Newsletter

Volume 12, No. 1, April 2012

Change: An integral part of the regulatory business

In this edition of the SCC Newsletter, you will see a number of articles dealing with change: changes in the German Plant Protection Law, the upcoming revision of the Biocidal Products Directive 98/8/EC (BPD), changes and improvements in how dietary risk assessments are made are just a few of the changes you will read about.

When we look back on the last 20 years in the regulatory business, the changes in regulatory framework and laws that have been seen are astounding. The changes reflect new knowledge, situations, science and, last but certainly not least, political goals.

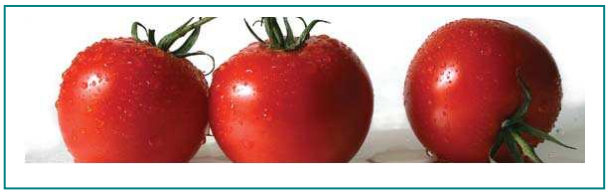
Consequently, it is of the utmost importance for those who work in the regulatory business to remain on top of the regulatory scene, to have good contacts with the authorities on national and EU levels, and to have the knowledge and ability to translate the changes into reality. In short, exactly what SCC does for its clients.

The current edition of the SCC Newsletter brings you the newest information on the regulatory level: the information you need to know.

SCC: We take care.

Dr. Friedbert Pistel
President

In this issue:



AGROCHEMICALS

Restructuring of Plant Protection in Germany

In recent years, several new regulations and directives have come into effect in the European Union to establish a basis for the safe and sustainable future use of plant protection products, with regard to new scientific as well as socio-economic requirements. With the coming into force of the new German plant protection law (Gesetz zum Schutz der Kulturpflanzen - Pflanzenschutzgesetz – PflSchG) on 14 February 2012, the existing European legislation is now considered in or to be implemented into national law. The new European and German plant protection laws are peculiar to the extent that agriculture, and thus plant protection, now are strongly linked to other areas of common interest, as specified for example in the Common Agricultural Policy (CAP) of the EU. The new German plant protection law is primarily based on: Regulation 1107/2009 concerning the placing of plant protection products on the market; Directive 2009/127 concerning machinery for pesticide application; the Pesticides Statistics Regulation 1185/2009; the Sustainable Use Directive 2009/128 (SUS). Due to the legislative nature, both regulations are self-executing and do not have to be implemented into national law. Thus, no further reference to these regulations is made in the German plant protection law except for national executive orders or responsibilities, for example.

The novel character of the new German plant protection law is more or less due to the implementation of the Sustainable Use Directive 2009/128 and acts of law linked to this directive, as well as its national implementations, with priorities becoming obvious from the constitution of this legal act. Article 3 specifies the definition of ‘Good Agricultural Practice’ and the obligatory implementation of Integrated Pest Management. Articles 4 and 5 specify the establishment and

implementation of the future German National Action Plan (NAP). The aims are a sustainable use of plant protection products, to reduce dependency on the use of chemical pesticides, as well as to minimize the risks and impacts of pesticides on human health and environment. Thus the new plant protection law is linked to other national and European laws, conservation acts, and activities. For example, in Article 22 the interaction of future plant protection measures and water conservation regulated by the Water Framework Directive (WFD) 2000/60 is described. This is of particular interest with regard to plant protection products for a number of reasons. For one, the WFD and subsequent Directives, such as the "Priority Substances Directive" 2008/105 (Directive on Environmental Quality Standards; EQSD) or COM(2011)876 final of 31 January 2012, define priority or priority hazardous substances, some of them active substances in plant protection products, which are liable to special monitoring and reduction programs. Whereas the Priority Substances Directive 2008/105 contains 33 priority substances, the revised proposal for a Directive amending the WFD and EQSD (COM(2011)876 final of 31 January 2012) lists 15 additional substances including Quinoxyfen, which is additionally classified as a priority hazardous substance, Aclonifen, Bifenox, and Cypermethrin. On the other hand, in the scope of National Action Plans which have to be established in all European Member States by 14 December 2012, the use of plant protection products can be restricted further according to national requirements, such as the buffer zone requirements for plant protection products in vulnerable areas. This is also true for other existing legislative acts such as the "Birds" or "Conservation" Directives 79/409 and 92/43. In Germany and other European countries, the basis for decisions regarding such areas is the "Natura 2000"-project, or the Eco-Region Project, in which the Baltic States aim to establishment the world's first eco-region.

