

IMERY5315001

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A	B	C	D
1	Science Strategy Development		
2	Topic	Objective	Current Status
3			
4			
5	Borates - EU Biocides registration	Complete registration process to get borates listed on Annex 1	EU reviews completed. Listing on Annex 1 successful. Need to carry over some conclusions to RA and other EU reviews. Need to contest some conclusions in future reviews.
6	Borates - EU Classification	Provide technical justifications to demonstrate Cat II as inappropriate	Review of NIOSH/China occupational studies to provide summary of the preponderance of no adverse findings on male repro health at high exposures
7	Borates - EU Risk Assessment - exposure	Prepare exposure scenarios following TGD framework. Need to collect data to avoid using overly-conservative default values	Underway with EBRC, need funding from EBA and RTM, need cooperation from downstream users
8	Borates - Gender ratio	Use population census data from Boron site and Los Angeles County to evaluate male:female ratio	Project underway. Data not available as anticipated so approach being revised. Inactive since death of PI
9	Borates - Pesticide transfer rates	Obtain data to quantify transfer of borate pesticides from treated surface to hand/mouth	Summary report completed, submitted to US EPA, supports less-than-complete transfer
10	Borates - REACH implementation	Prepare data needed for REACH implementation: occupational exposures	Measure dust exposures at EU-based operations following TGD framework
11	Boron - China diet and chronic disease	Preliminary investigation into possible link between Kashin-Beck disease and low-boron diet	Analyses of typical foods
12	Boron - Diet and human health	Evaluate dietary intake of boron in China and identify any associations with chronic health problems	Planned work at Univ in Beijing (Gao). Presentations at ISTERH October 2007
13	Asbestos - redefinition	Provide support/participation in efforts to redefine asbestos by supporting an expert to help with biologically-based aspects of definition	Annual Johnson conference, 2008 includes session on definition. Possibly find/support expert to initiate biologically-based thinking about defining criteria; future possibility to co-sponsor with ATSDR or similar a conference to advance discussion.

	E	F	G	H	I
1		Version of	4-Jun-08		
2	Potential Collaborators	Potential Research Opportunity	Priority & Urgency	Draft Rating	
3					
4		Specific implementations may be considered, possible role for data on handling and use exposure factors		0	
5		Critical review of Chinese studies to prepare manuscript for publication		0	
6	EBA: EURAS, WES; borate customers	Data collection; initial exposures timed to meet 1 Dec 08 obligation for RA		0	
7	Whorton			0	
8	R Krieger (UC-Riverside)	Follow-up work possible; plan to meet summer '08		0	
9	Liberty Mutual, WES, EURAS	On-site survey (time & activity) plus monitoring to develop exposure scenario	high priority, immediate urgency	1	
10	Gao	Support analyses of foods for boron content; samples already collected		0	
11	Gao			0	
12	Pier, outside expert, other Rio Tinto	Perspectives article by expert reviewer on how to relate definition criteria to health effects	medium priority, urgency - 2008	1	
13					

	A	B	C	D
10	Borates - California Prop 65 listing	Prevent California from listing boron as Prop 65 reproductive toxicant	OEHHA trying to list based on EPA IRIS assessment. RTM successfully delayed initial proposal but another action pending	
14				
11	Borates - Canadian PMRA	Health Canada reviewing procedures for determining uncertainty factors in pesticide risk assessments. Provide technical justification to follow US EPA derivation or similar PBPK-based approach	Potential to participate or comment on PMRA workshop and proposals	
15				
12	Borates - Irritancy survey	Improved survey of Boron workforce in light of needs for GLP-like study, more rigorous protocol, and peer-reviewed publication	Survey planned, but no adequate protocol developed.	
16				
13	Borates - Male reproductive health	Evaluate whether borate exposure is associated with human reproductive impacts	NIOSH study publications under review. Robbins final report due to NIOSH 30-Sept-07. It appears no adverse effects at WHO-recommended exposures	
17				
14	OEL - feasibility review	Engage appropriate organization (AIHA, WEL committee) to develop role in recommending OEL but including consideration of feasibility	Concept proposed. May involve External Affairs professionals in RTM	
18				
15	OEL - irritation definitin	Work toward consensus of "irritation" that distinguishes it from perception and is consistent with other categories of OEL endpoints (eg fraction affected, etc)	Concept proposed. Need to clarify crossover point from "feel" to "irritation".	
19				
16	Prod Stewardship - GHS implementation	Determine GHS-compliant ratings and statements for RTM products	Preparation of GHS for RTM products underway based on UN framework. Need country-specific revisions	
20				
17	Prod Stewardship - IUCLID database update	Transfer data to IUCLID 5 but provide technical review of entries	Part of proposed work for EURAS under EBA contract within scope of EU RA	
21				

