January 16, 2018

Data Quality Record for Strategic Measures

Strategic Measure Text: By September 30, 2022, reduce the Pesticide Registration Improvement Act (PRIA) registration decision timeframe by an average of 60 days.
Goal Number/Objective: Goal 1: Core Mission/Objective 1.4: Ensure Safety of Chemicals in the Marketplace
NPM Lead: Office of Chemical Safety and Pollution Prevention (OCSPP)/Office of Pesticide Programs (OPP)

1a. Purpose of Strategic Measure:
The purpose of this strategic measure is to expedite the review and licensing of pesticides new active ingredients. More specifically, the intent is to bring EPA's decision time frames for applications closer to the time frames specified for those PRIA categories in the law. Currently exceedance of the mandated decision time frames usually occurs when the registrant and EPA agree to a negotiation of the PRIA due date beyond the original due date. By reporting on this measure, EPA will be able to determine whether or not process changes, streamlining efforts, and performance measures under the strategic measure are resulting in a reduction in average decision time frames for new active ingredient applications.

1b. Performance Measure Term Definitions:
Decision: A decision is a discrete PRIA action associated with a PRIA category and therefore receiving a PRIA decision timeframe and due date. While usually there is a one-to-one correlation between a decision and an application received under PRIA, multiple PRIA categories- and therefore multiple decisions- can be associated with a single application. Within the context of this performance measure, there are almost always multiple applications and decisions associated with a new active ingredient submission. For example, a new active ingredient submission for a pesticide food use will include an application for a technical product registration, end use product registrations (sometimes over 20 of these), and a tolerance petition requesting the establishment of legally enforceable residue levels in/on foods for which registration is proposed. Such a new active ingredient submission will have a single primary decision (usually the technical product application) and one or more secondary decisions. For purpose of this measure, only the primary decision (usually that associated with the technical new product) is counted in the data set, so that each new active ingredient is counted only one time, instead of multiple times based on the total number of decisions associated with the new active ingredient submission.

Primary decision: The primary decision in a series of related applications is the decision to which the PRIA fee is applied (usually the new product associated with the technical source of active ingredient). There will typically be one primary decision for each new active ingredient "package"- or series of applications- related to the registration of the new active ingredient. By only using primary decisions in reporting towards the measure, all active ingredients are weighted equally.

Completed: An action or decision is completed when OPP makes a decision on the application, i.e. the product is registered, a label is stamped, protocol reviewed, or the action is denied, the label not approved, etc. A decision memorandum is issued describing the decision made and the date that the delegated official signs the memo is the date that the decision is completed. In the case of a label, the date that the label is stamped as approved is the date that the application to register or amend a label is completed.

Decision statuses that will not be considered for purposes of this measure are "pending" decisions, decisions for which a "not grant" determination has been made, "rejections" as a result of non-payment or failure to clear the PRIA 21-day Completeness or Preliminary Technical screen, and actions "withdrawn" as a result of the 21-day Completeness or Preliminary Technical screen.

Negotiated Due Date: PRIA allows the original due date to be extended by mutual agreement between the applicant and the Agency. The new due date is called a negotiated due date. Negotiated due dates occur predominately as a result of missing information from the application or data deficiencies identified during an in-

depth review of the application. The due date then is extended to allow the applicant the time to submit the data or information and for the Agency to review the data and make a determination. The EPA cannot unilaterally reset a due date; it must be negotiated with and agreed to by the applicant. Documentation of the request for negotiation by the applicant is saved as part of the application's record and can be subject to scrutiny under the annual PRIA audit should that application be selected in the audit sample.

PRIA: The Pesticide Registration Improvement Act (PRIA) of 2003 established pesticide registration service fees for registration actions. PRIA has been reauthorized twice, the most recent being the Pesticide Registration Improvement Extension Act of 2012 (PRIA 3), which became effective October 1, 2012, and reauthorized PRIA for five more years until 2017. The expiration date of PRIA 3 was extended through February 8, 2018, by the Continuing Resolution signed on January 22, 2018. The PRIA 3 legislation increased the number of actions covered by fees, modified the payment process and application in-processing. The category of action, the amount of pesticide registration service fee, and the corresponding decision review periods by year are prescribed in these statutes. Their goal is to create a more predictable evaluation process for affected pesticide decisions, and couple the collection of individual fees with specific decision review periods. They also promote shorter decision review periods for reduced-risk applications.

