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NEWSLETTER

SCC Newsletter Vol. 18, No. 4, October 2018

REGULATORY NEWS

Dear Subscribers,

Welcome to the latest edition of the SCC Newsletter.

We start this issue with an announcement: Due to increasing levels of interest in international registration services among our Japanese and European customers in recent years, we have taken our next decisive step and opened *SCC Scientific Consulting Company Japan*, which was officially founded on 30 July 2018 this year on the basis of our Liaison Office Japan. We are delighted to announce that **Mr Atsushi Ohtaka** has been appointed as head of SCC Japan to offer regulatory support under the Chemical Substance Control Law (CSCL) and the Industrial Safety and Health Law (ISHL) in Japan; read more about the Representative Director in the related article. We look forward to guiding your products through their journey to successful registration, whether in Europe or the Asia-Pacific region. To find out more, flip through to the article on our international services, which presents the latest developments from SCC in the Asia-Pacific region.

We would also like to draw your attention to a guest contribution on the A*uthorisation of a plant protection product in the zonal authorisation procedure* written by **Dr Alexander Koof** (Lawyer at the law firm Koof & Kollegen, Germany).

With regard to the important issue of endocrine disruption the plant protection products criteria will apply from 10 November 2018 onwards. This change will affect all active substances in the renewal process and all active substances scheduled for renewal in the future. This issue includes a brief report on 'Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption'. SCC is a dedicated and experienced partner who can help you assemble all of the required evidence. We will support you in gathering, evaluating, and compiling all of the information required for establishing whether the ED criteria are fulfilled.

This issue of the SCC Newsletter also includes articles containing important information on the fields of agrochemicals, chemicals, and regulatory science.

Following its decision to leave the European Union (EU), Great Britain is nearing the final straight of Brexit (the UK is scheduled to leave the EU on 29 March 2019). But what precisely will happen on Brexit day, what kind of deal, if any, Britain will depart with, and the final destination of the negotiations remain to be seen. Following talks with European leaders in Brussels, Theresa May stated in October that 95% of the Brexit deal had been agreed. However, the issue of the Irish border remains unresolved. The UK and the EU both agree that a backstop is needed – both parties signed up to this idea in December 2017. Ultimately, if no compromise is reached and there is no backstop, there will be no Withdrawal Agreement and no transition period – which will inevitably mean a hard Brexit. Please refer also to the article on the guidance on chemicals regulation in case of 'no deal' Brexit, published by UK in this month.

In the fast-moving world of regulation, SCC is committed to keeping its customers on course for success. We provide high-quality support and consulting services for your scientific and regulatory needs. Our expertise includes exposure modelling and risk assessment and extends over a broad range of areas, including agrochemicals and biopesticides, biocides, chemicals, consumer products, feed and food additives, 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.

Please contact us by email at newsletter@scc-gmbh.de.

Dr Friedbert Pistel

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GUEST CONTRIBUTION - Dr. Alexander Koof, Koof & Kollegen, Germany

Authorisation of a plant protection product in the zonal authorisation procedure: limited examination competence of Germany as cMS

Dr. Alexander Koof*

In November 2016, the Administrative Court of Braunschweig issued a landmark ruling on the mutual recognition procedure according to Article 40 et seq. Regulation (EC) No. 1107/2009 (Administrative Court of Braunschweig, Judgements of 30 November 2016, 9 A 27/16 and 9 A 28/16). Recently the court issued a further landmark ruling on the system of zonal authorisation according to Article 36 Regulation (EC) No. 1107/2009 (Administrative Court of Braunschweig, Judgement of 12 April 2018, 9 A 44/16). In addition to some questions of procedural law, the system of zonal authorisation in particular was specified in more detail.

I. Zonal Authorisation Procedure

The court stresses, that in the zonal authorisation procedure, the applicant proposes to the Member States of a zone which Member State (so called zonal Rapporteur Member State or zRMS) should examine the application. If this proposal is complied with, the applicant shall apply to that Member State for a zonal authorisation and indicate in which other Member States of the zone he also intends to apply for authorisation (Article 35 Regulation (EC) No. 1107/2009).

The other Member States within the zone to which an application is to be submitted are the so called concerned Member States (cMS). In addition to the application to the zRMS, the applicant submits the application for admission to all cMS simultaneously. Documents to be attached to the application are listed in Article 33 Regulation (EC) No. 1107/2009.

The application is then examined by the zRMS in accordance with Article 35 (1) Regulation (EC) No. 1107/2009. According to Article 36 (1) Regulation (EC) No. 1107/2009 the zRMS shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge on the basis of all guidance documents available at the time of application. It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29 (6) Regulation (EC) No. 1107/2009, to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 Regulation (EC) No. 1107/2009 in the same zone, where used in accordance with Article 55 Regulation (EC) No. 1107/2009, and under realistic conditions of use.

