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## **Analysis of Cost Estimates and Additional Resources Required for Timely FIFRA/ESA Pesticide Registration Review**

### **Summary Overview and Methodology Documentation**

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October 2013

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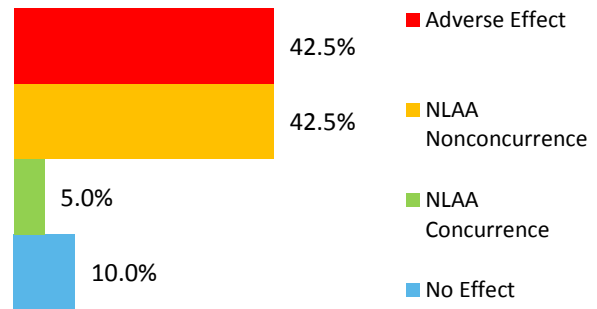
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# FIFRA/ESA PESTICIDE REGISTRATION REVIEW

## COST ANALYSIS OVERVIEW

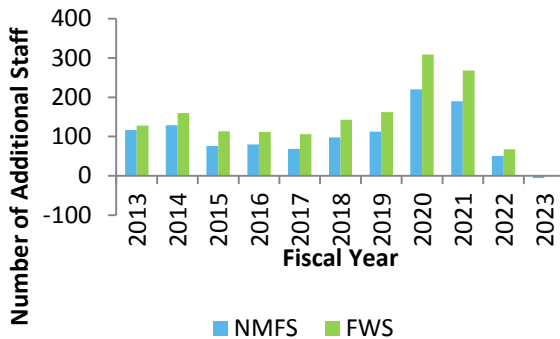
Under the current process to review pesticides required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), completing the currently scheduled 744 Registration Review docket by FY 2023 will result in a 13-fold and 25-fold increase over the current budget and a 17-fold and 71-fold increase over the current staffing levels at Commerce’s National Marine Fisheries Service (NMFS) and Interior’s Fish and Wildlife Service (FWS), respectively. These increases to ensure compliance with the completion deadline reflect an estimated increase of \$474 million over ten years (FY 2013-2023) representing an average estimated increase of \$43.1 million per year between the NMFS and FWS. The analysis shows that a substantial increase in resources at the Services would be necessary to comply with deadlines.

### Registration Review Decisions



All decisions except the "No May Affect" decision require consultations by either the NMFS, FWS, or both.

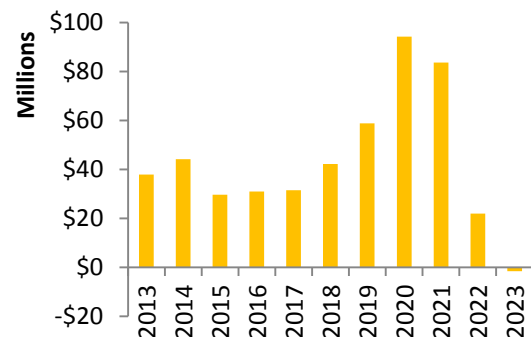
### Additional Staff Requirements



The Environmental Protection Agency (EPA) is required under FIFRA to complete Registration Reviews of existing pesticides. These reviews include evaluating possible impacts on endangered species and critical habitats under Section 7 of the Endangered Species Act (ESA). In some cases, EPA is required to consult regarding endangered species and their critical habitats with one of two service agencies, NMFS and/or FWS. An estimated 90% of dockets will require consultations by the NMFS/FWS.

A cost analysis was completed to estimate the additional staffing levels needed at the Services to meet Registration Review deadlines. This report provides an analysis of process cost and current budgetary resources at the EPA, NMFS, and FWS. Using the assessment and consultation processes observed from recent examples conducted on pesticides, the analysis indicates that current resource levels are insufficient to complete review of the 744 dockets by the FY 2023 deadline imposed by FIFRA.

### Additional Services Resources Needed



## BACKGROUND

CropLife America (CropLife) has engaged Summit Consulting, LLC (Summit) to produce cost estimates for the Pesticide Registration Review Process conducted by the Environmental Protection Agency (EPA) in conjunction with the National Marine Fisheries Service (NMFS) and Fish and Wildlife Service (FWS), or collectively, the Services.

### Pesticide Registration Review

Registration Review for pesticides is required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA is statutorily required to complete the current round of reviews by October 1, 2022 (beginning of 2023 fiscal year). To meet this deadline, all review dockets are to be opened by October 2017. The Endangered Species Act (ESA), Section 7, requires that federal agency actions potentially affecting endangered species or critical habitats be subject to consultation between the action agency (here, EPA) and the NMFS and/or the FWS, as appropriate<sup>1</sup>. Currently, out of the 744 dockets scheduled for review, around than 300 dockets have been opened, of which 30 dockets have been completed<sup>2</sup>. The remaining 444 dockets are scheduled to be opened by 2017. However, the current pace of Registration Reviews is insufficient to meet the deadline for completion by fiscal year (FY) 2023.

In light of these scheduling concerns, cost estimates were produced and are presented below for both a base scenario and an “Enhanced Services” scenario. In the latter scenario, resources are increased at NMFS and FWS sufficiently to bring the Registration Review process to compliance with the FY 2023 deadline.

### About Summit

Founded in 2003, Summit Consulting, LLC (Summit), specializes in blending expert academic knowledge in economics and econometric methods with real-world experience in budget cost estimation to design and implement quantitative solutions for Federal agencies and private-sector clients. Summit Consulting is led by PhD economists and Federal Budget experts, including a former member of the Office of Management and Budget (OMB) Credit Crew, with significant and direct experience reviewing and approving Federal Credit Reform Act of 1990 (FCRA)-compliant model methodologies.

CropLife engaged Summit to produce cost estimates for the operation of the pesticide Registration Review costs associated with ESA Section 7 consultations. These cost estimates involve documenting the review process through the individual agencies, a review of agency budgetary capacity, and determination of the breakdown of estimated costs on a temporal basis. The following sections of this report detail the methodology and results of this analysis.

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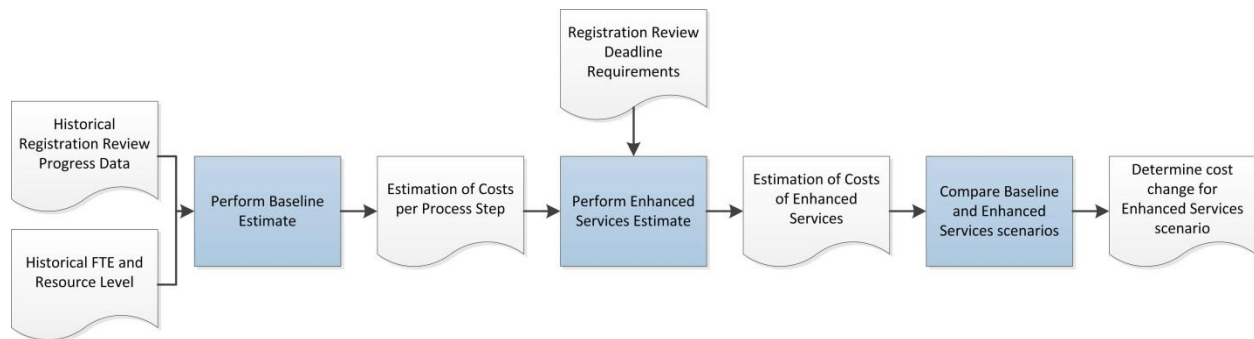
<sup>1</sup> Consultations by the NMFS or FWS depend on the jurisdiction of the two service agencies. At times, the jurisdiction of the two agencies may overlap, requiring actions from both.

