

## Volcano Ash and Regulatory Affairs

Recently most of Europe's airports were shut down because of a volcano far away in Iceland with an unpronounceable name. Thousands of people got stuck in airports or experienced odysseys of travelling in full trains, busses, ferries or cars. After closing the airspace in large parts of Europe, it didn't take long for the responsible authorities to be harshly criticized by the airlines: surely that cloud of ash wasn't nearly as dangerous as one supposed, weren't the authorities overreacting? A result of this week-long chaos: experts are now calling for obligatory limit values for volcanic ash particles in the atmosphere below which safe air traffic is indeed possible and officially authorized.

With all the criticism from the airlines that closing down the European airspace was unnecessary, it seems perfectly reasonable to those of us working in regulatory affairs why the authorities had to react this way: in absence of any specific regulations, measures had to be taken quickly to ensure the safety of travellers. Isn't it good to know that something like this doesn't occur in our industry – even though we would like to see less regulation and more comfortable limit values set?

Fortunately, this edition of the SCC newsletter was in no way affected by the volcano ash. As usual, we give you an update on the regulatory developments in agrochemicals, biocides, chemicals and feed & food additives, and an overview on where to meet our staff is available in our "Calendar".

Also in this edition you will find for the first time the column "REACH in practice", giving you some practical advice from our day-to-day technical experience with the fast moving regulatory regime around the REACH and the GHS Regulations.

I hope you will find this edition of the newsletter interesting and helpful. For any questions, feedback or needs for specific consulting, please contact us at our offices in Wendelsheim or at our SCC Liaison Office Japan.

Dr. Friedbert Pistel  
President

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## AGROCHEMICALS

### Regulators face many changes with the new Regulation (EC) No 1107/2009

This year's Informa Conference "Registration of Agrochemicals in Europe", held in April in Brussels, placed special emphasis on the changes facing regulators with the new Regulation (EC) 1107/2009 and the transition to the new regulations. The new Regulation, which went into force on 14 December 2009 and will be applicable starting 14 June 2011, foresees amendments with impact on the following activities: minor uses fund, the "pesticide passport", parallel trade and mutual recognition as well as comparative risk assessments and candidates for substitution.

Dr. Wolfgang Reinert, DG Health and Consumers, European Commission discussed the implementation measures and deadlines facing the European Commission (COM): an advisory procedure regarding the format of the dossier and summary dossier to be submitted by industry and an advisory procedure for the draft assessment report (both prior to 14 June 2011); transformation of Annexes I-VI of Directive 91/414/EEC into Regulations (14 June 2011); establishment of a European fund for minor uses (14 December 2011); pesticide passport, providing traceable information concerning the PPP applications on agricultural products (14 December 2012); list of candidates for substitution (14 December 2013); specific scientific criteria for determining endocrine disrupting properties (14 December 2013). In addition, a work program for the gradual review of synergists and safeners (14 December 2014), expiration of application of derogation providing for provisional authorizations (14 December 2015) and detailed rules for the implementation of the provisions for co-formulants (prior to 14 June 2015) were listed.

Reinert further stated that a new regulation, currently under discussion as a draft proposal with Member States (MSs), EFSA and applicants, will set out details rules for new active substances under Directive 91/414/EEC, allocating deadlines, working to reduce the current backlog, creating a smooth transition and providing a

rolling program. Furthermore, workshops on EU and zonal levels regarding zonal evaluation and mutual recognition have been held, with an envisioned outcome of procedural guidance documents and standing groups. Work is still ongoing here.

Lastly, AIR-1 (Annex-I-Renewal stage 1) is currently ongoing, involving 7 active substances while AIR 2 (Stage 2), with 31 active substances expiring 2011 and 2012, is presently still in draft form. About 20 MSs will be involved as RMS and co-RMS in AIR 2, and the dossier submissions will be made in February, April and June 2012. And, with respect to classification and labeling, an amendment to Regulation 1107/2009 will be necessary, with a transition phase for products labeled according to Directive 91/414/EEC. COM, MSs, ECHA and EFSA are working together here.

Euros Jones, Regulatory Affairs Director, ECPA, reported on the workings and implications of the transitional period. A summary of these measures includes:

- Art. 80.1: The procedures and approval conditions under 91414/EEC will continue to apply for new actives for which a completeness check has been published prior to 14 June 2011, AIR-1 actives, actives resubmitted under the accelerated procedure (Regulation 33/2008), and actives resubmitted prior to 14 June 2011 under the "normal" procedure of Regulation 33/2008.
- Art. 80.2: Data protection rules and "old" data requirement rules will continue to apply to actives under Art. 80.1, for 5 years from date of inclusion for "old" actives, 10 years from date of inclusion of "new" actives, and 5 years from date of renewal of inclusion for actives whose Annex I inclusion expires before 24 November 2011.
- Art. 80.4: Applications for renewal must be submitted no later than 2 years (instead of 3) for compounds where the Annex I inclusion expires before 14 December 2012.
- Art. 80.5: Product authorization applications pending in the MSs on 14 June 2011, or which are due to be amended due to an Annex I listing prior to 14 June 2011, will be decided according to the national law in force before that date (i.e., current law implementing Directive 91/414/EEC).
- Art. 80.7: By 14 December 2013 the Commission will establish a list of actives listed in Annex I of 91/414/EEC which are to be considered as



"candidates for substitution". The application of comparative assessment and substitution by the MSs will be made from the date of publication of this list.