According to Article 35 sentence 4 Regulation (EC) No. 1107/2009 the cMS shall refrain from proceeding with the file pending assessment by the zRMS. The zRMS shall then, in the course of the evaluation, prepare a draft Registration

Report (dRR) in a format agreed between the Member States. This draft will then be sent to all Member States of the zone for comment (Article 36 (1) sentence 2 Regulation (EC) No. 1107/2009). At the end of the commenting period, the zRMS draws up the Final Registration Report (RR) taking into account the comments of the Member States and decides on the authorisation of the respective plant protection product. Then the zRMS sends the Final Registration Report and its admission decision to the other Member States in the same zone. The cMS shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the zRMS decide on the application as

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referred to Article 36 (2) and (3) Regulation (EC) No. 1107/2009 (see Article 37 (4) Regulation (EC) No. 1107/2009).

1. 120-Days-Deadline

The court stresses that according to Article 34 (4) Regulation (EC) No. 1107/2009 the 120-days-deadline begins with the receipt of the assessment report and the copy of the authorisation of the zRMS, rather than upon receipt of a translation of the authorisation in German, as this is not a mandatory part of the documents to be submitted within the framework of the zonal authorisation procedure.

Please be aware, that this is different in the mutual recognition procedure according to Article 40 Regulation (EC) No. 1107/2009. According to Article 42 (1) lit. a) Regulation (EC) No. 1107/2009 in the procedure of mutual recognition the applicant shall provide a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application. In Germany, a translation into German is generally required because according to Section 23 Administrative Procedure Act (VwVfG) the official language is German. However, the BVL currently also accepts a translation into English. Please be aware, that this may change in the future.

2. No reason for refusal according to Article 36 (3) Regulation (EC) No. 1107/2009

The court clarifies, that the applicant has not automatically a right to claim an authorisation solely with expiry of the 120-day period of Article 37 (4) Regulation (EC) No. 1107/2009. The legislator has not attached a specific legal consequence to a Member State of the European Union exceeding the specified processing deadline. Accordingly, the expiry of the period may not give rise to any claim for authorisation or preclusion on the part of the Member State for reasons which it has not invoked within the period. Failure to reach a decision on an application in due time may at best be relevant for asserting a claim for damages due to loss of profit.

However, a claim arises from the fact that the requirements of Article 36 (3) Regulation (EC) No. 1107/2009 are not applicable. According to Article 36 (2) Regulation (EC) No. 1107/2009 the cMS shall grant or refuse authorisations on the basis of the conclusions of the assessment of the zRMS. Notwithstanding Article 36 (2) Regulation (EC) No. 1107/2009 and subject to the Community law, appropriate conditions may be laid down with regard to the requirements referred to in Article 31 (3) and (4) and other risk mitigation measures derived from the specific conditions of use. Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has legitimate reasons to assume that the product in question still poses an unacceptable risk to human or animal health or the environment.

3. Limited scope of cMS audits

The court makes it clear, that according to Article 36 (2) Regulation (EC) No. 1107/2009 the cMS is obliged, with the exception of cases within the meaning of Article 36 (3) Regulation (EC) No. 1107/2009, to grant or refuse authorisations on the basis of the conclusions of the assessment by the zRMS. In principle, the cMS has no further competence to examine the decision of the zRMS. Germany, as cMS, is therefore neither

authorised nor obliged to check the legality of the reference authorisation. This already follows from the wording of Article 36 (2) Regulation (EC) No. 1107/2009, which expressly stipulates that the cMS grant or refuse authorisations on the basis of the conclusions of the assessment by the zRMS. The Regulation (EC) No. 1107/2009 does not provide for the possibility of an examination going beyond the examination competence referred to in Article 36 (3) Regulation (EC) No. 1107/2009. It would have been up to the legislator to standardise further examination competence for the cMS, but it did not make use of this. The purpose of the zonal authorisation procedure is precisely to ensure that the cMS involved do not carry out their own examination of all the conditions for authorisation, but base their own decision on the examination already carried out by the zRMS. According to the recitals and the purpose of Regulation (EC) No. 1107/2009, its purpose is not only to provide a high level of protection for human and animal health and the environment, but also to ensure the competitiveness of agriculture, to harmonise authorisation practices within the Community, and to accelerate and improve efficiency.

The common European system for the authorisation of plant protection products is based on the principle of mutual trust in so far as all countries involved respect the requirements laid down in Regulation (EC) No. 1107/2009 and ensure a high level of protection. This leads to the assumption that the processing of applications for authorisation for plant protection products in each Member State complies with the requirements of the Regulation (EC) No. 1107/2009.

The purposes of the Regulation would not be achieved if the cMS would or should carry out a full legality check of the reference authorisation.

The court makes it clear, that the exceptions set out in Article 36 (3) Regulation (EC) No. 1107/2009 are the only grounds on which a cMS can rely in order to refuse the recognition of an authorisation granted by the zRMS. The zonal authorisation procedure therefore leaves no room for refusal to authorise a plant protection product for reasons other than those mentioned in Article 36 (3) Regulation (EC) No. 1107/2009.

