



Public Workshop on the Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening

December 17, 2007 – 9:00 AM to 5:00 PM

Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202



Welcome

Elizabeth Resek, Acting Director
Office of Science Coordination and Policy
Office of Prevention, Pesticides and Toxic
Substances (OPPTS)



Today's Agenda

- 9:00 Welcome & Introductory Remarks
- 9:15 Overview of the EDSP (Background) - Linda Phillips
- 9:30 Introduction To EDSP Policies & Procedures - Bill Wooge
- 9:45 Legal Authorities for EDSP Policies and Procedures - Laurel Celeste
- 10:30 Procedures for EDSP Test Orders - Angela Hofmann
- 11:15 Contesting, Cost Sharing, Compensation, and CBI - William Jordan
- 12:00 Lunch
- 1:00 Information Collection Request (ICR) - Angela Hofmann
- 1:30 Questions Posed in the Policies & Procedures Document - Bill Wooge
- 2:00 Questions from the Public



Overview of the EDSP

Linda Phillips, Director
Exposure Assessment Coordination & Policy Division
Office of Science Coordination and Policy
Office of Prevention, Pesticides and Toxic Substances (OPPTS)

EPA's Statutory Authority

- Federal Food, Drug, and Cosmetic Act (FFDCA)
 - Requires EPA to:
 - Develop a screening program using validated assays to identify pesticides that may have estrogenic effects in humans
 - Authorizes EPA to include:
 - Other endocrine effects, as designated by the EPA Administrator (e.g., androgen and thyroid; endocrine effects in species other than humans)
 - Other non-pesticide chemicals that:
 - *Have “an effect cumulative to that of a pesticide,” and*
 - *To which a substantial human population may be exposed*
- Safe Drinking Water Act (SDWA) Amendments
 - Allow EPA to require testing of chemical substances found in sources of drinking water, if a substantial human population may be exposed

Endocrine Disruptor Screening Program (EDSP)



- Established in 1999 following recommendations of:
 - The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) of 1996-1998
 - Public comment
 - EPA's Science Advisory Board & FIFRA Scientific Advisory Panel





Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC)



- Chartered Oct. 16, 1996
(www.epa.gov/scipoly/oscpendo)
- 39 members representing a wide range of stakeholders
- Recommendations proposed in 1998:
 - Estrogen, androgen and thyroid
 - Human and ecological effects
 - Priority setting for broad universe of chemicals
 - 2-Tiered Approach

Two-Tiered Approach

- Tier 1
 - In vitro and in vivo screens
 - Detect potential to interact with endocrine system
- Tier 2
 - Multi-generation studies covering a broad range of taxa
 - Provide data for hazard assessment





Tier 1 Assays Recommended by EDSTAC



- Primary recommendation:
 - Steroidogenesis (in vitro)
 - Estrogen / Androgen receptor binding and/or transcriptional activation assays (in vitro)
 - Uterotrophic
 - Hershberger
 - Pubertal female assay
 - Amphibian metamorphosis assay
 - Fish screen
- Potential alternative assays to validate:
 - Aromatase (in vitro)
 - Pubertal male assay
 - 14-Day adult male

Tier 2 Assays Recommended by EDSTAC



- Multi-generational tests in
 - Mammals*
 - Birds
 - Amphibians
 - Fish
 - Invertebrates

* Rat 2-generation Reproductive and Fertility Effects assay already used for food-contact pesticides, perhaps with additional endocrine endpoints



Current EDSP Activities



Assay
Validation

Priority Setting

Procedures

- **Assay Validation**
 - Development and validation of test assays (Tier 1 screening & Tier 2 testing)
- **Priority Setting**
 - Selecting chemicals to be screened
- **Procedures**
 - Developing procedures to require the data

Validation Process for EDSP



- Method development and preparation of Detailed Review Paper (DRP)
- Pre-validation
 - Demonstration of relevance
 - Development of standard optimized protocol
 - Determination of readiness for validation
- Validation in multiple laboratories
 - Demonstrate reliability across labs
- Independent scientific peer review of validation effort: Integrated Summary Report (ISR)
- Regulatory acceptance



Validation Update on Tier 1 Assays Tentative Peer Review Schedule



- | | |
|---------------------------|-----------|
| ■ Uterotrophic | Complete |
| ■ Hershberger | Complete |
| ■ Adult Male | Complete |
| ■ Female Pubertal | Complete |
| ■ Male Pubertal | Complete |
| ■ AR Binding | In Review |
| ■ Aromatase | In Review |
| ■ Amphibian Metamorphosis | In Review |
| ■ Fish Screen | 2007-Q4 |
| ■ Steroidogenesis | 2008-Q1 |
| ■ ER Binding | 2008-Q2 |



Validation Update on Tier 2 Assays

- Mammalian 2-generation – Complete
- Avian 2-generation – 2009/10
- Amphibian Growth/Reproduction – 2009/10
- Fish 2-generation – 2009/10
- Mysid 2-generation – 2009/10



Priority Setting Approach

- Approach to selecting Chemicals for Initial Screening was established on Sept. 27, 2005, after considering comments.

- Based on potential human exposure
 - PAIs with food, water, residential, occupational exposure
 - HPV inerts in human and eco biomonitoring, water, air

- Based on chemicals found in multiple pathways



Priority Setting: Draft List

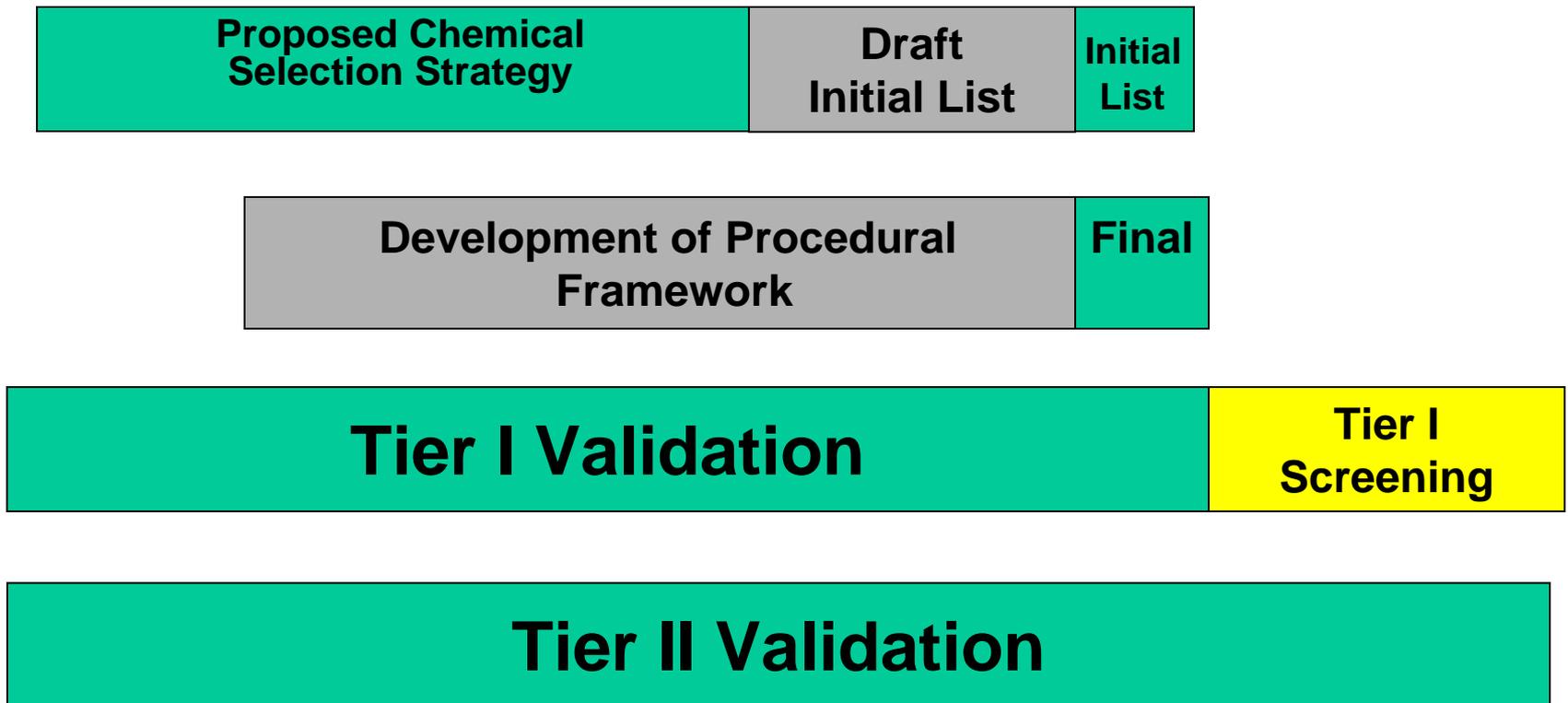
- Issued the Draft List of Chemicals for Initial Screening on June 18, 2007
 - 64 Pesticide actives and 9 HPVs / pesticide inerts
 - Not a list of “known” or “likely” endocrine disruptors
- Comment period ends on December 31, 2007
- EPA will review comments on draft list and finalize list for Tier 1 screening in first half of 2008

