



SCC Newsletter

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REACH: The future of chemicals registration

Currently in the EU the registration of chemicals has been made under the mélange of various guidelines, directives and regulations which developed over time but which did not have any real framework as a basis. Rules for existing chemicals are different from those for new chemicals (unlike plant protection products, where the evaluation process for inclusion in Annex I is the same). Testing requirements for chemicals placed on the market after 1981 are much more stringent than those required (if at all) for those chemicals marketed prior to 1981.

In order to provide a uniform regulatory framework for chemicals, REACH (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals) has been developed as a regulatory Directive that will go into effect in 2007. REACH will require the following information:

Technical Dossier: for all manufacturers or importers of more than 1 t of a specific chemical substance per year. This will be registered in a central database and will include:

- identity of the manufacturer or importer
- identity of the substance
- information regarding manufacture and the intended uses
- proposed classification and labelling
- guidance regarding safe use
- testing proposals (if necessary)

For those substances exceeding annual manufacture or import of 10 t, a Chemical Safety Report will be required that must demonstrate the safe use of the substance throughout the entire supply chain. This report includes:

- risk assessment
- classification and labelling
- documentation of safe use including preparation of extended safety data sheets.

Some 30,000 chemical substances will be affected by this directive. Although concessions have been made to the industry, manufacturers will now have to provide information regarding the risks involved in the manufacture and use of the substances, as well as details safety data sheets for the substance. In all, REACH will accomplish much the same as 91/414/EEC and the BPD has: a uniform regulatory mechanism that will eliminate the discrepancies in registering “new” and “existing” chemicals.

SCC has extensive experience in the notification of chemicals and is prepared to meet the challenges of REACH. We'll be at the ChemCon 2006 in Budapest. For further information, contact Dr. Werner Köhl (werner.koehl@scc-gmbh.de).

Plant Protection Products

New list of Contact Points for Plant Protection Products now available

A new list of Contact Points for Plant Protection Products (competent authorities and others) is now available from the EU. To download this Excel file, refer to the EU website http://europa.eu.int/comm/food/plant/protection/evaluation/contact_points.xls.

Status of Annex I Inclusions

Some movement has been made in the plant protection products evaluations. A summary appears below:

Phase	No. of substances	Being examined	To be examined / notified	Not supported or withdrawn	In Annex I
First	90	9	0	28	53
Second	148	47	0	98	3
Third	387	150	0	237	0
Fourth	342	0	255	87	0
TOTAL	967	206	255	450	56

With 56 existing and more than 66 new active substances listed in Annex 1, it can be difficult to keep track of what has and has not been evaluated. Below you will find tables with this information in concise form.

Table 1: Stage 1 Annex I Inclusions Existing Active Substances (53 active substances)

2,4-D	Diquat (dibromide)	Metiram
2,4-DB	Esfenvalerate	Metsulfuron
alpha-Cypermethrin	Ethofumesate	Molinate
Amitrole (aminotriazole)	Fluroxypyr	Paraquat
Benalaxyl	Glyphosate	Pendimethalin
Bentazone	Imazalil	Phenmedipham
beta-Cyfluthrin	Ioxynil	Propiconazole
Bromoxynil	Iprodione	Propineb
Chlorothalonil	Isoproturon	Propyzamid
Chlorotholuron	lambda-Cyhalothrin	Pyridate
Chlorpropham	Linuron	Thiabendazole
Chlorpyrifos	Maleic hydrazide	Thifensulfuron
Chlorpyrifos-methyl	Mancozeb	Thiophanate-methyl
Cyfluthrin	Maneb	Thiram
Cypermethrin	MCPA	Triasulfuron
Daminozide	MCPB	Warfarin
Deltamethrin	Mecoprop	Ziram
Desmedipham	Mecoprop-P	

Table 2: Stage 1 Annex I Non-Inclusions Existing Active Substances (28 active substances)

Acephate	Endosulfan	Parathion-ethyl
Aldicarb (w)	Fenthion	Parathion-methyl
Amitraz	Fentin acetate	Permethrin
Atrazine	Fentin hydroxide	Propham
Azimphos ethyl	Fenvalerate	Pyrazophos
Benomyl	Ferbam	Quintozene
Chlozolinate	Lindane	Simazine
Cyhalothrin	Metalaxyl	Tecnazene
Dinoterb	Monolinuron	Zineb
DNOC		

Table 3: Stage 2 Active Substances: Inclusion (3 substances)

Tribenuron
Tolyfluanid
Oxamyl

Table 4: Stage 2 Active Substances: Non-inclusion (3 substances)

Methidathion
Naled
Triazamate

Table 5: Stage 3 Active Substances: Non-inclusion (18 substances)

