I. Executive Summary & Overall Evaluation

The Advanced Environmental Health/Advanced Food Technology Standing Review Panel (SRP) evaluated risks to astronaut health during space flight due to inadequate food, exposure to lunar dust, and risk of infection, along with the ongoing and emerging plans to study these issues and potentially propose and/or develop countermeasures. The areas of focus included: 1) The risk of inadequate food system; 2) The risk of adverse health effects from lunar dust exposure; and 3) The risk of adverse health effects due to alterations in host-microorganism interactions.

For the risk of inadequate food system, the gaps and tasks place too much emphasis on achievement of five year shelf-life solely through package improvements. A restructuring of the gaps and tasks is recommended. More attention should be given to the design of vehicles and habitats that provide stowage environments to extend the storage life for foods. Specific attention should be given to storage environments external to the crew habitat, taking advantage of naturally occurring low oxygen, moisture and temperature environments. This will reduce the need for elaborate packaging and reduce waste. Focus should be on the testing of products and packaging for these environments. More emphasis should be placed on developing and testing bio-regeneration concepts in the near term, with the lunar missions being used as a test bed.

The risk of adverse health effects from lunar or Martian dust exposure was judged to be critical during long duration missions in potentially contaminated vehicles or on planetary surfaces. The plan to assess the unique properties of lunar dust and its affect on physiology is appropriate. Care must be taken during experimental activation (mechanical grinding of lunar rocks to create simulants) so that the grinding process does not contaminate the dust with metals from the grinding chamber. The in vivo toxicity studies of inspired lunar dust are appropriately planned for their relevance to astronauts. If the schedule permits, in vitro tests should be used as a cost-effective screening assay for toxicity after “activation” before proceeding to in vivo tests. This work should be benchmarked against what is known for silica and nuisance dust (e.g., titanium dioxide (TiO$_2$)). The dermal and ocular toxicity of lunar dust is unknown, but it is likely to be a major acute problem on surface missions and possibly on return missions. Acute toxicity in the eye should be assessed in some formulation of a Draize test. More chronic dermal and ocular irritancy, and possibly hypersensitivity testing should also be done following a comprehensive literature search for the most relevant cost-effective models. A formal risk assessment for the pulmonary toxicity of lunar dust should be conducted based on a No Observed Effect Level (NOEL) or No Observed Adverse Effect Level (NOAEL) from the rodent inhalation bioassay. A minor restructuring of the existing gaps was recommended and two new knowledge gaps were identified (see bullets below). These can be filled by a review of the literature for other particulates. The results of these literature reviews should be used to update the Permissible
Effect Level (PEL) for lunar dust by including acute and chronic cardiovascular risk and cancer risk.

- What is the potential for acute or chronic cardiovascular toxicity of lunar dust?
- What is the potential for carcinogenicity, especially pulmonary, from chronic exposure to lunar dust?

The risk of adverse health effects due to alterations in host-microorganism interactions was judged to be potentially mission critical. In the close living conditions of a spacecraft, some relatively common infections (e.g., meningococcal meningitis, Methicillin resistant Staphylococcus (MRSA)) can become life-threatening and a threat to the mission. Astronaut morbidity may also ensue from fungal hypersensitivity or the degradation of the normally protective intestinal microflora. In addition, the SRP recognized the likelihood of increased susceptibility to infection among astronauts chronically breathing dust, in which case macrophages are overwhelmed processing dust and are unavailable for fighting infection. Less well documented, is that immune suppression associated with long-term missions could alter the toxic effects of inhaled and deposited particles. This is hypothesized to result from a diminished host response during the period of immune suppression.

The current and planned microbial risk tasks, although appropriate, do little to close the gap – “What are the infectious disease risk factors and how do they affect the risk to crew health during manned space flight missions?” This is a large gap that has only begun to be addressed. Unaddressed issues include: whether there is a real increase in virulence among pathogens likely to infect astronauts; whether the immune system of astronauts changes during long duration missions in which they are exposed to cosmic radiation; and the physiological response of astronauts exposed to irritants/toxins in space habitats such as planetary dust, fungal spores, and endotoxin. There are missed opportunities to reduce microbial risks by infection control practices, and to control fungal colonization of the space habitat.