Comparative assessment and substitution of products will occur at the MS level during the assessment of the application, at use level (i.e., crop/pest level), with withdrawal becoming effective 3 years after MS decision or at the end of the AS approval period. Plant protection products containing candidates for substitution are not excluded from zonal authorization and mutual recognition, but there is no guarantee that other MSs will not apply the same or similar restrictions. Furthermore, the authorization is renewable for a maximum duration of 7 years. This could be less, however, in order to synchronize the re-evaluation of similar plant protection products.

All in all, the changes facing the industry are considerable, with a number of deadlines already looming on the horizon. SCC is prepared to assist agrochemical producers through the regulatory jungle in their endeavor to register their products on an EU and/or national level.

## **AGES Academy Meeting on the national and zonal evaluation and registration procedure for plant protection products**

On 1 March 2010 AGES invited stakeholders to discuss the impact of the new regulation on national evaluations.

Mr. Girsch (AGES) gave a general presentation on the new guideline and clearly expressed that changing from a risk based to a hazard based assessment was considered a negative development and a step backwards. Ms. Barcza-Leeb (AGES) and others gave an overview of the different aspects that are to be implemented when the provisions of Regulation (EC) No 1107/2009 will be applied after 14 June 2011. AGES is already conducting several pilot projects to assess these changes and to implement measures to cope with them.

It was indicated that a new zonal Steering Committee will be set up which will consist of one representative from each Member State in a given zone. A notifier should contact the Steering Committee at least 6 months prior to an intended submission of application and provide information on the formulations and the

intended uses in the different Member States to be supported. The notifier should also designate the zonal Rapporteur Member State of his choice. Subsequently a pre-evaluation meeting should be arranged between the zonal Rapporteur and the notifier identifying the critical GAP and thus the risk envelope. The risk envelope might differ according to the different areas of evaluation, i.e. toxicology, fate, and ecotoxicology.

For the time being, the dossier format for submission should be in line with the guidance document on the presentation and evaluation of dossiers according to Annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (SANCO/6895/2009 rev. 1). However, it was clearly stated that this format is considered inadequate and modifications to the format will soon be made.

The Rapporteur Member State will evaluate the dossier in close cooperation with the applicant and finally provide a draft registration report for all of the members of the zone. The zonal Member States will then have the possibility to comment on the draft registration report prior to its finalization by the Rapporteur Member State. The applicant has a total of only 6 months to provide additional information or data if data gaps should be identified. It was stated that this restricted timeframe could entail the rejection of applications should larger data requirements be identified during an evaluation. After finalization of the draft registration report the individual Member States have then 120 days for their national evaluations and subsequent registrations of the respective national plant protection products.

Uses in glasshouses, post-harvest uses, empty storage halls and seed treatment uses are exempt from the zonal evaluation procedure. In these cases applications for the entire EU can be filed. Comments made by other Rapporteur Member States should be included into the evaluation. As of now it is not clear who will review and possibly assess the comments made by the different Member States during the commenting period.

Austria, being a Rapporteur Member State which has participated in several zonal evaluation pilot projects, has included in its zonal evaluation Annex II confirmatory data and intends to also include efficacy data as much as possible in the core evaluation. With respect to residue data, Slovenia and Romania are currently being considered belonging to the southern zone, although Regulation (EC) No 1107/2009 assigns those two Member States to the central zone. Austria indicated that a new guidance document is intended for

March 2010 where Slovenia and Romania will also be included into the central zone for the evaluation of residues.

## **BVL Workshop on the electronic application for the registration of plant protection products in Germany**

Mr. Bruno (BVL) indicated at the beginning of the workshop that there was a very clear increase in the number of electronically registered applications in Germany. In 2006 and 2007, ca. 11 % of the total number of applications were submitted to the BVL in electronic form; in 2008 and 2009 this number went up to 24 % and in 2010 currently 19 applications have been filed in total, 47 % of which were electronic.

Ms. Gall (BASF) presented the company software AIDA, which provides the possibility to fill in the BVL application form offline. The program also provides an XML-scheme for the structure of the application form on the online portal of the BVL. To be able to fill in the application form, an XML-editor would be needed. BASF and BVL are currently in discussion how AIDA could be made available for other applicants.