Policy & Procedures

- Topic of Today's Workshop
- Generally, these are the procedures EPA is considering using to require data under the EDSP
- Must have an ICR in place to collect data
- Draft Policy, order templates & ICR issued on December 13, 2007
- Comment period ends on February 11, 2008.
- EPA will review comments and finalize these by mid 2008

EDSP Timeline

2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010





For More Information



www.epa.gov/endo



Introduction to EDSP Policy & Procedures

Bill Wooge

Exposure Assessment Coordination & Policy Division

Office of Science Coordination and Policy

Office of Prevention, Pesticides and Toxic Substances (OPPTS)



FFDCA §408(p)(5) Directive



- Minimize duplicative testing
 - i.e., promoting joint data development
 - “To the extent practicable”

- Develop, as appropriate, procedures for fair and equitable cost sharing
 - i.e., promoting sharing of costs by joint data developers and data compensation by people who enter the marketplace after data are submitted

- Develop, as necessary, procedures for handling confidential business information

EPA's Policy Goals:

- Fulfill FFDCA §408(p)(5) directive
 - Minimize duplicative testing
 - Promote fair and equitable cost sharing
 - Protect data from inappropriate public disclosure

- Minimize burden to the extent practical by building on existing procedures & infrastructures
 - Internally (EPA)
 - Externally (Affected Entities)

EPA's Proposal

- EPA Intends to Issue Orders
 - Under FFDCA §408(p)(5)
 - Under FIFRA §3(c)(2)(B)
- 2 Types of Orders
 - Manufacturers and Importers
 - Pesticide Registrants





Legal Authorities for EDSP Policy & Procedures

Laurel Celeste
Office of General Counsel



Legal Authorities

FFDCA §408(p) - Authority for EDSP Testing

- Directs EPA to screen all “pesticide chemicals” for potential to affect endocrine systems
- EPA may issue “test orders” to require screening and testing
- EPA may send FFDCA §408(p) “test orders” to a registrant or to a manufacturer/importer of a pesticide chemical
- Allows enforcement (suspension of registrations) if a registrant fails to comply with a FFDCA §408(p) test order
 - If a non-registrant fails to comply, EPA may impose fines

Legal Authorities

FFDCA §408(p) - Authority for EDSP Testing

- Directs EPA to adopt procedures that:
 - Minimize duplicative testing
 - Promote fair and equitable sharing of test costs
 - Provide for protection of CBI

- FFDCA §408(p) does not provide independent authority for EPA procedures

Legal Authorities

FFDCA §408(i)

– Extension of “FIFRA Protection”

- Provides that data submitted in support of a tolerance action are entitled to protection under:
 - FIFRA §3 - data compensation provisions
 - FIFRA §10 - data disclosure provisions

Legal Authorities

FIFRA §3(c)(2)(B) - Authority to Require Data

- Authorizes EPA to issue Data Call-In (DCI) notices for additional data necessary to support continued registration
- FIFRA §3(c)(2)(B) creates procedures that require DCI recipients to share costs of generating data and to use specific procedures to resolve disputes over a fair way to share costs
- Requires that all DCI notices be sent to all registrants to whom the data requirement pertains

Legal Authorities

FIFRA §3(c)(2)(B) - Authority to Require Data

- Allows enforcement (suspension of registrations) if a registrant fails to comply with DCI notice
 - Failures include :
 - To offer to share costs
 - To participate in procedures to determine a fair share of costs
 - To pay a fair share of costs
 - To generate data

Legal Authorities

FIFRA §3(c)(1)(F) - Data Compensation

- Requires an applicant for registration to provide data to demonstrate safety of the pesticide proposed for registration
- Allows an applicant, in certain cases, to cite data submitted by another person as a way of fulfilling the requirement to provide safety data
- Data submitted under FIFRA §3(c)(2)(B) becomes compensable under FIFRA §3(c)(1)(F)

Legal Authorities

FIFRA §3(c)(1)(F) - Data Compensation

- “Citable” data are either “exclusive use” or “compensable”
 - Data get “exclusive use” protection for 10 years from the date of initial registration of the active ingredient to which the data relate
 - Applicants may cite “exclusive use” only with the original data submitter’s permission
 - Data are “compensable” for 15 years from the date of submission
 - Applicants may cite “compensable” data by making an offer to pay reasonable compensation to the original data submitter

Legal Authorities

FIFRA §3(c)(1)(F) - Data Compensation

- If an applicant and an original data submitter cannot agree on reasonable compensation either may initiate binding arbitration to resolve the dispute
 - Both are bound to accept the arbitrator's decision
- Allows for enforcement if an applicant fails to comply with the FIFRA §3(c)(1)(F) requirements:
 - EPA may deny an application for a registration or may cancel an existing registration if registrant:
 - Fails to make a required offer to pay
 - Fails to participate in binding arbitration
 - Fails to pay required compensation

Legal Authorities

FIFRA §3(c)(2)(D) - “Formulators’ Exemption”

- Referred to as the “Generic Data Exemption” or “Formulators’ Exemption”
- Exempts an applicant from providing data to the extent that the data would be required to evaluate a registered pesticide product that the applicant buys from another person and uses to make the applicant’s product
- EPA administratively determined to extend the “formulators’ exemption” in FIFRA §3(c)(2)(D) to recipients of DCI notices

Legal Authorities

FIFRA §10(b) & FIFRA §10(g)

- Prohibits EPA from disclosing to the public trade secret or confidential business information (CBI)
- Prohibits EPA from disclosing information submitted by an applicant or registrant to a person working on behalf of a foreign or multinational pesticide producer