4. No committal in case of systematic violations

However, the presumption that the processing of applications for authorisation for plant protection products in each Member State complies with the requirements of Regulation (EC) No. 1107/2009 can be rebutted. A rebuttal of the presumption, however, is made extremely difficult due to the important purposes of the Common European System. Therefore, not every deficient examination and not every infringement of the requirements of Regulation (EC) No. 1107/2009 is sufficient to confer examination competence on the cMSs. In any case, as long as it does not appear that a reference Member State systematically violates the legal provisions to be observed in the respective authorisation procedure, there is no room for a further review in the national authorisation procedure.

Please be aware, that Germany is already collecting respective violations by other Member States.

5. Refusal according to Article 36 (3) Regulation (EC) No. 1107/2009

The court stresses, that a refusal according to Article 36 (3) Regulation (EC) No. 1107/2009 should be an exceptional ultima ratio. For a refusal of an authorisation, all conditions of Article 36 (3) Regulation (EC) No. 1107/2009 must be fulfilled. In particular, risk mitigation measures should be examined. A total refusal is therefore only possible if the establishment of such risk mitigation measures cannot address the existing

concerns with regard to human or animal health or the environment. The refusal of authorisation can only be justified in the light of “specific environmental or agricultural circumstances”. In addition, the Member State must have “legitimate reasons to assume” that the product in question still poses an “unacceptable risk” to human or animal health or the environment.

Regarding the criterion for the risk assessment, the court stresses that the cMS must have legitimate reasons to assume that the product in question still poses an “unacceptable risk” to human or animal health or the environment. For this, it is not necessary to prove that unacceptable risks exist, only to present a "legitimate reason to assume" that they do. However, a legitimate reason for such an assumption is more than just a mere presumption. The exceptional provision of Article 36 (3) Regulation (EC) No. 1107/2009 cannot already be used in cases of suspicion and an uncertain scientific basis. Fears and suspicions alone are not enough. The identification of a potential risk, which ultimately has not yet been examined in studies, does not reach the threshold of a “legitimate reason to assume that unacceptable risks exist”. If an authorisation has been granted by the zRMS, the deviation from this fundamental decision cannot be made on the basis of suspicion and reference to data gaps. Any data gaps cited by cMS that prevent a more precise risk assessment (to the extent of identifying legitimate reasons for unacceptable risks) must be closed by the Member State that relies on the exemption in Article 36 (3) 2 Regulation (EC) No. 1107/2009. Even if the precautionary principle pursuant to Article 1 (4) of Regulation (EC) No. 1107/2009 applies in an authorisation procedure, the exception is not to be interpreted in such a way that the possibility of an unacceptable risk should already be ruled out by the refusal of authorisation.

In addition, the court clarifies that the high hurdles of the exceptional circumstances cannot ultimately be cancelled out by the zRMS itself by any opening clauses and the transfer of further examination competences. The scope of the examination competences under the Regulation is not in the hands of the zRMS. However, such a "transfer of examination competences" could warrant a further examination of the authorisation if a systematic deficiency is identified therein (see point 4). In any case, however, as long as it does not suggests itself that a zRMS systematically violates the legal provisions to be observed in the respective authorisation procedure, there is no scope for further review in the national authorisation procedure.

II. Action for failure to act: No justification for inaction

In addition, the court clarifies the legal situation concerning the filing of actions for failure to act against the BVL for failure to comply with the time limits according to Article 37 (4) Regulation (EC) No. 1107/2009. Pursuant to Section 75 German Rules of Administrative Courts (VwGO), the action shall be admissible if an application to carry out an administrative act has not been decided on the merits within a suitable period without sufficient reason. The action may not be lodged prior to the expiry of three months after the lodging of the objection or since the filing of the application to carry out the administrative act, unless a shorter period is required because of special circumstances of the case.

The court now expressly clarifies that the outstanding agreement of UBA does not constitute sufficient grounds within the meaning of Section 75 (1) VwGO. A reason can only be "sufficient" in this sense if it is in accordance with the legal system. Article 37 (4) Regulation (EC) No. 1107/2009 determines the appropriate time limit for processing the application for authorisation.

The cMS shall decide on the application at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the zRMS.

It is irrelevant here that the BVL may not have decided on the application within the decision deadline only because the UBA has not yet reached an agreement. Whether and which possibilities the BVL may have to ignore an unlawfully withheld or failed agreement of the UBA is irrelevant to the question of the unlawfulness of the withholding of the authorisation. The question of unlawfully refused agreement is only an administrative, internal matter for which the BVL is responsible to the applicant in its external relations. The lack of agreement of the participation authority is of no importance for the court's decision on an obligation claim, as it is only an internal administrative issue. The BVL cannot effectively withdraw in court on a failed or withheld agreement.

