SCC
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# NEWSLETTER

SCC Newsletter Vol. 14, No. 2, July 2014

# SCC: 25 YEARS AND BEYOND – OPTIMAL SERVICE IN A NEW DESIGN

**Dear Subscribers,**

It all started in a small house in Biebelsheim/Germany with the aim to understand and to manage the regulatory world of pesticides…
…25 years have passed since then and it seems that change is the only constant in time and space…

Please welcome the jubilee edition of the SCC-Newsletter on the occasion of the company's 25th anniversary!

As already indicated, SCC has moved further on to become more attractive and to expand customer relationships in the future.

In the last 25 years, SCC has specialized in regulatory management services in the areas of agrochemicals, biocides, chemicals, and much more.

Whether we are supporting our customers in regulatory affairs, dossier preparations, or task force / consortium support, they can rely on us when disadvantageous situations threaten their business and success.

Our efforts in solution management on the regulatory level also help to create profitable customer relationships. Nurturing relationships with our customers is crucial to gaining our clients trust in our scientific and personal expertise, when they want to reach their target aims without serious setbacks.

Without the dedication and competence of all our talented, highly skilled and competent employees in Germany and Japan, this development would not have been possible, nor would there have been such a long period of continuous growth and success in the fast-moving regulatory world.


**Our work is based on three principles that guide our business practices throughout our worldwide activities:**

- As autonomous company being independent of any Contract Research Institute to make the best choice of the testing facility for our customers to enable an outstanding study quality under any circumstances.
- Application of smart approaches to minimize efforts for dossier submissions by reasoning and preventing additional, time-consuming studies, if reasonable.
- Dedicated well-trained specialists able to handle each issue in an adequate and reliable way by their in-depth knowledge of regulatory issues. Their basis is an enormous pool of successfully arranged and finally registered agrochemical and biocidal products, chemicals and other products.

The anniversary of SCC was the occasion for the renewal of our corporate image including internet presence and newsletter.

The new corporate design expresses our intention to expand our services in a fast-moving world. The regulatory field offers many challenges and new developments; we strive to guide our customers through this complex environment. Furthermore, it symbolizes that we want to claim a noticeable contribution to fulfill the needs of our customer in a way straightforward, always on a rational basis.

## That is the reason why our customers rely on us: “when it gets difficult go to SCC”.

Based on the new corporate design, the new web presence allows a clear and concise approach to get all information that is needed in case of questions concerning the regulatory field. Please refer to: http://www.scc-gmbh.de

We are proud of our long-standing partnerships with our customers, some of which already last for more than 20 years. I would like to take this opportunity to thank our customers for their continued support, their faith in our ability and their ongoing loyalty.

Satisfying our customers is our biggest motivation.

Dr. Friedbert Pistel
President

**IN THIS ISSUE:**



## New expert for veterinary medicinal products joins SCC

To extend our services in the field of veterinary medicine, SCC has hired a senior expert with long-lasting experience in the registration of veterinary medicinal products. With his expertise and SCC's already established reputation, SCC is now able to support clients from the veterinary pharmaceutical industry with a unique portfolio of scientific and regulatory services. You will learn more about the new colleague and the services provided by SCC in the field of veterinary medicine by visiting http://www.scc-gmbh.de and in the next newsletter.

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

## HISTORY

# 22 $m^2$ ➡ 5,300 $m^2$

**From a basement in Biebelsheim to our modern COMPANY BUILDING in Bad Kreuznach**

# 2 ➡ 200 in 25 years

**Since our foundation in 1989, our CUSTOMER BASE grew from 2 to more than 200 – worldwide**

# 1 ➡ 110 – to be continued

**Our founder Dr. Friedbert Pistel gathered more than 100 well-educated PROFESSIONALS into his SCC team, and we keep growing**

# 2 to 9 = 360° Regulatory Consultancy

**Over the last 25 years, we continuously enlarged our BUSINESS UNITS: Now we cover all regulatory areas and fulfill all your regulatory needs, no matter how large or small**

# Germany ➡ The World

**From our beginnings in Germany, we broadened our WORKING AREAS to the whole world, from Europe and the Americas to Africa, Australia and Asia**

## OUR MANAGEMENT

### Over 25 years of experience in the regulatory world and more!

**Dr. Friedbert Pistel**
President

**Dr. Albrecht Heidemann**
Vice President /
Head of Agrochemicals
and Biopesticides

**Dr. Monika Hofer**
Vice President /
Head of Regulatory Science,
Pharma Pre-Clinical

**Dr. Werner Köhl**
Head of Chemicals/REACH,
Consumer Products,
Cosmetics,
Feed & Food Additives

**Dr. Hans-Josef Leusch**
Head of Biocides

**Our sincere thanks go to our valued Customers and Partners, as well as to all our Employees.**

## AGROCHEMICALS

### REGISTRATION OF AGROCHEMICALS IN EUROPE: A REVIEW OF SOME PRESENTATIONS

The Conference was held on 9 and 10 April 2014 in Brussels and was the 21st Annual conference. The main topics were the discussion about the **zonal product authorization procedure** including feed-back from authorities from Central and Southern zone and industry. Other items were, e.g. **the impact of Article 43 on product renewals** with its tight time-lines on Member states and industry or the status of the expected list for candidates of substitution.

Some presentations were the same as in the ECPA/ECCA conference in March this year and were presented in SCC Newsletter 1-2014. Some other interesting issues are summarized below.

**Please note that the following abbreviations appear in the summaries below:**

| | |
|---|---|
| AIR2 | Annex I renewal; list 2 |
| ANSES | Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail |
| a.s. | active substance |
| CfS | Candidate for substitution |
| CLP | Regulation on Classification, Labelling and Packaging of Substances and Mixtures |
| cMS | concerned Member State(s) |
| COM | EU Commission |
| dRR | draft Registration Report |
| ECCA | European Crop Care Association |
| ECPA | European Crop Protection Agency |
| EFSA | European Food Safety Authority |
| GAP | Good Agricultural Practice |
| iZSC | interzonal steering committee |
| MR | Mutual Recognition |
| MS | Member state(s) |
| PPP | Plant protection product(s) |
| Q4 | 4th quarter |
| RMS | Rapporteur Member State(s) (for a.s. approval) |
| SEZ | Southern European Zone |
| SCFCAH | Standing Committee on the food chain and animal health |
| SMS | Southern member states |
| zRMS | zonal Rapporteur Member State(s) (for zonal authorisation) |

- **Feedback from the EU Commission (COM)**
  Wolfgang Reinert
  EU Commission, Belgium

Although the approval of new active substances according to Reg. 188/2011 is nearly finished, there are still three a.s. in the review procedure according to Directive 91/414/EEC. For new a.s. evaluated according to Reg. 1107/2009, the CLP process is going to be integrated in parallel.

List of CfS (according to article 80(7)) is basically finalised and covers a.s approved until January 2013 (see also separate article in this newsletter). For products containing such substances, comparative risk assessments apply from 1 January 2015.