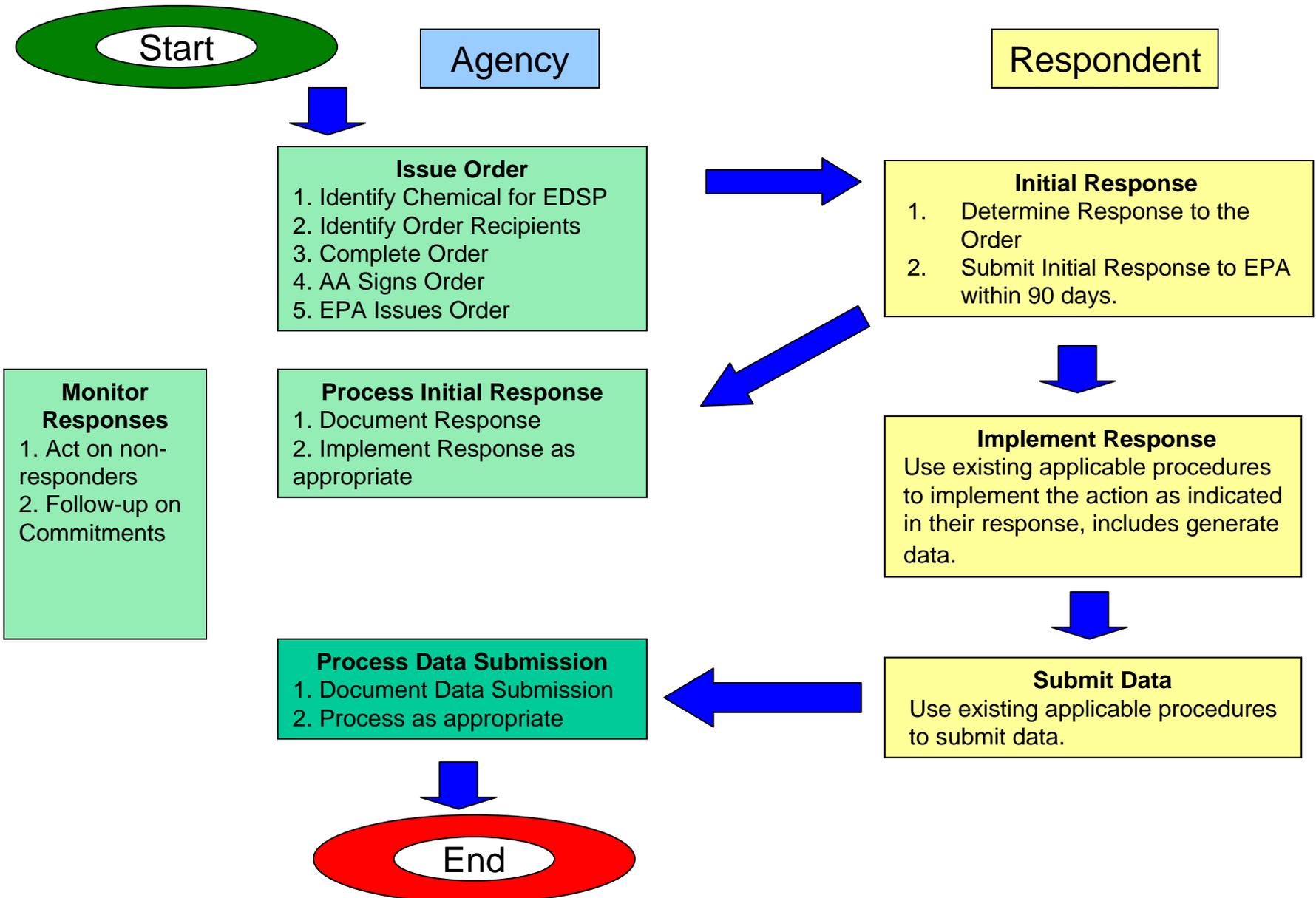


Procedures for EDSP Test Orders

Angela Hofmann, Director
Regulatory Coordination Staff
Office of Prevention, Pesticides and Toxic Substances



Overall Process for EDSP Orders





Who Would Receive the EDSP Test Order?



- Pesticide Active Ingredients
 - Send test orders under FFDCA §408(p) & FIFRA §3(c)(2)(B) to technical registrants

- Inert Ingredients
 - Send test orders under FFDCA §408(p) to manufacturers/importers



How Should Recipients Respond to a Test Order?

- (1) *Read instructions*
- (2) *Plan activities*
- (3) *Submit an Initial Response to EPA within 90 days*
 - Indicates intentions
 - Uses Initial Response Form
- (4) *Read &, if appropriate, discuss the protocol w/ EPA*
- (5) *Generate the data/ participate in consortia*
- (6) *Compile & review the data for submission*
- (7) *Complete paperwork to assemble the submission package*
- (8) *Submit the data*
- (9) *Maintain records*

| | | | | | | | | |
|---|--|-----------------------|---|-----------------------|-----------------------|-----------------------|-----------------------|-------|
| [Insert seal] | UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460 | | Form Approved. OMB Control No. 2070-[Insert] | | | | | |
| INITIAL RESPONSE FORM for The Endocrine Disruptor Screening Program FFDCA §408(p) Order/FIFRA §(3)(c)(2)(B) DATA CALL-IN (DCI) | | | | | | | | |
| Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response. Send comments regarding the burden estimate to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, Washington, DC 20460. Do not send the form to this address. | | | | | | | | |
| PART 1 | Recipient Information (From the Order/DCI - Completed by EPA): | | | | | | | |
| 1-1. Company Name: | | | 1-3. Address: | | | | | |
| 1.2. Contact Person: | | | | | | | | |
| 1-4. Chemical(s): | A. Chemical #: | B. Chemical Name: | C. EPA Registration #: | | | | | |
| 1-5. Date of Order/ DCI: | | | 1-6. Initial Response Due Date: | | | | | |
| PART 2 | Recipient's Initial Response Options: | | | | | | | |
| 2-1. Your Response Options: | A. I Intend to Generate New Data. B. I Intend to Enter (or Offer to Enter) Into an Agreement to Form a Consortium to Generate the Data. C. I Intend to Cite Existing Data . (Must provide supporting material.) D. I Am Not Subject to the Test Order. (Must provide supporting material.) E. I Intend to Voluntarily Cancel or Reformulate the Product Registration or Discontinue the Manufacture/Importation of the Chemical. (Must provide supporting material.) F. I Am Claiming a Formulators' Exemption. (Must provide supporting material.) G. I have enclosed/attached the supporting materials related to my response. | | | | | | | |
| 2.2. Assay Name | 2.3. Recipient Response To Order | | | | | | | |
| | A | B | C | D | E | F | G | Note: |
| Amphibian Metamorphosis Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| ER Receptor Binding <i>in vitro</i> Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| AR Receptor Binding <i>in vitro</i> Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Aromatase Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Fish Screen Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Hershberger Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Female Pubertal Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Male Pubertal Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Steroidogenesis Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| Uterotrophic Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 15-Day Intact Male Assay | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| PART 3 | 3-1. Certification. I certify that the statements made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fin or imprisonment or both under applicable law. | | | | | | | |
| 3-2. Company's Authorized Representative: | | | | | | 3-3. Date | | |
| Signature: Name and Title (Please Print or Type): | | | | | | 3-5. Phone Number | | |
| 3-5. Email address: | | | | | | | | |

