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NEWSLETTER

SCC Newsletter Vol. 16, No. 5, December 2016

LOOKING FORWARD TO 2017 – REGULATORY NEWS

Dear Subscribers,

This supplement comprises several important news items regarding agrochemicals/biopesticides and chemicals. One article refers to an EPPO Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high-growing crops held in Vienna last October. Another report deals with the new EPPO standards on tank mixture adjuvants and cleaning of pesticide equipment, both published in December.

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

We appreciate your feedback and comments regarding the SCC Newsletter. Please drop us an email at newsletter@scc-gmbh.de.

Finally, all of us here at SCC would like to wish you a joyful festive period and an opportunity for some rest and relaxation before the year ahead.

Dr. Friedbert Pistel

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SEASONAL GREETINGS AND A HAPPY NEW YEAR FROM EVERYONE AT SCC

AGROCHEMICALS

New revision of Guidance document

An update of the Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/2010/13170 rev. 14) is available since October 2016 and should be applied from 1st January 2017 onwards. Revision 14 contains updates about the notifications, the necessary actions during the Article 43 process, the data matching and the so called Cat. 4 process.
An indicative "data matching list" is to be submitted within 2 months following the publication of the EFSA conclusion. The data matching check should be performed as soon as possible after the 3 month deadline for application, whereby the RMS of the active substance should examine whether the studies submitted were conducted according to GLP, used the same methodology as the data to be matched and that the endpoint was within the same order of magnitude as the reference study. Under certain circumstances, such as the change of EU endpoints, Cat. 4 studies can be considered for alternative authorisation holders by the RMS within 1 month, unless the changes are provided in the active substance renewal regulation.

New dRR section

An update of the dRR part B6 (Mammalian Toxicology) is now available. This document considers the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders of 2014. An Annex to the guidance document (SANTE/6895/2009 (rev. 1)) is published, which outlined that the new template of the dRR should be used as from 1 January 2017.

Publication of the official list of biocontrol products in France (DGAL/SDQSPV/2016-853 03/11/2016)

In support of the public policies aiming at promoting sustainable agro-ecological production systems, France would like to support the development of biocontrol solutions by ensuring that the evaluation and the authorization of such products are accelerated. To achieve this, the French Ministry of Agriculture, Food and Forestry has published an official list of biocontrol plant protection products in accordance with articles L.253-5 and L.253-7 of the Rural Code, which will be subject to certain benefits. The list will be updated at least two times a year.

Biocontrol plant protection products were therefore defined as agents and products with natural mechanisms that can be used in integrated pest management. It includes in particular

1. The macro-organisms, and
2. Plant protection products comprising of micro-organisms, chemical mediators such as pheromones and kairomones and natural substances of vegetable, animal or mineral origin.

For the inclusion on the list, three criteria should be taken into account:

- Regulatory status:
  - Products should have a valid market authorization in France.
  - Products without a valid market authorization, a grace selling period due to a withdrawal or an amendment of a market authorization or emergency use products will not be considered for inclusion in the biocontrol list.

- The nature of the active substances used in their composition;
  - Biocontrol plant protection products include microorganisms, chemical mediators (*e.g.* pheromone traps) or natural substances of animal, vegetable or mineral origin (naturally extracted or chemically synthesized identical to natural substance).

- Safety for health and the environment.
    - The products should comply with specific provisions on health and environmental safety.
    - The products must not be classified as acute toxic (categories 1, 2 and 3), mutagenic, carcinogenic or reprotoxic or have specific target organ toxicity. They must not be classified as skin or respiratory sensitizers.
    - The products must not be classified as acute or chronic toxic (category 1) to the aquatic environment, except if there is no risk of transfer to the environment or if this risk is negligible.
    - Braod spectrum insecticides will also not be considered for inclusion in the biocontrol list.

The plant protection products referred to under point 2 of the definition above, benefit from reduced evaluation periods and are subject to reduced application fees by ANSES for applications for approval and authorizations. The products quoted in the biocontrol list will further also benefit from a reduced tax rate on sales revenues.

