Conducting NEPA Analysis for In Situ Homeland Security Research, Development, Testing and Evaluation

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Abstract

The founding principle of the Department of Homeland Security (DHS) is to protect the American people from terrorist threats. To that end, DHS seeks to develop and deploy technological solutions enabling enhanced protection. The confluence of homeland security; research, development, testing and evaluation (RDT&E); and application of the National Environmental Policy Act (NEPA) process can pose significant challenges for government, stakeholders and the public, particularly when activities necessarily transition from beyond the confines of the laboratory to the public environs.

It is well documented that application of the NEPA process early in project planning can lead to better decisions, through consideration of reasonable alternatives and their potential impacts upon the human environment. NEPA practitioners frequently cite large land-use projects or policies as examples of the process well (or not so well) applied, emphasizing the importance of focusing on the decision to be made and avoiding narrow consideration of the purpose and need. Yet, agencies are required to apply the process to all "major federal actions", and certain types of actions present inherent challenges to open-minded consideration of the purpose and need. Particularly, RDT&E activities generally seek to examine specific phenomena, often times reducing the scope of potential alternatives. Given this constraint, how do decision-makers employ NEPA to add value in making decisions for in-situ RDT&E? Can NEPA be a vehicle to better engage and inform the public, allowing decision-makers to better understand public and stakeholder concerns, and the public to better understand technologies designed to protect the community? Recognizing the innate challenges in applying the NEPA process to in-situ homeland security RDT&E initiatives, case study examination revealed several lessons learned and recommendations.

Introduction

Applying NEPA to decision making involving homeland security RDT&E activities, particularly those involving technology transition from the laboratory to the end-user environment and thus occurring in the public environs, presents unique challenges to NEPA practitioners and decision-makers alike. This examination seeks to identify recommendations and lessons learned for conducting the NEPA process to inform decision making for homeland security RDT&E activities undergoing technology transition to the end-user, or “in-situ” environment. Discussion will revolve around two general inquiries:

1) How do decision-makers employ NEPA to add value in making decisions for in-situ RDT&E?
2) Can NEPA be a vehicle to better engage and inform the public, allowing decision-makers to better understand public and stakeholder concerns, and the public to better understand technologies designed to protect the community?

Section One introduces the context for homeland security RDT&E, discussing the creation of the Department of Homeland Security (DHS) through the Homeland Security Act of 2002, the role of RDT&E within the Act, and NEPA consideration in DHS RDT&E decision-making. Section Two provides a brief discussion of the application of NEPA to date and its role in Federal decision-making, including recognition of its intent, requirements, and critiques for consideration in improving the employment of the process. Section Three discusses RDT&E within the context of NEPA, and the associated constraints and challenges as RDT&E projects are brought from the laboratory to the in-situ, end-user environment (technology transition) as required by the Homeland Security Act of 2002. Review of a case study, the DHS “Detect to Protect” project, follows. Section Four offers lessons learned from the case study, and recommendations for future NEPA analyses and decision-making within the homeland security RDT&E discipline.

Section 1: The Homeland Security Act of 2002, RDT&E, and NEPA

The Homeland Security Act of 2002 (hereafter referred to as “the Act”) was passed as Public Law 107-296 on Nov. 25, 2002 and established the Department of Homeland Security, or DHS, as an executive department of the United States. Section 101(b) generally defines the mission of the Department, to:

- Prevent terrorist attacks within the United States;
- Reduce the vulnerability of the United States to terrorism; and
- Minimize the damage, and assist in the recovery, from terrorist attacks that do occur within the United States.

The application of science and technology (more specifically, RDT&E) to the challenge of homeland security was highly prioritized within the Act. Title 3 of 17 is entitled “Science and Technology in Support of Homeland Security”, which established among other things, the Under Secretary for Science and Technology (and the accompanying Science and Technology Directorate, or S&T), the Homeland Security Advanced Research Projects Agency, federally funded research and development centers, and the Homeland Security Science and Technology Advisory Committee. The Act charges the Under Secretary with developing technologies to identify and develop countermeasures for chemical, biological, radiological, nuclear, and other emerging terrorist threats; and supporting infrastructure protection through assessing and testing vulnerabilities and possible threats. Beyond the sponsorship and direct conduct of RDT&E toward this end, the Under Secretary was further charged with transitioning developed technologies to the end-user community, including Federal, State, local government and private sector entities.

