



2010: Changes and New Challenges

The end of a decade is always a good opportunity to make a short break and take a look back on what has happened before going back to work.

From an overall regulatory point of view, the REACH Regulation is without a doubt the most remarkable milestone of the past ten years having a considerable impact on the chemical industry as a whole. For the SCC Chemicals department, 2010 will be a buzzing year as the first wave of phase-in substances is due for registration under the REACH-regulation by the end of November. In the Chemicals section of this newsletter issue, you can find more information on some important technical issues under REACH such as the upcoming release of the new IUCLID version 5.2.

A regulatory highlight in the area of plant protection was the adoption of a completely revised legislation repealing Directive 91/414/EEC. Last year, we informed you in detail on those developments in two special newsletters. In this issue, we focus on a new regulation on pesticide statistics which came into force on 30 December 2009. This regulation will be applicable to plant protection products from 2010 on; at a later stage its scope will be extended to also cover biocides. Furthermore, we give you an update on the ongoing development of scientific guidance documents and we report from two interesting workshops.

In the Biocides section we comment on the ongoing efforts to set up a workable authorization system for biocides and how

SCC can assist you if you intend to apply for authorization or registration of a biocidal product.

In November 2010, there will be an important regulatory deadline for the re-authorization of feed additives. This and more information on what is going on in the novel food area is summarized the section Feed & Food Additives, Veterinary Medicine.

Last but not least, you can also read more about the further development and refinement of our unique regulatory database EDDMS.

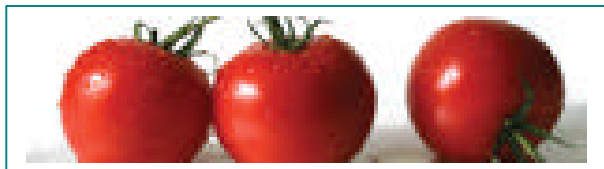
In 2009, SCC celebrated its 20th anniversary. Looking back from our point of view, the past years were years of hard work and stable growth. Our success encourages us to work even harder for our clients and to take care of their regulatory needs.

For now, let me wish you all a healthy, successful and happy new year 2010.

Dr. Friedbert Pistel
President

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AGROCHEMICALS

EC statistics Regulation 1185/2009 aims towards a “significant reduction of the risks and the use of pesticides”

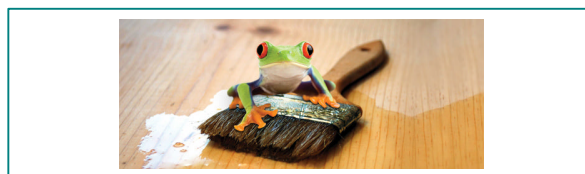
On 30 December 2009 the new Regulation (EC) No 1185/2009 establishing a common framework for the systematic production of Community statistics on the placing on the market and use of pesticides entered into force.

Together with Regulation (EC) No 1107/2009 (which will replace Directive 91/414/EEC) concerning the placing of plant protection products on the market, and Directive 2009/128/EC which establishes a framework for Community action to achieve the sustainable use of pesticides, the new Regulation on pesticide statistics completes the European law package on plant protection products. The new Regulation 1185/2009 will contribute to a significant reduction of risks and the use of pesticides.

The statistics apply to the annual amounts of pesticides placed on the market as well as the annual amounts of pesticides used. The data collection itself is regulated by Article 67 of Regulation 1107/2009, which states that producers, suppliers, distributors, importers and exporters of plant protection products shall keep records of the plant protection products they place on the market. Furthermore it is stipulated that professional users of plant protection products are to keep records of the plant protection products they use. Those records shall contain the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used. Data concerning the use of pesticides will be collected

and evaluated by the Member States from 2010 onwards; the first reference period for the statistics on the placing on the market of pesticides will be 2011 (similar procedures are already in place in Germany and Austria). Results of the data collection are to be transmitted to the Commission for further decisions. As a “Regulation”, the new law is binding for the Member States without them having to enact domestic legislation.