The products on this list are also exempted from the following prohibitions which generally concern all plant protection products referred to in article L.253-1:

- The prohibition of commercial advertising
- Obligation to implement actions to reduce the use of plant protection products, within the context of the implementation of plant protection products saving certificates (CEPP, Article 55 of the LAAAF).
- Ban on the use in amenity areas, forests, public roads, and walking paths accessible or opened to the public from 1st January 2017,
- Ban on direct sales in self-service to amateurs from 1st January 2017,
- Ban on placing on the market, delivery, use and holding for amateur use from 1st January 2019.

EPPO Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high growing crops Vienna, 18 – 10 October 2016

The Austrian Agency for Health and Food Safety Ltd. (AGES) organized and hosted an "EPPO workshop on harmonized dose expression for the zonal evaluation of plant protection in high growing crops" in Vienna from the 18th to 20th October. A total of 86 participants from 18 EPPO countries with 35 participants from national Authorities, Research Institutes and Universities, 29 participants from Industry and 20 participants from CROs and consulting companies followed the invitation and attended the workshop. This workshop was organized at request of EPPO member states that have been involved in the harmonization of dose expression in 3-dimensional crops. With entry into force of the Regulation (EC) 1107/2009, the efficacy evaluation has become a challenging task for the zonal Rapporteur Member States involved in the zonal or even EU-wide evaluation of plant protection products.

The need for harmonized dose expression in all EPPO countries for all crops was already expressed in a conclusion of an *ad hoc* Meeting on Expression of dose rate held in 2001 (EPPO document 01/8780). Even though an agreement on a single system of expression of the dose was not achieved during that meeting, the EPPO Standard PP 1/239 Dose expression for plant protection products was first published in 2005, and revised in 2012. However, as extreme differences exist regarding cropping practices and training systems of high growing crops between countries and even within countries, the dose expression of plant protection products applied in efficacy trials varies from country to country as well as the dose expression on the national label and the implementation in practice. Therefore, it was the aim of the workshop (1) to make applicants, contractors and authorities aware of the current challenges and needs in the efficacy evaluation of high growing crops, (2) to specify of the most appropriate dose expression for zonal efficacy evaluation, (3) to exactly define the used terms and, (4) to exactly define the parameters to be measured in the field.

The agenda of the workshop comprised a whole-day-lecture-session with 14 plenary talks given by representatives of the national authorities, research organization and industry. For the 2nd day, participants were divided into four working groups: Grapevine, Pome fruit, High growing vegetables, Olive and citrus. Within the working groups, topics as for instance the

different types of dose expression and the terms used for dose expression had been discussed. The final conclusions of each working group were presented in the final plenary session during the 3rd day which was closed with general workshop conclusions and recommendations.

Vlasta Zlof (EPPO) chaired the first plenary session and gave a short introduction to the European Plant Protection Organisation (EEPO) and the history of the development of the EPPO guideline 'PP 1/239 Dose expression for plant protection products' which began with an ad hoc Panel on Expression of dose rate held in Paris in 2001.
The conclusion of this meeting was that there was no agreement on a system of expression of dose rate for fruit tree crops that could be accepted by the countries represented. A few years later, the EPPO Standard PP 1/239 was finally agreed and published. A revision of this standard in 2012 included a description of various dose expressions methods with a conversion table and recommendation which dose expression can be used for 3-dimensional crops. Moreover she announced that the results of a questionnaire for a survey on dose for seed treatment and authorized dose in general sent to Heads of national plant protection organizations will be published in EPPO Bulletin 46(3) in December 2016.

Ingrid Langer from AGES emphasized in her talk the need to harmonise dose expression in the zonal efficacy evaluation. She clearly explained the difficulties in the evaluation of efficacy trials during the zonal evaluation process and pointed out that the dose expression influences the correctness of the results and their value for registration and local practice. She recalled, that for high growing crops the area of application is not the ground area but the (treated) leaf wall area (LWA) that can vary to a high extent. Dose expressions in kg or L per ha ground and efficacy values based on these measures do not consider efficacy in regard of the real application area eventually questioning the validity and correctness of the efficacy results. Therefore, there is a need that data calculated for the zonal efficacy evaluation are based on the most accurate dose expression and the zonal conclusions should include information on parameters which define other reference units used by other Member States.