Section 308 of the Act outlines the conduct of RDT&E within S&T, both intramural and extramural. Intramural activities include those conducted directly by DHS, in DHS laboratories or those owned and operated by other entities of the Federal government. Extramural activities include those conducted by universities and private enterprises through grants, cooperative agreements and contracts.

Following the Act, the newly created DHS developed its NEPA implementing procedures and categorical exclusions (CATEXs), and compiled its administrative record for the review of CEQ and the public (DHS, 2006). Among CATEXs were specific categories for operational activities, and within that set, descriptions of RDT&E activities appropriate for categorical exclusion. The majority of RDT&E activities are addressed by exclusion *B1*, which reads: *"Research, development, testing and evaluation activities, or laboratory operations conducted within existing enclosed facilities consistent with previously established safety levels and in compliance with applicable Federal, tribal, state, and local requirements to protect the environment when it will result in no, or de minimus, change in the use of the facility. If the operation will substantially increase the extent of potential environmental impacts or is controversial, and EA (and possibly an EIS) is required."*

It can therefore be stated that *B1* excludes from further review activities occurring within the confines of a facility engineered for the type of RDT&E being conducted. This category is generally representative of the exploration of technologies earlier in the development process, prior to in-situ testing, evaluation and ultimate deployment.

Other CATEXs can potentially apply to RDT&E activities, particularly *B8* and *B9*. *B8* reads: *"Acquisition, installation, maintenance, operation, or evaluation of security equipment to screen for or detect dangerous or illegal individuals or materials at existing facilities and the eventual removal and disposal of that equipment in compliance with applicable Federal, tribal, state, and local requirements to protect the environment. Examples of the equipment include, but are not limited to:*

a. Low-level x-ray devices,
b. Cameras and biometric devices,
c. Passive inspection devices,
d. Detection or security systems for explosive, biological, or chemical substances, and,
e. Access controls, screening devices, and traffic management systems.

B9 reads: *"Acquisition, installation, operation, or evaluation of physical security devices, or controls to enhance the physical security of existing critical assets and the eventual removal and disposal of that equipment in compliance with applicable requirements to protect the environment. Examples include, but are not limited to:*

a. Motion detection systems,
b. Use of temporary barriers, fences, and jersey walls on or adjacent to existing facilities or on land that has already been disturbed or built upon,
c. Impact resistant doors and gates,
d. X-ray units,
e. Remote video surveillance systems,
f. Diver/swimmer detection systems, except sonar,
g. Blast/shock impact-resistant systems for land based and waterfront facilities,
h. Column and surface wraps, and,
i. *Breakage/shatter-resistant glass.*

CATEXs *B8* and *B9* move further along in the technology transition process, excluding activities that draw technological solutions from the laboratory to the end-user, operational environment. Both exclude most in-situ evaluation of technologies from further review, in most cases. Still, some technologies (e.g., sonar) are not appropriate for categorical exclusion (*B9*), and in some cases, technologies that would otherwise involve categorical exclusion require evaluation methods that trigger extraordinary circumstances and thus require further review in the form of and environmental assessment (EA) or environmental impact statement (EIS).

Section 2: NEPA as applied to date

One of the great challenges of implementing NEPA for Federal agencies is applying the process in such a way that it provides useful information for making decisions, rather than being a burdensome bureaucratic hurdle that provides little value for project proponents. NEPA analyses require the consideration of alternatives suitable for meeting the goals of the agency (National Environmental Policy Act of 1969). Too often, however, inadequate consideration is given to alternatives, which can lead to potentially poor decisions. Reasons abound, from enthusiasm to complete important missions, to poorly developed or improperly followed agency business processes that do not allow for the early application of NEPA in agency decision-making, and/or misunderstanding of the intent of NEPA requirements on the part of proponents, management and agency NEPA staff. Given finite resources, the goal for any agency NEPA program should be to focus on those activities most likely to cause harm to the human environment. Section 1500.1(b) of NEPA states, "…Most important, NEPA documents must concentrate on the issues that are truly significant to the action in question, rather than amassing needless detail." Inadequate consideration of alternatives often leads to exhaustive analyses and explanations – and perhaps alibis – of why the action does not significantly impact the environment.

