

# NEWSLETTER

SCC Newsletter Vol. 16, No. 3, July 2016

## REGULATORY CHALLENGES AND OTHER CHALLENGES IN EUROPE

### Dear Subscribers,

Please allow me a few words about the recent European developments, i.e. "Brexit".

Although the British voted in favour of Brexit, it will not take immediate effect. As you are following the news, you will have noticed that the British seem to be surprised by their own courage and exact developments cannot be foreseen at the moment.

The formal aspects of Brexit are the following:

1. the British government must notify the European Commission of their desire to leave the EU
2. the EU will accept their wish to exit
3. all (!) existing contracts must be newly negotiated between the EU and Britain

As you know, the first step is not seen as urgent by the (current) British government and will (most likely) not happen before fall. A timeline of two years is set for negotiations once Britain triggers Article 50 and gives notice of their intent to leave, but we assume that they take much longer than that. For plant protection there are precedences for non-EU members to co-operate with the EU, namely Switzerland and Norway. In the latter case, Norway already takes up EU tasks from the Nordic EU members, i.e. collecting information on Article 43. This could be a model that Britain might want to follow and the EU might accept, since the authorities are already overloaded with the responsibilities of RMS and zRMS.

It is therefore our current assessment that the changes that will take place will not have an immediate effect, but will come into force in two years' time or even (much) later than that. If there are changes, they will influence future developments, such as the selection of RMS or zRMS or the acceptance of an English assessment of a.s. or PPP on the Continent. We believe that this will not affect currently existing assessments, on which the mutual recognitions are based, as long as the UK is a full EU member.

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Of course, many things are currently being reassessed and not much can be taken for granted, but the above seems to be the most reasonable and also most probable way forward.

This edition of the Newsletter comprises several important news items regarding Agrochemicals, Biocides and Chemicals. Especially, as key topic in this Newsletter, criteria are discussed for identifying endocrine disruptors for plant protection and biocidal products in detail. These criteria have recently been published by the Commission.

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

Furthermore, we appreciate your feedback and comments regarding the SCC Newsletter.

Please drop us an email at [newsletter@scg-gmbh.de](mailto:newsletter@scg-gmbh.de).



Dr. Friedbert Pistel



## EUROPEAN COMMISSION ADDRESSES ENDOCRINE DISRUPTORS FOR PLANT PROTECTION PRODUCTS AND BIOCIDES

Endocrine disruptors are already considered in the EU legislation, but, until now, no formal criteria have been established, as requested in Regulation (EC) 1107/2009 and Regulation (EU) 528/2012.

On 15 June 2016, the Commission published two draft legal acts which set criteria to identify endocrine disruptors as well as further relevant documents ([http://ec.europa.eu/health/endocrine\\_disruptors/policy/index\\_en.htm](http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm)).

An additional Communication document (COM(2016) 350 final) gives an overview of the scientific and regulatory context.

The Commission staff working document (SWD(2016) 211 final) is the main report of the impact assessment defining criteria for identifying endocrine disruptors for plant protection products and bio-cidal products and possible consequences. An executive summary is given in the document "SWD(2016) 212 final".

Two draft legal acts (C(2016) 3751 project and C(2016) 3752 project) and their Annexes are setting out the final criteria for determining the ED properties with reference to Regulation (EC) 1107/2009 [PPP] or Regulation (EU) No 528/2012 [BPR].

The WHO proposed a definition for ED and adverse effects in 2009, which was endorsed by EFSA in its Scientific Opinion on endocrine disruptors from 2013 and which was the basis for the new criteria to identify endocrine disruptors.

The criteria to identify ED should be based on:

- The weight of evidence following the methodology provided for in Regulation (EC) 1272/2008
- The OECD guidance document No. 150 (Evaluation chemicals for endocrine disruption)
- All relevant scientific evidence (studies based on internationally agreed study protocols)

With regard to Plant Protection Products, the criteria outlined in point 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009 will be replaced by those new criteria presented in the draft legal act C(2016) 3751.

According to Regulation (EC) 1107/2009, an a.s., safener or synergist meeting the criteria to be identified as having ED properties shall only be approved if the exposure of humans or non-target organisms (NTO), respectively to these substances (a.s., safener or synergist) under realistic conditions of use is negligible or a serious danger to plant health exists.

A definition of negligible exposure is described in the draft guidance document SANCO-2014-12096.



## EUROPEAN COMMISSION ADDRESSES ENDOCRINE DISRUPTORS FOR PLANT PROTECTION PRODUCTS AND BIOCIDES (continued)

With regard to Biocidal Products, the scientific criteria for the determination of endocrine-disrupting properties referred to in the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 shall be as set out in the Annex to the draft legal act C(2016) 3752 after implementation.

The biocides legislation only allows approval of endocrine disrupting compounds based on negligible risk or based on socioeconomic considerations.

Consequently endocrine disruptors are still subject to risk assessment and not only to hazard assessment, to determine if the level of concern is reached.

*Please refer also to the newsletter article  
"Scientific criteria for the identification of endocrine disrupting chemicals".*

The draft legal acts C(2016) 3751 project and C(2016) 3752 project will be the subject of the normal procedure with member states and other EU institutions before adoption by the Commission. The new criteria should apply as soon as possible. EFSA and ECHA should already start to use the criteria of the draft texts published on 15 June 2016 to identify EDs in order to be ready to apply the criteria when they enter into force. The published criteria are closely related to Option 2 and Option 3 Cat. 1 of the impact assessment. Thus, it can be expected that the compounds listed in these Options will be in the focus of regulators. For any pending procedure under Reg (EC) 1107/2009 and Reg (EU) 528/2012 a case-by-case decision will be used.

### BIOCIDES & ENDOCRINE DISRUPTION



For more information, please contact  
Dr Hans-Josef Leusch at  
[hans-josef.leusch@scc-gmbh.de](mailto:hans-josef.leusch@scc-gmbh.de)

### AGROCHEMICALS & ENDOCRINE DISRUPTION



For more information, please contact  
Dr. Albrecht Heidemann at  
[albrecht.heidemann@scc-gmbh.de](mailto:albrecht.heidemann@scc-gmbh.de)



## SCIENTIFIC CRITERIA FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS

Scientific criteria for the determination of endocrine disrupting properties have been set out by the European Commission in two draft legal acts in the areas of plant protection products (PPP) and bio-cidal products (BP), pursuant to legal obligations specified for PPP in Point 3.6.5 of Regulation (EC) No 1107/2009 [PPPR] and for BP in Article 5(3) of Regulation (EU) No 528/2012 [BPR].

