NEWSLETTER

SCC Newsletter Vol. 20, No. 1, April 2020

REGULATORY NEWS

Dear Subscribers,

Please find in this issue relevant information on agrochemicals (PPP with stereoisomers), chemicals (*e.g.* check of registration dossiers, Brexit update), medical devices (impact of COVID 19), and regulatory science (PEC_{soil} modelling).

With regard to the current situation in the EU and worldwide, please note SCC's information on the company's measurements regarding Coronavirus/ COVID 19 on the next page.

In the fast-moving world of regulation, SCC is still 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.

Stay healthy and safe!

Do not miss **our free webinar** on understanding K-BPR and obligations on April 23
and **our temporary online academy** launched in April
(for both events see page 8)

Content

SCC's Information regarding Coronavirus / COVID 19

Dear Subscribers, dear Clients,

SCC is following the COVID-19 situation very closely and has taken immediate action to manage potential health and business risks within our organization.

Our primary focus is to protect the health of our employees, visitors and clients along with their families.

We have taken preventive measures in order to avoid the presence of the virus on our premises. At the same time, SCC management took action to minimize disruption of our services.

We have put in place the following preventive measures:

- Travel restrictions to minimize the spread of the virus
- Minimize direct contact by means of virtual communication methods like webinars, online internal and external meetings
- Provide employees with the technical equipment to enable them to work from home and individualize workplans for the employees whose work cannot be done remotely
- Heightened hygiene controls and prevention measures

Our preventive measures are developed based on national and regional-specific guidance.
We are monitoring the situation in our community along with the official announcements from national and local authorities, and we will be adapting the measures to ensure protection of health of our staff and our clients as well as maintain the service to our clients as much as possible.

Although at present, SCC does not experience any significant effects, this may change if the circumstances worsen. In such case we would inform you immediately should your projects-timeline be affected.

We thank you for your understanding as we manage through this difficult time together.

Kind regards

Dr. Friedbert Pistel
President

Florian Pistel
President

AGROCHEMICALS

Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers – a brief overview from a chemist's perspective

EFSA has published a guidance document on the required information to perform risk assessments of pesticides which have stereoisomers (EFSA Journal 2019;17(8):5804). The document has not yet been endorsed by the PAFF Committee but is likely to be endorsed in March. Stereoisomers, which are mirror images of each other, are called enantiomers. The focus of this article is not on stereoisomers in general (e.g. diastereomers, E/Z isomers) but on enantiomers.
A considerable amount of active substances have stereogenic elements and can therefore consist of several enantiomers. Some pesticides are 1:1 mixtures of two enantiomers (racemates) or have an excess of a specific enantiomer. The ratio of the different enantiomers should be taken into consideration when the risk assessment is performed. This is due to the fact that enantiomers could in principle have different biological activity or toxicity. They might also behave differently in the environment, *e.g.* show different degradation rates. Therefore, enantiomers generally need to be treated as different chemical components for the risk assessment according to the guidance.
If no information on the specific toxicity of enantiomers is available and it is not known if the enantiomeric ratio changes, an uncertainty factor needs to be used in the risk assessment. This factor depends on the number of individual enantiomers of the technical active substance. For example if an active substance is a 1:1 mixture of two enantiomers and no information on the behaviour of the individual enantiomers is available, an uncertainty factor of 2 is to be used in the risk assessment. If the active substance consists of 4 enantiomers (at equimolar amounts) the uncertainty factor to be used is 4. This approach is to be used in all sections and is considered as the worst case scenario, e.g. that toxicity is originating from one enantiomer and that all determined residues consist of this enantiomer. Depending on the available data the uncertainty factor can be adjusted. For example where the toxicity data is only available for the racemate, but it is known that the enantiomeric ratio changes, it is assumed that the toxicity originates from the major enantiomer that is formed in excess. According to the guidance a change of 10% or more in the enantiomeric excess compared to the ratio in the technical material is considered significant.
Further guidance is given on how to assess the required data, especially in cases where information on the individual enantiomers is not available. The primary objective is to reduce the need to repeat studies involving vertebrates. A special case occurs when active substances without any stereogenic element may generate metabolites containing such an element. For these substances, the guidance should not be applied to the active substance but should be applied to assess metabolites that contain a stereogenic element.
The guidance also provides information which data on enantiomers should be generated if new studies are conducted. Depending on the data to be generated, studies must be conducted with isolated enantiomers (*e.g.* to determine the specific biological activity or toxicity of one enantiomer) or with the mixture of enantiomers but with analytical methods able to separate them (*e.g.* in metabolism studies in order to investigate if the ratio of enantiomers changes).