In 1997, the President's Council on Environmental Quality (CEQ) conducted a study of NEPA effectiveness entitled "The National Environmental Policy Act – A study of its Effectiveness after Twenty-five Years". In the report, CEQ credits NEPA as an overall success, a brief but powerful statute that has gone far in making agencies "take a hard look at the potential environmental consequences of their actions", and has "brought the public into the agency decision-making process like no other statute" (p. iii). However, CEQ goes on to identify shortfalls in its implementation, chiefly that agencies often conduct environmental analyses and develop the associated detailed statement "as an end in itself", rather than as a tool actually applied to decision-making (Council on Environmental Quality, 1997).

Although the CEQ NEPA effectiveness study was conducted in 1997, the findings identified remain timely for RDT&E projects within DHS, and can be the end result of symptoms inherent the in implementation of NEPA for DHS RDT&E initiatives in the public environs. NEPA Section 1500.2(b) states that Federal agencies shall "implement procedures to make the NEPA process more useful to decision makers and the public." With respect to homeland security RDT&E, large, capital-intensive projects such as laboratory construction have employed the NEPA process in decision-making and to involve stakeholders and the public. More well-known examples include the decisions to build the National Bio- and Agro- Defense Facility (NBAF) (Department of Homeland Security, 2009) and how to divest the Plum Island Animal Disease Center (PIADC) (Department of Homeland Security, 2012a).

Other RDT&E programs, however, present unique challenges to employment of the NEPA process as a decision-making tool. RDT&E activities generally seek to examine specific phenomena, often times reducing the scope of potential alternatives. This is particularly true for those undergoing technology transitions where the initiative must undergo testing in-situ. Because RDT&E projects typically seek to examine specified phenomena, and locations may be somewhat pre-determined, proponents of these activities are particularly limited and thus susceptible to premature decisions, at least in the context of NEPA. Yet, these actions still constitute "major federal actions" for the purposes of NEPA and require review and the consideration of alternatives. So, how can the requirements of NEPA add value to the decision-making process? Furthermore, these projects occur in the public environs, increasing the importance of engaging the public. Can the NEPA process meet that need?

Section 3: In-situ homeland security RDT&E and NEPA: A case study

Inherent in the RDT&E lifecycle is the anticipation that technologies developed will be fielded for operational use, with potential testing in the intended operational environment. Although safety consideration of technologies for deployment is integrated into design processes, further testing beyond the laboratory setting may be required for adequacy, siting or further development. These considerations are generally part of the "technology transfer" process, whereby technologies and associated operational data are transferred to the end-user. For DHS, this process generally involves transference from S&T to one of the operational components of DHS (e.g., U.S. Customs and Border Protection, U.S. Secret Service, Transportation Security Administration) or state/local first responder entities (e.g., City of New York).

Depending on the technology and the developer, the degree of real-world, "in-situ" testing required or desired can vary significantly. This section investigates the "Detect to Protect" Program for testing biosensors in the Massachusetts Bay Transit Authority (MBTA) subway system, by the DHS S&T Chemical/Biological Division, with a focus on the value the NEPA process adds to decision-making and the results of engaging the public through NEPA for these projects.

Background

In 1995, an organization called "AUM Shinrikyo" released the chemical nerve agent sarin in the Tokyo subway system, resulting in 13 deaths and 5,000 injured people (Pletcher, 2012). An ability to detect and respond to an attack in a transportation hub in the future, whether chemical, biological, or radiological, could enable authorities and first responders to take steps such as strategic evacuations that could potentially save lives.