In the annexes to both draft legal acts the criteria for the determination of endocrine disrupting properties have been established based on the authoritative and widely accepted definition of endocrine disruptors provided by WHO/IPCS (2002):

*An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.*

In the two draft legal acts the scientific methodology for the implementation of these criteria has been based on a weight-of-evidence assessment, which is intended to cover all available scientifically valid information\*

The key features of both proposed legal acts are summarized in the following:

### 1. Approval

The exclusion criteria defined in Annex II to the PPPR have been amended in the draft act for PPP, while the exclusion criteria defined in the BPR have remained unchanged. The present criteria for both regulatory areas can be summarized as follows:

#### Hazard-based assessment / hazard-based ban

A substance (active substance) shall not be approved if it is considered to have endocrine disrupting properties that may cause adverse effects in humans (PPP, BP). For PPP, this includes also safeners and synergists.

#### Risk-based exception from non-approval

A substance can be approved if the health risk from exposure to the substance is negligible [PPP] or the risk is negligible [BP] under the conditions of use, and the default exposure value for food and feed is not exceeded [PPP].

**\* Note:** *The present newsletter presents modified excerpts of the draft acts to highlight the quintessence. For exact wording and detailed information, please refer to the original documents.*



## SCIENTIFIC CRITERIA FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS (continued)

Referring to endocrine disruption and the associated health risk, it is important to note, that no decision on the applicability of a “safe threshold” concept has been included in the draft legal acts. The applicability or non-applicability of a safe threshold concept is not relevant for hazard identification (the latter representing the primary aim of the draft legal acts), but it has a significant impact on risk assessment conduct, *i.e.* on the reliable identification of negligible health risks. This important issue remains unresolved. Overall, scientific consensus has been reached that the assessment of potential risks from endocrine disruptors on human health and the environment would require consideration of dose-response relationships, exposure assessment and risk characterization (Solecki *et al.*, 2016).

The “potency” for endocrine disruption will have to be considered when evaluating the risk that endocrine disruptors may pose even though it is not part of the criteria to define an endocrine disruptor.

### 2 Criteria for the identification of substances having ED properties with respect to humans

The criteria for the identification of a substance having endocrine disrupting properties have been defined in the annexes to both draft legal acts. An active substance [safener or synergist] shall be considered as having endocrine disrupting properties with respect to humans, if it is a substance that meets all of the following criteria:

- The substance causes an adverse effect for human health  
and
- the substance has an endocrine mode of action  
and
- the endocrine mode of action induces the adverse effect  
(causal link based on biological plausibility)

#### Hazard-based assessment / hazard-based ban

A substance (active substance) shall not be approved if it is considered to have endocrine disrupting properties that may cause adverse effects in humans (PPP, BP). For PPP, this includes also safeners and synergists.



## SCIENTIFIC CRITERIA FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS (continued)

According to both draft legal acts the identification of a substance having endocrine disrupting properties shall be based on (key aspects):

- all relevant scientific evidence according to internationally agreed study protocols and other relevant scientific information
- a comparison of the weight of the evidence on endocrine-mediated adverse effects with the criteria for identification
- an assessment of quality, reliability, reproducibility and consistency of the scientific evidence
- the presence of a specific primary endocrine mode of action leading to an adverse effect (non-specific secondary effects of other toxic effects shall not be considered for the identification of a substance as endocrine disruptor)
- the presence of an adverse effect for human health (if the adverse effect is clearly not relevant to humans, the substance is no human endocrine disruptor)

### 3. Criteria for the identification of substances having ED properties with respect to non-target organisms

The criteria for the identification of a substance having endocrine disrupting properties have been defined in the Annexes to both draft legal acts. An active substance [safener or synergist] shall be identified as having endocrine disrupting properties with respect to non-target organisms if it is a substance that meets all of the following criteria:

- it is known to cause an adverse effect for non-target organisms, which is a change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences, considered relevant at the population level  
and
- it has an endocrine mode of action  
and
- the adverse effect relevant for the non-target organism at the population level is a consequence of the endocrine mode of action.

In principle, these criteria are similar to previously discussed and published definitions for an endocrine disrupting substance. Please refer to the corresponding Scientific Opinion on the Hazard Assessment of Endocrine Disruptors ([EFSA Journal 2013 \(11\(3\):3132\)](#)).



## SCIENTIFIC CRITERIA FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS (continued)

It is emphasised in the draft Commission Regulations that for identification of an endocrine disruptor all available relevant scientific evidence should be considered. This information could be based on *in vivo*, *in vitro* and mechanistic studies conducted in line with internationally agreed study protocols. Based on all information a weight of evidence approach should be performed where both positive and negative scientific evidence should be considered. It is further stated that evidence from field studies shall have precedence over other data. However, in the next sentence it is written that "positive results from well-conducted laboratory studies shall be considered even in the case of lack of positive results in field studies." This means that in case a field study indicates no significant effect at population level, a single publication based on laboratory experiments could challenge the favorable results of a field study.

Furthermore, as the criteria mentioned above are linking an adverse effect (based on an endocrine mode of action) with the population level, the development and validation of reliable population models is of major importance.

### Consequences of the draft legal acts

Referring to the criteria for the identification of a substance as having endocrine disrupting properties, the concept of an "*endocrine mode of action*" has been introduced, which reflects the intrinsic property of a substance to affect the endocrine system. Exposure to a substance with an endocrine mode of action may lead to altered biological function, which then either results in adverse health effects (*i.e.*, the substance is an endocrine disruptor) or not (*i.e.*, the substance is no endocrine disruptor).\*\*

The causal link between an endocrine mode of action and adverse health effects is crucial for the reliable identification of endocrine disruptors. Since current methodology for the assessment of (eco)toxicological hazards is largely based on endpoints indicative for altered biological function, the distinct identification of an endocrine mode of action and of a causal link to adverse health effects is considered to represent a major new challenge in hazard identification.

*Expert judgment will be of pivotal importance, especially in cases where the scientific evidence is ambiguous or contradictory.*

Within this context, the European Commission (2016) has noted that the causal relationship between the endocrine mode of action and adverse health effects shall be determined based on "*reasonable evidence*" ("biological plausibility") instead of "*conclusive evidence*". The concept of reasonable evidence is considered to be more practicable than the concept of conclusive evidence.

In any case, again expert judgment will be required for application of the criterion of biological plausibility for identification of substances with endocrine disrupting properties.



## SCIENTIFIC CRITERIA FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS (continued)

The scientific methodology for the identification of a substance as having endocrine disrupting properties is based on a comprehensive weight of evidence assessment. In addition to the reliable identification of an endocrine mode of action and the thorough assessment of the biological plausibility for a causal link to adverse health effects, the accuracy of discrimination between primary and secondary adverse effects (endocrine-related adverse effects vs. non-endocrine related toxicity) is considered to represent an important issue.

*This further underlines the high relevance of expert judgment for the identification of substances having endocrine disrupting properties according to the criteria defined in the draft legal acts for PPP and BP.*

The Commission requested EFSA and ECHA to start immediately after the publication of the criteria to use these criteria to identify EDs in order to be ready when the criteria will enter into force. The published criteria are closely related to criteria behind Option 2 and Option 3 Cat. 1 of the impact assessment. Hence, one can expect that the compounds listed in these Options will be in the focus of regulators. Therefore, it is worthwhile to contact the contractor JRC (Joint Research Center) or the Commission to obtain detailed information which data resulted in the classification of an individual compound to the Options. This information can be used to check the data base used for the assessment and the correctness of the conclusions. Subsequently, on a case-by-case basis further testing could be needed to support the future assessment of the compound with regard to a definitive conclusion on its endocrine disrupting properties.