For more information, please contact
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CHEMICALS / REACH

Manual Completeness Check of registration dossiers by ECHA

In parallel to the Technical Completeness Check (TCC), ECHA now also intensifies the Manual Completeness Check of all submitted registration dossiers. The technical completeness of the dossier can be checked using the validation assistant available in IUCLID. In addition, however, there are further issues not covered by the validation assistant but checked manually by ECHA. ECHA explains its focus points in a separate document "Information on manual verification at completeness check" (latest version of 21 February 2020). This document is available on the ECHA Homepage at https://echa.europa.eu/de/manuals under "How to prepare registration and PPORD dossiers". It is thus strongly recommended to thoroughly check the IUCLID dossier for technical completeness by the validation assistant as well as the IUCLID dossier and CSR for compliance according to the latest guidance before submission to ECHA (see also the next article on the revised completeness check).

Revised completeness check: what changes and how you can prepare

ECHA announced a revision of the completeness check with more explicit rules on hazard information in key endpoints and its extension to CSR. It will take effect after the release of the new IUCLID version which is scheduled for end of April 2020. Computer-based checks will ensure that specific requirements are addressed in IUCLID, e.g. for endpoints such as biodegradation, mutagenicity and reproductive toxicity. Moreover, a revised manual and standardized completeness check will check the content of a CSR and the completeness of exposure assessment and risk characterization. The one-to-one match of use and corresponding exposure scenario is very important (presence will be checked, not the quality). Here, CHESAR helps to ensure consistency between IUCLID and CSR. In their webinar “Revised completeness check: what changes and how you can prepare” ECHA also pointed out that CSR “waiving” is valid only under very specific conditions and that e.g. the argument “no relevant release expected” is incomplete without specification / quantification (for details see https://echa.europa.eu/de/-/revised-completeness-check-what-changes-and-how-you-can-prepare).

REACH and nanoforms – practical advices from ECHA

Since 1 January 2020 the new REACH requirements for nanomaterials are in force. Half of the incoming dossiers did not pass the completeness check (status: mid-February 2020). Therefore, ECHA gave practical advice on the preparation of registration dossiers for nanoforms in the recent webinar “Registering nanoforms – practical advice”. This webinar is available on the EUON* homepage (https://euon.echa.europa.eu).
During the webinar, ECHA has reported typical mistakes made by registrants. They especially addressed how to properly define boundaries and report sets of nanoforms in IUCLID 6.4. They also provided a template for waiving Annex VII/VIII information requirements, where no test guidelines are available yet. The template can be found on the ECHA homepage (https://echa.europa.eu/de/regulations/nanomaterials). Furthermore, ECHA gave an overview of test guidelines under development (https://euon.echa.europa.eu/reach-test-

methods-for-nanomaterials) and existing guidance documents.
Once more, ECHA pointed out that importers and manufacturers should get active to ensure a valid registration of their nanoforms. **By 1 January 2020, ECHA only received 10 % of the expected amount of registrations, based on French and Belgian nano-inventories**. Please keep in mind, that if a nanomaterial falls under the scope of REACH, it must have a valid registration. Otherwise, the nanomaterial is illegally on the market. If you need our support on the registration of nanoforms under REACH, do not hesitate to contact us.

*European Union Observatory for Nanomaterials

Brexit Update

Since 1 February 2020 the UK is not a Member State of the EU any more. During the transition period that has been agreed to last until 31 December 2020, current terms of market access and thus EU-UK trade remain unchanged.
What does it mean for businesses operating in the chemicals sector?