Ms. Busch (BVL) guided the workshop through the online application which is available on the BVL portal. The access to the portal is password protected (individual password instead of a company related password). The BVL will check whether this could be changed. It was also indicated that a limited number of individual studies could be submitted to the BVL via the portal for post submissions. In any case, an appropriate online form has to be filled in. In the case of efficacy studies it is possible to combine studies belonging to a single application and provide them to the BVL in this combined form.

BVL will accept the dRR dossier format starting in October 2010. Mr. Bruno indicated that the BVL will insist in any case on the submission of an overall reference list in the format required by the BVL. The BVL will publish guidance how the dRR dossier will fit into the CADDY format.

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



## ***BIOCIDES***

### **New draft guidance documents released for consultation**

Since the beginning of this year, the Commission has published four new draft guidance documents for biocides. Two of them deal with the assessment of biocidal active substances, the other two draft guidance documents focus on product authorization. Generally speaking, after having been endorsed at a Competent Authority meeting (CA meeting), new draft guidance documents for biocides are published on the Commission DG Environment website and released for a consultation period before being finalized based on the comments received.

A draft guidance note on **leaching rate estimations** for substances used in biocidal products in product types 7 (film preservatives), 9 (fiber, leather, rubber and polymerized materials preservatives) and 10 (masonry preservatives) was endorsed during the 36<sup>th</sup> CA meeting and released for a 3-month consultation period. Many applicants are concerned that, unlike for wood preservatives or antifouling paints, there are no harmonized methods for estimating the leaching from materials which are treated with PT 7, 9 and 10 biocidal products. The draft guidance proposes harmonized approaches for each of the three PTs. The draft guidance can be downloaded from the EU website: [http://ec.europa.eu/environment/biocides/pdf/Guidance\\_document\\_leaching\\_rate.pdf](http://ec.europa.eu/environment/biocides/pdf/Guidance_document_leaching_rate.pdf). Deadline for comments is 15 July 2010.

The experience gained so far in the review program for existing biocidal active substances shows that different approaches were used and some inconsistencies resulted with respect to the evaluation of the biocidal **efficacy**. Often, the detailed evaluation of the efficacy of a biocidal active substance is in fact deferred to the product authorization stage. In a new draft guidance document on the role of efficacy in the evaluation of active substances for Annex I inclusion, the Commission proposes a common approach for the evaluation of efficacy in both the active substance and

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the product authorization procedures. The paper was endorsed at the 36<sup>th</sup> CA meeting and can also be downloaded the EU website: [http://ec.europa.eu/environment/biocides/pdf/Role\\_of\\_Efficacy\\_BPD\\_Process.pdf](http://ec.europa.eu/environment/biocides/pdf/Role_of_Efficacy_BPD_Process.pdf). The deadline for comments is 15 July 2010.

A harmonized standard **application form** for the authorization of biocidal products is now available. After longer discussions in the Product Authorization and Mutual Recognition Facilitation Group (PA&MRFG), this document was finally endorsed during the 35<sup>th</sup> CA meeting published for a 6-month consultation period of stakeholders. The draft application form is available at [http://ec.europa.eu/environment/biocides/pdf/application\\_form\\_public%20consultation.pdf](http://ec.europa.eu/environment/biocides/pdf/application_form_public%20consultation.pdf). All comments should be sent to the Commission by 30 June 2010.

**Frame formulations** under Directive 98/8/EC have been discussed intensively and controversially. Based on a paper drafted by the UK competent authority and after short discussions in PA&MRFG under the Swedish presidency, a new draft note for guidance on frame formulations was endorsed during the 36<sup>th</sup> CA meeting and released for a 6-month consultation period. The paper tries to provide provisional pragmatic solutions for the first product authorization dossiers that have to be submitted under the inadequate provisions on frame formulations in the current EU biocides legislation. The paper is available under <http://ec.europa.eu/environment/biocides/pdf/Frame%20formulation.pdf>. Comments to the draft guidance can be made by 30 September 2010.

## News from the R4BP

The Commission announced that a R4BP (Register for Biocidal Products) industry interface is now available in all official EU languages. By using the R4BP, it will be possible to generate and print the harmonized application forms in all official EU languages.

Furthermore, a test version of the R4BP is now available on-line, which can be used for purposes of getting started with R4BP. This is of particular importance, as the Commission has decided first to invest in the development of the functionalities of the R4BP database and wait with the publication of a user manual until the system is properly running.

The present version of the R4BP is considered to be a non-legally-binding electronic tool to facilitate communication between applicants and authorities, and to help Member States with their different reporting obligations. However, it should be kept in mind that based on today's R4BP, a *Community Register for Biocidal Products* will be established as an official database which has to be used by industry and authorities once the new biocides legislation comes into force.

For passwords to test R4BP, as well as for further information regarding biocidal products in general, contact Dr. Hans-Josef Leusch ([hans-josef.leusch@scc-gmbh.de](mailto:hans-josef.leusch@scc-gmbh.de)) or Dr. Holger Zitt ([holger.zitt@scc-gmbh.de](mailto:holger.zitt@scc-gmbh.de)).