### References

- European Commission (2016). Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products.
- Solecki R *et al.* (2016). Scientific principles for the identification of endocrine disrupting chemicals – a consensus statement. [http://www.bfr.bund.de/en/international\\_expert\\_meeting\\_on\\_endocrine\\_disruptors-197246.html](http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html)
- WHO/IPCS (2002). Global assessment of the state-of-the-science of endocrine disruptors. World Health Organisation, International Programme on Chemical Safety, WHO/IPCS/EDC/02.2.
- EFSA (2013). Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132

### REGULATORY ASPECTS OF ENDOCRINE DISRUPTION



For more information, please contact  
Dr. Monika Hofer at  
[monika.hofer@scg-gmbh.de](mailto:monika.hofer@scg-gmbh.de)



## AGROCHEMICALS



### BVL Applicants Conference, Braunschweig 2016

During the applicants conference at the BVL on 8 June 2016 representatives of the BVL gave presentations on the planned German procedures to avoid delays in evaluation as well as on new approaches.

#### **New ZV1 approach (Zonal authorisation procedure, Germany is zRMS; initial application)**

The ZV1 approach applies to applications for zonal authorisations (Article 33 to 39 of Regulation (EC) No 1107/2009), applications for use extensions (Article 45 of Regulation (EC) No 1107/2009) and applications for provisional authorisations (Article 30 of Regulation (EC) No 1107/2009) with Germany as zRMS. For all applications after the 15th April 2016, Germany will conduct a technical check as a first step of evaluation. Target is the reduction of delays in evaluation and rejection of incomplete or deficient applications. In the later evaluation phase only one stop of the clock phase will be granted. At this time the complete evaluation of the national regulatory authorities (UBA, JKI, BfR, BVL) will be available to the applicant.

#### **Article 43 of Regulation (EC) 1107/2009 - Cat. 4 studies**

Cat. 4 studies are directly related to a (new) endpoint coming from the renewal of approval of the active substance (SANCO/2010/13170 rev. 13). The time to perform these studies until the submission deadline of Article 43 is too short and an extension of the deadline to submit these studies will be given.

The submission deadline of the Cat. 4 studies has to be clarified with zRMS. Germany will follow the zRMS and current German authorisations will be extended up to 3 years. A complete updated dRR is to be submitted with submission of Cat. 4 studies considering the new endpoints and the new chapters of the dRR. In contrast to the mutually agreed position of the other member states, Germany will only act as zRMS in the case where products are registered in Germany.

#### **Article 43 of Regulation (EC) 1107/2009 - DE-only authorisations**

DE-only are authorisations granted under the Directive 91/414/EEC. For these authorisations an application for re-registration is independent from the re-authorisation according to Article 43 of Regulation (EC) 1107/2009. Already submitted applications for re-authorisations (where the evaluation is before evaluation phase I) will be stopped (in agreement with the applicant), for re-authorisations with outstanding application and for which it is necessary to apply in future, only the application form and a declaration of no adverse effects known is necessary. A prolongation of the current registrations up to 3 years is foreseen. A re-evaluation will be done after the active substance is renewed.

#### **Comparative assessment (Article 50 of Regulation (EC) 1107/2009)**

Article 41(2)b of Regulation (EC) 1107/2009 indicates that member state may grant an authorisation for mutual recognition (MR) if the product containing a candidate for substitution.

According to SANCO/12415/2013 rev.6, member states have the choice either to perform the comparative assessment or to accept or refuse the mutual recognition if products include a candidate for substitution (CfS). There is no obligation to mutually recognise in the case of those products.

In Germany no application for MR according to Article 40 of Regulation (EC) 1107/2009 is possible if the product contains a CfS substance. Only in exceptional cases (e.g. the product is important for the German market) an authorisation will be granted by MR. That procedure is in line with the guidance document SANCO/12415/2013 rev. 6.

#### **Not relevant metabolites (nrM) in groundwater**

For drinking water the GOW trigger value (Gesundheitlicher Orientierungswert; Health orientation value) is 1-3 µg/L. Exceedance of the GOW in groundwater must be reported by water suppliers. Authorities will assess the values and inform the concerned stakeholders. The exceedance of the GOW will be listed. The clarification of findings must be done by stakeholders simultaneously with listing the substance. Target is a reduction of the respective substance in drinking water either by banning the product in this region or by using additional risk mitigation measures.

## AGES Applicants Conference, Vienna, 11 May 2016

### Separation of evaluation

Since 1st January 2016, the evaluation for registration of plant protection products is split. BAES (Federal office for food safety) is responsible for the risk management, AGES (Austrian Agency for Health and Food Safety Ltd.) for the risk evaluation. The separation does not change anything for the applicants.

### Electronic application system

For applications of registration of plant protection products an electronic application system will be implemented in Austria approximately in 2nd quarter of 2018. Prior to that deadline an applicant's workshop will be conducted by AGES.

### Unacceptable co-formulants according to Article 27 of Regulation (EC) 1107/2009

The deadline for the list of unacceptable co-formulants will not be kept. Discussions are on-going and it is not clear when the list will be available.

### Negligible Exposure (SANCO-2014-12096)

The draft guidance document of 2015 (SANCO-2014-12096) is to be used as required by Commission. In future revisions ecotoxicology and endocrine disruption will be included.

### Article 4(7) of Regulation (EC) 1107/2009 - Serious danger

In Article 4(7) of Regulation (EC) 1107/2009, an active substance which is necessary to control a serious danger to plant health and which cannot be contained by other available means including nonchemical methods, may be approved for a limited maximum period of five years.

It is discussed whether approvals in accordance with Article 4(7) of Regulation (EC) 1107/2009 will be granted for the whole EU or only for the member state where the derogation was applied for.

### Bee guidance document (SANCO/10606/2014)

The finalisation of the bee guidance document (EFSA Guidance Document on the risk assessment of plant protection products on bees – and implementation plan, SANCO/10606/2014) is foreseen in 4th quarter of 2016. At the same time the uniform principles (Regulation (EC) 546/2011) must be revised.

### Future Co-operation between EFSA and ECHA

The evaluations from ECHA (Classification, CLH report) and EFSA (Classification and labelling, Peer review) should be coordinated in future. It is foreseen

to involve ECHA in the EFSA peer review and PRAPeR meetings (Pesticide Risk Assessment Peer Review). To speed up the evaluation process of the renewal of approval and to include the ECHA classification, the CLH report should be included in Volume 1 of the renewal assessment report (RAR). A template and further open points are under discussion.