Similar developments as described for Germany are also to be expected in the other European Member States. For example, ten European Member States have so far published their own National Action Plans or drafts thereof.

Additionally, other distinctions in the national plant protection laws of the European Member States have to be expected in the future. In Germany for example, the new plant protection law provides for the possibility of registration applications for plant protection products not only by the producer of the product but also by third parties such as farmer organizations. Among other things this became possible as, based on Directive 2003/35, the SUS especially promotes the participation of the public regarding plans and programs related to environmental issues. Realignments in national plant protection laws are also to be expected regarding the existing national 'special classes' of substances used in agriculture until now, such as plant strengtheners, soil conditioners, etc. According to the new German plant protection law, for example, the special class of plant strengtheners was redefined. In the future, this class may only contain substances or mixtures which maintain the health of plants if they are not additionally listed as plant protection products according to Regulation 1107/2009, or substances or mixtures which protect plants against non-parasitic adverse effects.

In spite of the harmonization of e.g. the registration and evaluation processes for plant protection products due to Regulation 1107/2009, it can be seen that there are various regulatory aspects to be considered in the future, considering not only registration procedures but also regarding utilization and sales of plant protection products. Because the process of reorganization of the agricultural sector in Europe is still ongoing, and new national laws are under development right now in many European Member States, these issues will also be topics of future SCC newsletters.

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Newsletter
Volume 12, No. 1, April 2012

BIOCIDES

Parliament adopts Draft Biocidal Products Regulation at second reading

At its plenary sitting in Strasbourg on 19 January 2012, the European Parliament adopted its position regarding the draft Biocidal Products Regulation (BPR) at second reading. The members of Parliament broadly voted in favor of the trilogue agreement, which was reached in November 2011. Although not yet legally binding, the text of the draft BPR can now be considered as final with regard to its contents and provisions. The final legislative step before publication of the BPR in the Official Journal of the EU will be the vote of the Council at second reading. It is expected that the Council will adopt the text. The next Environment Council meeting is scheduled to take place in Brussels on 11 June 2012.

Three new draft guidance documents published for consultation

New draft guidance documents are available in the "Technical Notes for Guidance" series having been recently published by the European Commission:

- Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products
- Notes for guidance to applicants for product authorization and mutual recognition
- EU Evaluation Manual for the Authorisation of Biocidal Products.

The documents were endorsed by the biocides competent authorities at the 36th and 44th CA meetings, respectively. Although the draft guidance documents are released for a 6-month consultation period of stakeholders, they are supposed to be used by the authorities and the industry from now on. Comments to the draft guidance documents should be made in writing to ENV-BIOCIDES@ec.europa.eu by 30 June 2012.

Recent Annex I inclusions of existing biocidal active substances

At the beginning of 2012, two inclusion directives were published in the Official Journal of the EU for the following existing biocidal active substances:

- copper (II) oxide in product type 8
- copper (II) hydroxide in product type 8
- basic copper carbonate in product type 8
- bendiocarb in product type 18.

The legal basis for the inclusion of the copper substances is Commission Directive 2012/3/EU and Commission Directive 2012/2/EU for bendiocarb. Date of inclusion will be 1 February 2014 for all four substances.

The Standing Committee on Biocides has lately taken a positive vote for the following existing biocidal active substances:

- chloralose in product type 14
- DDA carbonate in product type 8
- flufenoxuron in product type 8
- hydrochloric acid in product type 2
- margosa extract in product type 18
- methylnonyl ketone in product type19.

Please note that the inclusion of these six substances is not yet legally binding as the respective inclusion directives have not yet been published.

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Newsletter
Volume 12, No. 1, April 2012

CHEMICALS, REACH, CONSUMER PRODUCTS

Community rolling action plan (CoRAP): first list published

The first final Community rolling action plan (CoRAP) contains 90 substances that the Member States will evaluate under the substance evaluation process of the REACH Regulation. These substances are evaluated in 2012, 2013 and 2014.

In the CoRAP, the grounds for the initial concerns are briefly described for each substance. In many cases, the concerns are related to potential persistency, bioaccumulation and toxicity, endocrine disruption, or carcinogenicity, mutagenicity and toxicity to reproduction, in combination with wide dispersive or consumer use(s). The CoRAP also indicates the Member State which is responsible for the evaluation of each substance. In 2012, 36 substances will be evaluated by 17 Member States. The remainder have been listed for 2013 and 2014, but the number and selection of substances listed for those years is expected to be amended in the annual updates of the CoRAP.