III. Summary

The decision is a further landmark ruling. The court specifies the responsibilities of the zRMS and the involved cMS in more detail. The principles developed for the mutual recognition procedure are now expressly transferred to the zonal authorisation procedure. In addition, the rights of applicants will be further strengthened. Even if the court did not comment on whether the BVL is entitled and obliged to carry out the examination itself in place of the UBA in the event of a dispute, it did state expressly that whether and which possibilities the BVL may have to ignore an unlawfully withheld or failed agreement of the UBA is irrelevant for the question of the unlawfulness of the withholding of the authorisation. It remains to be seen whether the BVL will change its administrative practice in the event of a missing or outstanding agreement by an involved authority.

Please be aware, that the decision is not yet final. The decision may still be appealed against.

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KOOF & KOLLEGEN
RECHTSANWÄLTE

A Short Note on Koof & Kollegen:
Koof & Kollegen is a German law firm. The highly specialized team around lawyer Peter Koof advise and represent companies, agricultural businesses and in particular the agrochemical industry in all product-related and regulatory legal issues for more than 30 years. They represent their clients before the German authorities and may act before the German courts.

A Short Note on the Author:
Before joining Koof & Kollegen, Alexander Koof worked for an international law firm in the field of patent law. Since the beginning of 2017 Alexander become a part of the law firm Koof & Kollegen. He serves international clients in agrochemicals and biocide matters.

SCC JAPAN

On 30 July, SCC established Scientific Consulting Company Japan K.K. After 11 years of operating the Liaison Office Japan in Tokyo, we decided to take this key step pursuing the objective of enhancing our services in the Asia-Pacific region.

In Japan, we offer our customers regulatory support in accordance with Chemical Substance Control Law (CSCL) and Industrial Safety and Health Law (ISHL). We are further expanding our services portfolio by elaborating our expertise in registration of plant protection and biocides products in Japan.

SCC Japan is managed by Atsushi Ohtaka, representative director, who has a long-year management experience and profound technical skills which he acquired and broadened while working for large manufacturing and multinational chemical companies.

Mr. Ohtaka and his experienced team of currently five senior consultants will be the main point of contact for our Japanese and Asian customers. Feel free to contact our SCC team in Japan to learn how SCC can assist you in finding solutions to your specific regulatory needs, be it in Europe, Japan or other Asia-Pacific countries.

SCC Japan is located in the heart of Roppongi, Tokyo's international business district:

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STRATEGIC BUSINESS DEVELOPMENT

Targeting Asia Pacific

Further to the establishment of SCC Japan, we are expanding our regulatory services to various regions across the globe. In this newsletter, we give you a brief account of SCC's recent developments in the Asia-Pacific region.

India

The registration of plant protection products (PPP), household insecticides and public health products in India is regulated by the Central Insecticide Board and Registration Committee (CIBRC) which was established after the Insecticides Act became effective in August 1971. In the recent years, India's agrochemical and pesticide market has been showing a strong annual growth rate, ranking third after China and Egypt. The demand for pesticides is steadily increasing due to the rising need for food grains, limited availability of arable land and increasing exports. At the same time, public awareness in regards with health and environmental hazards of pesticides has significantly increased lately.

In this respect, the biopesticide segment is forecast to witness even faster growth than that of chemical pesticides. In general, the issue of safe and efficient pesticides will dominate the development of the Indian regulatory environment in the next years.

Relying on decades of a hands-on experience in registering plant protection products and biocides in the EU and having established a partnership with a renowned regulatory consultant in India, SCC offers full-scale product registration services in India in the fields of:

- Crop protection
- Control of house-hold nuisance pests and
- Public health pest control.

Our consulting services range from market analysis over study planning and monitoring up to dossier submission and defence. Our customers benefit from SCC's in-depth scientific expertise, backed up by our partner's profound understanding of the Indian regulatory environment and his good connections to the authorities.

Korea

South Korea as a major chemical trading country in Asia (4th rank in Asia in 2017 based on GDP) has strongly changed its chemicals and biocides legislation in recent years, resulting in new requirements for importers, manufacturers and Only Representatives. By the recent 2nd novel of the Act on Registration, Evaluation, etc. of Chemical Substances (ARECS, also known as "K-REACH"), the Korean chemical registration system gets even closer to the principles of EU-REACH.

According to the latest amendment, which will come into force on 1st January 2019, it will be obligatory to register all existing chemical substances exceeding 1 ton/year, following a tonnage- and hazard-dependent phase-in scheme. Existing substances can benefit from registration grace periods - provided they were pre-registered on time. The pre-registration period starts on 1st January 2019 and lasts until 30st June 2019.

Those substances have to be fully registered within registration deadlines (first registration deadline: 31 December 2021). In analogy to EU-REACH, foreign companies can appoint a Korean Only Representative to fulfill these obligations.