### Article 43 of Regulation (EC) 1107/2009 - Selection of the zRMS

For AIR 2 substances, the zRMS could be selected by the applicants.

This led *inter alia* to different evaluations of products containing the same active substance. For AIR 3, it is foreseen that the RMS of the active substance should also act as zRMS for all respective products, although a product with this a.s. might not be authorised in the respective country. Germany and Slovenia do not support this decision.

### Article 43 of Regulation (EC) 1107/2009 - Compensation studies for generic products

For generic companies compensation studies are necessary to avoid data gaps. At the time of application a declaration is sufficient that these studies will be conducted. The studies must be available at time of re-authorisation of the reference product (for generic products) or at time of re-authorisation of the first product containing the active substance (for generic a.s.).

### Article 43 of Regulation (EC) 1107/2009 - Cat. 4 studies

According to SANCO/2010/13170 rev. 13, the so called category 4 (Cat. 4) studies are data which are directly related to a (new) endpoint decided at the time of the renewal of the approval of the active substance and for which the time is too short to produce the requested study until the submission deadline of Article 43.

Therefore, for Cat. 4 studies a prolongation depending on study type up to 2 years (in exceptional cases longer) will be given. The submission of all documents (Cat. 4 studies and dRR) should be done when all Cat. 4 studies are available, but it should be discussed with the zRMS. Further information about the categories of studies and what to be provided when by the applicant/authorisation holder can be found in the guidance document SANCO/2010/13170 rev. 13.

### Article 43 - dRR format and data requirements

The old dRR format (SANCO/6895/2009) has been replaced by the new dRR format as approved in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) in March 2015. In general, the new format is required for all product submissions since

1st January 2016. For submissions in accordance with Article 43 of Regulation (EC) 1107/2009, the dRR format depends on the a.s..

For the data requirements transitional measures apply as described in Regulation (EC) 283/2013, Regulation (EC) 284/2013, and SANTE/11509 /2013– rev. 5.2. Consequently, the data requirements to be used for or Article 43 of Regulation (EC) 1107/2009 also depend on the a.s..

According to these prerequisites, for products with one AIR 2 substance, the old dRR format should be submitted and the old data requirements (Regulation (EC) 544/2011, Regulation (EC) 545/2011) apply. For products with AIR 3 substances the new dRR format and new data requirements (Regulation (EC) 283/2013, Regulation (EC) 284/2013) are necessary. For mixed products, containing one AIR 2 and one AIR 3 substance, the requirements depend on the interval of both expiry dates. If it is less than one year, the old dRR format should be submitted and the old data requirements apply.

For substances with an interval of more than one year, the old dRR format and the old data requirements are applicable after renewal of the AIR 2 substance, and after the renewal of the AIR 3 substance the new dRR format and the new data requirements are required. Optionally, the new dRR format can also be used for AIR 2 substances.

#### **Article 43 of Regulation (EC) 1107/2009 - on-going evaluations**

There is still some discussion at Commission level about applications which are not finished at the dRR submission deadline of Article 43. All evaluations must be finished either in the zRMS country at renewal of approval of the active substance or in the CMS countries at latest 3 months after the renewal of approval of the active substance.

#### **Article 43 of Regulation (EC) 1107/2009 - Combined toxicology exposure**

Combined exposure is an obligatory point in the new dRR format (see dRR Part B6, point 6.6.6) which is required for all product submissions since 1st January 2016.

For Article 43 of Regulation (EC) 1107/2009, one major question is, how to combine the exposure for mixed products containing two a.s. with an expiry date interval of more than one year. For this case, AGES recommends using the available endpoints of the a.s. independent from the status of renewal. After the 2nd active substance is renewed, an update of the combined exposure calculations is necessary.

### **New “Guidance Document on Semiochemical Active Substances and Plant Protection Products” (SANTE/12815/2014 rev. 5.2) published by European Commission**

SANTE/12815/2014 rev. 5.2 is based on OECD guidance No. 121. The new EU Guidance Document “aims to provide practical solutions on how procedures and data requirements [e.g. for human and environmental risk assessment] can be applied to facilitate the approval of semiochemicals at EU-level and the authorisation of plant protection products containing these active substances at Member State level.”

The guidance states, that an exposure assessment needs not to be provided where the release of the product is by vapour phase only and is similar to natural release rates of the semiochemical or a group of related semiochemicals.

It is emphasized that according to Regulation (EU) No 1107/2009 no tests and studies shall be considered in a dossier involving the deliberate administration of the active substance or the product to humans.

If residue levels are unlikely to exceed natural exposure levels during outbreak of the pest, an application for inclusion in Annex IV of Regulation (EC) No 396/20054 should be submitted by the applicant at the same time as is applied for the approval of the active substance. It is highlighted, that the plant or animal origin of a substance does not automatically confer the low risk active substance status according to the requirements laid out in Annex II of Regulation (EC) No 1107/2009.

Regarding efficacy requirements as a minimum a “demonstrable measure of either pest control, crop damage or crop yield, or sufficient magnitude to be beneficial from an agronomic perspective” is requested.

The new guidance will apply to applications submitted from 1 January 2017 onwards.

#### **New Commission address**

Since 27th May 2016, a new Commission e-mail address is available:

[SANTE-PESTICIDES-RENEWAL-OF-APPROVAL@ec.europa.eu](mailto:SANTE-PESTICIDES-RENEWAL-OF-APPROVAL@ec.europa.eu)

This mail box should be used for correspondence and documents relating to the renewal of approval process of AIR 3 and AIR 4 substances.

## 'PANAMA' at a glance

PANAMA is a Belgian acronym for Plant protection products And Nutrients Authorisation Management.

PANAMA will be the Belgian on-line system for the submission of applications for

- Plant Protection Products
- Fertilizers
- GEP
- Products for experimental purposes

The PANAMA-system is currently under development. After announcing PANAMA in 2015, a first test was now possible for submissions of

- Zonal application for authorisation
- Application for mutual recognition
- Duplicate authorisation
- Second version of an existing product (change in composition, extension, ...)

SCC had the chance to participate in the first tests of the system in Brussels.

The system worked stable and allowed for an extensive test including the upload of dossiers (dRRs) and relevant documents. The studies for the dRR will still be sent on CD or DVD to Brussels as an upload of the huge amount of data might difficult.

The usage of the system is straightforward. As in usual application forms the following information has to be given:

1. Contact information
2. Details on the application (e.g. type of application)
3. Details on the product (e.g. formulation type, code number, name)
4. Composition: It is planned to provide the information on EU-approved a.s. and common formulants in a database.
5. Labelling
6. Package (e.g. material, size)
7. Use: This is where the GAP is to be inserted. Several comments of the participants of the testing session had comments on this tool in order to facilitate the data entry.
8. Documents: Upload for dRR and documents like letter of access or cover letter. Studies for dossiers will be sent on CD.

The data entry in the system is not more complicated than filling in an application form. There are some details to be solved by the programmers yet, but the official start of the system which has earlier been announced for 2016 is within reach.