Erwin Mol from NPPO the Netherlands gave a short introduction to the EPPO Standard PP 1/239 'Dose expression of Plant Protection Products' history. He recalled the results and agreements of the Meeting on 'Tree fruits dose expression and adjustment discussion group' held in Wageningen in 2009 with the most important agreements and conclusions: all relevant information should be available in trial reports to convert to other dose expression, 3-dimensional expressions should be used and more harmonization is needed. Although the EPPO Standard PP1/239 was adjusted as a result of that meeting, again no agreement on a harmonized system of dose expression was achieved. His talk ended with the conclusion that this EPPO standard is an efficient converting tool; however, it can be questioned if it is the real solution for zonal evaluation.

Martin Teichmann (BASF) and Frank Meyer-Runge (Syngenta) presented the ECPA view on the need for harmonisation of the dose rate expression in vertical growing crops. Their talk pointed out the need for differentiating between dose expression, dose rate and dose rate adjustment. Both speakers analyzed the strengths and weaknesses of the concept of treated Leaf Wall Area (tLWA) which would be consistent with any kind of spray application (*e.g*. field crops, vertical crops). They proposed to use tLWA as a common dose expression unit in efficacy trials and Biological Assessment Dossiers for most 3D crops for new active ingredients and for new projects. Additionally, they emphasized the need of the Crop protection Industry for planning security and clarity on transition and implementation timeline as well as clarity on validity of existing risk assessments and existing efficacy trial data.

Véronique Mironet (ANSES, FR) presented in detail the results of the questionnaire that had been sent to the countries of the Southern Zone and which was answered by six out of the nine countries. She highlighted the fact that more than 90 % of the production area of 3D-crops is located in the Southern zone. Her talk clearly showed that the question on a harmonized dose expression is still under discussion in the Southern zone and that many questions remain open. Several countries are of the opinion that there is no need for a change in the dose expression and that the current models are satisfying. Other countries had been of the opinion that a change to LWA can be an improvement of the current situation.

Lise Christina Deleuran (Aarhus University, DK) reported the results of the questionnaire for the Northern zone which was answered by three countries (Denmark, Finland and Lithuania), only. Giving a short summary of this talk, there was no clear decision pro or against the introduction of a harmonized dose expression in the EU.

Pierre-Henri Dubuis (Agroscope) summarized the results of the questionnaire for Switzerland and also introduced to the auditorium the Swiss calculation tool that enables the growers to adapt the allowed application rate in relation to the leaf surface with the aim of a constant deposit of the active substance throughout the growing season. This system is available for grapevine, fruit trees and just starting for high growing vegetables.
The final presentation on zonal surveys was given for the Central Zone by Géza Nagy (National Food Chain Safety Office, HU). The questionnaire was answered by nine out of 14 countries.
His talk showed the diversity in dose expression used the in the central zone and the variability of parameters considered during efficacy evaluation. He also pointed out that changes of the crop structure are considered for the evaluation. His talk drew the attention to an interesting aspect of the weaknesses of the currently available trial reports as some of the key parameters needed for application of the LWA concept are frequently missing in the trial reports.

Pierre Hucorne (CRA-W) spoke about the Belgium experience on the implementation of the dose expression per hectare leaf wall area in 3-dimensional crops that was finally established in glasshouse fruiting vegetable, small fruit and grapevine. He emphasized in his talk the need for a harmonized system of dose expression for the evaluation at the European level and again drew the attention of the auditorium to several dose expressions used in trial reports and dossiers and to the quality of trial reports. He concluded in his talk that MS Regulators should establish a listing of “equipment and crop” parameters that must be reported in trials with vertical crops, that GEP organisations should note all the “equipment and crop” parameters in the efficacy trial reports and finally applicants should present a concise table of the “equipment and crop” parameters for each trial in the BAD in order to be prepared for the future.

