the approval, as well as the transfer of the registration from the registration holder Sumitomo to the company Chrystal were requested and granted.
The competent Netherlands authority also extended the parallel trade permit until 01.12.2025, relying on Art. 52 of Reg. 1107/2009, since the parallel traded product and the reference are identical and they were produced by the same manufacturer.
Against this decision Chrysal, the authorization holder of the reference product, appealed.
The appeal was granted.
In turn, Vaselife, the holder of the parallel trade permit, filed a lawsuit against this decision.
Chrysal changed the name of the product VBC-476 in Chrysal BVB.
Furthermore, the competent Netherlands authority extended the grace period for the parallel traded product.
Now Chrysal has filed a lawsuit against this decision.

In those circumstances the Administrative Court of Appeal for Trade and Industry decided to suspend the proceedings and to ask the Court of Justice for clarification.

The Court decided as follows:

1. The Regulation (EC) No 1107/2009 must be interpreted as not precluding a national procedure under which, in accordance to Art. 52 of Regulation (EC) No 1107/2009, the competent authority is empowered to adapt the period of validity of a

parallel trade permit to the period of the validity of the renewed authorisation of the reference product.

The adaption of the period of validity of a parallel trade permit does not automatically follow from the decision to renew the authorisation of the reference product, but requires that a decision be taken in this respect. The conditions for obtaining that permit laid down in Article 53(1) to (3) of Regulation No 1107/2009 must be satisfied and it is for the competent authority of the Member State concerned to determine whether that is indeed the case.
According to Art. 52 (3a) of Regulation No 1107/2009 two products are identical even if they are manufactured in two different locations but using the same process provided there is a long-term arrangement between the two manufacturers similar to a licensing arrangement.
In case that the authorisation holder of the reference product and the holder of the parallel trade permit disagree whether the products concerned are still 'identical' acc. to Article 52(2) – (4) of that regulation then the holder for the parallel trade has to submit a new complete application in order to demonstrate that the products concerned are still identical.

Relaunch of BVL website in November 2019

BVL completely revised its website and has the goal to present its website in a new, user-friendly and modern design. In addition, it was a central goal of the redesign of BVL's website to increase the accessibility of the content to consumers. BVL states that its web presence is also optimized for mobile devices and all content can be easily displayed on tablets or smartphones (https://www.bvl.bund.de/SharedDocs/Pressemitteilungen/07_dasbundesamt/2019/2018_11_20_Neue-BVL-Website.html).
However, information relevant for applicants that was summarized and clearly arranged on one screen is now displayed on several screens and more clicks are needed to find the information searched for or can be found at the very end of the relevant web site.
The online data base on approved plant protection products still exists in the old style with the same functions and functionality. When searching for registration reports the user of the website can now find so-called old and new registration reports in the respective data base of BVL. Unfortunately, the display of more than 10 records or a search by first letter of product or active substance is not possible.
It remains to be seen whether further development will also increase the functionality for other users than consumers.

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BIOCIDES KOREA

K-BPR: Preparing for the joint submission together with your consortia members

Did you notify your active substances under the Korean consumer chemical products and biocides safety act (so called K-BPR)? Then you should get ready to prepare the joint submission with your consortia members within the respective deadline. If you look at the list of notified active substances, you will find out that there are (nearly) always several notifiers (consortia members) per substance.

Notified active substances

On 18 November, the Korean government published the list of notified existing active substances, the result of the notifications which were done by end of June 2019 (see our news from 21 Nov. 2019). Through this list, you can check whether your substance is successfully notified, when your approval deadline on active substances is, and who your consortia members are.

The notification period was very short and many applicants thus missed the deadline of 30 June or were not able to properly address all data

requirements. Therefore, a second notification period was implemented starting on 11 December 2019 and ending on 11 December 2019. Based on this survey, a final list of existing active substances marketed in Korea will be published by the MoE (Ministry of Environment) on 31 December 2019 at the latest. From 1 January 2020 onwards, biocidal products and treated articles containing active substances have to be fully approved previous to import and being made available on the market, unless concerned active substances are listed as existing active substances and have been notified for your supply chain, i.e. by your Korean branch or importer(s). If these conditions are fulfilled, specific grace periods according to the respective product type are granted (see below).