## France: Positive list for natural biostimulants

The French Decree No. 2016-532 of 27 April 2016 on the procedure for national authorization of natural biostimulant substances<sup>1</sup> was published on the 30th April 2016

Natural biostimulant substances are authorized without further procedures provided they fulfill the following conditions:

- Lack of any harmful effects on human and animal health or the environment (as assessed by ANSES) or,
- The substance is listed in Article D 4211-11 of the French Public Health Code<sup>2</sup> (Article D 4211-11 contains a list of more than 100 authorized natural substances that can be freely sold in France).
- The substance is of plant, animal or mineral origin (excluding microorganisms and GMO's).
- The substance is unprocessed or minimally processed (manual, mechanical or gravitational, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water).

This list will be supplemented by other substances, after an evaluation of ANSES ensuring that they have no harmful effect on human and animal health or the environment.

The Decree simplifies and accelerates the authorization process of these substances and allows the manufacturers to produce and market their biostimulant products without further formalities.

<sup>1</sup>[https://www.legifrance.gouv.fr/jo\\_pdf.do?id=JORFTEXT0032472048](https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT0032472048)

<sup>2</sup><https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006913464&dateTexte=&categorieLien=cid>

## Simplification in application procedure for field trial permits in France

In February 2016 France has issued a decree which establishes the conditions for the trials and experiments referred to in Article D. 253-32 of the Code rural and sea fishing with respect to plant protection products. This order enables a simplified permission procedure to start experimental trials in France: it defines the conditions for exemption from application for experimental trials and tests of plant protection products and adjuvants.

In case the below mentioned criteria for the tested prototype or product are met, a trial permit is no longer necessary

### 1. Research trials and tests:

- The maximum surface area per trial site and crop is below 0.1 ha,
- The maximum cumulated surface area of all trial sites in France is below 2 ha and
- The maximum amount per year/season is below 15 L or kg

### 2. Development trials and tests

(except those mentioned in point 3):

- The maximum surface area per trial site and crop is below 1 ha,
- The maximum cumulated surface area of all trial sites in France is below 30 ha and
- The maximum amount per year/season is below 200 L or kg

### 3. Development trials and tests for chemical mediators used by passive diffusion without contact with the vegetation:

- The maximum surface area per trial site and crop is below 5 ha,
- The maximum cumulated surface area of all trial sites in France is below 50 ha and
- The maximum amount per year/season is below 18.75 kg.

A declaration should be made by filling out the accordant form dated 11.03.2016 available at the ANSES website

(<https://www.anses.fr/fr/content/documents-dinformation-pour-la-constitution-de-dossiers-pour-les-produits>), which should be sent to ANSES at least 10 days before the implementation of the trial. If a trial is qualified for exemption from trial permit, crop destruction after trial closure is mandatory.

As the next step a form for declaration of officially recognized testing needs to be filled (form dated 7 June 2016, which is available on the above mentioned ANSES website).

This form replaces the old COLEOR portal and needs to be used, if a trial permit is not necessary. A first declaration needs to be made at the latest 20 days after the first application of the test product. The second declaration is due no later than 20 days after the end of the assessments or crop destruction. All declarations should be sent to ANSES by post or via email to [damm.essais@anses.fr](mailto:damm.essais@anses.fr).

## Efficacy requirements in the Northern Zone as part of the renewal of authorizations in accordance with Art. 43 of 1107/2009

In the 5th version of its "Guidance Document on work-sharing in the Northern zone in the authorization of plant protection products" the Northern Zone has issued detailed and clearly defined information about efficacy requirements for dossier submission as part of the renewal procedure in accordance with Art. 43.

Generally, the six countries in the Northern zone belong to two different EPPO zones with Denmark, and Sweden being part of the Maritime EPPO zone and Finland, Estonia, Latvia and Lithuania belonging to the North-East EPPO Zone. The non-EU country Norway, which takes part in the registration process of the Northern zone is located in the Maritime EPPO zone. If an applicant would like to apply for authorization in both EPPO zones, efficacy data from both zones should be part of the submission. Nevertheless, the applicant can justify that data from one of these two EPPO zones is acceptable for registration in the other EPPO zone as well (and *vice versa*) but data from other zones than Maritime and the North-East zone should not be included in the dRR.

Unlike the situation in the other zones, a label extension as part of the renewal procedure is possible but only for uses which are already authorized in at least one of the countries in the Northern zone. It is important to note that an accordant GAP amendment must be agreed with the zRMS and also the cMS already at pre-notification time, since otherwise the application may be rejected. Applications for new uses which are not covered by previously authorized uses will not be accepted at all which is comparable to the situation in the Central and Southern zone where authorities would not support any use extension within the Art. 43 procedure.

Generally, the Northern zone will consider GAP changes in connection with a renewal procedure, if these changes are covered by the efficacy data previously evaluated as part of the national authorizations.

Dose extrapolations of +/- 10% are accepted without further justification.

Also other extrapolations are possible in the dRR, but in this case justifications are needed. Bridging options between pests and crops, respectively, are admissible as well and the applicant can rely on a detailed Guidance document on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern zone ([www3.kemi.se/.../Guidance-efficacy-data-Northern-zone.pdf](http://www3.kemi.se/.../Guidance-efficacy-data-Northern-zone.pdf)).

Considering the presentation of data, a dRR with all sections must be submitted as part of the renewal of authorizations. This means that also a complete efficacy section has to be provided. Therefore, applicants are strongly encouraged to submit also a BAD, since the dRR is considered as a concise summary of the BAD. If a BAD is not submitted, the applicant is obliged to provide information on the origin of the data summarized in the various tables/figures of the dRR.

Also the implementation of Comparative Assessments (CA) has to be considered as part of the renewal of authorizations in case that the active ingredient is a candidate for substitution. Such a CA has to start with the consideration of efficacy issues like e.g. the relevance of resistance risk or the detailed presentation of alternatives. Since a CA is a national and not zonal issue, the justification for maintaining the product on the market should be included in the National Addenda, and not in the core assessment.

### **Application of plant protection products in three-dimensional crops**

The application of plant protection products in three-dimensional crops or high growing crops (e.g. grapes, pome and stone fruits, supported tomatoes) and the correct reporting in accordant efficacy trial reports is sometimes a reason for discussions between the efficacy evaluators of the competent authorities and the applicants. Although EPPO Standard PP1/239 (2012) already notes that 'per treated leaf wall area unit' shall be a common dose expression method in three-dimensional crops, the accordant conversion is still not given in all submitted efficacy trial reports.

In order to be able to carry out a detailed assessment of a submitted efficacy dossier and data package, efficacy evaluators expect in the provided efficacy trial reports a detailed and exact description of the used application devices (e.g device type and techniques, drift reduction measurements, nozzle types,

pressure). Special emphasis is placed on the detailed and accurate description of the applied product application rate and the spray volume, not only per hectare but also per 10,000 m<sup>2</sup> treated foliage wall. Authorities, especially in the Central Zone, indicate that the last point is not always presented in submitted efficacy trial reports, but that such information is essential for a data assessment related to agricultural practice. Therefore, it is strongly recommended to present or amend such information in any recent report on trials in three-dimensional crops.

