Dear Subscribers,

We are delighted to announce that Ms. Martina Galler will be the new head of Biocides starting January 1st, 2018. She currently heads up the preservatives group within SCC’s Biocides business unit and has more than 15 years of experience in biocides regulatory affairs. You can find out more on this in the Biocides section.

The draft guidance document for identifying endocrine disruptors under EU legislation for pesticides and biocides was prepared by ECHA and EFSA and published for discussion in December 2017. This issue of the SCC Newsletter also features other important news about agrochemicals/biostimulants, chemicals/REACH and regulatory science.

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 for your scientific and regulatory needs. Our expertise here 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.

Take a look at our calendar to find out where you can meet with SCC experts to discuss your needs and find answers to your questions on scientific and regulatory issues.

We appreciate your feedback and comments regarding the SCC Newsletter. Please send us an e-mail 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
Harmonization of Dose Expression in High Growing Crops – impact on product authorisations

Attempts to harmonize the dose expression for high growing crops in EU already date back to the last century. In the most recent workshops, meetings and discussions by the various stakeholders it was concluded that the Leaf Wall Area (LWA) approach is an appropriate dose expression for plant protection products in pome fruits, grapevines and high growing vegetables. Therefore, the LWA is to be reported in the respective GAP table of a plant protection product and should replace dose expressions such as kg or L/ha ground in the zonal efficacy evaluation of plant protection products.

While in arable crops the area treated with plant protection products is similar to the ground area, in high growing crops such as grapes, fruit trees or high growing vegetables, the treated area (leaf wall area) can be much higher than the ground area. This can influence the efficacy of a product considerably and entails several risks in regards to product evaluation and use. For sites with low leaf wall areas for example, the resulting overdosing can lead to phytotoxicity as well as unnecessary risks for humans or the environment. In case of high leaf wall areas, pest control levels may be reduced and the risk of resistance development increases if the dosage is not based on LWA. In addition, a more precise dosage such as LWA may reduce the required maximum amount of plant protection products used per hectare which is in line with the requirements of Directive 2009/128 and its implementations in National Action Plans (NAPs).

At the moment, many product development strategies still do not take the leaf wall area concept into account and the dose expression is based on the amount product (and active substance) per ha or even based on not-EPPO conform rates such as amount of product per hl. In addition, very often efficacy study reports do not contain LWA-relevant parameters such as spacing between rows or plants, spray band height or spray volume per ha ground area to allow for conversion to LWA. There are several short-term actions scheduled to foster and extend the LWA approach such as revision of EPPO Standard PP 1/239 (Dose expression for plant protection products). At a meeting of EU efficacy evaluators in Oct 2017 in Athens, it was already agreed that from January 2020 Central Zone applications for new products will only be accepted when they are based on the LWA approach. From January 2018 onwards, respective trials have to be carried out using LWA. Labels for plant protection products will also have to be amended as the BBCH/EPPO-scale, describing the development stages of a plant, will no longer be used to fix conditions for application. Instead, the site-specific plant growth and growing conditions will determine the conditions of use at each individual application.

http://archives.eppo.int/EPPOStandards/efficacy.htm

New EU fertiliser regulation – status quo

On 24 October 2017, 392 amendments to the upcoming EU fertiliser regulation and thus the future of CE marked fertilizing products and biostimulants were debated in the European Parliament.

The proposed amendment 20 on Recital 16 of the regulation was adopted, thus clearly separating biostimulants and biocides: “Products with one or more functions, one of which is covered by the scope of Regulation (EC) No 1107/2009, are plant protection products covered by the scope of that Regulation. Those products should remain under the control tailored for such products and provided for by that Regulation. Where such products also have the function or the action of a fertilising product, it would be misleading to provide for their CE marking under this Regulation, since the making available on the market of a plant protection product is contingent on a product authorisation valid in the Member State in question. Therefore, such products should be excluded from the scope of this [the fertiliser] Regulation”. In conclusion, a possible “dual use” for biostimulants and plant protection products was therefore rejected.

