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NEWSLETTER QUICK NEWS

SCC Newsletter Vol. 18, No. 1, February 2018

ECHA PROVIDES SOLUTIONS FOR INCOMPLETE REACH DOSSIERS

Dear Subscribers,

On a short track we inform you about the following important issues concerning

CHEMICALS / REACH

ECHA PROVIDES SOLUTIONS WHEN REACH DOSSIERS ARE INCOMPLETE BY THE REGISTRATION DEADLINE

On 15 December 2017, the directors contact group (DCG) discussed how to help registrants when facing the problem that data required for the REACH dossier will not be ready for submission until 31 May 2018.

The proposed solutions for companies being in such exceptional circumstances can be found following this link. The proceedings how to benefit from these solutions were published by ECHA in a press release on 31 January 2018 in the course of the ECHA stakeholders' day and can be found here.

In case a company cannot provide a complete REACH Annex VII or VIII data set until 31 May 2018 through no fault of its own, a claim being an exceptional case can be filed.

ECHA defines prerequisites in order to benefit from this procedure:

- exhaustive list of reasons that prevent the registrant from submitting the required data;
- the missing test(s) must have been ordered before 31 March 2018;
- the SIEF members must have communicated with one another about the situation.

The complete notice can be found here.

In case a company can provide documentary evidence for the three prerequisites an enquiry needs to be sent to ECHA via the helpdesk.
The enquiry must have been submitted before dossier submission and by 24 May 2018 at the latest. Thereafter, ECHA will send an acknowledgment of receipt and instructions on how to proceed. The lead dossier of the joint submission will not pass the completeness check but ECHA may grant a reasonable time period to complete the dossier.

This solution has the potential to reduce the time pressure for all parties involved (CROs, lead and member registrants) but bears some uncertainty, *inter alia*, due to the wording used within the ECHA note, *i.e*. "*ECHA may grant*" or "*that it is at ECHA's sole discretion to grant or to decide otherwise*".

SCC recommends initiating the following actions as soon as possible in case you intend to benefit from ECHA's aforementioned solutions:

Firstly, one should inform the SIEF about the expected delay and about the intention to involve ECHA in this case.
Secondly, one should get into contact with the CRO(s) and request a written confirmation about the delay on the commissioned test(s) for a specific substance and a binding timeline for the completion of the test(s). We assume that only such a detailed letter will be accepted by ECHA.
Thirdly, one should prepare a statement summarising the reasons for the delay (in case the delay at the CRO is not the only aspect). This data should be compiled in a timely manner and submitted to ECHA as soon as possible.

Whether the ECHA solutions should be used depends on the specific circumstances of each substance and should be carefully assessed.

In case of any further questions, please contact Dr Thomas Roth, Head of Chemical Department (thomas.roth@scc-gmbh.de).

LINKS:

https://echa.europa.eu/documents/10162/23556156/171219_dcg_four_solutions_en.pdf/9451fa44-266c-74d5-40d9-8beebd0e5c8b

https://echa.europa.eu/-/helping-registrants-in-exceptional-cases

https://echa.europa.eu/documents/10162/23556156/notice_on_all_issues_en.pdf/ec2d7daf-4517-1d01-1f85-87a5eac911bd

RESTRICTION PROPOSAL FOR THE USE OF FORMALDEHYDE AND FORMALDEHYDE RELEASERS

In accordance with REACH Article 69 (1), the European Commission – represented by the DG Internal Market, Industry, Entrepreneurship and SMEs and the DG Environment – requested ECHA to prepare a restriction proposal for the use of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses.
In addition, ECHA was asked to gather existing information on the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses (please find the official letter here).

The background and justification for the restriction proposal is the preliminary assessment from ECHA which was published in a report on 15 March 2017 (click here).

ECHA submitted its intention for the restriction proposal on 11 January 2018. Within 12 months after the entry into the registry of intention (RoI), ECHA will finalise the Annex XV dossier.

During this time period ECHA is collecting risk and socio-economic information and thus, requested stakeholders to provide any relevant information.

ECHA indicated that this information will be used to determine if any derogation will be required.

We strongly recommend to check if your substances will be affected by this restriction proposal and if so to provide relevant data to ECHA.
In case ECHA concludes that a restriction proposal is justified and an Annex XV dossier will be filed, we recommend to prepare for the public consultation process in parallel.
During the public consultation industry can argue against the restriction proposal but this needs to be accompanied by a full risk and socio-economic justification.