Details can be found on the ECHA Website: http://echa.europa.eu/web/guest/view-article/-/journal_content/c26e0b90-8d88-4580-9954-842a934486a1

Registration dossier update due to tonnage band increase in case of joint submissions: technical aspects

In order to meet the basic principle of the REACH Regulation (EC) No 1907/2006, "One substance one registration", registrants of both phase-in and non-phase-in substances are obligated to register a substance jointly (Art. 11). In the context of such a joint registration, some information is submitted jointly in accordance with Article 11(1) by the lead registrant on behalf of the members of the joint submission. Other information is submitted individually by every member registrant. In the event of a registration dossier update due to a member registrant's tonnage band increase going beyond the lead registrant's tonnage band, there are two possibilities on how to proceed: Either the member registrant makes use of the so-called "opt-out" possibility, where separate information is submitted on e.g. C&L, (robust) study summaries and proposals for testing listed in Annexes IX and X, or the role of the lead registrant has to be exchanged between lead and member registrant. The exchange of the lead registrant role is accomplished via REACH-IT.

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REGULATORY SCIENCE

Fresenius Conference "Food Safety and Dietary Risk Assessment" in Mainz (Germany)

On 27 and 28 February 2012, SCC participated at the 10th International Fresenius Conference on "Food Safety and Dietary Risk Assessment" in Mainz (Germany).

After discussions of general communication strategies, which were presented by R. Löfstedt (Kings College, London), A. Epp (BfR) summarized the new report "Risk perception of German consumers in regard to pesticide residues in food – lessons to learn for risk communication". It was concluded that co-operation of risk-communicators and researchers as well as the co-operation with the media is very important.

P. Marx-Stölting from the BfR presented the latest discussion about the criteria for substances with endocrine properties. The BfR has conducted a project with a number of selected chemicals/active substances in order to evaluate the impact of the different criteria. The criteria will be discussed with

Newsletter
Volume 12, No. 1, April 2012

an EU expert group in 2012. The decision on criteria by EU Commission is planned for 2013.

T. van der Velde-Koerts from the National Institute of Public Health and the Environment, NL, presented the updated short-term intake models used by FAO/WHO JMPR, which can be downloaded on the website http:/www.who.int/foodsafety/chem/acute_data/en/index1.html.

The model integrates new "large portion data" for individual commodities. In addition, further age groups such as toddlers, young children, women and the general population are considered.

The data call is still open, thus the model will be updated again in 2012. In the discussion, it was highlighted that at this stage JMPR will not use probabilistic risk assessments and will stick to the deterministic approach.

T. Coja from AGES presented the impact of metabolic and degradation processes on the toxicological properties of residues of pesticides in food commodities. EFSA has launched three projects: TTC (toxic threshold concept), QSAR and the above described AGES project. All three projects will be used to create the "Guidance document on the establishment of residue definition for dietary risk assessment" which should be finalized by the end of 2012.

Regarding toxicity tests with metabolites, Coja recommended to do either a 28-day extended rat study if 28-day study with parent is available, or a 90-day rat study or developmental toxicity studies if the metabolite is critical for reference values. It was highlighted that the notifier should not conduct acute toxicity studies with metabolites found in food/feed commodities.

Besides plant protection products, the dietary risk assessment for biocides was also presented by K. Gottlob from the BfR. For applications in animal husbandry, the MRL setting will be in accordance with Regulation (EC) No 470/2009, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin. The risk characterization approach is similar to veterinary medical products. For all other biocidal active substances, the authority which is to be responsible for setting the MRL has not yet been designated.

For the dietary risk assessment of biocidal products, the following guidance documents have been published for consultation: guidance on estimating livestock exposure to active substance used in biocidal products (DRAWG), guideline on risk characterization, and assessments of MRLs for biocides (EMA).

For the external exposure of livestock, a tiered approach for estimating external exposure of livestock was shown. Further guidance on risk characterization and MRL setting is to be developed by the authority setting MRLs. It was discussed that a procedure to handle the definition of MRLs set for biocides, veterinary drugs and plant protection products is not yet available, but needed as it is already requested in EFSA's reasoned opinions.

