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NEWSLETTER

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LOOKING FORWARD TO 2016 – REGULATORY NEWS

Dear Subscribers,

This edition of the Newsletter comprises several important news regarding Agrochemicals, Biocides, and Chemicals. Furthermore, one report deals with the EFSA model, which will be the major model from 2016 onwards to evaluate the non-dietary risk of plant protection products.

In the fast-moving world of regulation SCC is ready to keeping its customers on a successful course. Regardless of whether your needs are in scientific and regulatory support for agrochemicals and bi-opesticides, biocides, chemicals, consumer products, feed and food additives, archiving solutions or Task Force management, SCC can provide you with high quality service and consulting.

Furthermore, we appreciate your feedback and comments regarding the SCC Newsletter. Please drop us an E-mail at newsletter@scc-gmbh.de.

Finally, all of us here at SCC would like to wish you joyful festive days and an opportunity for some regeneration before the challenging year ahead of us.

Dr. Friedbert Pistel

IN THIS ISSUE:

SEASONAL GREETINGS AND A HAPPY NEW YEAR FROM EVERYONE AT SCC

AGROCHEMICALS

A brief reminder from the Regulatory Department

As you certainly are all aware, the following important changes will apply as of 1st of January 2016:

1. the new draft Registration Report (dRR) format, as detailed in SANTE/6895/2009 of 20 March 2015, is obligatory for product authorisation applications (http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents/active_substances_en.htm)

2. applicant's entries into the Commission's Plant Protection Products application management system (PPPAMS) are obligatory (http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams/index_en.htm)

Regulatory information from France

On 30th October 2015 the new decree on compliance of marketing authorizations and parallel trade permits of plant protection products and adjuvants in terms of 'amateur' and 'professional' uses was published (Arrêté du 21 octobre 2015 relatif à la mise en conformité des autorisations de mise sur le marché et permis de commerce parallèle des produits phytopharmaceutiques et des adjuvants au regard des deux gammes d'usage «amateur» et «professionnel»).

The decree states that products will not be authorized as professional and home-and-garden (amateur) products simultaneously anymore but that for each use (professional or amateur) a separate product name and authorization number is required.
A reclassification application request should be submitted to ANSES no later than the 31st of December 2015 to separate the products.

Authorization holders have until the 31st of December 2016 to change the labels of their separate products accordingly.

Products whose first marketing occurs within twelve months following the notification of the administrative reclassification decision can be distributed and used until stocks are exhausted, with no obligation to update labels under this reclassification.

Products whose first marketing takes place beyond the twelve-month period (after the 31st of December 2016) shall be labelled according to the reclassification.

Revision of EU Fertiliser Regulation included in Commission's Circular Economy Package

Draft of Fertiliser and Biostimulant Regulation available early 2016?

Circular economy[1] has become an integral part of the **Europe 2020 strategy**[2] for smart, sustainable and inclusive growth. On 2 December 2015 Commission has adapted an **EU action plan for the circular economy** (COM (2015) 614/2)[3]. This action plan also includes a revision of the EU regulation on fertilisers including organic and waste-based fertilisers and incorporating bio-nutrients in the circular economy strategy.

Even more than bio-nutrients and organic fertilisers, biostimulants have the potential to foster the **Sustainable Development Goals (SDGs)**[4] and the circular economy strategy. For one, biostimulants can increase the nutrient use efficacy of plants for example of nitrogen and phosphorus as well as improve the performance of plant protection products and thus help to meet the resource efficiency goals of the Circular Economy Strategy. Furthermore, biostimulants are often produced from renewable raw materials of plant or animal origin, thus converting waste into raw materials and "*closing the loop of product lifecycles through greater recycling and re-use, and bring benefits for both the environment and the economy*[5]".

According to Annex I of the EU action plan for the circular economy[6] a proposal for a revised fertiliser regulation is scheduled for early 2016. Early publication of the proposal would bring much-needed planning security for industry, science and regulators.

[1, 5] Circular economy: http://ec.europa.eu/environment/circular-economy/index_en.htm
[2] Europe 2020 strategy: http://ec.europa.eu/europe2020/index_en.htm

[3] EU Action Plan for the Circular Economy: http://ec.europa.eu/priorities/jobs-growth-investment/circular-economy/docs/communication-action-plan-for-circular-economy_en.pdf
[4] Sustainable Development Goals(SDGs): https://sustainabledevelopment.un.org/post2015/transformingourworld
[6] Annex I to EU Action Plan for the Circular Economy: http://ec.europa.eu/priorities/jobs-growth-investment/circular-economy/docs/annex-communication-action-plan-for-circular-economy_en.pdf

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BIOCIDES

Review of Biocidal Active Substances under Regulation (EU) No. 528/2012

Active substance / product-type combinations for which an application for approval has been submitted under Directive 98/8/EC or Regulation (EU) No 528/2012 are listed on the ECHA webpage:

http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

The summary table lists include "existing" active substances and "new" active substances.