The DHS S&T "Detect to Protect" project represents the next step in the development of "technologies and sensors to rapidly detect a potential biological attack on the Nation's transportation infrastructure in order to minimize public exposure and strengthen security" (Department of Homeland Security, 2012b, p. ii). Detection systems undergo testing in laboratory and other settings to validate effectiveness, however ultimately they must be functional in the intended environment. The subway environment provides a mechanism for dispersion of any introduced threat agent through the movement of trains and passengers, and success in detecting threat agents would require a sensor network installed in multiple stations. The intended end-user environment of the subway presents environmental attributes, such as temperature and humidity extremes, and airflow phenomena that are not easily replicated accurately in a controlled laboratory setting. In order to validate the performance of sensor networks in the subway environment, it was determined that challenge testing of in-situ networks was required, using a released challenge material to verify the capability of the networks to identify a threat agent. The networks tested detect biological threats, requiring a simulant material of biological origin, containing proteinaceous, genetic material. *Bacillus subtilis* (or *B. subtilis*) was selected as a challenge material, a well-characterized, non-pathogenic, microbiological organism. The test location of the Massachusetts Bay Transit Authority (MBTA) subway system of Boston, MA, and the specific station locations in bordering Cambridge and Somerville, MA were selected due to an existing data set from prior, unrelated airflow studies within the system, allowing for strategic placement of the sensor network (Department of Homeland Security, 2012b).

DHS is conducting the testing, begun in August 2012, in coordination and consultation with the MBTA Transit Police, Massachusetts Department of Public Health, Massachusetts Emergency Management Agency, City of Somerville, City of Cambridge, Centers for Disease Control and Prevention (CDC) and the Massachusetts Institute of Technology (MIT). Results from the studies are slated for use by first responder and emergency management organizations, in the interest of planning and preparing for such an attack (Department of Homeland Security, 2012b).

Public and Other Stakeholder Involvement

As indicated in the background, the testing includes the participation of several state and local first responder, public health, and administrative government entities. Their common interest in adequate environment, health and safety analysis of the project, along with local requirements for and interest in public participation greatly influenced the methods for engaging the community. Both Cambridge and Somerville, the jurisdictions for the testing, have particularly well-informed, highly engaged communities with a high level of interest and record of public participation in locally occurring initiatives, as do many communities across the U.S. One distinctive element of the Cambridge community, however, is a local biosafety committee codified in the municipal code. Chapter 8.20 of the Cambridge Municipal Code establishes the Cambridge Biosafety Committee (CBC), which issues permits and regulates biological research at institutions in the community (City of Cambridge, Massachusetts, 2012). The 1960s and 1970s brought about significant advances in the history of genetic engineering research, and two of the leading research institutions engaged in advancing the understanding of genetic engineering, Harvard and MIT, were and continue to be located in Cambridge. The small city bordering Boston arguably became the global center for biotechnology research and development (Lipson, 2003). In the midst of these advances, the general public and the Cambridge community in particular became concerned with the public health implications of the research. For reasons similar to those that brought about NEPA in 1969, including increased awareness of human impacts upon the environment and a desire for greater transparency on the part of government and industry, the community demanded oversight of the research initiatives. To this day, community participation is intertwined with the well-known research institutions within the Cambridge jurisdiction, including both university (MIT, Harvard University) and commercial (Novartis, Pfizer, Vertex Pharmaceuticals) research and manufacturing biotechnology and pharmaceutical laboratories. Institutional Biosafety Committees are required at each regulated entity, for which each must include two members of the local community (City of Cambridge, Massachusetts, 2012).

Given the community relationship with research institutions, stakeholder expectations, and the goals of the testing, DHS conducted several meetings between the stakeholders to achieve consensus on the proper way to proceed. Representing the local community, the CBC was involved at the earliest stages from a technical review and community relations standpoint, and provided input to the health and safety analysis, including comments and suggestions regarding scoping, and reviewed and concurred with the final EA. MBTA management participation proved critical in coordination with local governments, logistics, and security for the tests themselves. State and local elected representatives and mayoral staffs were briefed well in advance of planned start dates and solicited for input.