The new data requirements apply to all a.s. and PPP from 1 January 2016. However, for a.s in PPP dossiers submitted after that date which contain a.s. of AIR2 or new a.s. submitted before 31 December 2013, the old data requirements continue to apply. On the other hand, new data requirements for the product apply in all cases as foreseen.

Guidance documents are under preparation for the interpretation of negligible exposure which relates for non-dietary exposure to the so-called cut-off criteria for carcinogenicity, reproduction toxicity, and endocrine disruption.

Regarding to Zonal system, recent analysis from industry and member states (MS) reveal that the system does not work as desired.

Problems are:

- failure to comply with deadlines
- resource issues
- lack of streamlining in the procedure
- economic crisis hits human resources

COM is of opinion that by improvement and streamlining mutual recognition (MR), the functioning of the system will be increased.

- **The zonal procedure – Feedback from the Southern Zone**
  Léa Riffaut
  ANSES, France

  At present the Southern zonal steering committee is chaired by France. In regular correspondence, conference calls and face to face meetings the following most important topics are discussed and solutions were pursued

  - Timelines
  - Distribution of the work for re-registration
  - Application for new products
  - View and opinions of SMS on various topics
  - Discuss topics from iZSC and report issues from the SEZ

  In order to facilitate the scheduling of the work, applicants must notify as soon as possible to allow zRMS to plan workload and check if the capacities are guaranteed at the proposed date of submission. Applicants must inform zRMS and cMS when submission is postponed. At present there is no availability in the SEZ for new applications prior to mid-2015. France is not able to act as zRMS prior to Q4 2015. Harmonization of evaluations is important and national data requirement in SEZ are limited and dedicated to specific crops/situation or higher tier assessment. In particular, French national addenda are requested for groundwater when refinement is needed. Risk mitigation measures are not fully harmonized but common measures are discussed to gain efficiency in work-sharing.

- **Industry; examining product renewal and Article 43 – Challenges for applicants**
  Katie de la Fuente
  Syngenta Crop Protecton AG, Switzerland

  There was a session on challenges to meet re-authorisation requirements under Article 43 with speakers from authorities and industry. It seems to be not unusual to expect more than 50 product application for one active substance.

  The main workload challenges which were identified for applicants are GAP re-evaluation and dossier delivery in less than 9 months after EFSA endpoints. This means that zonal notification has to be made one year before estimated application which is likely before EFSA endpoints are available. Therefore, it may not be possible to provide final GAPs. As at that time not all studies to be generated are known, the final proposed study list cannot be provided.

  Zonal application must be received three months after renewal of an active substance. Otherwise, existing authorizations will be revoked. Justification for non-available data have to be provided but it is not clear what is justifiable (missing of formal studies, confirmatory information, studies in order to fulfil new endpoints, data gaps related to new data requirements/new guidance documents).

  The main workload challenges for regulators are the rapid increase in article 43 applications in the context under the present situation that some zones lacking capacities for current workload and struggling to allocate zRMS. Starting next year, top-up submissions have to be dealt with, together with additional workload due to comparative assessments, due to authorisations database and due to national data protection list which must be made available for each product authorization.

  Some member states estimate a 20 – 40% increase of the workload per dossier according to the zonal evaluation approach of Regulation 1107/2009 as compared with the old approach according to the Directive 91/414/EEC.

# EFFICACY AT SCC

Twenty-five years of SCC, this is also 25 years of efficacy work in our company. With this article we want to inform about actual developments and to give a short review of the developments in the area of efficacy between 1994 and today. Finally we want to give an outlook on the future developments in the efficacy section.

**Efficacy enters the international agenda**
Since the start of the zonal registration procedures on 14 June 2011, triggered by Regulation (EC) No 1107/2009, efficacy requirements, which always were an important issue for national product registration procedures, entered the agenda of international conferences on Plant Protection Product (PPP) registrations. Various contributions of authority representatives mention the problems associated with Section 7 of the draft Registration Report (dRR). Often national data requirements were not followed and sometimes even complete Biological Assessment Dossiers (BADs) and dRRs had to be re-written by applicants as they did not fit official requirements. In order to understand the current problems one has to take a brief look into the past.

**Late start of EU harmonisation**
In the last decades of the 20th century and in the first years of the new millennium the efficacy assessment was a purely national enterprise and the work of the efficacy specialists restricted to national dossiers, following national rules. Unlike other dossier sections where national models were compared with each other and adjusted to harmonized models in long lasting processes, the efficacy experts worked in splendid isolation until recently, despite the first attempt of international legislators to harmonize efficacy guidelines and criteria EU-wide with Guidance document SANCO 7600/VI/95 in 1995.

The main reason for the procrastination of international harmonization in the efficacy section that the efficacy evaluation was not part of the Annex I listing process of Council Directive 91/414/EEC.

Due to the lack of legal pressure, the harmonization process in the efficacy section started about 15 years after the other sections.

“In fact it is stated in document 1663/VI/94 that for the purpose of inclusion of an active substance in Annex I, the consideration of efficacy or of unacceptable effects on plants or plant products does not arise and therefore Annex III dossiers submitted need not include efficacy study reports” (7600/VI/95 rev.6 dated 14 July 1997). Each authority had its preferences how efficacy dossiers should be written.

Therefore, the same set of data had sometimes to be re-organized if an application to a neighboring country was foreseen, and the authority specialist in charge was known to dislike the way the neighbors made their assessment. However, at that time this was not a great disadvantage as member states hardly took into consideration study results from across the border.

Before the introduction of GEP in 1999 it was also very difficult to judge the credibility of the test results generated outside of the own territory, especially if the results were reported in the local language, only.

**Mutual recognition: first steps to harmonization**
The real wind of change arose when the first companies dared to apply for product re-registrations according to articles 10 and 11 of Council Directive 91/414/EEC. The difficulties for mutual recognition applications were so enormous in several countries that in 2008 the commission issued the Guidance document SANCO/00298/2006 rev 9b dated 2 December 2008 on mutual recognition of PPPs which aimed “to clarify the conditions to be met and the procedures to be followed in order to pave the way to a more frequent application of the principle of mutual recognition, and hence to work-saving for all Member States.” The guidance document stated that “National conditions in the test area `efficacy´ are often comparable in various countries of the EC, particularly if conditions are similar in respect to cultivation/storage conditions and climate. The international European plant protection organization EPPO has now submitted a study on comparability based on comparable regions for efficacy.” This EPPO Guidance on comparable climates (PP 1/241(1) from 2005) was in fact a very important precondition for international harmonisation. Even though it restricts its validation to climatic aspects, it is now common sense to aggregate data according to the zonal classification made in this document.

**Efficacy: EPPO is in the lead**
It is impossible to summarize in a few sentences the various actors and their initiatives which lead to a much better understanding between the efficacy experts within the EU. However, one should mention that the Commission leaves it “up to EPPO”, to determine the technical rules of the efficacy evaluations. After a long process several new or revised EPPO guidelines were issued in 2012 which lead the way to zonal registration procedures, also in the efficacy section. Most important in this context are EPPO Standard PP1/278(1) `Principles of zonal data production and evaluation` which describes the general rules according to which EU-wide efficacy programs have to be set up and evaluations to be carried out and EPPO Standard PP1/276(1) `Principles of efficacy evaluation for microbial plant protection products´ which confirms that the rules set up for chemical products are, with few variations, also valid for “biopesticides”. Workshops organized by EPPO allow to participate in the process of guideline development and are a unique chance to meet many of the evaluators in one place.