<sup>2</sup> Docket completion figures as of April 2012.

## METHODOLOGY

The following section details the methodology used to generate the cost estimates. This methodology overviews the assumptions, inputs, and process for generating baseline and Enhanced Services cost estimates, and employs the following analytical approach:

**Figure 1: Methodology Overview**



### Scope of Cost Estimation

The Pesticide Registration Review process is a complex endeavor. It involves both public and private entities, including: participation of the EPA, the Services (NMFS and FWS), registrants and members of the public. Its purpose is to review the potential environmental effects of previously-registered active ingredients.

In order to standardize the estimation of costs, a number of assumptions were made regarding the scope of completed dockets. These are identified as this presentation proceeds.

The base and Enhanced Services scenarios analyzed in this cost estimation include costs of:

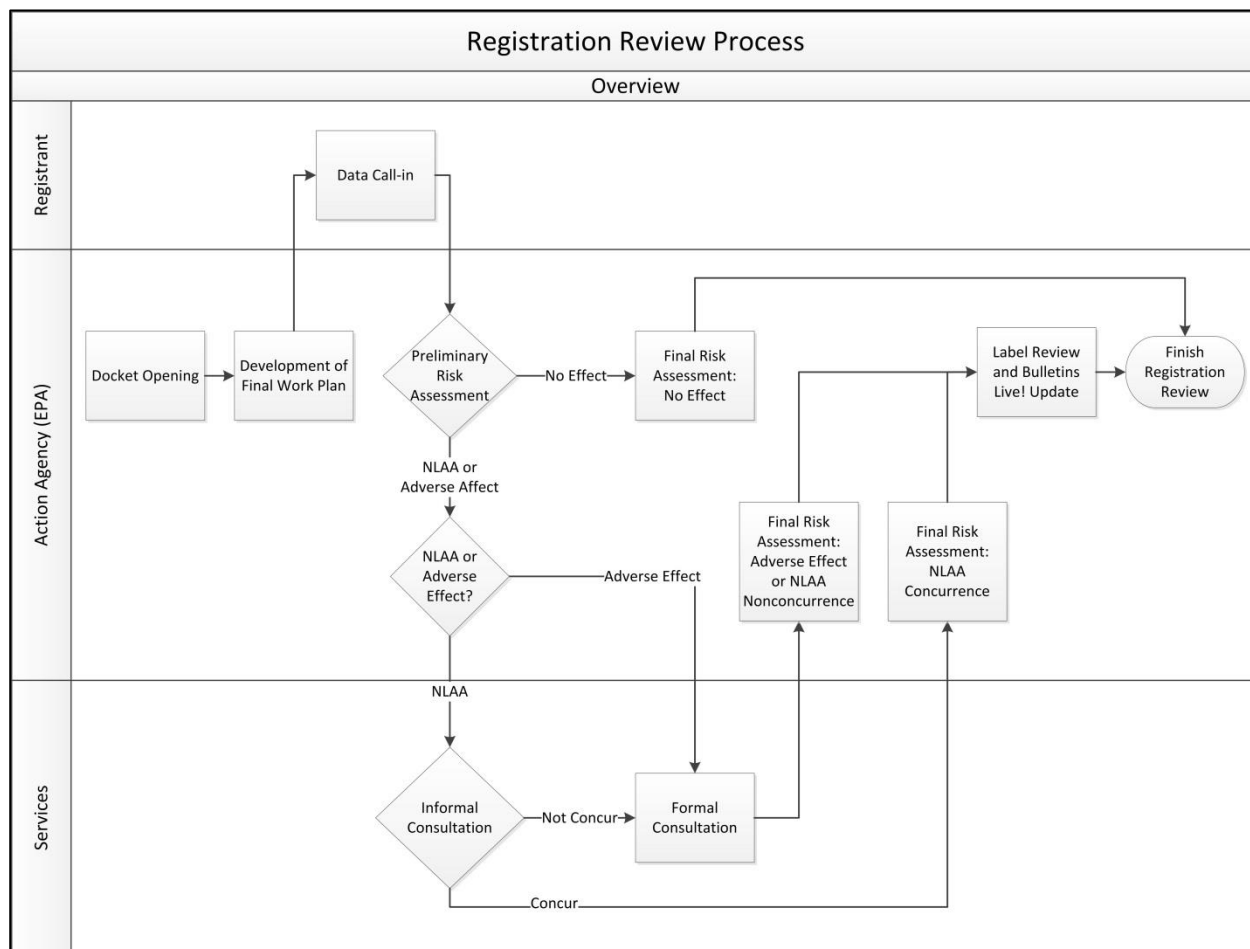
- Registration Review for currently-identified dockets only. New registrations, new uses, and other regular functions of the EPA regarding review of pesticides under FIFRA are not considered under this cost estimation. Including these additional dockets will likely increase estimated costs of Registration Review.
- Nation-wide scope of Registration Review

In addition, costs for Registration Review were determined on an annual basis between the fiscal years 2013 and 2023. The estimates produced in this report reflect publicly available information regarding the Registration Review process and status as of April 2012.

## 1. Determining Registration Review Process

The Registration Review process can take any of several trajectories based on assessments findings at key points of the review process. These trajectories then determine the risk assessment decision for a specific docket. Figure 2 shows an overview of the Registration Review process.

Figure 2: Registration Review Process Overview



Note: Registration Review Process Overview diagram above does not display where public comment periods take place.

According to EPA<sup>3</sup>, the main processes of Registration Review include the following:

- Docket Opening:** Dockets for review are opened. This process involves holding focus meetings with relevant parties and the production of a draft work plan and problem formulations for the assessments to be conducted. Discussions with CropLife estimate that this process takes roughly 6 months. Dockets slated for completion by FY 2023 should be opened by October 2017.

<sup>3</sup> From "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives."