The efforts to prepare such justifications are much higher compared to efforts usually needed during ECHA's data gathering process.

LINKS:

https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

https://echa.europa.eu/documents/10162/13641/formaldehyde_review_report_en.pdf/551df4a2-28c4-2fa9-98ec-c8d53e2bf0fc

For more information, please contact
Dr Thomas Roth at
thomas.roth@scc-gmbh.de

CALENDAR

In-cosmetics Global 2018 in Amsterdam, The Netherlands
17-19 April 2018

We are happy to announce that SCC will be present at in-cosmetics Global 2018, taking place in Amsterdam in April 2018.

The exhibition is the global launch place for innovation in ingredients and technologies, providing high-level scientific education and consumer insights for formulators, R&D and regulatory professionals. For more information, please visit the event website.

Dr Mathias Rietzel-Röhrdanz, Senior Manager Regulatory Affairs, will be happy to welcome you at our *stand No. K154* in the Testing and Regulation Zone. Mathias has long-standing international hands-on experience in the cosmetics field and looks forward to discussing with you about company's support needs for cosmetic technologies, ingredients and products.

Click here to request a meeting with our expert at in-cosmetics Global 2018 in Amsterdam.

The 5th ECPA Regulatory Conference in Brussels, Belgium
7 - 8 March, 2018

Please meet
Dr Monika Eder, Senior Manager Regulatory Science – Residues, Consumer Risk Assessment,
Dr Norbert Weissmann, Senior Manager Regulatory Affairs – Agrochemicals and Biopesticides - Efficacy,
Dr Joachim Kranz, Manager Regulatory Affairs – Agrochemicals and Biopesticides – Efficacy,
at the **5th ECPA Regulatory Conference,** taking place in Brussels on 7 - 8 March, 2018. For more information, please visit the event website.

We are pleased to invite you to join us for the workshop on ***Product Efficacy and Precision Farming***, which SCC is sponsoring this year. Norbert will chair the workshop in which experts from CNH Industrial, BASF, Syngenta, EPPO/MUCF and SCC will provide first hand information on two important areas:

How will precision farming technology revolutionise the agricultural production and how can this new technology be used to refine the pesticide registration process. The second focus of the workshop will be on the current and future challenges to simplify efficacy evaluations. Please use this chance to approach our experts regarding any challenges you might be facing with registration of Agrochemicals and Biopesticides or any regulatory or scientific question you would like to ask them.

Click here **to request an individual meeting with our experts** at the ECPA & ECCA Regulatory Conference 2018.

Risk assessment for biocides – Training course in Berlin, Germany
27 - 28 February 2018

We are pleased to invite you to a training course brought to you by Biocides Hub in partnership with SCC on Risk Assessment for Biocides, taking place in Berlin on 27- 28 February 2018.

The training course focuses on providing a comprehensive overview of environmental (ERA) and human health risk assessments (HHRA) based on theoretical and practical sessions, including the use of software tools and models. In the changing landscape of the regulatory requirements for ERA and HHRA it becomes more and more challenging for the industry to stay up-to-date and meet constantly rising standards.

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 or visit directly the event website.

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

CONTACT DETAILS

SCC Scientific Consulting Company
Chemisch-Wissenschaftliche Beratung GmbH

Dr Friedbert Pistel, President

Headquarters Bad Kreuznach

Am Grenzgraben 11
D-55545 Bad Kreuznach
Tel. +49 671 29846-0
Fax +49 671 29846-100
info@scc-hq.de
www.scc-gmbh.de

Office Berlin

Dr Achim Schmitz
Branch Manager SCC Office Berlin
Senior Expert Ecotoxicology
Tel.: +49 30 2592-2569
achim.schmitz@scc-gmbh.de

Address
Friedrichstraße 40
D-10969 Berlin

Liaison Office Japan

Coordinator Agrochemicals & Biopesticides, Pharma, Pre-Clinical
Mr Toshiyasu Takada
Director Agrochemicals and Biopesticides
toshiyasu.takada@scc-japan.com

Coordinator Chemicals/REACH, Biocides and other services
Mr Kozo Inoue
Director Chemicals/REACH, Biocides and other services
kozo.inoue@scc-japan.com

Chemicals/REACH and OR Services
Mr Kenji Makita
Senior Consultant
kenji.makita@scc-japan.com

Chemicals/REACH, Biocides and other services
Mr. Takashi Nishimura
Senior Consultant
takashi.nishimura@scc-japan.com