Five new tasks are suggested to close the gap of infectious disease risk factors. 1 – The SRP thought that astronaut microflora should be screened before and after long duration space flight to see whether there are changes in virulence of the microflora and whether the microflora maintains its protective role. 2 - The SRP thought that it would be critical to determine the nature and causes of changes in astronaut immune function during long missions outside of LEO; lunar missions will provide a natural experiment. 3 – The additional immune insults of dust, endotoxin, and fungal spores, which are likely to contaminate space habitats – need to be assessed for causing hypersensitivity and global immune dysfunction in astronauts. 4 - The SRP suggested that trade studies be made to determine the extent that microbial risks could be lessened by comparing current operational practices to a) instituting infection control practices, b) vaccination for meningococcal meningitis, MRSA, and other common human pathogens, and c) preflight microbial decolonization of astronauts. Fungal colonization of space craft, with its attendant risks to astronaut health and integrity of electronic systems, was seen to be potentially mission critical in long duration missions. 5 - The SRP suggests a trade study be conducted to determine the degree of reduction of fungal colonization when moisture controls are instituted as compared to current operational practices.
II. Critique of Gaps and Tasks in the *RISK OF INADEQUATE FOOD*

**AFT1: How can the food system deliver the required level of nutrition throughout the mission?**

AFT1 is an important and appropriate gap to be addressed. The primary deliverable is the assurance that the nutrient content of the product is adequate throughout shelf-life. These are appropriate and important tasks in response to AFT1 and should be achievable in their scheduled time.

**Current Tasks:**
- In-suit food for Contingency Operations (AFT - Directed)
- In-suit food for Lunar EVA operations (AFT - Directed)
- Effect of Processing on the Nutritional Content of Food (AFT - Directed)
- Stability of Pharmacotherapeutic and Nutritional Compounds: Stability Supplemental
- Medical Objective (SMO) (Flight) (NxPCM with collaboration by AFT - Directed)

**AFT2: How can the nutrition and acceptability of the food system be maintained throughout the mission?**

AFT2 seems to be redundant to AFT1 and AFT3. Deliverables from these tasks include shelf-life and packaging, and the tasks respond to the other two gaps. These are important tasks required to ensure delivery of required nutrition to the crew. All three of the tasks are closely related to AFT1 and AFT 3, and should be reassigned to those gaps.

**Current Tasks:**
- Thermostabilized Shelf-Life Study (AFT - Directed)
- Department of Defense (DoD) Collaboration (AFT - Directed Study in collaboration with DoD)
- Effect of Space Radiation on Shelf Life (Directed Study for Summary; Additional research, if required, will be External Research)

**AFT3: How can the acceptability of the food system be maintained throughout the mission?**

AFT3 is an important gap that addresses the variety, acceptability and usability of the foods, and responds to the psychological needs of the crew. This task is appropriate and important in responding to the gap.

**Current Task:**
- Sensory Qualities in Microgravity (AFT - External research)

**AFT4: What technologies can be developed that will efficiently balance appropriate vehicle resources such as mass, volume, and crewtime during exploration missions with the safety, nutrition, and acceptability requirements?**
Higher priority should be given to tasks associated with bio-regeneration to ensure that these systems will be developed and demonstrated in the near term. Lower priority should be given for tasks involving the development of packaging materials for extending shelf-life. As suggested in the Executive Summary, more effort should be devoted to creating appropriate storage environments for the product, taking advantage of naturally occurring low oxygen, moisture and temperature environments, while reducing package mass and waste.

**Current Tasks:**

- Comparative Packaging Study (AFT - Directed)
- Small Business Innovative Research (SBIR) Program Advanced Packaging Material Development (AFT – Directed)
- Total System Approach to Packaging Material Selection

All three of the tasks listed above should be reevaluated or assigned lower priority as compared to tasks associated with the achievement of longer shelf-life using appropriate storage environments (naturally occurring low oxygen, moisture, temperature conditions). An additional task should be developed: a trade study comparing shelf-life and mass/volume/power requirements for: 1) using improved packaging to achieve a 5 year shelf-life under ambient crew habitat conditions; versus 2) using available low temperature, low oxygen and low moisture storage environments external to crew habitat with minimal packaging.

- Packaged food mass reduction trade study (AFT - Directed)
- Bulk Overwrap Packaging Alternative (AFT - Directed)

The importance of the tasks listed above has been demonstrated and similar efforts should be continued.