Public scoping was limited to consultation with the CBC. As recognized in Section 2, RDT&E projects often begin with a relatively narrow range of potential alternatives, due to the specific research needs and questions to be answered. Therefore, an open-ended discussion with the lay public of a wide range of alternatives would provide little to no value, given the specific and relatively technical needs of the investigators. However, it was recognized that a public meeting, including an informational session followed by public discussion of a realistic range of alternatives as determined by the research proponent together with the stakeholder community would be appropriate, informative, and useful. Together with the public comment period for the EA, press releases to local news organizations in the cities of Cambridge, Somerville and Boston, and the local press coverage resulting, the final result was an informed community generally supportive of the project[1].

The public meeting was held in Cambridge on May 16th, 2012, at the beginning of the public comment period for the EA. Public meetings there historically follow the town-hall format, an

[1] Disclosure: the author was involved in providing consultation for the project proponent for the NEPA process, and attended the public meeting as a representative of DHS S&T.

expectation that the proponent and stakeholder team did not challenge. Following the informational presentations from the project proponent and the state epidemiologist, an open question and answer session followed.

Members of the community voiced several questions, concerns, and statements of support, before, during and after the meeting. Questions ranged from the technical to the logistical. There was some clarification required regarding the use of dead bacteria and associated risks (T. Friedrichs, e-mail communication, May 11, 2012; M. Testa, e-mail communication, May 10, 2012). One commenter was unconvinced that dead bacteria could not cause infections (D. Williams, e-mail communication, May 20, 2012). Others requested clarification regarding how the release would not trigger allergies or colds (A. Clayton, e-mail communication, May 11, 2012). The proponent responded that the relative small quantities used in testing would result in concentrations less than background dust levels in the stations initially, followed by dispersion throughout the system, likening the testing to the release of a few sugar packets in order to provide perspective (A. Hultgren, e-mail communication, May 11, 2012). This appeared to allay the concerns of the commenter. During the meeting, questions also arose regarding the need for the test, what threats precipitated the decision to test, and project costs from a taxpayer concern, which were addressed by the proponent and stakeholders in general terms to the satisfaction of the questioners. A questioner also indicated concern that knowledge of the airflow patterns and materials in the subway might be dangerous knowledge for would-be terrorists. The proponent indicated the practice that specific data is not be published largely for those reasons according to the May 16, 2012 Public Forum Q&A Transcript.

Of particular concern was whether prior notification of the public would be given to allow patrons to avoid the stations where testing was to occur would be given. Upon receiving questions about this during the public meeting and before/after, the proponent worked to ensure the occurrence of timely news releases, including prior notification on the 11 o'clock news the day prior to the beginning of testing, posting on the MBTA website prior to testing and affected stations, and posted signage at station entrances.

The meeting and public comment period ended with all relevant questions answered, by all indications to the satisfaction of the questioners. Overall, although the technical aspects of the project were determined prior to the time of the meeting and largely determined the range of alternatives, the question and answer session allowed the general public an opportunity to discuss their questions and concerns directly with DHS S&T, and allowed deserved explanations for the testing to be conducted in their community; this was to the benefit of all parties.

<u>Environmental Assessment</u>
DHS determined that an EA was required, and conducted an analysis entitled "Environmental Assessment for *Bacillus Subtilis* Particles to Challenge Bio-Detection Sensors in Subway Stations" (Department of Homeland Security, 2012b). Although the simulant chosen for use to challenge the detectors, *B. subtilis*, was not suspected to present a hazard to human health or the environment, it should be noted that, particularly in the early stages of the project prior to the safety analyses of the challenge material, there were general concerns regarding any release of a simulant material within an operational subway station, primarily because of the presence of the general population. This was of particular concern for *B. subtilis*, because it is a bacterium. The

concerns generally revolved around the anticipation of public controversy, without any specific technical concern of a hazard to human health or the environment, and so it was recognized that an EA would provide an appropriate tool for DHS S&T to conduct a "hard look" at any potential impacts to the human environment, particularly human health. Also, it would give the stakeholders listed above the opportunity to review the project in more detail from a human health, safety, environmental and public concern perspective. Furthermore, as discussed in Section 1, the established CATEXs for RDT&E activities are only applicable to activities occurring within a controlled environment, with appropriate engineering, administrative and safety controls (e.g., a laboratory).

