Newsletter

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MESSAGE FROM THE PRESIDENT

⇒ SCC visits Japan 5-9 November 2007
⇒ New review process for 91/414/EEC substances
⇒ Plant Protection Co-Formulants under REACH

During the week of November 5, 2007, our specialists on REACH, Dr. Werner Köhl (Senior Manager), and on plant protection, Mr. Horst Neufurth (Senior Manager Consultation and Liaison), will visit Japan. Together with our colleagues from our Japanese liaison office, Mr. Norio Ohta (Director) and Mr. Kenji Makita (Senior Consultant), they will use their stay to update an interested audience from the chemical industry about the current situation with regard to the registration of chemical substances in light of Directive 91/414/EEC and the new proposed plant protection regulation for the European Union, as well as topics related to REACH.

On 28 September 2007, the new regulation (EC) 1095/2007 entered into force. With this new piece of legislation, the review process for list 3 and 4 substances under Directive 91/414/EEC was amended. On 19 October 2007, the European Commission presented the new process as well as the proposed draft regulation on the re-submission for substances not included in Annex I. SCC attended the meeting. Please see section "Agrochemcials" for a detailed meeting report.

REACH legislation entered into force on 1 June 2007. Registrations under REACH are the full responsibility of producers and importers, resulting in significantly increased industry awareness. In that respect, it is important to note that co-formulants must be registered under REACH. This is the conclusion which was drawn based on an European Chemicals Agency's (ECHA) statement. For details please check section "Chemicals".

Although SCC has a very full work schedule now and in the future, we are and will always be personally available for any of our clients' individual needs. Please contact SCC in Wendelsheim, or at our SCC Liaison Office Japan, if you have any questions.

With best regards,

Dr. Friedbert Pistel
President

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Review of stage 3 and 4 substances (regulation 1095/2007) and re-submission of dossiers for substances not included in Annex I to Directive 91/414/EEC (SANCO/758/2007, draft)

ECPA organized a meeting for notifiers with European Commission (COM) representatives on 19 October 2007 in Brussels. COM was represented by Mr. Smeets, Ms. Törnqvist and Mr. Spinosi of Health and Consumer Protection Directorate General (DG SANCO).

The purpose of the meeting was to clarify the process on the review of list 3 substances under regulation 1095/2007 which entered into force on 28 September 2007 and the process on re-submission of dossiers for substances not included in Annex I to Directive 91/414/EEC (SANCO/758/2007).

Mr. Spinosi presented the detailed process of the so-called "fast track procedure" (regulation 1095/2007). There will be three tracks for the review of substances. Substances without any harmful effects ("green track") will be included on Annex I after the draft assessment report (DAR) is available. EFSA will review these substances until the end of December 2010. Substances which are categorized as harmful ("red track") will not be included on Annex I after the DAR is available. Authorizations for harmful substances will be withdrawn within 6 months. All other substances ("yellow track") will be peer reviewed or evaluations on specific points will be prepared by EFSA. The regulation offers notifiers the possibility to withdraw these substances on a voluntary basis until 28 November 2007 in case the DAR was received by COM from EFSA before the entry into force date of regulation 1095/2007. Substances for which the DAR was received by COM from EFSA later than 28 September 2007 can be withdrawn until two months after receipt of the DAR. If the substance is withdrawn on a voluntary basis, the Member States have the possibility to maintain authorizations of plant protection products until end of December 2010 by the latest.

Submission of additional information after the DAR has been submitted to EFSA is only allowed if requested by EFSA or RMS. Information that has been submitted without request will not be taken into account during the evaluation.

Ms. Törnqvist gave an overview about the current discussion status of draft Commission regulation SANCO/758/2007, Rev. 9 on laying down further detailed rules on the re-submission of a dossier for substances not included in Annex I. It is expected that the Standing Committee on the Food Chain and Animal Health (SCFCAH) will vote on the draft during their next meeting in November 2007. The draft regulation is intended to apply for existing actives. An additional regulation will be prepared covering the new actives. SANCO/758/2007 (draft) describes the re-submission procedures for list 1 substances by submitting a full new dossier and for list 2, 3 and 4 substances for which a DAR has already been prepared, by submitting information or studies on the critical issues raised. The new application with all pertinent information or studies must be re-submitted at the latest six months after the publication of the non-inclusion decision in the Official Journal of the European Union. In the course of the re-evaluation process, notifiers get 6 months to provide additional information upon request to RMS and/ or EFSA.

In the subsequent discussion session, many unclear items were addressed. A brief summary of the issues is presented below:

One major discussion item was the voluntary withdrawal by the notifier. Currently some notifiers must take the decision to withdraw or support their substances based solely on the DAR. Whereas COM will decide on the acceptance of the withdrawal by taking into account comments received by Member States. It was proposed to send the Member State comments, if available, to the notifiers so that they can be taken into consideration before the final decision (withdrawal or support) is taken by the notifier. COM will discuss this issue internally, but due to the tight deadline for withdrawal (28 November 2007), the chance of getting Member State comments is low.