Santiago Planas (University of Lleida) presented a proposal for dose expression and dose adjustment in the EU-Southern zone and introduced the DOSAFRUIT system. In his talk he recalled the extreme differences in the cropping structures in the Southern zone and the variability in spraying equipment. His talk summarized the history and the research done for the development of the DOSAFRUT system which allows the grower to calculate and to adjust the application volume to the individual field situation.

Jo O’Leary-Quinn (CRD) gave also a talk on simple and practical solutions for the pesticide dose adjustment to the crop environment (PACE) as it is available in the United Kingdom. The online-tool PACE adjusts the “ground” dose for different orchard canopy sizes and orchard conditions without compromising efficacy. She again recalled the importance of differentiating between dose expression and dose adjustment.

Florence Verpont (Ctifl) gave a talk about a national multidisciplinary project, involving different Ctifl, IRSTEA, regional experimental stations, the cider sector, in close cooperation with sprayers manufacturers, UIPP, INRA and Agricultural Ministry with the aim to propose a set of ways to improve spray in fruit growing, sustainable technically and economically, and fulfilling the objective of the French National Ecophyto Plan.

Gregor Kral (BVL) addressed in his talk the upcoming changes of dose expression for plant protection products into kg or L/ha leaf wall area (LWA) considered for the evaluation and registration in Germany. To adjust the dose rate to changes of the leaf wall area during the season, a “factor system” is currently used for the dose expression in Germany. In his very interesting talk, G. Kral outlined the German approach of changes of dose expressions for expression for already authorized uses, for uses of renewal, and for uses of new applications. He analyzed the difficulties in recalculating and adopting dose expressions from a maximum application rate per hectare ground area towards leaf wall area and, he addressed the advantages and disadvantages of having or not having harmonized standards.

The last talk of the first day was given by Ralph-Burkhardt Toews (Bayer CropScience) who summarized the technical aspects of crop parameter measurement to give all participants a common base for the discussions during the 2nd day. He presented the current definitions of terms, the ways of how to measure these parameters, the classifications of cropping systems and their characterizing features.

The 2nd day was filled with vivid discussions in the working groups and between working group members during coffee breaks as it was the aim of the day for each working group to present conclusions and recommendation for a plenary discussion during the morning session at the last workshop day. In contrast to most earlier EPPO workshops there was no rotation of participants between the different groups to allow an in-depth discussion of the situation in each of the four crop groups.

At the end of the 2nd day, the working group on grapevine came to the conclusion that dose expression in kg or L/ha ground is not sufficient and that any step forward considering the crop structure would be an improvement. This group also suggested establishing a subgroup working on examples for conversion of LWA to local label expression.
The working group on pome fruit finished their day with an agreed glossary of terms and a parameter list for trials conducted today and in the future.

This group agreed on the dose expression in treated Leaf Wall Area (tLWA) with inclusion of the dose expression as a rate /ha (cGAP) and spray volume for conversion into other systems as important additional information. These data should be summarized in table format for each trial within the BAD/dRR.

The working group on High growing vegetables had a one voice agreement to the proposal to use tLWA as dose expression for efficacy. They also presented a list of required parameters to be measured when dose expression will be done in a harmonized way. Comparing the advantages and disadvantages of tLWA, this working group pointed out that tLWA provides a simple model which is more accurate than the dose expression on kg or L/ha ground. However, implementing this model needs training of technicians and identification of tLWA prior application. Additionally, they re-called to the auditorium that reference products are not registered with this dose expression and that old data should be accepted as valid if no unpredicted GAP changes occur. It was also discussed that the dose expression change in efficacy should be considered by "the right group" of residue experts.

The renamed "Working group on Globular Tree Orchards (Citrus, Olives…)" concluded that the Vienna workshop was a Kick-off Meeting on dose expression (and adjustment) for this working area. During their discussions it became very clear that they are at an initial stage of harmonisation. Their proposal for a short term approach (next season) is to continue with the use of product concentrations in combination with rationalized water rates. Additionally, scientific guidelines for modeling water rates to be used in globular tree orchards (GTOs) should be developed. For the mid-term they suggested to generate new trial data with harmonized study protocols and to independently analyze the anonymised data by crop experts. Their list of parameters to be measured additionally included both diameters of canopy width in globular trees and the distance between the trees planted in a row.