- Food system requirements for Lunar PDR and Mars missions (FY2017)
- Food Processing vs. Packaged Food System Trade Study (AFT - Directed)
- Support Development of Processing and Preparation Equipment and Procedures (AFT – Directed or External)
- Vegetable Growth (AFT– Directed or External)

All four of the tasks listed above emphasize bio-regeneration to provide production, processing and preparation of food on the lunar surface or Mars. These tasks should be moved up in the schedule and be given higher priority. Early lunar missions should be used as test beds for food production, processing and preparation.

**III. Critique of Gaps and Tasks in the RISK OF ADVERSE HEALTH EFFECTS FROM LUNAR DUST EXPOSURE**

**AEH 1: What are the unique properties of lunar dust that affect physiology?**
AEH1 gap and the related tasks are appropriate. It is worth noting that to prepare lunar simulant samples by mechanical grinding, care must be taken that the grinding process does not contaminate the simulant (e.g., erosion of the jet mill chamber by abrasive minerals).

Current Tasks:
- AEH, LADTAG directed study Geology, Geochemistry and Lithology Science Support Activities. (Lunar Dust - Geology)
- Dust Size Factor (Physiology) Studies (Directed Studies – Shape & Chemistry Analysis Study; Forensic analysis of Apollo artifacts)
- Activation Factor Study – (Directed Study – Reactivation studies, solar wind impact studies)
- Size, Shape, Chemistry Analysis and Lunar Activation Studies

AEH 2: What is the toxicity of respired lunar dust in the respiratory system?

AEH2 is an important gap and the task is appropriate. It is worth noting that if residence in space is associated with significant immune suppression, the toxic effects of inhaled and deposited particles could be modified by a diminished host response during the period of immune suppression.

Current Task:
- Pulmonary Toxicity Studies of Lunar Dust in Mice and Rats (Lunar Dust – ITI) (Dose, Species & Activation Factors) – Inhalation Toxicity, Intratracheal & Intrapharyngeal Instillation Testing (AEH, LADTAG – via directed study)

AEH 3: What is the mode of action of lunar dust at the respiratory cellular level?

AEH3 gap is better seen as a subset of the AEH2 gap. Its tasks should be part of AEH2 and they should be used to inform the design of the AEH2 in vivo studies. In particular, they should be used as a screening assay for toxicity of the stimulant after “activation”.

Current Tasks:
- Study of Lunar Dust and Lunar Simulant Activation, Monitoring, Solution and Cellular Toxicity Properties (Lunar Dust-Cell) (AEH, LADTAG – via directed study)
- Lunar cell culture toxicity testing (Active vs. Non-Active Dusts)

Space habitats may be contaminated with both planetary dust and endotoxin, if the habitats (space craft and stations) are moist. The respiratory toxicity of both contaminants should be considered in combination, across a range of humidity levels likely to be found in space habitats.

Positive controls using silica and nuisance dust (e.g., TiO2) benchmarks are essential and need to be included. The experimental endpoints and length of the inhalation exposure as planned are relevant to astronaut exposures.

AEH 4: What is the dermal and ocular toxicity of lunar dust?
AEH4 is an appropriate gap.

**Current Task:**
- Studies to Evaluate Lunar Dust Toxicity in Dermal and Ocular Systems (Lunar Dust D/O) (AEH, LADTAG – via directed study)

The extent of hazards to skin or eye from lunar dust is not known. It is appropriate to investigate the inflammatory response to lunar dust in the eye in some formulation of a Draize test. It is also appropriate to undertake some type of dermal toxicity evaluation using intra-, epi-, and percutaneous administrations focusing on irritancy, and hypersensitivity assessments, following a comprehensive literature search for the most relevant and cost-effective models. A literature search should be conducted for relevant models of chronic dermal or ocular toxicity from dusts, in particular mineral dusts and soils.

Appropriate testing can include:

1. Skin studies (human patch testing for acute exposures): The dust samples can be tested using the Human Repeat Insult Patch Test (RIPT) using ISO 10993 guidelines (this can include abrasion, primary irritation and sensitization).

2. Ocular Studies (rabbit model): The dust samples can be tested using a Draize Rabbit Score as follows:
   A. 1 day - read at 72 hrs, 100 ul aqueous and 100 ul sesame oil extracts
   B. 7 days (repeat daily); read up to 72 hr after last dose
   C. 3x/day (100 ul/dose) x 7 days; read daily and 72 hr after last dose

Readings should include: (1) Draize Score (erythema and edema), cornea, conjunctiva and sclera; (2) Histopathology of the eye (including serial sections of the cornea); also include adnexa, eyelids, puncta, lacrimal ducts.