Approval plan

If grace periods have been granted to your active substance you should start arranging its approval. In a first step, you should prepare for submitting so called "approval plans" (by end of 2020).

Because of the lack of an Only Representative (OR) function under K-BPR, you should have notified the active substances through your branch office or your importers in Korea (see our news from 29 Nov. 2019). However, the representative - under Korean civil law - will be adopted as the only representative also for K-BPR (so far only under K-REACH). This means you will be able to submit the approval plan through your consulting company. That is good news for the non-Korean companies who do not want to reveal their sensitive information to their importers.

For each active substance which a company wants to have approved, an approval plan must be submitted to NIER (National Institute of Environmental Research) by the end of 2020. It must contain information as to which data requirements can be covered by already available data, for which data points new studies need to be generated and which data points will be covered by justifications, etc. If the applicant indicates that new studies are necessary, he needs to report which test house is performing or going to perform the study and when the results will become available. Furthermore, the applicant must inform when he is planning to submit the final dossier and whether he is going to submit an individual dossier or whether he is cooperating (in a consortium) with other applicants in preparing a joint dossier.

The contents of the aforementioned approval plan can be mostly prepared by DGA (Data Gap Analysis). Fortunately, the data requirements under K-BPR are very similar to EU-BPR. This gives advantages to the European companies, which already have data and experience on EU-BPR. We assume that the study summaries from the EU review (final commented summaries) under the BPR could be used as a basis for the preparation of the K-BPR dossier.

The grace period for getting the approval on active substances is different depending on the product types (uses) of your active substances (see the picture 1 below). For one active substance used in different product types, there can be different grace periods. Please note that the dates in the following picture do not stand for the submission deadlines but for the deadlines by which the active substances must be approved for the respective product types. Regulators familiar with EU-BPR must keep this in mind. It is also worth mentioning that the product types of K-BPR are not numbered as are the product types under EU-BPR.

Picture 1: Grace periods for active substances per product type under K-BPR

How to prepare the dossier for active substances and biocidal products?

There are two kinds of data in both active substances and biocidal products dossiers (see the table below); one is the test-based data set (study reports and study summaries), and the other is non-test based data like risk and exposure assessments.

Study reports written in English can be attached to a dossier in English (no need to have them translated into Korean). If it is written in a third language, it needs to be translated into both English and Korean. Therefore, we advise you to produce study reports at least in English. However, the study summaries in the dossier format must always be in Korean language.

Non-test based data (exposure and risk assessments) should be all in Korean. You may use your European risk assessment data as a basis for preparing the K-BPR assessments in Korean language.

The good news is that, according to our contact in NIER (National Institute of Environmental Research), the risk assessment tool for K-BPR is in preparation but the bad news is that it is still on evaluation, so the public release date is not yet decided. Regarding this point, SCC will monitor the latest developments and keep you up to date.

According to official guidance, the evaluation process of active substances is planned to take at maximum one and a half years. Thus, to meet the deadlines from picture 1 above is highly recommended to submit the dossier at least one and a half years before the grace period expires.

Table 1. Overview on data requirements for active substances and biocidal products

	Criteria	Test data is required?
1	Chemical composition and identification information	Y
2	Physico-chemical or biological properties	Y
3	Exposure information including uses, major exposure routes, exposure type, etc.	N
4	Information on hazards and risk to humans, animals and the environment	Y
5	Effects / efficacy	Y
6	Classification & labeling	N
7	Precaution in handling	N
8	Domestic / overseas use and regulations	N
9	Raw materials and manufacturing process used to manufacture active substances	N
10	Comprehensive data on safety	Partially

What are the obligations for the biocidal products?

The biocidal products have to get approval within 2 years of the active substance approval in the respective product types.

If a product contains several actives which are approved at different deadlines, the approval date of the products depends on the active substance with the latest approval deadline.

NIER estimates that Biocidal product dossier evaluation will take about six months; therefore, you need to submit your product dossier not later than six months before your product deadline. In other words, after timely approval of your active substance, there would be 1 ½ years for generating data and dossier on the respective products.

In case of questions, please contact us. And we will keep you updated on upcoming news.

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CHEMICALS / REACH

What is new in IUCLID 6.4 for nanoforms?