Initial Response Form

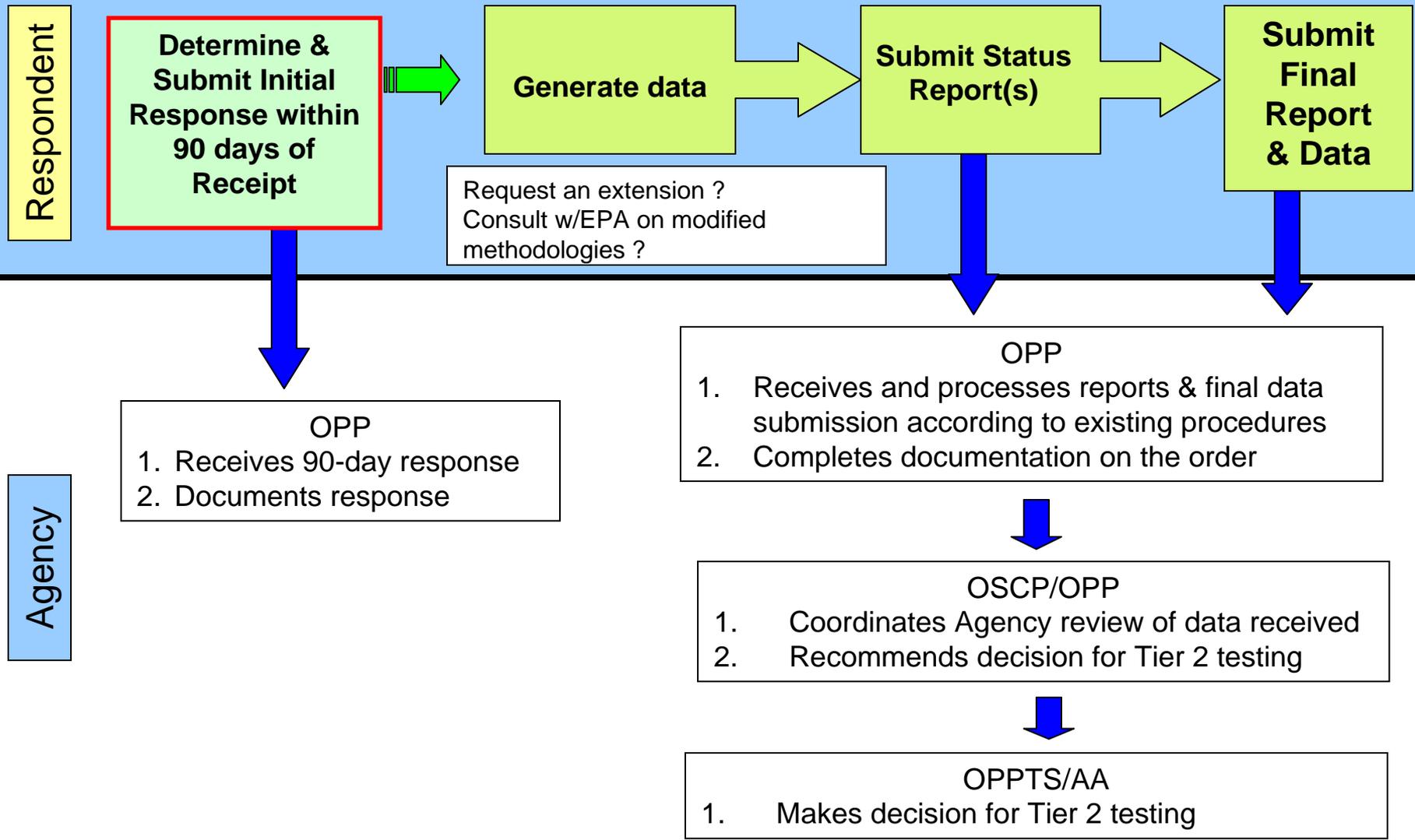
- Attached to the Order.
- Pre-populated with recipient & chemical information.
- Recipient completes Parts 2 & 3 and sends to EPA **within 90 days** of receiving the Order.
- Response would include supporting material for certain options.
- Indicates recipient's intentions.

Summary of Basic Response Options

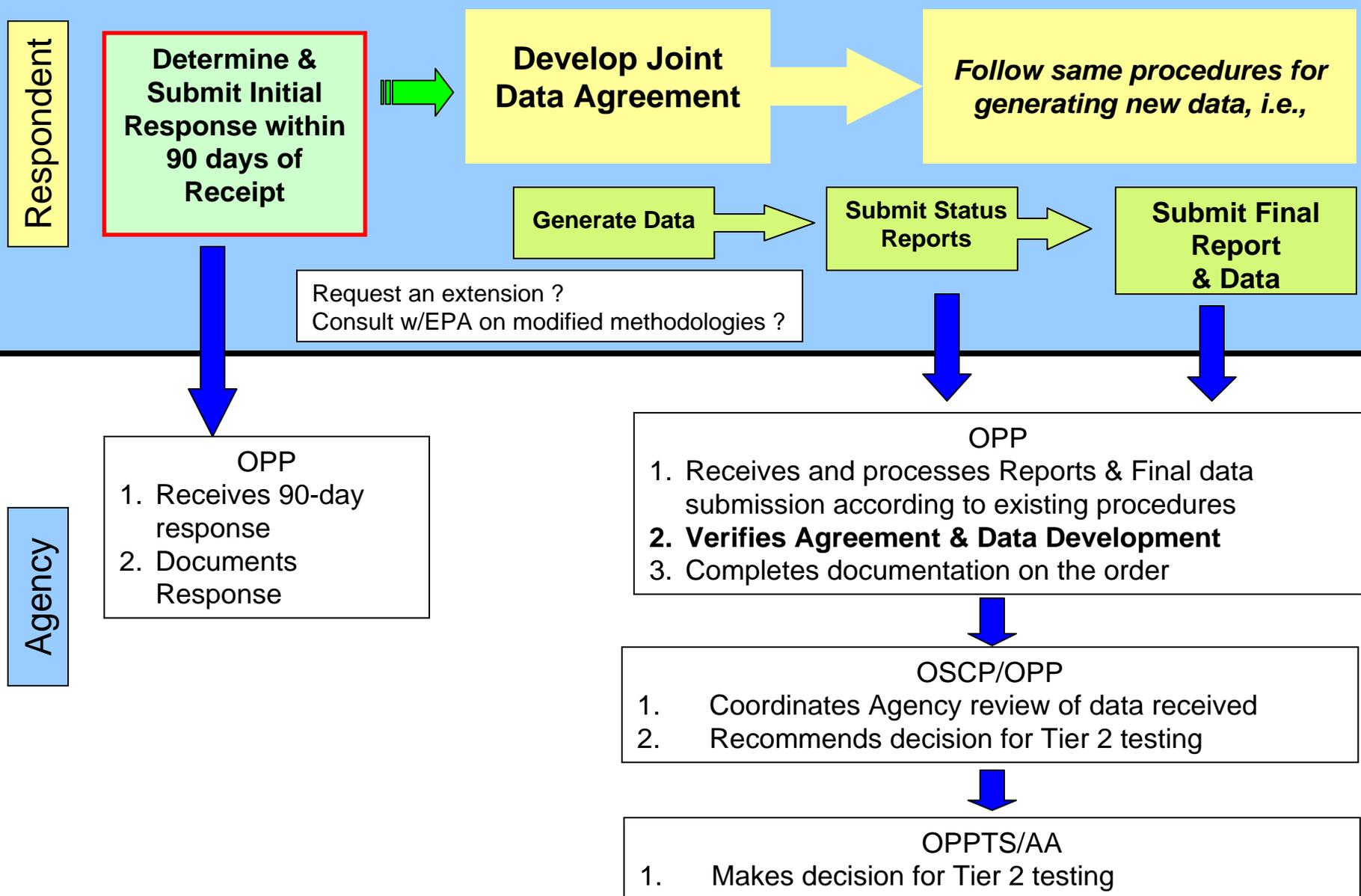


- (1) I will generate new data.
- (2) I have entered (or offered to enter) into an agreement to form a consortium to generate the data.
- (3) I am citing or submitting existing data.
- (4) I am not subject to the test order.
- (5) I request voluntary cancellation of my registration, I am applying to reformulate my product, or I commit to discontinue the manufacture and importation of the chemical.
- (6) I am claiming a formulators' exemption.