With an understanding of the proposal, and having decided to conduct an EA, the following elements were identified as appropriate for analysis:

- Human health and safety effects
- Indoor air quality
- Environmental effects on wildlife
- Environmental compliance
- Environmental justice
- Historic properties

Note that the focus of the analysis was on the potential impacts to human health and safety, regarding exposure to the *B. subtilis* challenge material. While the other elements were briefly analyzed, several factors, including the indoor location; relatively small quantities of challenge material dispersed; the geographic locations of the subway stations used for the experiments and their surrounding demographics; environmental, health and safety procedures and test protocol; and lack of historic designation, it was determined relatively quickly that no potential for significant impact in the areas of wildlife, environmental compliance, environmental justice, or historic properties existed. Therefore, discussion of the EA in this paper will concentrate on the human health and safety aspects, and indoor air quality as a related matter, both resulting from the release of the challenge material, *B. subtilis*.

B. subtilis was initially chosen as a challenge material because of its genetic similarities to targeted threat agents; its status as a well-characterized, non-pathogenic microbiological organism; its ubiquity in the natural environment (soils); and previously conducted studies indicating its safety for use in various capacities. Additionally, there is precedent for challenging biological sensors with *Bacillus* sp., to include *B. subtilis*. Prior to, and during the development of the EA, several factors required consideration surrounding the proposed use of *B. subtilis* in a public transit station. Discussion of these considerations and research for answers was an iterative process that began prior to the decision to conduct an EA, and throughout its development. The analysis led to the development of the alternatives, and ultimately, selection of the proposed action. The questions that arose, were discussed, and finally answered included:

1. Is the challenge material *B. subtilis* generally safe for use?
2. Does the existing literature support the use of *B. subtilis* as proposed for this battery of experiments?
3. What exposure limits apply, and to which populations?
4. What are the risks, if any?
5. How can any risk be minimized or mitigated?

Given that the study methodology already included detailed requirements, including location, systems for testing and the specific challenge material, the logical questions arose – what is the decision to be made? What are the alternatives? Following discussion among the proponent, scientists, stakeholders, NEPA practitioners, and environmental and legal reviewers, it was determined that the final question to be answered, for which the EA could provide value and inform the decision, was – "how do we conduct the study, meet the requirements for successful testing, and pose no or negligible threat to human health and the environment?" This led to the development of the following alternatives:

- Alternative 1: Aerosolize known quantities of *B. subtilis* within the subway system to demonstrate positive detection of the material by the sensor network installed in several underground stations. Activity in the subway stations should be at peak operational capacity for trains and passengers to most closely simulate the conditions that would likely exist in the event of a true bio-terrorist attack.
- Alternative 2: Aerosolize nonviable (killed) *B. subtilis* spores for testing the sensors during revenue hours. This alternative alters the test material, but not the test conditions in Alternative 1.
- Alternative 3: Aerosolize nonviable (killed) *B. subtilis* spores for testing the sensors during non-revenue hours. This alternative alters the test conditions, but not the test material described in Alternative 2.
- Alternative 4: Conduct a "spike test" into the air sampling inlet of the sensor. This approach would ensure no release of challenge material into the subway environment, but would eliminate the test conditions.

In the EA, the alternatives were analyzed as a group for the environmental effects on wildlife, environmental compliance, environmental justice and historic properties, given the limited variation between the alternatives with respect to these elements of the analysis. All four alternatives involved the same stations, and none of the alternatives presented a potential impact to wildlife or environmental compliance risk. The indoor air quality and human health and safety elements were analyzed individually for each alternative, and provided the distinctions, strengths and weaknesses of each alternative and presented a standout alternative as an effective compromise without potential for significant impact to the environment or human health. Based upon the analysis, the main questions and associated findings in consideration of indoor air quality and human health and safety are discussed below.