**AEH 5: What are the permissible exposure limits for inhalation of lunar dust?**

AEH5 is an appropriate gap.

**Current Tasks:**
- LADTAG Lunar Dust Health Standard (LDHS)
- AEH Watch Item/NSBRI Research: What are the effects of lunar gravity on permissible exposure limits for inhalation of lunar dust?
- Aerosol Deposition in the Lung in Fractional Gravity: Risk Mitigation for Lunar and Martian Habitats (Aerosol Deposition) (NSBRI – NRA selected task)
- Clearance of Particles Depositing in the Human Lung in Low Gravity (Human Lung low g) (NSBRI – NRA selected task)

In addition to these tasks, a formal risk assessment should be conducted based on a NOEL or NOAEL from the rodent bioassay.
IV. Critique of Gaps and Tasks in the \textit{RISK OF ADVERSE HEALTH EFFECTS DUE TO ALTERATIONS IN HOST-MICROORGANISM INTERACTIONS}

This gap is large and recently identified. It may be appropriate to split the gaps into smaller, more tractable elements. The tasks, although appropriate, do little to close the gap. Knowledge gaps remain in the areas of increased pathogen virulence, astronaut immunosupression, infection control practices, and fungal control.

Virulence: Several studies have documented increased virulence in several pathogenic bacteria when cultured in space or in microgravity analogs. However, these studies do not reflect the risk to astronauts. The pathogens studied are unlikely to cause disease in astronauts who have undergone quarantine. The culture studies have been done in broth, in log-phase, and are not comparable to the conditions during human infection. A new task (Task #1 below) is recommended to compare astronaut gut, skin and mucous membrane microflora (especially \textit{E. coli}) before and after space flight. Microflora composition and virulence should be assessed.

Immunosupression: Immunosupression has been noted following space flight, but the reasons for the changes have not been identified, and the extent of suppression during long term space missions has not been elucidated. A new task (Task #2 below) is recommended to assess the change in immunity and their causes during long duration missions. Planetary missions represent an even greater challenge to the immune function of astronauts because of exposure to planetary dust and to microbial antigens and toxins (endotoxin, fungal spores) in space habitats. A new task (Task #3 below) is recommended to assess the likelihood of global immune dysfunction in astronauts in the presence of these agents using rodent and cell culture bioassays.

Infection control practices: A formal infection control program should be designed to minimize the transmission of microorganisms between astronauts during space flight. This should include, but not be limited to, hand hygiene, decontamination of frequently touched surfaces, and covering coughs and sneezes. A new trade study (Task #4 below) is recommended to quantify the reduction in risk provided by an infection control program. This program should also include pre-flight decolonization of astronauts, as well as vaccinations for meningococcal meningitis, and other common human pathogens.

RECOMMENDED NEW GAPS:

The SRP identified two additional gaps, which can be filled by a comprehensive literature review on other particulates, and used to adjust the PEL for lunar dust to include the risks of cardiovascular toxicity and cancer.

- What is the potential for acute or chronic cardiovascular toxicity of lunar dust?
- What is the potential for mutagenicity/carcinogenicity, especially pulmonary, from lunar dust?
Fungal colonization of space craft: Fungi colonize space craft, often extensively. Remediation is attempted, but prevention is a better strategy. Immunosuppression and changes in microbial virulence may significantly increase the risk of opportunistic infection or hypersensitivity on long space flights. Extensive fungal growth may also compromise contents and structure of the space craft, especially with respect to electronics. A new trade study (Task #5 below) is recommended to assess the rates of fungal contamination using procedures to minimize fungal colonization of the space habitat as compared to current operations. Fungal anti-colonization measures include the prevention of condensation, splashing, and other means by which water contaminates surfaces in the spacecraft.

The SRP recommends five new tasks to address the gap:

1. A task to assess microbial species present on the mucous membranes, skin, and gut of astronauts and their virulence prior to flight and after return to Earth. The two sets of samples should be cultured and then examined for phenotypic and genotypic differences affecting virulence. This type of study would provide better data for assessing the risks to crew members.