The proposal was referred back to the Committee on Internal Market and Consumer Protection, opening up the interinstitutional negotiations with the Council again (for more information please refer to SCCs Current News of Oct. 23 and Nov. 06)
EBIC (The European Biostimulants Industry Council) welcomed the adoption of the report of the EU Fertilizing product regulation by the plenary of the European Parliament and stated that the “European Parliament supported key elements to establish an equitable EU market for biostimulants, including defining biostimulants and clarifying the boundary with plant protection products, the requirement to develop safety criteria and harmonized standards, in particular for micro-organisms and promoting a circular economy with the efficient use of plants and plant extracts”. According to EBIC they will continue to work throughout the Trilogue process to achieve further improvements of the new regulation to fully support the biostimulant industry.

For further information on biostimulants and the upcoming EU Regulation please also refer to the special edition of SCC Newsletter No. 2/2016 on the Draft Fertilising Products Regulation (COM(2016) 157 final), the critical review on current development of biostimulants by Dr Lars Huber in Agrow’s supplement Biologicals 2017 or SCCs Current News of Oct. 23 and Nov. 06.


Sustainable pesticide use – progress, shortcomings and implications for registration of plant protection active substances and products

Directive 2009/128/EC on the sustainable use of pesticides (Sustainable Use Directive; SUD) was adopted on 21 October 2009 as part of the EU 2006 Thematic Strategy on the Sustainable Use of Pesticides. The Directive aims at reducing the risks and impacts of pesticide use on human health and the environment by introducing different targets, tools and measures such as Integrated Pest Management (IPM) or National Action Plans (NAPs).

Since entry into force, the regular reporting requirements of the Directive were met by various means such as a Commission assessment of the NAPs, two audit series on sustainable pesticide use performed between 2012-2016, a survey of all Member States as well as fact-finding visits to some Member States in 2017 to investigate the overall progress made with implementation of the Directive and the National Action Plans. “By 14 December 2018, the Commission shall submit to the European Parliament and to the Council a [final] report on the experience gained by Member States on the implementation of national targets established in accordance with paragraph 1 in order to achieve the objectives of this Directive. It may be accompanied, if necessary, by appropriate legislative proposals” (Dir. 2009/128, Art. 4).

History and background

Despite the progress in limiting the risks linked to the use of pesticides, and to prevent any undesirable effects, by adapting the 6th Environment Action Programme (EAP; Decision No 1600/2002/EC) further measures were agreed upon by European Parliament and the Council. The Action Program mainly focussed on two issues: Full implementation and revision of the relevant legal framework existing at this time as well as the development of a Thematic Strategy on the Sustainable Use of Pesticides.

First and foremost this led to a survey of Directive 91/414/EEC on the placing of plant protection on the market replacing it with Regulation 1107/2009 in 2011 (entry into force) and simultaneously bringing into force additional pesticide-related legislation such as Regulation 1185/2009 concerning statistics on pesticides, Directive 2009/127 on machinery for pesticide application and the SUD.

The 2006 Thematic Strategy on the Sustainable Use of Pesticides identified several new targets that could not be integrated into the instruments existing back then, mainly: Establishment of National Action Plans (NAPs), Involvement of stakeholders, Establishment of a system of training of professional pesticide users, Awareness raising of the general public, Regular and compulsory inspection of application equipment, Prohibition of aerial spraying, Handling and storage of packaging and remnants of pesticides, Development and Establishment of harmonised risk indicators, Establishment of a system of information exchange at Community level, Development of systems for the collection of information on distribution and use of plant protection products, Promotion of low pesticide-input farming, Implementation of Integrated Pest Management (IPM), Definition of areas of significantly reduced or zero pesticide use and the Enhanced protection of the aquatic environment. SUD was the pertinent tool to implement several of these targets.
The EU Thematic Strategy on the Sustainable Use of Pesticides is complemented and flanked by various direct and indirect regulatory, scientific and legislative measures such as the EU action plan for the Circular Economy, FOOD 2030 or the new EAP 2020 for example. On a global scale EU strongly supported and fostered the 2030 UN Agenda for Sustainable Development.