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



BIOCIDES

Looking back – Review of biocidal active substances

To people involved in regulatory affairs of biocides, the past decade must have been like years of pioneer work trying to find their way on terra incognita. The reason is the Biocidal Products Directive 98/8/EC, a piece of legislation comprising some 60 pages aimed at introducing a harmonized pre-marketing authorization system for the diverse bunch of non-agricultural pesticides not yet covered by the EU legislation 91/414/EEC.

For both the competent authorities and the producers of biocides, it certainly would have been challenging enough to get along in this new regulatory regime if the Directive had only focused on product authorization. In fact, the Directive additionally foresees that a review program on existing active substances has to be

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completed before the phase of product evaluation begins.

The teething problems of the regulatory system for biocides occurring over the last ten years coincided with the review program, and it seems that this legislation is still going through its growing pains. The review program on existing actives has just been prolonged for another four years, which reminds us of similar developments in the field of EU plant protection regulations.

Today, many experts involved in biocides seem to hope for a turning point in the form of the revised biocides legislation. After lengthy interservice consultations, the Commission published the draft of a Biocidal Products Regulation in summer last year. The proposal and selected important elements of the draft (e.g. the Community authorization) were welcomed by the Member States on occasion of a policy debate held at the Environment Council on 22 December 2009.

Looking back with a positive attitude, you could say that things can only get better.

Looking ahead – Product authorization

In the meantime, about thirty actives have made it to Annexes I and IA of the Directive, and there is still a steep way to go in the final stage of the extended biocides review program. With each existing active substance entering Annex I, the next wave of dossiers for biocidal products comes in. This wave looks like a tsunami, however, when one keeps in mind that an estimated number of ca. 50,000 existing biocidal products are currently placed on the market in the European Union.

Even if not all of these products are supported with a dossier, the evaluation will be a huge task for the competent authorities. This is complicated by the fact that there are different views on both sides – authorities and industry – as to what exactly is needed for a complete product dossier. Not only that there are different views among the Member States themselves with regard to the detailed dossier requirements. From the point of view of a consultant, you could say that things will be more complicated than was anticipated by the industry.

The biocides industry will have to carefully consider how full compliance with the complex legislation can be established in the most efficient way. In this special case, efficiency does not mean preparing a “cheap dossier” that will fail and ultimately lead to a market loss. In fact, regulatory efficiency will mean obtaining authorizations as quickly and as cost-effectively as possible, keeping potential additional data requirements by the authorities to a minimum.

Only very rarely will the preparation of biocidal products dossiers be possible without refining existing exposure and risk assessments or even performing new ones. In this field, SCC has established routine procedures, so that assessments can be done in a fast and cost-effective way. Of course, we are also prepared to prepare a full product dossier for you.

For more information, contact Dr. Hans-Josef Leusch (hans-josef.leusch@scc-gmbh.de) or Dr. Holger Zitt (holger.zitt@scc-gmbh.de).



CHEMICALS, REACH, CONSUMER PRODUCTS

Lead Registrant Issues

In general, one Lead Registrant will be appointed by the SIEF members who will take care for the joint submission dossier. As the role and obligations of the Lead Registrant are defined by the REACH Regulation, the appointment of a Lead Registrant is mandatory for each SIEF and will not automatically be designated to the SIEF Formation Facilitator. Instead, each Lead Registrant has to be elected by the SIEF members and ECHA has to be informed about the nomination using a specific form available via the ECHA homepage (<https://comments.echa.europa.eu/Comments/LeadRegistrantNomination.aspx>).

As already communicated by ECHA in December 2009, a separate Lead Registrant Information Box is under preparation in REACH-IT; there are some initial problems which are only of technical nature. The Information Box is intended to facilitate the communication between the Lead Registrant and the SIEF members including late pre-registrants. In addition, ECHA offers specific information and access to specific workshops dedicated to nominated and “registered” Lead Registrants.

Release of IUCLID 5.2

In its newsletter dated November/December 2009, ECHA announced that a new version of IUCLID is going to be released in February 2010 (see also <http://iuclid.echa.europa.eu/index.php?fuseaction=home.news&type=public&id=27>). Numerous OECD harmonized templates were amended and enhanced, resulting in more than one hundred changes which have been made for the new IUCLID version 5.2.

