

SCC's Website Relunched: User-Friendly Concept Provides Clients with Comprehensive Information

SCC is very proud to present its new website! Please go to www.scc-gmbh.de to see the result of this major restructure.



The screenshot shows the SCC website homepage. At the top, there is a navigation bar with a search box and links for Home, Company, Newsletter, Brochures, Links, and Contact. Below this is a banner featuring the SCC logo, a molecular structure diagram, and three red tomatoes. The main content area is divided into three columns. The left column, titled 'Our Business', lists various services: Agrochemicals, Biocides, Chemicals / REACH, Consumer Products, Feed & Food Additives, Veterinary Medicine, Regulatory Science, and Archiving. The middle column, titled 'Welcome to SCC!', contains a brief introduction to the company and a grid of images representing different business areas. The right column, titled 'News', lists recent updates, including a non-inclusion decision for biocidal substances and a European Parliament recommendation. At the bottom of the page, contact information for SCC GmbH is provided, along with an imprint notice.

The aim of this complete new concept is that visitors can more quickly and effectively find the information they are looking for. At the same time we tried to make the overall appearance even more friendly and inviting. Our areas of expertise, business activities and information regarding Annex I listings for both 91/414/EEC and 98/8/EC are easier to find as well as current news and information about our company. We are very satisfied with this new presentation of our work at SCC and we sincerely hope that we have succeeded in our attempt to make the information more accessible to you. Please feel free to let us know what we can still make better.

Also in this issue of the SCC Newsletter, you will find an overview under “Calendar” on where to meet our specialists and upcoming conventions and conferences.

SCC is always personally available for any of our clients’ individual needs. For questions, please contact SCC in Wendelsheim, or our SCC Liaison Office Japan.

With best regards,



Dr. Friedbert Pistel
President

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AGROCHEMICALS

New regulation following directive 91/414/EEC adopted by the Council

On 24 September 2009 the Council of the European Union adopted the new regulation concerning the placing of plant protection products on the market and repealing Directives 79/117/EEC and 91/414/EEC. According to the Council, this step harmonises, simplifies and tightens the procedures for the approval of active substances and authorisations of plant protection.

The voting by the Member States as well as comments from different organisations and newspapers indicate that consequences arising from the new regulation as well as possible specifications to the new regulation are still in discussion. Hungary and Ireland abstained from voting, while the UK voted against the new regulation. Hungary stated that there must be a more rigorous definition of the risk of very harmful effects on consumers from the use of endocrine disruptors. In this connection, however, Hungary believes that the number of plant protection products available to combat the pests affecting strategically important crops will decrease. The UK agrees that the use of substances which have endocrine disrupting properties and consequently may cause adverse effect in humans should be appropriately controlled. It notes, however, that consumers are exposed to endocrine disrupting substances from various sources, including pharmaceuticals and foodstuffs such as meat and pulses. The UK is concerned that this important provision is not definitive and consequently that no proper assessment of its potential impact on agriculture in the European Union, or of its benefits for consumers, is possible. The UK has repeatedly stressed the importance of understanding the

impact of these measures before it could commit itself to the regulation. Without this understanding, the European Union risks taking measures would have significant adverse impacts on crop protection, but secure no considerable health benefits for consumers.

CRD Workshop on New Plant Protection Products Regulation

On 30 September 2009, the British authority CRD held a conference on the “New Plant Protection Products Regulation” in York. The key topics were the new Regulation on plant protection products replacing Council Directive 91/414/EEC and the Sustainable Use Directive.

The new regulation on plant protection products and the Sustainable Use Directive are foreseen to be published in October 2009. The former shall apply 18 months after the entry into force date, i.e. approximately April 2011. The latter shall apply two years after the entry into force date, i.e. approximately October 2011.

Managing the transition from the current Directive 91/414/EEC to the new regulation was considered as the “real challenge” by CRD. Transitional measures are planned to be implemented for the continuation of application of 91/414/EEC, for existing active substances, for new active substances, for Annex I renewal substances, for re-submissions, and for PPP applications. According to CRD, the “challenge” behind this becomes obvious when looking at the relevant time sequences: entry into force date, application date, renewal program, new data requirements and new uniform principles, endocrine disruptors, lists of candidates for substitution, comparative risk assessment, safeners and synergists, and in addition, the integration of all these tools.