- **Development of Final Work Plan:** A final work plan is developed for Registration Review of a docket prior to in-depth assessment by the EPA. Discussions with CropLife estimate finalization of a work plan takes roughly 2 months.
- **Data Call-in:** Once a final work plan is developed, additional data may be required to fulfill new test guidelines or update the existing data base. This data generation is completed by the registrants of products included in the docket. Though time for data call-in varies depending on the data to be collected, as a general matter this process is expected by EPA generally to span approximately 18 months (1.5 years).
- **Preliminary Risk Assessment:** EPA conducts preliminary risk assessments based on the final work plan and data collected during the data call-in. Discussions with CropLife estimate this process to take 12 months. At this point, the EPA makes a decision stating EPA's determination of whether the products included in the docket do not affect, benignly affect, or adversely affect identified endangered species or critical habitats. This decision by the EPA determines the trajectory of Registration Review for the remainder of the process. A revision of the Preliminary Risk Assessment is estimated to take 6 months following the end of a public comment period to incorporate public feedback.
- **Informal Consultation:** If necessary, EPA and the Services will conduct informal consultation on the docket. Discussions with CropLife estimate that this informal consultation is used to determine the need for more formal consultation and takes roughly 6 months. If the EPA determines there to be no effect or adverse effects from the Preliminary Risk Assessment, this step is skipped.
- **Formal Consultation:** If necessary, EPA and the Services will conduct formal consultation on the docket. This process involves the production of a Biological Opinion, Incidental Take Statement, and Reasonable and Prudent Measures related to the docket and effects on endangered species and critical habitats. Though the time expended on this process is expected to vary substantially, discussions with CropLife estimate this process to take around 48 months (4 years) based on recent examples of formal consultations conducted for pesticides.
- **Final Risk Assessment:** The final risk assessment step finalizes the decision of the Registration Review process. Discussions with CropLife estimate this to take 2 months for No Effect decisions and 6 months for all other decisions. Final Assessment for all dockets should be reached by October 1, 2022.
- **Label Review and Bulletins Live Update:** If necessary, at the conclusion of Registration Review, EPA intends to amend pesticide labels and update the Bulletins Live application to implement changes as a result of the review. Discussions with CropLife estimate this process takes approximately 6 months following determination of Final Risk Assessment.
- **Public Comment Periods:** The Registration Review process contains several points for the public to comment on review completed on a docket. Public commentary periods are held for roughly 2 months each.

There are four possible effects decisions, each of which results in a unique path and timeline through the Registration Review process. These decisions include the following:

- No Effect
- Not Likely to Adversely Affect, Concurrence
- Not Likely to Adversely Affect, Non-Concurrence
- Adverse Effect



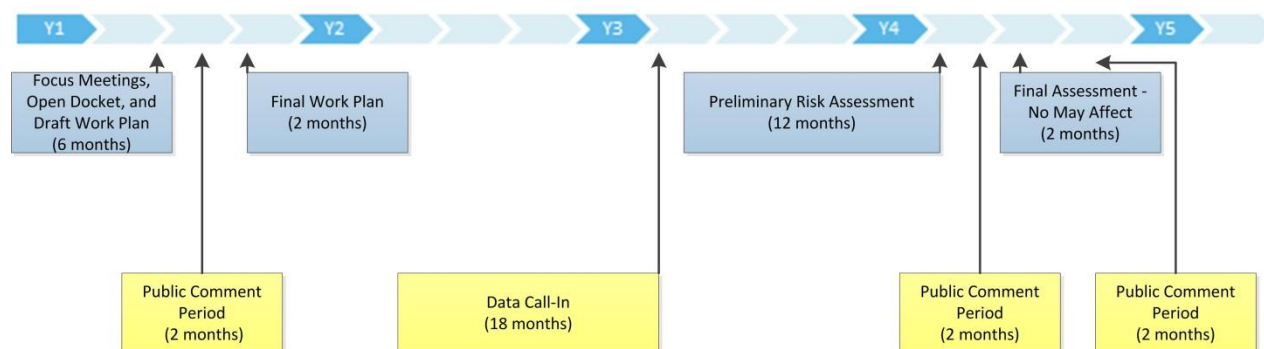
The four effect decisions are described in detail in the sections below.

### Decision Type 1: No Effect

A no effect decision indicates that the use for a particular active ingredient will not produce effects on endangered species or critical habitats. The EPA retains the authority to make a no effect decision and this decision does not require consultations with the Services.

Figure 3 shows the overall timeline and process flow for No Effect Registration Review decisions.

Figure 3: No Effect Decision Process Flow



Based on discussions and past experience with the Registration Review process, CropLife estimates the No Effect Decision process flow to take approximately 3 years and 10 months and encompass the processes shown in Table 1.

Table 1: No Effect Decision Process Flow

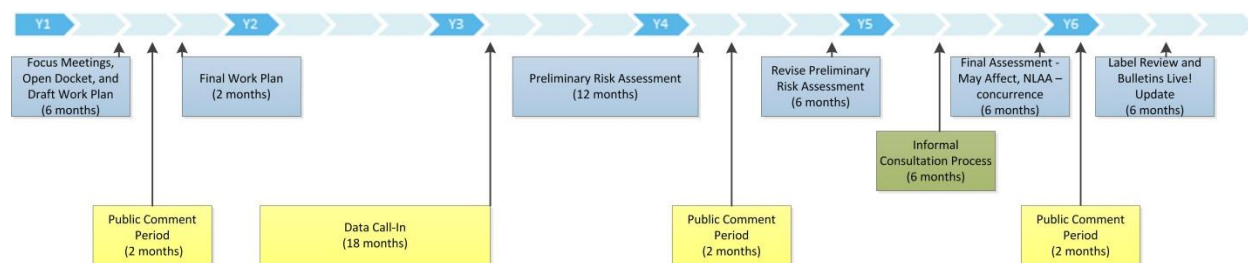
Step	Process Name	Main Party	Estimated Time
1	Docket Opening	EPA	6 months
2	Public Comment Period 1	Public	2 months
3	Development of Final Work Plan	EPA	2 months
4	Data Call-in	Public	18 months
5	Preliminary Risk Assessment	EPA	12 months
6	Public Comment Period 2	Public	2 months
7	Final Risk Assessment	EPA	2 months
8	Public Comment Period 3	Public	2 months

### Decision Type 2: Not Likely to Adversely Affect, Services Concurrence

A not likely to adversely affect, services concurrence decision (NLAA Concurrence) indicates that any effects from use of a particular active ingredient will have either benign or otherwise negligible effects on endangered species or critical habitats, and the Services concur with the EPA designation of such a decision. For this decision, the Services will conduct informal consultations to determine that any effect is indeed benign or negligible.

Figure 4 shows the overall timeline and process flow for NLAA Concurrence Registration Review decisions.

Figure 4: NLAA Concurrence Decision Process Flow



Based on discussions and past experience with the Registration Review process, CropLife estimates the NLAA Concurrence process flow to take 5 years and 8 months and encompass the processes shown in Table 2.