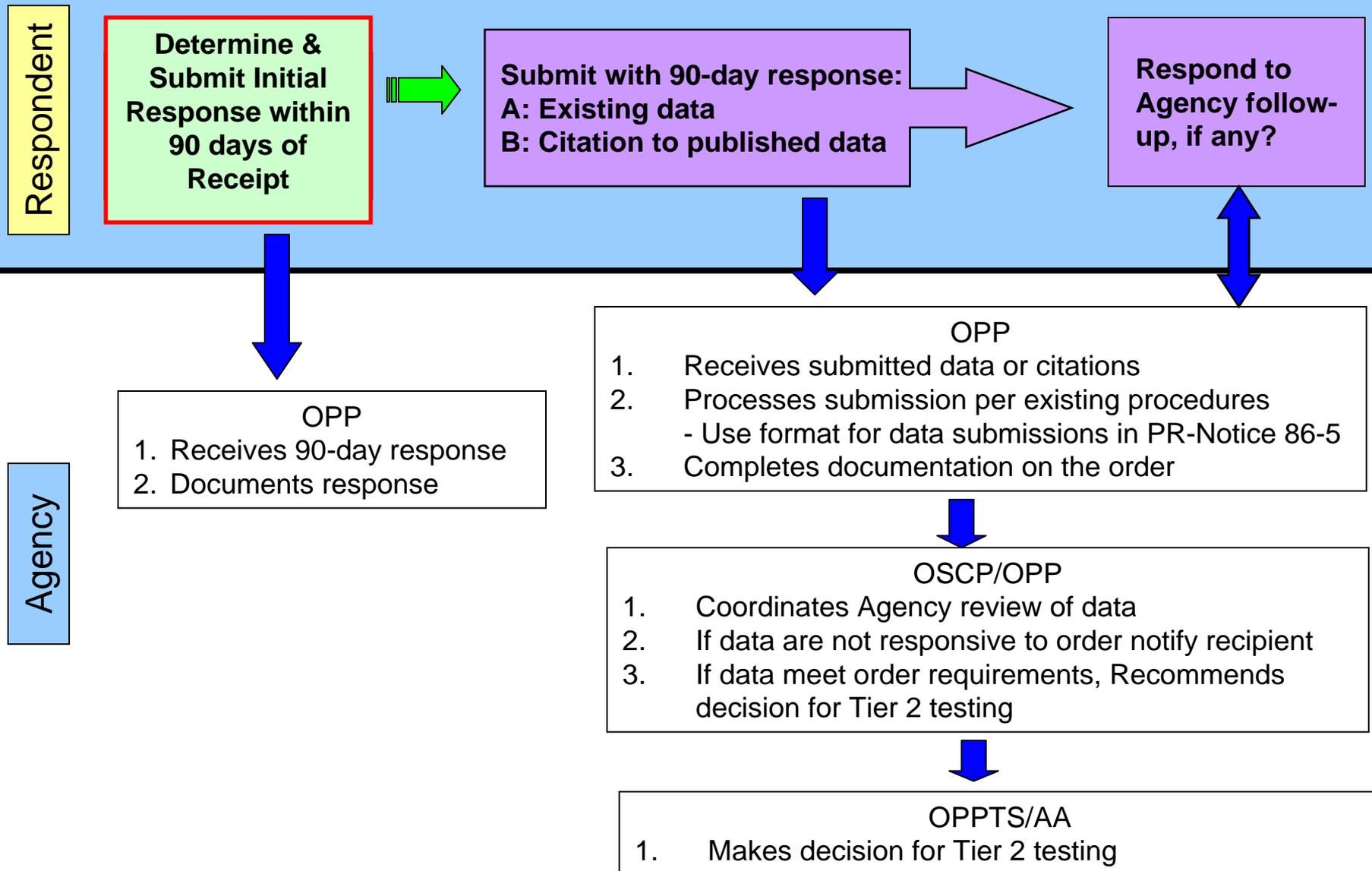
If Respondent agrees to generate new data . . .



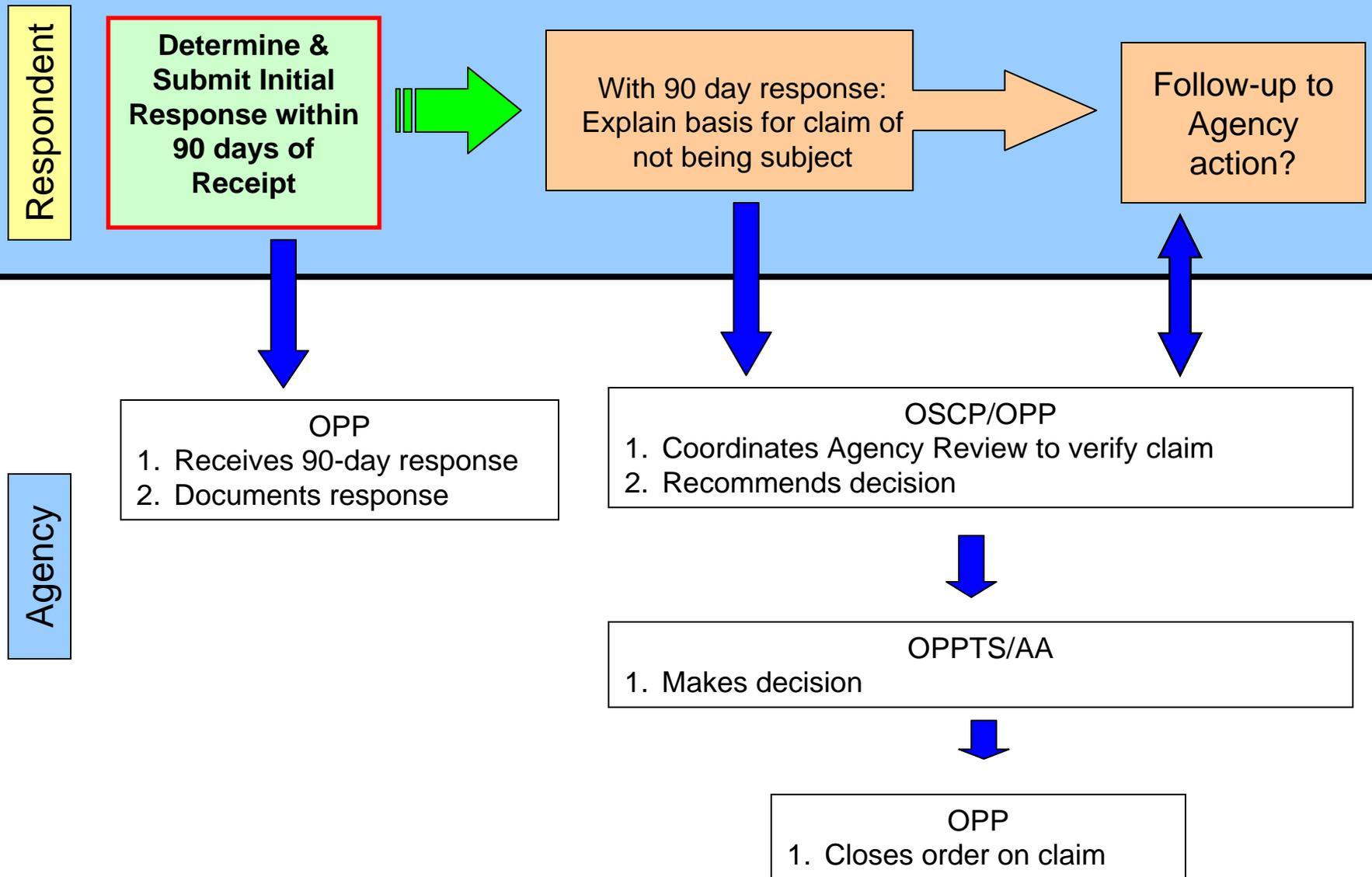
If Respondent offers to enter a joint data development agreement . . .