In the `EPPO Workshop on Experiences with implementation of zonal evaluation of PPPs`, which was held in Sofia in October 2013, workgroup sessions discussed efficacy requirements in the context of formulation changes, the registration of co-formulated products, the relations of dRR and BAD and the data requirements in the case of applications which cover all EU zones (protected crops, seed treatments and stored products). A blueprint how to achieve harmonised zonal guidance has been provided by the Nordic States who implemented a clear guidance for the Northern Zone already on 01 June 2011.

**New Efficacy Guidance Document**
Since 3 April 2014 the new requirements of SANCO/10055/2013 rev.4 on efficacy composition of core dossier and national addenda are valid. This new guidance describes the efficacy composition of core dossier and national addenda. The most important improvement from the aspect of dossier writing is the combination of the previous annex points “minimum effective dose tests” and “efficacy tests” into one annex point “Testing Effectiveness”. This allows a much more straight forward presentation and discussion of results. Especially in the case of very complex BADs or BADs with a high number of uses this will lead to time and cost savings.

**IPM compatibility in focus**
Compatibility with IPM programs is getting increasingly important and if specific label claims are made, these have to be backed by data. “In addition, the Sustainable Use Directive (2009/128/EC) requires Member States to establish or support the establishment of the necessary conditions for the implementation of Integrated Pest Management (IPM).” According to SANCO/10055/2013 applicants therefore have to take into consideration the national action plans for individual member state requirements and “may need to provide further information and/or data in the national addenda, including national labeling policies.”

**Training of efficacy experts by SCC**
According to our experience at SCC one key to success in the efficacy area is to keep in close contact to evaluators and EPPO specialists in order to be fully aware of upcoming data requirements and to be able to plan efficacy programs which are state of the art.

In two pre-conference workshops to CIR Informa conferences in Barcelona in 2011 and 2012, SCC facilitated direct linkages between clients, efficacy regulators, experts of EPPO and the European Crop Protection Association (ECPA). It is worthwhile to mention that ECPA managed, as advocated also by PSD/CRD, the BAD to be kept as confidential study report one level below the dRR Section 7 which serves as executive summary of the BAD. The concept was first published in ECPA technical Guidance Paper 2011/1 and presented in detail in the SCC chaired CIR preconference workshop in 2011.

**Efficacy outlook**
For the years to come SCC expects an increased importance of efficacy aspects in registration procedures based on chemical substances as well as microbial pesticides and other biopesticides. New national efficacy data requirements will have to be followed up closely in order to avoid problems during the evaluation process.

Detailed procedures for efficacy evaluations of candidates for substitution have already been set up by EPPO PP1/271(1) and are in progress at CRD for the conduct of comparative assessments. These will start once the list of candidates for substitution has become available.

Furthermore GIS based expert statements (e.g. Site Similarity Certificates by SBI) are expected to be integrated into dossiers more frequently, allowing the use of one trial in several EPPO zones. Finally one has to mention that there is a trend towards world-wide efficacy programs based on EPPO PP 1/269(1) ´Comparable climates on global level`. In order to handle very large efficacy programs and to process results of hundreds of efficacy trials in a reasonable time, ARM and ARM-ST software are the ideal tools.

The SCC efficacy team is experienced to accompany all kinds of PPPs through the entire life-cycle from the development phase to EU-wide zonal product registrations.

## CANDIDATES FOR SUBSTITUTION AND COMPARATIVE ASSESSMENT

According to Article 24 and Article 80(7) of Regulation (EC) 1107/2009 active substances, which are identified as candidates for substitution (CfS) shall be listed separately by 14 December 2013. This process is currently still ongoing.

In Annex II, point 4 of the Regulation (EC) 1107/2009 the criteria for CfS are defined. For some of them (so called 'static conditions') the definition is clear and the criteria are based on relevant endpoints (e.g. PBT criteria). For these quantitative criteria, no further discussion is needed. However, for others, so called 'dynamic conditions' (e.g. lower ADI), further clarification is necessary.

**Ad hoc study**
In July 2013, a final 'ad hoc study' was presented by Commission to support the initial establishment of the CfS list. In this report, all seven criteria were tested. Of particular concern was, to find statistical measures (e.g. percentile, standard deviation or median) to sufficiently quantity the dynamic conditions. Member states and stakeholders commented this report.

As of end of January 2013, 422 active substances were in the EU pesticide database. After removing double input according to varieties, sub-forms etc., 378 active substances were analyzed in the 'ad hoc study' and only these were considered in the CfS-list. Substances, which were approved later, will be checked and published in a new list. It is as of yet unclear, when this new list will be prepared.

The first draft list based on the 'ad hoc study' and subsequent discussions is available at Commission. Only minor amendments are foreseen before finalization. For the definition of CfS criteria it has been concluded that only agreed endpoints are to be considered. Furthermore, active substances, which are no longer approved, have been removed from the list.

**Conditions for CfS**
Seven different criteria are laid down for the assessment of CfS, five are static and two are dynamic criteria. For these dynamic criteria, the active substances are arranged by functional groups (e.g. fungicides, herbicides…).

For clarity, this overview will first address the static criteria, which are identified as numbers 2, 4, 5, 6 and 7 in the ad hoc report.

With respect to the **static condition 2**, i.e. two of the PBT criteria are met, 81 active substances were originally included in the report. After feedback from member states, stakeholders and clarification that soil persistence field data supersede laboratory data, 56 active substances remained.

**Static condition 4**, i.e. significant proportion of non-active isomers, is more difficult to implement. Currently, there is no clear definition which percentage of non-active isomers is regarded as significant proportion. Based on official review documents, like review reports, EFSA conclusions, Draft Assessment Reports etc. The 'ad hoc study' concluded a racemic mixture is to be considered as CfS, particularly, if enantiomerically pure alternatives are available and approved. Two substances met this condition in the ad hoc report and this assessment is still upheld.

For **the remaining static conditions**, currently no active substances were identified to meet the CfS criteria 5 (carcinogen). 9 substances meet one of the criteria of condition 6 (toxicity for reproduction) and 7 substances are currently identified as CfS under condition 7 (endocrine disrupting properties). Data for these three static conditions were taken from EU database and ECHA-website.