In order to achieve a harmonized approach for data assessment following the implementation of the EC Regulation 1107/2009 (EC, 2009), EPPO organizes in collaboration with the Austrian Agency for Health and Food Safety (AGES) a Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high growing crops (Vienna, 18/20 October 2016). SCC will inform about the outcome of this workshop.

### **Sustainable Resistance Management Strategy**

Resistance to pesticides is a major concern in control of vectors and pests of public health importance as well as in the agricultural sector (FAO, 2010). The problem of resistance development is threatening the sustainability of agriculture. Over many years specialists have emphasized to official regulators and the public that the lack of a comprehensive and effective toolbox will undermine farmers' competitiveness, productivity and viability and reduce the choice of high-quality food for consumers. It will conflict with the overall principles of sustainable agriculture and IPM, where all methods, cultural, physical, biological and chemical, play a crucial role to prevent or manage pests. In her opening presentation of the EC-CA/ECPA Brussels conference earlier this year Lin Field; Head Department Biological Chemistry and Crop Protection at Rothamsted Research, UK explained that "it is paramount to develop and implement a 'Sustainable Resistance Management Strategy' in Europe, which includes schemes, conditions and tools to effectively tackle this problem of increased resistance, while also drawing the attention of policy makers, regulators, supermarkets, public opinion and other stakeholders."

To do so a consortium composed of Research Institutes and Agri-Food Chain Stakeholders and led by Rothamsted Research and ECPA is being built in order to work towards implementing a long-term “Sustainable Resistance Management Strategy” at EU level. Pesticide producers esp. the actual main notifiers of active substances are invited to support this initiative via active participation in the relevant Resistance Action Committees: FRAC, HRAC or IRAC.

Resistance is not only in the political area an increasingly important topic but also of actual importance for product registrations. SCC made the experience that field monitoring data were required from an authority from the Central European Zone even for a well-known fungicidally active substance with unspecific multisite activity. This is one extreme example which shows that one can expect field monitoring data to be required by national authorities for many pesticide products in the near future. SCC efficacy experts are prepared to support interested companies in their resistance management activities e.g. by taking care for resistance monitoring activities, conducting resistance risk analyses or writing resistance dossiers



For more information, please contact  
Dr. Albrecht Heidemann at

[albrecht.heidemann@scg-gmbh.de](mailto:albrecht.heidemann@scg-gmbh.de)

## BIOCIDES



### France: National requirements during the transitional period significantly simplified

The transitional marketing authorization, which was previously required in France for the making available and the use of biocidal products containing active substances which are not yet approved for the relevant product type (PT), is no longer obligatory for most biocidal products, since the entry into force of Act No. 2015-1567 of 2 December 2015.

Only certain products are currently subject to an authorization. This chiefly concerns:

1. Biocidal products used against notifiable contagious livestock diseases or diseases that are subject to State-organised collective prophylaxis.
2. Disinfectants for public swimming pools, drinking water, hot and cold water supplies (mainly PT 2, 4, 5), under marketing authorisation from the French Ministry of Health.
3. Disinfectants used for embalming and taxidermy (PT 22) under marketing authorisation from the French Ministry of Health.

All biocidal products in the transitional regime must fulfill the following requirements:

- The contained active substances must comply with Article 95 of the BPR and must be under review for the relevant product type and use.
- The labelling of the BP must comply with Article 10 of the national Ministerial Order of 19 May 2004.
- They must be declared to the Ministry of Environment via Simmbad (<https://simmbad.fr/servlet/accueilMinistere.html>), and to the French National Research and Safety Institute (INRS) for the purpose of toxicovigilance.

For further details, please refer to the website of the Helpdesk Biocides:

[http://www.helpdesk-biocides.fr \(...\)](http://www.helpdesk-biocides.fr (...))

## Commission Implementing Decisions on several borderline cases issued

Recently, several Commission Implementing Decisions were issued, dealing with borderline cases between the BPR and other regulatory areas:

1. Commission Implementing Decision (EU) 2016/903 dealt with the question whether a horse rug impregnated with permethrin for the purpose of controlling nuisance insects in the environment of the horse shall be considered a treated article, a biocidal product or even a veterinary medicinal product. With regard to the function of the rug, the concentration and mode of action of the active substance and the prominence and importance of the biocidal claim, the biocidal function of the horse rug was considered a primary one, and thus the described horse rug impregnated with permethrin shall be considered as a biocidal product of product type 18. It was considered not to be a veterinary medicinal product as the horse rug is neither designed to be applied as a topical insecticide, nor to have an action on physiological functions, nor is it presented as having properties for treating or preventing horse diseases.
2. Commission Implementing Decision (EU) 2016/904 clarified that propan-2-ol containing products for hand disinfection, including surgical hand disinfection, for the purpose of reducing the risk of transmission of microorganisms shall be considered as biocidal products of product type 1. The question was raised by Germany, as, historically, particularly surgical hand disinfectants had been seen as medicinal products by the German competent authority for medicinal products, BfArM.
3. On 29 April 2016 the Commission Implementing Decision (EU) 2016/678 on dried lavender blossoms contained in a pad placed on the market to repel moths was published. It lays down that the product is neither a biocidal product nor a treated article. The reason is that, according to agreed Union Guidance, "whole living or unprocessed dead organisms (e.g. yeast, freeze-dried bacteria) or parts thereof (e.g. body parts, blood, branches, leaves, flowers, etc.)"

do not fall under the REACH definitions of substances, mixtures and articles.

4. In analogy to the decision on lavender blossoms, the UK Competent Authority HSE, having consulted the EU Commission and the other member states, published on 17 June 2016 in their Biocides eBulletin the analogous opinion that untreated barley straw is not a biocidal product. Untreated barley straw products have been marketed for the purposes of controlling blanket weed and other algae in lakes and ponds for some time. This consideration does not apply to barley straw extract, as this does not meet the conditions for unprocessed barley straw.

## Deadline of 1 October 2016, resulting from the repeal of the Manual of Decisions

Under the Biocidal Products Directive 98/8/EC, the Manual of Decisions (MoD) was a 'living document', which contained decisions which were agreed between the Commission services and the Member States, e.g. on borderline cases similar to the ones described in the previous chapter, or other case-by-case decisions.

As the MoD has been obsolete since 1 October 2015, "pursuant to Article 16(1) of Regulation (EU) No 1062/2014, persons placing biocidal products on the market and having relied on the guidance previously provided through this Manual of Decision to conclude that their products were out of the scope of the biocides legislation, are entitled to submit a declaration of interest to notify a substance/product-type combination at the latest by 1 October 2016 when their products now fall under the scope of the BPR."