2. A task to determine the extent and mechanisms of immune dysfunction in astronauts during long duration space flight or deployment on the moon. Astronauts deployed on the moon or engaged in long duration space flight beyond the Van Allen belt will be subjected to greater radiation than in low Earth orbit (LEO) and should have their immune system function assessed over time. Studies on immune function after exposure on the moon could be performed using one of three protocols:
   a. Samples of blood could be taken at appropriate times and immediately tested using instruments present at the lunar station.
   b. Samples of blood could be taken at appropriate times and stored in the lunar station until transportation back to Earth was available. For this approach, additional studies would need to be performed to determine what would be the most effective storage protocol to prevent degradation of the blood samples prior to return to Earth. Data from these studies could be used to set the parameters for storage of blood in the lunar station.
   c. Since travel from the lunar station to Earth takes only three days, astronauts could have blood samples drawn for immunological testing immediately after return to Earth. Another option that could be added to this approach would be to draw blood just prior to departure from the lunar station and return those samples to Earth with the astronauts. Test results on samples drawn on the moon could then be compared with test results from the blood drawn immediately after return to Earth. A weakness of this approach is that the time course of changes in immune function could not be determined.

3. A task to assess global immune function in the presence of dust, endotoxin, and fungal spores that are likely to contaminate space habitats during long planetary missions. However, the immune response may depend on whether or not immune systems have been exposed to radiation typical of space above LEO. Studies may find that these irritants are not a problem for suppressed immune systems exposed to radiation, but may become problematic as the immune function recovers.

4. A trade study should be undertaken to compare the risk reduction of an infection control
program compared to current operations. This trade study should also compare infection risks of current practices compared to a system using vaccination against common pathogens (meningococcal meningitis) and pre-flight decolonization of astronauts.

5. A trade study to assess the rates of fungal contamination of the space habitat using procedures to minimize fungal colonization as compared to current operations. Fungal anti-colonization measures include the prevention of condensation, splashing, and other means by which water contaminates surfaces in the spacecraft.

**AEH 6: What are the infectious disease risk factors and how do they affect the risk to crew health during manned spaceflight missions?**

**Current Tasks:**
- Microbial Risk Assessment (Micro-Risk) (AEH, Directed Study)

The variables being examined in this directed study are appropriate for understanding microbial risk. However, the issue of possible contamination of recycled water by endotoxin produced by gram-negative microorganisms in biofilms should be addressed. While absorption or reverse osmosis may remove endotoxin from recycled water, the biofilms in the conduits downstream from the reprocessing unit will have biofilms that may release endotoxin into the processed water. Concentrations of endotoxin could build up over a long journey to Mars. Given the very limited volume of water in the system, endotoxin concentrations could reach levels that would be toxic to the crew.

- A Comprehensive Characterization of Microorganisms and Allergen in Spacecraft Environment (Micro-SWAB E-049) (AEH, NRA)

The data being collected in this study should be useful in determining how to minimize environmental contamination that might put crew members at risk for infection. However, little information on the design of the study was presented and it is unclear what types of microorganisms are being detected on environmental surfaces. It will be important to detect viruses on surfaces since crew members may shed reactivated Herpes viruses asymptotically. These studies should include the ISS where microorganisms are being continuously shed by crew members and where microorganisms on surfaces would more likely be recovered. The SWAB study should include sampling of biofilms in the water delivery and processing systems, if it doesn’t currently.

- Data Mining (AEH, Directed Study)

This appears to be an appropriate source for the Microbial Risk Modeling Study. Insufficient information was provided for this task to assess the adequacy of the study design.

- Host - Microbe Interactions Workshop (AEH, Directed Study)

The relevance of changes in the virulence characteristics of *Salmonella typhimurium* and other human pathogens based on growth in culture media cannot be assessed with respect to whether
or not crew members are at an increased risk of infection.

Healthy crew members who have been quarantined prior to space flight are unlikely to be colonized or infected with *Salmonella typhimurium*. The greatest risk for infection is from the microorganisms they carry into space that colonize skin and mucous membranes. Astronauts could be asymptomatically colonized with *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Neisseria meningitidis* or *Hemophilus influenzae*. These microorganisms can be carried asymptomatically for prolonged periods of time and shed at anytime, exposing other members of the crew. These microorganisms present a risk of invasive disease throughout a mission.

It is not yet known whether microorganisms colonizing the mucous membranes or skin of astronauts would undergo the same changes in virulence observed for *Salmonella typhimurium* cultured in broth. Microorganisms that colonize mucous membranes and skin are not in the log phase of growth while colonizing these sites. New task 3 above is recommended to adequately address this gap.