Moving on to the dynamic conditions, numbered 1 and 3 in the 'ad hoc study', the situation is as follows.
**Dynamic condition 1** (ADI/ ARfD/ AOEL significantly lower than those of the majority of the group as defined above) is met if any one of the three endpoints above shows the described behaviour. To arrive at a meaningful assessment, the statistical basis of the qualitative description "significantly lower" must be assessed. Therefore, the criteria vary with the number of elements of the respective group. Thus, the 5 % percentile is used for groups with more than 20 active substances. Between 5 and 20 active substances, a definition via the 5 % percentile is statistically not possible. In this case 'significantly lower' is defined as below or equal to 0.001 mg/kg/bw/d for ADI and AOEL or 0.004 mg/kg/bw/d for ARfD, respectively. With less than 5 active substances in a group a definition is not possible. 20 substances met one of these criteria and consequently are qualified as CfS.

**Condition 3** would be met, if there are reasons for concern linked to the nature of the critical effects. This condition is only generally defined in regulation (EC) 1107/2009 as developmental neurotoxic or immunotoxic effects and high potential of risk to groundwater. Further clarification and harmonised methods/criteria need to be developed and established. Discussion between member states and stakeholders is on-going. No active substances meet this criterion at the moment.

**Current Status of discussion on CfS**
In the 'ad hoc study' approximate 100 substances were identified to meet met the CfS-criteria. After combination of some individual substances to one entry (e.g. copper compounds) and correction of erroneous entries, 78 of the active substances assessed are still classified as CfS. The final list has to be established by 31 December 2014. Voting in the Standard Committee was scheduled for May, but has been postponed without setting a new date. The list will be published as part of a regulation.

## COMPARATIVE ASSESSMENT OF PLANT PROTECTION PRODUCT USES

Applications for authorization submitted from 1 January 2015 are subject to comparative assessment for all plant protection products containing CfS substances. Whereas the identification of CfS substances is defined at EU level, comparative assessment is a member state issue. The framework for comparative assessment is provided in Regulation (EC) 1107/2009. An EPPO guidance document (EPPO Standard PP1/271) elaborates how to perform comparative assessment. A new draft guidance document (SANCO/11507/2013 rev. 10) for comparative assessment implements further details of Regulation (EC) 1107/2009, but is not yet voted upon.

With respect to the comparative assessment, some uncertainties were identified. The role of the applicant is unclear and no harmonization between member states can be seen. One member state currently foresees that the applicant should submit a comparative assessment of his own product, which subsequently is evaluated by the authorities. Germany is preparing an own guidance document. A draft version will be available within the next two months and will be discussed with stakeholders.

Further clarification and harmonisation is needed, like consideration of minor uses and the comparability of mutual recognition.

## NEW GUIDANCE ON BOTANICALS

The European Commission's Health and Consumers Directorate General (DG SANCO) has updated the guidance on the assessment of botanical active substances for plant protection products (SANCO/11470/2012 – rev. 8, 20 March 2014). The document was updated to extend the scope of methods used to obtain 'plant extracts or plant components, to include water and ethanol (distillation) extraction processes as well as physical extraction methods like pressing, milling and crushing. The term plant extracts was also replaced by 'botanical active substances' or 'botanicals'.

It is highlighted that the updated guidance document only covers active substances obtained from plant material whereas substances such as natural-identical synthesized molecules, biosimilars or analogues are not covered by the revised guidance.

The new guidance document aims to provide practical approaches on procedures and data requirements in order to facilitate botanical active substance approvals at EU level as well as product authorizations by member states. The guidance takes account of the greater variation in qualitative and quantitative composition of botanicals compared with synthesized chemicals, e.g. by using the 'lead component' concept.

The guidance document highlights the importance of literature and literature reviews on the specific botanical active substance to be included in the registration dossier for example as a basis for scientific rationales. Furthermore, for all 'botanical active substances', reference is made to the Nagoya Protocol on Access to genetic resources and fair and equitable sharing of benefits. The Nagoya Protocol is an international agreement, which aims at sharing the benefits arising from utilizing genetic resources in a fair and equitable way. It was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan. For the use of 'botanical active substances' it has to be made clear in the registration dossier that the Nagoya Protocol has been respected.

The guidance document has been finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014. It will apply to applications submitted from 1 October 2014 onwards.

## BIOSTIMULANTS – DO WE NEED BIGGER ROOTS?

A conference on Biostimulants and Plant Growth was hosted by Informa Life Sciences' on 14-15 May 2014 in Brussels. The conference focussed on scientific and regulatory diversity of the so called **Biostimulants** and the need for a better understanding of this component of the agronomic tool set.

In a biostimulant market review gap analysis, Aaron Powers of Agrinos and Benoit Genot of Arysta LifeSciences analysed the main macro drivers for the increasing interest in plant biostimulating substances. Socioeconomic drivers such increasing public awareness, increasing demand for safe, residue-free food or the demand for sustainable agriculture to keep up biodiversity are well-known and often discussed.

**Besides these well-known drivers, biostimulants became of increasing interest as they are possible candidates to fight the consequences of soil degradation, increasing demand for agricultural products due to the increasing word population, increasing food prices as well as other pushing boundaries such as nitrogen inputs or the annual crop losses caused for example by drought and heat. These issues cannot be solved by the use of fertilisers and plant protection products alone.**

Peleg Chevion of Syngenta mentioned these drivers as one of the reasons why also multinational companies show an increasing interest in biostimulants. According to the speaker annual losses by heat and drought trigger the need for new approaches to agricultural production methods and the "move from technology to integrated solutions", including biostumulants. But to remediate the negative impacts of heat and drought on crops, do we need 'bigger roots' and are they sufficient, the speaker asked. Or are there additional criteria and requirements to characterise biostimulants and to what extend does these traits have to be assessed

and evaluated? Defining bio-stimulants and integration of the definitions derived into regulatory frameworks, is one of the key issues which is currently addressed and discussed worldwide.

The work currently under way in Europe regarding a regulatory framework for biostimulants was presented by Kristen Sukalac from Prospero & Partners in behalf of the European Biostimulants Industry Council (EBIC) as well as Eric Liégeois from the European Commission. As the first order of business Ms Sukalac identified the need to agree on a common definition of biostimulant. For this, EBIC refers to Prof. Patrick du Jardin of the University of Liège who in his bibliographic analysis on biostimulants highlighted the importance to consider that

"Biostimulants are defined more by what they do than by what they are, since the category includes a diversity of substances."

and, as becomes more and more evident, biostimulants have very complex and different modes of action and effectiveness even for example on crop cultivar level.

Thus, 'bigger roots' alone don't live up to complexity of biostimulants and their regulatory definitions. This problem becomes even more complex as substances and products showing biostimulant or biostimulant-like characteristics currently are subject to various national or country-specific regulatory frameworks.

Thus, to be able to agree to a common definition and regulatory framework for biostimulants, also the existing regulations have to be taken into consideration. Therefore, for Europe, the temporary conclusion on the definition of biostimulants is: **"A plant biostimulant is any substance or microorganism, in the form in which it is supplied to the user, applied to plants, seeds or the root environment with the intention to stimulate natural processes of plants benefiting nutrient use efficiency and/or tolerance to abiotic stress, and/or crop quality, regardless of its nutrients content, or any combination of such substances and/or microorganisms intended for this use."**
At present similar work on the regulatory framework for biostimulants is on-going worldwide. In the US for example, the Biostimulant Coalition was founded to amend for the significant regulatory differences between US stats. In Brazil similar activities are advanced by Abiosolo which has convened a specialised working group to develop the biostimulant market.

