

Newsletter



Volume 13, No. 4, December 2013 / AgChem Forum 2013, Barcelona

2014 or the shape of things to come: Regulatory Developments in Toxicology and Ecotoxicology

Dear SCC Newsletter subscribers,

please find within this last edition of the SCC Newsletter for the year 2013 some articles on the latest progress in regulatory toxicology, ecotoxicology, and environmental fate beneath some news on REACH and agrochemicals. Recently a new guidance document about the evaluation of the dermal absorption of plant protection products and biocides was published by BfR. The German authority will be taking into account also criteria recently named by EFSA and listed by OECD to evaluate the dermal absorption values. Furthermore, EFSA has published this year several guidance documents to evaluate the role of dose addition in human health risk assessment and about the risk assessment of plant protection products on bees.

This edition of the Newsletter comprises also a longer report on the last CIR Conference in Barcelona focused on the AgChem Forum. A review of selected presentations on regulatory frameworks is given and relevant aspects of human and environmental safety in condensed form.

Please have also a look at the calendar to find out where you can meet with SCC experts to express your needs or clarify your questions on scientific and regulatory issues.

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

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

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

Dr. Friedbert Pistel
President



*SCC GmbH
wishes
happy holidays
and
all the best
for 2014*

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AGROCHEMICALS

Recent progress in the regulatory field

Heraklit was right when he thought, "everything flows", because along with registration of plant protection products many aspects of regulation and of toxicological and ecotoxicological risk assessments evolve. Relating to this and many other issues like (new) data requirements for submission of agrochemicals, please refer to the report about the AgChem Forum which was held in Barcelona on 4 and 5 September 2013 (see on page 6ff.).



CHEMICALS, REACH, CONSUMER PRODUCTS

News from the Chemicals & Consumer Products Department

Several issues with relevance for REACH are presented below. For more information, please contact Dr. Werner Köhl at werner.koehl@scg-gmbh.de.

C&L Platform

The C&L platform of the ECHA C&L inventory gives C&L notifiers the opportunity to harmonize the classification of a substance with more than one (diverse) notification. ECHA encourages companies

to agree on one harmonized classification. As tier 2 REACH deadline has successfully passed, this option is quite frequently used by companies. Especially for lead registrants having established C&L in their tier 1 and 2 REACH dossiers based on reliable data, it is regarded as important to establish a common C&L in the market to avoid different C&L for preventing problems in selling market substances / mixtures in Europe. Thus, doing the first step and opening the discussion should be considered especially in contradictory C&L in the market. Please contact SCC, if you require scientific, regulatory or technical support with regard to the C&L platform.

New guidance on extended SDS

ECHA is currently preparing a new guidance on the compilation of safety data sheets: Including relevant exposure scenario information into Safety Data Sheets. In this upcoming guidance rules for scaling and advice on generation of extended SDS (eSDS) for mixtures are given. In this context, SCC registrants should keep in mind always to keep their MSDS updated as this document represents the relevant communication document within the supply chain. This include also results of the registration (e.g. registration number, uses and RMMs defined in the CSR) addressed in the main part of the eSDS. Especially, relevant changes due to updates of dossiers (IUCLID and/or CSR) require an update of the respective sections of the eMSDS.

ECHAs targeted compliance check in dossier evaluation process

Since 2012 ECHA has started to focus on developing and improving IT-tools for the screening of registration dossiers. ECHA is aiming to identify quality deficiencies in as many registration dossiers as possible with a minimum of personal effort. The so-called targeted compliance check is conducted based on concerns via formal IT routines. The focus at the moment is put on physico-chemical endpoints with a direct impact on the safety assessment (e.g. log Pow, water solubility, vapour pressure). Furthermore, the dossier is screened for inconsistencies (e.g.

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waiving of the water solubility endpoint due to fast hydrolysis with a missing hydrolysis study in the dossier). Moreover, ECHA has specified the acceptance criteria for the waiving of higher tier toxicological and ecotoxicological studies and how this has to be presented in the dossiers to pass the targeted compliance check.

Thus, ECHA identifies specific dossier issues (*e.g.* prioritised endpoints, PBT related properties, substance ID) that have immediate impact on chemical safety. For these criteria all submitted registration dossiers will be screened to identify insufficient dossiers. The specific endpoints in selected dossiers are then evaluated manually under a REACH compliance check. If non-compliant, the registrant receives a draft targeted compliance check decision (CCH) from ECHA. An opportunity for informal communication with the ECHA is not foreseen during the 30-day commenting period. ECHA will only take dossier updates into account during the 30-day commenting period. Afterwards the draft decision is forwarded to the member state competent authorities (MSCA). If the MSCA will make proposals for amendment of the dossier (*e.g.* test data required) the registrant has again 30 days for commenting. Otherwise, ECHA will send a final decision with a timeframe in which the dossier has to be updated with regard to the objected quality deficiencies (*e.g.* new test data).

Instead of informal communication with ECHA, a series of Webinars “How to bring your registration dossier in compliance with REACH” is offered. The scopes of these webinars were/are to provide information on focal points that are considered for targeted compliance check and how to address them adequately to avoid compliance check decision.

A dossier update is required in order to become compliant after a targeted compliant check decision. This may cause additional work for the dossier preparation, especially if the dossier was submitted in a former IUCLID version. Moreover, whether endpoint adaptations are objected, the registrant has a very tight timeframe of 30 days to improve these

adaptations in order to avoid a draft decision requesting testing. ECHA provided a new fact sheet “Follow up to dossier evaluation decisions” which explains and summarizes the process after a dossier evaluation decision by ECHA has taken place.

In conclusion ECHA indicates their future development for dossier evaluation. Besides the (complete) evaluation of single registration dossiers, the focus will be put more and more on targeted endpoints which will be screened IT-based in all registration dossiers. Thus, the likelihood of targeted compliance check decisions has increased and will rise with the improvement of the ECHA IT-tools. Due to the short and demanding time lines as well as the potential impact (additional testing requirements) SCC recommends to preparing registrations in compliance with the ECHA specifications as far as possible and to consider those aspects if an update of the dossier is planned in the near future anyhow due to new data (*e.g.* higher tier testing becoming available) to avoid non-compliant dossiers.



REGULATORY SCIENCE

Concerning Tox-Ecotox-Fate

Several issues on toxicology, ecotoxicology and fate with relevance for the submission of plant protection products are presented below. For more information, please contact Dr. Monika Hofer (monika.hofer@scc-gmbh.de).

BfR issues note to harmonize assessment of dermal absorption

The German Federal Institute for Risk Assessment (BfR) has issued an explanatory note¹ on the assessment of dermal absorption, published in

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German language in the Journal of Consumer Protection and Food Safety on 13 September 2013. The publication describes the approach currently taken by the BfR to derive the dermal absorption rates of active substances in plant protection or biocidal products.

The authors state that despite of the latest efforts to unify the testing and evaluation of dermal absorption, in particular the recently released guidance documents by EFSA² and OECD³, discrepancies frequently remain not only between applicants and authorities, but also among the assessing European Member States. They consider their contribution to be a first step towards the harmonization of assessment in the authorization processes of plant protection and biocidal products.

The following summary in this newsletter will not list matters that are more or less unanimously demanded, but will focus on those points that tend to unify inconsistencies or points that differ from existing demands.

Similarly, to the OECD³ guidance, studies are disapproved in case the mean mass balance is not between 90% and 110%. The BfR performs a normalisation in case of a mass balance between 90% and 95%.

In vitro studies are generally disapproved in case exposures exceed 24 hrs. In vitro tests on human split thickness skin are recommended, but the BfR accepts tests on human or rat epidermis as well. In accordance to EFSA², the use of eight evaluable samples from four donors is preferred. Studies using a minimum of three evaluable samples are accepted; a minimum number of donors is not specified. In case of the described limitations, the highest value measured instead of the arithmetic mean has to be used for further calculations. In vivo tests on rats are still acceptable on their own. Usually the highest group mean measured shall be used for further calculations.

The BfR will accept calculations that subtract the stratum corneum from the total amount absorbed for each dose group independently, using the criteria listed by EFSA² (75% absorbed within the first half of the study). In case of a “triple pack” calculation,

the total amount absorbed from human and rat skin must be calculated consistently within dose groups, but may still be calculated independently between dose groups. Flux data should not be used for triple pack calculations and are only accepted in justified exceptional cases.

If the intended spray dilution differs from the concentration tested experimentally, pro rata adjustments to calculate dermal absorption are not accepted. In case where the factor between field dilutions used and the dilution tested experimentally is less or equal two, the dermal absorption results may be conferred between them.

Where experimental data on dermal absorption are unavailable, a read-across between “similar” formulations containing the same active substance (one-to-one approach) or between chemically comparable active substances (many-to-one approach) may be submitted.

For the evaluation of “similarity”, the BfR accepts the EFSA² criteria for a one-to-one approach and the OECD³ criteria for a many-to-one approach. A one-to-one read-across between different formulation types of the same active substance, like for example a wettable powder and a suspension concentrate, is usually not possible.

SCC concludes: It is apparent that many of the recently developed regulatory specifications for the assessment of dermal absorption have obliterated the conclusions in established studies and are escalating the need for re-analysis of existing data as well as for new data.

Valid and GLP compliant product studies at appropriate concentrations are the preferred basis to derive the dermal absorption of active substances. However, experimental testing is still not mandatory when safe uses of a product can be demonstrated using the existing default values or a read-across approach.