Table 2: NLAA Concurrence Decision Process Flow

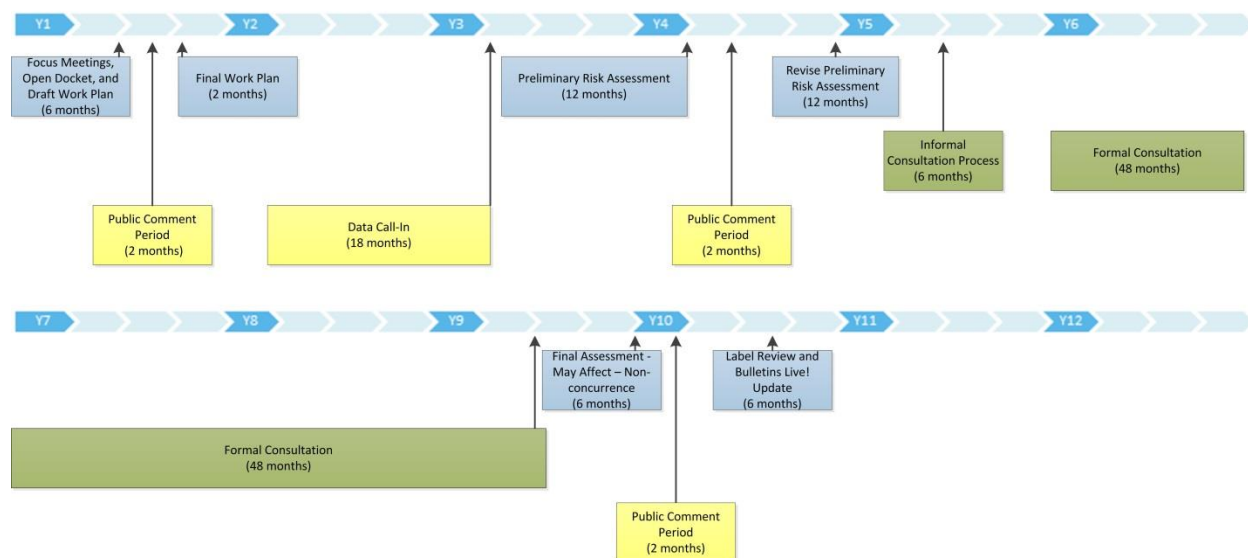
Step	Process Name	Main Party	Estimated Time
1	Docket Opening	EPA	6 months
2	Public Comment Period 1	Public	2 months
3	Development of Final Work Plan	EPA	2 months
4	Data Call-in	Public	18 months
5	Preliminary Risk Assessment	EPA	12 months
6	Public Comment Period 2	Public	2 months
7	Revised Preliminary Risk Assessment	EPA	6 months
8	Informal Consultation	Services	6 months
9	Final Risk Assessment	EPA	6 months
10	Public Commentary Period 3	Public	2 months
11	Label Review, as necessary	EPA	6 months

### Decision Type 3: Not Likely to Adversely Affect, Services Non-Concurrence

A not likely to adversely affect, services non-concurrence decision (NLAA Non-Concurrence) indicates that the EPA believes any effects from use of a particular active ingredient will have either benign or otherwise negligible effects on endangered species or critical habitats; however, the Services do not concur with the EPA designation of such a decision. For this decision, the Services will conduct informal consultations to determine that any effect is indeed benign or negligible, and then formal consultations to determine the potential adverse effects of use.

Figure 5 shows the overall timeline and process flow for NLAA Non-Concurrence Registration Review decisions.

Figure 5: NLAA Non-Concurrence Decision Process Flow



Based on discussions and past experience with the Registration Review process, CropLife estimates the NLAA Non-Concurrence process flow to take 9 years and 8 months and encompass the processes show in Table 3.

Table 3: NLAA Non-Concurrence Decision Process Flow

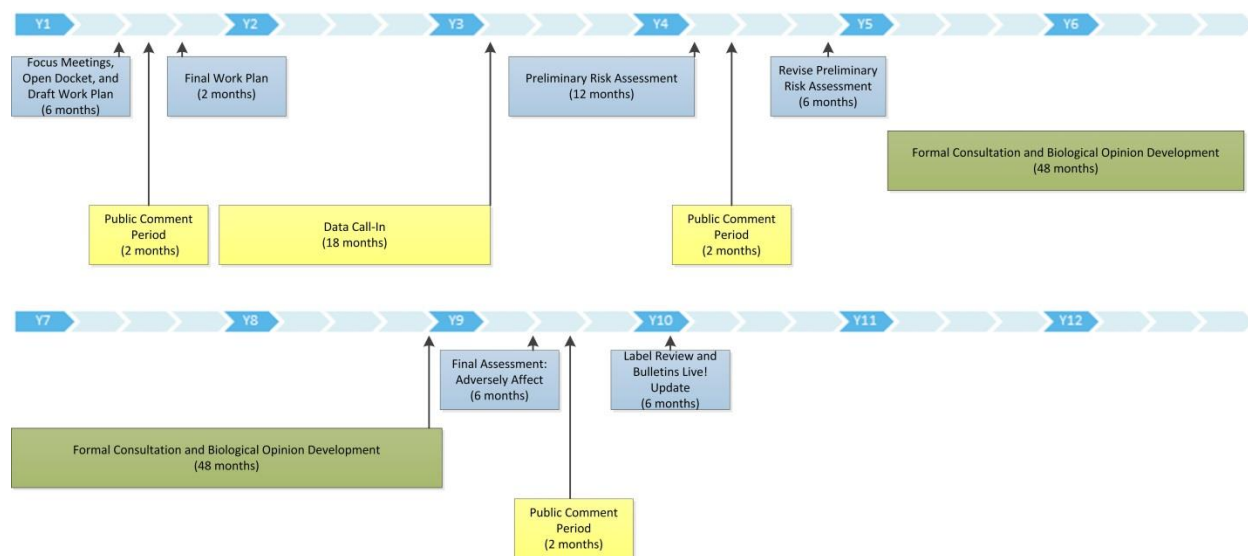
Step	Process Name	Main Party	Estimated Time
1	Docket Opening	EPA	6 months
2	Public Comment Period 1	Public	2 months
3	Development of Final Work Plan	EPA	2 months
4	Data Call-in	Public	18 months
5	Preliminary Risk Assessment	EPA	12 months
6	Public Comment Period 2	Public	2 months
7	Revised Preliminary Risk Assessment	EPA	6 months
8	Informal Consultation	Services	6 months
9	Formal Consultation	Services	48 months
10	Final Risk Assessment	EPA	6 months
11	Public Commentary Period 3	Public	2 months
12	Label Review, as necessary	EPA	6 months

### Decision Type 4: Adverse Effect

An adverse effect decision indicates that the EPA believes the use of a particular active ingredient is likely to cause an adverse effect on an endangered species or critical habitat. This decision requires formal consultation by the appropriate Service agency.

Figure 6 shows the overall timeline and process flow for adverse effect Registration Review decisions.

Figure 6: Adverse Effect Decision Process Flow



Based on discussions and past experience with the Registration Review process, CropLife estimates the adverse effect decision to take approximately 9 years and 2 months and encompass the processes shown in Table 4.

Table 4: Adverse Effect Decision Process Flow

Step	Process Name	Main Party	Estimated Time
1	Docket Opening	EPA	6 months
2	Public Comment Period	Public	2 months
3	Development of Final Work Plan	EPA	2 months
4	Data Call-in	Public	18 months
5	Preliminary Risk Assessment	EPA	12 months
6	Public Comment Period	Public	2 months
7	Revised Preliminary Risk Assessment	EPA	6 months
8	Formal Consultation	Services	48 months
9	Final Risk Assessment 2	EPA	6 months
10	Public Commentary Period	Public	2 months
11	Label Review, as necessary	EPA	6 months

## 2. Determining Docket Review Schedule

In order to estimate the cost of processing dockets through the Registration Review process, it is necessary to determine the schedule and composition of dockets entering the Registration Review process at the EPA, as well as the status of dockets currently being processed.