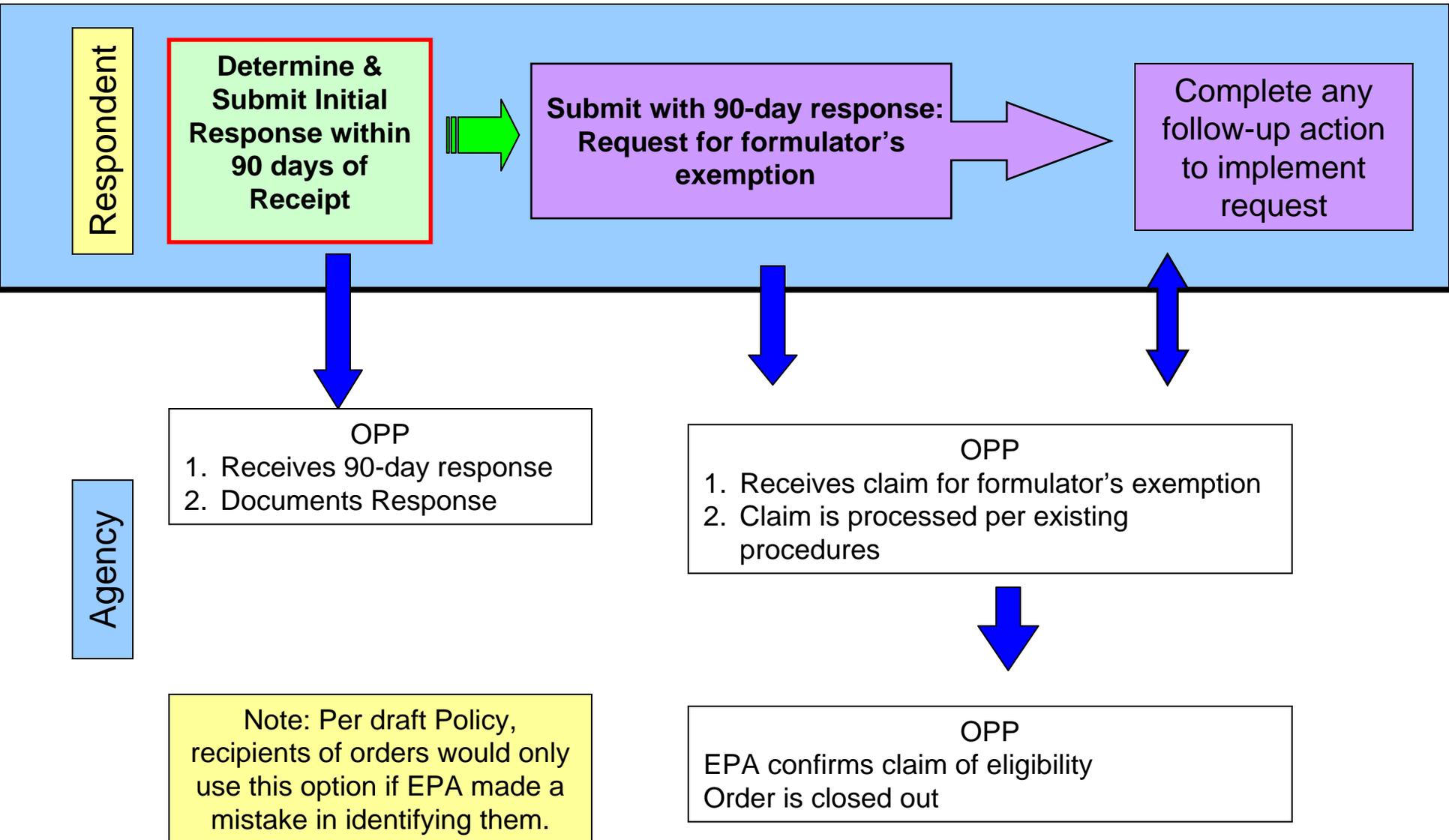
If Respondent chooses to cite or submit existing data . . .



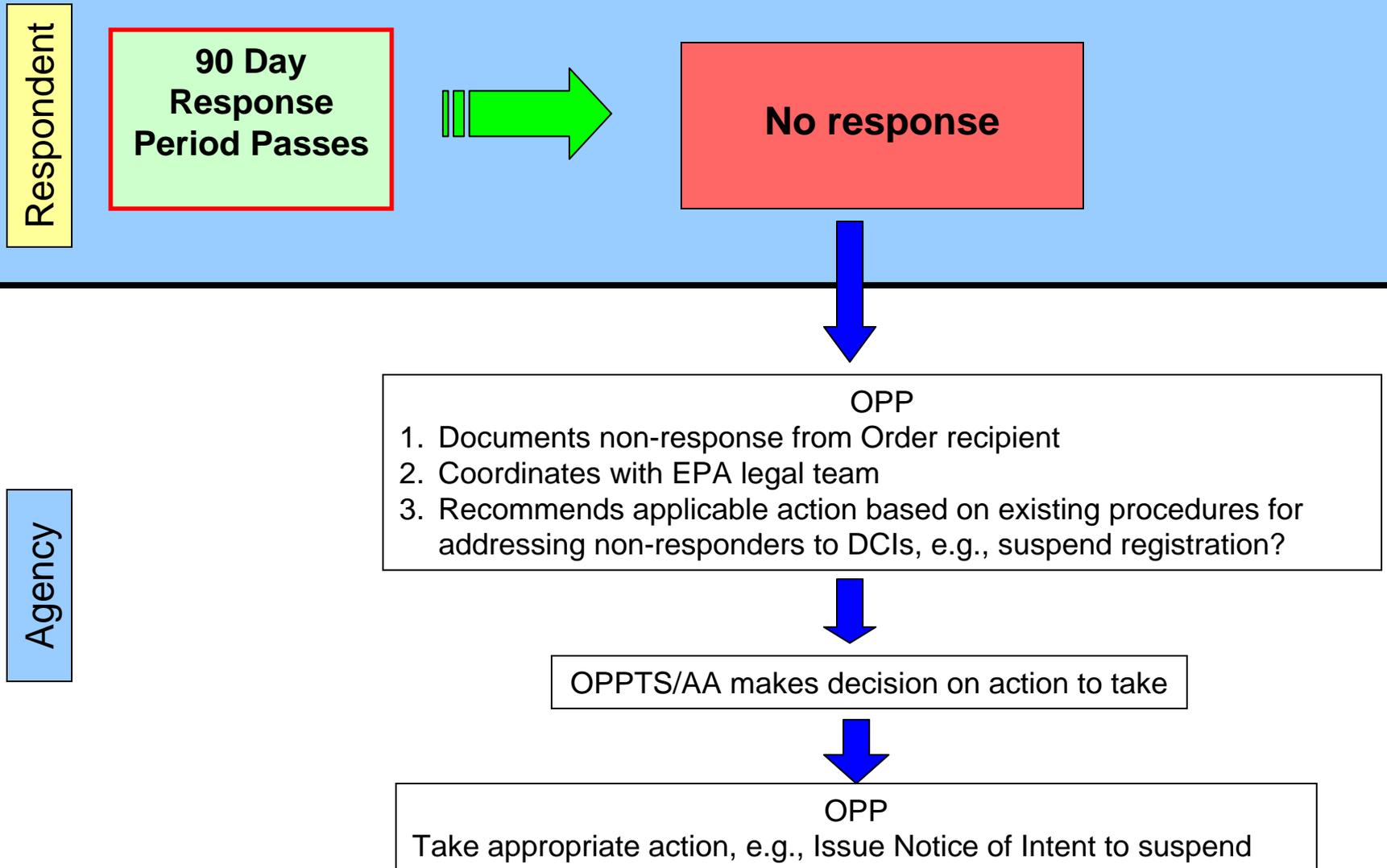
If Respondent claims they are not subject to the order . . .



If Respondent chooses to claim a formulators' exemption . . .



If Respondent chooses not to respond . . .



FFDCA §408(p)(4) Exemptions



- EPA can grant an exemption under FFDCA §408(p)(4) if it determines that a “substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.”
 - At this time, EPA has determined that the development of criteria to exempt certain substances or to otherwise identify any pre-determined or blanket exemptions from endocrine disruptor testing is premature.
 - For the initial screening, EPA is not aware of sufficient data that would allow the Agency to confidently determine that a chemical meets the statutory standard for an exemption—*i.e.*, that it is not anticipated to interact with the endocrine system.
 - However, EPA will consider requests for such an exemption on a case-by-case or chemical-by-chemical basis in response to individual submissions. In order for the Agency to make the necessary statutory finding to issue the exemption, the request would need to provide any hazard-related information that would allow EPA to make the necessary statutory determination.