The updated REACH Annexes for nanoforms begin to apply as of 1st January 2020 for all new and the existing registrations that cover nanoforms of substances. So registrants need to update existing dossiers with the nanoform-specific information.

For dossier preparation the new IUCLID Version 6.4.0 is mandatory. It includes additional data fields for reporting nanoforms. To activate these new fields the registrant has to choose the term "solid: nanoform" in Section 1.2 under the field "state/form" from the pick list. It is not possible to submit data on nanoforms with previous IUCLID versions.

In Section 1.2 it is possible to report characteristics of nanoforms like shape, size etc. for a single nanoform, but also a set of nanoforms can be created. For a set of nanoforms a justification needs to be provided and ECHA will check it manually during the completeness check.

Once activated, the new fields for reporting characterisation parameters of nanoforms in Section 1.2 are:

- particle size distribution

Report in IUCLID: D10, D50, D90 values; histogram and table of values, number fraction of constituent particles

- surface functionalization

Report in IUCLD: IUPAC name and CAS or EC No. of each surface treating agent and molar ratio; description of main features of the surface treatment process

- shape

Report in IUCLID: select "shape category" and specific shape of particles from a pick list

- specific surface area

Report in IUCLID: range of specific surface area; skeletal density if volume specific area is reported based on BET

- crystallinity

Report in IUCLID: name(s) or crystal system (s) of the structures; concentration of each crystal structure present

The information provided for **the relevant characterisation parameters in Section 1.2 will be published** unless it is marked confidential. For each parameter reported in section 1.2 corresponding data have to be provided in Section 1.4.
Both Sections should be linked through "related composition".

ECHA has also updated guidance documents[1] to help registrants fulfil the new requirements under REACH.

[1]ECHA Guidance: Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification, Version 1.0, September 2019

ECHA Guidance: Appendix R7-1 for nanomaterials applicable to Chapter R7a Endpoint specific guidance Version 2.0 May 2017

Improving the quality of REACH registration dossiers – Update your dossiers proactively

On 26th November 2019 ECHA presented a webinar 'Improving the quality of your REACH registration dossier – what authorities are planning and how you can prepare'. Most important are the objectives planned by ECHA from 2019 to 2027 for the review of the REACH registration dossier as also described in the Joint REACH Evaluation Action Plan from the European Commission and ECHA launched at the end of June 2019. By 2023 for

substances in tonnage bands above 100 tonnes per year and by 2027 for substances in tonnage bands between 1 and 100 tonnes per year ECHA will have screened all registration dossiers submitted by the 2018 deadline and performed a compliance check for all substances where data gaps prevent from concluding whether there is a concern or whether a substance is of low priority for further regulatory action. In this context, ECHA strongly recommends the registrants to proactively review and update their dossiers. SCC also encourages companies to set up a program for review and update of registered dossier. Please contact us in case you need any support.

In this webinar ECHA also referred to the REACH Action plan for Review and Improvement of REACH dossiers as set-up by Cefic on a voluntary basis with the intention to support the efforts that European chemistry to review and improve their REACH registration dossiers. With this plan Cefic wants to support companies in evaluating existing registration dossiers and implement follow up actions, while keeping close contact with ECHA and its strategy.

In June 2018, Cefic and ECHA signed a Joint Statement whereby they agreed to cooperate to promote a gradual and planned improvement of the quality of the REACH registration dossiers and identify (groups of) specific substances, or scientific and technical challenges, which require expert discussion.

In addition, on 4th December 2019 ECHA published a list of > 21 000 REACH registered substances mapped in the so called “chemical universe” which is divided into five pools depending on the regulatory actions in place, initiated or planned. The “chemical universe” is a tool that helps Member States and EU authorities to focus on substances of (potential) concern and identify appropriate regulatory actions, where needed.

In order to reach the aims of this Action Plan a close collaboration with ECHA, National Associations and other stakeholders will be essential. All its member companies and members of Cefic Member/Associate Federations are invited to sign a “Declaration of Intent” to state their intention to review their REACH registration dossiers, provide further information where appropriate, and keep Cefic informed of dossier reviews. Cefic will collect the feedback and make the progress reports available to the public annually.

More detailed information on the content of Cefic’s Action Plan including a list of all companies that had already joined is available at https://cefic.org/our-industry/reach-dossier-improvement-action-plan/

The slides of the ECHA webinar can be accessed via …(https://cefic.org/our-industry/reach-dossier-improvement-action-plan/).