1. Is the challenge material *B. subtilis* generally safe for use?

   Previously conducted studies of the safety of *B. subtilis*, addressing the potential routes of exposure (inhalation, ingestion, ocular, and dermal) were reviewed (Department of Homeland Security, 2012b, p. 22-26), including (but not limited to):

   - The Environmental Protection Agency (EPA) March, 2010 final review of *B. subtilis* for registration as a bio-fungicide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (Environmental Protection Agency, 2010). This review evaluated the potential for direct and indirect hazards to humans and the environment posed by the application of *B. subtilis* to food crops and plants. For the FIFRA review, EPA conducted toxicity tests, human risk assessment, and ecological risk assessment. Results indicated that adverse effects were unlikely for any population exposed. The study did indicate a requirement for applicators subjected to prolonged exposure to take measures to minimize exposure.

- Review of the *B. subtilis* Material Fact Sheet, regarding its use as an organic insect and disease management product. The fact sheet describes results of reviews by the United States Department of Agriculture (USDA) and the Organic Materials Review Institute (OMRI), a not-for-profit organization with the goal of providing clients with an independent review of products intended for organic use and slated for the USDA organic label. The study indicated that foods treated with *B. subtilis* are eligible for USDA-organic standing. In its determination, OMRI cited a lack of any documented adverse reaction resulting from its agricultural use (Cornell University, 2012).
- A study published in the *Journal of Applied Microbiology* in 2008 investigating the safety of *B. subtilis* for use as a probiotic – "The safety of *Bacillus Subtilis and Bacillus indicus* as food probiotics". The study concluded *B. subtilis* to be non-pathogenic and safe for human consumption (Hong et al., 2008).
- The EPA's Toxic Substances Control Act (TSCA) review of the use of *B. subtilis* in industrial settings, particularly fermentation facilities. The TSCA study concluded that industrial use of *B. subtilis* as practiced does not present significant risk of adverse impact to human health or the environment (Environmental Protection Agency, 1997).

The results of all studies reviewed supported the safety of *B. subtilis* for use in each particular context – as a pesticide, as an organic pesticide, as a probiotic, and in fermentation facilities. While these studies do not directly apply to the use of *B. subtilis* as a test challenge material as proposed, they consistently indicate non-pathogenicity and general low likelihood for adverse effects to any exposed populations.

2. Does the existing literature support the use of *B. subtilis* as proposed for this battery of experiments in a subway environment?

   Although the literature indicated use of *B. subtilis* in each specific context was safe, the proposed testing presented a novel use of the material that had not been specifically tested for safety. The FIFRA study indicated the safety to consumers of foods containing *B. subtilis* residues, and the low ecological risk of its application. Still, it recommended the used of respiratory equipment for workers as a best practice during application, a common procedure for pesticide application. The TSCA study indicated the safety of *B. subtilis* as used in fermentation facilities in an industrial setting, but was specific to the worker population. The studies involving ingestion, whether accidental through residues when applied to food as a pesticide, or intentional when taken as a probiotic, indicate the low likelihood of infection from *B. subtilis*. And although extremely rare, the TSCA study indicated a very small number of cases (2 in 1,038) of bacteremia caused by *B. subtilis* in a hospital setting among patients with pre-existing medical conditions, including immune-compromised and those with long-term in-dwelling foreign bodies (Environmental Protection Agency, 1997).

This presented some concern regarding exposure of certain segments of the general population (e.g. immune-compromised, children, the elderly, and asthmatics) to viable, or live aerosolized material. The use of non-viable, killed material would remove any risk associated with the characteristics of the live material.

3. What exposure limits apply, and to which populations?

   In the course of the experiments, both workers and the general population would be exposed to *B. subtilis*. No specific exposure limits exist for the live material, however the studies reviewed indicated exposure levels for each route of exposure that were deemed safe in that particular context. For nonviable, killed *B. subtilis*, the only potential hazard presented is that of a nuisance dust, under "particulates not otherwise regulated" in 29 CFR 1910.1000; this is also the case with the inert filler also part of the compound. OSHA sets a permissible exposure limit (PEL) for nuisance dust for the worker population, an 8-hr time weighted average that is an order of magnitude higher than the calculated exposure to a passenger during revenue hours, or a "maximally exposed individual". The calculated dose range for the releases falls within typical subway background nuisance dust levels (Department of Homeland Security, 2012b).