Moreover, in the course of the 2nd novel of K-REACH, regulation of biocides was restructured and transferred to the "Consumer chemical products and biocide safety management Act" (also known as "K-BPR"). As a result, biocidal active substances currently on the market or in use must be notified in the period from 1 January to 30 June 2019 (i.e. simultaneously with the pre-registration phase for chemicals under K-REACH). The deadline for authorization of those biocidal active substances depends on the product type. A total of 15 product types are named, compiled to 4 product categories (disinfectants, pest control, preservatives and others). Important to note: If companies do not notify these substances within the given time-frame, no grace period for authorization will be granted.

We have the experience and knowledge to take care of your regulatory needs for the registration of chemicals (K-REACH) and biocides (K-BPR) in South Korea. Together with our local cooperation partner, we support registration projects in the field of existing and new chemical registration as well as biocides authorization.

China

The regulatory compliance environment of China's agrochemicals market has undergone quite a few changes recently, after the revised Regulation on Pesticide Administration (RPA) became effective in June 2017. Similar trends are witnessed in the chemical sector, which is regulated by China MEP Order 7 which stands for The Measures for Environmental Administration of New Chemical Substances issued by the Chinese Ministry of Environment Protection (MEP) in 2010. Meanwhile, the name of MEP has been changed to Ministry of Ecology and Environment (MEE).

China's MEP Order 7 is often compared with the EU REACH due to a number of parallels between both regulations and is therefore often referred to as "China REACH". Among similarities, there are such aspects as GHS-based hazard communication criteria, data requirements according to tonnage band, submission of a risk assessment report, post-notification tracking and appointment of a Local Agent for oversee notifiers.

Together with our cooperation partner in China, SCC has been monitoring the latest developments and trends in the Chinese pesticides and chemicals markets to keep our regulatory expertise up-to-date for our customers.

In China, we can offer you our registration services for:

- Agrochemicals and biorationals as well as
- Chemicals.

It's up to you to decide whether you need our support for certain regulatory issues or would like us to take care of the complete registration process.

Whatever your needs are, cooperating with SCC, you can count on our qualified scientific competence, profound experience of the Chinese chemical and agrochemical regulatory system contributed by our partner in China, as well as negotiation support with the responsible authorities for smooth registration of your products and substances.

Our international services at a glance:

- Data gap analysis
- Developing individual registration strategies in line with the realities of the target market
- Indicating waiving opportunities
- Study planning and monitoring
- Environmental fate and modelling / human and ecotoxicological risk assessments
- Preparation and submission of federal and state registrations and renewals
- Translation support
- Communication with registration authorities

For more information on SCC's international services, please contact
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AGROCHEMICALS

Brexit – New Information provided by BVL for applications for plant protection product authorizations in Germany when the United Kingdom is/was zonal Rapporteur Member State

The United Kingdom will leave the European Union on 30 March 2019 00:00 (CET) and will then become a "third country".

After first information at the Applicant Conference on 14 June 2018, the German Federal Office of Consumer Protection and Food Safety (BVL) has now clarified its position regarding the handling of timely decisions by the United Kingdom on plant protection product authorizations after Brexit.
According to the Federal Ministry of Food and Agriculture (BMEL), the following position applies here:
The United Kingdom was (at the time of approval) an EU Member State and the evaluations and decisions were made in accordance with EU law. Accordingly, evaluations and/or authorizations issued by the United Kingdom prior to Brexit may also be the basis of ZV3 applications (Germany is concerned Member State) or ZVU applications (Mutual recognition) in Germany, even after Brexit.

Specifically, this means:
1) Germany is concerned Member State (ZV3), United Kingdom is Rapporteur Member State
If the United Kingdom concludes the evaluation procedure at least with the conclusions of the evaluation pursuant to Article 36 (2) of Regulation (EC) No 1107/2009 by 29 March 2019, Germany will also finalize the procedure as a concerned Member State.
If the United Kingdom fails to complete the timely completion of the evaluation, the applicant is asked to seek a new Rapporteur Member State.

2) Mutual recognition
All authorizations granted by the United Kingdom as an EU Member State under Regulation (EC) No 1107/2009 are in principle also applicable beyond 29 March 2019 in order to apply for Mutual Recognition in Germany.

3) Already approved authorisations
The Brexit has no effects on authorisations of the application types ZV3 (Germany is concerned Member State) and ZVU (Mutual recognition) when the authorisation was already granted and will be granted before the withdrawal date. Only when a renewal of the authorization is pending, a new rapporteur must be found, provided that the United Kingdom has been the rapporteur.

Further information of EU regarding Brexit:

https://ec.europa.eu/food/sites/food/files/plant/docs/notice_brexit_pesticides.pdf

Implications of Brexit for fertilisers

On Sep 25th the European Commission published a new notice to stakeholders on the withdrawal of the United Kingdom and EU rules in the field of fertilisers. In general, the EU rules for EC fertilisers, that is Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, will no longer apply in the United Kingdom after Brexit which will affect imports and exports of fertilisers in various ways. In regards to the responsibilities for importers of fertilisers, the notice to stakeholders highlights that due to this, 'a manufacturer established in the United Kingdom will no longer be an economic operator established in the EU [as required for EC fertilisers]. As a consequence, an economic operator established in the EU-27 and placing EC fertilisers coming from the United Kingdom on the EU-27 market, until then considered as a distributor, will become an EU importer in relation to such products. This operator will therefore have to comply with the respective obligations for manufacturers'.
Further information and updates are available on the EU Commission website.