Currently it is not yet clear when the re-submission draft regulation will enter into force. In addition, it is questionable if the final re-submission regulation will be published before 28 November 2007. COM

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recommended proceeding with studies in order to be prepared for a possible re-submission. Re-submission is expected to start mid-2009 depending on the non-inclusion decision by COM.

Questions were posed on how COM will deal with addenda to DARs. As stated in the regulation, submission of additional information after the DAR has been provided to EFSA is not allowed. Nevertheless, COM representatives stated that addenda will be taken into account if the substance has already passed the expert meetings and EFSA is close to preparing the conclusion report. Other addenda that were submitted prior to 28 September 2007 and addenda submitted later on will most likely not be considered. COM is currently discussing this issue with lawyers.

It is important to note that if additional information is requested for substances in the peer review, EFSA and COM do not expect to receive new studies.

It was criticized that notifiers still do not know how substances are categorized under the new regulation. COM explained that notifiers of substances with or without harmful effects (green and red track) will receive an official letter soon and could get specific substance-related information from COM upon request.

Industry criticized the lack of equal treatment: in the 91/414/EEC review process for list 1 and 2 different legal procedures applied, and now different procedures for list 3a and 3b substances also have to be considered. The different provisions for list 1, 2 and 3 were discussed with the COM lawyers. However, they accepted the provisions in the new regulation.

In the re-submission process, COM does not expect to evaluate full dossiers (which would not be completed before 2010). Rather, they expect to evaluate studies that provide additional information to points raised in the evaluation process. They count on reviewing 2 to 4 studies during 6 months.

According to COM, change of criteria and guidance should not be relevant for the re-submission process.

Further, industry representatives asked how to proceed if upon re-submission of studies after non-inclusion into Annex I, the RMS does not deliver requested comments in time. COM stated that there is no rule on how to proceed in this case. However, notifiers are free to change RMS, in case another Member State still has resources.

COM recommends Member States to keep national product authorizations until 2010 if notifers withdraw the substance voluntarily. However, COM clearly stated that Member States are not obliged to follow this recommendation.

Furthermore, it is unclear whether authorities will maintain re-registrations when the registrations expired during this period.

COM stated that current data protection rules of Directive 91/414/EEC for data submitted under the re-submission regulation will apply.

Industry brought up the list of protected data for substances which are evaluated under the "green track" in the regulation. COM could not give an answer as to who will validate this list of protected data. This issue shall be discussed later on.

The PIC process will be followed only for harmful substances. For all other substances, the process is pending.

In a nutshell, it can be said that the review process under regulation 1095/2007 and SANCO/758/2007 (draft) as presented through COM still shows many open questions. Based on the discussion summarized above, industry representatives mostly need clarification on the voluntary withdrawal process and if they will be allowed to take into consideration Member State comments for their decision. Furthermore, it must be clarified if Member States will follow COM's proposal to maintain two years of additional product authorizations after the voluntary withdrawal through the notifier. In addition, it must be clarified which data (addenda to DAR) will be taken into account during the evaluation process.

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CHEMICALS

Co-formulants in plant protection products – registration under REACH required

Co-formulants used in plant protection products must be registered under REACH. This is the conclusion which was drawn based on an European Chemicals Agency's (ECHA) statement from 27 September 2007 (helpdesk inquiry). This conclusion is also supported by the "Guidance Document on Registration, Section 1.6.5.2, Active substance for use in plant protection products".

In principle, only active substances contained in plant protection products are regarded as registered under REACH. Co-formulants are excluded from this provision because, under the current European plant protection related legislation, only active substances are reviewed and assessed. Co-formulants are not covered by the current European legislation.

If companies plan to export plant protection products into EU territory, for example, it is recommended to consider the following steps:

1.) Portfolio analysis of the plant protection product and its ingredients (active ingredients, co-formulants, chemical names, volumes, exceptions under REACH, etc.).

2.) Decision on which components to be used (REACH registered substances versus non-EU manufactured substances) and cost-benefit analysis. Ascertain future export of plant protection products into Europe. Decision on if/ how to register the substances used in plant protection products (registration strategy, EU representative).

3.) Pre-registration of relevant chemicals (Deadline: 1 June 2008 – 1 December 2008) If the substances will be (pre-) registered, an EU representative must be assigned (Only Representative, Third Party Representative for reasons of confidentiality) or importers in the EU have to register the substances in question.

4.) Information / data needed
Clear picture of the chemistry of given ingredient
EINECS/NLP Number
Indications for read across if relevant

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