This resulting workload for the regulatory authorities is considered immense: re-submission program, peer review of “green” inclusions, new active substances, confirmatory data, national



program of re-registration 2010 – 2014, and additionally the application of the new Regulation in 2011. However, CRD feels that they are well prepared for this amount of work and are currently already starting to plan their work.

Overall, one has to bear in mind that this working program applies not only to authorities, but also to applicants/industry.

News from the AgChem Forum

This year's AgChem Forum was held in Barcelona from 23 – 24 September.

In a key lecture, Professor Witzke of Humboldt University of Berlin, indicated that based on his research, the prices of agricultural commodities would increase significantly in the future due to an increase in world population and the limited area which can be used for farming worldwide. He predicted significant civil unrest and migration as a result. As the areas used for farming cannot be extended much beyond the current level, he emphasized that it is mandatory to increase productivity of the agricultural sector in developed countries.

With respect to the new regulation replacing the current Directive 91/414/EEC, Ian Denholm of Rothamstead Research called this a very clear step in the completely wrong direction.

Robert Sturdy (MEP) emphasized that the use of pesticides is vital to grow healthy crops and that at the core of all laws should be the concern about human health. He called the hazard based approach in the new regulation fundamentally flawed and pointed out that the costs of any increased regulating of the agricultural sector will eventually be passed on to the consumer.

In the scientific presentations, the uncertainties concerning the definition and assessment of endocrine disrupting properties were presented and discussed (L. Becedes, Swedish Chemicals Agency; I. Fegert, BASF). The comparative risk assessment prescribed in the new regulation was

clarified from different angles as well (L. Mohimont, EFSA, J. van Kleveren, RIKILT, P. Parsons, Syngenta). Vibeke Bernson (Swedish Chemicals Authority) pointed out that comparative risk assessment would immediately be stopped if no suitable replacement was available. Therefore, a loss of products would not occur and any concern about resistance management was unfounded. This resulted in animated discussion.

Bernd Brielbeck (SCC) presented the diverse requirements set for the registrations of plant protection products at national levels.

Workshop on product chemistry

The BVL (German Federal Ministry of Consumer Protection, Food and Agriculture) presented a workshop on 8 September in Braunschweig regarding basic and current assessment criteria and procedures in the areas of identity of the active substance, changes of specifications, methods of analysis, as well as changes in the formulation; and reported about developments to be expected due to the new regulation replacing 91/414/EEC.

Dr. C. Vinke discussed the equivalence of different sources for the same active substance has been addressed. The equivalence of different sources of technical material has to be assessed based on SANCO/10597/8003 – rev. 8,1 May 2009. If the material is equivalent according to the TIER I approach of the guideline, an announcement to the authorities is sufficient and the material may be sold. If a TIER II approach is necessary, the authorities must perform an assessment before the material is allowed to be sold.

Dr. A. Steer explained the requirements on Material Safety Data Sheets. Safety data sheets have to be prepared according to the REACH regulation and should not be older than one year. Otherwise a statement from the manufacturer is

necessary, saying that the given MSDS is still valid.

Furthermore he explained the procedure in case of changes in the chemical composition of plant protection products. Two approaches are possible.

- **Procedure of notification:** If a change in a formulation only consists of exchanging co-formulants for the same amount of chemically equivalent co-formulants, a notification is sufficient. The preparation code does not change. The new formulation can be placed on the market as from the date of the notification and is the applicant's own responsibility.

- **Procedure of change:** In principle, all changes where co-formulants are exchanged, added or omitted, or whose content is changed are to be applied for in a procedure of change. Depending on the extent of the change, new studies may be required, or a scientific comment has to be made that no changes are to be expected in comparison to the old formulation. The preparation code will change. The new formulation can be placed on the market as soon as the notification of change enters into force.

The old formulation may still be marketed in both cases until the regular period of authorisation has expired.

Dr. D. Goebel discussed the identity of technical active substances. According to the new regulation, the formation of impurities has to be described. Furthermore the formation of potential undesirable impurities (e.g. nitrosamines) has to be discussed.

Batches for "five-batch studies" should not be older than five years. QC data can be presented to support the specification.

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



BIOCIDES

Revision of the EU biocides legislation

Since we first reported on the ongoing activities regarding the two-step revision of the Biocidal Products Directive 98/8/EC (the BPD), major progress has been made during 2009: the long-awaited "major revision" proposal was published by the Commission on 12 June 2009, and the discussions in Council and Parliament on the prolongation of the review program, the "mini revision", were concluded in an agreement that was recently published as Directive 2009/107/EC in the Official Journal of the European Union.