The actual as well as the theoretical water volume (L/m^3) should be noted. The development of an Excel tool was proposed for dose conversions.

At the last day of the workshop, all participants met again in a plenary session that was moderated by Ingrid Langer (AGES) and Claudia Jilesen (NPPO) for the presentation of the conclusions of each working group and for the discussion of the general conclusions and recommendations. The official general conclusions and recommendations are available on the EPPO-website (http://archives.eppo.int/MEETINGS/2016_conferences/dose_expression.htm). Briefly, the leaf wall area was agreed as an appropriate dose expression for plant protection products in pome fruit, grapevine and high growing vegetables. It was concluded that Kg or L/ha ground dose expression is not to be used in the zonal efficacy evaluation of plant protection products as it is not linked to any crop structure parameters. Nevertheless ,dose/ha of ground area is to be reported in the GAP table. For other dose expressions, proposals should be drafted by the applicant and included in the draft Registration Report. Finally it was proposed that a summary table has to be added to the BAD including the dose ranges used in each trial for the different dose expressions.

It was decided to establish two *ad-hoc* working groups by EPPO: A first group will work on examples for conversion of dose from LWA to other dose expression systems. A second group will work on a glossary of terms and on a guide for measurement of crop parameters.
Finally the revision of EPPO Standard PP 1/239 will be discussed in the next EPPO Panel on General Standards in February 2017.

Based on the results of the EPPO workshop in Vienna, SCC wants to stress two points relevant for the 2017 trial season: 1.) In all efficacy and residue trials in high growing crops, all trial parameters under discussion at EPPO should be measured and carefully reported 2.) As the registered dose rate for reference products is still expressed in most countries of the CEZ in kg or L/ha ground area and in the countries of the SEZ in addition in terms of concentration/hl, a concept has to be developed and ideally agreed with the relevant efficacy expert of the prospective zRMS at which dose rate the reference standard(s) should be applied.

New EPPO Standard on tank mixture adjuvants

The new EPPO Standard "PP 1/291(1) Evaluation of the influence of tank mix adjuvants on the efficacy of plant protection products" has been published "*for countries with national requirements for efficacy data to support claims on adjuvants marketed for use with plant protection products*" in December.
"*It may also be of use to manufacturers of adjuvants during development of their products and to manufacturers of plant protection products to support label claims. Differentiation is made between voluntary recommendations and requirements of mandatory mixtures (e.g. twin packs) on label claims of plant protection products, as this latter case should be considered as a plant protection product use covered by the relevant EPPO Standards (PP 1).*" The standard makes clear that for mandatory mixtures the full efficacy data set is required, whereas in case of voluntary mixtures the overall benefits of the addition of the adjuvant when compared to the solo use of the plant protection product have to be shown.

As a first step the function of the adjuvant (*e.g.* spreader, antifoam) has to be clearly described and proven by data. The standard provides a number of testing methods for 7 different adjuvant functions in the appendix. Then the possible plant protection products to be supported, the possible intended crops and the possible target organisms have to be determined. The general strategy for preliminary studies is being described which should be performed to define the ratio between plant protection product and adjuvant in the spray mix. Unlike for mandatory mixtures, it is not necessary for voluntary mixtures to demonstrate the efficacy against each single target.
"*Efficacy trials can be performed on representative combinations of crop/target/plant protection product for herbicides and crop/target combinations for other product types that can be tested to demonstrate the efficacy of the adjuvant/plant protection product mixture in a well-defined area of use. The number of trials should be decided on a case by case basis according to the crop/pest combinations claimed.*"
PP 1/291 (1) also gives some useful guidance on the specific design of efficacy trials with adjuvants (efficacy, dose justification and adverse effect assessment).