J. von Klaveren (National Institute for Public Health and the Environment, NL) presented an update on the ACROPOLIS project regarding cumulative risk assessment, which should improve the cumulative exposure and hazard assessment, develop new models for aggregated exposure assessment, and set up new toxicological testing for identifying possible synergistic effects.

In early January 2012, a training with stakeholders in ACROPOLIS was held. The new model for the risk assessment MCRA 8 is expected to be tested in April-July 2012.

X. Sarda from ANSES presented the misunderstandings with regard to minor crops and minor uses by showing the distinct definitions. According to Art 51 of Regulation 1107/2009, Member States are to establish and regularly update a list of minor uses. In France the publication of an official catalogue of uses is planned for Feb/March 2012.

A. R. Boobis from the Imperial College, London, presented the recent developments in the TTC approach, a human exposure threshold value for a chemical of unknown toxicity below which there would be no appreciable risk to health following oral exposure for a lifetime. The adequacy of TTC was shown even for neurotoxicants, reproductive and developmental toxicants, adverse effects of endocrine-active substances, and for substance of Cramer Class I and III.

Newsletter
Volume 12, No. 1, April 2012

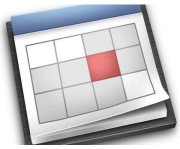
The Fraunhofer Institute has developed regulatory testing procedures to study the metabolism of pesticides in farmed fish. Such studies would be required when pesticide use may lead to significant residues (>0.1 mg/kg) in fish feed. A fish metabolism study with *Oncorhynchus mykiss* or *Cyprinus carpio* should assess total radioactive residues (TRR) in muscle / skin (fillet), and show the efficiency of extraction procedures for these components. Extraction and characterization of metabolites would be needed when TRR > 0.01 mg/kg; if TRR in the edible commodities > 0.01 mg/kg, identification of metabolites by analysis of the tissues. Even if the residues levels in the edible commodities are < 0.01 mg/kg, identification of metabolites should be attempted by analysis of the liver. A guidance document on the nature of residues in fish was submitted to EU Commission on February 2012.

Two representatives of ANSES (A. Faure and C. Vergnet) developed a decision tree for setting maximum residue limits in honey. The residue definition would be set as the sum of all metabolites included in residue definition in plants and foods of animal origin. The focus would be on potential exposure (veterinary medicinal product, crop attractiveness, residue systemic activity, application before or during flowering, residue levels in aerial parts of the crop). In the pre-registration, different methods (e.g. use of data on residue level in aerial parts of the crop, monitoring data or use of new data such as studies on transfer from syrup to honey, trials on the residue stability in honey) could be chosen; in the post-registration, the provisional MRL could be refined based on monitoring data or on specific residue trials.

H. Reich from EFSA presented the recent status of MRL evaluation according to Art. 12 of the MRL regulation 396/2005. Lowest priority is given to substances where confirmatory data have been generated for green track substances and Annex VI substances, and if re-submission of the Dossier for Annex I inclusion has not been finalized. K. Hohgardt (BfR) commented on the review of the existing EU MRLs from a risk management perspective. The MRL evaluation could be improved as it was agreed to evaluate in a first step the residue definition within the confirmatory data and then proceed with the MRL setting according to Art. 12. It was recommended that risk management options proposed by EFSA should be clearly specified (less options would be better) and that the evaluation of a fallback GAP is necessary and should be noted. In order to further improve the MRL setting process, a guidance document for risk management decision, e.g. when to change the LOQ, when to introduce new models, is in preparation.

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

Newsletter
Volume 12, No. 1, April 2012



CALENDAR

Registration of Agrochemicals in Europe - 17-18 April 2012, Brussels, BE

With the introduction of Regulation 1107/2009 in June 2011 Registration of Agrochemicals 2012 will provide the first chance to exchange knowledge and share experiences on the implementation of the new regulation. The agenda has been specifically designed to ensure you achieve success under 1107. At this 19th international conference you can hear first experiences from the EU Commission, EFSA, eight Member States, ECPA and all the leading industry experts. This is a unique opportunity to hear from and put questions to key stakeholders 10 months after the implementation, and gather vital information on the registration of your crop protection products.

SCC's Dr. Albrecht Heidemann, Vice President, Head of Agrochemicals and Biopesticides Department, and Dr. Monika Hofer, Vice President, Head of Regulatory Science will be at this interesting and important conference. Contact them at scc@scc-gmbh.de to set up an appointment during the conference to discuss your specific regulatory needs.

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