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SCC Newsletter Volume 5, No. 1: January 2005 2005: A busy year for SCC is on its way The year 2005 should prove to be an interesting and busy year for the staff at SCC. In the plant protection products sector, the last phase of dossier submissions will be made in June and in November, thus completing the ten year process begun in 1995. In addition, the re-evaluation process for the first substances added to Annex I will also soon begin. The defense of List 2 and List 3 dossiers will also begin, along with the submission of numerous national Annex III dossiers. In the realm of biocides, the evaluation of PT 8 and PT 14 dossiers will continue, with preparation for the next round of dossiers (submission date 2006) already underway. Close work with the authorities with respect to techical guidance is also underway. Further preparation for the introduction of REACH in the chemicals sector is also underway, so that we will be prepared for the start of this evalution process when it begins in 2006/2007. Continued enhancements and improvements to customer databases, the awarding of GLP certification (see page 5), and the development of the pharmaceuticals sector round out the year for SCC. A significant undertaking, to be sure, but one in which our customers will certainly benefit from. As our motto says, "WE TAKE CARE" for regulatory needs in all areas of chemicals, biocides, plant protection products and pharmaceuticals, GLP archiving, toxicological expert opinions and task force management. The staff at SCC is ready to take on your project and your special needs. We wish all readers and clients a happy, healthy, productive and prosperous 2005. Dr. Friedbert Pistel President SCC GmbH *** *** *** *** *** *** *** *** *** *** *** *** News from the Plant Protection Products Sector (contact: albrecht.heidemann@scc-gmbh.de) Status of New and Existing Actives Since the last SCC Newsletter (Vol. 4, No. 2), no new decisions on existing actives have been made. However, there has been some movement in the new active substances. The status is as follows:

Table 1: Annex I Inclusions of stage 1 substances (40 ais)

2,4-D	Isoproturon
2,4-DB	lambda-Cyhalothrin
alpha-Cypermethrin	Linuron
Amitrole (aminotriaizole)	Maleic hydrazide
Benalaxyl	Mecoprop
Bentazone	Mecoprop-P
beta-Cyfluthrin	Metsulfuron
Bromoxynil	Molinate
Chlorpropham	Paraquat
Cyfluthrin	Pendimethalin
Deltametrin	Phenmedipham
Diquat (dibromide)	Propiconazole
Desmedipham	Propineb
Esfenvalerate	Propyzamid
Ethofumesate	Pyridate

Fluroxypyr	Thiabendazole
Glyphosate	Thifensulfuron
Imazalil	Thiram
Ioxynil	Triasulfuron
Iprodione	Ziram

Table 2: Non-Inclusion of stage 1 substances (27 ais)

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

Table 3: New Actives □ Annex I Inclusion (59 ais)

Acibenzolar-s-methyl	Flufenacet	Oxasulfuron
Acetamiprid	Flumioxazine	Paecilomyces fumosoroseus
Ampelomyces quisqualis	Flupyrsulfuron methyl	Picolinafen
Azimsulfuron	Flurtamone	Picoxystrobin
Azoxystrobin	Foramsulfuron	Prohexadione calcium
Benzoic acid	Fosthiazate	Propoxycarbazone
Carfentrazone-ethyl	Gliocladium catenulatum	Prosulfuron
Cinidon ethyl	Imazamox	Pseudomonea chlororaphis
Coniothyrium minitans	Imazosulfuron	Pymetrozine
Cyazofamid	Iodosulfuron-methyl-sodium	Pyraclostrobin
Cycloanilide	Iprovalicarb	Pyraflufen-ethyl
Cyhalofop-butyl	Isoxaflutole	Quinoxyfen
Dimethenamid-P	Kresoxim-methyl	s-Metolachlor
Ethoxysulfuron	Laminarin	Silthiofam
Famoxadone	Menanipyrim	Spiroxamine
Fenamidone	Mesosulfuron-methyl	Sulfosulfuron
Fenhexamid	Mesotrione	Thiacloprid
Ferric phosphate	Metalaxyl-M	Trifloxystrobin
Flazasulfuron	Methoxyfenozid	Zoxamide

Florasulam Oxadiargyl

Table 4: Current review status for existing active substances

Phase	No. of substances	Being examined	To be examined / notified	Not supported or withdrawn	In Annex I
First	90	23	0	27	40
Second	148	51	0	97	0
Third	387	64	80	243	0
Fourth	343	0	256	87	0
TOTAL	968	138	336	454	40