Besides scientific and regulatory issues, also the need of manufacturers, distributors, registration holders and, last but not least, of farmers have to be considered. Thus, there is still a lot of work to be conducted until new regulatory frameworks will enter into force for biostimulants. Due to this, none of the speakers put forward a possible date of entry into force of the new European legislation during the conference. A broad consensus of all parties participating in the process seems to exist regarding the need for a regulatory framework especially regarding the proof of effectiveness of every biostimulant product to be registered in future. **Therefore, efficacy tests, at least on laboratory level will be one part of the registration dossier.** Besides proof of efficacy, current discussions on the contents of a registration dossier indicate that similar topics will have to be addressed as for the registration of plant protection products in Europe.

Toxicity and ecotoxicity risk assessments for a product will be based on a tiered-approach for example, where at tier 1 comprises of the identification and hazard characterisation, tier 2 of an exposure assessment in case a hazard was identified under tier 1. Risks assessments will have to be conducted if applicable during the tier 3 assessment. For microbials, special considerations are to be made for example regarding their infectivity or their relatedness with known human or plant pathogens. Decisions of evaluation level, that is species or strain, will most likely depend on the primary characteristics of the microorganism. Special attention regarding the evaluation is to be given to public peer-reviewed literature as well as already existing evaluations for a substance/product under other regulatory frameworks.

The provisional registration procedure for Europe discussed at the moment includes a completeness check by authority after dossier submission which is to be conducted in one month.

Access to the market will be possible if no obstacles were identified during the completeness check. Within six months after the completeness check a compliance check is to be conducted after which the marketing authorisation for a product can be withdrawn if necessary. The compliance check most likely will be further assessed by volunteering member states. In addition to this evaluation process, an EU register for authorisations as well as a negative list is foreseen at the moment.

Thus, 'bigger roots' alone are not sufficient, neither from the regulatory nor the scientific point of view to achieve a harmonised, efficient and economic regulatory framework for biostimulants.
**But due to the future challenges for agriculture the need for 'bigger roots' became evident during the Infoma Life Sciences' Conference on Biostimulants and Plant Growth.**

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

# BIOCIDES

## BPR amendment entered into force on 25 April 2014

On 5 April 2014, the European Parliament and the Council have adopted Regulation (EU) No. 334/2014, amending the BPR (Regulation (EU) No. 528/2012). The amendments include several changes and fixes in the BPR, including:

- Revised provisions concerning biocidal product families.
- Revised transitional rules for existing biocidal products and treated articles.

For a detailed discussion of the changes, please refer to the previous SCC newsletter (Volume 14, No. 1, April 2014).

## New procedure for the renewal of biocidal product authorisations that were initially obtained via mutual recognition

Under the BPR, national authorisations of biocidal products obtained in a reference member state are usually "multiplied" in further member states concerned via mutual recognition.

So far, the BPR laid out provisions for the renewal of single authorisations only, but did not foresee a concerted process to renew such "multiplied" national authorisations.

On 14 May 2014, the European Commission has adopted the Delegated Regulation (EU) No. 492/2014, which provides for a procedure how the renewal of national authorisations, which have been multiplied via mutual recognition in several additional member states, can be handled in a more effective way.

**Similar to the procedure of applying for a first authorisation and multiple mutual recognitions in parallel, the new regulation foresees that renewal of these authorisations are managed by one reference national authority, which can be chosen by the applicant. All applications have to be submitted at least 550 days before the authorisations' expiry date. After the reference national authority provides its assessment report and the draft summary of product characteristics (either 180 days, or, in case a full evaluation is necessary, 1 year after the application has been validated), the concerned national authorities decide about their renewal within 90 days and renew the authorisations accordingly within 30 days.**

It has to be noted that the procedure laid out by the new regulation applies not only to authorisations having the same terms and conditions in all the member states where mutual recognition is sought, but, explicitly, also to cases where the terms and conditions of the respective authorisations in different member states vary, for instance, due to administrative changes or due to national derogations in accordance with e.g. Article 4 (4) of the BPD (Directive 98/8/EC) or Article 37 (2) of the BPR.

For more information, please contact
Dr. Hans-Josef Leusch at
hans-josef.leusch@scc-gmbh.de

## Final draft of a new regulation on the review programme

Commission Regulation (EC) No. 1451/2007 (3rd review regulation) lays down the rules for the review programme of all existing active substances as provided for by Article 16 (2) of the BPD. The rules define the rights and obligations of the competent authorities (CAs) and of participants in the work programme. Since the BPD has been replaced by the BPR, it is appropriate to adjust the provisions of the review programme accordingly. Therefore, the draft of a new regulation which is intended to replace the 3rd review regulation was published on 2 May 2014 on CIRCABC, among the documents discussed on May's CA-Meeting (CA-May-Doc.3.1).

The main amendments which are made by the new regulation concern simplification of the processes and establishment of stricter deadlines for the evaluating member states.

The substances included in the review programme remain almost unchanged, however the Commission highlights the inclusion of three silicon dioxide based nano compounds (Annex II, entries 1017, 1018, 1019) which are the first nanomaterials that are supported under the review programme.

It is also important to note that Article 15 of the new regulation opens the door to the review programme for other new active substance/product type-combinations if either of the following conditions apply:

- There have been objectively justified reasons to believe that the substance/product type-combination was not within the scope of the BPD or the BPR.
- The substance has, so far, benefitted from the derogation for food and feed provided for by Article 6 of the 3rd review regulation.
- The biocidal product belongs to a different product type under the BPR than under the BPD, but the active substance was notified for the old product type under the BPD.

You can find information on how to access CIRCABC on the SCC homepage under Links – Biocides http://scc-gmbh.de/links/links/links-biocides

## Ongoing discussions in the CA-meetings

Further, concerning the scope of the BPR, currently ongoing discussions in the CA-Meetings have led to the publication of several important and interesting documents, some of which are summarized in the following. All documents published in the context of CA meetings can be accessed on CIRCABC.

**Treated Articles (Note for Discussion with Competent Authorities) (CA-May14-Doc.6.1).**
This document features selected written and oral comments received from various stakeholders (trade and industry associations, third country governments) on the current interpretation of the topic "treated articles", which is laid down in the Note for Guidance: Frequently asked questions on treated articles, endorsed by the CA meeting in September 2013.

One main concern which was articulated by the industry was that the provisions described in aforementioned Note for Guidance would result in the majority of all finished goods falling under the definition of a treated article because a biocide (a typical example would be a preservative) has been used at some point upstream in the production chain. An example for this would be a monomer, which is protected by a biocide from bacterial deterioration, while after polymerization of the monomers, this hazard of decay no longer exists and, thus, the biocide has no further function in the polymer (neither for the later stages of the production chain nor for the article as it is placed on the market).

The current document proposes a new approach which bases on the definition of a treated article in Article 3(1)(l) of the BPR: "…any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products".