The mini revision

On the basis of document COM(2008) 618 final, the European Parliament brought forward a new proposal which provides for a prolongation of the review program until 14 May 2014. For "difficult" existing active substances, there is to be an option to further extend their review for a maximum of two additional years. Proposals by a few Member States to also address issues regarding free-riding and data protection in the mini revision were eventually rejected in the Council.

The recently published Directive 2009/107/EC of the European Parliament and of the Council from 16 September 2009, amending the BPD with regard to the extension of certain time periods, stipulates – as proposed by the Parliament – that the review program and the transition phase will be extended until 14 May 2014. A further extension of the review program beyond 2014 is restricted to certain conditions: In recital 8 of Directive 2009/107/EC, a link is made to the major revision of the BPD, stating: "Any extension of the review programme and the



corresponding transitional period for any remaining active substances after 14 May 2014 should be limited to a maximum of two years and should take place only if there are clear indications that the legal act intended to replace Directive 98/8/EC will not enter into force before 14 May 2014.” Furthermore, in article 1 (2) (a) (i), the Commission is requested to “forward to the European Parliament and to the Council a report on progress achieved with the programme” not later than 2012. Depending on the conclusions of that report, it may be decided to extend the transitional period and the review program for a period of no more than two additional years.

The major revision

The Commission proposal for a regulation concerning the placing on the market and use of biocidal products (COM(2009)267final) was finally published after lengthy internal consultations on 12 June this year. Some highlights of this proposal:

Legal form: as in the area of plant protection, the directive will become a regulation.

Scope: treated articles and *in-situ* generated biocides come into the scope of the new regulation.

“Cut-off” criteria for active substances: hazard-based exclusion criteria are introduced, i.e. biocidal active substances that meet certain conditions (e.g. substances classified as carcinogen category 1A or 1B) will only be included in Annex I in exceptional cases. Furthermore, criteria for active substances are established which make them “candidates for substitution”.

Authorisation: new administrative procedures are created for the authorisation of biocidal products, such as a community authorisation (which is restricted to low-risk biocidal products and biocidal products based on new active substances) and a decentralised procedure called “mutual recognition in parallel”. The European Chemicals Agency in Helsinki (ECHA) will manage certain tasks in the new biocides system,

e.g. the coordination of applications for Annex I inclusion of new active substances, the coordination of applications for Annex I renewal of biocidal active substances or the coordination of applications for community authorisation of biocidal products. ECHA will set up and manage a *Biocides Data Sharing Register*. In order to apply for biocidal product authorisation, it will be compulsory to use the *Community Register for Biocidal Products* (i.e. today’s Register for Biocidal Product, “R4BP”) which is managed by the Commission.

Data requirements: a two-tiered system is introduced for active substances, while for biocidal products data requirements remain virtually unchanged. A new Annex IV to the proposed regulation provides for legally binding data waiving rules.

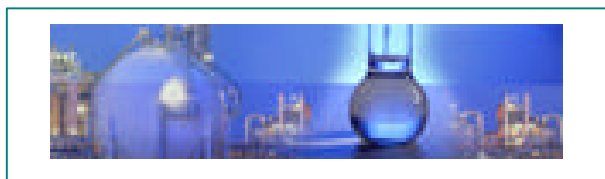
Simplified procedures: The concept of frame formulations has been broadened. A new concept of low risk biocidal products is established: Annex IA is repealed, criteria for low-risk products are defined, low-risk products fulfilling those criteria can be authorised even if they contain active substances not listed in Annex I.

Research on animals: compulsory data sharing for vertebrate data is introduced.

Parallel trade is addressed in the legal proposal.

The Commission proposal is now subject to the co-decision process between the Council and the European Parliament: Council working group meetings are currently being held under the Swedish Presidency in order to prepare a policy discussion at the Environment Council on 22 December. As the elections for a new European Parliament occurred just when the proposal was adopted by the Commission, the appointment of a rapporteur was delayed and thus the work in the Parliament is still in its early stages. According to recent information, the plenary vote of the first reading is scheduled to take place in May 2010.

For more information, contact Dr. Holger Zitt at holger.zitt@scg-gmbh.de.