References

¹ Niemann *et al.*, Die Vorgehensweise des Bundesinstitutes für Risikobewertung bei der Abschätzung der dermalen Absorption von Wirkstoffen in Pflanzenschutzmitteln und Biozidprodukten. J. Verbr. Lebensm. Published online: 13 Sep. 2013.

² EFSA (2012) Panel on plant protection products and their residues (PPR). Guidance on dermal absorption. EFSA J 10(4):2665–2695.

³ OECD (2011) Guidance notes on dermal absorption. Adopted 18 August 2011. OECD series on testing and assessment, No. 156. ENV/JM/MONO(2011)36, JT03305971.

8th SETAC Europe Special Science Symposium on pollinators

The new EFSA guidance on risk assessment of plant protection products on pollinators (bees, bumble bees, and solitary bees) was the focus at the eighth SETAC Europe Special Science Symposium held in October this year in Brussels. Especially the impact of the new guidance on the forthcoming registration processes was discussed between the experts from research, consultancy, industry, and government. In this context, several open points were addressed.

The new risk assessment follows a tiered approach divided into separate risk assessment schemes for honey bees, bumble bees and solitary bees. Thus, the new guidance document newly demands additional data on the toxicity to bumble bees and solitary bees, but for both groups of organisms no respective international accepted testing guidelines have been implemented so far, and for most of the PPPs no data are yet available. Therefore an assessment factor of 10 is proposed to extrapolate from honey bee endpoints to endpoints for bumble bees and solitary bees. Due to this very conservative assessment factor, a risk will be indicated for a vast number of PPP triggering higher tier studies (which partly are not further defined). Another very important alteration is that already at tier 1 step the risk assessment scheme for honey bees requires the histopathological investigation of the hypopharyngeal glands. At present there is barely experience in the CROs for conduction and interpretation of this endpoint.

From the regulatory point of view, it is unclear when this new EFSA guidance will apply, since it is not implemented yet. Thus, up to now, it is unclear how to deal with the new guideline within the AIR process and for national submissions starting 2014. A

workshop of the European Commission and Member States is planned for December 2013 to discuss open points, e.g. that the specific protection goals provided appear to be too conservative, that validated test guidelines for a majority of the required toxicity tests are still missing, or that there is a discrepancy between the data requirements given in the EU regulations EC283/2013 and EC 284/2013 and the new guidance document.

Taken together, the new EFSA guidance document, considers new risk assessment schemes, which cover a wide range of routes of exposure and toxicological endpoints to pollinators. However, due to highly conservative specific protection goals and thus based on highly conservative risk assessments, most substances refinements, and higher tier testing will be needed.

Draft EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values

EFSA has issued a draft Guidance Document (draft GD) 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 modelling purposes. The draft GD was issued in July 2013 with a commenting phase until September 2013. Detailed procedures for deriving DT50 values from “old” field dissipation studies, where the available information on field conditions may be limited, are given.

Furthermore, procedures for assessing the applicability as compared to laboratory data is given, being basically in line with the EFSA Scientific Opinion “Guidance for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil (EFSA Journal 2010;8(12):1936.

[67 pp.]. doi:10.2903/j.efsa.2010.1936.

Available online: www.efsa.europa.eu).

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The draft GD comprises an Excel sheet (Appendix E) that can be used for the assessment of applicability of the available field data. In Appendix A guidance on designing field studies are listed. Appendices B to D summarizes information EFSA's opinion regarding the use of Koc/Kom and crop interception values as well as substance processes on the crop surface. It may be expected that the information given in Appendices B to D will further increase the variability of modelling parameter selection between different European authorities.

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

- AS, a.s. = active substance(s)
- CIRCA = document management system used by EFSA
- DAR = Draft Assessment Report
- ECPA = European Crop Protection Agency
- EFSA = European Food Safety Authority
- IPM = Integrated Pest Management
- LoA = Letter of access
- MS = Member State(s)
- cMS = concerned Member State(s)
- MR = mutual recognition
- MRL = maximum residue level
- NAP = national action plan
- NGO = non-government organization
- PPP = plant protection product(s)
- RA = risk assessment
- SUD = sustainable use directive
- (z)RMS = (zonal) Rapporteur Member State(s)
- (d)RR = (draft) registration report

AgChem Forum, Barcelona

4-5 September 2013

A Review of selected Presentations

As a sponsor of this year's CIR 2013 Conference, which included the 13th annual AgChem Forum, SCC was a major participant, both at the exhibition and as presenter. Dr. Bernd Brielbeck, Senior Regulatory Manager Agrochemicals and Biopesticides informed as speaker about the feedback from industry on the implementation of Regulation (EC) 1107/2009. Two other colleagues, Dr. Norbert Weissmann, Senior Regulatory Manager Efficacy, and Dr. Bernd Holger Briese, Regulatory Science Manager Toxicology, were also present at the conference to respond customer requests and to meet customers' needs.

The following presentations provide you with information and insights made regarding the status of regulatory frameworks, proposed timelines and (new) data requirements.

In addition, relevant aspects on toxicology and ecotoxicology are provided as a survey below.

For more information, please contact Dr. Bernd Brielbeck (bernd.brielbeck@scc-gmbh.de) or Dr. Albrecht Heidemann (albrecht.heidemann@scc-gmbh.de).

STREAM 1:

REGULATORY FRAMEWORKS

1. Implementing sustainable Agricultural Practices to ensure global food security

Mark Davies

**Team Leader Pesticides Management,
FAO, Rome, IT**

Mark Davies presented elements of an approach which should allow adopting farming systems to the demands of the future (produce more on the same land): the save and grow program of FAO. This includes care for soil health, improved and adapted crops and varieties, better water management, sensible plant protection with new active substances and promotion of IPM and lastly policies and institutions which encourage smallholders to adopt sustainable crop protection. Further details are given at <http://www.fao.org/ag/save-and-grow/>.

The speaker emphasized that in improvement of yields is important due to increasing world demands and growth of world population.

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Thor Gunnar Kofoed
Chairman, Danish Seed Council,
Kopenhagen, DK

“It takes 10 minutes to explain the European PPP legislation but 2 hours to explain the Danish laws.” These laws put a very high pressure on Danish farmers and consequently the key role of knowledge transfer was also the emphasis of the presentation of Thor Gunnar Kofoed who cares for 600 ha of farmland. In order to keep yields on a high level under more and more stringent legislative pressure and facing a public which regards pesticides in general as poisons, several strategies have to be followed: IPM demo farms for general education of farmers, communication websites as source of inspiration and for IPM-toolbox development. There are 10 climatic areas in Denmark, and every climate needs to develop its solutions. The Danish agricultural knowledge center is dedicated to information exchange between farmers. The Danish laws and a very restrictive approval procedure for PPs have achieved a strong reduction of the treatment frequency indices which, however were without strong implications on yield. This could only be achieved by continuously optimizing many production factors. Some examples: 90% of the large tractors in DK have autopilots. The driver supervises of the computer which take care that fertilizer and pesticides are only applied where they are needed. In many farms the Nitrogen demand is known on a 100 sqm basis and thistles are sprayed selectively as tractors are often being equipped with 3 to 4 independent spraying systems with single nozzle stop-and-go technology. Tractor- and even drone-mounted optical diagnostic systems for fungal diseases are under development. Another important contribution will come from automatic mechanical weeding systems in row crops which work GPS- and optical sensor-based day and night at speeds up to 40 km/h. These robotic row cleaners work on dry soils with incorporation depths of ca. 2 cm and are therefore safe for earthworms. They are especially interesting for vegetables and may lead to the substitution of herbicides in certain crops. Apart from identifying the location of pests, drones will serve to determine the right dose rates. Most big agricultural equipment suppliers are working on these technologies.

Sylvain Lhermitte
Representative of French Agricultural
Brussels, BE

Since the mid 1990ies the yield of wheat production is stagnating. Innovation can happen if the interaction between farming practice and research is intensified. For this purpose a joint technology network has been established by the Burgundy chamber of agriculture which gathers 60 stakeholders from R&D, advisory services, training facilities, and many farm groups and which aims to develop new and improved cropping systems. This network is part of the European Innovation Partnership (EIP) “Agricultural Productivity and Sustainability” (see <http://ec.europa.eu/agriculture/eip/>). The EIP aims to provide a working interface between agriculture, bio-economy, science and others at EU, national and regional level. Good communication between all partners and innovation networks to create trust between stakeholders is key for the success of this ambitious program. The EIP is being supported by the Focus Group on knowledge transfer and innovation which was launched in June 2012 by the ENRD Coordination Committee (see http://enrd.ec.europa.eu/themes/research-and-innovation-gateway-development/kt-innovation/kt-focus-group/en/kt-focus-group_en.cfm).

Romano de Vito
Head of sustainable Agriculture & Stewardship,
Syngenta, Basel

Romano de Vito stressed the need for higher production efficacy in the near and far future, facing an expected growth of world population from 7 to 9 bn in 2050. Grain demand is expected to increase by 50% from 2011 to 2050. Innovations can reduce the volatility of crop prices which increased by 300% since 2002. Two thirds of the world surface will be stressed by climate change leading to a reduction of water and arable land. Solutions can be found in new business models, which link technology, people and land. Several Syngenta projects try to enhance the cornerstones of sustainable agriculture which are better solutions, resource efficacy and rural economies. Further details are given at: <http://www.syngenta.com/global/corporate/en/grow-more-from-less>

2. Latest Update on the Development of Guidance Documents and Future Changes to Pesticide Legislation

Darren Flynn
Health and Safety Executive,
CRD, UK

Good guidance supports harmonised processes and outcomes, provides consistency and predictability and increases the efficiency of processes. There are two main types of Guidance: procedural guidance as issued in general by the European Commission and risk assessment guidance as mainly issued by EFSA. Even though Guidance documents “do not intend to produce legally binding effects”, Regulations impose a legal obligation to apply guidance and there is only a limited scope for interpretation. Very confusing are the dates of applicability of Guidance documents which vary between regulations. Another obstacle are the long term studies which may already be superseded, if shortly before the date of submission a new Guidance document is being issued. The presenter regarded it as unfair, if rules are different for a second applicant of a plant protection product: rules should be fixed to the active substance approval, thus staying the same for the authorizations of all Plant Protection Products in that period.