For more information, please contact
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CHEMICALS/REACH

Harmonization of Poison Centre Notifications (PCN) in the EU

EU Product Notification according to Annex VIII to the CLP regulation is a new harmonised legal obligation that is not covered by REACH and also not by current CLP notifications. Importers and downstream users (formulators) placing hazardous mixtures on the EU market will have to notify such mixtures in the coming years, deadlines depending on the type of use: consumer use (by 1 Jan. 2020), professional use (by 1 Jan. 2021), or industrial use (by 1 Jan. 2024). The objective of the new regulatory requirement is to enhance the quality and consistency of emergency health response due to availability of reliable information about classified mixtures.

Background: Importers and formulators of hazardous chemical mixtures, placed on the EU Community market, must notify certain information to the appointed national member state poison centres. In accordance with CLP Article 45(4), Annex VIII 'harmonising information relating to emergency health response' was added to CLP in March 2017. The amendment was triggered by the fact that the interpretation and implementation of Art. 45 varied between the European countries. Thus a harmonized format for notifications was created along with a Unique Formula Identifier (UFI) on the product label that will allow the poison centres the unequivocal identification of the concerned mixture(s) in case of a reported emergency.

What chemical mixtures should be notified? A chemical product must be notified to a poison centre when all of the following conditions are met:

- **It is a mixture,** as defined by CLP Article 2(8): "a mixture or solution composed of two or more substances"; and
- **It is classified as hazardous,** on the basis of its (eco)toxicological or physical-chemical effects, as stated in CLP Article 45(1); and
- **It is placed on the EU Community market.** CLP Article 2(18) defines 'placing on the market' as "supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market."

The legal obligation for submission using the new harmonised format does not apply until 2020; however, the draft Poison Centre Notification (PCN) format and editor versions of the tools, along with Q&A's are already available on the ECHA website, along with the Unique Formula Identifier (UFI) generator.
Some companies are expecting to submit more than 100,000 poison centre notifications under the new system. The EU Commission is estimating that the total number could be up to 20 million per year, the steady figure resulting from the necessity to update the notification whenever changes are made to the initially notified composition.

What is your degree of preparedness for PCN? Please come and talk to us if you want to enhance your ability to stay agile and to secure your supply chains in Europe!

For more information, please contact SCC at info@scc-hq.de - thank you.

Draft guidance update on the assessment of the safety of feed additives for the environment published

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has published an updated draft guidance on the assessment of the safety of feed additives for the environment. The open consultation on the document can be reached via this link. Although not finalised yet the updated guidance includes a lot of changes for the environmental risk assessment of feed additives. The decision tree for Phase I includes further questions in order to evaluate if a Phase II assessment needs to be performed. Data requirements for the different sections of Phase I and II as well as default values e.g. N (nitrogen) load for manure application, default mixing depth, etc.

were newly set based on recent scientific developments and the experience gained during the assessment of feed additives.

The changes applied in the draft guidance will have an impact on future feed additive applications. Please contact Dr Thomas Roth, Head of Chemicals Department (thomas.roth@scc-gmbh.de) if you would like to obtain more information or need further support.

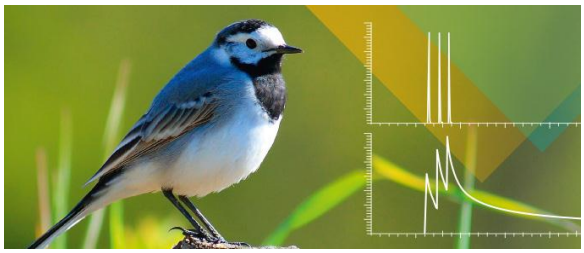
UK releases guidance on chemicals regulation in case of 'no-deal' Brexit

In view of the approaching Brexit in March 2019 the United Kingdom published in October 2018 technical notices as guidance in case UK leaves the EU without an agreement ('no deal' scenario). Although negotiations with the EU are ongoing, UK intends to ensure therewith to be prepared for all eventualities from day 1 after Brexit.
These published technical notices cover the following topics:

- Classification, Labelling and Packaging (CLP) regulation - 'Classifying, labelling and packaging chemicals if there's no Brexit deal'
- Biocidal Products Regulation (BPR) - 'Regulating biocidal products if there's no Brexit deal'
- Plant Protection Products (PPP) regulation - 'Regulating pesticides if there's no Brexit deal'
- Prior Informed Consent (PIC) regulation - 'Export and import of hazardous chemicals if there's no Brexit deal'
- Regulation on mercury - 'Control on mercury if there's no Brexit deal'
- Regulating Persistent Organic Pollutants (POPs) - 'Control on Persistent Organic Pollutants if there's no Brexit deal'
- Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) - 'Regulating chemicals (REACH) if there's no Brexit deal' (already published in September 2018)