CHEMICALS, REACH, CONSUMER PRODUCTS

REACH News, Documents, and Tools

ECHA News

1) The Candidate List of Substances of Very High Concern and Annex XIV Recommendations

The REACH Regulation has set up a system under which the use of substances with properties of very high concern (SVHC substances) can be made subject to an authorisation requirement prior to their placement on the market. The authorisation provisions require those using or placing SVHCs on the market to apply for an authorisation for each use regardless of the quantity of the substance used, within deadlines set by the Commission.

Substances of very high concern include substances which are:

1. Carcinogenic, mutagenic or toxic to reproduction (CMR) classified in category 1 or 2;
2. Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation; and/or
3. Substances identified from scientific evidence, on a case-by-case basis, as causing probable serious effects to humans or the environment of an equivalent level of concern as those above e.g. endocrine disrupters.

Initially SVHC substances are identified by Member State competent authorities or by the European Chemicals Agency (ECHA) on behalf of the European Commission. Following the identification process, substances are included for

prioritisation in a “Candidate List”. Substances on the “Candidate List” may then be recommended for inclusion in Annex XIV and are subject to authorisation.

Currently there are 15 substances on the Candidate List. Note that for all these substances listed there are immediate obligations placed on the companies for the substances: alone, in preparations, and present in articles. Making use of the commenting period can be vital. On 1 June 2009, ECHA recommended the first seven substances for inclusion on Annex XIV to the European Commission.

Authorisation requirements will significantly increase regulatory burdens for manufacturers and importers and limit market availability for downstream users. The SVHC obligation starts with inclusion of a substance on the Candidate List. Initial identification of SVHC substances is thus most critical – watch out for the SIN (Substitute It Now!) List and Trade Union Priority List of substances – and take action now!

2) Lead Registrants Workshop

On 11 September 2009 over 500 companies (including SCC), Lead Registrants and Candidate Lead Registrants, met in Brussels or participated in a webstream to share practical experiences made thus far after taking the lead position in the SIEFs.

The event was jointly organised by the European Commission and the European Chemicals Agency. Speakers from ten companies and associations shared their experiences.

In general, companies intending to register the same substance have to work together in a Substance Information Exchange Forum (SIEF) to share data on hazards and safe use, and to prepare a single registration dossier. There must be only one Lead Registrant and one “joint submission dossier” for a given substance. The Lead Registrants were urged to “*dare to share*” and to “*be early - at least 2 months*” before the official deadline when submitting their dossiers.



Members of ECHA and industry discussed several issues such as problems causing registration dossiers to fail and practical steps that may be taken to speed up/simplify processes (e.g. classification and labelling).

One major concern was that the Technical Completeness Check Tool, urgently needed for a reasonable submission process, is not yet available. Without the tool, it is very difficult for registrants to understand what kind of dossier ECHA expects to ensure passing the completeness check in the first run. Therefore, a lot of back and forth communication with ECHA regarding corrections, re-drafting and resubmissions of dossiers is the rule rather than the exception. Consequently, the release of the Completeness Check Tool at the end of 2009 is eagerly awaited by potential registrants.

Companies were also informed about further support enabling them to fulfil their roles: further webinars are planned for the near future and will be addressed to Lead Registrants already notified to ECHA. Additional exclusive services for Lead Registrants including direct access to ECHA's Helpdesk and an electronic discussion platform, the Lead Registrant Forum, were also mentioned.

A list of actually nominated Lead Registrants is available on the ECHA homepage. The list is updated weekly and can be consulted via http://echa.europa.eu/sief_en.asp.

3) List of registered substances now available on ECHA homepage

The list of registered substance is based on the complete registration dossiers submitted by companies to ECHA prior to 24 September 2009. It contains 156 substances. Not all substances for which a registration has already been submitted are included thus far. ECHA will update the database and include any of the substances concerned as soon as the non-confidential character has been confirmed or a suitable name for publication is available. Please note that listing does not mean the dossiers (including CSR, if applicable) have undergone a

review/evaluation by ECHA and are considered acceptable in the form submitted. The list is available under http://echa.europa.eu/chem_data/registered_substances_en.asp.

4) Downstream users to inform their suppliers of the use

ECHA advises downstream users to communicate their uses to the respective suppliers to allow for the uses to be covered in the registration. If suppliers are not informed, downstream users may eventually need to prepare a Chemical Safety Assessment on their own.