- On one hand, an "intentional incorporation" implies that the biocidal product is added (on the final product or at an earlier stage) with the intention to equip the "final" article, as it is placed on the market, with a biocidal property (e.g. increased storage- or use life) or even a biocidal function.
- "Treated with", on the other hand, is interpreted in the document to be rather a short-term application of a biocidal product in order to control harmful organisms already present in the article, which does not result in a lasting incorporation of the active substance in the treated article and, thus, the article as placed on the market does not have a biocidal property, although residues from the treatment may remain.

The document states that such residues are likely to be of lesser relevance if further processing of a treated component takes place (due to loss, dilution etc.), and therefore such an article without a biocidal property should be considered a "treated article" only if the treatment has taken place on the final production stage immediately before the placement on the market.

The document provides a list of examples which illustrates the application of this interpretation to different kinds of articles and mixtures. The Commission services welcome views and suggestions on the document.

**Classification and Labelling of Treated Mixtures (CA-May14-Doc.6.3).**
This document is a follow-up to a discussion of this March's CA-Meeting, concerning specific provisions introduced in approval regulations for several active substances which are classified as skin sensitizers, e.g. the general duty for labeling of articles containing these active substances. The positions of different member states (NL, DE, SE) as well as of industry stakeholders (A.I.S.E., CEFIC) are presented in an Appendix to this document.

The Commission services invites the member states' competent authorities to revise these specific conditions to approval of the active substances, in order to limit the labeling requirement to treated articles which are 'articles' and not 'mixtures' by the REACH definition, as comprehensive rules concerning the labeling of mixtures containing skin sensitizing substances already exist under the CLP legislation. The commission services therefore suggest that the approval regulations including these provisions on labelling should be aligned with the approval Regulation (EU) No. 437/2014 on DCOIT for PT21, which takes into account if the sensitizing potential is relevant under normal conditions of use (e.g. if there is skin contact).

**Links between the Water Framework Directive and the BPR (CA-May14-Doc.4.3).**
This document was drafted by the Commission services with the aim of developing guidance on the interactions of the BPR and the Water Framework Directive 2000/60/EC (WFD), especially regarding the identification and handling of "priority substances" (PS) or "priority hazardous substances" (PHS, which include PBT substances or such substances which give rise to an equivalent level of concern), for which the WFD provides for measures to reduce, phase out or cessate discharges, emissions and losses.

The following interactions between the BPR and the WFD are highlighted in this document:

- Environmental risk assessments carried out under sectorial legislation (e.g. biocides legislation) play an important role in the identification of PS (including PHS) for the purposes of the WFD.
- For substances falling within the scope of the BPR, the biocides legislation foresees regular assessments whether the measures for the mitigation of risks, or for the cessation or phasing out of PHS, are adequately followed and if they are effective in achieving the intended effects.
- The establishment of a list of substances for which Union-wide monitoring data are to be gathered, where the decision which substances are to be monitored can be based on, inter alia, data gathered in accordance with the biocides legislation, e.g. tonnage data, use patterns, intrinsic properties (e.g. particle size), (predicted) concentrations in the environment and effects.
- The establishment of Environmental Quality Standards (EQS), that protect both fresh and salt water bodies against short- and long-term exposure of PS. The derivation of the EQS is also supported by data gathered under the biocides legislation.
- The provisions of the WFD are taken into account when deciding on the approval or non-approval of an active substance under the BPR.

It is clarified that active substances that are already listed as PS under the WFD may be approved, given that the provisions of the WFD against the pollution of water are followed and that, in the approval of such active substances and the authorisation of biocidal products, special attention is paid to compliance with the EQS.

It is also clarified that active substances which are PHS according to the WFD should not normally be approved, but nevertheless, the principles set out in document "CA-March14-Doc.4.1 – Final – Principles for substance approval" should be taken into account before reaching such a decision.

The summaries given above represent only a small outline of the present discussions still ongoing in the CA Meetings.

## CHEMICALS/REACH

### Technical advice how to update your jointly submitted Chemical Safety Report (CSR) resp. Guidance on Safe Use (GoSU) to individual

In case the lead registrant has submitted the CSR resp. the GoSU on behalf of the member registrants and then decides (or the members decide) to submit the documents individually instead, the lead registrant has to contact ECHA Helpdesk and request to change this information in REACH-IT. Before this change is possible, the lead registrant must provide ECHA with a written acceptance declaration from each member registrant of the joint submission (including those who have only signed up for the joint submission object, but not yet submitted a registration dossier) that they agree to the requested changes, their consequences and accept them.

After ECHA has received these declarations, they will arrange the necessary changes in REACH-IT.
Before submitting the acceptance declaration form, all the members who have successfully submitted their dossiers indicating that the lead will provide the CSR resp. GoSU must submit an update to ECHA providing their own CSR resp. GoSU. In their IUCLID 5 dossier header, they should indicate that the lead is not providing the CSR resp. GoSU on their behalf by not ticking the respective box "Chemicals safety report" resp. "Guidance on safe use".

### REACH-IT update in April 2014 The most important changes to be considered – short survey

The latest update of the REACH-IT system in April 2014 brought some essential changes, which are important to consider. First of all, as the Terms and Conditions have been updated every user will have to accept this new version when logging into the new REACH-IT system for the first time and validate his e-mail address. Further, the structure of the REACH-IT message box, the only route ECHA uses to provide decisions and other communication, has also been updated.

Here a short overview of the most important changes to be taken into consideration:

- The message box is now divided into two parts: important messages and general information
- When a message has been opened by one user of your company account, it has been legally received (this is now definitely defined in the Terms and Conditions and thus acknowledged by each user when accepting these with the first login)
- All messages are considered received seven calendar days after they were sent —even if they have NOT been opened – and what is most important – this date can set deadlines in motion!
- Possibility to identify a main contact person for important messages – the so called “ECHA Regulatory Contact”

## Be ready for the REACH deadline in May 2018

After having successfully passed the previous REACH deadlines in November 2010 and May 2013, SCC is currently preparing the first substances for the last REACH deadline in May 2018 which is applicable for phase-in substances with a tonnage band of 10-100 t/a and 1-10 t/a. It is expected that the number of substances for this deadline will be significantly exceed the sum of the substances for the other two deadlines. To be able to successfully register this high number of substances by May 2018, SCC encourages companies to start now with their activities. It is very important to know your portfolio of substances and to prioritize the most important substances. Some big players started already with their first package of substances to avoid problems with limited testing capacities and men power at a later stage. Other companies announced to have their most important lead substances ready by 2016 to have enough time for dossier finalization and e.g. LoA purchase in the SIEF. SCC recommends to identify at least the high priority substances and to initiate the analytical work to have the substance identity defined before starting any testing and be ready for substance ID discussions in the SIEF. Substance ID is still one of the major deficiency in the submitted dossiers, as continuously emphasized by ECHA e.g. in the most recent ECHA Stakeholder Day in May 2014.