1c. Unit of Measure: Days

2a. Data Source:

- Relevant information system: All registration actions received under the PRIA and its reauthorizations are entered and tracked in the Pesticide Registration Information System (PRISM), in the registration module called OPPIN. Reports developed in Business Objects (using PRISM as the data source) allow senior management to more effectively track the workload (e.g., pending actions with upcoming PRIA due dates, actions for which the PRIA date appears to have passed etc.) and ensure that PRIA or negotiated due dates are met.
- Entity that reports data to the system: Data are tracked and maintained internally by EPA, by front end staff entering new applications into the tracking system and by risk managers conducting and completing review of the applications. Negotiated due dates are manually entered by the risk management divisions and the rights to enter a negotiated due date belong to only branch chiefs, the Division Directors and other individuals designated such rights by a Division Director in those divisions.
- Frequency of reporting primary data: Data are entered into EPA's tracking system throughout the year as new applications are received, existing applications are completed, and PRIA due dates of these applications are negotiated.
- Reference to Quality Assurance Project Plan: OPP adheres to its Quality Management Plan (December, 2016: http://intranet.epa.gov/opp00002/reference/guidance/quality_assurance/OPP-QMP-Rev-2.1.pdf) in ensuring data quality and that procedures are properly applied. OPP uses several internal controls within the OPPIN/PRISM system. Users must be FIFRA CBI cleared in order to access the system. Within the system, security measures are taken to allow only authorized users to perform certain operations, which are managed by our Data Base Administrator (DBA). For example, only Branch Chiefs can enter a negotiated due date in the Registration Division (RD). The DBA must receive an Access Form from users wanting to use the system and their supervisor must sign the Access Form.
    - Applications are date-stamped upon receipt by a NOWCC in ISB/ITRMD/OPP and the stamped date is entered into OPPIN by another NOWCC in ISB. The stamped date is the receipt date in OPPIN. The EPA team leader overseeing front-end processing in the Document Processing Center performs periodic/random checks of their work. Expert coding teams from the three registering divisions review each application and place it in a PRIA fee category generally on the date of receipt.

- Any issues related to assigning a fee category are discussed with division management and may be elevated. If a full fee is being paid, the date that begins the PRIA timeframe or start date is the latest of 21 days after receipt of the application or the day payment is received by the Washington Finance Center/ OCFO. Staff in OCFO enter the amount and date of receipt of the payment into COMPASS. OPP downloads COMPASS and electronically transfers the data into OPPIN.
- Once the COMPASS data are transferred to OPPIN, OPPIN automatically calculates due dates from the start date using the time frames in the Federal Register. Notice on the fee schedule. Due dates can be extended through negotiations with the registrant or applicant. Negotiated due dates are manually entered and the rights to enter a negotiated due date belong to only branch chiefs, the Division Directors and other individuals designated such rights by a Division Director. In the Biopesticide and Pollution Prevention Division (BPPD), negotiated PRIA due dates are entered in OPPIN by the branch chiefs, branch team leaders, or its Administrative Specialist. In RD, the branch chief enters the negotiated due date in OPPIN. According to OPP's procedures, a negotiated due date cannot be entered into the Webforms system until the Deputy Office Director or Office Director approves the negotiated date by signing the negotiated due date form. A copy of the negotiated due date form and documentation of the applicant's agreement with the due date are filed. Forms are routed, approved, and retained electronically. The Webforms system was replaced at the end of calendar year 2017, as it resided on the Lotus Notes platform which is no longer supported by the EPA. OPP developed an alternate negotiation form workflow for the creation, routing, and approval of negotiated due date forms, which went into production on January 2, 2018.
- The date that an action is completed is entered by staff in RD, BPPD, and the Antimicrobials Division (AD) according to their internal procedures. Documentation of the date of completion is filed in the product's file. Once data is entered into OPPIN, start dates and due dates cannot be changed by staff in the regulatory divisions. Changes are made by staff programming OPPIN in ITRMD. Correction of errors in the system must be requested by generating a Systems Change Request (SCR). These requests are reviewed by ITRMD staff and management and representatives of the regulatory divisions. Questions and issues are elevated to the PRIA Senior Advisor and if needed to OPP management. OPP management holds a Bi-weekly PRIA meeting in which these issues are discussed and resolved. The OPP Immediate Office uses a number of monitoring reports to identify actions that are past their due date as well as erroneous entry of dates which results in the completion date being past the due date. An issue is then resolved with the appropriate division and generally involves an action that needs to be logged as completed or a negotiated due date that needs to be entered. OPPIN software issues have also been identified through this oversight effort and an SCR is developed to make the necessary programming corrections.
- OPPIN is an internally generated tracking data base with data entries being made during normal business hours.
- Annually, the Office of the Inspector General conducts audits that include verifying the accurate entry of the dates actions are received, extended and completed.