What are the Consequences of Non-Compliance?

- If a registrant fails to comply with the EDSP Order, EPA may suspend any affected registrations.
- If a non-registrant (i.e., inert manufacturer/importer) fails to comply, EPA may impose fines under TSCA.



Contesting an Order, Cost Sharing, Compensation, and Confidential Business Information

William Jordan, Senior Policy Advisor
Office of Pesticide Programs
Office of Prevention, Pesticides and Toxic Substances (OPPTS)

Contesting a 408(p) Order/Decision



- Informal Administrative Review Procedure
 - Recipients will be required by 408(p) order to raise issues to EPA informally
- Process for Contesting a Test Order/Pre-enforcement Review
 - Following EPA response, judicial review in appropriate federal district court



Pesticide Active Ingredients

- Proposed Procedures:
 - Send test orders under FFDCA §408(p) & FIFRA §3(c)(2)(B) to technical registrants
 - Issue FFDCA §408(f)(1)(C) notices for import tolerances
 - i.e., unregistered, foreign-produced AIs
 - New applications will be subject to data compensation under FIFRA
- Does Not Address:
 - Commodity chemical AIs



Pesticide Active Ingredients

■ Advantages:

- Applies FIFRA protections to submitted data
 - By sending the data requirements notice under both statutory authorities, the provisions of FIFRA §3(c)(2)(B) that facilitate joint data development and dispute resolution clearly become applicable
 - Ensures compensability
 - Encourages joint data development
- Minimizes use of resources
 - Sending orders to only technical registrants would reduce the number of recipients significantly, and
 - Make the formation of data development groups less challenging administratively
- Regulated community familiar with process
 - Similar to OPP's DCI process

■ Disadvantages:

- Enforcement limited
 - Can not suspend all registrations if no registrant generates data

Food-Use Inerts

■ Proposed Procedures:

- Send test orders under FFDCA §408(p) to manufacturers/importers
- Issue FFDCA §408(f)(1)(C) notices for import tolerances
 - i.e., unregistered, foreign-produced inerts
- Compliance achieved only by:
 - Generating data or stopping ALL production/importation
- “Catch-up” FFDCA §408(p) test orders to be sent to manufacturers/importers who enter the marketplace after the data are submitted
- Compliance ensured by under FIFRA §3(c)(1)(F) with data compensation as applications arrive

■ Does not address:

- Proprietary mixtures

Food-Use Inerts

- Commence negotiations regarding the amount and terms of paying a reasonable share of the testing cost, and have included an offer to submit to a neutral third party with authority to bind the parties, to resolve any dispute over the recipient's share of the test costs, e.g., through binding arbitration or through a state or federal court action.



Food-Use Inerts

■ Advantages:

- Encourages joint data development
- Ensures compensability under FFDCA §408(i)
- Applies FIFRA protections submitted data
- Minimizes use of resources
 - Sending orders to only manufacturers/importers would reduce the number of order recipients significantly, and
 - Makes the formation of data development groups less challenging administratively

■ Disadvantages:

- Delays systematic accounting by registrants for the sources of their inerts

Non-Food-Use Inerts

■ Proposed Procedures:

- Send test orders under FFDCA §408(p) to manufacturers/importers
- Allow data generators to partner with a cooperating registrant/agent
- Allow compliance only by generating data or stopping ALL production/importation
- Send “catch-up” FFDCA §408(p) test orders to manufacturers/importers who enter the marketplace after the data are submitted
- Under FIFRA §3(c)(1)(F) ensure compliance with data compensation as applications arrive

■ Does not address:

- Proprietary mixtures



Non-Food-Use Inerts

■ Advantages:

- Encourages joint data development
- Ensures compensability under FIFRA §3(c)(2)(B)
- Applies FIFRA protections to submitted data
- Reasonable balance of resource expenditures and other goals

■ Disadvantages:

- Delays systematic accounting by registrants for the sources of their inerts





What Procedures Can EPA Apply for Handling Confidential Business Information?



- Active Ingredients
 - FIFRA sec. 10
- Food use inerts
 - FFDCA sec. 408(i) & FIFRA sec. 10
- Non-food use inerts
 - Trade Secrets Act
 - If data submitted by a registrant, FIFRA sec. 10

Summary

| Chemical Category | Order Recipient | Data Development | Cost Sharing/Minimize Duplication | Data Compensation by Subsequent Entrants | Disclosure |
|--------------------------------|---------------------------------------|------------------------------------|---|--|---|
| Active Ingredients | Technical Registrants | FFDCA §408(p) FIFRA §3(c)(2)(B) | FIFRA §3(c)(2)(B) | FIFRA §3(c)(1)(F) | FIFRA §10(b), §10(g) |
| | Producers with only import tolerances | FFDCA §408(f)(1)(C) | FFDCA §408(i) | FFDCA §408(i) & FIFRA §3(c)(1)(F) | FFDCA §408(i) & FIFRA §10(b), §10(g) |
| Food Use Inert Ingredients | Domestic Manufacturers & Importers | FFDCA §408(p) | FFDCA §408(i) | FFDCA §408(p) "catch up" orders | FFDCA §408(i) & FIFRA §10(b), §10(g) |
| | Producers with only import tolerances | FFDCA §408(f)(1)(C) | FFDCA §408(i) | FFDCA §408(i) & FIFRA §3(c)(1)(F) | FFDCA §408(i) & FIFRA §10(b), §10(g) |
| Non-Food Use Inert Ingredients | Domestic Manufacturers & Importers | FFDCA §408(p) | "Discretion" (effectively the same rights) | FFDCA §408(p) "catch up" orders | - |



Information Collection Request (ICR)

Angela Hofmann, Director
Regulatory Coordination Staff
Office of Prevention, Pesticides and Toxic Substances (OPPTS)



Calculating Paperwork Burdens

- ICR scope is on the 73 chemicals identified for initial screening
- Similar ICRs were used as guides in terms of identifying activities, related burdens, and methodologies used in this ICR
 - Five currently approved ICRs involving DCIs
 - One currently approved ICR involving testing under TSCA
- Paperwork burden includes both **administrative** and **data generation** burden
 - Administrative burden is calculated based on the paperwork activities and the estimated time need to complete those activities
 - Data Generation burden is calculated as a percentage of the testing costs
- Estimated test costs are from a survey done for EPA & actual costs incurred during validation (see handout)

Respondent Activities



ICR considered Respondents would engage in the following paperwork related activities:

1. Read instructions
2. Plan activities
 - Participate in Consortium Discussions
3. Submit an initial response to EPA
 - Response options may involve other activities involving established procedures & existing ICRs
 - This ICR assumes everyone will respond by participating in the generation of the data
4. Read and discuss the protocol
5. Generate the data
6. Compile and review the data submission
7. Complete paperwork to assemble the submission package
8. Submit final data to EPA
9. Maintain records

EPA's Activities

ICR considered EPA would engage in the following paperwork related activities:

1. Prepare instructions
2. Identify chemicals to be screened
3. Identify Recipients
4. Prepare the EDSP Test Orders
5. Review & Approve Orders
6. Issue the Orders
7. Process Initial Responses
8. Provide Assistance
 - Review modified methodologies
9. Complete Follow-up, as needed
10. Identify non-responders
11. Process Data Submissions
12. Analyze Data
13. Incorporate/Use Data Received
14. Store Data in Retrievable System

Methodologies

Method Used To Calculate the Loaded Labor Rates

- Used average wage data for the relevant sectors of respondents from the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) to calculate a loaded labor rate
 - For Respondents: Managerial = \$103.62; Technical = \$76.92; and Clerical = \$33.60
 - For EPA: Managerial = \$101.16; Technical = \$66.89; and Clerical = \$39.23