For the registration deadline 1 December 2010, downstream users need to inform their suppliers by 30 November 2009 (http://echa.europa.eu/home_en.asp).

Cefic News

Cefic, the European Chemical Industry Council, has developed a series of documents and tools supporting any required activities under REACH. The documents are related to SIEF work, risk assessments, polymers, and Only Representative issues. They can be viewed/downloaded from the following website: <http://www.cefic.be/templates/shwPublications.asp?HID=750>. Selected documents and tools (a total of approximately 25) are presented below.

Reporting and communication of uses

The Downstream Users of Chemicals Coordination (DUCC) Group has developed an EXCEL spreadsheet for reporting uses under REACH. According to the Cefic description, "*the purpose of this template is to provide a tool to downstream user associations (and their members) for mapping and reporting uses for their respective sectors*" (<http://www.cefic.be/Templates/shwPublications.asp?HID=470&T=806>)

Exposure Assessment & Communication in the Supply Chain

The German Chemical Industry Association, VCI, and Cefic have jointly prepared a practical guide on how to prepare a Chemical Safety Report. According to the authors, “*the guide is primarily written for ‘non-experts,’ which so far have not been engaged intensively in these topics. For these, it clarifies what they must do, and what they do not have to do.*” (<http://www.cefic.be/Templates/shwPublications.asp?HID=470&T=806>)

SIEF

Sameness of substances

A spreadsheet template to generate a Substance Identification Profile (SIP) has been developed to facilitate the sameness discussion process (<http://www.cefic.be/Templates/shwPublications.asp?HID=470&T=812>).

SIEF organisation

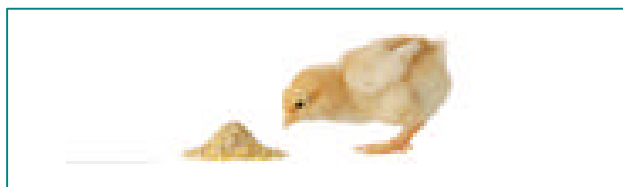
A series of SIEF agreements helpful for the efficient and clear SIEF organisation has been developed by Cefic. This document can be found on the Cefic website. (Refer to http://www.cefic.be/Files/Publications/Overview-Cefic-model-agreements-in-the-SIEF_05.10.09.doc). Rights and obligations of the different parties are defined in these agreements. A careful check is required as to whether these documents might be useful for a specific SIEF. This depends very much on the attendant circumstances (number of SIEF members, consortium in place or not, role within the SIEF, etc.).

REACH in Turkey: New Regulation on Inventory and Control of Chemicals in Turkey

In December 2008 the Ministry of Environment and Forestry in Turkey issued the Regulation on Inventory and Control of Chemicals. Several requirements, conditions and terms are very

similar to the EU REACH legislation. According to the Regulation, manufacturers who produce new and available substances, or importers who import substances on their own or in preparations (three years prior to the effective date of this regulation) in quantities between 1 and 1000 t/year and substances manufactured in volumes equal to or greater than 1000 t/year shall notify the Turkish Ministry. Minimum information is required for lower volumes, higher volumes require submission of additional data. In an amendment to the Regulation of August 2009, the final date for data submission was set to 30 June 2010. Please do not hesitate to contact us, in case you need further information on this issue.

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



FEED & FOOD ADDITIVES, VETERINARY MEDICINE

The world of **feed additives** is currently mostly concerned with the major re-authorisation operation of all existing products (mainly non-holder specific authorisations). SCC is working on numerous dossiers in various categories of additives. Only those additives of which an application dossier has been submitted to the European Commission (EC) on 7 November 2010 will remain in the Community Register and may therefore be used as additives in animal feeds. Time is, however, getting short. We can only urge everybody to start the process of data collection as soon as possible (if not already started). SCC can take care of a few more dossiers: contact us if

you need our assistance in establishing your application dossiers.

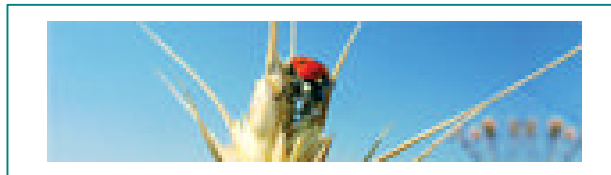
On the 1 September 2009, the long expected new Regulation (EC) No 767/2009 on the placing on the market and use of feed, was published. This new regulation repeals seven previous legislations. With this regulation, a community catalogue of **feed materials** will be established. The first version shall consist of those substances listed in Part B of the Annex to Directive 96/25/EC and columns 2 to 4 of the Annex to Directive 82/471/EEC.