Darren Flynn's propositions:

1. Have clearer and better-documented guidance development processes. The process should be more transparent for stakeholders and draft Guidance Documents to be easier accessible for discussion and commenting. He encouraged stakeholders to participate in the relevant consultations and explained that key information would be provided after subscription to “Public consultations” on the EFSA website.

2. The potential impact of new guidance should be systematically assessed in the development process as the work involved in the new Guidance Document requirement may result in the need for significant additional resources from both sides: applicants and evaluators, without providing more information/safety. It therefore has to be ensured that new initiatives are proportionate and potential costs and benefits are systematically considered by MS (COM & EFSA) at the onset.

3. Information on existing guidance and on new initiatives is difficult to access as they are not

displayed on a specific website. However, there are improvements ongoing on Commission level. Commission Communications (<http://ec.europa.eu>) publishes test methods and guidance for a.s.s and PPPs and refer to further websites which provide guidance. Technical and procedural guidance can be found on the Commission website (<http://ec.europa.eu>). The listings provided on the EFSA website (<http://www.efsa.europa.eu>) still can be improved, by e.g. following the design of the guideline-overview on the European medicines agency website (<http://www.ema.europa.eu/ema/>).

4. After implementation there should be a mechanism for training in use, feedback and review, which could include web feedback forms.

Discussion: EFSA and Commission have seen that there are problems: even MS do not know exactly which guidance they should apply. There will be a workshop in October. CRD thoughts are shared by many MS but EFSA is reluctant to consult stakeholders due to their wish to be completely independent.

3. New data requirements Industry perspective – Practical Experience and Challenges in Implementation

Jane West
European Regulatory Lead,
ECPA Regulatory Policy Team
Syngenta Crop Protection, CH

The old data requirements (CR EU 544/2011 for AS and 545/2011 for PPP) include both chemical substances and micro-organisms. The data requirements for chemical substances have been reviewed and the new data requirements been published on 3 April 2013 (CR EU 283/2013 for AS and 284/2013 for PPP). The annexes of the two latter Regulations in which the data requirements are being listed, can be easily updated as new test guidelines and guidance documents are finalized. There is a revised structure in the annexes with some new locations for “old” information and data and new annex points for new data requirements.

SANCO 10181/2013, which will be regularly updated, gives a good overview of the changes. The new rules apply from 23 April 2013 for procedures

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concerning the renewal of approval of active substances whose approvals expire on 1 January 2016 or later (AIR-3) and from 1 January 2014 for all other procedures. A COM guidance document on the interpretation of the transitional measures, which will allow applicants to comply, is in preparation.

For AS procedures, 1 January 2014 is the key date:

Type of submission	Data Requirements (DR)
'AIR-2'	Submitted in 2012 – Old AS and PPP data requirements applied
Renewal under 1107/2009 (Reg 844/2012) 'AIR-3'	New AS and PPP DR apply
New AS	Submit before 1 Jan 2014 – Old AS and PPP DR apply Submit after 1 Jan 2014 – New AS and PPP DR apply
Amend AS approval conditions	Submit before 1 Jan 2014 – Old AS and PPP DR apply Submit after 1 Jan 2014 – New AS and PPP DR apply

For PPP procedures, 1 January 2016 is the key date:

Type of submission	Data Requirements (DR)
'AIR-2' Product Renewal	Submit before 1 Jan 2016 – Old AS and PPP DR apply Submit after 1 Jan 2016 – New AS and PPP DR apply <i>NB Applicant can choose to submit New AS and PPP DR from 1 Jan 2014 but this is an irrevocable choice (required to put it in writing with the application)</i> <i>NB – This reflects COM interpretation named in draft Guidance Document</i>
'AIR-3' Product Renewal	New AS and PPP DR apply to 'AIR-3' AS; N.B. if PPP is a mixture with another AS scheduled for later review then existing data for that AS are sufficient

The question is which data requirements should apply for PPPs with AIR-2 AS, if the timeline of 1 September 2015 for AS renewal will be extended? In particular for mixture products clarification is needed, or in case of use extension applications for PPPs, where the main submission had been done before the deadline.

Type of submission	Data Requirements (DR)
New AS Product Renewal	Submit before 1 Jan 2016 (and where new AS application was submitted before 1 Jan 2014) – Old AS and PPP DR apply Submit before 1 Jan 2016 (and where new AS application was submitted after 1 Jan 2014) – New AS and PPP DR apply Submit after 1 Jan 2016 (irrespective of whether AS was submitted before/after 1 Jan 2014) – New AS and PPP DR apply <i>NB Applicant can choose to submit New AS and PPP DR from 1 Jan 2014 but this is an irrevocable choice (required to put it in writing with the application)</i> <i>NB – This reflects COM interpretation named in draft Guidance Document</i>

Type of submission	Data Requirements (DR)
New PPE Use Extension	Submit before 1 Jan 2016 – Old AS and PPP DR apply Submit after 1 Jan 2016 – New AS and PPP DR apply – including new AS data not yet required or assessed for the AS in the structured renewal programme! <i>NB Applicant can choose to submit New AS and PPP DR from 1 Jan 2014 but this is an irrevocable choice (required to put it in writing with the application)</i> <i>NB – This reflects COM interpretation named in draft Guidance Document</i>

Special cases:

Type of submission	Data Requirements (DR)
Confirmatory information	Confirmatory information should be to the same DR as the original submission for the AS unless specified otherwise
MRL submission in accordance with Regulation (EC) No 396/2005	Submit before 1 Jan 2016 – Old AS and PPP DR apply Submit after 1 Jan 2016 – New AS and PPP DR apply
Import tolerances	Submit before 1 Jan 2014 – Old AS and PPP DR apply Submit after 1 Jan 2014 – New AS and PPP DR apply

Whereas SANCO/10181/2013 provides guidance for applicants how to comply in their dossiers with the new data requirements, the template to be used for writing the assessment reports is laid down in SANCO/12592/2012 which should be used in conjunction with SANCO/11114/2012. SANCO/10181/2013 applies to dossiers for new AS submitted as of 1 January 2014 and AIR-3 renewal of AS approvals according to CR 844/2012; it does not apply to applicant dossiers for national authorizations and re-authorizations of products (dRRs). SANCO/10181/2013 includes, besides listings of new terminology (MII =>MCA, MIII=>MCP) and new documents (N3 = structures, N4 = GW non-relevance and N5 = isomers) also templates for summary documents and a cross-walk to OECD and Caddy TOC (table of content).

There are a number of practical challenges. For some new data requirements there is lack of test methodology, guidance and also of time to deliver long-term studies (e.g. for AIR-3). However, SANCO/10181/2013 confirms that waiving of data requirements without test methodology or GD is considered acceptable and that, if justified, it may be considered acceptable to deliver the final reports of long term studies after dossier submission. Currently there is no similar guidance for PPPs, even though similar waivers are required for PPP re-authorizations and new PPP applications.

In 2014 and 2015 the applicant has the irrevocable choice to apply the old or new data requirements for PPP applications. The Post Approval Issues group has given informal feedback that the choice applies to the entire dossier and not to individual sections or data points. The new dRR format is still under development by the dRR Member State Working Group. It is still unclear when it will be available and if there is a transition period for implementation; it is envisioned to be mandatory from 1 January 2016.

Even though after 1 January 2016 new data requirements will apply to PPPs, some PPPs will contain AS evaluated to old data requirements. This applies to

- AIR-2 product renewal if not submitted before end of 2015,
- AIR-3 product renewal – mixture products with AIR-1,3, NAS

- New AS product renewal – if not submitted before end 2015, mixtures
- New formulated products or use extensions – solo and mixtures.

If new data become available, they should not be evaluated outside the EU review process.

For all these points guidance is required, both for applicants and evaluators.

In conclusion, even though basic parts of the puzzle are now available a number of challenges remain:

- PPPs compliance with new data requirements where there is no test methodology or guidance or insufficient time to finalise long term studies
- Dossier format for dRRs not yet available
- Unclear how to manage AS data in the context of PPP submissions.

Therefore it is critical that applicants and regulators continue to work together to ensure that new data requirements are implemented in a pragmatic approach effectively and consistently.

4. Experiences and Difficulties in the New Authorization System

Gábor Tökés

Deputy Director,

Nébih, National Food Chain Safety Office,

Directorate for Plant Protection,

Soil Conservation and Agri Environment, HU

Some interesting comments were provided from the key country of the South-Eastern EPPO zone, Hungary. Especially in the area of efficacy there is need for improvements. Sometimes the number of efficacy trials conducted in the South-Eastern EPPO zone is not sufficient. For new active substances 6 to 15 trials are being required per EPPO zone or 20 to 30 trials for the complete central zone. Rapporteur member states from the maritime EPPO zone often do not evaluate the South-Eastern efficacy trials presented by the applicant. This puts evaluators in the cMS under high pressure as they have only 120 days for their evaluation.