Methods Used for Administrative Activities

- The burden hours are calculated by considering the activities themselves and the expected amount of time that the activity involves on average
- The costs are calculated using the loaded labor rates

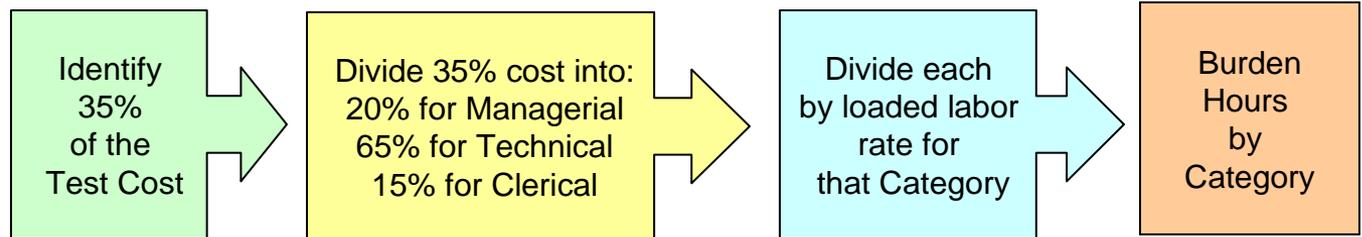
Method Used for Data Generation Activities

- We calculated the paperwork burden for the data generation activities as a percentage of the testing costs
 - based on method established in consultation with OMB in the 1980's
 - accounts for potential variation in burden associated with the paperwork component of data generation based on the complexity of the test performed



Method for Calculating Data Generation Burdens

- EPA used 35% of the estimated total test cost to calculate the total potential cost for the paperwork activities related to data generation
- The 35% of test cost is disaggregated by labor category, and then burden hours are extrapolated by using the loaded labor rates





Key Assumptions for Estimating Burden & Costs

- Assumed that each chemical would do all 13 assays
 - Battery will not consist of 13 assays
- Assumed that data will be generated for all 73 chemicals
 - Respondent has other less burdensome options
- Assumed that contract laboratory would do tests
 - Respondents doing tests in-house may have less burden
- Assumed that Respondents for a chemical will join forces and share burden/costs
 - Result is an assumed 1 chemical = 1 response
 - Added burden for consortia participation
 - Companies aren't required to join forces

Total Estimated Burden and Costs

(Estimates presented in more detail in the ICR.)



- Respondent Burden and Costs:
 - Per chemical: 2,649 hours & \$195,022
 - Administrative: 703 hours & \$63,932
 - Data Generation: 1,946 hours & \$131,090
 - Total: 280,965 hours & \$20,662,254
 - Administrative: 138,907 hours & \$11,092,680
 - Data Generation: 142,058 hours & \$9,569,574
 - Annualized over 3 years
 - Per chemical: 883 hours & \$65,007
 - Total Annualized: **93,655 hours & \$6,887,418**

- Agency Burden and Costs:
 - Per chemical: 773 hours & \$50,921
 - Total: **56,429 hours & \$3,717,233**





Questions for Commenters

Bill Wooge

Office of Science Coordination and Policy

Office of Prevention, Pesticides and Toxic Substances (OPPTS)





Questions for Commenters

A. Minimizing Duplicative Testing

1. If there are multiple entities who manufacture or import a substance for which EDSP data are needed, under what circumstances, if any, should EPA send test orders only to a single entity?
2. When issuing test orders for EDSP data on an active ingredient, should EPA issue the test order under the authority of FFDCA section 408(p), under FIFRA section 3(c)(2)(B), or under both authorities?
3. When issuing test orders for EDSP data on an inert ingredient, should EPA issue the test order under the authority of FFDCA section 408(p), under FIFRA section 3(c)(2)(B), or under both authorities?



Questions for Commenters

B. Cost Sharing

1. What evidence of a willingness to share the cost of generating EDSP data should EPA require?



Questions for Commenters

C. Data Compensation

1. What evidence of a willingness to pay compensation for previously submitted EDSP data should EPA require?
2. Should EPA issue “catch-up” FFDC section 408(p) test orders to people who begin to manufacture or import an inert ingredient after required EDSP data have been submitted?
3. If so, at what point (e.g., during registration review) and for how long should EPA issue such “catch-up” test orders?
4. What alternatives should EPA consider for the 15–year period proposed, and why?



Questions for Commenters

D. Who Should Receive Test Orders?

1. If EPA relies on FIFRA section 3(c)(2)(B) as an authority to require data for an active ingredient, should EPA send the DCI only to technical registrants or to all registrants whose products contain the active ingredient?
2. Should EPA send FFDCA section 408(p) test orders to producers of commodity chemicals that do not hold a pesticide registration for a product containing the substance to be tested?
3. How should EPA address the issuance of test orders for an inert ingredient that is contained in a “proprietary mixture”?
4. After EPA has received compensable EDSP data on an inert ingredient, which authority should EPA use to ensure that pesticide registrants are buying their inert ingredient only from sources on the “Inert Suppliers List”: FIFRA section 3(c)(1)(F) only, FIFRA section 3(c)(1)(F) and FIFRA section 3(g), or FIFRA section 3(c)(1)(F) and FIFRA section 3(c)(2)(B)?



Questions for Commenters

E. How to Identify Potential Recipients of Test Orders

1. Please suggest an efficient approach to identify potential recipients of FFDCA section 408(p) test orders for inert ingredients. Please identify any databases that will provide the best information.
2. Please comment on the preferred mechanism for making the list of recipients of FFDCA section 408(p) test orders public.
3. Please comment on a mechanism to identify entities that should have received a test order, but that were not initially identified.
4. How should EPA evaluate requests for exemptions under FFDCA section 408(p)(4)?



Questions for Commenters

F. How to Respond to Test Orders

1. Is 90 days sufficient time for recipients of a test order to respond with their intentions for complying with the order?
2. Should EPA allow a person to “fulfill” the requirements of a test order by promising not to manufacture or import an active ingredient? An inert ingredient?
3. Should EPA allow a person to “fulfill” the requirements of a test order on an inert ingredient by promising not to manufacture or import the inert ingredient for use in a pesticide product? If so, how would EPA enforce such an agreement?



Questions for Commenters

G. Procedural Issues

1. When should a recipient of a test order for EDSP data on an inert ingredient be able to judicially challenge the issuance of the order?
2. Should EPA include an optional or mandatory informal administrative review procedure by which a person who wishes to judicially challenge the validity of a test order would raise the objections first with the Agency?
3. Should the 90–day response form be mandatory or optional?
4. Should test protocols be attached to the order and/or posted on a website?
5. Should the Agency establish a website of FFDCA section 408(p) test order recipients to facilitate the formation of consortia?



Questions for Commenters

H. Due Process Options

1. EPA requests comment on whether the informal administrative review procedures (as outlined in this document) would be appropriate. Please also comment on the appropriate parameters for such a requirement, including the deadline for order recipients to initially provide their concerns, and the time frame for the Agency's response.



Questions for Commenters

I. CBI

1. Provide comments on how best to address CBI concerns associated with notifying HPV inert manufacturers, including the difficulty of informing registrants, without disclosing the identity of the inert.



Questions for Commenters

J. Estimated Test Costs and Paperwork Burden

1. Please provide comments on the estimated test costs and burden hours presented in the draft ICR. Explain the basis for your estimates in sufficient detail to allow EPA to reproduce the estimates.
2. Provide comments on the methodology used by EPA to estimate the burden for data generation, which is based on the total estimated test costs.
3. Is it reasonable to continue to assume that as much as 35% of the test costs represents the paperwork burden?

Questions from the Public