For feed intended for **particular nutritional purposes**, application dossiers have to be made demonstrating that the specific composition of the feeds fulfils the particular intended nutritional purpose and that it has no adverse effects on animal and human health, the environment or animal welfare. Unfortunately, the guidelines that the EC wants to establish for these dossiers are not yet available. SCC is in direct contact with the responsible persons of the EC to get more first-hand information. The establishment of application dossiers is the core business of SCC, so let us take care of these dossiers for you!

A lot is also going on in the area of **novel food**. A revision of the Novel Food Regulation is expected next year and EFSA is preparing new guidelines for applicants. SCC will attend EFSA's 13th Scientific Colloquium in Amsterdam in November and will follow all developments closely so that we can advise our clients in the best possible way.

For **veterinary medicine** we can help our clients with various aspects of a registration dossier. Most notably we have 20 years of experience in establishing full **environmental risk assessments**, which have also been required for these products for the last few years. Let our experience be of your advantage!

For more information regarding these topics, contact Ruud Huibers at ruud.huibers@scg-gmbh.de.



REGULATORY SCIENCE

AgChem Forum: Topics in Environmental Risk, Ecotoxicology, Environmental Fate and Behaviour, and Human Health

The AgChem Forum, held on 23 and 24 September 2009 in Barcelona, was subdivided in three streams, one of which was "Environmental Risk", with separate sessions on ecotoxicology, environmental fate and behaviour, and human health topics.

In the ecotoxicology session, 15 presentations on different topics were given by speakers from EFSA, several national authorities, from industry as well as from research institutes.

Mark Egsmose (PPR Panel, EFSA) reported about EFSA's work on a series of guidance documents (GDs). Due to a forthcoming urgent situation in the PRAPeR unit early 2010, the transfer of scientific staff (e.g. from the PPR Panel) to the PRAPeR unit for 6 to 9 months will result in delays of work on GDs. While the end of the scientific work on the GD on risk assessments for birds and mammals is still scheduled for the end of 2009, either the adoption of the GD on terrestrial ecotoxicology (scheduled for adoption end 2011) or the GD on aquatic ecotoxicology (scheduled for adoption end 2010) will be delayed for 9 months. The subsequent GDs on environmental fate and behaviour are also concerned: revision of the GD on persistence in soil (SANCO/9188VI/1997, scheduled for adoption in 2010, delay expected), the new GD on emission from protected crops (scheduled for adoption in 2010, delay expected) and the GD on FOCUS groundwater scenarios (start of work postponed to 2011).



Theo C.M. Brock (Alterra, Wageningen, The Netherlands) summarised the main outcome of the ELINK EU & SETAC Workshop. Specialists in aquatic exposure and effect assessment of plant protection products worked out nine recommendations to improve guidance on linking exposure and effects in the risk assessment under Directive 91/414/EEC. A SETAC publication will be issued in October 2009 with the following main topics:

- Exposure regime in ecotox tests to be adapted to FOCUS (pulse) exposure scenarios. A proposal of ten idealised exposure profiles is suggested; ECPA has developed a user-friendly tool called EPAT (Exposure Pattern Analysis Tool), available later in 2009.
- Further recommendations deal with the use of TWA values, HC1 or HC5 values, recovery in mesocosms, etc., to derive the Regulatory Acceptable Concentration (RAC).

Robert Luttk, (National Institute for Public Health and the Environment, The Netherlands), reported on behalf of the joint working group of representatives of EFSA, the Commission, and the Member States regarding the status of work on the new GD on risk assessment for birds and mammals.

Key discussion points of the risk managers' meeting were as follows:

- **Dietary risk assessment: LD₅₀/m² or traditional approach?** The risk managers preferred to have one method for the different assessments: for birds and mammals as well as for acute and reproductive assessments. As the LD₅₀/m² approach is suitable for the acute risk for birds only, the traditional approach will be followed.
- **Geometric mean approach for toxicity values:** *“The geomean should be used for the acute assessment, except when the value for the most sensitive species is more than a factor of 10 below the geomean. Where this is the case, the most sensitive species will be used for the risk*

assessment but generally without an additional assessment factor unless there are specific reasons to believe that this is not appropriate.”