Chlorflurenol	Mefluidide
Cinosulfuron	Nuarimol
Cresylic acid	Polyoxin
Dichlorophen	Pretilachlor
Flamprop-M	Primisulfuron
Flurenol	Quinclorac
Hexaflumuron	Streptomycine
Imazethapyr	Triadimefon
Kasugamycin	Tridemorph

Table 6: New Active Substances: Inclusion in Annex I (66 substances)

Acetamidprid	Flufenacet	Oxadiargyl
Acibenzolar-s-methyl	Flumioxazine	Oxasulfuron
Ampelomyces quisqualis	Flupyr-sulfuron methyl	Paecilomyces fumosoroseus
Azimsulfuron	Flurtamone	Picolinafen
Azoxystrobin	Foramsulfuron	Picoxystrobin
Benzoic acid	Forchlorfenuron	Prohexadione calcium
Bifenazate	Fosthiazate	Propoxycarbazone
Carfentrazone-ethyl	Gliocladium catenulatum	Prosulfuron
Cinidon ethyl	Imazamox	Pseudomonea chlororaphis
Coniothyrium minitans	Imazosulfuron	Pymetrozine
Cyazofamid	Indoxocarb	Pyraclostrobin
Cyclanilide	Iodosulfuron-methyl-sodium	Pyraflufen-ethyl
Cyhalofop-butyl	Iprovalicarb	Quinoxifen
Dimethenamid-P	Isoxaflutole	Silthiofam
Ethoxysulfuron	Kresoxim-methyl	s-Metolachlor
Etozole	Laminarin	Spiroxamine
Famoxadone	Menanipyrim	Sulfosulfuron
Fenamidone	Mesosulfuron-methyl	Sulfuryl-fluoride
Fenhexamid	Mesotrione	Tepraloxdim
Ferric phosphate	Metalaxyl-M	Thiacloprid
Flazasulfuron	Methoxyfenozide	Trifloxystrobin
Florasulam	Milbemectin	Zoxamide

Biocides

New list of Contact Points for Biocides now available

A new list of Contact Points for Biocides (competent EU authorities and others) is now available on the ecb website. To download this pdf-file, click onto the SCC website – Biocides, Background and News (www.scc-gmbh.de), Archive 2005.

Draft Competent Authorities Reports for Active Substances

In accordance with Article 12 of Regulation (EC) 2032/2003, the competent authority reports concerning the evaluation of active substances in the review programme are available to the public by electronic means, except for information that is to be treated as confidential. Currently, reports for the wood preservatives Dichlorfludanid, Etofenoprox, Sulfuryl fluoride and Tebuconazole are available. These can be reviewed on the SCC website. Please refer to the Background and News section under Biocides, news item dated 13.02.2006. In addition, reports for the rodenticides Coumatelralyl, Difenthialone, Warfarin, and Warfarin sodium are also available.

No change in status of active substances

It's still too early to expect any major changes in the status of biocidal active substances: The authorities are busy with the completeness checks and further evaluations necessary on the dossiers. A complete list of the current status can be found below:

Table 1: Current review status for existing active substances (biocides)

Phase	PT	No. of substances notified*	Not supported or withdrawn	To be examined	Being examined	Inclusion Annex I
First	8	81	43	38	38	0
	14	17	4	13	13	0
Second	16	13	3	10	0	0
	18	104	3	101	0	0
	19	42	1	41	0	0
	21	28	2	26	0	0
Third	1	88	3	85	0	0
	2	163	4	159	0	0
	3	105	7	98	0	0
	4	105	0	105	0	0
	5	52	1	51	0	0
	6	142	4	138	0	0
	13	104	0	104	0	0
	Fourth	7	88	0	88	0
	9	137	3	134	0	0
	10	94	0	94	0	0
	11	127	3	124	0	0
	12	118	1	117	0	0
	15	2	0	2	0	0
	17	3	0	3	0	0
	20	26	3	23	0	0
	22	24	1	23	0	0
	23	4	0	4	0	0
TOTAL		1667	86	1581	51	0

* It is important to note that one active substance can be notified for a number of different product types, hence the high number of substances notified. Actual number of active substances equals 359.

R&D

MRL-related Regulations

COMMISSION DIRECTIVE 2006/9/EC of 23 January 2006 amends Council Directives 90/642/EEC regarding the maximum residue levels of diquat, and Commission Regulation 178/2006 amends Regulation 396/2005 (establishment of Annex for MRLs) to include all products for which presently Community or national MRLs exist as well as those for which it is appropriate to apply harmonised MRLs. Both Regulations can be found on the SCC website (www.scc-gmbh.de), under plant protection, background and news.

GLP Archives

It's a well known problem: too much paper, too many samples, no room to store them BUT the authorities require GLP studies to be held a minimum of 5, 10 or 15 years or more. What is the way out of this dilemma?