Scope, progress and shortcomings of Directive 2009/128 (SUD)


In regards to the establishment of a system of training of professional pesticide users for example the level of compliance is very high in most Member States. The same is the case in regards to regular and compulsory inspection of application equipment which is established in most Member States or the prohibition of aerial spraying.

In addition, progress in the reduction of pesticide use in specific areas frequented by the general public or by vulnerable groups, protected areas or recently treated areas frequented by agricultural workers according to Article 12 of the SUD. In this context the pesticide ban in Ecological Focus Areas (EFAs) was a matter of serious discussions in 2017. EFAs were established as part of the Common Agricultural Policy (CAP 2020) objectives for sustainable management of natural resources and climate action whereas 30% of direct payments to farmers are tied to greening of which EFAs are a part. Where the arable area of a holding exceeds 15 ha, 5% of the area must be designated as EFA. EFAs can be fallow land, field margins, hedges and trees or buffer strips. It is also possible to assure the EFA requirement indirectly through cutting the use of agricultural inputs or better soil protection e.g. in areas covered by catch crops, which are fast-growing crops grown between plantings of main crops or nitrogen-fixing crops. Commission even planned pesticides-free EFAs. This met with high opposition and a veto by Parliament was proposed. However, in the respective voting in June 2017 the resolution objecting to the Commission’s delegated act was rejected, the pesticide ban in EFAs entering into force!

Whereat huge progress could be observed for several objectives of SUD as detailed above, other targets obviously fall short compared to the aims set out by SUD. This is especially true for the “promotion of low pesticide-input farming and the creation by Member States of necessary conditions for implementation of Integrated Pest Management” (IPM) and the enhanced protection of the aquatic environment.

In the 2017 report Commission highlights that, besides organic farming, IPM, which is mandatory for professional users since 01 Jan 2014 in EU (SUD, Art. 14) “is a cornerstone of the Directive, but compliance with the principles of IPM at individual grower level is not being systematically checked by Member States. Furthermore, Member States have not yet set clear criteria in order to ensure that the general principles of IPM are implemented by all professional users.” SUD defines Integrated Pest Management as a strategic approach using “careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. Integrated pest management” emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms”. The respective general principles of Integrated Pest Management are set out in Annex III of the SUD.

However, some sub-goals are already met, e.g. in regards to publicly funded systems for forecasting, warning and early diagnosis for pest and disease control or the implementation of IPM in the national farm advisory systems, a mandatory requirement of Regulation 1306/2013.

One of the main challenges regarding the implementation of the principles of IPM seems to be the current lack of appropriate control instruments as well as clear rules and guidance. According to many national authorities another major hurdle is the lack of sufficient non-chemical low risk pesticides which would broaden the range of IPM tools available to growers. In regards to low risk active substances and low risk plant protection products several developments took place in the recent past. For one, the criteria defining low risk active substances were revised by Regulation 2017/1432, amending Annex II of Regulation 1107/2009 accordingly. For another, the
lack of low risk substances and products available, the reasons and possible solutions, were subject of intensive political discussions in the recent past (e.g. Motion for a European Parliament resolution on technological solutions for sustainable agriculture in the EU (2015/2225(INI)); European Parliament resolution of 15 February 2017 on Low-risk Pesticides of biological origin (2016/2903(RSP))). In addition to efforts to foster low risk substances and products on an EU wide level, e.g. by establishing a faster approval/authorisation process, there are already several national actions on going to promote registration of low risk plant protection products. In Denmark for example a funding programme to support the costs of authorising non-chemical pesticides is in place since 2010 which refunds up to 100 % of the total costs associated with gaining authorisation for a new pesticide. In France, the General Council for Food, Agriculture and Rural Areas (CGAAER) made extensive proposals how to increase availability of low risk products (for more information on low risk substances and products see here).