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The clock starts for cMS when evaluation and copy of authorization in zRMS arrived at cMS, not at time of upload of the Registration Report on CIRCA.

cMS may grant authorization despite non-registration in the zRMS in case of lacking efficacy data or non-acceptance of models which apply to the zRMS, only. Misuse of MR application according to Art. 40 in order to avoid the zonal system can be a risky approach.

Germany is the only country which still completely refuses MR after product authorizations according to 91/414.

In general the national requirements are decreasing with the exception of efficacy and fate due to non-comparability of agro-ecological conditions.

A refusal of an authorization due to lack of efficacy data is possible, as according to Art. 29 of 1107/2009 efficacy is an essential part of the evaluation.

Remarks

- Re-registration of PPS: Step 4 not manageable acc to Art. 43: Processes have to be discussed esp. If several AS in one product.
- Data requirements for generics are unclear.
- New Step 2 can lead to the collapse of the system
- Lack of staff in several authorities is a big obstacle
- Fees are often not linked to staff but serve to feed the general country budget.

5. Feedback from Industry on the Implementation of Regulation (EC) 1107/2009

Bernd Brielbeck
Senior Regulatory Manager,
Agrochemicals and Biopesticides,
SCC Scientific Consulting Company, DE

The presentation gave an overview over the existing legislation, as well as on the experiences that have been made in the implementation of this legislation.

The speaker gave an overview over the timeframe and the milestones of the Annex I approval and re-approval procedure according to Regulation 1107/2009 and the implementing Regulation 844/2012. As well as the timeframes laid out in the SANCO/13169/2010 revision 7 laid down the zonal

approach of the authorization and the re-authorization of plant protection products. The zonal procedure was intended as a work-sharing procedure to avoid duplication of work. This can be achieved by standardization of the core assessment allowing the acceptance of the assessment within the whole zone. Furthermore a risk envelope approach in the core assessment is mandatory as well as a harmonization of formulations and GAPs across the zone. In the broad experience contrary to the ideals of zonal approach there have been new national requirements implemented, such as individual reference lists or documents O. In one case within the Member States of the EU there is now the requirement to submit a full dossier as well as all individual study reports in the respective national language. Furthermore in other Member States there is not only the need for authorization of product but after finalization of this procedure as described in Regulation 2007/2009, an application for label approval, taking one month in addition, is required. Regulation 1107/2009 stipulates that duplication of testing should be avoided. The idea to implement this request is providing a list of test and study reports as well as registration reports to the prospective applicant. In both cases this has been differently implemented by the individual Member States, in some Member States the documents are available in English language on their home page; other Member States expect a specific request and payment to compile the information whereas in some Member States the information is not available at all. Even the rules of examination and the procedures are not harmonized. Some Member States are now refusing to give any indication as to when the application can expect the finalization of their authorization. Confusion with respect to the organization of the zonal authorization procedure arises from the fact that some Member States considered it sufficient if the zonal Rapporteur Member State provides the assessment on the CIRCA network. Other Member States explicitly request the notifier / applicant to submit an application / information when they should start their work as concerned Member States. This even lead to the fact that concerned Member States refused to act as such and implement an authorization because they were not informed of the termination of the zonal Rapporteur Member States assessment within a 30 day period.

With respect to the efficacy planning of studies it is important not only to address the three political zones as detailed in Regulation 1107/2009, but more importantly to cover all relevant EPPO Zones. Spreading efficacy trials across the EPPO Zones is important to be able to cover the political zones within one application.

With respect to data protection a brief mention was made of the draft guidance document as SANCO/12576/2012 - revision 1.1. One point which was raised and which seems still to be unclear with respect to data protection is the fact that the period awarded to proprietary studies starts with the first authorization in a Member State. If a re-approval on an approval of an active substance is granted, Regulation 1107/2009 stipulates that the latest one year later a re-authorization of the product is to be issued by the Member States. The speaker raised the questions how and whether it might be possible to intrude into the data protection period within this one year during which no formal data protection is awarded to a given study.

With respect to the new data requirements only brief excursions were made with respect to the applicability of these new data requirements. For actives the general rule is as follows:

- For active substances the switch will be made between 2013 and 2014
- For plant protection products the switch will be made between 2015 and 2016

Details of the transitional measures for Plant Protection Products were given. There are some very special cases for example MRL submissions, being related to a product authorization, where the new data requirements are obligatory starting on the 01.01.2016. With respect to import tolerances, however, being related to active substance issues, the new data requirements will be obligatory starting on 01.01.2014.

A key issue here is who should review new active substance data that are required to be submitted with a product authorization, if the new data requirements apply.

6. Update on the Development of Regulatory Framework for Comparative Assessment and Candidates for Substitution

Maarten Trybou

**Head of Service Pesticides and Fertilizers,
Federal Public Service for Public Health,
Food Chain Security and Environment, BE**

The criteria for Comparative Assessment (CA) are laid down in EPPO standard PP1/271(1) as approved in September 2011 and in a draft Guidance Document which is still under development (Swedish proposal November 2011).

The efficacy issues are dealt with in the EPPO Standard on a use level. It is important to note that for resistance reasons 2 to 4 different MOAs (modes of action) should be kept available for all uses and that at least one major use should also be kept as a restriction to minor uses may lead to the complete withdrawal of an active substance by the registration holder.

The Draft Guidance document is complementary to the EPPO standard and focuses on health and environment issues. It discriminates between mandatory (Step 1) and optional (Step 2) CA. Step 1 is obligatory for every single authorization, e.g. WPs must not be registered if a comparable WG is available. Step 2 is optional and consists of 4 steps.

CA is still a very difficult issue as it is a purely national task and guidance is still very vague. However, a commission note with instructions is currently discussed in the Standing Committee.

A list of candidates for substitution will be published 14 December, including an implementation date. CA is obligatory following that date. An ad hoc scientific study report has been presented by an EU consultant in June and comments by the MS are expected by 6 September 2013. In the report all 422 AS evaluated in EU before February 2013 have been checked against the 7 conditions for CA. Data have not been interpreted as only agreed endpoints have been used. There is full transparency of assessment for each AS and for each condition. Raw data are traceable in the document via source & links.

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- Condition 1 (significantly lower ADI, ARfD or AOEL): A group has been defined as functional group, i.e. fungicides, insecticides. To assess as there are a number of options to define the term “significantly lower”: percentiles, standard deviation etc. It also is difficult to fix values as there is a constant evolution of thresholds values. Therefore the statistical thresholds may need to be converted into absolute values. The report uses the 5th percentile as threshold, if 20 a.s. were in a group. This led to 22 a.s. being included on the list.
- 81 substances qualify for the list according Condition 2 (2 PBT criteria fulfilled)
- The definition of Condition 3 (critical effects) is too vague and no substances qualify for the list.
- For condition 4 (non-active isomers) 71 substances which were identified by name search only to contain isomers, might be on the list of candidates for substitution. But only 2 of these are currently registered as single enantiomers: Mecoprop and Metalaxyl.
- Condition 5 (carcinogen category 1 A or 1B): 0 substances
- Condition 6 (toxic for reproduction Category 1A or 1B): 9 substances
- Condition 7 (endocrine disruption in humans): 7 substances (based on interim criteria only)

According to this study, 102 out of 422 substances qualify for CA.

7. Improving the Efficiency of the Regulatory Process using the Phased Submission Process for New Active Substance Applications

John Dale
CRD, UK

The presentation is given in 2 parts, first John Dale of CRD presents the authorities point of view and subsequently Stefano Turati of DAS, the industry's perspective of the pilot project.

The phased submission as published by CRD in Regulatory update 02/2013 on 16 January 2013 is a

new UK national procedure for NAS which tries to bypass the lack of provisional approvals which had been possible under 91/414 but are no longer available under 1107/2009. The key issue is to save evaluation time through pre-application study evaluations of those final reports, which are available ahead of the planned submission at a time when longer-term and higher tier studies are still ongoing. The work of CRD before submission is limited to study evaluation and endpoint determination. It does not involve risk assessments. Nevertheless, phased submissions provide a greater degree of endpoint certainty ahead of formal application and therefore also possibly reduce the need for re-modelling. They allow an early identification of areas needing further work, reduce post-application issues and should lead to improved dossier and DAR quality.

Phased submission is ideally a two shot process which has to be discussed with and agreed by CRD on acceptability. Background and proposed timelines will be emailed by applicant to CRD. CRD considers the size of evaluation and timings of pre and final application. Pre-submission meeting is the likely next step.

Applicant is expected to provide a partial OECD dossier with available studies accompanied by Tier II summaries, a reference list and the endpoints completed as far as possible and an indication of what is outstanding incl. timelines.

Phase 1 output of CRD are study evaluations in draft DAR format, annotated with comments/requests for clarifications and/or areas needing more work. There is a possibility for exchanges or clarification during the evaluation. The applicants response is expected to be made in the final dossier. However, areas may be identified for a pre-submission meeting.

There are no fixed fees for this procedure, however due to more communication requirements; costs will be higher than single core evaluation fee.

The lessons learned in the still ongoing pilot project:

- Communication and coordination are especially important,
- Allows bigger window to address issues (especially important!)
- endpoints may change on submission of second phase

- need metabolism/residue definition data to make residue data worth evaluating
- DAR of pilot project not in Peer review yet, therefore it is still too early to see whether there will be quality related benefits
- Regulatory update 02/2013 can be found on the CRD homepage.