	E	F	G	H	I
14	RTM, consultants, California farm industry	OEHA proposals to exempt "naturally-occurring" but not additions, or releases. Data may not be route to success; use advocacy efforts.	high priority, immediate urgency	1	
15		Support data-based evaluations of UF, including consideration of PBPK, new European approach	medium priority, immediate urgency	1	Expects comments from others, need to finish/repeat our comments. Level of effort not great.
16	Greaney; Katchen (Phylomar); others?		high priority, immediate urgency	1	Upgrade of current planned survey to GLP-level. Need to discuss with TERA what they need to complete their MS. Discuss with Bill Cain some of survey tools.
17	Wei	Need to read report to NIOSH, formulate position.	high priority, immediate urgency	1	Not extensive effort for review, but follow-up may be needed
18	AIHA	Make initial contacts, evaluate interest and who might participate	medium priority, medium urgency	2	May not affect compliance but could affect future compliance, can do some informal contacts now; then may decide further opportunities
19	Consultant, industry associations	Contract for a white paper to discuss issues and status of "irritants"	high priority, immediate urgency	1	
20	RTM internal	Data gaps may be identified during review	Early implementation in 2008 in Asia	1	
21	RTM, EURAS	Data gaps may be identified during review, especially of low quality work	Deliver to meet 1 De 08 obligation	1	

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A	B	C	D
18	Talc - IARC publication	Monitor IARC publication for opportunities to incorporate reclassifications into IIB classification	Waiting for publication in 2008 (Aug, Sept?). Success rates of changes to text after meeting are extremely low. May affect texts via US Depts. Can use some of working draft documents to identify specific texts/wordings. Conclusions III - inhalation no risk - is good for occupational. Product conclusions not favorable, but products unclearly identified. May be able to challenge contention that there have been no public alerts to hazards of talc, but any review unlikely to be successful in modifying IARC decision.
22	Redacted		
23	Redacted		
24	Redacted		
25	Borates - Canadian PMRA assessment of wood treatments	Resolve issues on PMRA use of low quality (dog) data to drive endpoints	Pending 3rd party review
26	Borates - EU Risk Assessment - terrestrial data	Limited terrestrial ecotoxicity data will likely drive a very large application factor	Austria now re-reviewing data set. EURAS also to evaluate.
27	Borates - German OEL	Monitor dust exposures in Germany with customers in compliance with lowered German OEL (separate from MAK)	
28	Borates - GHS implementation in US	Monitor and comment as needed during development of US implementation process, particularly at OSHA	Provide technical comments in response to regulatory proposals. No evident activity by OSHA and US EPA at present moment (Ju 08)
29	Borates - MAK	Provide technical justifications to demonstrate why reduced OEL is not needed	Provide technical comments. Clarify whether this is broader issue, eg Dutch authority
30	Borates - Nasal irritation of dusts	Evaluate level of dust exposure associated with perception and symptoms	Survey at Boron, Calif planned but not conducted

	E	F	G	H	I
22	RTM internal	Opportunity to communicate via US Dept Commerce, Dept State to identify concerns, issues. Review timetable in 6-9 months. (after Sep 07)		3	
23	Redacted				
24				2	
25		Data gaps may be addressed. Also need to push for procedure that incorporates essentiality in hazard description		2	
26	RTM internal	Clarify what German agency has done, how it relates to MAK process, feasibility assessment		2	
27				2	
28		Communicate results of Boron irritation survey when available		2	
29	Peter Greaney, Mark Katchen (Phylomar)	Provide data to document perceptions of nasal irritation	(See other item regarding Boron survey, using more rigorous protocol)	2	
30					

A	B	C	D
27	Borates - Nasal irritation of dusts	Evaluate level of dust exposure associated with perception and symptoms	Experimental work completed. Manuscript on boric acid results published. Cain probably shutting down this lab (no other funding of Cain's work). Do we see utility in testing other dusts? How does this fit in with doing GLP survey - would this detract from that? Cost of \$50K/year may be needed to maintain capability. Original intent was to describe 5 mol as "feel" not "irritancy" but not achieved, at least in use of Cain studies by ACGIH, MAK. Data may be too novel for regulatory readers.
31	Borates - occupational exposure level evaluation	Prepare OEL recommendation for borate dusts in response to ACGIH revised TLV	Draft document prepared, waiting for survey data from Boron mine. However, dust monitoring program may indicate that number of workers possibly included in survey would be too small to be persuasive.
32	Borates - REACH implementation	Prepare data needed for REACH implementation: occupational exposures at downstream sites	Measure dust exposures at downstream users' sites following TGD framework
33	Borates - terrestrial ecotoxicity	Risk assessment of borates under EU TGD likely to assign large application factor because of data limitations	Potential to conduct additional studies; potential to summarize efficacy data as ecotox data by deriving NOEC/LOEL
34	Borates - Zinc Borate Re-registration with US EPA	Complete re-registration process	US EPA will publish data needs in 3Q08. Based on discussions with EPA we anticipate several studies being required. A rodent inhalation study is the biggest item.
35	Incorporate LCA analysis in regulatory schemes	How to apply work in LCA and SD benefits to discussions with regulators	Inactive. Potential benefit may come from using LCA information in discussions with regulators.
36	R&D sustainability/energy workgroup	looking to identify projects related to energy efficiency	Inactive for RegAffairs. Potential to consider biofuel alternatives; use in processing to improve efficiency; hydrogen storage; animal wastes
37	SD in gate review	improved method of analysis	better tool to describe SD aspects
38	Sustainability	Previous RTM commitment to sponsoring 3 projects/year in support of Sustainable Development	No funding provided in support of this. Will need to use projects developed for science strategy.
39			