As in case of IPM, the lack of measurable targets in many NAPs prevent the full implementation of SUD in regards to Article 11 of SUD on measures to be taken to protect the aquatic environment and drinking water supplies from the impact of pesticides. This is partly due to the diverse, country-specific conditions and targets and the respective national approaches to implement respective measures as highlighted, for example, in the Commission staff working document on agriculture and sustainable water management in Europe. In general, measures to be taken to protect the aquatic environment and drinking water supplies from the impact of pesticides are subject not only of SUD, but of several legislative frameworks such as the Water Framework Directive (2000/60/EC), Directive 2006/118/EC for Groundwater, Directive 2008/105/EC on Environmental Quality Standards in Surface Water or Directive 1998/83/EC for drinking water. Depending on national/regional requirements, the focus can vary considerably between Member States. According to the Member States over one million water samples were tested for pesticide residues in 2014 and 2015 and extensive measures were taken for example in regard to buffer zones or drift reducing equipment. Some Member States, such as Denmark, established extensive monitoring and research programs. Under the Danish Pesticide Leaching Assessment Programme, authorised pesticides are tested in regard to leaching to groundwater at six representative test fields in line with normal agricultural practices. Based on these studies, for some previously authorised pesticides authorisations were withdrawn, for others conditions of use have been modified. In Member States such as Denmark, protection of groundwater is an issue of national importance as all drinking water is sourced from groundwater, which is, besides some exceptions, not treated before consumption (Final report fact-finding mission Denmark (DG(SANTE) 2017-6007), 2015 Organic Action Plan for Denmark).

Implications of SUD for plant protection product registrations

In its 2017 report to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of SUD, COM concludes that “the Directive [2009/128] offers the potential to greatly reduce the risks derived from pesticide use. However, until it is more rigorously implemented by Member States, these improvements are limited and certainly insufficient to achieve the environmental and health improvements the Directive was designed to achieve”. To amend this, extensive measures are already under way or foreseen for the near future.

As a good part of the instruments and tasks provided by SUD are part of the NAPs, the revision of these based on the audit results is one of the most important tasks for Member States. In the general process of NAP review, which is required at least every 5 years, only France and Lithuania presented revised NAPs until now. Revisions are intended until end of 2018 by 25 Member States. As identified by the 2017 report there will be a focus especially on those tasks for which significant gaps were identified, such as aerial spraying, information to the public, the gathering of information regarding poisoning cases, measures to protect the aquatic environment or implementation of Integrated Pest Management.

Commission already indicated that several EU actions are scheduled. These include, for example, extensive monitoring of Member State obligations by Commission. Commission also will give consideration to infringement actions. In addition, as already quoted before, “by 14 December 2018, the Commission shall submit to the European Parliament and to the Council a report on the experience gained by Member States on the implementation of national targets established in accordance with paragraph 1 in order to achieve the objectives of this Directive. It may be accompanied, if necessary, by appropriate legislative proposals” (Dir. 2009/128, Art. 4). Commission already indicated that it will initiate various supporting actions, such as a web portal linking to the currently available relevant information on IPM and Sustainable Agriculture.
The use of pesticides at EU and Member State level (already launched in Oct. 2017), provision of a guidance on monitoring and surveying of impacts of pesticide use on human health and the environment (C(2017) 6766 final; already published Oct. 2017), support to Member States for development of suitable risk indicators or a more strict inclusion of SUD targets in the system of cross-compliance as eligible through the Regulation on the financing, management and monitoring of the common agricultural policy and repealing (Reg. 1306/2013).