A pilot project experience with the “phased submission” process for new active substance Halauxifen-methyl (DE-729)

Stefano Turati
Regulatory Science & Governmental Affairs, European Regulatory Team Leader,
Dow AgroSciences, IT

The phased submission focus is on “what” and “how” can be done before the formal process starts. It aims at reducing the delays in the first stages of the evaluation process. Generally, the submission timeline is driven by the long term studies but > 50% of the studies are available from 1 to 1.5 years before submission. 60% of the authorities time is devoted to evaluation of studies as such (quality, acceptability, summaries), determination of endpoints and DAR formatting. 40% of the time is devoted to preparation of risk assessments, incorporation of long term and higher tier studies and to the final review of the DAR.

The phased submission should take place 1 year before official application, provided

- RMS and notifier resources are available and both are able to respect timelines and to react to additional workload
- Critical mass of studies per section are available
- Final reports available (i.e. no draft reports)

In the pilot project

- DAS made the “phased submission in August 2011 when 75% of studies were available
- In May 2012 CRD provided the evaluation output in DAR format
- In September 2012 the full submission was made in the official EU process
- DAR preparation started by CRD in November 2012

8. Global Development and Registration of New Active Substances

Gary Dean
Expert Consultant Group Manager,
Crop Protection & Chemicals,
LSR Associates Ltd, UK

Dealing with global development and registration of NASs one has first to outline the two fundamentally different approaches of hazard based (EU and Brazil) and risk based (US and Japan) assessments. The consequences have been estimated in a recent Croplife America report (Brenner, 2013) on the impact of EU hazard based regulation on agri-food exports from USA to EU. Considering 24 AS with US MRLs are likely to be subject to prohibition (endocrine disruption) approx 4 bn USD exports will be prevented from entering the EU which is ca. 25% of total exports in 2012.

In most countries, a number of institutions are involved in PPP regulation, complexity leading to timelines from 18 to 24 months (US) to 3 to 6 years (JP, Brazil) and EU in the middle with 26-36 months, from first application to registration of a PPP containing a new AS. Global harmonisation has been improved by

- harmonisation of data requirements for a set of key endpoints
- submission of a single formatted dossier containing all key studies acceptable to all national authorities (OECD dossier format)
- a standard review format used by all authorities (templates for study reviews and OECD format of the monograph).

Nevertheless, for real harmonisation there is still a long way to go. Benefits and barriers to the process have been summarised by the speaker. It is promising that generally the same scientific conclusions are made, so consistency and trust is increasing, but there is still only a little number of national authorities and companies involved in global applications. Pilot projects are slow and not yet really global. The first trilateral (Australia, Canada, USA) joint review was completed in 2007 and in total six reviews have been completed to date with Australia, Ireland, New Zealand, UK, USA and Canada participating. A new review is planned involving the US, Canada, Japan and the EU.

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Lessons learnt from pilot phase: planning and intensive communication with carefully selected countries should start at least 2 years before submission. The GAP should be harmonised and number of formulations minimized whereas crop groupings should be maximized.

HOWEVER, there is a reluctance to submit in Europe for several reasons:

- hazard based cut-offs
- potential for becoming a candidate for substitution
- classification and labelling issues and
- uncertainty about emerging guidance

An example of a potential new insecticide was provided. The AS consisted of isomers with high soil persistence (>180 d) and chronic toxicity to daphnia (<0.01 mg/L). Obstacles for developing such a substance in Europe were discussed in detail. However, the speaker proposed not to avoid registering the product also in the EU and concluded that Europe needs to find a way to accommodate Global Joint Review.

9. Products Renewal – Article 43 of Regulation (EC) No 1107/2009

Rebecca Reboul
Regulatory Affairs,
Institute for Plant Protection Products,
Austrian Agency for Health
and Food Safety, AT

The timelines for authorization renewal as laid down in Article 43 of Commission Regulation 1107/2009 pose a big challenge to all parties involved. It is unclear what the applicant should submit according to Art 43(2) within the 3 month timeframe after renewal of the approval of an active substance. A further burden are the new data to be submitted for PPP according to regulation EC 283/2013 (i.e. for the AS!) and the high number of PPP applications to be processed by MS (within 6 months) and cMS (within 3 months).

Authorities propose early pre-submission meetings and communication by e-mail in order to insure that dRRs are of high quality. However some dossiers will

not be complete due to lack of time to comply with new data requirements. Experts of COM, MS and Industry developed the idea that applications could be made with reasoned cases that certain data (name each data point) will be post-submitted within 2 years. It is also under discussion

- if it should be permitted to post-submit the whole dossier or only parts thereof
- and when the data protection period of 30 months after re-registration approval will start.

In case of a significant formulation change the PPP does not fall under Art. 43.

For treatment of mixture products there are three options:

1. Evaluation after each renewal of an AS (as required by 1107/2009)
2. Evaluation only after last AS has been approved (as was customary under 91/414)
3. detailed evaluation after 1st AS and “light touch” after next AS approved

Compromise: if AS approvals are less than 2 years apart option 2 applies.

10. Practical Strategies for Product Renewal under Article 43 - Industry Feedback

Andreas Horn
Team Leader European Regulatory Affairs,
BASF, DE

Renewal of approval of an AS is very often associated with new data requirements, e.g. triggered by lower AOEL, new residue definition, or revised relevance assessment for metabolites. Therefore, there is a need to consider a process to submit data after the 3-month deadline set for the application of product re-authorization in justified cases.

ECPA proposes a 2 step process.

- Submission 1: within 3 months after approval submit all available information (as required by 1107/2009)
- Submission 2: latest 2 years after approval submit full data set and dossier

Submission 1 should contain:

- Copy of the authorization □ Art. 43.2(a)

- List of authorizations to support
- List of new information required
- New studies already available
- Dossier with updated content where possible + justification where not possible
- Timetable for on-going studies with protocols and risk assessment with justification Art. 43.2(b)-(d)
- Monitoring data if required Art. 43.2(e)
- Claims for data protection and data confidentiality Art. 59, Art. 63
- Stepwise approach allows to comply with requirements from 1107/2009 and approval conditions from AS renewal

The EFSA proposal takes into account that impact analysis for the PPPs involved can only start when the endpoints are available: at the date of the EFSA conclusion which is ca. 9 months before formal AS renewal.

In the simplest case (PPP with one AS) the sequence of actions would be as follows:

- 9 months: EFSA conclusion on AS, start of impact assessment for PPP
- 0 months: AS renewal
- 3 months: Submission 1 for PPP
- 9 months: Compliance decision of zRMS
- 12 months: Compliance decision by cMS
- 24 months: Submission 2 for PPP
- 33 months: final decision zRMS
- 36 months: final decision cMS

An update of SANCO 72010/13170 is being proposed to clarify the triggers for the second submission and for rules concerning the deadline for submission 2 (standard time interval or case by case?). A zonal secretariat could help to monitor the processes. It also has to be clarified if there will be a stepwise evaluation or one full evaluation after the completion of the data package, which would be more effective for authorities.

For mixture products, two guiding principles are being proposed:

- 1.) full review only once, after dossier submission driven by the last AS renewal.

- 2.) If renewals of AS are close together (timeframe to be determined): combine submissions

ECPA proposes that data protection period of 30 months should start 12 months after AS renewal for available data and 36 months after AS renewal for the post-submitted data, i.e. the date of decision on the respective data package.

In the following discussion one MS representative (Tokes, HU) proposed to change 1107 due to the unrealistic article 43.

11. Member State Feedback on Zonal Submissions – The Netherlands: Feedback from the Central Zone

Annette Smits
Ctgb, NL

The Central Zone is currently evaluating approximately 270 applications for authorization of new plant protection products. 200 more applications are currently already planned and a total of 30 applications have been finished. The Central Zone “system”, which is comprised only of an excel data sheet into which Member States enter their information, does not provide any information on the number of amendments that have been processed. With respect to the voluntary work-sharing system, approximately 400 evaluations are ongoing in the Central Zone and approximately 60 have been finalized. The Netherlands will no longer except to act under the voluntary work sharing system (no more ‘national dossiers’ as they do not fit into the ctgb-scheme). For 12 new product applications currently work-sharing (of zone independent work) is ongoing. The ongoing evaluations of interzonal applications are approximately 30, with an additional 35 envisioned and nine evaluations (variations of one product) finished.

With respect to the Netherlands there are currently 20 evaluations on new products ongoing, two where finished, three withdrawn and 15 are planned to be commented in 2013 or early 2014. Four amendments of evaluations are ongoing. In 60 cases the Netherlands is involved as concerned Member States, and participates in 11 cases in work-sharing. The

Netherlands have room for 30 new applications in 2014.

The problems with the current system have been identified to be within the complexity of the system, missing guidance as not all articles are well understood, the available resources at the evaluating authorities, as well as the quality of the dRRs submitted, which are often incomplete or incorrect. The complexity of the process is due to the missing of detailed Regulation on basic and low risk substances and the use of new data. Furthermore, the co-existence of transitional laws add to the complexity. Finally there is a significant increase of information that needs to be handled, such as the new guidance document on birds and mammals which require additional information to be evaluated. With respect to the availability of resources to do the evaluation, the CTGB had internal rulings that they could not hire new people for some time. Having overcome this they have now hired 30 to 40 new people within two years. The total staff is now at 120 people.