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

REGULATORY SCIENCE



Developments in the context of adsorption/desorption studies based on OECD Guideline 106

Adsorption/desorption studies provide some of the key parameters in environmental fate modelling. As a consequence, consideration has increasingly been given to the reliability of data generated using the batch equilibrium method according to OECD 106 over the last years. During a multilateral process, EFSA, UK and other Member States developed a checklist for the evaluation of these studies that has finally been published via EFSA in November 2017 (Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017: EN-1326. 17 pp.doi:10.2903/sp.efsa.2017.EN-1326). The checklist is intended to increase consistency and quality in the conduct, evaluation and report of the respective studies, providing a more consistent basis to ensure their reliability. The main target is to avoid overestimation of adsorption with parameters like reliability of the analytical method, the appropriateness of soil/solution ratios and the impact of possible losses of test substance during the equilibration time being taken into account. The checklist is supposed to be additionally considered whenever an OECD 106 study is evaluated under Regulation (EC) No 1107/2009 together with an Excel spread sheet that supports carrying out some of the recommendations in the checklist.

While the adsorption/desorption test according to OECD 106 is based on the assumption of equilibrium state, it is also a known phenomenon that adsorption may increase as the time of interaction between substances and soil increases. The implementation of 'aged sorption' in higher Tier modelling has therefore been frequently discussed and exercised in the regulatory context. Therefore, the UK Chemicals Regulation Directorate (CRD) has

been involved in developing a respective guidance that has recently been reviewed by the EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues, 2018. Scientific Opinion about the Guidance of the Chemical Regulation Directorate (UK) on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments. EFSA Journal 2018;16(8):5382, 86 pp. https://doi.org/10.2903/j.efsa.2018.5382). While the PPR Panel generally approves of the use of the guidance, applicability is limited to groundwater assessments as surface water modelling has not been evaluated. Aged sorption data should only be generated in laboratory studies that follow the recommendations of the guidance. However, all available data on adsorption and degradation (including field data) should be considered for higher Tier assessments using a simplified procedure for derivation of modelling inputs. Further, the Panel recommends the development of a user-friendly software tool as the modelling requires a number of manual steps and can thus only be used by experienced modellers at the moment.

Residues in honey - guideline SANTE/11956/2016 rev. 9

Mid of September 2018 the honey guideline SANTE/11956/2016 rev. 9 has been adopted, which gives technical information on studies and data required to refine maximum residue levels (MRLs) for honey after treatment of crops with pesticides. The guideline is implemented by 1 January 2020. The determination of residues in honey might be relevant,

- when a substance is applied during the flowering stage (BBCH 60-69) of a targeted or non-targeted crop which is foraged by bees
- when a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), including treatment of seeds, of a crop which is foraged by bees
- in case of a persistent and systemic active substance, when residues are found in succeeding crops
- in case of honeydew collected from plant-sucking insects in forestry (such as *Picea* spp., *Abies* spp, *Pinus* spp. and *Quercus* spp.).

The guideline lists the main agricultural crops in Europe, from which it is possible to produce honey. A flow-chart shows how the MRL in honey will be derived.
Even if residues in honey are **not** expected, it is recommended to set a default MRL at the limit of quantification (LOQ) determined for the active substance in honey or at the default value of 0.05 mg/kg.
If residues in honey are expected either data on residue levels in aerial part of the crop treated, transfer data from syrup to honey or field / tunnel tests with bees are required for setting an MRL in honey. It has been clarified that for field and tunnel tests, a worst case representing crop (e.g. rapeseed, phacelia) can be used, even if this is not a proposed use.
Should you need further information regarding the design of studies to derive MRLs in honey, please contact Monika Hofer at monika.hofer@scc-gmbh.de.

SETAC GLB - Conference „Umwelt 2018"/"Environment 2018" in Germany

The conference „Umwelt 2018"/"Environment 2018" was held in September (9th to 12th) at the Westfälischen Wilhelms-Universität Münster. It was supported by the expert group Environmental Chemistry and Ecotoxicology of the Society of German Chemists (GDCh) and by the Society of Environmental Toxicology and Chemistry - German Language Branch (SETAC GLB).

The focus of presentations was on analytical methods (e.g. analytical methods for determination of microplastics, nanoparticles and polymers in the environment), ecotoxicological effects of chemicals and chemical mixtures as well as on environmental monitoring and environmental risk assessments. For example

- validation process of toxicokinetic/toxicodynamic (TKTD) models; validated TKTD models can be used for the risk assessment of pesticides.
- suitability of watercourse-mesocosms to investigate direct and indirect effects of fungicides on aquatic food webs.
- effects of multiple stressors in the agricultural landscape on the terrestrial communities; it was suggested to develop con-

cepts for agricultural landscapes as reference values to analyse the potential of the specific landscape.
- importance to connect the chemical monitoring with an effect-based approach was emphasised.
- consideration of effects of priority mixtures in environmental monitoring, assessment and management of water pollutions.