It has to be considered that efforts in regard to sustainable use of pesticides in most cases are not based on general “green thinking” and related to ideological ideas on biodiversity, green environment, etc. Rather, economic considerations and requirements as for example in case of the price and availability of drinking water, financial consequences of pesticide resistance or insufficient pollination are triggering efforts to make agriculture more sustainable. Therefore, new and stricter regulations on sustainable use of plant protection products are to be expected in future.

**New Organic Farming regulation to be expected in 2021?**

The trilogue agreement for a new organic regulation of June 2017 was adopted by the Special Committee on Agriculture (SCA) on 20. November 2017 and by the Parliamentary Committee on Agriculture (AGRI Committee) on 22.11.2017.

According to the European Commission a new organic regulation will enter into force on 1 January 2021 and “will apply to the live and unprocessed agricultural products, including seeds and other plant reproductive material and processed agricultural products used as food and feed. Processed products could be labelled as organic only if at least 95 % of the agricultural ingredients are organic”.

Organic farming is one of the most dynamic sectors of EU agriculture, currently growing at around 400.000 ha per year with a growth peak of 800.000 ha per year in the last two years. Organic market had a mean yearly growth of 12.5 % in the last 10 years and is worth around €27 billion.

The new legislation shall provide a simpler and more harmonized approach. Commission states that the main improvement of the new regulation will be the introduction of one set of EU-wide rules covering the whole EU organic sector and is going to apply also to non-EU farmers who export their organic products to the EU market.

IFOAM (International Federation of Organic Agriculture Movements) EU acknowledged the huge effort made by the stakeholders to improve the text. However, IFOAM EU also showed some concerns as voting did not result in a strong majority in favour of the existing draft whereat Austria and Germany, two of the biggest players in the organic sector, did not endorse the text. Therefore, IFOAM called for a strong commitment by the EU Institutions and by the Member States to work together on further improvements on the legislative text.

For more information, please contact Dr Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de
New head of Biocides business unit starting in January 2018

We are pleased to introduce Martina Galler who will be the new head of Biocides starting January 1st, 2018.

Martina Galler has a PhD in biology and more than 15 years of experience in biocides regulatory affairs.

She currently heads up the preservatives group within SCC’s Biocides business unit and will take up her new role at the beginning of 2018.

Martina’s field of expertise comprises all BPR activities relating to biocidal active substances and products as well as the environmental risk assessment of biocides in nearly all product types.

For more information, please contact Dr Martina Galler at martina.galler@scc-gmbh.de

The US TSCA Reform approaches a first important implementation milestone – the Reset of the TSCA Inventory of existing chemicals to designate “active” vs. “inactive” chemicals

Latest by 7 February 2018, all manufacturers in the US and all importers into the US need to notify all chemicals on TSCA Inventory manufactured, imported or processed since 21 June 2006 as “active”.

The purpose for this requirement is to focus the subsequent EPA review on those substances truly still in commerce.

The EPA review of the inventory of existing active chemicals will focus on high-priority chemicals in these steps: prioritization, risk evaluation (RE), and regulation (of individual substances or substance classes).

Regulation of chemicals may include e.g.

- Restrictions on specific uses, quantities etc.
- Requirements for specific engineering controls and personal protective equipment
- Requirements for specific waste disposal conditions
- Phase-outs and bans of substances

In the context of the TSCA Inventory Active-Inactive Designations, what are relevant questions for importers into the US?

- Do you know all of the chemical ingredients in the raw materials you import?
- Are any of these ingredients proprietary?
- If so, the non-US supplier must file a joint notification with the US importer, providing chemical identity directly to US EPA only.
- If you are a non-US supplier, your US importer may require this from you.
Turkey: KKDIK will come into effect on 23 December 2017

The new chemicals Regulation KKDIK will come into effect on 23 December 2017. All substances manufactured or imported into Turkey with a volume $\geq 1$ tpa must to be registered under KKDIK until 31 December 2023 (registration deadline). Pre-registrations must be submitted by the end of 2020. Substances or mixtures covered by other regulations are exempted from the registration under KKDIK. The information to be provided for the registration is similar to EU REACH but KKDIK requires submissions to be made in Turkish. An official KKDIK translation into English is not yet available.