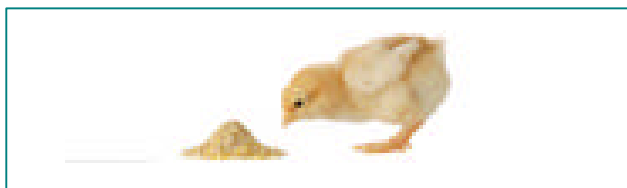
According to recent guidance from the ECHA helpdesk, only the new IUCLID 5.2 will be compatible with REACH-IT 2.0, which is planned to be released shortly after the IUCLID update in March 2010. Thus, it will be only possible to submit dossiers created in IUCLID 5.1.1. until the new REACH-IT is released.

The Technical Completeness Check (TCC) made available in December 2009, will be updated accordingly to work with the new IUCLID 5.2 format.

Obviously, all dossiers that will be submitted in the future under REACH-IT 2.0 must be in accordance with the new IUCLID 5.2 format and the respective update of the TCC tool.

As a consequence, dossiers that are currently under preparation in IUCLID 5.1.1 have to be revised and modified to IUCLID 5.2 if they are to be submitted later than March 2010. This is seen as an additional burden on the industry.

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



FEED & FOOD ADDITIVES, VETERINARY MEDICINE

The year 2010 has one very important deadline for the world of **feed additives**: 7 November. By this date, all application dossiers for re-authorization of feed additives (according to Article 10 of Regulation (EC) No 1831/2003) have to be submitted to the European Commission (DG SANCO) at the latest. Also this article states that additives for which no dossier or incomplete information is supplied, will be withdrawn from the market by means of a separate Regulation. This Regulation foresees a limited grace period during which the product may stay on the market and may be used as a feed additive.

The Community Reference Laboratory for Feed Additives (CRL-FA) even recommends that Declaration Forms (*cf.* Administrative guidance for applicants) related to such applications should be submitted well in advance and in any case before 26 September 2010. This means that this year is shortened by about 3 months!

SCC is intensively working to get all dossiers for our clients ready well ahead of the deadline. Still we can only urge all companies again to come forward as soon as possible with all relevant data to complete the dossiers.

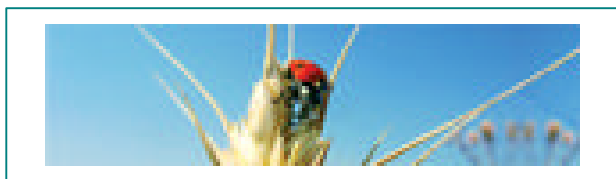
In the Standing Committee on Animal Nutrition, a first discussion took place concerning the implementing measures of Regulation (EC)

No 767/2009. A guideline will be made concerning the borderline between **feed additives** and **feed materials**. Also a discussion took place on the legal implementing act which should be adopted as the first version of the European Union Catalogue of feed materials before the 21 March 2010 in application of Article 24 (2) of Regulation (EC) No 767/2009. SCC will keep in close contact with the responsible persons within the European Commission to stay up-to-date on this issue.

This year a revision of the **novel food** regulation is also expected. SCC attended EFSA's 13th Scientific Colloquium on 'What's new on Novel Foods'. Discussions on the assessment of novel foods focused in particular on the history of safe use of traditional foods from non-EU countries but which would be considered "novel" in the EU, intake assessment, and the toxicology and allergenicity of novel foods. Participants also addressed the issue of nanotechnologies, in particular data requirements for demonstrating the safety of novel foods made using nanotechnologies.

Since most participants were scientists, a strong emphasis was placed on different types of toxicological tests and the lack of data on the safety of foods containing nanoparticles. This means a major load of extra work for the companies that want to register such a novel food! EFSA will open a public consultation before making the final guidelines. SCC will follow this subject closely to be able to inform our clients in the best possible way.

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



REGULATORY SCIENCE

EFSA Workshop PROTEA – Pesticide Emissions from Protected Crop Systems

In November 2009 EFSA held a workshop to inform about the development of a new Guidance Document on Pesticide Emissions from Protected Crop Systems. The aim of the workshop was also to obtain input from the stakeholders on the Guidance Document (GD) and to collect feedback from the stakeholders (Member States' regulatory authorities, industry representatives, consulting companies and others) during the development process.