New EPPO Standard on cleaning of pesticide equipment

The second new EPPO standard "PP 1/292 (1) Cleaning pesticide application equipment (PAE) – efficacy aspects" describes "*methods used to examine whether cleaning procedures are sufficient to ensure that residues of plant protection products do not remain in the pesticide application equipment (PAE) after cleaning, and that there is no unacceptable risk to subsequently treated crops*." The standard describes in a stepwise approach how the potential risk of carry-over of residues in a spray tank to the subsequently treated crop or land can be assessed. The Appendix 1 of the standard provides an elaborated decision-support scheme. The scheme follows the common practice which first considers the results of screening trials, eventual phytotoxicity in efficacy trials and esp. the results of non-target plant tests done for the ecotoxicology section. Standard EN/ISO 16119-2:2013 is cited as basis for model calculations in Appendix 4. The amount of 52 L spray solution in a 2000 L & 21 m boom sprayer is taken as example residue amount to be diluted two times with 390 L of water. The calculated dose of 0.1 g a.s. will be sprayed per ha on the subsequently treated crop and is the basis to calculate the toxicity:exposure ratio. These theoretical dilution values apply to water soluble active substances. If a cleaning agent is being proposed, the effects cannot be easily predicted. The standard proposes "small-scale/large scale tests" as "Tier 2b". Appendix 3 provides a very detailed example protocol for a tank cleaning procedure including analysis and evaluation in a small scale jar test. If the Tier 2 testing still cannot rule out phytotoxic effects, "*then a series of semi-field or field tests is necessary*", for which the outline is again described in detail in the standard.

For more information, please contact
Dr. Albrecht Heidemann at
albrecht.heidemann@scc-gmbh.de

CHEMICALS/REACH

Toxic Substances Control Act (TSCA) Updated

Signed by President Obama on 22 June 2016, the Toxic Substances Control Act (TSCA) of the US received a major update. From the long list of changes, the following points should be highlighted:

- The US Environmental Protection Agency (EPA) is now required to make an affirmative determination on new chemicals before they may enter the market.
- EPA has to check the complete inventory of chemicals to identify which are active/inactive and establish a screening process to determine substances of high or low priority.
- All high-priority chemicals require a risk evaluation performed by the EPA.
- From the day of enactment, all claims for confidential business Information (CBI) will be reviewed by EPA. Moreover, CBI claims will sunset after ten years (unless re-substantiated) in contrast to the 'eternal' CBI claims of the old law.
- The term "potentially exposed or susceptible subpopulation" is introduced. This may include groups of individuals as infants, children, pregnant women, workers, and elderly people.
- As in Europe, test on vertebrate animals should be reduced and replaced where possible.
- Mercury compounds were added to the export ban of elemental mercury.
- EPA is allowed to collect up to 25$ million annually from chemical manufacturers and processors.

Many rules, as those for risk evaluation, still need to be developed and established by the EPA. Therefore, companies need to closely watch and participate in EPA's activities to implement the updated TSCA.

Guidance on occupational exposure assessment updated

The Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.14 Occupational exposure assessment has been updated in August 2016.
The update aimed to improve the link between exposure estimation and the identification and communication of suitable risk management measures (RMMs).
The updated Guidance R.14 contains the following improvements:

1) Proper description of engineering controls and personal protective equipment, the former being the preferred means of controlling the exposure.
2) A short section describing the general aim of Specific Worker Exposure Descriptions (SWEDs).
3) Information on exposure estimation models has been updated and more specific details (e.g. domain of applicability) now can be found in the appendix.
4) The section "Assessment of acute exposures" has been revised, now containing recommendations of exposure estimation models for estimating short-term exposure.
5) A new section on exposure assessment for application for authorization has been included.

CoRAP and compliance check lists updated

ECHA has published a draft Community rolling action plan (CoRAP) list for 2017-2019. The Member States are planning to evaluate 117 substances (22 are newly selected). Please note that for the 24 substances subject to evaluation in 2017, dossier updates, where relevant, should be made before March 2017. The list can be found at the ECHA homepage. The final plan will be adopted in March 2017.
In addition, ECHA has updated the list of substances that might be chosen for compliance checks. The list includes 93 new substances. Registrants are advised to check this list and if needed, update their related registration dossiers by 13 January 2017.