## Be prepared for ECHA Compliance check decision

In the last months, ECHA has published several public versions of decisions on a compliance check (CCH) for registration dossiers. Within these decisions ECHA contesting the quality of quantitative structure-activity relationship model (Q)SAR information provided in the dossier. A particular focus is placed on the partition coefficient octanol water (log Pow) as the log Pow is an essential key information for the risk assessment. In various cases during the dossier preparation for the 2010 and 2013 deadline the column 2 adaptation of REACH Annex VII was applied. In some cases like fast hydrolysis, poor water solubility or high surface activity the ECHA guidance requests a QSAR estimation of the log Pow as this value cannot be experimentally determined. In these CCH decisions not the QSAR itself was challenged but the report format in the dossier.

More precisely the QSAR calculation has to be in line with the requirements of section 1.3 of REACH Annex XI. In addition, ECHA has highlighted in a series of webinars and guidance documents what they expect when providing QSAR results in a REACH dossier. Here a QSAR prediction reporting Format (QPRF) and a QSAR model reporting Format (QMRF) file in mandatory. In many cases this information is missing in the dossier and therefore ECHA regard the information requirements for this endpoint as not fulfilled. As a consequence letters of non-compliance will be issued. Thus, registrants should be prepared for ECHA compliance check decisions and to update the QSAR information in the dossier.

SCC has plenty of experience in QSAR modelling for physical chemical properties. SCC has QPRF and QMRF files for the most common QSAR models like EPIsuite and SPARC at hand and can offer support for dossier updates.

## CoRAP

In the Community Rolling Action Plan (CoRAP) ECHA lists 120 substances for evaluation. On a yearly base, the CoRAP is being updated always covering three subsequent years. With the latest CoRAP update in March 53 substances were newly allocated. Evaluation is being done by a designated Member State.
Based on the experience of the last years it becomes obvious that the evaluation process and the outcome may be different from Member State to Member State. In addition, substances evaluated under the CoRAP procedure and for example in the course of the authorization process might result in totally different conclusions even though hazardous properties, volumes and other criteria relevant for identification and for the assessment are similar.

## Philippines

In the Philippines the Department of Environment and Natural Resources (DENR) is the governing regulatory authority. The Environmental Management Bureau is the implementing agency. The Republic Act 6969 known as "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990" regulates the import, manufacturing and different issues for all unregulated chemical substances in the Philippines.
In the national chemical list - the Philippines Inventory of Chemicals and Chemical Substances (PICCS) - all existing chemicals and chemical substances in the Philippines are listed. If the substance is not listed in the PICCS a New Substance Notification is required for example a Small Quantity Importation (SQI) Clearance ≤ 1 t/a or Pre-Manufacturing and Pre-Importation Notification (PMPIN) > 1 t/a. Hence, different data are

required depending on the import volume. A local representative located in the Philippines is required for the registration.

Guidelines for the GHS implementation in the workplace have been issued on 6 March by the Department of Labour and Employment (DOLE). By March 2015 all plants/facilities using industrial chemicals in the work place must be compliant.

## South Korea

The Ministry of Environment (MoE) announced for this October guidance on K-REACH and the Chemicals Control Act (CCA). Guidance will not only address the registration process and documents required but also data requirements, substance identification, cost sharing and details on the only representative appointment and other topics. K-REACH and CCA will come into force on 1 January 2015.

A CCA website is scheduled for the second half of 2014 allowing online submissions.

## Taiwan

The supplementary nomination procedure is about to start on 1 June 2014 with a two months window. Substances eligible for this supplementary nomination are those, which have been manufactured, handled, used or sold in Taiwan as well as imported to Taiwan during 1 January 1993 and 31 December 2011. After this third nomination, the extended inventory will be available on the Chemical Substance Nomination and Notification website. Substances included in the inventory will qualify as existing substances and will thus not need to be registered as new substances.
By end of the year, the provisions of the chemical registration scheme are scheduled to enter into. Then, new chemical substances need to be registered at least 90 days before manufacturing, respectively import. Thus, it is advised that companies get to know their registration obligations, soon.

It might be possible that the government may grant a grace period to companies that placed substances on the market after the inventory nomination deadline and before 1 January 2015. Further details are not known yet.

## Turkey

The Turkish legislation equivalent to EU-REACH has not yet been adopted. However, there are intentions on REACH by law to close the existing gap. Thus, a new regulation on Safety Data Sheet (SDS) preparation bringing requirements for SDS in line with those in the EU is announced for the next months. In December 2013 the new regulation on classification and labeling in Turkey, the SEA Regulation (28848) similar to EU CLP, entered into force. The old SAE Regulation (27092) similar to DSD & DPD will be repealed on 1st June 2016.

Based on the available draft regulation it is clear that the SDS must be in Turkish (although suppliers may use more languages on their label than Turkish) and only trained and certified personal is entitled to generate these SDS.

From 1 June 2015 (for substances) and from 1st June 2016 (for mixtures), SDS must include classifications according to the new (SEA) Regulation. In the transition period, both the old (SAE) and the new regulation (SEA) are mandatory for a defined period. Substances placed on the market before 1.6.2015 are to be notified in a period from 1.6.2014 to 1.6.2015 and substances placed on the market after 1.6.2015 are to be notified within one month at the latest after placing on the market for the first time. The relevant IT Tool (known as KKS as a part of Turkey's Environmental Information system (EIS)) to be used for notification is not yet available but might be limited to be accessed by legal entities only having been previously assigned a submission number. It will not be compatible with REACH-IT and EU C&L notification files cannot be used.

## Vietnam

In Vietnam, the main chemical regulation is the Law on Chemicals No. 06/2007/QH12, issued on November 21, 2007, controlled by The Vietnam Chemical Agency (VINACHEMIA) under the Ministry of Industry and Trade. Furthermore, there are a lot of different subsidiary legislations regulating the registration of new chemicals but until now no national chemical inventory has been published yet. Nevertheless, a list of toxic chemicals (Decree No. 26) is available. The third revised edition of the GHS is now mandatory for substances since 30 March, and will be mandatory for mixtures from 30 March 2016 onwards.

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

## FEED & FOOD ADDITIVES

In accordance with Article 17 of Regulation (EC) No 1831/2003 on additives for use in animal nutrition, the Commission has established the European Union Register of Feed Additives. The Register was published for the first time in November 2005. It is composed of two parts. Both parts were just recently revised and released on 12 May 2014: http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm.

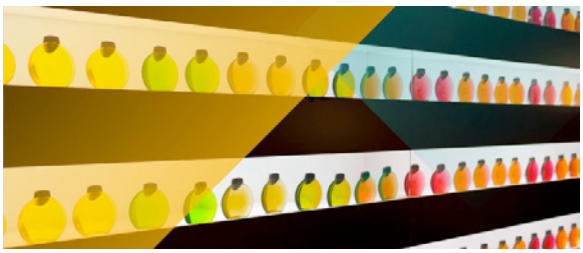
Another change was that appendix 3, with lists of modifications to the register is now split into 4 appendices Appendix 3a released 12 November 2010, Appendix 3b released 07 February 2012, Appendix 3c released 04 March 2013 and Appendix 3d released 08 August 2013.