The relevance of protected crops was shown by the fact that 33 % of the EFSA conclusions were evaluated for a protected or indoor representative use and that for 8 % protected or indoor use was the only representative use. However, there is still a lack of clear definitions and guidance when exposure cannot be excluded. An overview on the developments of the GD was presented with the wish that all stakeholders contribute to the inventory of protected crop systems, which will be split into 3 zones (North-Western, Southern and Eastern part of EU). On the one hand the crop systems were classified into different structures of protection, 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.

In three parallel break-out groups, the following topics were discussed: 1) protected crop structures and risk assessment (RA), 2) ranking emissions and 3) management practices in protected crop systems and innovations. Within group 1, several recommendations were given for the definition of

greenhouse while there were different views on the handling of temporary structures. Furthermore, it was advised to use consistent and harmonized terminology throughout the RA scheme and in other legislation. It was also wished that guidance should be available on MS level. In group 2 it was discussed that exposure to groundwater seems to be not relevant for greenhouses depending on the type of greenhouse. Concerning walk-in-tunnels, plastic shelters and low tunnels, emissions of these structures were regarded to be covered by the field use. With regard to the air, the higher temperatures are likely to increase the emissions to air in walk-in-tunnels and greenhouses. Thus deposition of volatilized substances becomes more important and should be considered. Group 3 discussed the applicability and cost-effectiveness of the management practices. It was also mentioned to consider new developments and alternative crop protection measures.

Overall it was commented that the development of new models should be avoided. Instead, protected crop systems should be implemented into existing models. Up to now there is only the 0.1 % drift approach of the Netherlands that deals with protected crops. However, this value is under discussion. A report about the workshop will be published in spring 2010.

Status within the procedure: the new Guidance Document (GD) is one of 10 GDs which are currently in preparation within the PPR panel/unit. The procedure of updating a GD is the following: Mandate → 1st public consultation & RM (risk manager) questionnaire → Core WG drafting document → Workshop with MS & other stakeholders (current status of PROTEA) → Core WG updates document → 2nd public consultation (expected for the end of 2010) → Meeting with MS → Final draft, PPR Panel adopts opinion → Joint WG with RM → SCFCAH takes note → Publication of final GD. For the GD on protected crop systems a follow up Workgroup (WG) is foreseen to develop scenarios for the risk assessments. For this WG it was mentioned that it



exclusively deals with relevance of emissions to protected structures.

Within this context, the status of the 10 GDs currently in preparation was discussed. Recently, the PPR unit had to transfer some staff to PRAPeR for some months which has consequences for the working plan of GDs: the GD on terrestrial ecotox is scheduled for adoption at the end of 2011; GD on aquatic ecotox which was scheduled for adoption at the end of 2010 will be delayed by 9 to 12 months; the comments of the public consultation on the GD on persistence in soil are published on the EFSA webpage, report of IRIS Workshop are published on the EFSA webpage; for the GD on emission from protected crop systems, one opinion is scheduled for adoption in March and one in autumn 2010. Concerning the GD on FOCUS Groundwater, the work on the opinion on the draft GD is postponed to the beginning of 2011.

EFSA Guidance Document on Risk Assessment for Birds & Mammals

Based on the opinion of the EFSA Panel on plant protection products and their residues (PPR) giving the scientific background for the risk assessment for birds and mammals, the long-awaited revised guidance document was adopted and published in December 2009 (EFSA Guidance Document on Risk Assessment for Birds & Mammals, EFSA Journal 2009; 7(12): 1438). The document and its appendices comprise more than 350 pages and can be downloaded under: <http://www.efsa.europa.eu/en/scdocs/scdoc/1438.htm>.

The Commission recommends that it is acceptable to already apply the new guidance document. It should be applied for all risk assessments submitted as of 1 July 2010 and will be revised in 2012.

Compared to the PPR Panel opinion, the document now available is much clearer, as unmistakable guidance on input parameters is

provided, where previously several options were given.

Some of the new risk assessment approaches introduced within the PPR Panel opinion are maintained in the new guidance document, but there are also some essential changes concerning in particular the long-term assessment for birds and mammals. The 'phase specific approach' has been moved to higher tier as one option for refinement and the 'short-term reproductive exposure scenario' only needs to be calculated if there is evidence for possible reproductive effects after single exposure to the substance of concern.