To overcome and solve the problems Commission and EFSA should provide new Guidance Documents on the scientific as well as procedural issues. Furthermore, a new EU database should replace the excel sheet. In addition more emphasis should be placed on the (inter) zonal steering committees.

The applicant can participate in solving the problems by providing early communication, one year before the intended submission of the dossier, and consultation with the Member State.

The Netherlands would appreciate to have pre-submission meetings on the basis on an existing dossier. Furthermore a delay in submission or cancelation of submission should also be notified to the authorities. The Netherlands would propose that all uses should be dealt within the core dossier of the dRR, even if an application (such as flower bulbs) is for the Netherlands only. In the dRR reference should never be made to any preview national evaluations but the strategy of the application should be well explained in the dossier.

The Member States apart from other issues can help solving the problem at hand by using reasonable worst cases instead of piling worst cases onto each other in their evaluations.

Finally it was emphasized that the magic word in overcoming all the problems at hand is further harmonization. Authorities should try to (better) understand the work of the other organizations.

12. Member State Feedback on Zonal Submissions: Feedback from the Central Zone

Pavel Minár

**Head of Plant Protection Products Section,
State Phytosanitary Administration, CZ**

Facing the demands of a self-complicating system, the speaker reminded of the goals of the zonal systems: the reduction of costs and workload, a better distribution of the work, speeding up the procedures and the aim to achieve similar conditions for farmers across the zone. He does not necessarily see the idea of harmonization and putting together all the national requirements, but attempts to achieve communally accepted individual requirements.

The quality of the dRRs received is described in the following part. The efficacy part is currently very often inconsistent, acknowledging that the trials presented are not sufficiently spread across the EPPO Zones. In particular in the Central Zone 70 % from the trials come from the maritime EPPO Zone. Often Poland and the South-East EPPO Zone are not supported in a balanced way. Furthermore different application rates are sometimes applied for without a clear scientific justification and major crops (which may be minor in other countries) are not backed by sufficient data. Often the national labels are not corresponding to the applications scope applied for in the dRR. These inconsistencies can be seen with submissions of even the same companies and even if they have been discussed before in a pre-submission meeting, which leads to the conclusion that communication within the applicant company needs to be improved too.

The most common mistakes by the Member States are that they might apply national requirements to the core assessment. Also very often there are different opinions on evaluation within the same Member State, if there are different individual evaluating authorities. Comments of cMS are put on CIRCA but

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there is no procedure how discrepancies should be solved. Therefore comments are often repeated, but with no consequences.

What has already been seen in saving workload and capacity is that there are less individual formulations being applied for registration now, there is no more duplication of assessments, the dRR is being written by the applicant, and obligatory mutual recognition is of definite benefit.

It is of importance to also harmonize the risk mitigation measures across the zone. First activities to this effect have already been started in the Central Zone. This is particularly important when a data GAP is identified but can be considered to be acceptable, as the risk can be mitigated by special measures. The Authorities in their evaluation should focus on effectiveness and priorities and stick to deadlines. Deadlines as set by the procedure should be put on a priority list. The commenting between the Member States should be limited to crucial issues (no formal points to be addressed). The speaker emphasized that in some Member State it is necessary to restructure and particularly to simplify the national authorization system. For instances CZ has two authorities which is already considered to be too much. On remedy to the current delays and confusions could be a central secretarial support and a central help desk to channel requests and questions from the applicants. In general more trust should be put into the new system the harmonization process should be quickened and more focus should be set on the effectiveness of the evaluation. Clear targets should be set for experts, the information exchange be improved, the proofers be monitored and controlled and the capacities in the system be coordinated and re-allocated if needed.

13. Feedback from The Southern Zone – Point of view from ANSES

Thierry Mercier
Deputy Director, Regulated
Products Department,
ANSES, FR

In the Southern Zone more than 100 registration reports have been finalized on the basis of a voluntary work-sharing assessment. Several are currently still ongoing and the Southern Zone is now starting with

the Plant Protection Product evaluation after AIR 1 active substance inclusion. With respect to new applications and labelling extension 195 registration reports are currently under evaluation and more than 250 are planned for submission. To accommodate this massive workload, the Southern Zone has regular conference calls (every two months) as well as face to face meetings once a year. For applications it is important to notify as soon as possible their intention of submission to the zonal Rapporteur Member State, so the workload can be planned and checked against capacities. The zonal Rapporteur Member State will then propose a date for submission. Currently no applications in the Southern Member States are possible prior to 2015. The speaker emphasized that it is also important for the applicant to inform the zonal Rapporteur Member State as well as the concerned Member States when a submission is postponed or withdrawn.

In the Southern Zone the national data requirements are limited and dedicated to specific crops/situations or higher tier risk assessments. It was conceded that risk mitigation measures are not fully harmonised yet. However there is a working group of Commission and SETAC on ecotoxicology to better harmonise the risk mitigation measures and to gain efficiency in work-sharing. A new guidance document for applications in the SEZ is expected to be published soon on the Commission website.

To facilitate work the dRR must be a standalone document and individual dRRs are to be submitted for each product. If for the same product indoor and outdoor uses are envisioned, two distinct dRRs (one zonal and one inter-zonal) should be submitted. The limited information provided in generic applications are in general insufficient.

When relevant, all residue trials (North and South) must be included and assessed in the core dossier. The national addenda must be justified, limited, and dedicated to specific tools or requirements, such as specific crops or higher tier risk assessments (groundwater), which are requested to be put into the French national addendum. Explanations are given on the French website.

Currently a revision of the dRR format is ongoing. The intention of this revision is to minimize the

duplication of work for Member States and industry and to find a good compromise between too detailed dRRs and dRRs with references to other evaluations.

The southern Member States have observed an increase of workload of 20-40 % per dossier if comparing the evaluation under 91/414 with the zonal evaluation under 1107/2009. This is a consequence of the dRR format and the commenting period. To increase the zonal evaluation system and make it more sustainable, an EU data base of applications and authorizations is envisioned. Furthermore, a permanent coordination secretariat, which should facilitate work-sharing and avoid duplication of work between the zones is being explored.

14. Member State Feedback on Zonal Submissions: Feedback from the Southern Zone

**Miriam Cavaco,
DGAV/DSMDS, PT**

Due to the very high number of Pests and the favorable climatic condition for them there is high demand of pesticides to protect crop production in the Southern Zone. Consequently a high number of new authorizations (550) plus a none-specified number of mutual recognitions, re-registrations, and authorizations of minor uses have been issued. At the same time the economic situation in some Member States is very serious and a constrained for effective work. In the Portuguese authorities for example the number of staff has been reduced from 100 to 40 and is expected to be reduced further to 30 in 2015.

2014 will be a particularly challenging year for the capacities of the Authorities, as first decisions for active substances under Regulation 1107/2009, the start of the comparative assessment, conclusion of the definition of Endocrine Disruptors and the first use of article 43 (renewal of authorization) are expected.

The speaker emphasised again that the registration report is to be designed as a standalone document. It was confirmed, that it is currently difficult to find a zonal Rapporteur Member State in the Southern Zone. As to the registration reports some deficiencies were absorbed in the use of the GAP. It does not represent in some cases the uses across the zone, it is

not the same in all parts of the dRR and sometimes the GAP used in the dRR conflicts with the GAP of the national uses. Of particular concern was the use and presentation of the efficacy data. Trials should cover the entire crop production area in the zone, but justifiable extrapolation is possible.

With respect to an MRL dossier, it was stated that reference to such an additional dossier is not sufficient, as the dRR is expected to be a stand alone document. Also the importance of obtaining valid MRLs was emphasised, as no use can be granted without such an MRL in place.

With respect to national, country specific data requirements the southern Member States know rely mostly on the EU data requirements. The particular national requirements are limited to specific crops or situations. There is a southern Zone guidance document available describing these particular situations. And applicants are advised to follow those requirements as described there in.

To improve the evaluation in zonal and interzonal submissions, industry is expected to time their submissions such as to facilitate work-sharing by all involved parties. From the side of the Member States it is expected that all information received on applications is also to be shared.

DGAV (the national Portuguese Authorities) is currently re-organizing its competent Authorities. They have updated their national procedures manual as well as their application forms. Both are available at the homepage www.dgav.pt, although currently only in Portuguese language. They are also working up their backlog of authorizations that have been pending.

15. Feedback from Industry on Experiences of Zonal Submissions in the Southern Zone

**Michael J. Carroll
Global Registration Manager,
Dow AgroSciences, UK**

This presentation with an excursion into Greek mythology the speaker linked the current situation in regulatory affairs to the Gordian Knot and wondered whether a new Alexander is needed to cut it apart.

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The regulator in the companies he sees as sitting on the throne of Damocles with his famous sword overhead.

He reported from experiences from submission to the southern zone, which mainly covers France as zRMs, as France is the major market in the southern zone. He stressed the importance of finding out the correct endpoints at an early stage, as during the evaluation any change might have significant consequences for subsequent work. The speaker recommended to industry and authorities to make sparingly use of the request of confirmatory data.

New formulation submissions he calls as relatively simple submissions as the situation seems to be quiet straight forward. In contrast the submissions for renewal of Authorizations are highly complex situations. The optional zonal process after Annex I inclusion under Directive 91/414 is no longer viable in the South as Member States have decided to only allow national processes for this procedure.