Where an active substance has been approved, a link to the relevant legal act is provided. Furthermore, there is a link to a factsheet that leads to the Assessment Report and to further non-confidential data, where available.

Where an active substance is not yet approved, it is indicated as "under review".

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CHEMICALS/REACH

Update about new IT tools prepared by ECHA

ECHA will provide the final IUCLID6 version at the end of April 2016; the updated REACH-IT will be released at the end of May 2016. From then on, Dossier submission will no longer be possible via the old REACH-IT. As the new versions include fundamental changes and in order to avoid the need to revise the Dossier and adapt it to IUCLID6, it is advisable to plan the completion and submission of already existing dossiers in time (before April 2016).
Another important change in the registration process accompanying the release of the new REACH-IT will be the implementation of the OSOR (one substance one registration) – principle in a more stringent approach: All parties intending to register the same substance need to submit one joint submission, individual submissions or further joint submissions will be blocked. This applies for the same registration type (full or intermediate).

ECHA identify high non-compliance rate for only representatives and importers

ECHA has recently published the final report of the REACH-EN-FORCE-3 project by ECHA's Enforcement Forum. In the course of the project in the years 2013 and 2014 overall 1169 companies dealing with 5746 substances were inspected. As result of this inspection ECHA noted that 13 % of companies did not fulfil all of their registration obligations.
One key message of the report is that only representatives and importers are more at risk of non-compliance than manufacturers of substances.
Thus, special focus was put on the investigation of supply chains involving more than one Member State. Therefore 104 only representatives were inspected.
According to the report “A third of them (32 %) did not comply with their specific only representative information duties as described by Article 8 of REACH.”

As most critical point the information flow in the supply chain was identified. The authorities criticize that it was often difficult to clearly identify the supply chain. In many cases it was reported that the respective importers could not specify the correct only representative and the only representatives did not keep reliable records of represented importers.

It can be expected that based on this recent experience with the REACH-EN-FORCE-3 project the authorities will keep track of this high rate of non-compliance.

SCC's experience with German auditors in its role as only representative show that besides of transparent information along the supply chain especially the quality and completeness of MSDS will be checked.

We highly recommend to non-EU manufactures to keep their only representatives informed annually of the exported volumes to all their importers in the EU so that registration obligations are correctly identified.

SCC can provide you support in preparing for and offer REACH audits at your site, trustee services for complex non-EU/EU supply chains and as only representative. Please do not hesitate to contact us, if you face such issue and look for a reliable and experienced partner.

Classification of substances and preparations according to the General Assessment Methodology (GAM) of The Netherlands

We would like to draw your attention to one additional requirement when compiling SDS for substances or preparations which shall be placed on the market in the Netherlands. Similarly to the water hazardous class in Germany (WGK) substances and preparations have to be classified according to the General Assessment Methodology (GAM) into categories of aquatic harmfulness and decontamination efforts.

This classification hast to be included in section 15 of the SDS as a national requirements. We have classified a lot of substances in the past and can provide you support for classification of your substance or preparation in the Netherlands.

Updated IR&CSA Guidance Chapter R.12 on use description

ECHA recently published an update of the Guidance IR/CSA R.12 on use description. The title of the guidance was changed to reflect the extended scope of the guidance (from Use descriptor system to use description).
With this update ECHA introduce a new use descriptor: the life cycle stage (LCS). This new use descriptor replaces the main user groups SU 3 (industrial uses), 21 (consumer uses), 22 (Professional uses), 10 (Formulation). Furthermore a new Process Category (PROC), Environmental Release Categories (ERC) and Product categories (PC) were introduced as well as the adaptation of categories for technical functions and Article categories (AC). In addition the naming of some PROCs and ERCs were changed in order to further clarify their scope. Please use this link (http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf) to get access to the full text document and to trace the significant changes in detail in this new guidance.
ECHA has also provided guidance how to manage the changes. The key message is that the update of this guidance as such does not trigger a requirement to update existing registration dossiers. Please get into contact with SCC if you need support with regard to future dossier updates, updates due to requests from authorities or dossiers which have to be prepared for the 2018 deadline where the updated guidance has to be followed. Please notice that this will also affect your extended MSDS.

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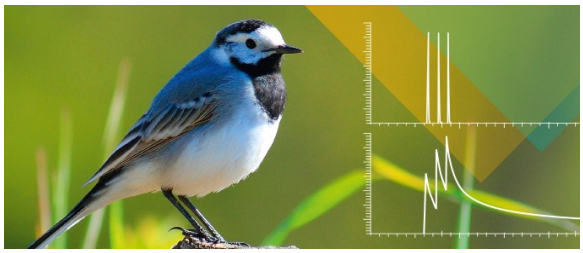
REGULATORY SCIENCE



EFSA's webinar on the calculation tool of the EFSA model - exposure assessment of operators, workers, residents and bystanders

EFSA has performed a webinar on "the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides" on 19 November 2015 (1). This tool is part of a guidance document that sets out a harmonised methodology for calculating exposure to pesticides for four major population groups - operators, workers, residents, and bystanders (2).