The annual docket schedule is informed by the document, "Registration Review: Summary of Planned Schedule for Opening Registration Review Docket by Fiscal Year 2012 to 2015."

**Table 5: Docket Opening Schedule**

	Currently Opened	FY2013	FY2014	FY2015	FY2016 and Later
Number of Dockets	300	72	73	73	226

The following lists the status of currently open dockets, as of April 2012<sup>4</sup>:

- Past Docket Opening Stage: 300
- Past Final Work Plan Stage: 250
- Final Decisions Issued: 30

In addition, out of those dockets past the final work plan stage, the EPA has requested consultation from the Services for approximately 111 dockets<sup>5</sup>.

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<sup>4</sup> [http://www.epa.gov/oppsrrd1/registration\\_review/highlights.htm](http://www.epa.gov/oppsrrd1/registration_review/highlights.htm)

<sup>5</sup> Joint Oversight Hearing Transcript (May 3, 2011). As of May 2011, EPA has submitted 147 consultation requests to either the NMFS or FWS. Of these consultation requests, NMFS has responded to 21 through the issuance of Final Biological opinions, 2 were NLAA Non-Concurrence opinions, and 13 are planned to be addressed by NMFS by April 2012. The remaining 111 consultation requests require additional information or substantive response.

### 3. Determining Costs

In order to approximate the costs of performing tasks related to Registration Review, it is necessary to determine the labor and non-labor costs incurred by the action agency and the Services to perform each step in the Registration Review process.

#### *Types of Costs*

Labor costs in this analysis are typically referred to in units of full time employees (FTE), representing the amount of labor available for use by a single employee working full time, excluding a reasonable amount of vacation and other time off. This designation does not imply that a process step requiring 1 FTE will be completed by a single employee, but that the labor output necessary to complete a step would be equivalent to that of a single employee working full time. The monetary costs associated with labor are assumed to encompass annual salary and other fringe benefits, such as healthcare coverage.

The non-labor costs associated with Registration Review are assumed to be direct costs of the Registration Review process, and do not encompass general administrative costs.

This cost, which may be further disaggregated into average monthly costs based on process time, can be used to determine the monthly and annual expenses associated with processing a number of dockets for a specific period of time for each participating agency.

#### *Costs Estimates by Agency*

The following section details the determination of costs by agency and available agency budget.

#### *Action Agency*

##### **Environmental Protection Agency**

The action agency for Registration Review is the EPA. It opens dockets and undertakes all actions other than the Services' consultation activities. A number of resources were consulted to gather an estimate for the EPA labor and non-labor costs of completing the Registration Review process.

Monetary costs of labor at the EPA are estimated from the costs of completing product registrations and label amendment for the Reregistration process. This amount is estimated to be approximately \$142 thousand per each FTE.<sup>6</sup>

The cost estimate for the EPA is assumed to be roughly 2.3 FTE and \$30,000 in non-labor costs<sup>7</sup> for completing a single Registration Review. In addition, a fixed cost of 2FTE and annual funding of \$300,000 is estimated to be needed for maintaining the Bulletins Live application.

For the 2013 fiscal year, the EPA has 75 FTE devoted to Registration Review<sup>8</sup> and an estimated \$10.6 million in supporting budget. The amount budgeted for the EPA for all pesticide reviews is \$129 million. Data for EPA budget estimates were taken from EPA's annual budget justification.

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<sup>6</sup> From "Pesticide Reregistration Performance Measures and Goals; Annual Progress Report; Fiscal Year 2011." The EPA used approximately 20.2 FTE or approximately \$2.86 million in FY2011 to review and process applications for fast-track (me-too) product registration and label amendments. Dividing \$2.86 million by 20.2FTE yields \$141,584 for each FTE.

<sup>7</sup> Joint Oversight Hearing Transcript (May 3, 2011)



## Services

### National Marine Fisheries Service

The NMFS serves as one of the two Service agencies which conduct informal and formal ESA Section 7 consultations when required for the Registration Review process.

Based on transcripts from the Joint Oversight Hearing, NMFS currently has 6 FTEs dedicated to EPA FIFRA registrations. NMFS estimates an additional 40 FTE, or \$6 million in labor costs (approximately \$150 thousand for each FTE), will be required for the NMFS to provide consultations to 70 Registration Reviews annually. No non-labor costs are assumed for the NMFS; this assumption is made to ensure that estimated process costs for the Services are conservative.

For the 2013 fiscal year, NMFS has 6 FTEs devoted to consultations for Registration Reviews<sup>9</sup>. NMFS budgeted a total of \$41,563,000 and 174 FTE supported activities that conserve and recover species threatened or endangered with extinction. This budget supports, in addition to consultations for Registration Review, ESA Section 7 consultations for authorizations (such as building roads, bridges, commercial fishing, etc.), issuance of permits and authorizations related to the direct and indirect take of listed species, and the Marine Animal Health and Stranding Response program. Assuming equal distribution of monetary budget by FTE, the NMFS is estimated to have budgeted \$1.43 million to support the 6 FTE devoted to pesticide Registration Review consultations in fiscal year 2013<sup>10</sup>. This estimated distribution of monetary budget by FTE is used so that the budgeted amount for Registration Review is linked to staffing level, which constitutes the bulk of NMFS costs for Registration Review.

Data for NMFS budget estimates were taken from NMFS's annual budget justification.

### Fish and Wildlife Service

The FWS serves as the second Service agency which conducts informal and formal ESA Section 7 consultations when required for the Registration Review process.

Because FWS has not currently completed ESA Section 7 consultations related to FIFRA, the labor and non-labor costs for FWS are assumed to be identical to those at the NMFS. This assumption was made as the types of consultations to be conducted for Registration Review are similar for both the NMFS and FWS; the two agencies share a handbook describing the procedures for completing consultations related to ESA Section 7.

For the 2013 fiscal year, FWS budgeted 2 FTE and \$1 million for ESA Section 7 consultations. Data for FWS budget estimates were taken from FWS's annual budget justification.

## Cost by Process Step

In order to determine the costs of Registration Review over time, the costs by process step is determined. For the purposes of estimation, it is assumed that the cost of each process step is borne only by the agency responsible for the completion of the step. Thus, it is assumed that though it is likely that other agencies may participate in the completion of step, this participation does not result in any

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<sup>8</sup> Joint Oversight Hearing Transcript (May 3, 2011)

<sup>9</sup> Joint Oversight Hearing Transcript (May 3, 2011)

<sup>10</sup> This \$1.43 million includes estimated labor costs of approximately \$900 thousand for the 6 FTE currently devoted to ESA consultations for pesticide Registration Reviews.

costs to the participating agency. In addition, the EPA and the Services are not assumed to realize costs during any of the public commentary periods or during the initial data call-in period.

