

# IMERYYS322476

## Metadata

|                             |  |          |
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| <b>AttRange</b>             | IMERYYS 322474 - IMERYYS 322489                                      | ORIGINAL |
| <b>Author</b>               | Borax User   | ORIGINAL |
| <b>Batesrng</b>             | IMERYYS 322476 - IMERYYS 322489                                      | ORIGINAL |
| <b>BegAttach</b>            | IMERYYS 322474   | ORIGINAL |
| <b>Color_Image</b>          | No   | ORIGINAL |
| <b>Custodian</b>            | Imerys   | ORIGINAL |
| <b>DATA_Application</b>     | Microsoft Excel Spreadsheet  | ORIGINAL |
| <b>DATA_AttachBegin</b>     | IMERYYS 322474   | ORIGINAL |
| <b>DATA_AttachEnd</b>       | IMERYYS 322489   | ORIGINAL |
| <b>DATA_Author</b>          | Borax User   | ORIGINAL |
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| <b>DATA_DateCreated</b>     | 01/30/2007   | ORIGINAL |
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| <b>DATA_Doc_Type</b>        | Emails   | ORIGINAL |
| <b>DATA_DocExt</b>          | xls  | ORIGINAL |
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| <b>DATA_FileName</b>        | 0709 RegAff TABL Science Strategy draft.xls                          | ORIGINAL |
| <b>DATA_Filesize</b>        | 45056.00   | ORIGINAL |
| <b>DATA_MD5HASH</b>         | 0ac9fa1809efa3c778b18a0056785efa                                     | ORIGINAL |
| <b>DATA_Prod_Vol</b>        | IMERYYS016;  | ORIGINAL |
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| <b>DATA_Relative_File</b>   | Top of Personal Folders\Inbox\2008 Emails\Agenda for Science meeting | ORIGINAL |
| <b>DATA_TextPath</b>        | \\IMERYYS016\TEXT\0002\IMERYYS 322476.txt                            | ORIGINAL |
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| <b>EndAttach</b>            | IMERYYS 322489   | ORIGINAL |
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| <b>ID</b>                   | 297300   | ORIGINAL |
| <b>Load_Source</b>          | Imerys Production - IMERYYS016 - 03-07-2016                          | ORIGINAL |
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| <b>Organization</b>         | Imerys   | ORIGINAL |
| <b>ParentID</b>             | IMERYYS 322474   | ORIGINAL |
| <b>Placeholder</b>          | No   | ORIGINAL |
| <b>RecordType</b>           | IMAGE ATTACHMENT   | ORIGINAL |
| <b>Trial_Ex_Number</b>      | Pltf_IMERYYS_00078826  | ORIGINAL |

|    | A | B                                       | C  | D  | E                        |
|----|---|---|--|--|--------------------------|
| 1  |   | <b>Science Strategy Development</b>     |  |  |                          |
| 2  |   | <b>Topic</b>                            | <b>Objective</b>   | <b>Current Status</b>  | <b>Collaborators</b>     |
| 3  |   |   |  |  |                          |
| 4  |   |   |  |  |                          |
| 5  | 1 | Borates - EU Biocides registration      | Complete registration process to get borates listed on Annex 1   | On-going; human health review concluded favorably with refusal to use poor-quality dog study data; ecotox review imminent                        |                          |
| 6  | 2 | 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  | 3 | Borates - EU Risk Assessment - exposure | Prepare exposure scenarios following TGD framework. Need to collect data to avoid using overly-conservative default values | Planning underway with EBRC, need funding from EBA and RTM, need cooperation from downstream users   | Battersby (EBRC), EBA    |
| 8  | 4 | 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  | Whorton                  |
| 9  | 5 | Borates - Pesticide transfer rates      | Obtain data to quantify transfer of borate pesticides from treated surface to hand/mouth                                   | Collaboration with UC-Riverside (Krieger), risksciences (J Ross) to summarize existing studies   | R Krieger (UC-Riverside) |
| 10 | 6 | Borates - REACH implementation          | Prepare data needed for REACH implementation: occupational exposures   | Measure dust exposures at EU-based operations following TGD framework  | ?? Battersby (EBRC)      |
| 11 | 7 | Boron - China diet and chronic disease  | Preliminary investigation into possible link between Kashin-Beck disease and low-boron diet                                | Analyses of typical foods  | Gao                      |
| 12 | 8 | 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  | Gao                      |