## Your feedback is important to us!

The SCC Newsletter strives to provide its readers with the latest information regarding regulatory affairs in the areas of agrochemicals, biocides, chemicals, REACH, feed and food additives, and regulatory science. However, without your feedback, we can't know if we are providing YOU with the information you need.

Tell us how we're doing. Please take 5 minutes and send us a mail. Tell us what we're doing right (or wrong) and what information you find important or would like to see more of.

Our e-mail address: [newsletter@scc-gmbh.de](mailto:newsletter@scc-gmbh.de)

**THANK YOU!**



## REACH *in practice*

### REACH-IT updated

The new REACH-IT version 2.0 became available on 25 March 2010.

Compared to the former version there are some updates and changes: for instance REACH-IT 2.0 accepts dossiers created in IUCLID 5.2 format only. In this context, the updated version of the Technical Completeness Check Tool for IUCLID 5.2 is also available; however, a further revision is expected to correct problems in the current version. In addition, invoices will only be provided electronically via REACH-IT, i.e. hardcopies will no longer be sent out, requiring continuous check of REACH-IT, as the time lines to pay the invoices are very stringent.

With this update several guidance manuals were revised or released for the first time, such as the Industrial User Manual Part 17 on information about Legal Entity Change, Industrial User Manual Part 15 managing groups of manufacturers or importers, as well as the Data Submission Manual Part 12 on the preparation and submission of a classification and labelling notification using IUCLID.

ECHA NEWS Alert, ECHA/NA/10/12, dated 25 March 2010 (available at ECHA Homepage via the "News" section) provides a short survey of the updated information and contains all important links to the relevant documents.

### IUCLID 5.2 and the new TCC-tool

The new IUCLID 5.2 became available in mid-February 2010. In this updated version of IUCLID, importing of files from IUCLID 5.1 is possible; however, it is no longer possible to import data from IUCLID 4. Once data are imported into IUCLID 5.2, some sections have to be reviewed because of partial or complete changes or due to an incomplete import (e.g. EC name and CAS number of the reference substance are not imported).

In the new IUCLID 5.2, several sections were shifted to other sections (e.g. section 3.5 "estimated quantities"), new entry fields were added (e.g. "public name" in section 1.1 Identification). Furthermore, some existing entry fields were renamed.

The endpoint study records do not exhibit remarkable differences when compared to the previous version. However, the endpoint summary templates include various modifications, e.g. pick-lists instead of entry fields and a different structure of format masks (which may make the comparison and the review of a substance file more difficult). Furthermore, instead of one fixed unit, it is now possible to choose between different units of the endpoints.

The Technical Completeness Check (TCC) tool for IUCLID 5.2 is also available now, but there are some problems with it. Some inserted data in the same section are not spotted. Thus, the dossier does not pass the TCC although the information is provided.

According to a statement made by ECHA at the Lead Registrant Webinar held on 26 March 2010, a first release of the Chemical Safety Assessment and Reporting Tool (Chesar) was scheduled for the end of April 2010, containing all functionalities to prepare a "standard" CSA (except assessment for waste life stage). A second release is scheduled for June 2010. Many companies have decided not to immediately switch to IUCLID 5.2 for dossier preparation before the up-dated CSR tool is available and working properly.



## CHEMICALS, REACH, CONSUMER PRODUCTS

### Classification and Labelling Notification

Companies have to notify all hazardous substances to ECHA at the latest by 3 January 2011 (or within one month after placing on the market) in order to be included in the Classification and Labelling inventory. It is important to keep in mind that all hazardous substances have to be notified, including phase-in substances with a deadline of 2013 or 2018, as well as substances not subject to REACH (e.g. which do not reach the tonnage threshold of 1 ton per year or hazardous polymers).

According to Article 8 of Regulation (EC) No 1272/2008 (the CLP Regulation) companies do not have to generate new data for toxicological and ecotoxicological endpoints. However, the situation is different if no adequate information is available to assess the physical-chemical hazards of a substance; in this case new data have to be generated.

In principle, there will be two ways to technically notify substances via REACH-IT at ECHA: The first possibility is to prepare a IUCLID5 dossier for the C&L notification. About 200 fields in the IUCLID5 sections 1.1, 1.2, 1.4 and 2.1 have to be filled in (see data submission manual 12, [http://echa.europa.eu/doc/reachit/data\\_submission\\_manual\\_12\\_c&l.pdf](http://echa.europa.eu/doc/reachit/data_submission_manual_12_c&l.pdf)). The second option is to upload the C&L notification by bulk upload with an xml-file comparable to the pre-registration process.

### Global Regulatory Developments for Chemicals

While the European Commission and the European Chemicals Agency are busy updating the REACH legislation (e.g. Annex V) and guidance documents for registration (e.g. Information requirements and chemical safety assessment), regulatory legislation for chemical substances are also being developed in other regions of the world. Some countries have recently implemented

new laws and regulations, other countries have strengthened their existing legislation. The following gives a short overview of most relevant regulatory developments throughout the world. Please do not hesitate to contact us, should you require assistance with your global registration requirements.