China to Review Plant Protection Products By the end of 2008, the Chinese Ministry of Agriculture plans to review 379 active substances used in plant protection products. All products having received a provisional registration prior to 23 July 1999 will be reviewed in an effort to improve the range of pesticides on the market in China. While the authorities state that the provisions registrations are only valid for four years, existing provisionals will be extended for those actives going through the review process. The actives have been classified in four groups. The first group contains a mere nine actives, with group 2 containing 95, group 3 containing 210 and group 4 containing 65 actives. The review process for group 1 was scheduled to be completed by the end of 2004, with group 2 targeted for the end of 2006, group 3 targeted for the end of 2007 and group 4 targeted for the end of 2008. OECD Format Required for BVL The German Ministry for Consumer Protection, Nutrition and Food (BVL) has recently announced that starting 1 January 2005, all dossiers submitted for active substances to be evaluated for Annex I inclusions under 91/414 EEC must be submitted in OECD format. Dossiers for national registrations are also to be submitted in OECD format, although there is a transitional period involving these dossiers until 15 July 2006. At that time, all further dossiers for national registrations will only be accepted in OECD format. *** *** *** *** *** *** *** *** *** *** *** *** *** *** News from the Biocides Sector (contact: hans-josef.leusch@scc-gmbh.de) Similar to the plant protection products, we will in the future periodically present the current review status for existing biocidal active substances. Although no decisions have been made as yet, the following table illustrates the work that needs to be accomplished over the next several years.

Table 5: Current review status for existing active substances (biocides)

Phase	**PT**	**No. of substances notified***	**Not supported / withdrawn**	**To be examined**	**Being examined**	**Inclusion Annex I**	**Non-Inclusion Annex I**
First	8	81	43	38	38	0	0
	14	17	4	13	13	0	0
Second	16	13	3	10	0	0	0
	18	104	3	101	0	0	0
	19	42	1	41	0	0	0
	21	28	2	26	0	0	0

Third	1	88	3	85	0	0	0
	2	163	4	159	0	0	0
	3	105	7	98	0	0	0
	4	105	0	105	0	0	0
	5	52	1	51	0	0	0
	6	142	4	138	0	0	0
	13	104	0	104	0	0	0
Fourth	7	88	0	88	0	0	0
	9	137	3	134	0	0	0
	10	94	0	94	0	0	0
	11	127	3	124	0	0	0
	12	118	1	117	0	0	0
	15	2	0	2	0	0	0
	17	3	0	3	0	0	0
	20	26	3	23	0	0	0
	22	24	1	23	0	0	0
	23	4	0	4	0	0	0

TOTAL

* 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 individual active substances equals 359. SCC and the Registration of Pharmaceuticals (contact: martin.brellochs@scc-gmbh.de) The registration of pharmaceuticals entails all types of dossiers for new MA applications, renewals, variations, and for format changes. New rules and guidelines, such as the "Note for guidance on environmental risk assessment", require database evaluations, studies, and updates of the dossier. And, although there is not yet a legal obligation for a risk assessment, to be fully prepared when it does become a requirement, you should get a feeling where you stand with your product portfolio. We can help to identify possible risks on the base of your in-house and bibliographical data. SCC□s experienced team can assist in all aspects which are related to the administrative part, the quality part and the non-clinical part of the pharmaceutical dossier, and it takes care of the necessary logistics. Our service includes: assessment of your data, report; discussion of strategy / clarification with authorities; study planning and monitoring, with studies replaced by scientific expert statements where possible and economic; final reporting. Contact Dr. Martin Brellochs to discuss your specific needs. SCC receives GLP certification (contact: bernd.brielbeck@scc-gmbh.de) It is now possible for companies to archive their GLP-compliant data and materials at SCC. SCC□s GLP (Good Laboratory Practice) archive provides storage for raw data and materials. Archiving is the lynchpin of the GLP process. And, because each country has prescribed a different storage period for their GLP studies, it is often difficult to determine for what period storage under GLP needs to be continued. If GLP storage is terminated too soon, the test loses its GLP validity and can no longer be used in the registration process. SCC is GLP-certified to provide GLP-compliant storage of test data and materials. The certificate

was awarded to SCC last October. 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 Previous Newsletters can be found on our website www.scc-gmbh.de , under Newsletter Archive. You can also subscribe to the Newsletter (free-of-charge) at this site. NOTICE: While we have compiled the enclosed information with the utmost care, SCC GmbH is not liable for the consequences of anyone acting or refraining from acting in reliance on any information. Further, SCC has no control over the websites that the reader is linked with using our Homepage/Newsletter. Users linking to other websites do so at their own risk and use these websites according to the appropriate laws governing their usage.