	E	F	G	H	I
	Bill Cain (UC-San Diego)	Proposal received from Cain after revision, has specific details. May be able to address crossover between perception and irritation. Metaborates may be assessed. Clarify aim of defining threshold.	med priority, med urgency, but need response to Bill regarding his proposal	2	
31	Andy Maier (TERA)			0	
32	EBA; Battersby (EBRC)			2	
33				2	
34	ZB registrants, Zn industry organizations	Rodent inhalation study, dissolution dynamics in water		2	
35	RTM internal	Procedures need elaboration to integrate with stages of development of projects/products; improve metrics for both positive/neg aspects; develop mitigation plans		2	
36	RTM internal			2	
37					
38	Andrea Russell			2	
				2	
39					

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	A	B	C	D
36	Talcs - Cosmetic Ingredient Review	Assist and provide input to CIR to assist in their review of cosmetic talc with objective to obtain "insufficient data" status	Review announced by CIR to begin 2008. Prioritization done in response to IARC action. Little relevant expertise at CIR. Need multiple representation to cover two panels. May request industry to provide additional data within timeframe. Customers likely to have more experience with CIR than RTM.	
40	Talcs - GHS implementation in US	Monitor and comment as needed during development of US implementation process, particularly at OSHA	Provide technical comments in response to regulatory proposals	
41	Borates - Animal development	Evaluate whether dietary supplementation with borate is efficacious in animals	Research in "Boron in Life Science" project underway in R&D (J. Owen)	
42	Borates - European water standards	Provide technical justifications to prevent French INERIS proposing unacceptably low water quality standards	?	
43	Borates - Occupational exposures - case history of borate dusts	Present overview of OEL reviews of borates using various studies at Boron mine	Proposal to prepare technical publication. No action	
44	Borates - Wastewater removal methods	Develop commercially viable technology for removing borates to ppm concentrations	Research at Univ Surrey concluded.	
45	Boron - Animal development - cartilage	Monitor effect of dietary boron and healthy development of pig cartilage/joints	?	
46	Boron - Cell membrane research	Evaluate mechanism of borate action	No sponsored work at present	
47	Talc - ACGIH TLV	Provide technical justifications to demonstrate why reduced OEL is not needed	Provide technical comments	
48	Talc - Ovarian cancer	Monitor and provide technical responses to publications of epidemiological association between peritoneal talc powder applications and ovarian cancer	Additional studies expected from Harvard	
49	Borates - US drinking water standards	Prevent implementation of US boron drinking water standard	US EPA stated will not develop drinking water standards for boron (CCL action)	
50	Boron - Dietary intake	Estimates of range of dietary intake of boron	No sponsored work at present	
51	Boron - Gene array using amphibians	Develop biomarkers for boron-deficiency	Minor sponsorship to complete publications (D Fort)	
52	Boron - Nutrition, chemoprevention	Evaluate role of boron in nutrition	No sponsored work at present. Previous publications in 2003, 2004	
53				

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	Kelley (CRE); external technical experts	Need outside support from epi and gynecological experts. Coordinate with J&J, Schering Plough. Find timings from CTFA. Need technical commentary work		2	
40	RTM internal			2	
41				5	
42				3	
43				3	
44	Dennis Paustenbach (ChemRisk)(?)			3	
45	Jiang, Univ Surrey			3	
46	Barbera Vertel (Rosalind Franklin Medical School)			3	
47	Carl Keen			5	
48	RTM internal	Consider options for further action		0	
		Response after publication of studies		3	
49				4	
50				4	
51	C Rainey			4	
52	Doug Fort			4	
53	Gigliardo-Williams			5	