Is a reduced import of phase-in substances below 1 ton per anno possible after 2018 deadline?

We would like to draw your attention to an important issue regarding the calculation of REACH relevant tonnage for phase-in substances. According to REACH article 3(30), for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on

the basis of the average production or import volumes for the three preceding calendar years.

This leads to two possible situations:
If the 3 year average for 2018 (based on the average 2015 to 2017) is *e.g.* 5 t/a and your company decides to stop manufacture / import after 31 May 2018, then there are no registration obligations regarding this substance. Furthermore, a selling form the stock is also not possible.

In contrary if the 3 year average for 2018 (based on the average 2015 to 2017) is e.g. 5 t/a and your company intends to continue manufacture / import after 31 May 2018, even with an manufacturing / import in 2018 below 1 t/a, a registration is required as the relevant tonnage is above 1 t/a.

Consequently, as the volumes for 2015 and 2016 are fixed, one has to take into account the above mentioned considerations when deciding about registration or stop of business. Please also keep in mind that according the REACH article 5 without a valid REACH registration a placing on the market (selling from the stock) is also not possible.

OECD Substitution and Alternatives Assessment Toolbox (SAAT)

At the OECD Substitution and Alternatives Assessment Toolbox (SAAT) website a link is available to a table of restricted substances lists and related laws and regulations organized by geographic scope.

http://www.oecdsaatoolbox.org/Home/Regulations

The linked lists provide descriptions of chemicals that are legally or voluntarily restricted or recommended for restriction due to their hazards or have been examined by jurisdictions based on potential concerns due to similar properties. These lists might help companies to identify potentially critical substances and to plan ahead for potential candidates for substitution.

Warning - time sensitive issue regarding joining of the correct SIEF

The main aim of late-preregistration is to cover recently started manufacture or import of a non-CMR phase-in substance in amounts of 1 to 100 t/a. Therefore, a pre-registration within six months after starting the activity is still possible. However, the last possibility is on 31 May 2017.

Furthermore, a late-preregistration is a quick option to join the correct SIEF in case substance ID data are at hand one concludes that the current SIEF is not appropriate for your substance.

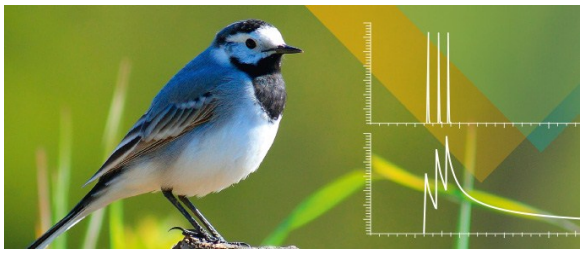
Thus, SCC strongly recommends to gather substance ID data for your lead or member registration and agree with the other SIEF members on substance sameness. After May 2017 an inquiry, including a detailed check of analytical data by ECHA staff, is the only way to join a SIEF. This means in particular more time and efforts for registration and, most critical, without having an appropriate pre-registration at hand one cannot benefit from the extended deadline of May 2018.

Different consequences of ECHA dossier checks during submission

Dossiers submitted via REACH-IT are subjected to different checks. The first check is the Business rules check. Here ECHA checks the administrative information of the dossier. In case the submission fails at this step (*e.g.* substance ID does not match the substance in the joint submission) the dossier will be rejected. A new submission with corrected data will be possible without any further measures or follow up actions by ECHA.
In case the dossier will have passed the BR check, the technical completeness check starts. One part of this step is the manual check by ECHA staff. If the dossier will be rejected during the technical completeness check, one will receive a communication letter including a deadline to submit an improved dossier. In parallel, the financial completeness check will not set on hold. Thus, you will receive an invoice for the registration fee with a due date. The updated dossier will be subject to the same completeness check. In case the invoice has been paid and ECHA rejects the updated dossier, the registration fee will not be refunded. A new dossier has to be submitted and a new registration fee has to be paid.