The cost of each process step is calculated separately for costs incurred by the EPA and costs incurred by the Services. The EPA and NMFS cost estimates cited from the Congressional Hearing are assumed to be average costs, which encompass all four types of decisions arising from Registration Review. In order to determine on a more granular level the costs associated with each type of Registration Review decision, the provided EPA and NMFS estimates were decomposed into the individual costs by decision type, based on docket composition using the following process:

1. Determine the total amount of time in each decision process associated with a particular agency.
2. Multiply the distribution of docket decisions to the total amount of time, in months, associated with each agency for the appropriate docket decision to determine the weighted time for each agency and decision type.
3. Aggregate the weighted time for each decision type to determine the total weighted time for the EPA and the Services. This total weighted time represents the average time spent by an agency in reviewing dockets for Registration Review. Table 6 reflects the results of the calculations completed in steps 1 through 3.

**Table 6: Total Hours by Agency and Decision Type**

Decision Type	EPA Time	EPA Docket Percentage	EPA Weighted Time	Services Time	Services Docket Percentage <sup>11</sup>	Services Weighted Time
No Effect	22	10.0%	2.20	0	0.0%	0.00
NLAA Concurrence	38	5.0%	1.90	6	5.6%	0.33
NLAA Non-Concurrence	38	42.5%	16.15	54	47.2%	25.50
Adverse Effect	38	42.5%	16.15	48	47.2%	22.67
Total	-	100.0%	36.4	-	100.0%	48.50

4. Use the total weighted time for each agency, as well as the provided cost estimate in FTE and non-labor costs to calculate the per-month FTE and non-labor costs per agency. This calculation is shown in Equation 1. Cost estimates provided for the EPA may be divided directly by the total weighted time, as they are assumed to cover the entire period of Registration Review, while annual cost estimates provided by the Services are first de-annualized to account for the longer timeframe of completing Registration Reviews. This calculation is shown in Equation 2.

<sup>11</sup> Docket percentage for Services are calculated on a pro-rata basis after excluding the 10% of dockets in the No Effect decision process. This adjustment is made to account for the lack of Services involvement in reviewing dockets in a No Effect decision process.



**Equation 1: Monthly Cost Calculation**

$$\text{Monthly Cost}_{i,j} = \frac{\text{Overall Process Cost}_{i,j}}{\text{Total Weighted Time}_i}$$

Where *i* represents the EPA or the Services, and *j* represents the labor or non-labor cost designation.

**Equation 2: Overall Services Cost Calculation**

$$\text{Overall Services Cost} = \text{Annual Estimated Cost} \times \frac{\text{Total Weighted Process Time}}{12}$$

- Once the monthly costs by the EPA and Services are determined, multiply the monthly cost (in FTE and non-labor costs) by the length of time required to complete the process by the appropriate agency. The resulting value will be the cost of completing each process step. This calculation is shown in Equation 3.

**Equation 3: Process Step Cost Calculation**

$$\text{Process Step Cost}_{n,i,j} = \text{Monthly Cost}_{i,j} \times \text{Process Step Time}_n$$

Where *i* represents the EPA or the Services, *j* represents the labor or non-labor cost designation, and *n* represents the specific process step.

The calculated process costs for each step are shown in Table 7 below.

**Table 7: Process Step Costs by EPA and Services**

Process Step	EPA Non-Labor Cost	EPA FTE Cost	EPA FTE	Services Non-Labor Cost	Services FTE Cost	Services FTE
Open Docket	\$ 4,945	\$ 53,653	0.38	0	0	0
Final Work Plan	\$ 1,648	\$17,884	0.13	0	0	0
Preliminary Risk Assessment	\$ 9,890	\$107,306	0.76	0	0	0
Informal Consultation	0	0	0	0	\$ 51,665	0.34
Formal Consultation	0	0	0	0	\$ 414,318	2.76
Final Decision (No Effect)	\$ 1,648	\$17,884	0.13	0	0	0
Final Decision (All Other Decisions)	\$ 4,945	\$53,653	0.38	0	0	0
Label Review and Update	\$ 4,945	\$53,653	0.38	0	0	0

### *Process Costs by Final Risk Assessment Decision*

Table 8 below show the costs evaluating a single docket by the EPA and each of the Services for labor and non-labor costs by decision status. The costs of each type of decision are calculated by aggregating the process-step costs from Table 7 appropriate for the type of decision.

The weighted average is calculated using the decision type breakdown shown in Table 9.

**Table 8: Per Docket Process Costs by EPA and Services**

Process	EPA Non-Labor Cost	EPA FTE Cost	EPA FTE	Services Non-Labor Cost	Services FTE Cost	Services FTE	Total Time (Years)
No Effect	\$ 18,132	\$ 197,727	1.39	0	0	0	3.67
NLAA, Concurrence	\$ 31,319	\$ 339,802	2.40	0	\$ 51,665	0.34	5.17
NLAA, Non-Concurrence	\$ 31,319	\$ 339,802	2.40	0	\$ 464,983	3.10	9.17
Adverse Effect	\$ 31,319	\$ 339,802	2.40	0	\$ 413,318	2.76	8.67
<b>Weighted Average</b>	<b>\$ 30,000</b>	<b>\$ 325,495</b>	<b>2.30</b>	<b>0</b>	<b>\$ 417,624</b>	<b>2.78</b>	<b>8.20</b>

## 4. Calculating Cost Estimates

### *Cohort composition*

To calculate cost estimates, dockets scheduled to enter Registration Review are assumed begin the process in October of each year, which is the beginning of the government fiscal year. The schedule of dockets is shown in Table 5<sup>12</sup>. The dockets which enter the Registration Review process at the same time are considered to be in a single cohort, which is assumed to exhibit a constant composition of Registration Review decision status. For each cohort, the decision breakdown assumed<sup>13</sup> is shown in Table 9:

**Table 9: Decision Type Breakdown**

Decision Type	Percentage of total Dockets
No Effect	10%
NLAA, Concurrence	5%
NLAA, Non-Concurrence	42.5%
Adverse Effect	42.5%

For example, a cohort containing 200 dockets would then include 20 dockets (*i.e.*, 10% of 200) which are expected to result in a No Effect decision, 10 in a NLAA Concurrence decision, 85 in a NLAA Non-Concurrence decision, and 85 in an Adverse Effect decision.

Based on this designation of effect decision, each set of dockets in a cohort will follow the Registration Review process flow appropriate for the resulting decision. The status of each docket is tracked on a monthly basis, which then determines the amount of labor and non-labor resources used by each of the agencies for the process.

For currently open dockets, the beginning status of each docket is assumed to be the following next step in the process, assuming the completion of any process involving public commentary. This assumption is made to shorten the necessary process time for completion for existing dockets in order to result in a conservative estimate for Registration Review costs. This is shown in Table 10. Currently open dockets are also assumed to display similar breakdowns between Registration Review decisions, with the exception of dockets with consultations requested, which assume breakdowns on a pro-rata basis between NLAA Concurrence, NLAA Non-Concurrence, and Adverse Effect decisions only.

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<sup>12</sup> Because the EPA only states the schedule of docket openings up to 2015, the remaining dockets enter the Registration Review process in 2016 in order to meet the deadline of opening all dockets by the 2017 deadline.

<sup>13</sup> The percentages of Registration Review decisions were determined from discussion with the CropLife ESA Economic working group. Based on historical review data, 10% of Registration Reviews are expected to be No Effect decisions. Due to the nationwide scope of these reviews, the remaining decisions were expected to initially be May Affect decisions, equally split between those determined by the EPA and those determined from Non-Concurrence from the Services.