SCC is equipped to store your raw data in a GLP-certified and compliant archive, without the risk of compromising their GLP status. A unique archive and database system for all GLP needs, designed and developed by SCC, proven and validated in day-to-day use, is the backbone of the complete documentation of storage conditions, comprehensive reports on storage history at SCC an automatic data administration, as well as exact, immediate and easy retrieval of individual units of archived materials/data, e.g. during audits. The GLP archive management system allows direct access by authorised personnel only to all available information of the archived data for each customer. A complete audit trail of all entries or changes of records is guaranteed. The risk of loss of data is eliminated through regular back-ups of the database system. The electronic system monitors all deadlines entered.

The archives are fully equipped according to official requirements, and allow storage at ambient temperature, ambient within a guaranteed temperature and humidity range, as well as refrigerated and deep-frozen conditions. All facilities are integrated in an alarm system which is activated and monitored 24 hours per day, 7 days per week.

Let SCC handle your GLP archiving requirements. Dr. Bernd Brielbeck (bernd.brielbeck@scc-gmbh.de) is available to discuss your specific needs.

CAREER OPPORTUNITIES AT SCC!!!

Are you interested in joining a dynamic group of motivated, experienced and team-oriented scientists in our modern facilities in Germany's Rheinhessen region? Then please send us your comprehensive CV and salary requirements, which will of course be handled in strict confidence. Presently we are seeking the following:

Manager Research & Development, Toxicology and Human Health Risk Assessments

For the expansion of our scientific team in the sector "Research and Development", we are seeking a scientist with a background in Toxicology.

Manager, Regulatory Affairs

For our growing new business sector "Pharmaceuticals", we are seeking a scientist specializing in pharmacy and biology to assist in consulting and assistance for our customer for a variety of projects during product development, registration and changes.

Senior Manager Regulatory Affairs, Biocides and Chemicals

For the expansion of our regulatory team in the area of biocides, we are seeking an experienced regulatory expert.

For further information regarding these positions, please see www.scc-gmbh.de – "Vacant Positions".

CALENDAR

Want to meet with SCC staff? Here is a listing of upcoming events that will be attended by SCC.

14.02.2006 - 14.02.2006 BUA Colloquium

Exposition modelling and QSAR applications in the evaluation of chemicals is the topic of this Colloquium scheduled to be held in Frankfurt. Dr. Werner Köhl will be there.

15.02.2006 Nationale Pflanzenschutzmittelzulassung Informationsveranstaltung

The German BVL will be conducting a conference on 15 February, 2006, dealing with the current status of the registration of plant protection products, parallel imports, MRLs, current measures to reduce the delay in the registration process, etc. Drs. Christian Beck, Bernd Brielbeck, Jutta Görg and Norbert Weissmann will be at this conference.

21.02.2006 - 22.02.2006 Fresenius Conference: Environmental Risk Assessment for Biocides and Chemicals

Risk management with regard to REACH, risk characterisation, exposure assessment, hazard assessment and the associated data requirements are the topics that will be discussed at this informative Akademie Fresenius seminar. Dr. Nikola Bitsch und Heike Schimmelpfennig will be there to garner more information on the requirements needed in the chemicals and biocides regulatory industry. You can meet with them during the conference -- send us an e-mail!

27.03.2006 - 29.03.2006 Pesticide Behaviour in Soils, Water and Air

Sven Peter and Dr. Christine Klein will be at this conference dealing with the latest research into the environmental behaviour of pesticides.

28.03.2006 - 29.03.2006 Preparing for Reach

The third annual conference dealing with the details in implementing REACH will be held in Brussels. This informative conference stretches over 3 days and is focused on exploring efficient strategies for compliance. Dr. Werner Köhl will be there as well, and would look forward to meeting you there.

09.05.2006 - 12.05.2006 ChemCon 2006

The ChemCon 2006, an international conference on chemical control legislation and trade aspects, will be held in Budapest (Hungary). Drs. Albrecht Heidemann and Werner Köhl will be attending this conference and will be able to meet with you to discuss your specific needs, especially with regard to REACH.

23.10.2006 - 25.10.2006 BCPC Conference in Glasgow

Once again, SCC will be attending the BCPC Conference and Exhibition in Glasgow. We will be at the Pentagon Centre, 36 Washington Street, just across from the Menzies Hotel. Make an appointment to discuss your specific needs for AIII plant protection dossiers, biocide dossiers, notifications of chemicals or SCC archiving systems (including GLP-certified archiving!). To make an appointment, contact Ms. Lisa Lawrenz at +49-6734-919117 (Tel.) or at lisa.lawrenz@scc-gmbh.de.

SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH
Dr. Friedbert Pistel, President
Mikroforum Ring 1 · D-55234 Wendelsheim · Phone +49 (0) 6734-919-0 · Fax +49 (0) 6734-919-191
scc@scc-gmbh.de · www.scc-gmbh.de

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