Opening event of the DAFA in Berlin

On 25th and 26th of September 2018, one of SCC's bee experts was invited to attend the opening event of the DAFA (German Agrarian Research Allianz) expert panel "Bees and agriculture" in Berlin (Germany). For details see: http://dafa.de/veranstaltungen/fachforum-bienen-und-landwirtschaft-auftakt/.
Aim of the opening event was to define the need for further research activities and to establish working groups to finalise a research strategy which will be presented during the next meeting in spring 2019.
During the meeting it was agreed that the conditions for honey bees and wild bees should be optimized as well as for the pollination of agricultural crops. It is foreseen to establish three fields of research:

- honeybees in the agricultural landscape
- wild bees in the agricultural landscape and
- honey and wild bees in urban space.

SCC will inform about the outcome of the follow up meeting in spring 2019.
For further information, please contact Monika Hofer at monika.hofer@scc-gmbh.de.

OECD TG 150

On 3rd September 2018 the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" was published by the OECD (OECD GD 150). This revised edition includes new and updated test guidelines that have been validated, or are currently in the further validation process. The document (which is nearly double the length of the first, approximately 700 pages) is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides, and Biocides.
The GD 150 contains 3 main sections to identify endocrine active substances (EAS):

Section A: Introduction
- Background on endocrine testing in the OECD context,
- The OECD Conceptual Framework (CF),
- A description of definitions and terms used,
- Objectives of the document,
- The assays and endocrine modalities covered,
- A list of OECD test guidelines with end points specific for EAS and TGs with endpoints that may be informative of but that are not specific to EAS.

Section B: General guidance on ED assessment, assays and endpoints
- Guidance on endocrine assessment,
- Guidance on assays,
- Guidance on specific endpoints,
- Distinguishing of non-test and test methods for evaluating EAS by the CF,
- A discussion of the use of weight of evidence approaches for integrating information from multiple assays,
- Regulatory experience using the document for evaluating chemicals for potential endocrine activity

Section C: Specific guidance for the test guidelines addressed
- A detailed description of each of the assays (background) listed in the CF,
- Suggestions for a single next testing step if a conclusion cannot be reached with available data

The Guidance Document (GD 150) is focused primarily on endocrine modalities included in the OECD Conceptual Framework; estrogen (E), androgen (A), and thyroid (T) mediated ED and chemicals interfering with steroidogenesis (S).
The revised GD 150 includes also various cross-cutting topics and a summary of some experiences gained from using the Guidance in the first edition. Additionally, the revised document discusses integrated approaches to testing and assessment, the use of adverse outcome pathways (AOPs) for evaluating endocrine disruption (ED), the extrapolation of assay results across mammalian and non-mammalian vertebrate species, and approaches for

evaluating chemicals with multiple modes of action (MoA).
Conclusively, the document is not proscriptive but provides suggestions for possible next steps in testing (if any) which might be appropriate to take, given the various data scenarios. It should be used as a general reference guidance document. On OECD web page (OECD GD 150) the document can be found. It is possible to read the GD 150 online or to download it completely or in parts separately down to the level of individual tests.

For more information, please contact
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CALENDAR

Biocides Europe 2018 in Vienna, Austria
27 - 28 November 2018

Meet our toxicology and regulatory experts at the Biocides Europe 2018, taking place in Vienna this November.

Dr. Katharina Gläser, Manager Regulatory Affairs, and **Dr. Annamaria Vickus**, Assistant Manager Regulatory Affairs, will be onsite and happy to talk to you about your regulatory needs for biocides registration within the EU.

The upcoming conference in Vienna will deal with key aspects of Regulation (EU) No. 528/2012 concerning the approval of active substances and authorisation of biocidal products and the latest developments from the European Commission and ECHA. For more information, please visit the official website of Biocides Europe 2018.

CRD - One Day Efficacy Biopesticide Workshop: Requirements and Assessment under EC 1107/2009, York, United Kingdom
6 December 2018

Anke König-Wingenfeld, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides, will join the conference. Please use this chance to talk to Anke about your regulatory needs regarding plant protection products.

This workshop will give an overview of the European Legislation, data requirements, and associated guidance for the efficacy evaluation of biopesticide active substances and plant protection products (Regulation EC 1107/2009).

European Mineral Fertilizer Summit, Amsterdam - The Netherlands,
28th November 2018 - 29th November 2018

Beate Tschöpe, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides, will join this summit Please use this chance to talk to Beate about your regulatory needs regarding plant protection products or fertilisers.

The objective of this event is to put an emphasis on the latest projects, the innovative specialty products, the new plant technologies and the best practices within operational production.

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

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