Ms Jane Richardson and Ms Manuela Tiramani (as EFSA's speakers) guided through the program while answering also questions of participants (interactive session, participants submitted questions via chat throughout the webinar and received answers during two dedicated sessions).

As a very important issue, EFSA's representatives pointed out that the exposure assessments for the operator and worker have to be determined on a European level by the EFSA model from 2016 onwards.
However, due to pending development of a harmonised approach to the setting of an acute non-dietary reference dose, applicants are not required to undertake acute non-dietary exposure assessments.

Furthermore, the following important issues of the EFSA model were underlined:

- The EFSA model should be used only for agricultural uses.
- Data entry sheet:
- The minimum water volume rate has to be chosen for every application.
- Entering an oral absorption value >80% will result in a value of 100% in the calculations (default parameter)

- OPERATOR:
  - No acute exposure assessment is needed in the absence of a corresponding reference value.
  - A potential exposure (body without any clothing) is calculated in the EFSA model besides the standard exposure (body with clothing, but without PPE), defined in other models as "no PPE". In the EFSA model, "no PPE" means body without any clothing, whereas the option 'body with clothing, but without PPE' is listed under the category "with PPE".
  - Concerning the option 'water soluble bags' for mixing/loading (m/l), only limited data are available, so 10% of the total m/l exposure amount is generally assumed.
  - For orchards, the season has to be indicated (early or late).
  - No greenhouse scenarios are implemented.
  - The option 'certified coverall' is indicated in the guidance document by EFSA, but this option is not included in the calculation tool.

- BYSTANDER and RESIDENT:
  - No acute exposure assessment is needed for the bystander in the absence of a corresponding reference value.

- WORKER:
  - The worker exposure is calculated for the scenario 'immediately after treatment' (worst-case).
  - Individual DT_{50} values and DFR values can be entered for refinement.

The calculation tool can be downloaded for free:

http://www.efsa.europa.eu/de/efsajournal/pub/3874

References
1: Webinar on the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides, http://www.efsa.europa.eu/de/events/event/151119

2: EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874 (published: 23 October 2014, last updated: 24 April 2015)

EFSA NTA Opinion

EFSA published the scientific opinion on the state of science on risk assessment of plant protection products for non-target arthropods (2015).
This opinion was a topic in the Environmental Safety: Ecotoxicology stream at the AgChem Forum in Barcelona in September 2015.

Regarding the opinion on the NTA risk assessment Mike Coulson from Syngenta provided an industry feedback on behalf of the ECPA NTA sub-team.
He stated that the scientific opinion review the existing risk assessment scheme for non-target arthropods (ESCORT 2 and ESCORT 3) including critiques on the current risk assessment scheme. Furthermore, the scientific opinion includes a series of proposals for consideration for future guidance and a suggestion for a new risk assessment scheme.

Non-target arthropods are an extremely diverse organism group that contributes highly to biodiversity in agricultural landscapes. Thus, there are a lot ecosystem services with respect to non-target arthropods like regulation of arthropod pest populations, food provision for organisms at higher trophic levels, *e.g*. birds and mammals. Furthermore, non-target arthropods are also effective pollinators. In face of these different ecosystem services there would be a lot of specific protection goals to be considered.

ECPA suggests to prioritise selected specific protection goals. In general it is agreed that this EFSA opinion can be used to refresh the database of surrogate species and to “re-calibrate” the existing HQ trigger values on the basis of the new data. Industry also acknowledges that there is time to work on the respective draft Guidance Document which is announced for 2018.

The following aspects should be reflected in the course of preparing the new Guidance Document for non-target arthropods:

- decide what should be protected
- a set of studies aligned to these selected protection goals
- should be clear for a regulatory reviewer to assess
- should take into account the experience gained from the current guidance

The overall aim should be to end with a new guidance that delivers the required level of protection and considers the need for plant protection products for effective, sustainable agriculture.

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CALENDAR

Crops and Chemicals Europe 2016
10-11 February, Berlin, Germany

SCC GmbH is a sponsor for this event which is aimed to bring together key stakeholders to develop innovative solutions within agriculture.
Dr. Bernd Brielbeck, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides, will present "Basic and Low Risk Substances - Europe´s Versatile Approach to Biopesticides?".
We are delighted to announce that SCC's President, Dr. Friedbert Pistel, will also attend the conference. Moreover, some further colleagues from SCC will be present there.
Meet with them to discuss your needs in registrations of Agrochemicals and Biopesticides, but also for any other business matters.

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Do you have any comments, questions or suggestions?
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