|    | F   | G                                | H                   | I   |
|----|---|----------------------------------|---------------------|---|
| 1  | Version of 16-May-08  |                                  |                     |   |
| 2  |   |                                  |                     |   |
| 3  | <b>Potential Research Opportunity</b>   | <b>Priority &amp; Urgency</b>    | <b>Draft Rating</b> |   |
| 4  |   |                                  |                     |   |
| 5  |   |                                  | 0                   |   |
| 6  |   |                                  | 0                   |   |
| 7  |   |                                  | 0                   |   |
| 8  |   |                                  | 0                   |   |
| 9  |   |                                  | 0                   |   |
| 10 | On-site survey (time & activity) plus monitoring to develop exposure scenario | high priority, immediate urgency | 1                   | Originally part of EBA proposal, but RTM might benefit by doing sooner and for ourselves. Activity might help design of surveys in Boron and Wilmington |
| 11 |   |                                  | 0                   |   |
| 12 |   |                                  | 0                   |   |

|    | A  | B                                    | C  | D  | E                                     |
|----|----|--------------------------------------|--|--|---------------------------------------|
| 13 | 9  | 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. | Pier, outside expert, other Rio Tinto |
| 14 | 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  | RTM internal                          |
| 15 | 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   |                                       |
| 16 | 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.  | Greaney; Katchen (Phylomar); others?  |
| 17 | 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  | Wei                                   |
| 18 | 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 (current/proposed Federal legislation), as well as IH professionals in RTM  | AIHA                                  |

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| 13 | Perspectives article by expert reviewer on how to relate definition criteria to health effects | medium priority, urgency - 2008    | 1 |   |
| 14 | React to OEHHA meeting 19 Se 07  | 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 |  | 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 | 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 | 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                      |

|    | A               | B   | C  | D  | E            |
|----|-----------------|---|--|--|--------------|
| 19 | 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". | Consultant   |
| 20 | 16              | Prod Stewardship - GHS implementation     | Determine GHS-compliant ratings and statements for RTM products  | Evaluate existing data and various GHS-implementing regulations                | RTM internal |
| 21 | 17              | Prod Stewardship - IUCLID database update | Transfer data to IUCLID 5 but provide technical review of entries  |  | RTM internal |
| 22 | 18              | Talc - IARC publication                   | Monitor IARC publication for opportunities to incorporate refutations into IIB classification  | Waiting for publication in 2008 (Aug, Sept?)                                   | RTM internal |
| 23 | <b>Redacted</b> |   |  |  |              |

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|----|---|----------------------------------|---|---|
| 19 | Contract for a white paper to discuss issues and status of "irritants"  | high priority, immediate urgency | 1 | 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 trona, titanium, soda ash, potash, kaolin, wollastinite, talc, may have similar concerns. Mechanisms may need clarification. Progress could assist in acceptance of Cain's work.  |
| 20 |   |                                  | 1 |   |
| 21 |   |                                  | 1 |   |
| 22 | Oppty to communicate via US Dept Commerce, Dept State to identify concerns, issues. Review timetable in 6-9 months. |                                  | 3 | 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. |
| 23 | <b>Redacted</b>   |                                  |   |   |

|    | A  | B   | C  | D  | F                                      |
|----|----|---|--|--|--|
| 24 | 20 | Talcs - California Prop 65 listing                    | Prevent California from listing talc as Prop 65 perineal carcinogen. Talc, TiO2, Carbon black all IIB      | If OEHHA makes mistakes, they might list talc. If they do not make mistake, they will never propose or list. | <b>Redacted</b>                        |
| 25 | 21 | 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 | 22 | Borates - EU Risk Assessment - terrestrial data       | Limited terrestrial ecotoxicity data will likely drive a very large application factor                     |  |  |
| 27 | 23 | Borates - German OEL                                  | Monitor dust exposures in Germany with customers in compliance with lowered German OEL (separate from MAK) | Provide technical comments   | RTM internal                           |
| 28 | 24 | 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   |  |
| 29 | 25 | Borates - MAK   | Provide technical justifications to demonstrate why reduced OEL is not needed                              | Provide technical comments   |  |
| 30 | 26 | Borates - Nasal irritation of dusts                   | Evaluate level of dust exposure associated with perception and symptoms                                    | Survey at Boron, Calif planned but not conducted   | Peter Greaney, Mark Katchen (Phylomar) |
| 31 | 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                                      | Bill Cain (UC-San Diego)               |