	A	B	C	D
50	Boron - Prostate cancer	Evaluate linkage between borate exposure and reduced incidence/severity of prostate cancer	Prostate tissue with higher boron showed decreased severity of tumors. Results published	
51	Boron - Trout in high-boron waters	Evaluate distribution of trout in Argentina Rio de los Patos regarding reproductive sites and ambient boron concentration	Master's thesis completed. Publication planned. Doctoral research requested	
52	Borates - Animal reproductive health	Analyze boron in pig sperm in animals with dietary supplementation	Results show no adverse effects. Presentation and publication prepared.	
53	Borates - Essentiality	Establish the essentiality of borates in mammals as rationale for revision to risk assessment and risk management	Historic emphasis of sponsored research. Minimal RTM studies at present. Transporter gene work published.	
54	Borates - Japanese PRTR listing	Remove boron from PRTR listing	"Boron study group" formed; consultant contacting Committee members	
55	Borates - Japanese water standards	Provide technical justifications to support appropriate water quality standards	Provide technical comments	
56	Borates - Mulch treatment	Evaluate potential phytotoxicity of borate-treated wood mulch on ornamental plants	Field tests in 2007 demonstrated toxicity and rapid migration to soil. 2008 evaluation of residual levels in soil and leachate	
57	Borates - Occupational Health studies in China and confounding factors	Evaluate potential confounding factors of any adverse effects attributed to borates in NIOSH study	Robbins group already identified smoking and alcohol as having adverse male repro effects	
58	Boron - Links to human health	Evaluate role of boron in nutrition	No sponsored work at present. Presenting at ISTERH: female mice offspring of low boron diet show metabolic syndrome (precursor to heart disease)	
59	Talc - Ovarian cancer	Evaluate whether talc use is associated with ovarian cancer	Micro-array analysis of genetic response	
60	Talc - Ovarian cancer	Evaluate whether talc use is associated with ovarian cancer	Meta-analysis of perineal powder studies	
61	Crystalline silica	Rio Tinto-wide (M)SDS statements and action	GHS-compliance revisions	
62	Talc	anti-carcinogenic properties of talc	Publication	
63	Boron - computational toxicology	Monitor US EPA project which includes boric acid as repro/developmental toxicant	EPA project to use variety of '-omic' screens to develop technique to predict tox properties of novel substances. Obtain data?	
64	Borates - ZB registrations		Track responses and requests from authorities, eg. Australia	

	E	F	G	H	I
54	Curt Eckert, Wade Barranco (UCLA)			5	
55	de Barros (Univ Nat de Salta), Joe Meyer (Univ Wyoming)			4	
56	Jerry Spears (Univ North Carolina)	Use pig as model for male reproductive effects at higher exposures	Lower priority	5	
57	Consultant			5	
58	Japanese trade group?			5	
59	Joseph Heckman (Rutgers Univ)	Evaluate movement of borate in field soil from surface application		5	
60				5	
61	Forrest Nielson, Curtis Hunt (USDA)			5	
62	Mossman (Univ Vermont)	Research is underway. IMA-NA will be able to review MS	high priority, wait for publication	5	
63	Huncharek & Muskat	New publication in process	high priority, wait for publication	5	
64	Hubbard, others	Proposals for >0.1% RCS being discussed		5	
65	Antony, Univ Florida	Ask Bob Glenn to make comments		5	
66				5	
67				0	
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A	B	C	D
65	Borates - women's health	Health of women in Chinese borate mine environs - evaluate possible beneficial effects	Proposal from Wei Fu-sheng, no action. Received in 2004, delayed pending conclusion of male reproductive health work
69	Borate - mechanism of biological effect	Provide biochemical mechanism to explain borate beneficial/toxic effects	New publication from W Barranco, C Eckhart, reporting B effect on Ca metabolism as likely mechanism
70			
71			

	E	F	G	H	I
	Wei Fu-sheng	Demonstrate beneficial health of elevated boron exposures			
69	Wade Barranco, Curt	Possible follow-up studies			
70	Eckhert				
71					

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Cell: E19

Comment: MCHarrass:

Does Nielson (DK) feel such as white paper could be written? Could he do it? Other irritants tend to be gaseous, have steeper slope in change from perception to irritancy. Dust exposures to irona, titanium, soda ash, potash, kaolin, wollastinite, talc, may have similar concerns. Mechanisms may need clarification. Progress could assist in acceptance of Cain's work.

Cell: D24

Comment: MCHarrass:

Labor Code method of listing of IARC IIB - two chemicals - actually was erroneous; LC cannot list "possible" human, only "Probable" or "known". Therefore talc cannot be listed via LC. Regarding Authoritative bodies procedure, talc could not be listed because not sufficient evidence - IARC said "only limited evidence" on perineal talc

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