**Japan** - The Chemical Substances Control Law (CSCL, Law 117 of 1973) was last amended in May 2009, with first implementation on 1 April 2010. With this, yearly volume tracking for all CSCL chemicals manufactured and imported is required, non-persistent chemicals were included in CSCL regulation, an exemption rule for polymers of low concern was introduced, communication of hazard information in the supply chain is obligatory, new chemicals were included on the Class I list, and further obligations for Class I and II chemicals were added. In May 2010 more products will be added to the list of prohibited products. Further implementations are foreseen for October 2010 and April 2011.

**China** - In May 2009 a draft amendment to the New Chemical Substance Environmental Management Method of 2003 was issued, set for implementation in October 2010. Changes to existing regulations include applications for R&D substances < 100 kg/year, Simplified Notifications for certain types of chemicals and polymers, volume triggered General Notification requirements with accompanying risk assessment requirements and risk classification, formal procedures for inventory listing as well as changes to handling of confidential business information. However, details to the amendment are still under discussion/modification and close watch is needed to remain fully compliant.

**Malaysia** - The voluntary Environmentally Hazardous Substances (EHS) notification and registration system was extended throughout 2010. This will become mandatory upon enactment of the regulation after 2010. Under this system notification is promoted for substances included on the EHS reference list, based on Annex I of the European Dangerous Substances Directive 67/548/EEC and known CMRs, or classified as hazardous according to the Malaysian GHS system. Note that not only domestic, but also overseas companies may register.

**Taiwan** - The setup of an existing chemical substances inventory is ongoing. Substances manufactured or imported between 1993 and the end of 2010 are eligible for inclusion. The deadline for nomination is 31 December 2010, but nomination and inclusion of

qualified substances at a later point in time may remain possible. Not only domestic manufacturers and importers, but also overseas companies can nominate substances. Following the publication of the list of existing chemicals in 2011, a new chemicals substance notification system will be implemented for substances not qualified and listed as existing chemicals. Thus, having evidence for import before the end of 2010 can be highly advantageous.

**Canada** – The first phase of the Domestic Substances List Inventory Update (DSL IU) was published in October 2009, in an effort to prioritize risk assessment and chemical risk management activities. The mandatory notice aimed to collect additional information on approximately 500 substances manufactured or imported in volumes of 100 kg or more in 2008, as such, in preparations, or in articles. Note that even if a company did not meet the notification requirements, information on uses for consideration in risk assessments can be submitted. The Schedule 1 deadline was 30 March 2010; however, re-submission is still possible.

**Turkey** – The 1983 Environmental Law (Law no. 2872) and 2003 Law on Establishment and Duties of Ministry of Environment and Forestry (Law no. 4856) were updated by a by-law in 2008. The new regulation aims to create an existing chemicals inventory. Reporting requirements apply to manufacturers and importers of substances as such and in preparations in volumes of  $\geq 1$  and  $< 1000$  t/year and  $> 1000$  t/year, within the preceding three years. Trustees may submit information on behalf of Turkish importers. The deadline for submission has recently been extended to 21 March 2011.

**Switzerland** – The revised version of the Swiss Chemicals Ordinance (ChemO, RS 813.11) came into force on 1 February 2009. With this, Switzerland adopted many REACH-like registration requirements for non-EINECS substances placed on the market in volumes of  $\geq 1$  t/year. As under REACH, new substance notification requirements are driven by volumes manufactured and imported. Notably, in the case of import total, volumes manufactured in the European Economic Community (EEC) are relevant, of which only a part may be imported into Switzerland. Differences to REACH remain especially with respect to polymers and intermediates.

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



## **FEED & FOOD ADDITIVES, VETERINARY MEDICINE**

### **Important deadlines for 2010!**

This year marks the very important deadline for the re-authorization of feed additives: 7 November 2010 (**Regulation (EC) No 1831/2003**). Since this is a Sunday, the European Commission has extended the deadline for one day to 8 November 2010. Nevertheless, in order to allow the CRL to have enough time for the administrative process of handling the samples, the methods of analysis and the collection of fees, the deadline in practice will be at the end of September! This means that there are only about five months left to finalize all application dossiers for re-authorization! SCC is working on several dozen dossiers simultaneously to assist the industry in meeting this target.

However, since the world does not end with this deadline, SCC is working on long-term co-operations with companies from all over the world who want to register completely new additives (feed and food) and veterinary medicinal products on the European market. SCC attended the VIV Europe 2010 in Utrecht (NL) and had very interesting and successful meetings with several companies.

The new **Regulation (EC) No 767/2009** on the placing on the market and use of feed, and especially the consequences on claims, labelling, controls and monitoring, are aspects that give rise to profound discussions with the European Commission and individual Member States. SCC is playing an active role in this process, which includes the establishment of a Community Catalogue for feed material and the process for the update of the list of feed intended for particular nutritional purposes (also called dietetic complementary feed). For the latter, application dossiers have to be prepared. Time is very short for those substances already listed in the annex of Directive 2008/38/EC, because their (re)application dossier has to be submitted to the EC before 1 September 2010!