**Table 10: Assumed Process Steps for Currently Open Dockets**

Current Docket Status	Assumed Beginning Process Step
Docket Opened	Final Work Plan
Final Work Plan Completed	Preliminary Risk Assessment
Consultation Requested	Informal or Formal Consultation

### Consultation Breakdown by Service Agency

Occasionally, the jurisdiction of the two Service agencies overlaps, resulting in the need for both the NMFS and the FWS to complete requested consultations. Based on the views of CropLife, an estimated 75% of all dockets are assumed to require dual review by the NMFS and the FWS<sup>14</sup>. In order to minimize the process time for review, the review by both Service agencies are assumed to take place simultaneously. These consultations are assumed to take equal efforts from both agencies, resulting in a doubling of associated costs related to consultations.

Of the remaining 25% of dockets to be reviewed by a single Service agency, 15% of all dockets requiring consultation will be reviewed by the FWS, and the remaining 10% will be reviewed by the NMFS. As the costs at both the Services are the same, the cost of completing a particular process step by the Services can be represented in Equation 4.

#### Equation 4: Combined Services Cost Calculation

$$\text{Combined Services Cost}_n = 75\% \times (2 \times \text{Process Cost}) + 25\% \times (\text{Process Cost}) \times \text{Cohort Size}_n$$

Where  $n$  represents a particular cohort.

### Aggregating Costs

Total cost per month is determined by aggregating the per-docket costs, by agency, for all cohorts in one month. The cost estimation analysis assumes that costs do not differ on temporal scale, and that learning curves and scales of economy from volume review are negligible. This is shown in Equation 5.

#### Equation 5: Monthly Cost Calculation

$$\text{Total Monthly Cost}_{i,j} = \sum_n \text{Monthly Cost}_{i,j}$$

Where  $i$  represents the agency,  $j$  represents the labor or non-labor cost distinction, and  $n$  represents the cohort of the docket.

The total annual cost is determined by aggregating the total per month costs, by agency, over a 12 month period, beginning in October of each year. This is shown in Equation 6.

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<sup>14</sup>CropLife determined the breakdown of consultations by the Services is as follows: 75% of dockets are reviewed by both Services, 15% are reviewed by FWS only, and 10% are reviewed by NMFS only. The relatively high percentage of consultations by both Services and by the FWS compared to those reviewed by the NMFS reflects the nationwide-scope of the Registration Review.

### Equation 6: Annual Cost Calculation

$$\text{Annual Cost}_{i,j} = \sum_{n=1}^{12} \text{Total Monthly Cost}_{i,j,n}$$

Where  $i$  represents the agency,  $j$  represents the labor or non-labor cost distinction, and  $n$  represents the month of the fiscal year (with October as 1).

### Baseline Scenario

For the baseline scenario, the fiscal year 2013 costs were assumed to be constant for all agencies, excepting a 2.5% annual increase for cost of living adjustments. FTE levels were assumed to remain constant at each of the agencies, while realizing the same 2.5% annual adjustment for cost of living.

### Enhanced Services Scenario

The costs associated with ESA Section 7 reviews resides mostly within the processes of informal and formal consultation, which are performed by the Services. The Enhanced Services scenario, which holds EPA performance consistent with the baseline, is used to determine the extra cost which would be required of the Services (NMFS and FWS) under the processes observed under recent reviews, which is specific to the costs associated with the ESA Section 7 specific costs of Registration Review.

In the Enhanced Services scenario, dockets for Registration Review enter the process at the same schedule as the baseline scenario. Though EPA performance is held consistent with the baseline, a number of additional assumptions are made with regard to the productivity of the Services in informal and formal consultation processes. These assumptions include:

#### Increased Efficiency based on Resources

The Enhanced Services scenario assumes that doubling the level of resources at the Services decreases the process time of consultations by 50%. For example, a process taking 2 FTE 6 months is assumed to take 4 FTE 3 months to complete.

This assumption is made to mitigate the potential issue in which the Registration Review process, as currently structured, is not brief enough to complete Registration Reviews by the FY 2023 deadline for the last cohort of dockets scheduled for opening in the 2016 fiscal year. The increased efficiency assumption is made as a method of decreasing the length of time of consultations performed by the Services.

#### Timing of Increased Efficiency

For the purposes of meeting the FY 2023 review deadline, formal consultations for all cohorts and the informal consultations for the 2016 cohort are assumed to be conducted at the accelerated pace.

Though a different combination of accelerated consultations might be assumed, this assumption attempts to resolve two issues: the long of time necessary to complete formal consultations, and the shortening of the Registration Review process necessary to complete Registration Reviews by October 1, 2022. Though the informal consultation process itself is short compared to the formal consultation process, decreasing the time for all Services consultations decreases the Registration Review process time to the extent that the final assessments for the 2016 cohort can be completed by the deadline.

### Ramp-Up Costs

The Enhanced Services scenario involves rapid increases in staffing at the Services, which impose an additional cost of hiring and training prior to use. For labor (FTE) increases of at least 10% on an annual basis, the agency experiencing the increase is assumed to experience ramp-up costs in the previous year associated with the costs of onboarding additional staff. Ramp-up costs are assumed to be 25% of the additional cost in the future year, during which the agency does not realize the labor of the new staff. Ramp-up costs are assumed to cover any costs detracting from normal operations with regard to consultation reviews. Equation 8 shows the calculation of ramp-up costs.

#### Equation 7: Change in FTE Calculation

$$\text{Change in FTE} = \frac{FTE_{t+1} - FTE_t}{FTE_t}$$

Where  $t$  represents the current year, and  $t+1$  represents the next year.

#### Equation 8: Ramp-Up Cost Calculations

For increases in FTE greater than 10%:

$$\text{Ramp Up Cost}_t = (\text{Labor Cost}_{t+1} - \text{Labor Cost}_t) \times 25\%$$

Otherwise,

$$\text{Ramp Up Cost}_t = 0$$

Where  $t$  represents the current year, and  $t+1$  represents the next year.

## RESULTS

This section presents the results of the two scenarios, based on the methodology described above. The Enhanced Services scenario estimates costs substantially higher than baseline costs at each of the Services. Table 11 and Table 12 display comparisons of the monetary and FTE costs for the NMFS and the FWS between the baseline and Enhanced Services scenarios.