The reproductive assessment should continue to be based on the most sensitive species pending additional research.

- **Reproductive assessment:** In the PPR opinion, it was proposed to use a phase-specific approach for assessing the risk on reproduction of birds and mammals. The Joint Working Group decided to move the phase-specific approach to higher tier. Single toxicological endpoints for mammals should be the lowest relevant endpoint from 2-generation rat study or the outcome of the teratogenicity study, if lower. For birds it will be the lowest or geomean of relevant endpoints. For the single exposure estimate, long term exposure should be used as default and short term exposure when evidence for substance is available.

Remaining questions to PPR Panel:

- Criteria for when to use short term exposure estimates
- Use of 1/10 LD₅₀ for birds needs to be confirmed
- TWA period for LTE – study duration or 21-day?

The finalisation of the scientific work is scheduled for the end of 2009. A calculation tool will be provided.

Peter Edwards, Syngenta, UK, gave an overview on the history of risk assessment for birds and mammals, starting with Kenaga (1973) over SANCO (2002, 44 pages + 30 pages appendix) up to today (EFSA PPR Panel Opinion, 181 pages + 574 pages appendix).

The importance of voles in the risk assessment was critically discussed. The phase specific approach was also criticised because the endpoints include a NOEC/NOEL derived from an unrealistically long exposure period of 20 weeks which are used in a risk assessment with a maximum 1-3 day TWA exposure. Other points



of criticism were the high workload (about 10 person-days, toxicologists and ecotoxicologists, per compound) and even with such teams, many endpoints could not be unequivocally identified (particularly those under “systemic toxicity”).

Anne Alix, Head of the Ecotoxicology and Environment Unit, AFFSA, and Gavin Lewis, JSC International, UK, presented proposals for a revision of the regulatory risk assessment for honey bees by the ICPBR Bee Protection Group.

In the first part of the presentation, Gavin Lewis gave an overview of the history of ICPBR and of the following current issues of ICPBR working groups:

- Systemic toxicity (seed coating and soil application products)
- Bee brood risk assessment (bee brood ring testing group)
 - A laboratory *in vitro* toxicity test on larvae (Aupinel et al., 2005) is in the ring test phase. Relevant endpoint (LC50/LD50, NOEC/NOEL) for use in RA is open.
 - Bee brood testing in field trial: revised EPPO 170 + specific brood evaluation (OECD Guidance Document 75) or alternative methods.
- Higher tier assessment (cage and field testing)
 - proposal for RA scheme was presented.

The revision process of EPPO guidelines (1999) aims to address issues identified and provide appropriate detail (schedules: to be published in 2009 (Julius Kühn Archive) and to be submitted to EPPO in October 2009).

In the second part of the presentation, Anne Alix went into details regarding the exposure of honeybees and other pollinators to residues of systemic plant protection products. It was concluded that exposure may concern various compounds with various modes of action which are not related to the level of toxicity and/or the exposure modalities. Thus, the need for a stepwise risk assessment approach was deemed necessary. A proposal for respective decision trees was

shown. Finally, uncertainties of the current risk assessment like extrapolation to other pollinators, flowering duration or other exposure routes (guttation drops or dusts) were discussed.

Current topics concerning Human Health presented at the AgChem Forum

- A German draft proposal of a guidance for the derivation of an ARfD was presented by Dr. Bernd Stein (Federal Institute for Risk Assessment, Germany). As a basis, a retrospective evaluation of ARfD values was performed showing that effects are mostly caused by repeated dosing and thus, ARfD derivation can be considered conservative and may restrict the use of pesticides. A refinement of the ARfD deduction process is considered including a tiered approach, harmonization of several currently available ARfD guidance documents and harmonized use of available data. Common principles should be established to know what to do if more data are necessary, and to reduce animal testing. The draft guidance follows steps 1-4 of the JMPR approach and is extended by a tiered OECD approach including the application of the ARfD in acute risk assessment (step 5), the refinement of the exposure calculation (step 6), and the experimental refinement of ARfD derivation (step 7). The revised draft was sent to the OECD in June 2009 and an expert meeting was held in September 2009 in Geneva.