For more information regarding these topics, contact Ruud Huibers at [ruud.huibers@scc-gmbh.de](mailto:ruud.huibers@scc-gmbh.de).



## REGULATORY SCIENCE

### EFSA Workshop PROTEA – Pesticide Emissions from Protected Crop Systems

In November 2009 EFSA organized a workshop to inform about the development of a new Guidance Document on Pesticide Emissions from Protected Crop Systems as announced in our last newsletter. The final report of the workshop is available (<http://www.efsa.europa.eu/cs/Satellite>).

For the development of this new Guidance Document, the crop systems were classified on the one hand into different structures of protection while on the other hand emission types were identified. The ongoing procedure is to cluster combinations of construction type, application type, cultivation system, receptor and emission type in order to reduce the number of possible scenarios that should be considered.

A special workgroup to follow up the Guidance Document on protected crop systems is foreseen to develop scenarios for the risk assessments. The workgroup will deal exclusively with the identification of relevant protected crop systems over Europe and their emissions.

For the Guidance Document on emissions from protected crop systems, one opinion was scheduled for adoption in March and another opinion in autumn 2010.

Furthermore, an inventory of protected crop systems was prepared, which is split into 3 zones (North-Western, Southern and Eastern part of the EU). For the Southern and Eastern zone the reports can be downloaded from the EFSA website (same link as above). The data collection on protected crop systems in the North-Western zone is in the reporting phase and it is expected that it will soon be published on the EFSA website.

Finally, in mid-April EFSA published the PPR panel opinion on the outline for another new guidance on emissions of plant protection products from greenhouses and crops grown under cover. The document is available on the EFSA website (see link above).

### EFSA Scientific Opinion on Preparation of a Guidance Document on Pesticides: Exposure Assessment for Workers, Operators, Bystanders and Residents

Based on the draft opinion (2008) of the EFSA Panel on plant protection products and their residues (PPR), which was available for public consultation in August 2009, in January 2010 (EFSA Journal 2010; 8(2):1501), the Panel set out a draft Guidance document on pesticide exposure assessment for workers, operators, bystanders and residents for use in regulatory risk assessment of plant protection products within the Appendix of the Scientific Opinion. The document can be downloaded under: <http://www.efsa.europa.eu/en/efsajournal/scdoc/1501.htm>.

The PPR Panel recommends that a new guidance document on human health exposure assessment should be adopted for a harmonized risk assessment to determine eligibility of plant protection products for inclusion in Annex 1 of Council Directive 91/414/EEC, which will be replaced by the new Regulation 1107/2009. In order to finalize the Guidance Document rapidly, EFSA has asked the Commission to give a timely response to the opinion. Meanwhile, further guidance on dermal absorption is under development and, as a follow-up, further guidance on the derivation of the reference value for the proposed additional acute risk assessment for plant protection products (PPPs) will be developed.

The risk assessment for individual PPPs should continue to use deterministic methods in a tiered approach. However, several renewals, add-ons and default assumptions are defined which increase the level of protection:

Where PPPs are acutely toxic, an additional acute risk assessment for operators, workers and bystanders should be carried out comparing estimated potential exposures with a separate toxicological reference value, an “acute acceptable operator exposure level” (AAOEL).

Estimates of potential exposure for acute risk assessment should then be based on the 95<sup>th</sup> percentiles of the relevant exposure distribution, whereas the 75<sup>th</sup> percentile should be considered for assessment of potential longer term exposures of workers, operators and residents. It is mentioned that long-term risk assessment of bystanders is covered by the long-term resident risk assessment.

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Parametric estimates of relevant percentiles should be derived with a default assumption that measured exposures come from a log-normal distribution. The estimated potential exposure for the risk assessment should be taken as the higher of the relevant percentile of measured exposures and the corresponding parametric estimate.

The available operator exposure model data for estimating exposures in different scenarios was reviewed and the most robust model for a given scenario was determined. In general, the estimated exposures from defined work tasks are assumed to depend on the amount of active substance handled in the tasks.

In a Tier 1 assessment it is assumed that an operator wears only shorts and T-shirt. The total dermal and inhalation exposure is divided by a standard body weight of 60 kg and then compared with the AOEL or AAOEL as appropriate. It is proposed to establish a spreadsheet together with the revised draft of the Guidance document and to provide the background data within a separate report.

Worker exposure estimation for scenarios entailing exposure to soil-borne residues (e.g. harvesting leeks, weeding in a leafy crop, compost treatment, harvesting root crops) should include any exposure through soil contact. In line with operators, the standard working clothes are defined as shorts and T-shirt. The dermal absorption figure should be the higher of the values for the product and for the in-use dilution. First tier inhalation exposure assessment for worker re-entry is adopted from EUROPOEM II.