Taking the geometric mean of toxicity endpoints from different species is still foreseen for the acute exposure scenario except when the endpoint from the most sensitive species is more than a factor of 10 below the geometric mean value. However, for the long-term assessment, the endpoint from the most sensitive species should be taken until further work on applicability of the geometric mean is completed. A short-term risk assessment for birds is no longer necessary. The LD_{50}/m^2 approach, which had been introduced as an alternative assessment scheme for the avian acute risk assessment, is removed.

The tiered approach of the risk assessment for sprayed applications for calculation of the toxicity exposure ratio (TER) has basically been kept. After the optional 'screening step' with worst case exposure assumptions, a second step ('first-tier') with more realistic assumptions follows. For refinements and higher tier assessments, the use of literature data is restricted, so that specifically designed field studies might be necessary in many cases (e.g. for focal species determination).

Similar to the PPR Panel opinion, full risk assessment schemes are given for granular formulations and treated seeds and some approaches are given to assess the risk from substances with endocrine disrupting properties or from metabolites.

Overall, within the new guidance document, many decisions are made so that in comparison to



the PPR Panel opinion, clearer guidance is provided. However, in comparison to the former guidance document, SANCO/4145/2000, the whole risk assessment approach has become much more complex. Although a calculation tool for the first tier assessment has been announced by EFSA for early 2010, especially higher tier assessments will involve considerable effort by the notifiers.

For further information, please contact Dr. Achim Schmitz achim.schmitz@scc-gmbh.de.

Latest news concerning MRL regulation

On 3 December 2009, the UK's CRD (Chemicals Regulation Directorate) presented the latest news concerning the MRL Regulation 396/2005. The following presents important Articles of the MRL regulation:

Article 6 – 11: routine MRL applications needed as MRLs are a prerequisite of authorization and import. The applications are normally assessed by the EMS (Evaluating Member State), except those for import tolerances which are processed by the RMS. The transfer of responsibility is possible but needs to be agreed upon by the applicant, MS and SCFCAH (Standing Committee on the Food Chain and Animal Health). EFSA has focused on these applications and has published 68 reasoned opinions (November 2009). For increased MRLs, SCFCAH could vote directly. However, in case where the MRL is to be reduced, SCFCAH has to be contacted twice.

Article 12(1): review of MRLs for actives included or not included on Annex I of Directive 91/414/EEC since September 2008. The EFSA opinion is due within 1 year of Annex I decision. The RMS is to complete the PROFile and Evaluation Report within 3 months of the decision. 245 actives (November 2009) are awaiting the review; however, no EFSA opinion has been published to date (November 2009). Nevertheless, EFSA has prioritized this work for the actives not included on Annex I including “red track” substances (Jan – Sept 2010). The

review for actives included in Annex I (including voluntarily withdrawn substances) is scheduled for April 2010 – March 2011.

Article 12(2): review of MRLs for actives included on Annex I of Directive 91/414/EEC before September 2008. EFSA's opinion was due by September 2009. No evaluation report is required, only the PROFile details are needed (RMS should have completed by March 2009). 167 actives were already in Annex I by September 2008. By November 2009 EFSA published four opinions. MSs are asked by the Commission to force this work. The outstanding opinions will then be prepared in 2010 and 2011.

Article 35 – emergency measures if MRLs endanger health: In case of danger to human and animal health, the Commission must decide within seven days for fresh produce. This was used for Amitraz (Regulation (EC) No 835 / 2009, November 2009).

Article 43 – EFSA opinions on other issues: Commission or MSs may request an opinion on any risk assessment measure. Commission requests to date include MRLs of concern following Directive 91/414/EEC review of certain actives and nicotine residues in mushrooms. By November 2009 EFSA published 15 opinions.

CRD informed that they cannot authorize a pesticide use that is likely to lead to residue levels above the relevant EU MRL. As CRD's evaluation is only the first stage of establishing the MRLs, the authorization might be significantly delayed while the additional stages on the European level are followed. Therefore, a separate MRL application submitted in advance of the application might be desirable. CRD is able to accept applications for import tolerances for pesticides when UK is the RMS; but they could also support other MSs if they would get permission.