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

REGULATORY SCIENCE

Current Hot Topics in Ecotoxicology, Vienna, 7 November 2017

Experts from the Ecotoxicology Department from the Austrian Agency for Health and Food Institute for Plant Protection Products (AGES), directly involved in evaluation of active substances and plant protection products, provided a one day technical session to address recent developments and updates in the field of ecotoxicology risk assessment to fulfil the requirements of Regulation (EC) 1107/2009. A wide range of topics, including the harmonization processes in the central zone, data requirements and risk assessment for bees as well as Endocrine disruptors, were covered. Some of the key points of each of these sections are summarized below.

Harmonisation processes in the central zone

Focal species for birds and mammals

During several meetings held between 2014 and 2017 no agreement on a “mandatory” list of focal species was reached. The study Dietzen et al. 2014 (Focal species of birds in European crops for higher tier pesticide risk assessment) cannot be considered the sole or major source of information. It is highly appreciated to include further information (study and literature) to back up the choice of the relevant focal species for the risk assessment. In this context AGES referred to the EFSA data collection project “Data collection for the estimation of ecological data, residue level and residue decline of pesticides on food items to be used in risk assessment for birds and mammals”.

Time moving window approach for birds and mammals

Calculation tools, developed by Germany, UK and Belgium, have been provided to all MSs and can be made available to applicants. Majority of the MSs are in favour using the moving time window of 21 days also in the in 1st Tier and propose its inclusion into the ongoing revision of the Birds and Mammals Guidance Document. Currently, AGES takes the state of
art of the current GD, where the time moving window is used in the second Tier and for changing application rates and intervals.

**Bee**

AGES recommends performing the bee risk assessment according to the EFSA GD (2013), which is currently not in force. The Commission roadmap Part A and the EFSA technical report (2015) are not uniform in terms of bee testing and risk assessment. Currently, AGES recommends following the Commission roadmap Part A. Furthermore, all data requirements should be addressed no matter if suitable GD or methods are available.

**Endocrine disruptors**

EU Parliament withdrew the draft regulation and requested the submission of a new draft regulation. In the meantime AGES recommends continuing to apply the Interim criteria. In contrast, the criteria for Biocides have been approved early in November this year.

**Short notice:**

**Endocrine disruption – draft guidance for identifying endocrine disruptors**

The draft guidance for identifying endocrine disruptors was published on 7 December 2017. The document addresses all relevant issues linked to endocrine disruptor criteria like assessment strategy to obtain information, assembling of the line(s) of evidence, mode of action analysis and appropriate test methods.

This draft guidance was requested by the European Commission and has been developed by the two agencies EFSA and ECHA with the support of the Commission’s Joint Research Centre (JRC). Earlier this year EFSA and ECHA conducted two targeted consultations on initial versions of the draft guidance with experts representing Member States and with stakeholders from industry and NGOs. Obtained comments were taken into account in a revised version of the guidance.

The deadline for providing comments is 31 January 2018.

**Reference:** Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/200

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

**CALENDAR**

**Biostimulants Europe**

Valencia, Spain

17 - 18 January 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.

The second Biostimulants Europe Conference is an occasion to discuss during two days the challenges and future opportunities in the field of biostimulants.

For further information on this event, please refer to: [http://www.rsc.org/events/detail/28079/biostimulants-europe](http://www.rsc.org/events/detail/28079/biostimulants-europe)

**Risk assessment for biocides – Training course in Berlin, Germany**

27 - 28 February 2018

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

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

This two-day course is designed for environmental and human risk assessors and regulators from industry, authorities and consultancies.

For further information, please download the programme or visit directly the event website.
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Do you have any comments, questions or suggestions? Drop us an E-mail at newsletter@scc-gmbh.de.