2b. Data needed for interpretation of (calculated) Performance Result:

- Baseline is an average timeframe of 655 days (range: 93-2,086 days) for PRIA decisions for 68 new active ingredients completed in FY 2015-2017.
- Reporting is done on an annual basis as needed

- The universe for full scope of measure is all primary decisions relating to new active ingredient applications completed in the fiscal year range being evaluated. New active ingredient categories associated with experimental use permits are excluded. Applications rejected or withdrawn as a result of non-payment or failure of the PRIA 21-day completeness and/or the 45/90-day preliminary technical screens are excluded.

3. Methodology:
Using the Business Objects Report titled "Completed Decisions Report", which pulls information from PRISM, the completed decisions for the reporting period are downloaded into an Excel spreadsheet. New active ingredient categories, excluding those related to experimental use permits under Section 5 and those withdrawn or rejected as a result of the PRIA 21-day completeness screen or the 45/90-day preliminary technical screen, are separated out into a separate spreadsheet and secondary decisions are deleted such that there are only primary decisions for each active ingredient application. The statutory decision time frame, which is calculated in the unit of months, is converted to days from the PRIA start date to the PRIA due date so that it can be compared to the actual decision time frame, which the report provides in days. The sample is sorted by the decision time frames for each primary decision (the column in the report is titled "Days Between Start Date and Completion Date") and an average is derived from the sum of decision time frames divided by the number of primary decisions reported.

4. Data Limitations/Qualifications:
New chemical applications associated with Experimental Use Permits under Section 5 of FIFRA are not included in the results, nor are Section 3 new chemical applications that are withdrawn or rejected as a result of the PRIA 21-day completeness screen or the 45/90-day preliminary technical screen. New chemical applications rejected or withdrawn for non-payment of the registration fee are not included in the results.

There are 36 PRIA categories relating to new active ingredient applications, with statutory decision time frames ranging from 7 to 24 months. EPA does not determine how many or what types of PRIA category applications will be submitted by applicants in a given year. On any given fiscal year, new active ingredient completions will reflect different combinations of categories with different statutory time frames, and a given category/timeframe may be represented one year but not the next year. By framing the strategic measure in as a reduction in days to the average decision time frame baseline of 655 days, the variability described above, and the relationship of the actual decision timeframes to the statutory decision times frame is not reflected. The number and types of applications that are received and completed in a given fiscal year, rather than programmatic efforts or efficiencies, could potentially be a determining factor in the result reported. Because statutory timeframes for some of the PRIA categories exceed the baseline of 655 days, it is possible to meet or better the statutory timeframes and not meet the target (or the baseline) described in the strategic measure. The performance measure (PRIA2) supporting this strategic measure does target a reduction of the exceedance of timeframes and therefore addresses this limitation.

5. Technical Contact:
Stephen Schaible/703-308-9362 (Handles all aspects of data collection and verification)

6. Certification Statement/Signature

I certify the information in this DQR is complete and accurate.

DAA Signature