PPQ Promising Practices Award Submission Form

Q56 Revision Rule Writing and Implementation Group

Name, Address, Job Title and organization, and Phone Number of Nominee Janel Barsi, Regulatory Analyst, PPD-RAD, (301) 734-5456 Charisse Cleare, Senior Regulatory Coordination Specialist, PPQ-PHP-PARC, (301) 734-0773 Phil Grove, Senior Regulatory Coordination Specialist, PPQ-PHP-PARC, (301) 734-6280 Cindy Howard, Chief, Regulatory Analysis and Development, PPD, (301) 734-5957 Sheila Novak, Deputy Assistant General Counsel, Regulatory Division, OGC, (202) 720-2670 Michael Olson, Economist, PPD-PAD, (301) 734-8388 Steve O'Neill, Assistant Chief, Regulatory Analysis and Development, PPD, (301) 734-4340 Matt Rhoads, Program Manager, PPQ-PHP-PARC, (301) 734-5117 Shirley Wager-Page, Branch Chief, PPQ-PHP-PRIM-CIAO, (301) 734-8453 Tom Walsh, Assistant General Counsel, Regulatory Division, OGC, (202) 720-5550 Donna West, Senior Import Specialist, PPQ-PHP-PRIM-CIAO, (301) 734-5298

Brief Narrative of the Promising Practice

Year after year, the APHIS Management Team makes improving and innovating our approach to regulating trade in agricultural products a priority. The regulatory process is generally perceived to be a barrier to APHIS and PPQ being able to take timely action on regulatory issues, and agency management has made it clear that to the extent that we can accomplish the Agency mission without rulemaking and still remain on sturdy legal ground, that should be our priority.

This year, a significant initiative to streamline the approval of certain imported fruits and vegetables was adopted as a final rule and implemented by PPQ. This rule represents a departure from existing practices in that it enables PPQ to approve certain new imports via a Federal Register notice-based process rather than via rulemaking, as has been the case for many years. The effect of the rule is to shave several months (i.e., 6-12 months, give or take) off the time that would typically be required to formally approve such imports via rulemaking. By providing for such timely action on imports, we expect to dramatically improve our ability to open up or retain export markets for our products in a similarly timely manner.

Under the new Q56 regulations, after we conduct a risk analysis on a new import request, if we determine that the risk posed by the import can be mitigated by one or more of 5 designated measures, we would make the risk analysis available for comment, and if the risk analysis withstands public scrutiny, we would begin issuing permits shortly after considering comments on the risk analysis. We expect that as many as 70 to 80 percent of future import requests could be approved using this new process. The Q56 rule also establishes a similar Federal Register notice-based process for the approval of pest-free

areas in foreign regions. Adopting this rule not only has the effect of expediting the approval of new imports, but the equally important effect of relieving pressure on our regulatory policymaking staffs in PPD and elsewhere in the Department, allowing those resources to focus on other significant regulatory issues while routine import issues are addressed administratively by PPQ under the new Q56 rule.

This initiative has become the model for many similar efforts to expedite regulatory actions by both PPQ and VS, and has been universally celebrated throughout USDA as perhaps one of PPQ's most significant strategic regulatory innovations in many years. Just yesterday (8/30/07), a Q56 team member was called by Associate Administrator Kevin Shea into a Veterinary Services "Comprehensive BSE Rule" meeting to offer strategic guidance as to how to set up that upcoming very important rule to make more "Q56-like.") Similarly, external stakeholders have reacted favorably to the initiative, citing it as an effort to decrease unnecessary procedural bureaucracy, while addressing and evaluating risks in a timely, but science-based fashion. PPQ has several new regulatory efforts in development that build upon this approach, including one to expand the applicability of the Q56 rule, a rule to streamline the approval of new phytosanitary treatments, a rule to streamline the listing of new quarantined areas and regulated articles, and a rule to streamline the approval of new interstate movements of fruits from Hawaii and US Territories and Possessions.

This project had its impetus in 2003 when PPQ and PPD, in consultation with the Regulatory Division of OGC, began planning to adopt a streamlined approach to evaluate and approve new imports of fruits and vegetables. After the idea to apply the new approach was hatched in OGC by Tom Walsh, several PPQ and PPD staff began working to frame the legal language to enable the approach to stand up to public scrutiny. After the draft proposed rule suffered through some particularly lengthy delays caused by lawsuits (BSE and BRS issues) and various other regulatory and legal crises, significant progress was finally made in the last year and half. The proposed rule was published in April 2006, followed by a 90 day comment period, several public hearings, and ultimately ending with publication of the final rule in July 2007. We have already released several pest risk analyses for African fruits and vegetables under the final rule, and several additional products are nearly ready for release.

Clearly, this rule represents a practice that is outside the scope of the four Safeguarding elements, but is a very significant improvement with immediate impact to improve upon a longstanding process that has frustrated PPQ and APHIS leadership for years. It supports the agency mission by continuing to provide protection against the introduction of new pests and diseases while enabling new safe trade to occur in more timely manner, thus ensuring an abundant, high-quality, and varied food supply, and creating opportunities for expedited marketability of U.S. agriculture in international commerce.

Critical to the success of the project has been the dedication and careful deliberation of the staff involved in this project. While based on a simple concept, there were many ways that this effort could have failed---from a poorly coordinated public roll-out, to inadequate legal, procedural, and policy schemes. From the germ of the idea to execution and implementation of the final rule, the members of the team have contributed their expertise to the success of a project which we expect to model project and novel concept for years to come.