**Table 11: Services Cost Comparison, FTE**

Agency/Fiscal Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Baseline NMFS FTE	6	6	6	6	6	6	6	6	6	6	6
Enhanced NMFS FTE	123	134	81	86	74	104	119	226	196	56	0
Difference (NMFS)	117	128	75	80	68	98	113	220	190	50	-6
Baseline FWS FTE	2	2	2	2	2	2	2	2	2	2	2
Enhanced FWS FTE	130	134	81	86	74	104	119	226	270	69	0
Difference (FWS)	128	132	79	84	72	102	117	224	268	67	-2

**Table 12: Services Cost Comparison, monetary**

Agency/ Fiscal Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Baseline NMFS Costs	\$ 900K	\$ 923K	\$ 946K	\$ 969K	\$ 993K	\$ 1.0M	\$ 1.0M	\$ 1.1M	\$ 1.1M	\$ 1.1M	\$ 1.2M
Enhanced NMFS Costs	\$ 18.4M	\$ 20.7M	\$ 12.8M	\$ 13.9M	\$ 13.5M	\$ 18.2M	\$ 25.3M	\$ 40.2M	\$ 35.8M	\$ 10.5M	\$ 0.0M
Difference (NMFS)	\$ 17.5M	\$ 19.7M	\$ 11.9M	\$ 12.9M	\$ 12.5M	\$ 17.2M	\$ 24.2M	\$ 39.2M	\$ 34.7M	\$ 9.4M	-\$ 1.2M
Baseline FWS Costs	\$ 300K	\$ 308K	\$ 315K	\$ 323K	\$ 331K	\$ 339K	\$ 348K	\$ 357K	\$ 366K	\$ 375K	\$ 384K
Enhanced FWS Costs	\$ 20.7M	\$ 24.8M	\$ 18.1M	\$ 18.4M	\$ 19.3M	\$ 25.4M	\$ 34.9M	\$ 55.5M	\$ 49.4M	\$ 13.0M	\$ 0.0M
Difference (FWS)	\$ 20.4M	\$ 24.5M	\$ 17.8M	\$ 18.0M	\$ 19.0M	\$ 25.0M	\$ 34.6M	\$ 55.1M	\$ 49.0M	\$ 12.6M	-\$ 384K

Note that Table 11 and Table 12 do not include Enhanced Services costs for FY 2023. This is a result of the limited scope of this analysis, which includes only those dockets currently scheduled for Registration Review.

Table 13 compares the estimated EPA budget with the estimated costs of the EPA under the Enhanced Services scenario. Though expected EPA costs are expected to differ due to the shifts in processing time, the costs of conforming to the timeline of the Enhanced Services scenario are within the EPA’s current budget.

**Table 13: EPA Cost Comparison**

Cost Type/ Fiscal Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023 <sup>15</sup>
EPA Budget	\$129M	\$ 132M	\$136M	\$139M	\$142M	\$146M	\$ 150M	\$153M	\$157M	\$161M	\$165M
Enhanced EPA Costs	\$17.2M	\$18.4M	\$27.8M	\$38.1M	\$24.5M	\$32.3M	\$31.5M	\$10.2M	\$12.6M	\$21.2M	\$ 12.4M
Budget Utilization	13.4%	13.9%	20.6%	27.4%	17.2%	22.1%	21.1%	6.7%	8.0%	13.2%	7.5%
Enhanced EPA FTE	110	104	156	228	132	185	176	55	53	110	63

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<sup>15</sup> Costs incurred in FY2023 by the EPA represent the costs of performing label review and updating the Bulletins Live application. These EPA process tasks are related to the Registration Review process, but take place after the determination of the final risk assessment decision.



Though the EPA continues to incur costs associated with Registration Review, the determination of Final Risk Assessment is assumed to be the endpoint for completing Registration Review for deadline purposes. Table 14 shows the number of dockets of each decision type to finish the Final Risk Assessment process (for No Effect decisions) or Final Risk Assessment 2 process (for all other decision types) under the Enhanced Services scenario. Docket values are rounded.

**Table 14: Enhanced Services Docket Completion Schedule**

Decision Type/ Fiscal Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Total <sup>16</sup>
No Effect	11	0	5	7	7	7	23	0	0	0	60
NLAA Concurrence	6	0	5	3	4	4	4	11	0	0	36
NLAA Non-Concurrence	0	0	52	0	46	21	31	31	32	96	309
Adverse Effect	0	52	0	46	0	21	31	31	31	96	309
Total	17	52	62	56	57	52	89	73	93	192	714

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<sup>16</sup> The total number show in Table 14 does not include the 30 dockets currently completed prior to April 2012. Including the 30 completed dockets results in the total number of completed dockets to the scheduled 744 dockets.

Finally, Table 15 summarizes the increase in Services costs and the number of dockets scheduled to be completed for each year between fiscal years 2013 and 2023. The decrease in costs in FY 2023 represents the savings realized by completing Registration Reviews for the scheduled dockets by the deadline. The figures show that over the ten year period, a total increase of \$474 million at the Services is estimated for completion of review by the deadline, with an average increase of around \$43.1million each year. This compares with the baseline cost at the Services, which is around \$15.4 million over the same ten year period.

**Table 15: Differences in Services Cost and Scheduled Dockets for Completion, by Year**

Line Item/ Fiscal Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Marginal Difference (Services Total)	\$37.9 M	\$44.2M	\$29.7M	\$31.0M	\$31.5M	\$42.3M	\$58.9M	\$94.3M	\$ 83.7M	\$ 22.1M	-\$ 1.5M	\$ 474M
Additional Staff (Services Total) <sup>17</sup>	245	288	188	192	174	240	275	529	458	118	-8	N/A
Dockets Scheduled for Final Decision	17	52	62	56	57	52	89	73	93	192	0	714

<sup>17</sup> Additional staff is the difference between estimated necessary staff in the Enhanced Services scenario and the current

## APPENDIX A: REFERENCES

### *Budget Material*

United States Department of Commerce: National Oceanic and Atmospheric Administration. "Budget Estimates, Fiscal Year 2013 Congressional Justification."

United States Department of the Interior: Fish and Wildlife Service. "Budget Justifications and Performance Information: Fiscal Year 2013"

United States Environmental Protection Agency. "Fiscal Year 2013: Justification of Appropriation Estimates for the Committee on Appropriations."

### *Registration Review Process and Schedule*

United States House of Representatives: Committee on Natural Resources and United States House of Representatives: Committee on Agriculture. "At Risk: American Jobs, Agriculture, Health and Species—the Costs of Federal Regulatory Dysfunction." Joint Oversight Hearing Transcript (May 3, 2011).

United States Environmental Protection Agency: Office of Pesticide Programs. "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives." (March 19, 2013).

United States Environmental Protection Agency: Office of Pesticide Programs. "Pesticide Reregistration Performance Measures and Goals; Annual Progress Report; Fiscal Year 2011." (March 14, 2012)

United States Environmental Protection Agency: Office of Pesticide Programs. "Pesticides: Registration Review. Program Highlights." [http://www.epa.gov/oppsrrd1/registration\\_review/highlights.htm](http://www.epa.gov/oppsrrd1/registration_review/highlights.htm)

United States Environmental Protection Agency: Office of Pesticide Programs. "Registration Review: Summary of Planned Schedule for Opening Registration Review Dockets by Fiscal Year 2012 to 2015. Revised April 25, 2012." [http://www.epa.gov/oppsrrd1/registration\\_review/schedule.htm](http://www.epa.gov/oppsrrd1/registration_review/schedule.htm)

United States Fish and Wildlife Service and National Marine Fisheries Service. "Endangered Species Act Consultation Handbook: Procedures for Conducting Section 7 Consultations and Conferences." (March 1998) <http://sero.nmfs.noaa.gov/pr/esa/pdf/Sec%207%20Handbook.pdf>