Standing Committees play a key role in ensuring that EU decisions and regulations on food and feed safety, animal health & welfare and plant health are practicable and effective. The Standing Committee on the food chain and animal health (SCFCAH) mandate covers the entire food supply chain - from animal health issues on the farm to the product on the consumer's table - helping the EU deal effectively with health risks any every stage of the production chain. It is chaired by a European Commission representative. The respective meetings in 2014 can be found here: Standing Committee meetings 2014.

The provision of safe, nutritious, high quality and affordable food to Europe's consumers is the central objective of EU policy, which covers all stages of the EU food supply chain, "from farm to fork".

SCC would like to indicate that a series of emerging challenges and risks could put the currently successful European food system under severe stress. To be prepared, a “Foresight analysis on Delivering on EU Food Safety and Nutrition in 2050 - Scenarios of future change and policy responses" as a first step was performed. The project aims to provide insight and guidance for future policy-making and the research by identifying the critical challenges to EU food legislative framework; future evolution of the challenges (in years 2020, 2030 and 2050); impacts of current challenges on EU’s food legislative framework; potential critical changes in the current framework necessary to maintain the prevailing high standards (Foresight analysis on "Delivering on EU Food Safety and Nutrition in 2050 - Scenarios of future change and policy responses").

## COSMETICS



### News on Cosmetics Regulations

Since 11 July 2013 cosmetics in Europe are regulated by Regulation (EC) No. 1223/2009 to ensure a high level of protection of human health. The most important changes can be viewed as an informatics graph: http://ec.europa.eu/consumers/sectors/cosmetics/images/cosmetics-infographic.jpg.

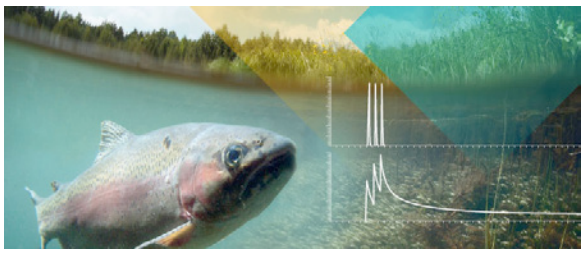
As this regulation is a dynamic feature, it is constantly updated. The most recent update came into force on 09 April 2014 by Commission Regulation (EU) No. 358/2014. This regulation amended Annex II and V to Regulation (EC) No 1223/2009 in order to ensure furthermore the safety of cosmetic products containing parabens and triclosan. These measures took into account final opinions of the Scientific Committee on Consumer Safety (SCCS).

As a general procedure, prior to adaptations of the Cosmetics Directive, the European Commission consults the SCCS by evaluating aspects of safety for human health based on a safety file submitted by Member States or industry. The results are published as an opinion. SCC monitors regularly the release of these opinions. The most recent one can be found here: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm.

In addition on 09th April 2014, the SCCS published an Addendum to the SCCS's Notes of Guidance (NoG) for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision (SCCS/1501/12) SCCS/1532/14. This Addendum replaced the sections 3-4.7 Mutagenicity/Genotoxicity and 3-4.8 Carcinogenicity of the NoG.

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

## REGULATORY SCIENCE



### EFSA continues to use deterministic methods for human health risk assessments of pesticides

In April 2014, the European Food Safety Authority (EFSA) has issued a draft "Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products". The guidance is based on an initial draft by the EFSA PPR Panel in 2010 that proposed a harmonized approach for pesticide exposure assessments, containing acute risk assessments and a new toxicological reference value (the AAOEL) as well as methods for the estimation of residential exposure. EFSA's pesticide unit is currently addressing the comments submitted until 20 May 2014 in an open consultation. A precise time point for finalization of the guidance has not been set.

The new draft guidance proposes that an acute risk assessment of operators, workers and bystanders will not be performed as long as guiding for the setting of the relevant reference value (AAOEL) is not available. EFSA stated that they continue to work on guiding for the setting of reference values (including AOEL and AAOEL).

A novel exposure calculator was provided, containing data that became available after the initial EFSA draft Model was released in 2010. Data from the "Agricultural Operator Exposure Model" (AOEM) have replaced the operator data set used in the initial EFSA draft model. The AOEM, based on thirty-four previously unpublished exposure studies conducted between 1994 and 2009, is a joint development between several European institutions (e.g. BfR, HSE, ANSES, JKI, BVL, IVA, ECPA), and shall reflect current application techniques and practices in the EU. Similarly, the new EFSA draft guidance has integrated contemporary parameters for arable crops that were developed within the "Bystander and Residential Exposure Assessment Model" (BREAM). EFSA states that the final guidance will be open for revision, e.g. by the inclusion of prospective data like the current EU funded project "Bystanders, Residents, Operators and Workers Exposure models for plant protection products" (BROWSE), which is expected to report revised or new exposure models in 2014.

### Recent activities of EFSA concerning Environmental Fate and Modelling

In the field of environmental fate, the following topics are under discussion in EU at present:

A guidance document for evaluating available laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil for modeling purposes has been published by EFSA May 8th 2014 (EFSA Journal 2014;12(5):3662). The guidance document will have an impact on PECgw and PECsw modeling via choice of DT50 values but also due to the fact that information regarding the use of Koc/Kom and crop interception values are given. Furthermore, detailed guidance for designing field dissipation studies with the aim to derive DegT50 values for modeling purposes is provided.

Recently, EFSA has also published a guidance document on emissions of active substances as well as transformation products from protected crops to relevant environmental compartments ((EFSA Journal 2014;12(3):3615; publishing date: March 20th 2014). The document provides guidance for users on how to assess these emissions when performing risk assessments according to Regulation EC no 1107/2009 under consideration of different greenhouse and other crop protection structures.

With respect to predicting environmental concentrations in soil, the respective EFSA guidance intending to introduce a tiered approach for PECsoil modeling under consideration of soil biocenoses and different site scenarios is still under preparation. Currently, a public consultation of the EFSA GD and the supporting software tool (PERSAM) is foreseen to be launched in mid-2014 (Minutes of the 11th meeting of the EFSA Working Group for developing an EFSA Guidance Document for predicting environmental concentrations of substances in soil).

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

## IMPRESSIONS OF THE ANNIVERSARY CELEBRATION




## CALENDAR

**CIR 2014**
**September 9-10, 2014**
**Barcelona, ES**

Informa's industry conference for Agrochemicals (AgChem Forum), Biocides, REACH and environmental risk assessment will be held again this year in Barcelona.

Dr. Bernd Brielbeck, Senior Regulatory Manager Agrochemicals and Biopesticides, will be at this event (AgChem Forum – *Uniting science and policy to ensure safe use of agrochemicals*). More information regarding SCC's involvement in this important industry gathering will follow soon.

For further information about AgChem Forum (Part of CIR), check out their website:
http://www.informa-ls.com/event/agchemforum14

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**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
scc@scc-gmbh.de
www.scc-gmbh.de

**Global Office Japan**

*Coordinator Plant Protection Products*
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