For more information, please contact
Dr. Werner Köhl at
werner.koehl@scc-gmbh.de

REGULATORY SCIENCE



EFSA Info session on applications - pesticides - technical meeting with stakeholders on EFSA GD on residue definition for dietary risk assessment
Parma, 26 - 27 September 2016

EFSA met with stakeholders to present – in advance – the final draft of "Guidance document on the establishment of the residue definition for dietary risk assessment" issued by the Panel on Plant Protection Products and their Residues (PPR) on 26 and 27 September 2016.

This session was held in the framework of the "EFSA Info Sessions on Applications" aimed at increasing regular interaction and exchange of views with EFSA's stakeholders. As main points answering of questions and collecting feedback on this new guidance document were claimed.

Applicants, representatives of industry associations, consultants, academics, representatives of national authorities and the COM met with EFSA experts from the PPR Panel and EFSA staff.

Assessment approaches proposed in the GD, which involve new tools and methodologies that have not been used before on a systematic basis in regulatory assessments of pesticides, were discussed in detail.

Several important issues were addressed in the meeting with reference to this new EFSA GD:

- Setting process for residue definition – stepwise approach
- Quantitative Structure-Activity Relationships (QSAR) – *in silico* techniques
- Threshold of Toxicological Concern (TTC)
- Toxicology testing strategies
- Assessment of conjugates

The several views on scientific issues related to the risk assessment of residues of pesticide active substances following the new EFSA GD as well as on benefits, challenges and concerns associated with the proposed assessment approach were exchanged between participants.

Special sessions focused on the assessment of the toxicological relevance of pesticide metabolites, dietary risk assessment considerations, and on launched and intended projects facilitating the application of the proposed assessment approach. Stakeholders, including representatives from Member States and applicants, appreciated the dedicated feedback session which gave them the possibility to express their point of view.
This event was considered as an important opportunity to enhance constructive dialogue and to increase interaction with EFSA.

The final version of the "Guidance document on the establishment of the residue definition for dietary risk assessment" was announced until the end of this year.

For information on the agenda, the presentations of the technical meeting and the list of participants please refer to
https://www.efsa.europa.eu/en/events/event/160926

Draft EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil

EFSA issued in July 2016 a new version of the Draft EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (EFSA Journal, 2016) and launched a corresponding public consultation which ended in September 2016.
In comparison to the draft versions of the document from 2014 and 2015, permanent crops and no-tillage systems as well as recommendations regarding crops grown on ridges are now included in the guidance.

The currently proposed methodology consists of four tiers starting with the analytical model PERSAM assessing one scenario per regulatory zone. The following tiers are considering specialized versions of PEARL and PELMO further assessing input derived with PERSAM (Tier 3A) and calculating a spatially distributed PECsoil for a number of scenarios (Tier 3B). A 4th tier envisages post registration monitoring. The current draft guidance is the outcome of a long-term process to replace the current guidance from 1997. It started in 2008 with a Project Plan for developing a guidance on soil exposure assessment, followed by an EFSA workshop in 2009 and several Scientific opinions and Technical/Scientific Reports between 2010 and 2012 and finally leading to the draft GD versions in 2014 and 2015. The finalization of the GD is currently expected until end 2017.

For more information, please contact
Dr. Monika Hofer at
monika.hofer@scc-gmbh.de

CALENDAR

Meet SCC at Crops & Chemicals Europe 2017 in Berlin, Germany 8 - 9 February 2017

Please meet
Dr Friedbert Pistel, President,
Dr Bernd Brielbeck, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides,
Dr Norbert Weissmann, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides

Don't miss the opportunity to hear the presentations of Dr Brielbeck and Dr Weissmann in the sessions on low risk substances and efficacy.

Use this chance to visit our exhibition stand No. 10 and to speak with our top experts spontaneously or request an individual meeting to specifically discuss your registration needs of Agrochemicals and Biopesticides or any other regulatory or scientific issues of your concern.

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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
Mr. Toshiaki Fukushima
Senior Consultant
toshiaki.fukushima@scc-japan.com