- EU REACH continues to apply to the UK (and so the UK will continue to implement REACH decisions but it will not be actively involved as a 'leading authority' any longer)
- All registrations, approvals, authorisations and classifications in place before the UK left the EU on 31 January 2020 continue to be valid.
- UK companies still need to register chemical substances under EU-REACH.

Whereas the legal and regulatory status for all the actors in the chemical industry is clear and reliable (at least) until the end of the year 2020, the outlook into the future EU-UK trade relationship and its impact on the chemical industry are almost impossible to predict at the moment. In their regulatory opening positions prior to entering the expectedly difficult negotiations (published on 3 February 2020), significant divergence between the EU and the UK has emerged. This means that the possibility of a no-deal scenario is not ruled out, in case both sides won't be able to make mutually accepted agreements on the future standards and regulations for chemicals.

Inventory notification period for imports of chemicals into Russia and other EAEU countries ends on 1 May 2020

The implementation of the new chemical regulation for the Eurasian Economic Union (EAEU)* started on 11 November 2019 with the opening of the chemical inventory notification period in Russia. After the initial deadline expired on 1 January 2020, the Russian ministry communicated the extension of the important period until 1 May 2020. Notification of the entire portfolio of manufactured or imported chemical substances ensures that manufacturers and importers benefit from the relatively light obligations for existing substances vs. the expected requirements for any new substances.
The EAEU Technical Regulation "On the safety of chemical products" (TR 041/2017) was published on 3 March 2017 and is planned to come into force on 2 June 2021. The inventory compilation of already existing chemicals is a pre-requisite and necessary first step in order to distinguish between existing and new chemicals. The inventory compilation concerns all circulating chemicals regardless of their tonnage.
This information needs to be submitted online to the ministry portal GISP (in Russian):

- Substance identification information (IUPAC name, CAS and EC numbers, name in English, synonyms), uses/application, annual tonnage, applicant details, customs code, structural formula, classification

We recommend making an inventory notification by 1 May 2020 in order to benefit from the reduced registration requirements for existing substances.
Contact us for more information. info@scc-hq.de
*The Eurasian Economic Union consists of these countries: Belarus, Kazakhstan, Armenia, Kyrgyzstan and Russia.

In case you have any questions or need support, please contact
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MEDICAL DEVICES

European standards for medical supplies made freely available to facilitate increase of production

Due to the COVID-19 crisis, the European Commission is working with industry and Member States to maximise the availability of masks, gloves, gowns and other medical supplies.

“Upon the urgent request of the Commission, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), in collaboration with all their members, have agreed to immediately make available a number of European standards for certain medical devices and personal protective equipment. This action will help both EU and third-country companies willing to manufacture these items to swiftly start production and place products on the internal market more easily while ensuring a high degree of safety”.

(Press release of the European Commission)
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_502

The standards are available for free download from the websites of CEN national members.
https://standards.cen.eu/dyn/www/f?p=CENWEB:5:::NO:::

Companies interested in producing medical devices or personal protective equipment and looking for additional support with respect to safety and performance requirements of medical devices are invited to contact Dr Alexander Theis.

12 months delay in the implementation of the medical device regulation?

Stella Kyriakides, the EU health and food safety commissioner twittered on 25 March 2020: "Vital devices needed to treat #COVID19 patients must remain available on EU markets. For that reason, at the @EU_Commission, we are working to put forward a proposal to delay the implementation of the new medical devices Regulation by 12 months."

On 3 April 2020, the proposal for the delay of the implementation of the new MDR has been published.

In the proposal, all dates referring to the original implementation date of 26 May 2020 have been replaced by 26 May 2021, with exception of the preparation of the guidelines on phthalates. In addition to keeping the requirements for existing devices, this allows placing new or modified medical devices on the market under the Directives 93/42/EEC and 90/385/EEC up to this new implementation date next year.

The deadlines for placing the UDI on the device and packaging, which were scheduled further in the future, remain unchanged.

The proposal also suggests implementing Article 59 of the MDR (EU) 2017/745 prematurely, which allows the Commission to extend, in exceptional cases, the validity of a national

derogation for a limited period of time to the territory of the EU. The national derogations in Article 59 are intended to authorise the placing on the market of medical devices for which the relevant conformity assessment procedures have not been carried out, but the use of which is in the interest of protection of health.