- In the context of the revision of Directive 91/414/EEC, the initiative to define endocrine disruptors (ED) by the ECETOC was presented by Dr. Ivana Fegert (BASF). As per Weybridge definition, only both adverse effects in an apical multi-endpoint *in vivo* study and ED activity in the available targeted endpoint studies give concern for ED. In such a case, specificity of the adverse effects, the relevance of ED mechanism of action to humans, and the potency, i.e. dose level, exposure duration, nature/severity of

adverse effects and number of species affected, should be determined in the available studies.

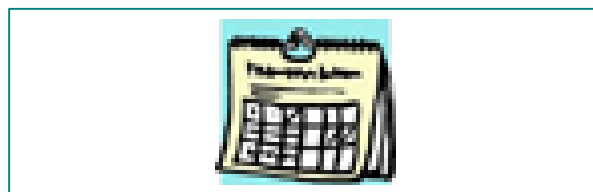
The risk assessment should be based on the endocrine endpoint with an uncertainty factor according to potency, unless the adverse effects are not specific and the mechanism is not relevant to humans.

- The bystander/resident risk assessment was discussed on the basis of the two currently available models, i.e. the German and the UK approach. As presented by Dr. Karsten Hohgardt, the Federal Office of Consumer Protection and Food Safety accepts refinement by drift reducing sprayers (drift classes according to Julius Kühn Institut / JKI list) and possibly will consider buffer zones in the future. They consider the AOEL as conservative enough for risk assessment, i.e. no need for an acute threshold value in the future. For home and garden products, the resident exposure will become an important point in the registration process of active substances and formulations. Dr. Richard Glass from FERA (UK) presented ongoing activities in field studies with bystander exposure measurements. Studies are focused on dermal and inhalation exposure of adults and children through volatiles and particles. In general, the inhalation exposure becomes more and more important. Whereas worst case model input parameters such as body surface area or breathing rate can still be expected in the future, adaptation of inhalation exposure calculation taking into account equipment, crop height, application rate, etc., is likely. Preliminary results of the studies in the UK show very low levels for non/low-volatile substances (0.5-1 ng/m³) but exposure peaking after a few hours and lasting several days after application with deposits at 100 to 200 metres away from application.

Dr. Manuela Tiramani from EFSA presented perspectives in exposure assessments with their proposed guidance document on pesticide Exposure Assessment and pointed out the need for harmonization of models for operator, worker

and bystander/resident over Europe. In EFSA's opinion, new and valid field data has to be considered in the future.

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



CALENDAR

Meeting the Challenges of REACH – 17-18 November 2009, Brussels, BE

Nicole Wagner will attend this sixth annual conference, with an emphasis on ensuring cost effective compliance with REACH and overcoming the challenges of registration of chemicals.

Crop Protection: Post Patent Products, Formulations and IPR – 18-19 November 2009, Brussels, BE

Dr. Norbert Weissmann will attend this conference, with topics including the current position and future prospect for the crop protection market, data protection at the national and EU levels, mutual recognition and worksharing programs, and much more.

13th EFSA Scientific Colloquium: What's new on Novel Foods – 19-20 November 2009, Amsterdam, NL

Ruud Huibers will attend this informative colloquium, the object of which is to bring together international experts and interested parties from different sectors for an open scientific debate on key issues related to the foreseen revision of the Novel Foods Regulation.

Newsletter

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biocides 2009 – 23-24 November 2009, Vienna, AT

SCC is one of the sponsors of this multinational conference that focuses on legal issues and trade aspects of biocidal products. Representatives from industry and authorities will come together to update and discuss the latest issues related to the legal framework in place in certain European countries as well as in the EU itself. Dr. Martina Galler and Dr. Stefanie Schirmer will attend.

European Maximum Residue Levels – Impact and benefits for authorisations and trade – 3 December 2009, York, UK

Dr. Monika Eder will attend this one-day seminar which will provide an update on recent UK and EU development in MRL legislation. The event is

aimed at registration specialists involved in the preparation and submission of MRL assessments to CRD and the EU.

9th International Fresenius Ecotox Conference: Aquatic and Terrestrial Ecotoxicology and Risk Management – 3-4 December 2009, Cologne, DE

Gunnar Schmidt and Boris Rosenkranz will attend this two-day conference, where the topics include reviewing PRAPeR peer review of pesticide environmental risk assessment under 91/414, guidance document on birds and mammals from an industry point of view, pesticide mixtures in environmental risk assessment, and much more.

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