CRD can also evaluate import tolerance applications for pesticides not intended for the European market or for pesticides withdrawn from the European market. Proposals for

exemption of pesticides not already included in Annex IV of Regulation 396/2005 require an MRL application. In case of limited residue data, a reasoned case must be submitted as to consumer safety and the enforcement of the relevant substance.

The application should include, in addition to a covering letter and the application form, a dossier with the relevant data listed. Electronic applications will be accepted. In case the residue data have already been submitted, a reference to the submitted data is sufficient. Furthermore, CRD is requesting an overview document summarizing the GAP and a summary table of all supporting residue trials.

If you have questions or need support either with placing, monitoring residue programs or in preparation, submission of MRL Dossiers and follow up of MRLs please contact Dr. Monika Hofer (monika.hofer@scc-gmbh.de) or Dr. Monika Eder (monika.eder@scc-gmh.de).



DATA MANAGEMENT

SCC has further improved its universal regulatory database “Electronic Dossier and Data Management System”, EDDMS with the incorporation of an essential update.

It is well-known that our “regulatory world” has become more and more complex. The preparation of a regulatory dossier has developed into an extremely demanding task in terms of scientific and administrative requirements. Extensive dossiers covering multiple data requirements must be generated by the applicant, requiring reliable documentation and tracking of submissions and corresponding information. With its experience obtained over more than two decades of working

for the chemical industry and its knowledge acquired from hundreds of dossier preparations and international submissions, SCC has developed and constantly further improved its regulatory database system.

These are the advantages of the upgraded EDDMS:

- Universal use, independent of regulatory area.
- Instant data access on individual PCs, computer networks, on a local or global scale, depending on your organization.
- Study compensation and other multiple user issues can be easily tackled for task forces and consortia. By using the newly developed EDDMS client manager, access rights can be defined in detail → complete records or selected data boxes can be hidden or shown for respective users.
- Generation of CADDY dossiers is considerably easier and faster, saving time and money.
- Complete regulatory information about your substances and products at hand everywhere you need it: in your office or while travelling, including electronic documents, submission details and project documentation.
- Flexibility for your specific in-house needs, including integration of already existing databases, guaranteed by SCC specialists.

EDDMS can be used for all regulatory submissions: for chemicals (REACH), plant protection products, biocides, pharmaceuticals, consumer products, feed and food additives or any other category.

For further details please see “Our Business/Archiving” and SCC’s flyer “EDDMS” at <http://www.scc-gmbh.de> under section “Brochures” or contact Dr. Friedbert Pistel (friedbert.pistel@scc-gmbh.de).

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CALENDAR

8th International Fresenius Conference: Food Safety and Dietary Risk Assessment – 22-23 February 2010, Mainz, DE

Dr. Monika Eder and Dr. Alexander Köhl will attend this two-day conference, where the topics include the New Regulation 1107/2009 for plant protection products, risk and exposure assessment issues, consumption data, and much more.

Consumer Risk Assessment Training – 23 February 2010, York, UK

Dr. Karin Lauber will attend this one-day seminar which is targeted at technical and regulatory staff involved in the production and submission of data to CRD. The aim of the day is to raise awareness, provide guidance in the appropriate use of residue values in risk assessment models and highlight commonly encountered problems.

ChemCon Europe 2010 – 01-05 March 2010, Prague, CZ

Dr. Carsten Baehr will be at this conference, a global platform bringing together more than 250 company experts representing companies, authorities and international organizations from over 25 countries, focusing on REACH, GHS and country specific information on inventories, labelling requirements, etc.

2nd International Fresenius Conference: Implementing the GHS – 26-27 April 2010, Cologne, DE

Dr. Michael Werner will participate in this two-day conference dealing with such topics as the transition to the new EU regulation, experience in industry, an update regarding the world-wide GHS situation, and the effects on consumers.

Registration of Agrochemicals in Europe, 21-22 April 2010 – Brussels, BE

Dr. Monika Hofer and Dr. Albrecht Heidemann will be attending this two day conference concerned with the registration of agrochemicals in Europe, with an emphasis on the implementation of the new regulation.

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