- Validation of Procedures for Monitoring Crewmember Immune Function (SMO 015/SDBI 1900) (Integrated Immune)

The studies on procedures for monitoring crew member immune function in low Earth orbit (LEO) are appropriate. Data derived from studies on crew members of the Shuttle and ISS may be applied to amelioration of immune suppression in LEO, but data on immune function relevant to missions to the moon and Mars will need to be collected on the moon. Adverse effects on crew members’ immunity beyond LEO will be more intense due to longer exposure to radiation and stress. Further, cosmic radiation will likely have a more deleterious effect on immune function than will radiation in LEO. Given that the data collected from crew members in LEO will likely not reflect the risk to those on trips to the moon and Mars, planning for studies on immune function of astronauts living on the moon for extended periods should be started in the near future (new task 2 above).

V. Discussion on the strengths and weaknesses of the IRP

The AEH/AFT Risk SRP addressed the risk to the food system, the risk of adverse health effect due to planetary dust exposure, and the risk of infectious disease. The identified risks are appropriate. The SRP suggested removing redundant gaps and identified new knowledge gaps. Several new tasks are recommended to close the gaps. The gap involved with microbial risks was noted to be vast, unlike the more targeted gaps in the other risks. This gap was not split, although new tasks were recommended for important subareas of the gap: microbial virulence; astronaut immune suppression; infection control; and fungal colonization of space craft. Specific recommendations concerning tasks are given in the sections above. The tasks involving risk to the food supply were thought to be mis-targeted, trying to achieve a five year shelf-life through packaging. Instead, stowage areas with natural low oxygen, moisture and temperature should be used to achieve a five year shelf-life. The gaps related to planetary dust exposure needed slight adjustment and two new gaps were identified: cardiovascular toxicity of dust and
carcinogenicity of dust. The tasks involving microbial risks, while appropriate, do little to close the knowledge gap. Five new tasks are recommended involving determining changes in composition and virulence of astronaut microflora before and after space flight, assessing immune dysfunction during long duration missions (including lunar deployment), and after exposure to dusts, mold spores, and endotoxins likely to contaminate space habitats during planetary missions.

VI. Discussion of element specific questions in addendum and/or any other issues or concerns the panel chooses to address.

1. Are there obvious, unrealistic aspects in the IRP schedule?

The schedule appears to be reasonable. Studies that may modify the PEL for lunar dust, such as cardiovascular toxicity and carcinogenicity of lunar dust, can be incorporated during the scheduled review. Bio-regeneration needs to be brought forward and proved on the moon for use on Mars missions. Astronaut immune dysfunction, contributed to by dust, microbial products, and cosmic radiation needs to be studied early and thoroughly. This will require laboratory facilities on the moon or facilities for effective storage of blood samples on the moon with tests performed after return to Earth. Another consideration would be to test samples of blood immediately after the astronauts return to Earth.

2. Does our portfolio of gaps and tasks allow us to understand the risk and its likelihood and consequence?

As written, the IRP tasks miss the mark (e.g., food system risk), does not fully assess risk (e.g., cardiovascular toxicity and pulmonary carcinogenicity of lunar dust), or only begin to assess risk (microbial risks).

However, the SRP has made suggestions that will allow the IRP to be revised and become a good plan to assess the risks and the consequences.

3. Is the portfolio of tasks developing appropriate deliverables? Will these deliverables be sufficient to mitigate the risk, or are others necessary?

For the food system, the deliverables – five year stability – is laudable, but can’t be achieved by packaging, given the limits to upmass and waste disposal. Instead, a focus on stowage compartments that provide low oxygen, moisture and temperature, can easily achieve a 5 yr shelf-life. Studies of bio-regeneration of foods should be moved to the front of the schedule and be part of provisioning during lunar missions.

For the lunar dust risks, the PEL is a worthy deliverable, but it will need to be revised with inputs on cardiovascular toxicity and pulmonary carcinogenicity. The role of dust exposure in immune dysfunction needs to be considered.

For the microbial risks, there are several areas within the gap that are not sufficiently addressed:
Virulence studies are not assessing the risk of infection for astronauts, microbial risk studies appear to be over-looking endotoxin, which could accumulate in the water systems during long missions, and the SWAB study may not be assessing biofilms for potentially virulent opportunistic pathogens.

