Polymerase Chain Reaction (PCR) White Paper Outline: Objectives and Process

Prepared for the ISAC Early Detection & Rapid Response Subcommittee
December 8, 2010

"Validation is the bridge between research and regulatory decisions!"
(Anything else is jumping across the abyss of unknown to conclusions)

BACKGROUND: At the June 2010 Invasive Species Advisory Committee meeting, the Early Detection, Rapid Response Subcommittee (EDRRSC) committed to develop an outline of a white paper on early detection monitoring, specifically on polymerase chain reaction (PCR) techniques, applicability, scientific ability, validation protocols, applicability, and regulatory review.

The increased interest in DNA-based tools for the identification, detection, and monitoring of invasive species has prompted widespread speculation on the future availability of inexpensive, rapid, and accurate means of identifying specimens and assessing biodiversity. There have been numerous examples in recent years of resource agencies struggling to make the right management decision because of inconclusive results from alternative laboratory analysis of invasive species (one example being dreissenid veliger plankton samples). In addition, agencies that are responsible for managing AIS require a separate and independent verification of early detection of AIS before taking any action. These agencies speak of a need to test the performance of individual laboratories and validate the reliability of their analytical results, as well establishing an accreditation program for lab certification.

The three primary issues on PCR technology and field uses are:

1) Technology:
- PCR technology has many unique protocols encompassing the basic detection of genetic materials.
- PCR assays are being adapted for field use before sensitivity, specificity, intended purpose, repeatability, robustness is known.
- There are not enough Polymerase Chain Reaction (PCR) assays for invasive species identification.

2) Validation/Standardization Process:
- Governmental agencies are utilizing PCR assays for regulation and decision making without the validation or standardization.
- Polymerase Chain Reaction technology is being developed and applied without independent validation.

3) Certification/ Regulation of approved field applications

- There is a need for ~~a~~ regulatory authority, framework and oversight for assay use.
- Recognition of oversight and assay development by a national/international certifying body.
- Administered by/thru a single unit at the national level, in developing tests and assays.

NEXT STEPS: At its December 8 meeting, the EDRR Subcommittee (EDRRSC) must determine a process for how ISAC can address the concerns regarding PCR technology, validation/standardization and certification. Discussion points will include:

1. Brief discussion on definition of terms: what do validation/standardization and regulation/certification mean?

2. Do we need to break the subject up into three topics? And what should we focus on first? For example, a validation framework (e.g. International Committee on Harmonization, ISO/IEC 17025) must come first as a methodology or assay cannot be certified until a validation is complete and approved. Does a technical "subcommittee" of validation experts need to be formed to work through the validation process? Is this something that can be put into an ISAC recommendation?

3. Process: Does the EDRRSC want to recommend an ISAC Interim Meeting (webinar) to inform ISAC as to the scope of the problem. The purpose would be to bring in PCR experts, validation experts, and experienced regulators to discuss the current state of technology, current uses and challenges, etc. Or do we want to keep the work at the EDRRSC level until the June 2011 ISAC meeting?

4. ISAC Role: Does ISAC have a <u>future</u> role in giving guidance to regulators on what standard to follow in reviewing invasive species identification, detection, and monitoring assays where regulatory decisions will be made with the results?

5. Do to the highly technical nature of this subject, who is going undertake the tasks and how will it be funded (e.g. APHIS Commodity Credit Corporation[1], NFWF)?

[1] The APHIS CCC was mentioned in thinking about possible ways to release emergency funding for invasive species response like we have done for plant and animal disease outbreaks that could have national effects. Could such funding mechanisms give a template for "emergency" assay development/validation in situations like we are looking at with Zebra/Quaggas or Asian Carps? REALITY CHECK: NOT w/ the federal deficit cut mentality underway