This means: If a biocidal product had been declared by the MoD as being out of the scope of the BPD, but now falls (or is suspected to fall) under the scope of the BPR, companies placing such biocidal products on the market are advised to seek confirmation by the Competent Authorities.



For more information, please contact  
 Dr Hans-Josef Leusch at  
[hans-josef.leusch@scc-gmbh.de](mailto:hans-josef.leusch@scc-gmbh.de)



## CHEMICALS/REACH



### ECHA announced to review completeness of registrations

The outcome of a recent Board of Appeal (BoA) decision (A-022-2013) forces ECHA to review the practice of their dossier check as part of the completeness check during dossier submission. In particular the BoA concluded that the Agency has failed to adequately examine the completeness of dossiers in accordance with Article 20(2) REACH. Thus, the current practice of IT based completeness check during dossier submission was regarded as not sufficient to fulfil the obligation of the Agency.

As consequence ECHA announced to recheck the completeness of the dossiers in its database with regard to the information requirements to verify that the information provided is meaningful. At the same time ECHA will retroactively check all dossiers which may be in breach of the 'one substance, one registration' principle of REACH. Taking the context of the BoA case into account a special focus will be on individual submitted dossier beside an existing joint registration.

In case ECHA will conclude that a dossier is incomplete, the registrant has to update the registration dossier with the missing information and in some cases it is required to join the existing joint submission for the same substance. This will of course requires discussions about substance sameness and negotiations of a Letter of Access and SIEF agreements.

If the registrants fail to update their dossier with the missing information and / or joining the joint submission within the timeline set, ECHA will revoke the REACH registration.

SCC strongly recommends becoming active if you receive a compliance check decision from ECHA and even before to make sure that your dossier represents the state of the art of today, as the timelines given by ECHA to solve/improve issues is very short.

*Please get into contact with SCC if you need support for the update of your individual dossier or negotiations with the lead registrant and discussions about substance sameness.*

### Creation of joint submission after REACH-IT 3 launch

REACH-IT was updated to Version 3.0 and launched on 21 June 2016. Beside other aims ECHA wants to implement measurements to enforce the measurements introduced by the Implementing Regulation (EU) 2016/9. In particular to enforce the "one substance one registration" principle (OSOR) ECHA had blocked some months before the update the possibility to submit individual submissions in REACH-IT when existing joint submissions were already established. In some cases companies have opened a joint submission in REACH-IT for substance for which they were not the elected lead registrant. Furthermore, ECHA noticed that several joint submissions were created before the update in order to bypass the OSOR principle. In order to solve this issue ECHA has deleted during the REACH-IT update all Joint submission for which no Lead Dossier was already submitted.

Therefore it is advisable for all elected or potential lead registrant to create a joint submission for the respective substance in REACH-IT. This is moreover essential to avoid situations where other SIEF participants create the joint submission without having the appointment from the other SIEF members.

With the REACH-IT update a new functionality regarding the joint submission was implemented. The Lead registrant can now decide whether the contact person given for that joint submission should be published on the ECHA homepage or not. The publication of the contact details on ECHA homepage can be useful in the context of marketing. By default the details will not be published but can be changed any time after creation of the joint submission.

*We have intensively gained experience with the new system in the last weeks and could assist you in managing the new REACH-IT system.*

## Implementing of “substance identity profile” (SIP) in IUCLID 6

During the 20<sup>th</sup> Meeting of Competent Authorities for REACH and CLP (CARACAL) the implementation of the “substance identity profile” (SIP) in IUCLID 6 and the requirement of an Implementing Regulation were discussed.

For a new Lead Registrant’s (LR’s) dossier, reporting of SIP is a mandatory field in section 1.2 of IUCLID 6 and will be verified by Business Rule check during the dossier submission. Thus, a lead dossier must contain the “boundary composition of the substance” defining the SIP and the “legal entity composition” (the LR’s own composition). An Implementing Regulation for this issue was not considered to be essential as Art 11 (1) and 19 (1) of REACH Regulation and the Implementing Regulation on Data Sharing are sufficient.

For lead dossiers which have already been submitted, the boundary composition must be included in a dossier update. For lead dossier updates requested by ECHA a transition period is taken into account for the submission of the boundary composition.

Administrative effort is considered to be minor for new registrations as the substance identity information must be known as a result of registrants’ agreement on sameness in the SIEF.

As part of a dossier update there is a need to define the boundary composition of the substance, to bring the SIP into agreement with the current members of the joint submission and to clarify if the given/used information is in line with ECHA’s expectation of the level of details to be provided in the SIP. This requirement could cause in some cases additional efforts within the SIEF. The level of detail for the SIP has increased significantly. Furthermore, ECHA anticipates that the provided Annex VII-XI data (where applicable) collected/generated demonstrably covers all compositional profiles in the SIEF.

*The boundary composition of the substance should comply with the requirement indicated in the SIEF Agreement.*

## IUCLID 6 now mandatory

With the update of REACH-IT on 21 June 2016, ECHA will only accept dossiers prepared in IUCLID 6 format. Not only the IUCLID format changed (now ending with .i6z) but also new functions were integrated.

Unsurprisingly, this leads to new completeness check failures for migrated IUCLID 5 dossiers revealed by the new validation assistant of IUCLID 6. That means that even small updates of IUCLID 5 dossiers might require extensive manual rework to fulfill the new requirements.

*Please consider for your own planning that dossier updates to IUCLID 6 are just a matter of time and will become necessary. ECHA will certainly find a way to force lead registrants to provide such an update.*

## Manual verification at completeness check during dossier submission

As consequence of a board of appeal decision (case number A-022-2013) the agency was obliged to revise the technical completeness check for registration dossiers. Formerly the agency did not verify the quality or the adequacy of any data or justifications submitted in the course of the technical completeness check (TCC). Thus it was possible to submit low quality dossiers including irrelevant text to simply bypass an information requirement. The board of appeal concluded that this procedure was not in accordance with the REACH provision of article 20(2) as the agency has to ensure the adequacy of the submitted data. Consequently the agency has supplemented the technical completeness check with a manual verification step. This measure entered into force with the update of REACH-IT to version 3 (life since 21-06-2016). The agency will perform a manual verification on both new registrations and updates of existing dossiers. The agency indicated that the main areas for the manual verification check will be the substance identification (e.g. analytical data, sufficient justification and descriptions), Data waivers (relevant justification), Testing proposals on vertebrate animals (considerations of alternative methods), Chemical safety reports (CSRs) (justification when no CSR is provided for dossiers over 10 tpa).

According to REACH article 20 the agency shall undertake the completeness check within three weeks of the submission date (or with respect to 2018 deadline: within three months of the relevant deadline for

registrations of phase-in substances submitted in the course of the two-month period immediately preceding that deadline).