4. What are the risks, if any?

   Literature review indicates that the relative risks for any of the alternatives, including both live and killed *B. subtilis*, are relatively low for any population. For live material, they may not be non-existent for some, particularly immune-compromised, children, the elderly, and asthmatics. For killed material as a particulate nuisance dust, the releases proposed are low enough in quantity and resulting airborne concentration that they will not significantly alter the nuisance dust background in the subway, and would be completely dispersed within 2 hours following each release. Additionally, no cumulative build-up of dust in the system would occur.

5. How can any risk be minimized or mitigated?

   It was determined that Alternative 3, the use of nonviable, killed *B. subtilis* during non-revenue hours, while still moving the trains to re-create most of the station network airflow phenomenology, would present the lowest level of risk while meeting the needs of the test. It would eliminate any risk of infection, limit nuisance dust exposure, and still fulfill the requirements to adequately test the sensor network.

Conclusions

Considering the alternatives in light of the literature review and understanding the concerns of the public and stakeholders, Alternative 3 was determined to be the best course of action, providing a balance between presenting very low risk while meeting the needs of the test. While testing with live material during revenue hours was preferred from the experimental point-of-view (Alternative 1), test conditions could be reasonably reproduced by running trains during non-revenue hours, thereby ensuring that the releases would not expose any passengers to the brief, limited concentrations of particulate prior to dispersal and dilution throughout the subway system station network.

Section 4, Homeland security RDT&E NEPA Analyses lessons learned and recommendations

The intent of this examination was to address two questions basic questions for considering impacts to the human environment when conducting the NEPA process for homeland security RDT&E projects in the in-situ environment.

1. How do decision-makers employ NEPA to add value in making decisions for in-situ RDT&E?
2. Can NEPA be a vehicle to better engage and inform the public, allowing decision-makers to better understand public and stakeholder concerns, and the public to better understand technologies designed to protect the community?

Review of the “Detect to Protect” Program provides several lessons learned to address these two questions. The recommendations that result may further enable project proponents to reap value from the NEPA process, and result in improved understanding between proponents and stakeholders.

- *Carefully consider alternatives* – taking time to understand the purpose and need leads to carefully considered alternatives that direct the analysis toward useful conclusions. In “Detect to Protect”, the proponent identified and proceeded with an alternative satisfactory to nearly all concerned that met the need of the program.
- *Avoid safety assumptions for novel activity* – operations that are safe in one context may not be safe in another. *B. subtilis* has multiple uses in industry and nutrition, and is generally considered safe. However, the data concluding safety for these applications is specific to those circumstances, which limits application to other uses such as that proposed for “Detect to Protect”. The proponent determined that using non-viable material during non-revenue hours avoided controversy and met the purpose and need.
- *Don’t underestimate stakeholders* – although RDT&E projects tend to be quite technical in nature, valuable resources can present themselves unexpectedly. The “Detect to Protect” proponent engaged the CBC and local public health departments, which helped with technical reviews, risk communication and even local logistics to ensure the involvement of interested parties. Furthermore, these organizations have the public trust, and their involvement goes far in allaying community concerns.
- *Use NEPA to communicate* – consider simple EAs and public meetings for RDT&E in the public sphere when the potential for controversy exists. Early consultation with stakeholders for “Detect to Protect” indicated that a public information meeting would be expected by all local stakeholders. The proponent wisely used that expectation to set up a public meeting following the completion of the EA, but before the public comment period, allowing for focused presentation, discussion, and a question-and-answer period.
- *Communicate the purpose and need* – provide ample context and take the time to explain the reason for the project. The public meeting in Cambridge began with presentations about the history of terrorist activity in public transit, providing the rationale for the

project and value it brings to the community and public safety. This allowed the public participant to view the project from the perspective of the proponent.

- *Provide several avenues for communication* – this demonstrates a commitment to considering community concerns. The "Detect to Protect" program proponent fielded questions during the public meeting, accepted written questions during the meeting for written follow-up, and responded to questions and concerns submitted during public review of the EA.

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