Personal protective equipment (PPE) and engineering/technical controls are specified with protection factors further harmonizing the risk assessment, e.g. 90 % and 80 % reduction by coveralls for operators and workers, respectively, and 10 % of exposure for air-assisted application with closed cab with positive air pressure and functioning filtration units.

A comprehensive bystander/resident exposure assessment should be performed which is a combination of the current UK and German approach, i.e. spray drift, vapor, surface deposits for children, and entry into treated crops. The potential for residential exposure through consumption of home-grown fruit and vegetables that have been contaminated by spray drift from neighboring land is not included yet due to lacking data.

Beside the recommendation of summing up exposure through all pathways, it should also be noted that Rautmann drift data for field crops, small vegetables, ornamentals and fruits were increased by the factor of 10 for conservative reasons. Also, exposure calculation for children of various ages (i.e. < 1, 1 to < 3, 3 to < 6, 6 to < 11, and 11 to < 16 years) according to their respective body weights, inhalation rates and transfer coefficients is foreseen.

Because the available data on exposures for some scenarios are particularly limited, EFSA pointed out the need for further research to improve the knowledge base. Especially worker exposure, i.e. transfer coefficients, DFR values, crop inspection and post-harvest scenarios, and several uncommon operator scenarios are the focus of further research. Other gaps in knowledge are being addressed in work that is already ongoing like exposure of residents to vapors. The proposed Guidance Document is intended to be reviewed periodically, and will be revised when new appropriate data become available. Thus, the Guidance document can be assumed to be updated for inhalation exposure assessment to vapor as soon as data from the ongoing UK BREAM study is available.

Although the PPR Panel has aimed for a level of precaution similar to or slightly greater than that currently applied, it can be concluded that the level of precaution in risk assessment for worker, operator, bystanders and residents will increase. Thus, an impact on the placing of plant protection products on the market can be expected in the light of the proposed revision of the Guidance Document.



## Data requirements for human health and ecotoxicology under the new Regulation (EC) No 1107/2009

### Data requirements for human health

At the Conference “Registration of Agrochemicals in Europe” in Brussels, 20-23 April 2010, Dr. Vleminckx presented the status of the recent discussion on data requirements for human health under Directive 91/414/EEC. The basis for her presentation was SANCO/10482/2006 rev 13 (21/01/2010), which was updated following an expert meeting of 25/11/2009 organized by DG SANCO.

The following summarizes the new aspects in data requirements.

ADME data for the active substance and/or its metabolite(s) in relevant species are necessary. For the extrapolation of animal data to humans, information on interspecies differences is essential. Thus, comparative *in vitro* metabolism studies on animal species used in pivotal studies and on human material (e.g. microsomes or intact cells). In addition, blood and tissue concentrations of the active substance and/or relevant metabolites should be generated in the context of short- and long-term studies in relevant species.

The acute dermal testing can be waived in case the LD50 (oral) is > 300 mg/kg bw and dermal absorption is < 10 %. Skin irritation will be tested in a tiered approach starting with an assessment of dermal corrosivity *in vitro*, assessment of dermal irritation *in vitro*, initial *in vivo* dermal irritation study using 1 animal, and finally, a confirmatory test using 1 or 2 additional animals. Also a tiered approach is followed to investigate the eye irritation, i.e. *in vitro* dermal irritation/corrosion test to predict eye irritation/corrosion, validated or accepted *in vitro* eye irritation study, initial *in vivo* eye irritation study using 1 animal and confirmatory testing using 1 or 2 additional animals. The skin sensitization properties will be investigated in the local lymph node assay (LLNA) in mice or if LLNA can not be conducted the Guinea Pig Maximization test should be used.

The phototoxicity needs to be tested where the active substance absorbs electromagnetic radiation in the range

of 290-700 nm and is liable to reach the eyes or light-exposed areas of skin (no testing may be necessary if molar extinction/absorption coefficient of the a.s. is < 10 L mol<sup>-1</sup> cm<sup>-1</sup>).

OECD 407 (28-day toxicity in rodents) is currently being updated to address neurotoxicity and immunotoxicity aspects as well as effects potentially related to changes in the hormonal system. The former requirement for a 1-year study in dogs has been omitted because no significant additional information was delivered from these studies compared to the 90-day study in dogs.

Concerning long term and carcinogenicity testing it was discussed whether the carcinogenicity study in mice is necessary. The majority of experts are of the opinion that the study in the second species is required.

To investigate adverse effects on the reproduction (impairment of male and female reproductive functions and capacity, induction of harmful effects on progeny), two generation reproduction toxicity studies or F1 extended one generation studies (according to the new test guideline including the investigation of immunotoxicity in offspring and developmental neurotoxicity aspects which is under preparation) will be conducted. Supplementary investigations may be necessary to obtain information on the affected gender and possible mechanism(s).