According to article 20 (REACH) TCC is performed by the Agency within three weeks from the submission date. The invoice will be issued at the same time with the start of the TCC process. They go in parallel. Should the dossier be considered incomplete for any TCC rule, irrelevant whether manual or automatic rule, the agency will issue a letter with the list of failures which will be made available via the REACH-IT 'Tasks' box within these three weeks.

The agency will set a deadline to correct the errors. This could be in particular requiring timely action insofar as e.g. waiver and analytical data will be checked / questioned by the agency.

After submission the update dossier will undergo a second TCC check. In case the dossier was again considered incomplete by the TCC then any money already paid to ECHA will not be reimbursed and the submission will be rejected.

Registrants should take into account this new procedure and ensure that the submitted dossiers are in-line with the current TCC. SCC recommends using the IUCLID 6 validation assistant in order to minimize the conspicuities.

*SCC can assist you with your dossier update offering different approaches (e.g. TCC conform update, full update using new templates). Thus, please get into contact with us for further information.*



For more information, please contact  
 Dr. Werner Köhl at  
[werner.koehl@scg-gmbh.de](mailto:werner.koehl@scg-gmbh.de)

## REGULATORY SCIENCE



### Draft Guidance on the Establishment of the Residue Definition for Dietary Risk Assessment published by EFSA

The European Food Safety Authority (EFSA) has published the draft "guidance on the establishment of the residue definition for dietary risk assessment" (EFSA Journal 2016;14(issue):NNNN)1 to harmonise the process of deriving residue definitions in food and feed.

According to the draft guidance document the assessment is divided into three modules.

#### Module 1: Exclusion of Genotoxicity

For the exclusion of genotoxicity, all metabolites identified at any level within plant, livestock or rotational crop metabolism studies, simulated processing studies or in groundwater needs to be considered. Within the decision scheme of Module 1, QSAR, read across and grouping of metabolites as well as exposure estimation and comparison with the TTC value for genotoxic compounds is foreseen. Finally, also genotoxicity testing might be concluded.

#### Module 2: Assessment of General Toxicity

After profiling the genotoxicity of the metabolites in Module 1, all metabolites without genotoxicological concern are considered for the general acute and chronic toxicity in Module 2.

#### Module 3: Decision on Residue Definition

Module 1 and 2 provide an inventory of toxicity and dietary exposure information which leads to the residue definition proposal within Module 3.

On 26/27 September there will be a technical meeting in Parma, Italy to present and explain this draft guidance document as well as to discuss the feedback from the public consultation and the proposed approaches.

As key point of this draft guidance document one should be aware that for the setting of the residue definition QSAR analyses and maybe further toxicity studies will be needed.

On 30 June 2016 EFSA published a call for tender<sup>2</sup> to clarify the applicability of existing QSAR, read across and grouping approaches in the context of Module 1 of the draft guidance for residue definition. This project lasts 19 months.

It is not clear whether the guidance for residue definition will need to be applied before the reliability and applicability of the Module 1 approaches are confirmed.

#### References:

<sup>1</sup> EFSA PPR Panel, 2015. Guidance on the establishment of the residue definition for dietary risk assessment. EFSA Journal 2016;14(issue):NNNN, 180 pp. doi:10.2903/j.efsa.2016.NNNN

<sup>2</sup> Evaluation of the applicability of existing (Q)SAR models for predicting the genotoxicity of pesticides and similarity analysis related with genotoxicity of pesticides for facilitating of grouping and read across (OC/EFSA/PRAS/2016/01)



For more information, please contact  
 Dr. Monika Hofer at  
[monika.hofer@scg-gmbh.de](mailto:monika.hofer@scg-gmbh.de)

## CALENDAR



### Chemical Regulation Meeting in Yokohama, Japan, 25<sup>th</sup>-26<sup>th</sup> August 2016

**Meet SCC REACH and regulatory experts at the Chemical Regulation Meeting 2016 in Yokohama.**

SCC experts will make a presentation on “Warning of time risk towards REACH 2018” in Japanese. Together with our experts from the headquarters, we will be happy to discuss your registration needs for the Japanese and European markets.

Feel free to visit our stand No. 53 and talk to:

**Dr. Werner Köhl**, Head of Chemicals / REACH, Consumer Products, Cosmetics, Feed & Food Additives,  
**Kozo Inoue**, Director - Coordinator Chemicals / REACH, Biocides and other services in Japan,  
**Kenji Makita**, Senior Consultant – Chemicals / REACH and OR Services,  
**Toshiaki Fukushima**, Senior Consultant – Chemicals / REACH.

Click [here](#) to make an appointment with SCC experts to discuss your specific regulatory needs at Chemical Regulation Meeting in Yokohama.

### CIR Chemical Industries Regulations in Nice, France, 7<sup>th</sup>-8<sup>th</sup> September 2016

**Meet SCC at the annual AgChem Forum 2016 in Nice.**

Our scientific and regulatory experts look forward to participate in sessions and workshops and to discuss key regulatory issues with their peers. **Dr. Bernd Brielbeck**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides, will make a **presentation on “Regulatory aspects of low risk substances in Europe”**. Use a chance to visit our exhibition stand No. 5 to speak with our top experts, i.a.:

**Dr. Friedbert Pistel**, President, **Dr. Norbert Weißmann**, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides – Efficacy, **Dr. Karin Lauber**, Manager Regulatory Affairs, Agrochemicals and Biopesticides, and **Dr. Felix Koziol**, Manager Regulatory Affairs, Biocides.

Click [here](#) to make an appointment with SCC experts to discuss your specific regulatory needs at CIR in Nice.

## CONTACT DETAILS

### SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH

Dr. Friedbert Pistel, President

#### Headquarters Bad Kreuznach

Am Grenzgraben 11  
D-55545 Bad Kreuznach  
Tel. +49 671 29846-0  
Fax +49 671 29846-100  
[info@scc-hq.de](mailto:info@scc-hq.de)  
[www.scc-gmbh.de](http://www.scc-gmbh.de)



#### Office Berlin

Dr. Achim Schmitz  
Branch Manager SCC Office Berlin  
Senior Expert Ecotoxicology  
Tel.: +49 30 2592-2569  
[achim.schmitz@scc-gmbh.de](mailto:achim.schmitz@scc-gmbh.de)

Address  
Friedrichstraße 40  
D-10969 Berlin

#### Liaison Office Japan

*Coordinator Agrochemicals & Biopesticides,  
Pharma, Pre-Clinical*  
Mr. Toshiyasu Takada  
Director Agrochemicals and Biopesticides  
[toshiyasu.takada@scc-japan.com](mailto: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](mailto:kozo.inoue@scc-japan.com)

*Chemicals/REACH and OR Services*  
Mr. Kenji Makita  
Senior Consultant  
[kenji.makita@scc-japan.com](mailto:kenji.makita@scc-japan.com)

*Chemicals/REACH*  
Mr. Toshiaki Fukushima  
Senior Consultant  
[toshiaki.fukushima@scc-japan.com](mailto:toshiaki.fukushima@scc-japan.com)

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