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| 24 | Could anonymous 3rd party communicate to OEHHA that listing talc via LC or Authoritative body procedures would not withstand legal challenge?  |   | 1 | 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  |
| 25 |  |   | 2 |  |
| 26 |  |   | 2 |  |
| 27 | Clarify what German agency has done, how it relates to MAK process, feasibility assessment   |   | 2 |  |
| 28 |  |   | 2 |  |
| 29 | Communicate results of Boron irritation survey when available  |   | 2 | Clarify whether this is broader issue, eg Dutch authority  |
| 30 | Provide data to document perceptions of nasal irritation   | (See other item regarding Boron survey, using more rigorous protocol)       | 2 |  |
| 31 | 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. Frank Sullivan will be asked to comment on revised proposal. | med priority, med urgency, but need response to Bill regarding his proposal | 2 | Lab doing dust sensitivity studies is in danger of being eliminated (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. RTM projects on dusts may be decided within 1 yr +/- . Original intent was to describe 5 mol as "feel" not "irritancy" but not achieved |

|    | A  | B   | C  | D  | E  |
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| 32 | 28 | 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   | Andy Maier (TERA)                        |
| 33 | 29 | Borates - REACH implementation                    | Prepare data needed for REACH implementation: occupational exposures at downstream sites                                       | Measure dust exposures at downstream users' sites following TGD framework  | EBA; Battersby (EBRC)                    |
| 34 | 30 | 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                     |  |
| 35 | 31 | Borates - Zinc Borate Re-registration with US EPA | Complete re-registration process   | May need to address data gaps or out-dated data  |  |
| 36 | 32 | Incorporate LCA analysis in regulatory schemes    | How to apply work in LCA and SD benefits to discussions with regulators  | Balance effort with stage of development of projects/products; improve metrics for both positive/neg aspects; develop mitigation plans | RTM internal                             |
| 37 | 33 | R&D sustainability/energy workgroup               | looking to identify projects related to energy efficiency  | considering biofuel alternatives; use in processing to improve efficiency; hydrogen storage; animal wastes                             | RTM internal                             |
| 38 | 34 | SD in gate review                                 | improved method of analysis  | better tool to describe SD aspects   | Andrea Russell                           |
| 39 | 35 | Sustainability                                    | 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.                                      |  |
| 40 | 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 but timetable vague (within 1 year?)   | Kelley (CRE); external technical experts |
| 41 | 37 | 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   | RTM internal                             |
| 42 | 38 | Borates - Animal development                      | Evaluate whether dietary supplementation with borate is efficacious in animals   | Research in "Boron in Life Science" project  |  |
| 43 | 39 | Borates - European water standards                | Provide technical justifications to prevent French INERIS proposing unacceptably low water quality standards                   | Provide technical comments   |  |

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| 32 |   |   | 0 |  |
| 33 |   |   | 2 |  |
| 34 |   |   | 2 |  |
| 35 |   |   | 2 |  |
| 36 |   |   | 2 | Reg Affairs may benefit from using LCA informatin in discussions with regulators   |
| 37 |   |   | 2 | Reg Affairs may benefit from using LCA informatin in discussions with regulators   |
| 38 |   |   | 2 |  |
| 39 |   |   | 2 |  |
| 40 | Need outside support from epi and gynecological experts. Coordinate with J&J, Schering Plough. Find timings from CTFA. Need technical commentary work | Med priority, urgency - following CIR timetable | 2 | Prioritization done in response to IARC action. Low priority at CIR. 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. |
| 41 |   |   | 2 |  |
| 42 |   |   | 5 | Contact with USDA and meat industry associations as part of market approval process.   |
| 43 |   |   | 3 |  |