For substances with structures similar or related to those capable of inducing neurotoxicity or which induce specific indications of potential neurotoxicity, neurological signs or neuropathological lesions in toxicity studies, neurotoxicity studies in rodents need to be conducted with single and repeated administration.

The acute toxicity, irritation and sensitization with formulated products are only required if the applicant cannot justify that Directive 99/45/EC can be invoked. The risk assessment requirements will include the necessity to estimate the exposure of residents.

In the light of the new regulation (Reg. (EC) No 1107/2009) the following aspects will have to be addressed as well: the definition of human health hazard criteria in relation to endocrine disruption, investigation of synergists and safeners, and consideration of scientific peer-reviewed open literature.



## Data requirements for ecotoxicology

Also during the Registration of Agrochemicals conference, the forthcoming requirements for ecotoxicology and risk assessment under Regulation (EC) No 1107/2009 currently under discussion were presented by Mick Hamer (Syngenta).

The guidance document concerning risk assessments for birds and mammals has been finalized, while the terrestrial and aquatic guidance documents are currently being updated. A workshop discussing protection goals was held in April 2010.

The proposed new data requirements may reduce the need to test both formulation and active substance at the EU level, whereas testing is required for metabolites dependant on exposure in relevant environmental compartments. Testing of primary metabolites may suffice if no toxicity/activity is shown.

The need to ensure protection of all species leads to demands for increasing data requirements. Regarding testing of reptiles and amphibians, the industry holds the view that these organisms should be covered by testing in birds, mammals and fish. Contrary to the EU requirements, the US does not focus on testing of soil-related organisms, as it is an accepted opinion that the soil has to be adequate to generate the food and is thus not considered as an "ecological entity".

Tier 1 testing of mammals for ecotoxicological assessments is limited to the rat as representative small wild mammal. Regarding bird studies, passerine species are often more sensitive than the Mallard duck, which is faced in the US EPA requirements. The short term dietary LC<sub>50</sub> study in birds is no longer adhered to. The higher tier assessment moves towards toxicokinetic

approaches (e.g. Pirimicarb approach) and will also be based not only on non-invasive testing, such as the determination of focal species and radio-tracking due to animal welfare, but also on determination of diets.

The requirements for aquatic organisms will be changed to the effect that the ELS replaces the juvenile growth test. Besides *Daphnia magna*, insecticides will have to be tested in an additional insect species. The endpoint derived from algae or aquatic plant studies should be the NOEC rather than the EC<sub>50</sub>. The investigation of effects in higher tier studies should be linked to exposure regimes in accordance with the course of concentrations and dissipation as modelled with FOCUS (ELINK workshop).

While the bee brood test was previously required for IGR, it will most likely be a general requirement under 1107/2009. In addition, guidance will be developed for systemic compounds and in higher tier tests for bees (semi-field, tunnel, field) investigations on residues and behaviour will be important information. Requirements for NTA assessment were recently discussed in the Escort 3 workshop, the results of which will be published in near future.

Concerning the soil compartment, the acute test in earthworms will be dropped and the chronic test over 56 days will become a core data requirement. The focus should be on structural (effects on populations of soil organisms) rather than on functional endpoints, which would make the litterbag test obsolete.

As long as data requirements and guidance documents are under review, one should make use of output from workshops and EFSA opinions.

For further information please contact Dr. Monika Hofer ([monika.hofer@scc-gmbh.de](mailto:monika.hofer@scc-gmbh.de)).

# Newsletter

Volume 10, No. 2, May 2010



## CALENDAR

### **ECHA's Fourth Stakeholders' Day – 19 May 2010, Helsinki, FI**

This regular event contributes to the constructive dialogue between ECHA and its stakeholders and their representatives and includes such issues as tips and tools for registration and C&L notification, and feedback from ECHA. Dr. Werner Köhl will be at this informative conference.

### **12th International Fresenius Conference: Behaviour of Pesticides in Air, Soil and Water – 21-22 June 2010, Mainz, DE**

Dr. Birgit Eickler and Erik Geibel will attend this two-day conference, where the topics include an update on Regulation (EC) No 1107/2009, MS experience with exposure assessment for national authorizations, issues in environmental fate, exposure and risk assessment, and much more.

### **Symposium on Authorisation/Registration of Biocidal Products – 23-24 June 2010, Vienna, AT**

Dr. Martina Galler and Dr. Holger Zitt will attend this two-day symposium which systematically focuses on the authorization/registration procedures of biocides, along with extensive Q&A and networking opportunities.

### **SETAC Europe Annual Meeting – 23-27 May 2010, Seville, ES**

The SETAC Europe Annual Meeting is Europe's biggest meeting on environmental toxicology and chemistry with more than 1500 presentations in parallel platform sessions and poster sessions, participants and scientific speakers from academia, business and government and a blend of scientists and practitioners, researchers and regulators all in attendance. Dr. Christine Klein and Dr. Gertraud Wirzinger will attend from SCC.

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