Many of the microbial risks could be greatly lessened with different practices – such as moisture control to limit fungal colonization of the habitat, infection control to limit the pathogens brought into the habitat and to make transmission among the crew more difficult.

4. Is the portfolio well balanced between risk description, development of requirements and recommendations, and technology development activities?

The IRP is well balanced between risk description, development of requirements and recommendations. Some technological developments identified by the SRP as important (e.g., bioregeneration crop facilities, stowage compartments for food, immunological studies on astronauts after exposure on the moon) are either not planned or are in early development. These need to be moved forward in the schedule.

5. Is the approach to prioritizing gaps appropriate?

The approach appears to be that gaps are prioritized by whether or not they are mission-critical. The SRP agrees that this is a reasonable approach. However, the SRP differs with the IRB in their assessment of the criticality of particular risks, as discussed more fully in the report.
VII. Advanced Environmental Health/Advanced Food Technology (AEH/AFT) SRP Charge

The SRP is chartered by the Human Research Program (HRP) Program Scientist at the NASA Johnson Space Center (JSC). The purpose of the SRP is to review and provide analysis on the status and progress of HRP Elements and Projects. Your report will be provided to the HRP Program Scientist and will also be given as a courtesy to the SHFH Element and AEH/AFT Projects at JSC.

The SRP should (to the fullest extent practicable):

1. Evaluate the ability of the Integrated Research Plan (IRP) to satisfactorily address the risks by answering the following questions:
   A. Have the proper Gaps have been identified to address the Risks?
      i) Are all the Gaps relevant?
      ii) Are any Gaps missing?
   B. Have the proper Tasks have been identified to fill the Gaps?
      i) Are the Tasks relevant?
      ii) Are any Tasks missing?

2. Identify the strengths and weaknesses of the IRP, and identify remedies for the weaknesses, including answering these questions:
   A. Are the risks addressed in a comprehensive manner?
   B. Are there obvious areas of potential integration across disciplines that are not addressed?

3. Address (as fully as possible) the questions provided in the charge addendum and to comment on any additional information provided to the Panel that is not addressed in #1 or 2 above.

4. Expect to receive review materials at least five weeks prior to the site visit.

5. Participate in a SRP teleconference to discuss any issues, concerns, and expectations of the review process approximately three weeks prior to the face-to-face meeting
   A. Discuss the SRP charge and address questions about the SRP process
   B. Identify any issues the SRP would like to have answered prior to the site visit

6. Attend the SRP meeting (and possible tour) at NASA/JSC
   A. Attend Element and Project presentations, question and answer session, and briefing
   B. Prepare a draft report including recommendations from the SRP that will be briefed to the Program Scientist by the SRP chairperson or panel. The report should address #1 and 2 above, the questions in the charge addendum, and any other information considered relevant by the SRP.

7. Prepare a final report (within one month of the site visit) that contains a detailed evaluation of the risks and provides specific recommendations that will optimize the scientific return to
the HRP. The final report should provide a comprehensive review of Item #1 and 2 above, address the questions in the addendum to the charge, and any additional information the SRP would like to provide.

8. Consider the possibility of serving on a non-advocate review panel of a directed research proposal or on a solicited research peer review panel; or otherwise advise the Program Scientist.

Addendum to charge (Element Specific Concerns):
1. Are there obvious, unrealistic aspects in the IRP schedule?
2. Does our portfolio of gaps and tasks allow us to understand the risk and its likelihood and consequence?
3. Is the portfolio of tasks developing appropriate deliverables? Will these deliverables be sufficient to mitigate the risk, or are others necessary?
4. Is the portfolio well balanced between risk description, development of requirements and recommendations, and technology development activities?
5. Is the approach to prioritizing gaps appropriate?
VIII. Advanced Environmental Health/Advanced Food Technology (AEH/AFT) SRP Roster

Panel Chair:
Howard Kipen, M.D., MPH
UMDNJ-Robert Wood Johnson Medical School

Panel Members:
Harriet Burge, Ph.D.
EMLab P&K

Terry Gordan, Ph.D.
New York University School of Medicine

Dennis Heldman, Ph.D.
Heldman Associates

Jeffrey D. Laskin, Ph.D.
UMDNJ-Robert Wood Johnson Medical School

C. Glen Mayhall, M.D.
University of Texas Medical Branch, Galveston

Anna Shvedova, Ph.D., D.Sc.
National Institute of Occupational Safety and Health

Art Teixeira, Ph.D.
University of Florida