The main problem the speaker sees with the confirmatory information that is to be submitted after Annex I inclusion. Particularly since it is difficult for MS to continue their assessment if significant confirmatory data is required and has not yet been evaluated by the RMS. This might lead to a freeze in the market as companies might not submit any new formulations due to this uncertainty. The situation might become worse under Regulation 1107/2009, as, contrary to the step I / step II procedure of 91/414, the time for reassessment of the authorization is shortened to one year. According to the speaker France does not register new formulations of new active substances unless the confirmatory data have been reviewed at EU level even if this data is available and has already been reviewed.

16. Section 7: Seeking Biology Solutions to the Zonal Challenge

Patrice Duvert
ECPA -EffEG
Bayer CropScience, FR

In the first presentation ever in AGChem Forum history with focus on efficacy issues, Patrice Duvert of Bayer CropScience on behalf of the ECPA

Efficacy expert group explained the task of Section 7 which is to balance the benefits of a PPP (e.g. efficacy performance, yield increase) vs. its potential risks (e.g. phytotoxicity, adverse effects on quality, processing, yield, impact on beneficials, resistance risks). EPPO Guideline PP1/278(1) lays down the principles of zonal data production and evaluation. It requires that a comprehensive data set is being provided justifying the performance of a PPP across a range of conditions present in the area where the registration is required. The factors influencing the performance of the PPP include climatic and edaphic conditions, agronomic practices, influences arising from the pest and properties of the active substance and the PPP.

The zonal Biological Assessment Dossier (BAD) is a detailed analysis of the overall trial work and as K-Document the key reference on the biology of the PPP. In contrast to the other sections not only the critical uses have to be evaluated but every single pest-crop situation to be addressed and presented in different clusters, according to various conditions (e.g. climatic zone).

Data should be critically evaluated in relation to the relevant general and specific guidelines and the conclusions be made by reference to the label claims proposed. Usually a zonal BAD covers many countries and situations and will result in a document of 200 to 500 pages or more.

The zonal dRR Section 7 is a concise summary of the zonal BAD with a critical evaluation of the overall work done. It should contain test and super-summary tables of the information contained in the BAD. Usually Section 7 of the dRR is 20% size of the BAD. For further information see ECPA technical guidance paper 2011/1 which can be downloaded from the ECPA homepage:

<http://www.ecpa.eu/information-page/regulatory-affairs/technical-guidance-papers>.

The homepage also presents further ECPA TGP:

- TGP 2012/1 has been developed to provide guidance for applicants in preparing a concise efficacy summary for the submission of a new active substance for inclusion in Annex I.
- TGP 2012/2 provides guidance for applicants in preparing the submission of efficacy information for Annex III submission

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following renewal of inclusion of an existing active substance in Annex I.

- TGP 2012/3 provides authorization holders with guidance on the process for the identification, assessment, communication and archiving of notifications of potentially harmful effects, as required under Article 56 of Regulation (EC) No. 1107/2009.

Another important aspect is the relation between core section 7 and national addenda for which a draft SANCO document is in creation. The guiding principles on content of core and addenda are clear:

Core submission:

- As much as possible the efficacy evaluation should be conducted by the zonal rapporteur.
- Should consider the range of main targets, pressures, resistance status, agronomic practices.
- Should include where possible all intended target species.

National addenda:

- Should principally be used to provide further information, *e.g.* justification for the proposed individual MS uses and address specific additional national risk management requirements.
- Should be restricted to very limited additional data (specific individual MS requirements).
- Should be produced to defend specific local label claims (*e.g.* target species) in a MS.

High standard study reports are the basis for a successful submission. The underlying trials should be of good quality, be conducted under GEP according to relevant EPPO guidelines and must report all relevant conditions of the trials.

ECPA has established a very useful central GEP certificate database onto which contract organisations can upload their certificates. Essentially the database is a table containing a list of certificates with hyperlinks to the certificates, which can be downloaded and copied/pasted into the dossiers. There is no more need to insert copies of certificates into the BADs. There is free access to the data base for all interested experts. Problems to be solved: in Italy there are no certificates but publications in

official journals and some countries the certificates have only be issued in local language so far.

In 2012 an EU Working Group was established to analyse the situation with dRR submissions for sections 1 to 7. Five authorities (ANSES, CRD, Ctgb, JKI, Benaki) and two companies representing ECPA are members of the Subgroup Section 7 which is lead by ANSES. Final recommendations are expected by the end of 2013.

The countries of the Northern Zone give a good example how MS can work together. Harmonisation is now required across the 27 MS of the EU. ZRMS should evaluate the dossiers not with a national but with a zonal view. Improvements are also needed with respect to keeping the evaluation timelines. Exchange of experiences with the implementation of zonal evaluation of PPPs and further international harmonisation are the aim of an EPPO workshop, which will be held in Bulgaria in October 2013.

A compilation of EPPO documents related to zonal efficacy can be found on <http://www.ecpa.eu/information-page/regulatory-affairs/technical-guidance-papers>

17. Strategies for Dealing with Data Protection and Confirmatory Data under 1107/2009

Claudio Mereu
Partner,
Field Fisher Waterhouse LLP, BE

The legal basis for data protection in 1107 is Article 59. The data protection period, if applicable, will commence under 1107 as of the first authorization of a PPP containing the a.s. in each MS. The actual data protection period, though identical in length, can thus be different in each MS. The data protection periods were details with respect to the different possible cases in the presentation.

The legal basis for the data sharing requirement in 1107 is laid down in Articles 61 to 62. It was emphasised that these provision apply to all studies (including non vertebrate and even non animal), but are only penalised for vertebrate studies, *i.e.* use of said data by the authorities, if no agreement is

reached by the parties involved (with the data owner having a claim on a fair share). It was emphasised that the legal texts contain many uncertain terms, such as, “every effort”, “an attempt”, and “sufficient time”. Further such undefined terms are “fair share” and “costs”.

Currently there is no European system of mandatory data sharing and arbitration, but many MS, like UK, Italy, Spain, Greece, adhere to their own procedures. Others have no system implemented.

Under Article 60, the RMS is obliged to prepare a list of studies, which were necessary for the first approval (or amendment / renewal) and each MS shall keep the list available for “interested parties”. It was noted that it is not clarified, what an “interested party” (versus a “prospective applicant”) constitutes and whether that definition might include NGOs.

Under AIR 2 it is stipulated that applicant shall take all reasonable steps to submit dossiers jointly. If not, applicants, must state reasons and provide details of the attempts made to avoid duplicate testing.

AIR 3 allows for a joint application to be submitted by an authorised representative. If dossiers are not submitted jointly, again applicants, must state reasons and provide details of the attempts made to avoid duplicate testing.

It was noted in the presentation that 1107 refers to studies “involving” animals, when speaking of vertebrate studies. Therefore, vertebrate studies do not necessarily involve the sacrifice of the animals involved. In 544/2011 and 545/2011 the scope of studies involved was widened by making reference to Directive 86/609 on the protection of endangered species, which meanwhile has been repealed by Directive 2010/63 on the protection of animals used for scientific purposes.

Letters of Access are addressed to the MS authorities to confirm the right to cite and rely upon studies. Any use restriction, such as territorial coverage, identity of licensee, list of studies, conditions and period of validity should be specified in the LoA. It is important to keep in mind that in issuing or refusing to issue LoAs, antitrust issues must be considered.

Finally, the much more concise and clear system of data protection and data sharing in the US under FIFRA was presented.

18. MRLs: Application, Setting and Monitoring in the EU - an industrial Perspective

Sabine Henning-Helbig
Regulatory Consultant,
GowanComércio Internacional e Servicos, BE

The main objectives of Regulation 396/2005/EEC are

- Ensure a high-level of protection of human health
- Ensure free circulation of goods by harmonized MRL, which are legally applicable in all MS
- Establish a transparent system for the setting of MRLs and import tolerances

The Regulations stipulates that MRLs are required

- When treated commodities are placed on the market in the EU or are used for animal feed in the EU
- When crops treated with substances that are approved or not approved in the EU are imported into the EU: “Import Tolerances”
- If no specific MRL is set on a crop, the default value is applicable

The speaker stressed the point that no product authorization of a specific use will be granted before a valid MRL has been allocated.

The Regulation 396/2005/EEC has seven individual Annexes, of which Annex VI: “Processing factors” is not yet been issued.

The Regulation provided two individual procedures. Depending on whether new MRLs are thought to be set or whether the existing MRLs are to be assessed and changed. It was indicated that the procedure might involved duplication of work, as the evaluation of the Active substances under 1107/2009 have to run in parallel to the assessment of an MRL dossier. Thus if the residues definition is changed within approval procedure “1107/2009”, residues trials which might

have for ready been setup to accommodate an existing MRL or to support a setting a new MRL might be obsolete.

Detailed information on the data requirements for an MRL dossier were given, that additional data are required in particular for import tolerances for active substance which are not registered in EU, i.e. a complete toxicological package.

An Important issue is the comparability of GAPs as indicated in SANCO 7525/VI/95 – rev. 9.

As a rule of thumb 25% deviation in one of the below mentioned areas can still be considered as comparable to previously conducted though.

Still be considered:

- Application rate
- Number of applications
- PHI
- Changes in interval between two applications

Also extrapolation between crop groups and similar formulations might be considered possible.

With respect to the risk assessment for consumers, clarity is needed on how to calculate the chronic risk (with or without default values).

The third revision of the EFSA PRIMo is currently under way, but not yet published.

This will contain Food Consumption Data and it also includes consumption data on honey and fish. The Chronic Exposure is presented in a chart that easily shows the main contributors.

It was noted that the amendment of a consumption data leads to more critical exposure for certain pesticide / residue combinations and thus result in revisions of existing MRLs.