At this moment, the delay of the MDR (EU) 2017/745 implementation is only a proposal by the European Commission, and has not yet been adopted by the European Parliament. We will keep you informed about further development. If you have questions with respect to the impact of the proposal on your company, please contact Dr Alexander Theis.

https://twitter.com/SKyriakidesEU/status/1242785168966004739?s=20

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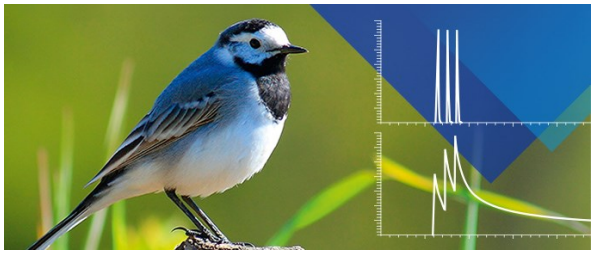
REGULATORY SCIENCE



New PERSAM version 3.0.0 for PECsoil modeling – waiting for updated versions of PEARL and PELMO for modeling Tier 3

The updated PERSAM software (version 3.0.0.) for calculation of PEC soil according to the EFSA Guidance Document (EFSA GD for predicted environmental concentration of active substances of plant protection products and transformation products of these active substances in soil, 2017) has been published together with an update of the user manual in December 2019. Diverse updates have been included in the new version, *e.g.* upgraded spatial data, including new maps for permanent crops and selection option for zonal or national assessment. Another new feature is the possibility to conduct PEC calculations for microbial active substances. The PERSAM tool itself is able to provide results for Tier 1 (predefined scenarios for annual and permanent crops based on their total area in a regulatory zone without the assumption of plant interception) and Tier 2 (implemented crop specific areas and interception of plants). The selection of a worst case scenario for the calculation of Tier 3 is part of PERSAM. The resulting transfer file is planned to be used for numeric Tier 3a modeling in PEARL or PELMO. For both numerical models updated versions are expected soon which will enable the use of those transfer files as input.
For the higher tier approach 3B (assessment based on spatial distributed numerical models) no officially supported modeling tools are intended.
The PECsoil guidance is not yet implemented by European Commission.
The PECsoil guidance does not provide information on the relevant focused soil depth, the information given on an information session on the PECsoil guidance held by EFSA in Parma last year is to stick to the 5cm depth until guidance on risk assessment of Plant Protection Products for in-soil organisms has been finalized.
All in all, there is substantial uncertainty regarding PECsoil derivation in the nearby future: both, regarding the most appropriate modeling approach for upcoming submissions as well as the resulting values when using the new EFSA GD.
SCC will keep you informed on the further progress on updating the models and the adoption of the EFSA Guidance Document for PECsoil by Commission.
Please get in contact to hear our ideas and make use of our skills for developing a forward-looking strategy for the soil risk assessment of your PPP.

For more information, please contact
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CALENDAR

Webinar on understanding K-BPR and obligations 23 April 2020, at 9:00 GMT (10:00 CET)

Join us for the free webinar on ***Understanding K-BPR and Obligations***, hosted by Chemical Watch and scheduled on 23 April, 9:00-10:00 GMT (10:00-11:00 CET).

Ji Yeong Kim, SCC's Asia Regulatory Affairs expert, will give an outline of the K-BPR and related regulations and speak of obligations for importers of biocides. She will specifically focus on the following topics:

- Differences between EU-BPR and K-BPR
- CCA, K-OSHA and K-REACH obligations for active subtance importers
- How to prepare an Approval plan by using EU data

Ji Yeong looks forward to welcoming you to the upcoming webinar on K-BPR!

"Temporary Online Academy"

We are happy to invite you to our "Temporary Online Academy" on plant protection registration and related issues.

We would like to provide you with short, daily articles on various issues of the plant protection regulatory framework and related legislations. Regulation 1107/2009, NAS/EAS,MR, CAT4, AIR, GLP, Article 43 - to name but a few.

We will run our Academy until the worst of the COVID 19 crisis is over ...unless, of course, your feedback is such that we will continue with pleasure.

Stay safe!

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