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MEDICAL DEVICES

Second Corrigendum of MDR (EU) 2017/745: Will class 1 devices get an extension?

On 25 November 2019, the Council of the European Union published a second corrigendum to MDR (EU) 2017/745. The corrigendum includes overall 12 edits, corrections or additions, changing Article 78, 84, 88, 120, 122 and Annex I and III. The most significant change affects class I medical devices, for which the conformity assessment procedure requires the involvement of a notified body. Such devices, for which the declaration of conformity was drawn up prior to 26 May 2020, could be placed on the market or put into service until 26 May 2024. This addition is suggested to Article 120 paragraph (3), which was previously only related to devices that already had been certified by notified bodies. In addition, Article 120 paragraph (4) should be modified to include all products related to paragraph (3). This second change would effectively allow these devices to be made available on the market and put into service until 26 May 2025. The change applies to class I devices, which are sterile, include a measuring function, or are reusable surgical instruments, but

also to medical devices which are classified from class I to higher classes.
Other revisions are about minor or formal changes or clarify EUDAMED transition obligations. Already at the end of October 2019, the European Commission informed that EUDAMED's launch for medical devices will be delayed by two years. It will now be done together with the launch for in-vitro medical devices in May 2022. Already last summer, the European Commission announced that not all modules of EUDAMED would be available in time. (See the SCC news on the MDR implementation of 27 June 2019).
The above changes however do not affect the date of application of the MDR in May 2020. In addition, Article 120 paragraph (3) clarifies that the requirements of the new regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and devices also apply to such devices, which are allowed to be placed on the market without a new MDR certificate until 26 May 2024.
As published by the German BVMed on 18 December 2019, the proposal by the Council of the European Union has been adopted by European parliament on 17 December 2019.

In case you have any questions or need support, please contact
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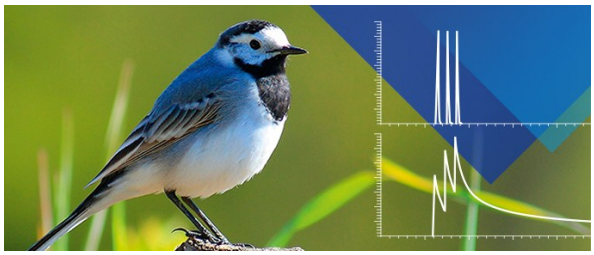
REGULATORY SCIENCE



EFSA exposure model is still under revision – inclusion of home and garden uses is on-going

In the 4th meeting of the EFSA Working Group on preparation of a Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (OPEX 2) held on 28-30 October 2019 in Parma, Italy, the new version of the online calculator was discussed, and further proposals for data entry were developed. With regard to the updated guidance, experts agreed to give further attentions to the updates of the BREAM approaches and to some results of the BROWSE activities. The next meeting of this EFSA Working Group will be in February 2020.

In addition, based on the minutes of the Central Zone Steering Committee teleconference (September 2019), harmonisation assessment of non-professional uses was addressed and with reference to adaptation of the EFSA Opex model to non-professional users, a draft working document was prepared and – followed by a commenting phase - will be used by the Working Group on the adaption of the "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products" so that amateur (home and garden) uses can also be incorporated into the EFSA exposure model.

Both topics were listed on the agenda of the Central Zone Steering Committee teleconference for November 2019.

SCC will keep you informed on the further progress on updating the EFSA exposure model for non-dietary exposure.

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CALENDAR

Risk Assessment Training Course for Biocides – Mainz, Germany
12 - 13 February 2020

In partnership with Chemical Watch, SCC will provide two days of intensive training on biocides with a comprehensive overview of environmental (ERA) and human health risk assessments (HHRA). The course will be held in Mainz on 12 - 13 February 2020.

The training is based on theoretical and practical sessions, explaining the essential principals of ERA and HHRA and demonstrating how to use software tools and models.

This two-day course is designed for environmental and human risk assessors and regulators from industry, authorities and consultancies.

For further information, please download the programme. To register for the training courses, visit the event website.

Do you have any comments, questions or suggestions?
Drop us an E-mail at newsletter@scc-gmbh.de

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