A further development will be the introduction of a cumulative RA in the near future. It should preferably follow the same principle as the US EPA approach. This is challenging to the European authorities as the US have huge data bases on consumptions enabling them to extend their risk assessments to cumulative risk assessments.

The grouping of substances requires the identification of Cumulative Assessment Groups.

Furthermore an in-depth exposure characterization (duration of effects, interaction etc.) is needed. Finally, appropriate software for such an assessment is required.

A rationalization of Risk Assessments and overall alignment of methods used by regulatory authorities is highly desirable.

19. Implementation of the SUD in Europe: National Challenges for Risk Reduction

Silke Dachbrodt-Saaydeh
Coordinator International
Collaboration,
Julius Kühn-Institute, DE

The speaker indicated that the sustainable use directive contrary to the 1107/2009 regulation has to be implemented by the national legislative bodies of the member states than thus allowing for some liberties in implementation. The objective of this directive is to achieve a sustainable use of pesticides by reducing the risk and impacts of pesticide use on human health and the environment, promoting the use of integrated pest management (IPM) and finding and promoting alternative techniques such as non-chemical alternatives to chemical crop protections. Article 4 of the directive stipulates that member states are to adapt national action plans, (NAP) in which quantitative objectives, targets, measures, and timetables are set up. That NAPs should also include indicators to monitor the use of plant protection products containing active substances of particular concern. The targets may cover different areas of concern, such as worker protection, protection of the environment, water, residues, use specific techniques, or use in specific crops. 21 Member States have published their national action plans. There have been particular challenges to Austria and Belgium with the original and federal setup. The NAPs are published on the EU homepage. Unfortunately some are still only in the respective national language.

The historic processes of reducing pesticides use was by setting qualitative targets: reduction of volume and frequency of application. In the new approaches, the NAPs set also quantitative goals on risk and impact as well as qualitative goals (e.g. Italy: IPM on 80 % of land, The Netherlands: improvement of water

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quality). All the goals indicated in the NAPs are to be achieved without compromising the yields of the harvested crops. It is of utmost importance to maintain an efficient and high quality agricultural production. It has been shown that the use optimisation of pesticides can achieve a high degree of risk reduction.

The Intergraded Pest Management being the core and key issue of the sustainable use directive is in the focus of all endeavours. The decisive elements for successful IPM implementation are:

- Structure of agricultural production
- Current dependency on chemical crop protection
- Farmer education, knowledge and experience in the use of alternative and non-chemical plant protection methods
- Farmers attitude towards IPM and risk
- Availability of tools to support the decision-making
- Availability of resistant varieties, bio-pesticides and alternative protection methods
- Reliable advisory services

The Member States have put different emphases on alternative viable methods to achieve the goals. In all cases, the farmers play the key role.

Human safety: Toxicology and Exposure – AgChem Forum 2013 and recent news

The main topics of this AgChem Forum stream with reference to Toxicology and Exposure were (i) cumulative and aggregate risk assessment, (ii) non-dietary/dietary exposure assessment, (iii) metabolite safety evaluation and (iv) alternative methods for evaluating toxicology.

With regard to operator, bystander/resident and worker exposure, several new attempts have been made to improve exposure assessments, i.e. generation of new data sets (e.g. Agricultural Operator Exposure Model (AOEM) published by the BfR in 2013; BROWSE). Probabilistic methods (e.g. ACROPOLIS) will be soon available in comparison to conventional, deterministic methods to evaluate exposure towards pesticides based on realistic, worst-

case approaches. After inclusion of new AOEM data in the EFSA draft guidance document, followed by a commenting phase, the EFSA model including a calculator will become available earliest in June 2014.

Another important topic was the new data requirement “*in vitro* comparative metabolism”. It was pointed out that no specific guidance is available yet how to perform such studies and how to address unique human metabolites in the further evaluation process.

With regard to dietary exposure an update of regulatory documents is ongoing, including probabilistic approaches and cumulative dietary risk assessments. EFSA published an opinion in 2013 on the methodology for grouping substances in cumulative assessment groups (CAGs) with focus on neurotoxicity and thyroid toxicity. A further opinion on dissimilar modes of action to safeguard and possibly refine the methodology in this CAG opinion is now also available (Scientific Opinion on the relevance of dissimilar mode of action and its appropriate application for cumulative risk assessment of pesticides residues in food, EFSA Journal 2013;11(12):3472). EFSA’s activities on “Cumulative risk assessment in the framework of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in food and feed” will be discussed in a Technical Meeting with stakeholders in February 2014.

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

Further links to relevant models, guidance documents and events:

ACROPOLIS: www.acropolis-eu.com

AOEM: Joint development of a new Agricultural

Operator Exposure Model - BfR-Wissenschaft 07/2013.

<http://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf>

BROWSE: www.browseproject.eu

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EFSA: Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile. EFSA Journal 2013;11(7):3293.

<http://www.efsa.europa.eu/de/efsajournal/pub/3293.htm>

Public consultation on the Scientific Opinion of the PPR Panel on the identification of pesticides to be included in cumulative assessment groups (CAGs) on the basis of their toxicological profile.

<http://www.efsa.europa.eu/en/consultationsclosed/call/130717.htm>

Info Session on Applications - Pesticides – Technical meeting on Cumulative Risk Assessment, Parma, 11 February 2014

<http://www.efsa.europa.eu/en/events/event/140211.htm>

Environmental safety: Ecotox and Fate - AgChem Forum 2013 and recent news

In the environmental stream of this year's AgChem Forum, 15 presentations on different topics were given by speakers from EFSA, national authorities, industry, research institutes and academia.

This AgChem forum part was focused on risk assessment for bees, implementation of environmental data requirements and aquatic/terrestrial ecotox and fate including ecological modeling.

The new data requirements for the environmental field were discussed and first experiences were presented. Aspects of aquatic and terrestrial ecotox and fate were presented including the discussion of some new guidance documents, which were prepared with reference to the PPR Panel's request to prepare a revision of the Guidance Document on Aquatic Ecotoxicology under Council Directive 91/414/EEC (SANCO/3268/2001 rev.4, 17 October 2002).

With regard to the EFSA Guidance Document (GD) on the Risk Assessment of Plant Protection Products on bees, several presentations highlighted the key points and the impact. In addition, also the European Commission Restriction on Neonicotinoids was presented.

According to the GD for bees, the risk assessment considers several routes of exposure: Exposure via contact, consumption of pollen, consumption of nectar, consumption of water, risk from metabolites present in pollen/nectar. The GD requests for all PPP data and assessment of the risk to honey bees, bumble bees and solitary bees. However, many of the new required laboratory studies are not yet standardized according to OECD protocols. It is expected that for the majority of pesticides higher tier testing and risk assessments will be necessary to pass the very conservative trigger values. The implementation of the EFSA Guidance Document is open (voting of SCFCAH outstanding). Further details on EFSA Guidance on bees were discussed in a recent SETAC Workshop (see separate article on page 5).

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

Further links to relevant models and guidance documents:

EFSA: Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295
<http://www.efsa.europa.eu/de/efsajournal/pub/3295.htm>

Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290
<http://www.efsa.europa.eu/de/efsajournal/pub/3290.htm>

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CALENDAR

Info Session on Applications - Pesticides - Technical meeting on Cumulative Risk Assessment, 11 February 2014

EFSA's APDESK Unit, in collaboration with the Pesticides Unit, is organizing a technical meeting with stakeholders to present EFSA's activities on "Cumulative risk assessment in the framework of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in food and feed". The main aim of this stakeholder information session is to present and get feedback on the legal framework for cumulative risk assessment and on the scientific basis and underlying principles for cumulative risk assessment. Further key issues are on-going and future activities with regard to implementation of cumulative risk assessment. *Dr. Monika Eder*, Senior Manager Regulatory Science Residues, Consumer and Health Assessments, and *Dr. Thomas Roth*, Senior Manager Regulatory Science Toxicology and Human Health Risk Assessments, will be at this event and would be pleased to respond your requests and to meet your needs. <http://www.efsa.europa.eu/en/events/event/140211.htm>

— Edition notice —

SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH
Dr. Friedbert Pistel, President
Am Grenzgraben 11 · D-55545 Bad Kreuznach
Phone +49 (0) 671-29846-0 · Fax +49 (0) 671-29846-100
scc@scc-gmbh.de · www.scc-gmbh.de

Liaison Office Japan
14-24 Tokiwadai,
Kashiwa-shi
Chiba-Ken 277-0087, Japan
Phone/Fax.: +81 (0)4-7162-4262

Mr. Toshiyasu (Ted) Takada, Director
e-mail: toshiyasu.takada@scc-japan.com

Liaison Office Japan
1-28-20, Fujimigaoka,
Ninomiya-machi, Naka-gun
Kanagawa-ken, 259-0122, Japan
Phone/Fax.: 81-(0)463-73-0912

Mr. Kozo Inoue, Senior Consultant
e-mail: kozo.inoue@scc-japan.com

Liaison Office Japan
6-2-14 Asagayakita,
Suginami-ku
Tokyo 166-0001, Japan
Phone/Fax.: +81 (0)3-6762-5261

Mr. Kenji Makita, Senior Consultant
e-mail: kenji.makita@scc-japan.com

Liaison Office Japan
14-8, Midori-cho,
Mishima-shi
Shizuoka 411-0848, Japan
Phone/Fax.: +81-(0)55-976-1686

Mr. Toshiaki Fukushima, Consultant
e-mail: toshiaki.fukushima@scc-japan.com

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