|    | A  | B   | C   | D  | E   |
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| 44 | 40 | 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  | Dennis Paustenbach (ChemRisk)(?)                        |
| 45 | 41 | Borates - Wastewater removal methods                            | Develop commercially viable technology for removing borates to ppm concentrations   | Research at Univ Surrey concluded.   | Jiang, Univ Surrey                                      |
| 46 | 42 | Boron - Animal development - cartilage                          | Monitor effect of dietary boron and healthy development of pig cartilage/joints   | Grant provided, pig chondrocytes, unclear results; 6 month extension. Now looking at chicken chondrocytes, possibly positive results | Barbera Vertel (Rosalind Franklin Medical School)       |
| 47 | 43 | Boron - Cell membrane research                                  | Evaluate mechanism of borate action   | No sponsored work at present   | Carl Keen   |
| 48 | 44 | Talc - ACGIH TLV  | Provide technical justifications to demonstrate why reduced OEL is not needed   | Provide technical comments   | RTM internal  |
| 49 | 45 | Talc - Ovarian cancer   | Monitor and provide technical responses to publications of epidemiological association between peritoneal talc powder applications and ovarian cancer |  |   |
| 50 | 46 | 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)   |   |
| 51 | 47 | Boron - Dietary intake  | Estimates of range of dietary intake of boron   | No sponsored work at present   | C Rainey  |
| 52 | 48 | Boron - Gene array using amphibians                             | Develop biomarkers for boron-deficiency   | Minor sponsorship to complete publications (D Fort)  | Doug Fort   |
| 53 | 49 | Boron - Nutrition, chemoprevention                              | Evaluate role of boron in nutrition   | No sponsored work at present   | Gillardo-Williams                                       |
| 54 | 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   | Curt Eckert, Wade Barranco (UCLA)                       |
| 55 | 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 being completed. Publication planned. Doctoral research requested  | de Barros (Univ Nat de Salta), Joe Meyer (Univ Wyoming) |
| 56 | 52 | Borates - Animal reproductive health                            | Analyze boron in pig sperm in animals with dietary supplementation  | Results show no adverse effects. Presentation and publication being prepared.  | Jerry Spears (Univ North Carolina)                      |
| 57 | 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.                            |   |

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|    |                                       |   | 3 |  |
| 44 |                                       |   | 3 |  |
| 45 |                                       |   | 3 |  |
| 46 |                                       |   | 3 |  |
| 47 |                                       |   | 5 |  |
| 48 | Consider options for further action   |   | 0 |  |
| 49 | Response after publication of studies |   | 3 | Additional studies expected from Harvard   |
| 50 |                                       |   | 4 |  |
| 51 |                                       |   | 4 |  |
| 52 |                                       |   | 4 |  |
| 53 |                                       |   | 5 | Has recently published papers (2003, 2004) |
| 54 |                                       |   | 5 |  |
| 55 |                                       |   | 4 |  |
| 56 |                                       |   | 5 |  |
| 57 |                                       |   | 5 |  |

|    | A  | B  | C  | D  | E                                   |
|----|----|--|--|--|-------------------------------------|
| 58 | 54 | Borates - Japanese PRTR listing  | Remove boron from PRTR listing   | "Boron study group" formed; consultant contacting Committee members  | Consultant                          |
| 59 | 55 | Borates - Japanese water standards                                     | Provide technical justifications to support appropriate water quality standards                    | Provide technical comments   | Japanese trade group?               |
| 60 | 56 | Borates - Mulch treatment  | Evaluate potential phytotoxicity of borate-treated wood mulch on ornamental plants                 | Field tests to be initiated April 2007, will monitor plants and soil-water concentrations  | Joseph Heckman (Rutgers Univ)       |
| 61 | 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  |                                     |
| 62 | 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) | Forrest Nielson, Curtis Hunt (USDA) |
| 63 | 59 | Talc - Ovarian cancer  | Evaluate whether talc use is associated with ovarian cancer  | Micro-array analysis of genetic response   | Mossman (Univ Vermont)              |
| 64 | 60 | Talc - Ovarian cancer  | Evaluate whether talc use is associated with ovarian cancer  | Meta-analysis of perineal powder studies   | Huncharek & Muskat                  |
| 65 | 61 | Crystalline silica   | Rio Tinto-wide (M)SDS statements and action  | GHS-compliance revisions   | Hubbard, others                     |
| 66 | 62 | Talc   | anti-carcinogenic properties of talc   | Publication  | Antony, Univ Florida                |
| 67 | 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?                   |                                     |
| 68 | 64 | Borates - ZB registrations   |  | Track responses and requests from authorities, eg. Australia   |                                     |
| 69 |    |  |  |  |                                     |
| 70 |    |  |  |  |                                     |
| 71 |    |  |  |  |                                     |

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|----|--|-------------------------------------|---|---|
| 58 |  |                                     | 5 |   |
| 59 |  |                                     | 5 |   |
| 60 |  |                                     | 5 |   |
| 61 |  |                                     | 5 |   |
| 62 |  |                                     | 5 |   |
| 63 | Research is underway. IMA-NA will be able to review MS | high priority, wait for publication | 5 |   |
| 64 | New publication in process                             | high priority, wait for publication | 5 |   |
| 65 | Proposals for >0.1% RCS being discussed                |                                     | 5 |   |
| 66 | Ask Bob Glenn to make comments                         |                                     | 5 |   |
| 67 |  |                                     | 5 |   |
| 68 |  |                                     | 0 |   |
| 69 |  |                                     |   |   |
| 70 |  |                                     |   |   |
| 71 |  |                                     |   |   |